AACI CRI
Clinical Research Innovation

CANCER CLINICAL RESEARCH
FROM ABSTRACT TO REALITY

2023 ABSTRACTS AND POSTERS

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D. Bitenas, J. Klingman, H. Rothering, M. Gadepalli, E. Lennstrom
Fred Hutchinson Cancer Center.....251

AACI's Clinical Research Innovation (CRI) convened its 15th annual meeting June 26-28, in Rosemont, IL. More than 500 clinical research professionals attended in person and 118 abstracts were submitted for presentation — both records for the increasingly popular event focused on clinical trial office operations.

Dr. Tara L. Lin, CRI steering committee chair, opened the meeting with a warm welcome and a look at CRI highlights from the past year. **Dr. Thomas J. George, Jr.**, steering committee chair-elect, moderated the first panel discussion, which looked at innovative strategies for clinical trial recruitment.

A session featuring **Drs. Min He** and **Gisele Sarosy**, of the National Cancer Institute, provided an overview of recent and proposed changes to NCI's Cancer Center Support Grant.

Day 2 kicked off with **Dr. Ted A. James** delivering a keynote presentation, "The Power of Positivity: Building a Stronger, More Resilient Clinical Cancer Research Team." Appearing virtually, Dr. James described how collaboration leads to innovation in clinical research, noting that strong relationships are key to achieving professional excellence.

Building on the themes of positivity and quality relationships from the morning's keynote, another session helped define the "work family" during a discussion of workplace values and culture, communication, and hiring practices.

Breakout sessions allowed attendees a closer look at topics including community outreach and diversity, equity, and inclusion; quality assurance, remote monitoring, and auditing; resource management and finance; training, career development, and staff retention; trial recruitment and study conduct; and trial start-up, activation, and protocol development.

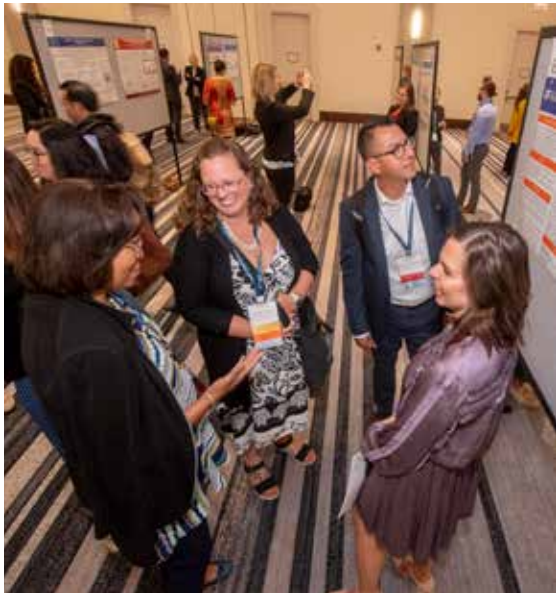
These topics were also the focus of the research highlighted in the meeting abstracts, with three winning abstracts presented by **Christina Wiess,** Yale Cancer Center, Yale School of Medicine; **Dr. Christy Spalink**, Laura and Isaac Perlmutter Cancer Center at NYU Langone; and **Dr. Jennifer Bollmer**, Medical College of Wisconsin Cancer Center.

The day closed with an interactive vendor presentation by Triomics, titled "Activating Clinical Data for Research," which explored new developments in health care data technologies and artificial intelligence.

The meeting's final day included a panel discussion about overcoming barriers to developing a community network for cancer clinical trials and two sessions focused on bridging the gap between clinical care and research operations.

Meeting supporters worked with AACI to create an environment conducive to learning, networking, and strategic innovation.

In addition to participating in plenary sessions and poster discussions, this year's CRI attendees also had an opportunity to interact with 13 contracted exhibitors that each demonstrate a strong commitment to working with academic cancer centers to help solve operational challenges.



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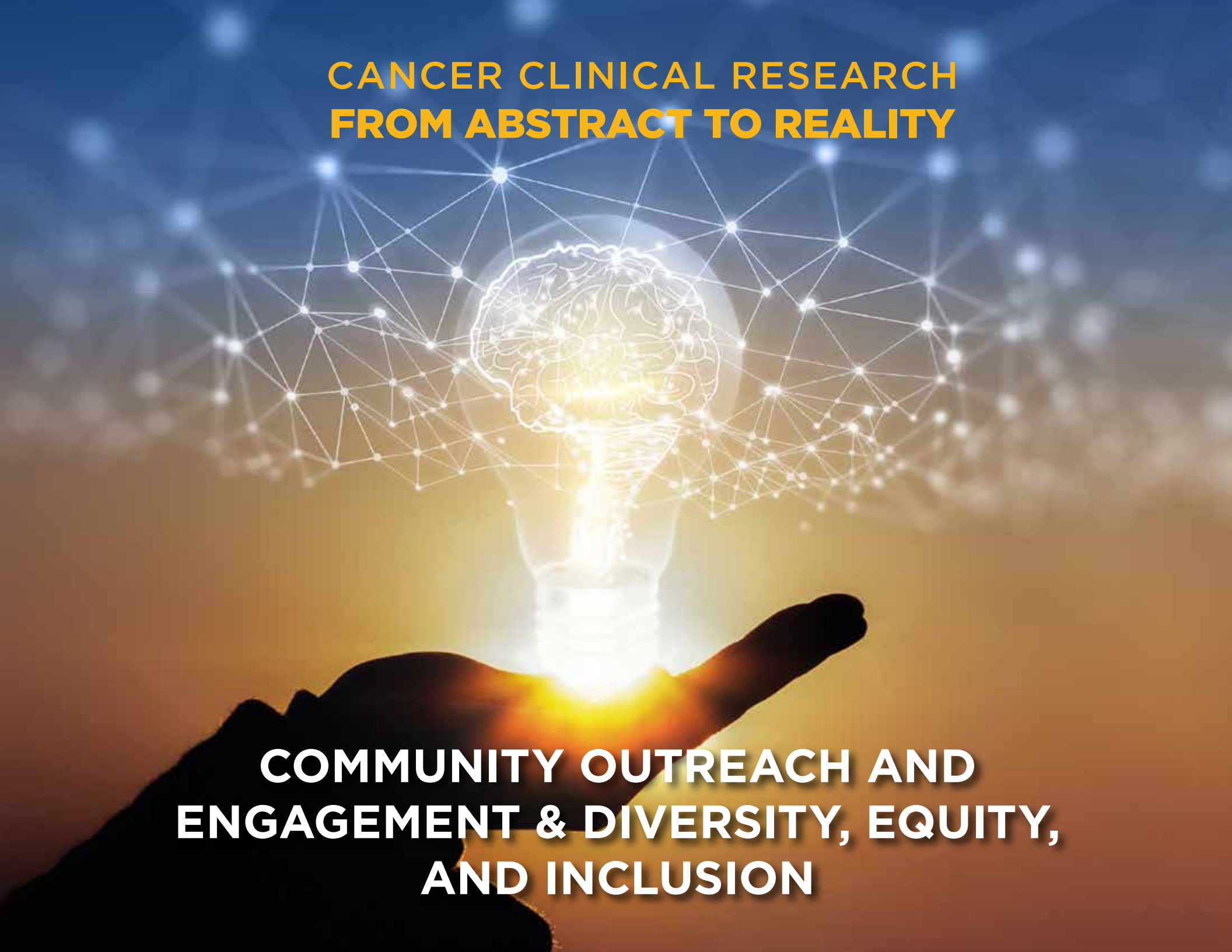
2023 ABSTRACTS AND POSTERS

CANCER CLINICAL RESEARCH

FROM ABSTRACT TO REALITY



COMMUNITY OUTREACH AND ENGAGEMENT & DIVERSITY, EQUITY, AND INCLUSION

Partnering and Building Opportunities Within North Carolina: A Qualitative Analysis of the Lineberger Comprehensive Cancer Center Clinical and Research Internship for Black, Indigenous, and People of Color (BIPOC) Undergraduate Students

A. Daye, S. Godfrey, A. Walens, V. Carlisle, B. Austin, C. Lee, A. Leak Bryant

UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

1. Background

Clinical trials are essential to improving cancer treatments for diverse populations. Almost 45 percent of the U.S. population consists of individuals from minority racial and ethnic groups; however, this diversity is not represented in the clinical trial participant population. Hesitancy of clinical trial participation includes historical trauma leading to mistrust, lack of access, lack of awareness, lack of comfort with the research process, and institutional discrimination and racism within the health care system. Enhancing clinical trial diversity is multifaceted. One solution is to enhance diversity of the clinical trial workforce, including principal investigators, clinical research coordinators, and research staff. To address this practice and research gap in clinical trial participation, Lineberger Comprehensive Cancer Center (LCCC) partnered with North Carolina Central University (NCCU), a historically black college and university (HBCU), to foster oncology workforce interest among undergraduate BIPOC students. The internship was presented by LCCC at the 2022 AACI CRI meeting.

2. Goals

1. Explore program expectations and perceptions of students and mentors through semi-structured pre- and post-internship interviews and focus groups
2. Evaluate strengths and areas of improvement in program from qualitative data

3. Solutions and Methods

This 10-week summer cancer clinical research internship included a two-week orientation with clinical trial training and four weeks of professional development including discussion of communication styles, creation of a LinkedIn profile, cancer clinical career panels, revision of their curriculum vitae or resume, and financial literacy. Each student (n=5) and mentor (n=5) received a stipend for participation. Each student was assigned a mentor and met bi-weekly to discuss roles of clinicians, scientists, and scholars in cancer and provided ongoing emotional and professional development support. Mentor interviews and intern focus groups were held to explore questions pertaining to expectations, impressions, experience, concerns, and feedback. Data was coded and analyzed for reoccurring topics and curriculum alterations.

4. Outcomes

Qualitative analysis concluded that concerns of variety and accessibility, content missing from curriculum, support, racial concordance, need for clarity, exposure, and communication were most uplifted. Mentions of concerns, missing from curriculum, and exposure were more apparent during post-internship data whereas mentions of racial concordance were seen more in pre-internship interviews. Overall, students and mentors shared concerns about curriculum and clarity of the program's goals. Students and mentors praised the program, various clinical exposures and opportunities, and ability to expand mentorship and networking skills. One intern stated, "Even though there were... like little bumps in the road or some inconsistencies, I still gained an experience that I probably wouldn't have gained anywhere else."

5. Lessons Learned and Future Directions

Qualitative analysis was integral to shaping the content, quality, and participant (mentor and intern) satisfaction. This analysis exemplified the essentiality to encourage and address continuous feedback to meet students' and mentors' needs. The overarching need for representation and equitable support was clearly expressed. Lessons learned from students and mentors will be applied to the Summer 2023 experience and include curriculum revision, on-campus housing, increased mentor involvement, and year-round career development and skill-building workshops. We have also differentiated the two consecutive summers: overview of cancer clinical trials and professional development (summer 1) and tailored curriculum and exposure (summer 2).

Partnering and Building Opportunities Within North Carolina: A Qualitative Analysis of the Lineberger Comprehensive Cancer Center Clinical and Research Internship for Black, Indigenous, and People of Color (BIPOC) Undergraduate Students

Aryana Daye, BS, Sherette Godfrey, PhD Andrea Walens, PhD, Veronica Carlisle, MPH, Barbara Austin, M.Ed, Carrie Lee, MD, Ashley Leak Bryant, PhD, RN

UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

Background

- ~45% of the US population are racial and ethnic individuals, however, this percentage is not represented in the cancer clinical trial participant population
- How can we enhance diversity of the clinical trial workforce?
- To address this practice and research gap in clinical trial participation Lineberger Comprehensive Cancer Center (LCCC) partnered with North Carolina Central University (NCCU), a historically black college and university (HBCU), to foster oncology workforce interest among undergraduate BIPOC students.

Aims

1. Explore program expectations and perceptions of students and mentors through semi-structured pre and post internship interviews and focus groups.
2. Evaluate strengths and areas of improvement in program from qualitative data.

Solutions and Methods

- 10-week summer cancer clinical research internship
  - clinical trial training and professional development
  - discussion of communication styles, creation of a LinkedIn profile, cancer clinical career panels, revision of their curriculum vitae or resume, and financial literacy
- Descriptive, qualitative approach
- Students (n=5) and mentors (n=5) met bi-weekly to discuss roles of clinicians, scientists, and scholars in cancer and provided ongoing emotional and professional development support.
- Mentor interviews and intern focus groups explored expectations, impressions, experience, concerns, and feedback.
- Data was coded and analyzed for reoccurring topics and curriculum alterations.

- ***"So for me the highlights were the more casual conversation, the more like unstructured time that we had together."*** - Mentor

Aryana Daye|aryana1@live.unc.edu

- ***"…even though there were, you know, like little bumps in the road or some inconsistencies, I still gained an experience that I probably wouldn't have gained anywhere else. And just being at UNC as a Black girl, that means a lot period. So I feel like, yeah, I wouldn't regret it."*** –Intern
- ***"…we got to meet a lot of people, make connections, and we were able to email and speak to other people. And the networking part, it's important which is really helpful."*** -Intern

Outcomes

- Qualitative analysis was integral to shaping the content, quality, and participant (mentor and intern) satisfaction, exemplified the essentiality to encourage and address continuous feedback to meet students' and mentors' needs.
- The overarching need for representation and equitable support
- Curriculum revision, on-campus housing, increased mentor involvement, and year-round career development and skill-building workshops.
- Differentiated summers: overview of cancer clinical trials and professional development (summer 1) and tailored curriculum and exposure (summer 2).

Implications

- Importance of programs exposing BIPOC individuals to various research and career options
- Expanding similar program collaborations in other communities

Acknowledgement

We would like to thank the UNC Lineberger Comprehensive Cancer Center and the V Foundation for their generous support for the program, Mechanisms to Enhance Our Workforce and Accrual of BIPOC Individuals into Clinical Trials.

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A Multimodal Approach to Increasing Participation of Underrepresented Communities in Investigator-Initiated Cancer Clinical Trials

J. Gomez, G. Gresham, E. Hautamaki, M. Malikowski, K. Reckamp, B. Rimel
Cedars-Sinai Cancer

1. Background

Cedars-Sinai Cancer serves a highly diverse catchment area, yet clinical trial participants do not always reflect the breadth of this diversity. Underrepresented populations do not participate at expected rates due to burdensome research procedures, restrictive eligibility criteria, cultural or language barriers, and other factors. The result is a research population that is not representative of the catchment area, impacting generalizability of results. Investigator-initiated trials (IITs) provide an opportunity to design and customize trials to meet the needs of historically marginalized populations by actively addressing barriers to participation for underresourced communities and designing trials that engage specific groups that have been economically/socially marginalized.

2. Goals

Develop a multimodal approach to IIT design that encourages diversity, equity, and inclusion (DEI) in all areas of protocol design, resulting in protocols that complement the overall cancer research portfolio and support DEI enrollment goals.

3. Solutions and Methods

A collaboration was formed between Cedars-Sinai Cancer's IIT Development Program, Clinical Trials Equity Program, and investigators to design strategies to support DEI accrual goals throughout the trial process, from protocol design to recruitment and retention, trial conduct, analysis, and reporting.

4. Outcomes

Multiple strategies are ongoing involving protocol development with DEI objectives, support of underserved patients, and increasing clinical trial awareness. The IIT protocol template was revised to include a section on expected enrollment targets by gender, race, and ethnicity. At the time of the initial IIT committee review, the principal investigator details how the trial addresses the needs of our catchment area and how to support enrollment of underrepresented groups; and reviewers comment on whether the trial supports our catchment area and underrepresented populations. To address language translation of informed consent forms, questionnaires, and other patient-facing study documents, the institution implemented a process to fund translation expenses for research where language translation was not budgeted. During the enrollment period, study teams offer patients an Inclusive Demographics for Research (IDR) questionnaire, which gathers granular demographic information allowing for measurement of progress towards DEI goals. Furthermore, a virtual, self-paced training is offered to all researchers, providers, scientists, and faculty, to develop a deeper understanding of health equity, our cancer catchment area, underserved communities of color, benefits of inclusive research, barriers for communities of color to participate in research, resources to support diverse enrollment, and education and awareness tactics to engage with communities of color for research consideration and enrollment. Based on these interventions, analysis of our accrual data for the Latinx population demonstrated increased in enrollment to interventional treatment trials from 11.1 to 18.3 percent (+7.2 percent), interventional and non-interventional non-therapeutic accruals have increased by 4 percent and 5 percent respectively in the past year.

5. Lessons Learned and Future Directions

Future directions include conducting real-time assessment of progress toward DEI goals, utilizing data gathered from the IDR questionnaire to refine outreach strategies, and continuing to engage participants from diverse backgrounds to understand motivating factors and barriers to clinical trial enrollment. We will expand our focus to enhance resources to improve enrollment of our underserved Asian and Black communities.

Cedars Sinai Cancer

Community Outreach and Engagement, Diversity Equity and Inclusion: A Multimodal Approach to Increasing Participation of Underrepresented Communities in Investigator-Initiated Cancer Clinical Trials

Cedars-Sinai Cancer Clinical Trials Office
Jose Gomez, MSW, Gillian Gresham, PhD, Emily Hautamaki, RN, MPH, CCRP, Marie J. Malikowski, MHA, CCRP, Karen Reckamp, MD, MS, B.J. Rimel, MD
Cedars-Sinai, Los Angeles

Background

Cedars Sinai Cancer serves a highly diverse catchment area, yet clinical trial participants do not always reflect the breadth of this diversity. Underrepresented populations do not participate at expected rates due to burdensome research procedures, restrictive eligibility criteria, cultural or language barriers, and other factors. The result is a research population that is not representative of the catchment area, impacting generalizability of results. Investigator-initiated trials (IITs) provide an opportunity to design and customize trials to meet the needs of historically marginalized populations by actively addressing barriers to participation for under resourced communities and designing trials that engage specific groups that have been economically/socially marginalized.

Goals

Develop a multimodal approach to IIT design that encourages diversity, equity, and inclusion (DEI) in all areas of protocol design, resulting in protocols that complement the overall cancer research portfolio and support DEI enrollment goals.

Solutions and Methods Implemented

A collaboration was formed between Cedars-Sinai Cancer's IIT Development Program, Clinical Trials Equity Program, and investigators to design strategies to support DEI accrual goals throughout the trial process, from protocol design to recruitment and retention, trial conduct, analysis, and reporting.

Outcomes and Data / Representing Change

Multiple strategies are ongoing involving protocol development with DEI objectives, support of underserved patients and increasing clinical trial awareness. The IIT protocol template was revised to include a section on expected enrollment targets by gender, race, and ethnicity. At the time of the initial IIT committee review, the Principal Investigator details how the trial addresses the needs of our catchment area and how to support enrollment of underrepresented groups; reviewers comment on whether the trial supports our catchment area and underrepresented populations. To address language translation of informed consent forms, questionnaires, and other patient-facing study documents, the institution implemented a process to fund translation expenses for research where language translation was not budgeted. During the enrollment period, study teams offer patients an Inclusive Demographics for Research (IDR) questionnaire, which gathers granular demographic information allowing for measurement of progress towards DEI goals. Furthermore, a virtual, self-paced training is offered to all researchers, providers, scientists, and faculty, to develop a deeper understanding of health equity, our cancer catchment area, underserved communities of color, benefits of inclusive research, barriers for communities of color to participate in research, resources to support diverse enrollment, and education and awareness tactics to engage with communities of color for research consideration and enrollment. Based on these interventions, analysis of our accrual data for the Latinx population demonstrated increased in enrollment to interventional treatment trials from 11.1% to 18.3% (+7.2%), interventional and non-interventional non-therapeutic accruals have increased by 4% and 5% respectively in the past year.

Figure 1

Lessons Learned / Pointing Toward the Future

Future directions include conducting real-time assessment of progress toward DEI goals, utilizing data gathered from the IDR questionnaire to refine outreach strategies, and continuing to engage participants from diverse backgrounds to understand motivating factors and barriers to clinical trial enrollment. We will expand our focus to enhance resources to improve enrollment of our underserved Asian and Black communities.

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A Multichannel Approach to Reducing the Health Equity Gap in the Black Community

J. Gomez, A. Levi, A. Hendifar
Cedars-Sinai Cancer

1. Background

The Black population has the highest death rate, and shortest survival time, after a cancer diagnosis. Simultaneously, this population is also systematically underserved and historically marginalized through educational systems regarding health care choices, leaving questions about where and when to turn to outside resources for help. Multichannel and cross-promotional content has served as the gold standard for capturing attention, generating awareness, and inspiring action amongst underrepresented demographic groups.

2. Goals

- Develop multichannel and cross-promotional content that provides education and enumerates clinical trial participation in the Black community within the Cedars-Sinai Cancer catchment area.
- Address the systemic information gap in Black communities by developing and distributing a tailored educational marketing campaign leveraging several pre-identified influencers.
- Distribute developed content through partnerships with key organizations that have extensive earned reach in targeted underrepresented communities.

3. Solutions and Methods

A collaboration formed between Cedars-Sinai Cancer's medical director of pancreatic cancer, medical director for outreach, Clinical Trials Equity Program, Pancreatic Cancer Action Network (PanCAN), a Cedars-Sinai Cancer patient, and various stakeholders to produce two public service announcements (PSAs). The short version of the PSA illustrated our patient's experience with cancer and participation in research. The PSA's long version highlights Cedars-Sinai's diverse staff, communicating the importance of Black populations joining clinical trials, safeguards protecting research patients, educational resources, and personal experience in research.

Upon completion of the PSAs, a distribution system and analysis were developed to release the PSAs on digital platforms between May and November 2022. A call to action encouraged audiences to learn more about research by calling the Cedars-Sinai Cancer Clinical Trials Hotline 310-423-2133. The hotline, managed by Cedars-Sinai's marketing team, provides analytics regarding the inbound calls relating to the PSA distribution. Digital publications were developed focusing on the Cedars-Sinai patient featured in the PSA, further amplifying messaging. These digital publications were distributed on the same platforms as the PSA.

4. Outcomes

Multiple strategies are ongoing. According to Cedars-Sinai's marketing data for the clinical trials hotline, an estimated 134 cancer trials referrals potentially resulted from PSA distribution. (See Figure 1.) According to data provided by Cedars-Sinai's social media team, the short version of the PSA reached 2,598 accounts, 2,987 impressions, 56 likes, 1 comment, 927 views and eight profile visits on Instagram and 521 views, 33 reactions, and 3 comments on Facebook. The long version of the PSA reached 1,327 views on Instagram, 622 views and 40 reactions on Facebook, 551 views and nine reactions on YouTube, and 1,199 impressions, 116 engagements, 18 profile visits, 14 link clicks, 24 likes, and nine retweets on Twitter. Early data show that these efforts have resulted in an increase to our accruals in interventional, therapeutic trials.

5. Lessons Learned and Future Directions

Future directions include refining the hotline process to add identifying intake questions to better understand if callers interested in cancer trials have viewed the PSAs. It is unclear if the PSA distribution had a direct impact yet on increased enrollment of the Black community in cancer clinical trials, yet it is our goal to continue a campaign to increase education and participation in cancer prevention and research.

Cedars Sinai Cancer

Community Outreach and Engagement, Diversity Equity and Inclusion: A Multichannel Approach to Reducing the Health Equity Gap in the Black Community

Cedars-Sinai Cancer Clinical Trials Office
Jose Gomez, MSW, Abrahm Levi, BS, CCRP, Marie J. Malikowski, MHA, CCRP, Andrew Hendifar, MD
Cedars-Sinai, Los Angeles

Background

The Black population has the highest death rate, and shortest survival time after a cancer diagnosis. Simultaneously, this population is also systematically underserved and historically marginalized through educational systems regarding healthcare choices, leaving questions about where and when to turn to outside resources for help.

Multichannel and cross promotional content has served as the gold standard for capturing attention, generating awareness, and inspiring action amongst underrepresented demographic groups.

Goals

Develop multichannel and cross promotional content that provides education and enumerates clinical trial participation in the Black community within the Cedars-Sinai Cancer catchment area. Addressing the systemic information gap in Black communities by developing and distributing a tailored educational marketing campaign leveraging several pre-identified influencers. Distributing developed content through partnerships with key organizations that have extensive earned reach in targeted underrepresented communities.

Solutions and Methods Implemented

A collaboration formed between Cedars-Sinai Cancer's Medical Director of Pancreatic Cancer, Medical Director for Outreach, Clinical Trials Equity Program, Pancreatic Cancer Action Network (PanCAN), a Cedars-Sinai Cancer patient and various stakeholders to produce two Public Service Announcements (PSAs). The short version of the PSA illustrated our patient's experience with cancer and participation in research. The PSA's long version highlights Cedars-Sinai's diverse staff communicating the importance of Black populations joining clinical trials, safeguards protecting research patients, educational resources, and personal experience in research.

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Digital publications were developed focusing on the Cedars-Sinai patient featured in the PSA further amplifying messaging. These digital publications were distributed on the same platforms as the PSA.

Cedars Sinai

Cancer - Clinical Trials Campaign

	FY22			FY23						
	April	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan
Referral Volume	*5*	*19*	*18*	*14*	*20*	*13*	*14*	*8*	*11*	*12*

Outcomes and Data / Representing Change

Multiple strategies are ongoing. According to Cedars-Sinai's marketing data for the clinical trials hotline, an estimated 134 cancer trials referrals potentially resulted from PSA distribution. See Figure 1. According to data provided by Cedars-Sinai's social media team, the short version of the PSA reached 2,598 accounts, 2,987 impressions, 56 likes, 1 comment, 927 views and 8 profile visits on Instagram and 521 views, 33 reactions, and 3 comments on Facebook. The long version of the PSA reached 1,327 views on Instagram, 622 views and 40 reactions on Facebook, 551 views and 9 reactions on YouTube, and 1,199 impressions, 116 engagements, 18 profile visits, 14 link clicks 24 likes and 9 retweets on Twitter. Early data show that these efforts have resulted in an increase to our accruals in interventional, therapeutic trials.

Lessons Learned / Pointing Toward the Future

Future directions include refining the hotline process to add identifying intake questions to better understand if callers interested in cancer trials have viewed the PSAs. It is unclear if the PSA distribution had a direct impact yet on increased enrollment of the Black community in cancer clinical trials, yet it is our goal to continue a campaign to increase education and participation in cancer prevention and research.

Figure 1

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Development of a Process to Share Plain Language Summaries of Clinical Research Results With Participants at Princess Margaret Cancer Centre

K. Zeman, H. Cole, S. Sellmann
Princess Margaret Cancer Centre, University Health Network

1. Background

There has been a call for greater transparency in communicating information related to clinical research to both participants and the public. A recent survey of over 14,000 people in the United States showed that 88 percent of respondents thought that "scientists should be sharing their results in easy-to-understand language." Various stakeholders, including medical journals, publishers, associations, and agencies, have responded to this appeal by making research outcomes available to lay audiences. For example, the European Union regulations governing clinical trial conduct require sponsors to submit plain language summaries (PLSs) of their trial results.

Sharing clinical research results with participants who contribute to the research helps promote inclusivity and transparency by making scientific information more accessible. At Princess Margaret Cancer Centre (PMCC), feedback received from a survey of over 500 of our clinical trial participants indicated that the top factor influencing their decision to participate in future studies was obtaining the overall research results.

2. Goals

The objective of our project is to develop a means of sharing clinical research results with participants and the public in an accessible and comprehensible format. By sharing results written in plain language, we endeavor to provide meaningful information to our participants and the public by facilitating knowledge translation and supporting patient-centered care. We hope that this initiative will serve to increase patient engagement, promote transparency, and acknowledge the value of participants' contributions to clinical research and the advancement of medical knowledge.

3. Solutions and Methods

Our project constitutes a new initiative to support PMCC investigators and study teams by developing PLS documents of their research results to share with their participants. The project will address an unmet need, fulfilling participants' expressed interest in obtaining the results of studies to which they contributed.

Our work will also support clinical researchers and study staff, who wish to improve participants' experiences, but who may lack the expertise or capacity to address the return of research results in lay language.

4. Outcomes

We completed a pilot study to assess the feasibility of developing PLSs, involving three academic clinical trials. We received positive feedback from investigators, study team members, and sponsors' representatives, who expressed support for our efforts to engage patients and translate research results into accessible formats. Following the success of the pilot, we proceeded to operationalize our initiative and formalize a process for requesting and developing PLSs. This includes the creation of an application form, process summary, guidance documents, and resources for study teams.

5. Lessons Learned and Future Directions

Piloting our PLS initiative highlighted the importance of developing a standardized process to assist study teams with requesting and obtaining requisite approvals for pls distribution to study participants. we are currently working with our research ethics board to standardize the application submission process for PLSs, to reduce administrative burden and turn-around times.
In an effort to promote patient and community engagement and foster transparency, we also plan to create a public-facing website to share the PLSs of our clinical research results.

Sharing Plain Language Summaries of Clinical Research Results with Participants at Princess Margaret Cancer Centre

Kathie Zeman, Heather Cole, Susanna Sellmann, Cancer Clinical Research Unit, Princess Margaret Cancer Centre

① Background

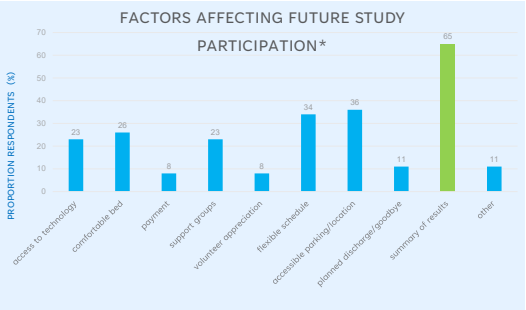
Greater transparency has been called for in communicating information related to clinical research to both participants and the public.

A recent survey of over 14,000 people in the United States demonstrated that 88 percent of respondents felt that "scientists should be sharing their results in easy-to-understand language".[1]

Multiple stakeholders, including medical journals, publishers, associations, and agencies, have responded to this appeal by making research outcomes available to lay audiences. For example, the European Union regulations governing clinical trial conduct require sponsors to submit plain language summaries (PLSs) of their trial results.[2]

Sharing results with the participants who contribute to the research helps promote inclusivity and transparency by making scientific information more accessible.

At Princess Margaret (PM), feedback received from a survey of over 500 clinical trial participants indicated that the top factor influencing their decision to participate in future studies is obtaining the overall research results.



*Princess Margaret participants were asked to select from a list of factors, those which they deemed important when considering future study participation

② Objectives

The project was conceived with the goal of developing a means of sharing clinical research results with participants and the public in an accessible and comprehensible format. By sharing results written in plain language, meaningful information can be provided to study participants and the public by facilitating knowledge translation and supporting patient-centered care.

This initiative was developed with the intention of increasing patient engagement, promoting transparency, and acknowledging the value of participants' contributions to clinical research and the advancement of medical knowledge.

③ Methods

The project constitutes a new initiative to support PM investigators and study teams by developing PLS documents of their research results to share with their participants. The project will thus address an unmet need - fulfilling participants' expressed interest in obtaining the results of studies to which they contributed.

The initiative will provide a service to support clinical researchers and staff, who wish to improve participants' experiences, although may lack the expertise or capacity to address the return of research results in lay language.

④ Outcome

A pilot study was completed, involving three academic clinical trials, to assess the feasibility of developing PLSs. Investigators, study team members, and sponsors representatives expressed support for the engagement of participants and translation of research results into accessible formats.

Following the success of the pilot, a standard process to operationalize requests for the development of PLSs was created. Resources were designed to support this initiative, including general information for users, an application form, a process summary and guidance documents (including a "frequently-asked-questions" sheet). Development of a standard operating procedure is currently underway.

⑤ Lessons Learned & Future Directions

Piloting our PLS initiative highlighted the importance of developing a standardized process to assist study teams with requesting and obtaining requisite approvals for PLS distribution to study participants.

We are currently working with our Research Ethics Board to standardize the application submission process for PLSs in order to reduce administrative burden and turn-around times. In support of promoting patient and public engagement and fostering transparency, we also plan to create a public-facing website to share the PLSs of our clinical research results with the broader community.

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Evaluating Clinical Trial Participation Across the Catchment Area: A Data Driven Approach

K. Sinclair, D. Forsyth, K. Hamade, C. McNair
Sidney Kimmel Cancer Center at Jefferson Health

1. Background

One of the primary missions of an NCI-Designated Cancer Center is to ensure alignment to the catchment area it serves across the research continuum, with a specific focus on clinical trial participation. Despite this, actively monitoring this population presents distinct challenges due to many factors, including data siloed in different systems, disparate levels of data specificity, and lack of technical expertise. Thus, the Sidney Kimmel Cancer Center (SKCC) Clinical Trial Informatics (CTI) group developed an interactive Shiny application to monitor trends in clinical trial accrual, while continuing to compare to both SKCC specific data, as well as publicly available information specific to our catchment area, with a focus on reproducibility.

2. Goals

- Develop reporting tools to monitor the accrual population that is user-friendly and interactive.
- Identify disparities between clinical trial participants and catchment area population.
- Highlight actionable insights around clinical trial metrics and reporting.

3. Solutions and Methods

Data sources:

- Clinical trial data: JeffTrial (SKCC's OnCore Instance)
- SKCC-specific cancer population data: Tumor registry (Metriq)
- Patient location data: EMR (Epic)
- Census level socioeconomic data (various public sources)

SKCC cancer population data is extracted from our tumor registry system and used to generate catchment level demographic metrics, while accrual data is linked with Epic to generate location information for patients at the census tract level and linked to public data resources of interest. These data are plotted using heat maps and other visualization tools within an interactive Shiny application that can be used to gain a better understanding of our trial population and provide an easy means of comparing and monitoring this population over time.

4. Outcomes

The applications that are developed are used both within our clinical trial organization and greater institution to consistently monitor the catchment population and ensure patients on clinical trials are representative. Additionally, teams are able to identify gaps and potential disparities, and work to identify barriers to participation.

5. Lessons Learned and Future Directions

Future work will aim to provide more insights on internal metrics that may illuminate potential hurdles for patients on studies. This will include examining distances between patients and their study sites, so we can ensure we are offering trials closer to home for all patients, as well as where there are geographic gaps in trial offerings within our community sites.

Evaluating Clinical Trial Participation Across the Catchment Area: A Data Driven Approach

Krystin Sinclair, Dan Forsyth, Khaldoun Hamade, Chris McNair
Data Informatics, Sidney Kimmel Cancer Center at Jefferson Health

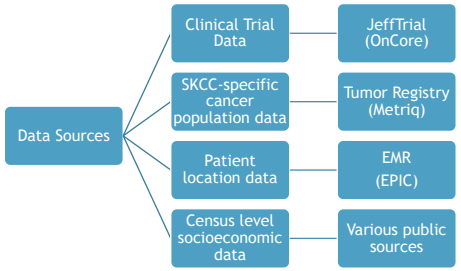
Background

One of the primary missions of an NCI-designated cancer center is to ensure alignment to the catchment area it serves across the research continuum, with a specific focus on clinical trial participation. Despite this, actively monitoring this population presents distinct challenges due to many factors including data siloed in different systems, disparate levels of data specificity, and lack of technical expertise. Thus, the SKCC Clinical Trial Informatics (CTI) group developed an interactive shiny application to monitor trends in clinical trial accrual, while continuing to compare to both SKCC specific data, as well as publicly available information specific to our catchment area, with a focus on reproducibility.

Goals

- Develop reporting tools to monitor the accrual population that is user friendly and interactive
- Identify disparities between clinical trial participants and catchment area population
- Highlight actionable insights around clinical trial metrics and reporting

Data Sources



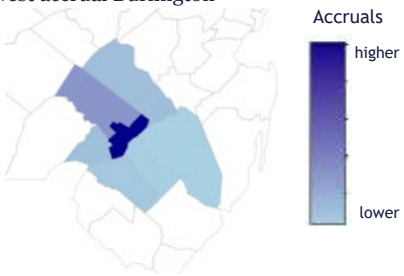
Methods

- Data are matched by patient and geographic areas
- Interactive Shiny Application
  - Heat Maps
  - Comparison points
    - By Accrual
    - By County
- Gain a better understanding of our trial population
- Provide an easy means of comparison and monitoring this population over time

Outcomes

The applications that are developed are used both within our clinical trial organization and greater institution to consistently monitor the catchment population and ensure patients on clinical trials are representative. Additionally, teams are able to identify gaps and potential disparities, and work to identify barriers to participation.

- Accrual by County 1st Quarter 2023
  - Highest accrual Philadelphia
  - Lowest accrual Burlington



Outcomes (cont.)

Accrual Heat Map 1st Quarter 2023

Lesson Learned and Future Directions

Future work will aim to provide more insights on internal metrics that may illuminate potential hurdles for patients on studies. This will include examining distances between patients and their study sites, so we can ensure we are offering trials closer to home for all patients, as well as where there are geographic gaps in trial offerings within our community sites.

Acknowledgements

Cancer in Focus, University of Kentucky, https://cancerinfocus.uky.edu

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Increasing Clinical Trial Accrual of Minority Patients by Expanding Clinical Operations at Satellite Sites

A. Dhadwal, D. Catmaero, A. Lieberman-Cribbin, C. Rodriguez, J. Richter, S. Jagannath
The Tisch Cancer Institute at Mount Sinai

1. Background

Multiple myeloma (MM) is the most common blood cancer among African Americans (AA). Despite the fact that AA comprise ~20 percent of the population of MM patients, they only represent 6 percent of patients in clinical trials. Moreover, the MM mortality rate among AA is two times greater than in whites with a five-year age-adjusted mortality rate of 6.2 per 100,000, vs. 3.1 per 100,000 among whites. However, when enrolled in clinical trials, AA patients fare as well as, or better than, white patients underscoring the critical need for inclusion of underserved minority patients in our clinical trials. There is also a clinical and regulatory need to generate efficacy and safety data in minority patient populations that are representative of the background incidence of the disease for inclusion in labeling.

2. Goals

There are many factors contributing to suboptimal clinical trial enrollment among minority MM patients, including being presented with the option to enroll in a trial, lack of awareness of clinical research, socioeconomic factors, and general mistrust of research due to historical maltreatment of minorities in medicine and research. One of the main contributing factors is that our trials are often not conducted at community sites where MM minority patients are treated due to lack of clinical trial resources, including infrastructure, study coordinators, and clinical staff.

Our center sees more than 500 new patients each year, making us a center of excellence for MM care in New York City (NYC). We are also home to one of the largest and most diverse patient populations, which affords us the opportunity to have an inclusive clinical trial program.

3. Solutions and Methods

We hired advanced practice providers (APPs) who worked with clinical trial managers (CTMs) to lead the MM-focused clinics and to advance the clinical trials programs at the sites. CTMs focused on clinical operations and logistics by assessing the feasibility of each clinical trial to the site population. AAPs train infusion nurses, pharmacy, and support staff on clinical trials and Good Clinical Practice.

4. Outcomes

Underserved areas in NYC were identified by using NYC.gov and overlaying a heat map of the MM patient population using underserved area parameters. We identified areas of the most need and matched the locations with our closest satellite site: Brooklyn and lower Manhattan. As of December 31, 2022, we have successfully opened clinical trials at our satellite and enrolled 12 patients. In addition, we have several clinical trials currently in the study start-up process.

5. Lessons Learned and Future Directions

Minority patients continue to be underrepresented in clinical trials. There are many barriers to clinical trial enrollment. Travel, cost, and lost wages from work can significantly impact enrollment. By attempting to offer clinical trials in the community, we hope to reduce the stressors of clinical trials and improvement overall patient representation.

Increasing Clinical Trial Accrual of Minority Patients by Expanding Clinical Operations at Satellite Sites

Amishi Dhadwal, Donna Catamero, NP, Alex Lieberman-Cribbin, Cesar Rodriguez, MD, Joshua Richter, MD, Sundar Jagannath, MD
Mount Sinai School of Medicine

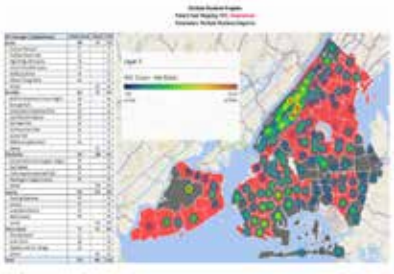
Icahn School of Medicine at Mount Sinai

BACKGROUND

Multiple myeloma (MM) is the most common blood cancer among African Americans (AA). Despite the fact that AA comprise ~20% of the population of MM patients, they only represent 6% of patients in clinical trials. Moreover, the MM mortality rate among AA is two-times greater than Whites with a 5-year age-adjusted mortality rate of 6.2 per 100,000 vs. 3.1 per 100,000 among Whites.[1] However, when enrolled in clinical trials, AA patients fare as well as, or better than, White patients underscoring the critical need for inclusion of underserved minority patients in our clinical trials. There is also a clinical and regulatory need to generate efficacy and safety data in minority patient populations that are representative of the background incidence of the disease for inclusion in labeling.

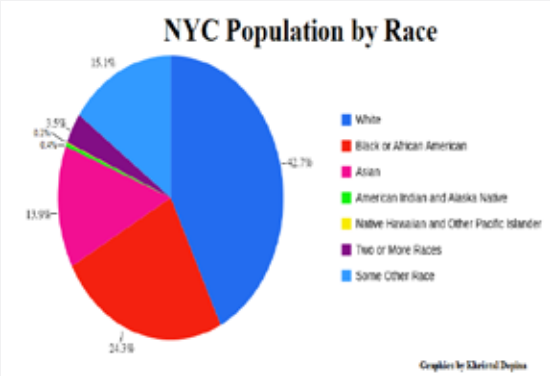
SOLUTIONS AND METHODS

Underserved areas in NYC were identified by using the NYC.gov and overlaid a heat map of the MM patient population using underserved area parameters. We identified areas of the most need and matched the locations with our closest satellite site: Brooklyn and lower Manhattan. We hired advanced practice providers (APPs) who worked with clinical trial managers (CTMs) to lead the MM focused clinics and to advance the clinical trials programs at the sites. CTMs focused on clinical operations and logistics by assessing the feasibility of each clinical trial to the site population. AAPs train infusion nurses, pharmacy, and support staff on clinical trials and Good Clinical Practice. As of 12/31/2022, we have successful opened clinical trials at our satellite and enrolled 12 patients. In addition we have several clinical trials currently in the study start up process.



OUTCOMES

There are many factors contributing to suboptimal clinical trial enrollment among minority MM patients including not being presented with the option to enroll in a trial, lack of awareness of clinical research, socioeconomic factors, and general mistrust of research due to historical maltreatment of minorities in medicine and research. One of the main contributing factors is that our trials are often not conducted at community sites where MM minority patients are treated due to lack of clinical trial resources including infrastructure, study coordinators and clinical staff.



GOALS

Minority patients continue to be underrepresented in clinical trials. Travel, cost and lost wages from work can significantly impact clinical trial enrollment. By offering our trials in the community, we hope to reduce the stressors of clinical trials and provide more equitable and representative care for our patients

LESSONS LEARNED AND FUTURE DIRECTIONS

Getting buy-in from industry sponsors to open clinical trials across the network

Regulatory, contract, budget needs

Educational needs
- Pharmacy
- Infusion nurses

Need for support services across the network sites
- Social work, scheduling support, medical assistances

Travel between sites can be challenging

1

Hybrid Decentralization of Early Phase Cancer Clinical Trials to Enhance Study Recruitment of Underrepresented Minorities

C. Wiess, A. Rodrigues, I. Palma, D. Wall, P. LoRusso
Yale Cancer Center, Yale School of Medicine

1. Background

Poor accrual of underrepresented minorities (URM) to clinical trials is a concern in cancer drug development, not only due to their lack of access to novel agents, but also the fact that limited diversity may fail to identify groups who could benefit, or have increased toxicity from, novel agents. This worry is even more predominant with early phase cancer clinical trials (EPCCT). EPCCT are often conducted in centralized locations, and, due to their complexity, require frequent safety assessments and extensive protocol requirements. Geographic location of trial execution is a major challenge for these patients. As such, the majority of URM patients are treated close to home in community clinics.

2. Goals

This project aims to implement a hybrid decentralization model (HDM), bringing feasible EPCCT components into community clinics where many URM patients already receive their treatment. The overall goal is to determine if, by bringing the trials to the patients, an increase in recruitment and retention will occur. We are opening two EPCCT clinics in community clinics in Connecticut: one in Fairfield County (12.9 percent Black, 20.5 percent Hispanic) and one in Hartford County (15.8 percent Black, 18.9 percent Hispanic).

3. Solutions and Methods

Infrastructure was established to support EPCCT at the community clinics, including dedicated space in the community clinic, a streamlined referral mechanism to schedule consults, and a feasibility assessment tool to allow for review of clinic capabilities to compliantly support protocol required visits; this tool provided a roadmap confirming which study visits must occur at the main Phase I Unit and which could occur at the community clinic. Feasibility considerations included, but were not limited to, drug administration route, timing and acuity of post-dose assessments, and onsite departments available (imaging, radiation, cardiology, ophthalmology, etc.).

To accommodate the multi-facility approach to Experimental Therapeutics Clinical Trials Network trials, formal guidance was drafted in collaboration with the National Cancer Institute, allowing participants to move between the community clinic and the main Phase I Unit without formally transferring the patient in the Cancer Trials Support Unit. Additionally, collaboration with study sponsors secured approval for key trials to be opened at the clinic, with appropriate steps taken to notate it as a participating location at the protocol level to ensure regulatory compliance.

Technological support was obtained through collaboration with Yale New Haven Hospital to allow EPCCT research staff to remotely manage protocol required visits. Community clinic research staff were identified, trained, and delegated to provide required onsite support including, but not limited to, video telecommunications setup, oral drug accountability, and PRO completion. Transportation and Structural and Social Determinants of Health resources were established for participants requesting assistance.

4. Outcomes

As of March 7, 2023, EPCCT trialist consultations at the Fairfield County clinic serviced an URM Category: Community Outreach and Engagement & Diversity, Equity, and Inclusion - Work in Progress population, including 21 percent Black and four percent Hispanic. Twenty-five percent of patients seen have consented to an EPCCT.

5. Lessons Learned and Future Directions

The HDM will be expanded to a Harford County community clinic. To ensure data integrity and patient safety, deviations and serious adverse events will be assessed and compared between the standard centralized model and HDM.

Funding: Roche-Genentech, Boehringer-Ingelheim, Gilead and Loxo Lilly Oncology

Hybrid Decentralization of Early Phase Cancer Clinical Trials to Enhance Study Recruitment of Underrepresented Minorities

Christina Wiess, BA, CCRP, Amy Rodrigues, CCRP, Ingrid Palma, MHS, Diane Wall, MSN, RN, Patricia LoRusso, DO

Goals

Aim: to implement a hybrid decentralization model, bringing feasible early phase cancer clinical trials components into community clinics where many underrepresented minority patients already receive their treatment.

Goal: to determine if, by bringing the trials to the patients, an increase in recruitment and retention will occur.

Background

- Poor accrual of underrepresented minorities to clinical trials is a concern in cancer drug development, not only due to their lack of access to novel agents, but also the fact that limited diversity may fail to identify groups who could benefit, or have increased toxicity from, novel agents. This worry is even more predominant with early phase cancer clinical trials.
- Early phase cancer clinical trials are often conducted in centralized locations and due to their complexity, require frequent safety assessments and extensive protocol requirements.
- Geographic location of trial execution is a major challenge for these patients. As such, the majority of underrepresented minority patients are treated close to home in community clinics.

Solutions and Methods

We are opening two early phase cancer clinical trials clinics in community clinics in Connecticut: one in Fairfield County (12.9% Black, 20.5% Hispanic) and one in Hartford County (15.8% Black, 18.9% Hispanic).

Infrastructure was established to support early phase cancer clinical trials at the community clinics, including:

Clinical Presence
- Dedicated space in the community clinic
- Streamlined referral mechanism to schedule consults

Feasibility
- Feasibility assessment tool to allow for review of clinic capabilities, considerations of which included, but were not limited to:
  - Drug administration route
  - Timing and acuity of post-dose assessments
  - Onsite departments available (imaging, radiation, cardiology, ophthalmology, etc.)

Technology
- Technological support obtained from Yale New Haven Hospital to allow EPCCT research staff to remotely manage protocol required visits

Stakeholder Collaboration
- To accommodate multi-facility approach to Experimental Therapeutics Clinical Trials Network (ETCTN) trials, formal guidance was drafted in collaboration with the National Cancer Institute, allowing participants to move between the community clinic and the main Phase I Unit without formally transferring the patient in CTSU.
- Secured study sponsors' approval for key trials to be opened at the clinic, with appropriate steps taken to notate it as a participating location at the protocol level to ensure regulatory compliance.
- Community clinic research staff were identified, trained, and delegated to provide required onsite support including, but not limited to, video telecommunications setup, oral drug accountability, and PRO completion.

Structural and Social Determinants of Health
- Each participant is being screening for structural and social determinants of health.
- Required resources were established for participants requiring assistance, including Uber Health

Outcomes

- As of 5/10/2023, early phase cancer clinical trialist consultations at the Fairfield County clinic serviced an URM population including 21.6% Black and 5.4% Hispanic.
- As of 5/10/2023, 40.5% of patients seen by an early phase cancer clinical trialist consultations at the Fairfield County clinic have consented to an early phase cancer clinical trial, with 26.7% of consented patients being Black.
- As of 5/10/2023, 80.0% of the patients consented to an early phase cancer clinical trial have been deemed eligible for and started treatment.

Lessons Learned and Future Directions

- The hybrid decentralization model will be expanded to a Hartford County community clinic.
- Structural and Social Determinants of Health will continue to be evaluated for appropriate intervention.
- To ensure data integrity and patient safety, deviations and SAEs will be assessed and compared between the standard centralized model and the hybrid decentralization model.

Funding

- Roche-Genentech, Boehringer-Ingelheim, Gilead Sciences, Inc., and Loxo Oncology, Inc. Eli Lilly and Co., Emerson Collective, Gateway for Cancer Research.

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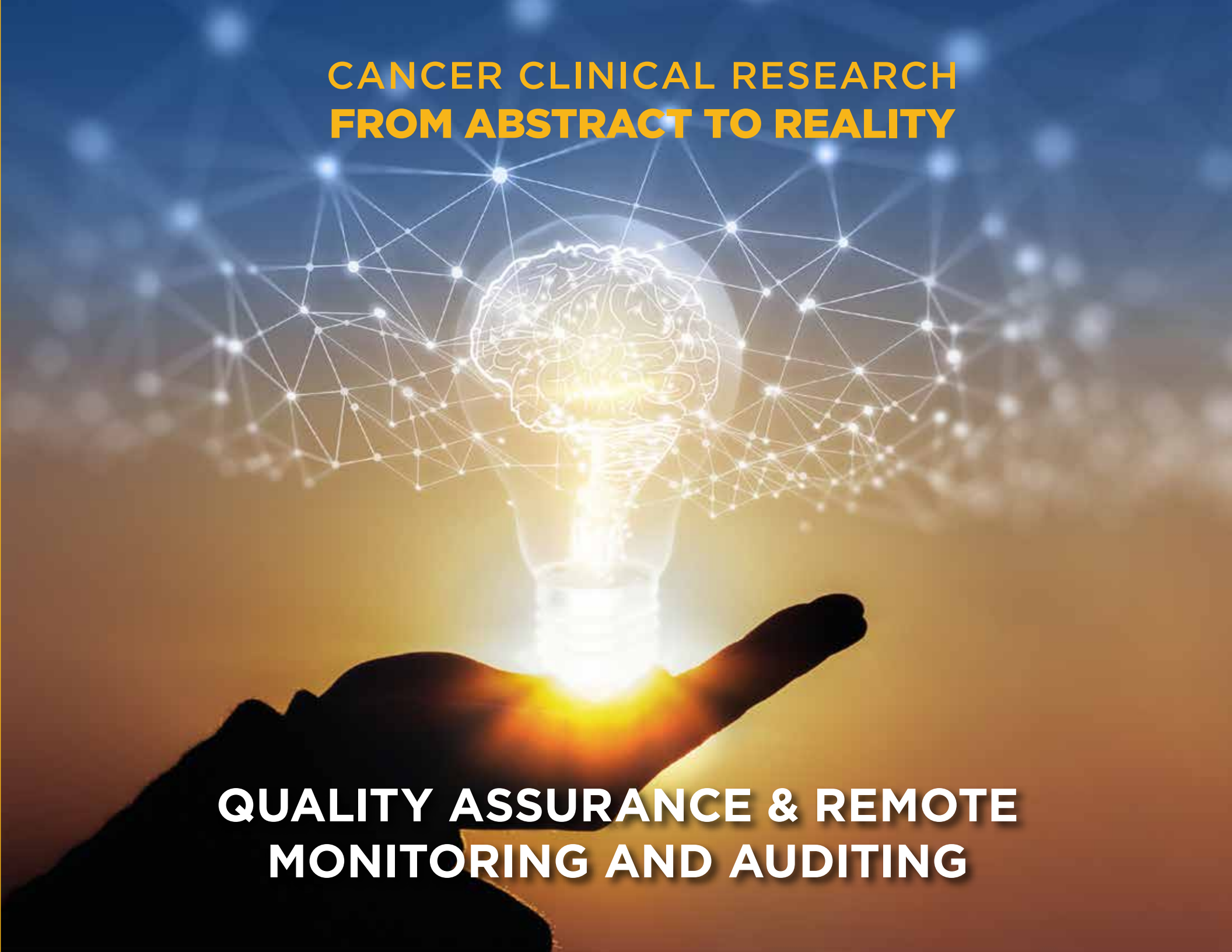
CANCER CLINICAL RESEARCH

FROM ABSTRACT TO REALITY



QUALITY ASSURANCE & REMOTE MONITORING AND AUDITING

Development of a Digital Audit Tracking Tool for FDA Audit Readiness

K. MacLennan, B. Koch
Abramson Cancer Center of the University of Pennsylvania

1. Background

To facilitate ongoing readiness of cancer clinical trials (CCTs) at risk for inspection by the Food and Drug Administration (FDA), the Abramson Cancer Center (ACC) Lymphoma Group enrolled FDA inspection high-risk CCTs (FDA CCTs) in an external inspection support program (EIS) operated by the ACC Department of Operations, Compliance and Monitoring. At initial EIS enrollment of the first FDA CCT, there was no consistent audit preparation process in place for the Lymphoma Group. A digital audit tracking tool (ATT) was developed to create a uniform, streamlined, collaborative process that could be utilized for current and future CCTs.

2. Goals

- To create a streamlined, collaborative process for research team members to maintain FDA CCT participant binders in an audit-ready state
- To create a standardized audit tool template to be utilized for trials enrolled in the EIS program, as well as adapted for all current and future FDA CCTs
- To efficiently identify and resolve all missing and/or incomplete source documentation by aggregating trial data in an accessible and secure location

3. Solutions and Methods

The EIS program requirements necessitated creation of the ATT to enable all research team members to review participant binders in a standardized and collaborative fashion via an online Excel spreadsheet shared through Penn+ Box. Each research team member is given access to the ATT, which permits documentation, review of, and resolution of all missing/incomplete source documentation in participant binders. The ATT assures that all audit review progress is available for review by all members of the research team and enables preparation and maintenance of FDA CCT participant binders in an FDA inspection readiness state.

4. Outcomes

The ATT was first created for use for a specific FDA CCT. To this date, this trial has not undergone FDA inspection at the ACC. However, the utility and efficiency of the ATT has resulted in exemplary monitoring reviews by the EIS program. The processes for audit readiness have become more streamlined and collaborative across the Lymphoma Group and have resulted in similar exemplary monitoring reports in other EIS program-enrolled trials. For this reason, the ATT has been adapted and now utilized across many lymphoma studies that have enrolled in the EIS audit readiness program.

5. Lessons Learned and Future Directions

The use of the ATT has been essential and extremely successful in maintaining audit-ready trial documentation across many studies in the Lymphoma Group enrolled in the EIS program. Initial implementation of the ATT was targeted for one FDA CCT. Its efficiency and inherent collaborative nature have resulted in the ATT being adapted for use in other FDA CCTs, based upon feedback from Lymphoma Group research staff. Suggestions have included: 1) the need for less data to be housed on one page of the ATT, and 2) the utilization of “tracked changes” for decreased margin of error in corrective data entry. The ATT will continue to be shared with other Clinical Research Unit research groups for implementation by their research staff for trials enrolled in the EIS program.

Development of a Digital Audit Tracking Tool for FDA Audit Readiness

Kaitlyn MacLennan– Clinical Data Manager
Abramson Cancer Center (ACC) Clinical Research Unit (CRU)
University of Pennsylvania, Philadelphia, PA

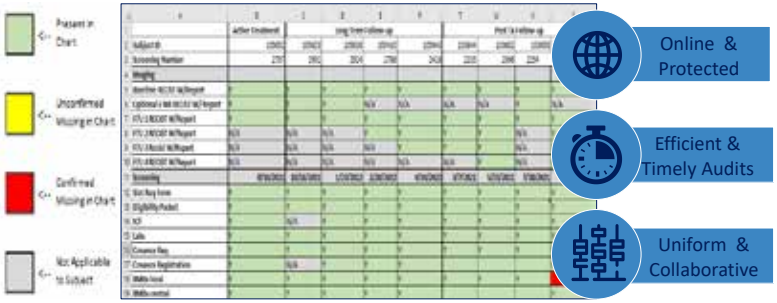
BACKGROUND

To facilitate on-going readiness of cancer clinical trials (CCTs) at risk for inspection by the Food and Drug Administration (FDA), the Abramson Cancer Center (ACC) Lymphoma Group enrolled FDA-inspection high risk CCTs (FDA CCTs) in an external inspection support program (EIS) operated by the ACC Department of Operations, Compliance and Monitoring (DOCM). At initial EIS enrollment of the first high risk CCT, there was no consistent audit preparation process in place for the Lymphoma Group. A digital audit tracking tool (ATT) was developed to create a uniform, stream-lined, collaborative process which could be utilized for current and future CCTs.

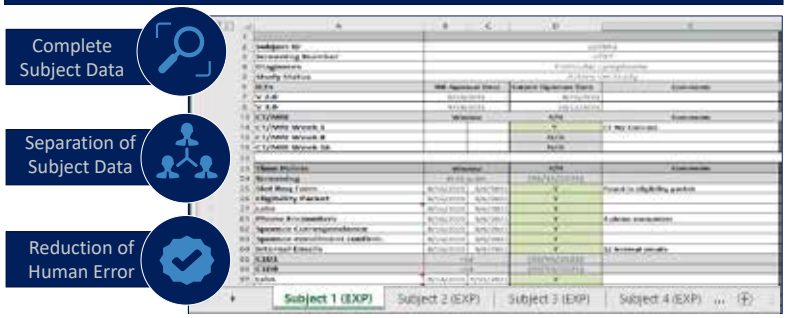
GOALS

- To create a stream-lined, online, collaborative process for research team members to maintain FDA CCT participant binders in an audit ready state
- To create a standardized audit tool template to be utilized for trials enrolled in the EIS program, as well as adapted for all current and future FDA CCTs
- To efficiently identify and resolve all missing and/or incomplete source documentation by aggregating trial data in an accessible and secure location

First Iteration of Audit Tracking Tool for FDA Inspection Readiness



Second Iteration of Audit Tracking Tool for FDA Inspection Readiness Following EIS



SOLUTIONS/ METHODS

The EIS program requirements necessitated creation of the ATT to enable all research team members to review participant binders in a standardized and collaborative fashion via an online Excel spreadsheet shared through Penn+ Box. The ATT assures that all audit review progress is available for review by all members of the research team and enables preparation and maintenance of FDA CCT participant binders in a FDA-inspection readiness state.

OUTCOMES

The utility and efficiency of the ATT has resulted in exemplary monitoring reviews by the EIS program. The processes for audit readiness have become more streamlined and collaborative across the Lymphoma Group and have resulted in similar exemplary monitoring reports in other EIS program-enrolled trials.

LESSONS LEARNED / FUTURE DIRECTIONS

The use of the ATT has been essential and its collaborative nature has resulted in the ATT being adapted for use in other FDA CCTs. The ATT will continue to be shared with other CRU research groups for implementation by their research staff for their CCTs enrolled in the EIS program.

Special Acknowledgement: Liudmila L. Mazaleuskaya, PhD, Terease S. Waite, PhD, RN, JD, MBE, Brittany J. Koch, MPH, CCRP

Improving Quality: First and Third Patient Review

A. Fritsche, K. Croghan, J. Zbacnik, A. Youssef, L. Winkowski, A. Holland, G. Nowakowski
Mayo Clinic Comprehensive Cancer Center

1. Background

The Mayo Clinic Comprehensive Cancer Center (MCCCC) was not immune to study staff turnover during the COVID-19 pandemic and the Great Resignation. To assure quality and patient safety, the MCCCC invested resources to assure the highest clinical trial quality through implementation of a database tracking system for first and third patient quality checks. The additional turnover of staff has further enhanced the database to include regulatory and research billing quality reviews.

2. Goals

The goals are to maintain patient safety and high-quality clinical trial operations while being able to proactively provide real-time feedback to staff; improve audit outcomes; and further collaboration among all Cancer Clinical Trial Office (CCTO) staff.

3. Solutions and Methods

First patient case file review occurs by the clinical research coordinator (CRC) and data coordinator (DC) completing a self-assessment form in the REDCap database to assure communication and understanding protocol and electronic data capture (EDC) requirements. These self-assessment forms are then reviewed by our Compliance and Quality Unit (CQU) auditor as a central reviewer. This is to help assist in the identification of educational and/or procedural gaps across the enterprise that need to be addressed.

Third patient case file, regulatory, and research billing quality review have forms in the REDCap database that are completed by the CQU auditor and team supervisors (research billing review). These quality reviews are conducted on all cancer-related trials and reports are sent to Data Safety Monitoring (DSM) for tracking and trending, and education intervention when needed.

4. Outcomes

The first patient review has improved the communication and relationship between the CRC and DC. It has also illustrated gaps in education that have been used to revise procedures and trainings. The third patient review has provided real-time feedback and correction of protocol and EDC understanding to assure the highest CCTO study conduct quality across patient and regulatory files. Again, the third patient reviews have helped to establish gaps in processes, procedures, and education, which have now become a fundamental part to sustain our CCTO Quality Management System (QMS). The research billing audits have assured that timely research charges and billing is taking place.

5. Lessons Learned and Future Directions

The REDCap tool, central review, and automation of first and third reporting has been critical to our QMS by ensuring quality at all levels. DSM also uses the information to help intervene and educate when systemic trends are first noticed and in real time.

Improving Quality: 1st and 3rd Patient Review

Authors: Angela Fritsche, MPA, Katrina Croghan M.S, CCRP, Lisa Winkowski, Keith Severson, Jade Zbacnik, Amanda Youssef, Adam Holland, Grzegorz Nowakowski, M.D.
Comprehensive Cancer Center, Mayo Clinic

BACKGROUND

The Mayo Clinic Comprehensive Cancer Center (MCCCC) was not immune to study staff turnover during the COVID-19 Pandemic and the Great Resignation.

To reassure quality and patient safety, the MCCCC invested resources to improve quality through implementation of an enterprise-wide database tracking system for all clinical trials performed within MCCCC. Reviews include:

- 1st and 3rd accrued patient quality checks
- regulatory reviews to ensure audit readiness
- research billing to assure timely research charges and billing

Previously reviews were conducted independently at each site but are now operating under a centralized process with detailed metrics and reporting.

GOALS

Maintain patient safety and high-quality clinical trial operations while proactively providing:

- Real-time feedback to staff
- Improve audit outcomes
- Furthering collaboration among CCTO staff

REFERENCES

REDCap 12.4.25 - © 2023 Vanderbilt University

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SOLUTIONS AND METHODS

These quality reviews are conducted on all clinical trials and reported to out Data Safety Monitoring teams to assess/track trends and educational interventions as needed.

FIRST PATIENT REVIEWS

Occurs when the first participant is accrued to the clinical trial.

REVIEW PART 1:

- Review is completed by the Clinical Research Coordinator (CRC) and Data Coordinator (DC) through a self-assessment form in the REDCap database.
- Assures communication between the CRC and DC.
- Addressed protocol and electronic Data Capture (EDC) requirements as a team.

REVIEW PART 2:

- Part 1 self-assessment form is then reviewed by our Compliance and Quality Unit (CQU) auditor as a central reviewer.
- Help assist in the identification of educational and/or procedural gaps across the enterprise that need to be addressed from a higher level.

THIRD PATIENT REVIEWS

Occurs when the third participant is accrued to the trial with subsequential review and as needed based off 3rd review findings.

- Central reviewer will complete a quality review on the 3rd participant following Cycle 1 completion.
- A REDCap tracking form will be used to complete all aspects of the review. Note: the REDCap form is similar to the 1st patient review form for consistency. This will help us determine trend capture between 1st and 3rd participants.
- When complete, the CQU auditor meets with the study team to discuss findings and how best to help correct and/or prevent future findings.
- Trends are reviewed across trial, unit and site to assist in the identification of educational and/or procedural gaps across the enterprise that need to be addressed from a higher level.

REGULATORY REVIEWS

Occur when the 3rd participant is accrued with subsequential reviews completed based off risk management.

- Regulatory central reviewer (also a CQU auditor) completed regulatory review using a REDCap form.
- When complete, the CQU auditor meets with the regulatory unit, who is charged with the trial's regulatory) to discuss findings and how best to help correct and/or prevent future findings

RESEARCH BILLING INVOICING REVIEWS

Occur when the 3rd participant is accrued with subsequential review as needed, based on original 3rd review findings.

- Site reviewer will complete the review using a REDCap form.
- When complete, the site reviewer meets with the DC to discuss findings and how best to help correct and/or prevent future findings.

FIGURE 1

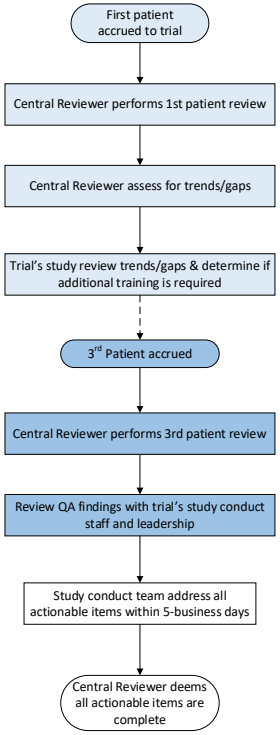

Figure 1 represents the Quality Assurance Review process.

OUTCOMES

1ST PATIENT REVIEW:

- Improved communication and relationship between the CRC and DC.
- Illustrated gaps in education, that have been used to revise procedures and trainings.

3RD PATIENT REVIEW:

- Provided real-time feedback
- Provided real-time correction of protocol and EDC understanding to assure
- Helped establish gaps in processes, procedures, and education, which helps sustain/maintain our CCTO Quality Management System (QMS) and education programs.

REGULATORY REVIEWS:

- Helped to verify consistency across site regulatory files.

RESEARCH BILLING INVOICE REVIEW:

- Established real-time feedback to study teams
- Help establish gaps that are being addressed by education and QMS

LESSONS LEARNED & FUTURE DIRECTIONS

The REDCap tool, central review, and automation of 1st and 3rd reporting has been critical to our QMS by ensuring quality at all levels.

DSM also uses the information to help intervene and educate when systemic trends are first noticed and in real-time.

Future directions to streamline the 1st and 3rd REDCap reports with the other quality trackers, such as our monitoring tracker, audit team tracker and Corrective and/or Preventative Action (CAPA) Plan tracker. The scope will be expanded to include all cancer-related clinical trials performed at Mayo Clinic

ACKNOWLEDGMENT

This work was funded solely by Mayo Clinic. Specific thanks to Michael Callahan, M.S.; Jacquelyn Gardner, M.B.A.; Heidi Kogut; Jay Ludescher, M.B.A.; Aaron Mansfield, M.D.; Leandra Pake, CCRP; Jessie Powell; Saundra Seabrook; and Carol Szumlanski.

Improving Quality: Audit Readiness Team

L. Winkowski, K. Croghan, K. Severson, H. Kogut, A. Jurrens, A. Fritsche, G. Nowakowski, A. Mansfield
Mayo Clinic Comprehensive Cancer Center

1. Background

Mayo Clinic Comprehensive Cancer Center (MCCCC) participates in an abundance of clinical trials, therefore increasing the chances of receiving an audit request. Audit requests range from industry sponsors, Food and Drug Administration (FDA), cooperative, and institutional. To assure our clinical research staff are "audit ready," the MCCCC designed and implemented an Audit Readiness Team (ART) to provide clinical research staff with the highest level of support and materials for every type of audit.

2. Goals

To ensure "audit ready" status and produce "clean"/ finding-free audits, the goals for ART are to:

- Provide audit prep assistance to clinical research staff
- Provide "on-call" resources during an audit
- Assist study teams with post-audit clean-up efforts, i.e., audit response, corrective and preventative action, implementation, and effectiveness assessment

3. Solutions and Methods

Since MCCCC spans across multiple locations, the ART is set up with enterprise-wide staff members from the Compliance and Quality Unit (CQU), Regulatory Unit, and Quality Management and Education, along with location specific "boots on the ground" subject matter experts (SME) from our Cancer Clinical Trial Office (CCTO) Coordination Units and Protocol Development Units (PDU). This setup ensures that the CCTO research staff have access to resources and SMEs; along with ensuring ART member availability during an audit.

When notified of an audit, the CCTO research team submits a REDCap audit notification eForm communicating key information to the CQU. This information includes team members (i.e., principal investigator, CCTO staff, etc.); location of audit; type of audit; protocol information; and the requested date for the audit to occur. The CQU then reviews the notification and assigns ART members to assist the research team. The CQU also provides the research team with materials to aid in their preparation for the upcoming audit.

Prior to the audit, the assigned ART members will then meet with the research team to provide introduction and clarity to ART's role and to also understand the rationale for the audit.

ART is available for all cancer-related trials and tracked through REDCap. Identified trends and/ or significant concerns are provided to the Data Safety Monitoring (DSM) chair for review and determination of next steps.

4. Outcomes

The implementation of the ART has improved the consistency of materials across all MCCCC locations. It has also provided the research teams with quick and direct access to SMEs and an abundance of resources to help in the preparation, conduct, and post-audit activities. It has shown that the research staff feel more confident, as they are better prepared and understand how to continue to improve their files to ensure "audit readiness." Development of this team highlighted gaps in the location of resources and materials, which has now been incorporated into key guidance documents, checklists, and trainings.

5. Lessons Learned and Future Directions

Tracking of audit results is critical in aiding us with process improvements and educational opportunities. Moving forward, the MCCCC DSM Committee will be reviewing the outcomes to assist with assessing and determining the operational and educational needs for our CCTO.

Improving Quality: Audit Readiness Team (ART)

Authors: Lisa Winkowski, Katrina Croghan M.S, CCRP, Keith Severson, Heidi Kogut, Angela Jurrens M.A., Angela Fritsche, MPA, Grzegorz Nowakowski, M.D., Aaron Mansfield, M.D.
Comprehensive Cancer Center, Mayo Clinic

BACKGROUND

Mayo Clinic Comprehensive Cancer Center (MCCCC) participates in an abundance of clinical trials, therefore increasing the chances of receiving an audit request.

Audit requests range from Industry Sponsors, Food and Drug Administration (FDA), Cooperative, and Institutional.

To assure our clinical research staff are 'audit ready' the MCCCC designed and implemented an Audit Readiness Team (ART) to provide clinical research staff with the highest level of support and materials for every type of audit.

ART is available for all Cancer-related trials and tracked through REDCap. Identified trends and/or significant concerns are provided to the Data Safety Monitoring (DSM) chair for review and determination of next steps.

GOALS

To ensure 'audit ready' status and produce 'clean'/finding free audits, the goals for ART are to:

- Provide audit prep assistance to clinical research staff
- Provide 'on-call' resources during an audit
- Assist study teams with post audit clean-up efforts, i.e., audit response, corrective and preventative action (CAPA), implementation, and effectiveness assessment

REFERENCES

REDCap 12.4.25 - © 2023 Vanderbilt University

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SOLUTIONS AND METHODS

AUDIT READINESS TEAM SET UP

- Enterprise-wide staff members from the Compliance and Quality Unit (CQU), Regulatory Unit, and Quality Management and Education
- Site specific staff members: include location specific 'boots on the ground' subject matter experts (SME) from our Cancer Clinical Trial Office (CCTO) Coordination Units, and Protocol Development Units (PDU).

This set-up ensures that the CCTO research staff have access to resources and SMEs; along with ensuring ART member availability during an audit.

AUDIT NOTIFICATION EFORM

- When study teams are notified of an audit, the CCTO research team submits a REDCap Audit notification eForm communicating key information to the CQU. The eForm includes information such as:
  - Team members (i.e., Principal Investigator (PI), CCTO staff, etc),
  - Location of audit,
  - Type of audit,
  - Protocol information
  - Requested date for audit

ART PROCEDURE

- The Notification eForm is then automatically submitted to the CQU
- CQU reviews the notification and assigns ART members to assist the research team.
- CQU provides the research team with materials to aide in preparation for the upcoming audit, including:
  - Audit Manual
  - Audit checklist (specific to each type of audit)
  - Tips and Tricks videos on communication best practices
- Prior to the audit, the assigned ART members will meet:
  - Provide introductions
  - Provide expectations of the audit and ART
  - Learn about the audit (i.e.- the rationale for the audit) in terms of the study team notation and workflow
- During the audit study teams will send questions to the ART members to help problem solve while the study team is addressing auditor questions.
- Post audit, ART will attend the Exit interviews/meetings to help focus on any outstanding items. After the finding have been submitted to the site, ART will help address questions, comments and concerns alongside the study team. Any CAPA items will also be addressed through the Compliance CAPA Plan process.

ART TRACKING

- ART procedure is tracked through REDCap starting with the audit notification eForm and walking through meeting updates, and audit findings. Tracking is intended to:
  - Identified trends and/or significant concerns
  - Provided all items to Data Safety Monitoring (DSM) chair for review and determination of next steps.

FIGURE 1

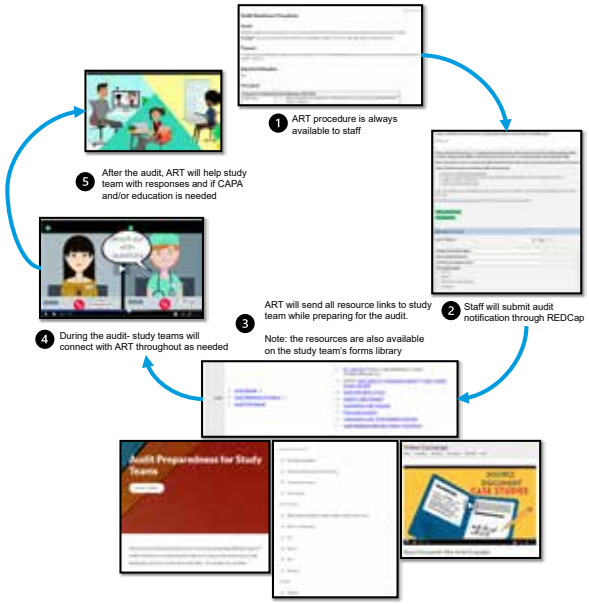


Figure 1 represents the ART process while presenting all identified audit resources for study teams

OUTCOMES

The implementation of the ART has:

- Improved the consistency of materials across all MCCCC locations.
- Provided the research teams with quick and direct access to SMEs and an abundance of resources to help in the preparation, conduct, and post audit activities.
- Shown that the research staff feel more confident, as they are better prepared and understand how to continue to improve their files to ensure 'audit readiness'.
- Development of this team highlighted gaps in the location of resources and materials, which has now been incorporated into key guidance documents, checklists, and trainings.

LESSONS LEARNED

Tracking of audit results is critical in aiding us with process improvements and educational opportunities.

FUTURE DIRECTION

Moving forward MCCCC DSM Committee will be reviewing the outcomes to assist with assessing and determining the operational and educational needs for our CCTO.

ACKNOWLEDGMENT

Huge thank you to the Audit Readiness Team members who have volunteered their time to help study teams through audits. To you we say, 'ART Assemble'.

Too Many Studies to Audit and Monitor? Let the Protocol Risk Assessment Tool System Help You Prioritize

A. Granobles, K. Yataghene
Memorial Sloan Kettering Cancer Center

1. Background

Clinical trials are a vital part of the development and approval of new medical treatments, but they also carry inherent risks to participants. To mitigate these risks, it is essential to ensure appropriate quality assurance oversight and selection of clinical trials for auditing and monitoring. Determining and prioritizing suitable studies to be audited and monitored can be difficult when the clinical trial portfolio of an institution is significantly large and complex. With the increasing number of clinical trials being conducted at Memorial Sloan Kettering Cancer Center (MSK), it is challenging for the MSK's Clinical Research Quality Assurance (CRQA) unit to prioritize and make decisions about the type, frequency, and extent of auditing and monitoring.

2. Goals

With a yearly average (2018-2022) of 230 active therapeutic institutional studies and 3,200 accruals, MSK's CRQA unit needed a strategic method to balance demand versus resource while ensuring appropriate quality assurance oversight.

3. Solutions and Methods

The MSK CRQA unit developed a scheme for defining, prioritizing, and assessing the risks associated with each therapeutic MSK-sponsored clinical trial by adopting a dual strategy. First, we use a Protocol Risk Assessment Tool (PRAT) to define the risks at the study level, using a simple risk categorization score for each key criterion (i.e., study phase, investigational new drug (IND) type, children risk level, etc.). Second, using PRAT scores and examining the trial design, population, and procedures, to identify specific areas of vulnerability, we can determine how risks can be mitigated via MSK's Audit and/or Monitoring Programs. PRAT is an in-house developed scoring system based on risk factors that have the potential to cause harm to participants. Each factor is assigned a score which in turn is used to calculate an overall CRQA Protocol Risk Score and assign a Protocol Risk Level (low, moderate, and high). The PRAT system is then able, in real-time, to automatically analyze large amounts of data and make recommendations for auditing or monitoring.

4. Outcomes

One of the key features of the PRAT system is its ability to handle large number of clinical trials and highlight studies that are most at risk. The PRAT system has helped CRQA navigate the growing list of clinical trials easily and efficiently by providing a user-friendly interface with advanced search and filtering capabilities. The system provides real-time alerts of new trials that are opened to accrual and meet CRQA's high-risk criteria.

5. Lessons Learned and Future Directions

The PRAT system has been tremendously useful to CRQA's workflow in identifying and managing studies for auditing and monitoring, and we look forward to further enhancements where real-time alerts can indicate recommendations to finalize monitoring activities based on specific timelines; real-time information on monitoring visit ratings; participant accruals; adverse event; and deviation reports. In summary, using a variety of data sources, advanced analytical techniques, and immediate updates, the PRAT system can identify high-risk trials and provide recommendations for auditing or monitoring. Additionally, it can handle large numbers of clinical trials, provide automated reports, and be integrated with existing systems, making it a powerful tool for risk assessment in clinical trials.

Memorial Sloan Kettering Cancer Center

Too Many Studies to Audit and Monitor? Let the Protocol Risk Assessment Tool System Help

Adrian Granobles; Karima Yataghene, MD

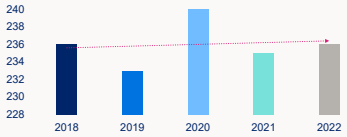
BACKGROUND

Clinical trials are a vital part of the development and approval of new medical treatments, but they also carry inherent risks to participants. To mitigate these risks, it is essential to ensure appropriate quality assurance oversight and selection of clinical trials for auditing and monitoring. Determining and prioritizing suitable studies to be audited and monitored can be difficult when the clinical trial portfolio of an institution is significantly large and complex. With the increasing number of clinical trials being conducted at Memorial Sloan Kettering Cancer Center (MSK), it is challenging for the MSK's Clinical Research Quality Assurance (CRQA) unit to prioritize and make decisions about the type, frequency and extent of auditing and monitoring.

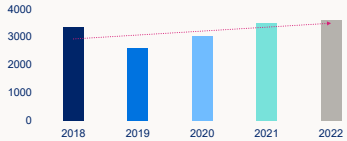
GOALS

With an average of 230 active therapeutic institutional studies and 3,200 accruals (2018 – 2022), MSK's CRQA unit needed a strategic method to balance the increasing demand versus available resources, while ensuring appropriate quality assurance oversight.

Therapeutic MSK Sponsored Studies: Active



Therapeutic MSK Sponsored Studies: Accruals



METHODS

DEFINE

MSK defined and assessed the risks of therapeutic MSK sponsored studies through the Protocol Risk Assessment Tool (PRAT), a CRQA-developed resource, using a risk categorization score calculated from predefined risk factors

PRIORITIZE

MSK prioritizes studies with the highest risk scores and ensures a balanced distribution of quality assurance oversight across all clinical departments and services by selecting studies from each to be audited and/or monitored

ASSESS

The PRAT system suggests which study should be audited or monitored (using a criteria based workflow). The Monitoring and Auditing Committee (MAAC) meet quarterly to review PRAT results and make final assignments/decisions

RESULTS

The PRAT system analyzes large number of clinical trials and highlight studies that are most at risk. The PRAT system has helped CRQA navigate the growing list of clinical trials easily and efficiently by providing a user-friendly interface with advanced search and filtering features. PRAT provides real-time alerts of new trials that are opened to accrual and meet CRQA's high risk criteria.

CONCLUSION

The PRAT system has been a valuable tool for CRQA's workflow in identifying and managing studies for auditing and monitoring. During the first quarter of 2023, the PRAT system was further enhanced with alerts indicating recommendations to finalize monitoring activities based on specific timelines, real-time monitoring visit ratings, participant accruals, adverse events, and deviations. In summary, using a variety of data sources, advanced analytical techniques, and real-time data updates, the PRAT system can identify high-risk trials and provide recommendations for auditing or monitoring. Additionally, it can provide automated reports and be integrated with existing systems for additional data analysis, making it a powerful tool for risk assessment and risk mitigation for clinical trials.

ACKNOWLEDGMENTS

Michael Ayerov, Kamala Mantha-Thaler, and Susan Puleio.

Getting Monitoring Deficiencies Resolved

A. Granobles, K. Mantha-Thaler, K. Yataghene
Memorial Sloan Kettering Cancer Center

1. Background

Clinical site monitoring visits play a crucial role in ensuring that the rights and well-being of the study participants are protected, the quality and integrity of the data is maintained, and all study files and conduct of trial are in compliance with regulatory requirements. During these visits, monitors identify deficiencies or areas for improvement in the study design, data collection, and/or management processes. If deficiencies are not resolved in a timely manner, serious consequences may ensue, leading to inaccurate data, jeopardized participant safety, and compromised trial integrity. Therefore, timely resolution of monitoring visit deficiencies is essential to ensure the success and safety of clinical trials. At Memorial Sloan Kettering Cancer Center (MSK), the Clinical Research Quality Assurance (CRQA) monitors identified concerns that were putting the integrity and quality of the research at risk. The timeframe for deficiency resolution was continuously increasing for study teams, while time and effort for CRQA monitors was also growing. CRQA needed to develop a deficiency management process that would streamline deficiency resolution and increase overall efficiency.

2. Goals

Deficiency resolution took, on average, 60 days. The primary goals with developing a deficiency management process were to reduce deficiency resolution timelines and streamline the deficiency management by removing the need for monitors to re-review deficiencies without knowing if the study team had resolved them. The additional re-reviews were the cause of not having a way to confirm that study teams had taken actionable steps to resolve previously reported deficiencies. The re-reviews were repetitive, blinded, and time-consuming.

3. Solutions and Methods

The strategy was to develop the deficiency management system in the same platform where monitoring visit activities were entered; this would keep deficiency data centralized and ensure that appropriate standards and deadlines were met. The integration within the Protocol Information Management System (PIMS), an MSK-built system, allowed for real-time tracking, reporting capabilities, and a streamlined deficiency resolution process. At the conclusion of a monitoring visit, the deficiency management system sends automated emails every two weeks to the study team as long as deficiencies are listed as unresolved; this feature would maintain visibility and transparency.

4. Outcomes

After the implementation of the deficiency management process, deficiency resolution was brought down to an average of 26 days – a 57 percent reduction. The deficiency management process has improved monitoring proficiency, accountability, quality assurance management, and resolution timeliness, and reduced the need for corrective and preventive action plans.

5. Lessons Learned and Future Directions

A key component of the deficiency management system is its implementation within PIMS, which provides a centralized integration for data sourcing and the automation of communication for identifying and tracking deficiencies. The system's data were designed to be easily retrieved and reviewed by monitors and study team members assigned to resolve deficiencies; but additional stakeholders, including study team management and regulatory units, were interested in accessing the system for management oversight. The need for additional high-level access to the deficiency management system data led to the development of a dashboard that receives 76 views, with an average of 20 unique users, per month.

Memorial Sloan Kettering Cancer Center

Getting Monitoring Deficiencies Resolved

Adrian Granobles; Kamala Mantha-Thaler; Karima Yataghene, MD

BACKGROUND

Clinical site monitoring visits play a crucial role in ensuring that the rights and well-being of study participants are protected, the quality and integrity of the data is maintained, and all study files and conduct of trial are compliant with regulatory requirements. During these visits, Monitors identify deficiencies or areas for improvement in the study design, data collection, and/or management processes. If deficiencies are not resolved in a timely manner, serious consequences may ensue leading to inaccurate data, jeopardized participant safety, and compromised trial integrity. Therefore, timely resolution of monitoring deficiencies is essential to ensure the success and safety of clinical trials. Memorial Sloan Kettering Cancer Center (MSK) was concerned with the increasing timeframe for deficiency resolution. Additionally, the dedicated follow up work by Clinical Research Quality Assurance (CRQA) Monitors on deficiencies was also growing as a result of the prolonged time to resolution. CRQA needed to develop a deficiency management process that would streamline deficiency resolution, increase overall efficiency, and ultimately maintain proper research integrity.

GOALS

In 2021, the average deficiency resolution time was sixty (60) days. The primary goals with developing a deficiency management process were to reduce deficiency resolution timeframe and streamline the management of deficiencies. One area of focus was to enable Monitors to identify unresolved and overdue deficiencies without additional time and effort. Improving the confirmation process of deficiency resolution would save Monitors from having to manually review, confirm the unresolved deficiency status, and re-issue them again. The confirmation process of deficiency resolution was repetitive, blinded, and time-consuming; a new process with more transparency needed to be implemented.

Reduce Timeframe

Streamline Process

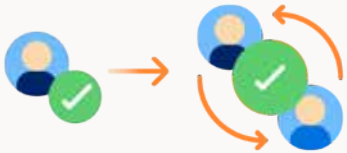
Improve Confirmation

METHODS

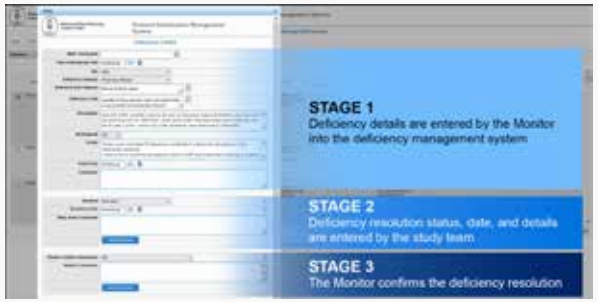
The strategy was to develop a deficiency management system using the platform already in place to support monitoring visit data. The use of this centralized platform would ensure consistent categorizations and leverage an existing powerful resource. At the conclusion of each monitoring visit, the deficiency management system sent automated emails to study teams informing them of deficiencies. Emails were sent every two weeks until resolution; this feature would maintain visibility, transparency for all stakeholders, and ensure accountability. Deficiencies would be considered resolved when deficiency resolution dates were entered by the study team and confirmed by the Monitor in the deficiency management system.

RESULTS

Deficiency resolution was brought down to an average of twenty-six (26) days, a fifty-seven percent (57% ↓) reduction.



The new deficiency resolution process change the engagement level of study teams from active participants to interactive participants.



CONCLUSION

The integration within the Protocol Information Management System (PIMS), an MSK-developed database system, allowed for real time tracking, reporting, and an overall streamlined deficiency resolution process. The deficiency management process improved monitoring proficiency, accountability, quality assurance management, and time to resolution.

Saved by Automation! A Continuation of the Story of How Technology and Innovative Thinking Significantly Increased Productivity Surrounding CAPA Completion

J. Simpronio, S. Puleio, M. Ayerov, H. Daggumati, K. Yataghene
Memorial Sloan Kettering Cancer Center

1. Background

In June 2020, the Clinical Research (CR) Audit Program, along with Clinical Research Informatics and Technology Unit and the Digital Products and Informatics Division, at Memorial Sloan Kettering Cancer Center, implemented the Protocol Information Management System (PIMS) audit submissions module to automate the audit report process. PIMS is an in-house developed application that manages all steps involved with the protocol life cycle. Details pertaining to this project were presented at the 2021 13th Annual AACI CRI Meeting.

From 2020-2022, an average of 116 audits were completed by the CR audit program with 97 percent requiring an internal corrective and preventive action (CAPA) plan to address audit deficiencies. A Microsoft Word CAPA template was used to capture CAPA responses. However, in preparation for completing a CAPA, a CAPA table had to be manually created for each unique audit deficiency, including manually entering each audit deficiency into the CAPA tables. A rigorous review and approval process was implemented to ensure audit deficiencies were appropriately entered into the CAPA template and to ensure effective CAPA completion and implementation. Naturally, this resulted in a workload increase exposing the limitations of manual CAPA completion in Microsoft Word.

2. Goals

As a result of the above and in continuation of the PIMS audit submissions module project, focus was turned to utilizing PIMS to increase productivity of CAPA creation, completion, and finalization.

3. Solutions and Methods

From late 2021 through October 2022, efforts were focused on incorporating a CAPA submissions component into the PIMS audit submissions module to automate the CAPA completion process, particularly to automate the input of audit deficiencies directly into a PIMS CAPA template. Other key features include automation and validation functionality, root cause drop-down options, recommended corrective/preventive action plan drop-down options based on the chosen root cause, a user-friendly interface and navigation, and a “My Queue” feature to track all pending CAPA assignments. Research staff completed a survey to estimate their time to completion (in minutes) for CAPAs worked on, pre-PIMS and post-PIMS (i.e., estimated time to: 1) create the tables in the Microsoft Word template, pre-PIMS; 2) complete the CAPA responses, pre-PIMS and post-PIMS; 3) review the CAPA prior to submission, pre-PIMS and post-PIMS; and 4) make updates and finalize the CAPA after receiving comments/corrections from the CR Audit Program, pre-PIMS and post-PIMS).

4. Outcomes

An average of 468 minutes is being saved per CAPA, resulting in a 41 percent increase in productivity. Specifically, 91 minutes are saved by avoiding manual entry of audit deficiencies into the CAPA template. Research staff is also saving 113 minutes, 29 minutes, and 236 minutes, respectively, on completing CAPA responses, on CAPA reviews prior to submission, and on updates after receiving comments/corrections from the CR audit program.

5. Lessons Learned and Future Directions

The automation of CAPA submissions has demonstratively increased the productivity of the CAPA completion process, resulting in efforts spent primarily on the quality of the CAPAs. Invaluable feedback has also been collected and will be taken into consideration for future modifications and enhancements to the PIMS CAPA submissions process.

Memorial Sloan Kettering Cancer Center

Saved by Automation! A Continuation of the Story of How Technology and Innovative Thinking Significantly Increased Productivity Surrounding CAPA Completion

Jacqueline Simpronio; Susan Puleio, ACRP-CP, CCRP; Michael Ayerov; Haritha Daggumati; & Karima Yataghene, MD

BACKGROUND

In June 2020, the Clinical Research (CR) Audit Program, along with Clinical Research Informatics and Technology (CRIT) Unit and the Digital Products and Informatics (DigITs) Division, at MSK, implemented the Protocol Information Management System (PIMS) Audit Submissions Module to automate the audit report process. PIMS is an in-house developed application that manages all steps involved with the protocol life cycle.

Details pertaining to this project were presented at the 2021 13th Annual AACI CRI Meeting. From 2020-2022, 116 audits, on average, were completed by the CR Audit Program with 97% requiring an internal corrective and preventive action (CAPA) plan to address audit deficiencies. A Microsoft Word template was used to capture CAPA responses. However, in preparation for completing a CAPA, a CAPA table had to be manually created for each unique audit deficiency, including manually entering each audit deficiency into the CAPA tables.

A rigorous review and approval process was implemented to ensure audit deficiencies were appropriately captured in the CAPA template and to ensure effective CAPA completion and implementation. Naturally, this resulted in a workload increase exposing the limitations of manual CAPA completion in Microsoft Word.

GOALS

In continuation of the PIMS Audit Submissions Module project, from late 2021 through October 2022, focus was turned to utilizing PIMS to increase productivity of CAPA creation, completion, and finalization.

METHODS

The PIMS CAPA Submissions Module was successfully launched in October 2022.

This Module allows CAPAs to be built directly into PIMS and includes key features:

- Automation and validation functionality
- Direct entry of CAPA responses into a database
- Root cause drop-down options with recommended Corrective/Preventive Action Plan drop-down responses based on the chosen root cause
- User friendly interface and navigation
- "My Queue" feature to track all pending CAPA assignments

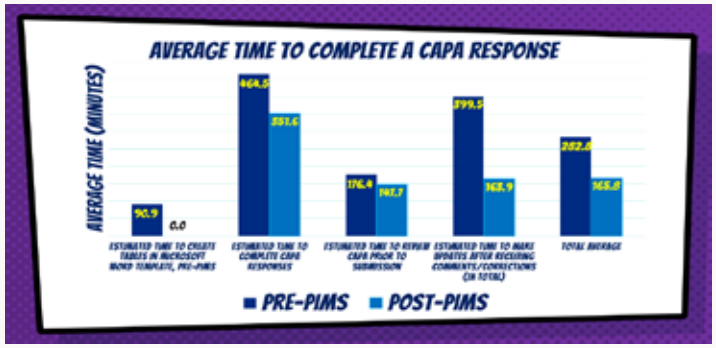
To understand time-saved and improved efficiency, research staff completed a survey to estimate their time to completion (in minutes) for CAPAs worked on, pre-PIMS and post-PIMS Submissions Module implementation.

CAPA Reporting Process Includes (measured in time)

1. Table creation in Microsoft Word Template, pre-PIMS
2. Completion of CAPA responses, pre- and post-PIMS
3. Review of CAPA prior to submission, pre- and post-PIMS
4. Updates and finalization of CAPA after receiving comments/corrections from CR Audit Program, pre- and post-PIMS)

RESULTS

Twenty-three (23) research staff responded from various MSK departments/services. Estimated time to complete CAPA responses, pre-PIMS (avg 8.5 CAPAs completed) vs. Post-PIMS (avg 3 CAPAs completed), was calculated.



How Much Time Does it Save and How Successful Is It?

TOTAL TIME SAVED...

CAPA COMPLETION PROCESS FOR RESEARCH STAFF	AVERAGE TIME SAVED POST-PIMS SUBMISSIONS
TABLE CREATION IN MICROSOFT WORD TEMPLATE, PRE-PIMS	90.9 MINUTES
COMPLETION OF CAPA RESPONSES, PRE-PIMS AND POST-PIMS	113.0 MINUTES
REVIEW OF CAPA PRIOR TO SUBMISSION, PRE-PIMS AND POST-PIMS	28.6 MINUTES
UPDATES AND FINALIZATION OF CAPA AFTER RECEIVING COMMENTS/CORRECTIONS FROM CR AUDIT PROGRAM, PRE-PIMS AND POST-PIMS)	235.7 MINUTES
TOTAL TIME SAVED PER CAPA:	468.2 MINUTES

• ON AVERAGE, RESEARCH STAFF ARE SAVING 7 HOURS AND 48 MINUTES PER CAPA!

CONCLUSION

1. PIMS CAPA Submissions Module has demonstrably increased productivity and efficiency of the CAPA completion process, resulting in efforts spent primarily on the quality of CAPA responses.
2. Most "human" errors have been eliminated as a direct result of PIMS automation.
3. CR Audit Program now handles a significant workload increase while reducing errors and omissions and improving quality.
4. Invaluable feedback has also been collected and will be taken into consideration for future modifications and enhancements to the PIMS CAPA Submissions process.

Most Common PRO: "It is organized and easy to follow. It allows the team to focus directly on resolving the issues/findings rather than building the template/form as we did in the past."

Most Common CON: "[PIMS CAPA Forms] cannot be edited by multiple parties at the same time."

ACKNOWLEDGMENTS

- MSK CRIT Unit
- MSK Clinical Research Administration (CRA)
- Adrian Granobles, Senior Project Manager, CR Quality Assurance

How to Conduct a Regulatory Review to Ensure a Quality FDA Inspection

G. Grimaldi, M. Reynolds, P. Chadha, S. Kling, V. Michel, C. Luk, F. Yeh, D. De Blasi, K. Yataghene, C. Houston, A. Drilon, M. Gounder
Memorial Sloan Kettering Cancer Center

1. Background

In January 2023, the early drug development (EDD) service was alerted to trial and regulatory management concerns from a study sponsor that could lead to an FDA inspection of two protocols. Given the operational constraints during the COVID-19 pandemic, the time during which most patients were enrolled in these trials, management staff began an in-depth review of all aspects of the trials. The comprehensive review conducted in preparation for this inspection is a process that can be utilized to maintain quality and for future potential audits.

2. Goals

- Conduct a systemic assessment of reportable safety events with clinical staff oversight
- Re-examine enrolled patients with a focus on consent processes and eligibility verification
- Organize an internal quality assurance (QA) review of the regulatory binders
- Review all monitoring letters and reconcile all pending findings.

3. Solutions and Methods

In preparation for the potential audit, management staff enlisted additional team members to allocate resources for a rigorous review of all facets of the trials. To ensure compliant reporting, a list of all safety events was created to track both initial and follow-up reports, then ensure all reports were filed in the regulatory binder. As queries related to these events were generated, we collaborated with clinical staff to expedite their resolution. With additional team members involved, a large-scale tracker was implemented to maintain an up-to-date record of patient reviews in a central location for collaborative work. Staff reviewed all consent processes, ensuring informed consent forms were present in source, and submitted deviations for any deficiencies noted. Additionally, patient charts were reviewed to ensure initial eligibility was correctly evaluated.

To supplement research staff review, internal QA auditors were brought in to target regulatory documentation such as the delegation of authority logs, financial disclosure forms, and FDA 1572s. Note to files were composed to address corrections and discrepancies between regulatory documents. Staff also reviewed amendment submissions, protocol trainings, and sponsor safety reports for appropriate acknowledgement and timely filing within the regulatory binder. Lastly, a review of the monitoring visit log was conducted and cross-referenced with the follow-up letters saved in the regulatory binder. Once all letters were filed, they were individually reviewed to confirm all findings were addressed and additional deviations were filed accordingly.

4. Outcomes

Extensive preparation in the weeks leading up to the inspection guaranteed the team was as prepared as possible. All pending monitoring findings were reconciled, thorough documentation of safety events and deviations was completed, and essential regulatory documents were confirmed to be current. Additionally, after reviewing patient charts, gaps in source documentation were eliminated. During the audit, the team answered questions raised by the inspector with certainty and in real-time, a feat made possible by comprehensive groundwork.

5. Lessons Learned and Future Directions

- The need for a comprehensive and standardized audit preparation procedures to ensure inspection readiness
- The importance of collaboration amongst the study team to maintain the quality of the trial throughout its lifespan
- Observations of deficiencies which led the team to re-evaluate current operational workflows

Memorial Sloan Kettering Cancer Center

How to Conduct a Regulatory Review to Ensure a Quality FDA Inspection

Margaret Reynolds, Grace Grimaldi, Puja Chadha, Sofia Kling, Victor Michel, Carly Luk, Fiona Yeh, Karima Yataghene, MD, Collette Houston, Alexander Drilon, MD, and Mrinal Gounder, MD.

BACKGROUND

In January 2023, the Early Drug Development (EDD) service was alerted to trial and regulatory management concerns from a study sponsor that could lead to an FDA inspection of two protocols. Given the operational constraints during the COVID-19 pandemic, the time during which most patients were enrolled in these trials, management staff began an in-depth review of all aspects of the trials. The comprehensive review conducted in preparation for this inspection is a process that can be utilized to maintain quality and for future potential audits.

CONCERN	GOAL
AE Reporting	Conduct a systemic assessment of reportable safety events with clinical staff collaboration.
Consenting Procedures	Review all patients with a focus on consent processes and eligibility verification.
Regulatory	Organize an internal Quality Assurance (QA) review of the regulatory binders.
Quality	Re-examine all monitoring letters and reconcile all pending findings.

METHODS

- Recruited additional staff, including internal QA auditors, to support preparation efforts.
- Listed all known safety events.
  Tracked initial and follow-up reports and their timelines.
  Submitted deviations for non-compliant AE reporting.
- Conducted systemic patient reviews including eligibility, consent processes and other supporting source documentation.
- Completed a regulatory review of DOAs, FDAs, 1572s
  Reviewed amendment submissions, protocol trainings, and sponsor safety reports.
- Created Notes to File to address corrections and discrepancies discovered during regulatory review.
- Conducted a review of all monitoring visit follow-up letters to ensure they were all filed.
  Reviewed the filed follow-up letters to ensure all findings were addressed and deviations filed accordingly.

RESULTS

Extensive preparation in the weeks leading up to the inspection guaranteed the team was as prepared as possible. All pending monitoring findings were reconciled, thorough documentation of safety events and deviations was completed, and essential regulatory documents were confirmed to be current. Additionally, after reviewing patient charts, gaps in source documentation were eliminated. During the audit, the team answered questions raised by the inspector with certainty and in real-time, a feat made possible by comprehensive groundwork.

LESSONS LEARNED

- The need for comprehensive and standardized audit preparation procedures to ensure inspection readiness.
- The importance of collaboration amongst the study team to maintain the quality of the trial throughout its lifespan.
- Observations of deficiencies which led the team to re-evaluate current operational workflows.

Innovative Approaches to Clinical Research Monitoring: The Power of Ingenuity at Memorial Sloan Kettering Cancer Center

S. Sanchez-Molero Perez, A. Granobles, K. Mantha-Thaler, L. Bello-Matricaria, K. Yataghene
Memorial Sloan Kettering Cancer Center

1. Background

The risk-based monitoring (RBM) approach prioritizes oversight of clinical trials based on potential risk to study data quality and patient safety. This approach has shown no evidence of inferiority compared to extensive onsite monitoring in terms of critical or major monitoring findings, according to a recent Cochrane review of monitoring strategies. Furthermore, staff resource was three to fivefold higher with extensive onsite monitoring. At Memorial Sloan Kettering Cancer Center (MSK), the number of active institutional therapeutic and diagnostic studies has increased 179 percent in the last three years, accruing over 4,700 participants in 2022. It is crucial to design strategies that maximize the power of monitoring to increase the reach of monitors to identify and mitigate risks to data quality and patient safety, while improving the efficiency of monitoring.

2. Goals

1. Maximize the efficiency of an RBM strategy to ensure proper oversight of investigator-initiated Trials (IIT)

2. Streamline the review of critical study areas such as eligibility and informed consent procedures by optimizing the process to reach as many participants as possible

3. Solutions and Methods

The Clinical Research Quality Assurance (CRQA) Monitoring team developed and implemented a multidisciplinary RBM strategy aimed to identify areas that pose the highest risk to participant safety and data quality while minimizing low yield monitoring activities through process automation. The following priorities have been established:

1. High-risk trials: RBM of IIT portfolio: A risk assessment tool selects single-center IIT for which a customized RBM plan is developed. Study participants are reviewed based on a targeted source data verification calendar focused on primary and secondary study endpoints.

2. High-risk processes: Eligibility Checklist Verification Program: A randomized sample of research participants undergo an independent review to ensure that registration and eligibility procedures are followed and are compliant with internal and federal regulations.

3. Low-yield monitoring activities: Process automation minimizes the possibility of deficiencies and the need for broad monitoring, focusing on compliance areas instead of transcription errors.

4. Outcomes

Our strategy has allowed prioritization of monitoring activities, selecting high-risk trials for customized RBM monitoring, and broad oversight of high-risk processes shared by clinical trials, such as eligibility and informed consent. Additionally, process automation has helped identify areas where monitoring can be reasonably waived without impacting trial safety. Over the past three years, this innovative approach to RBM has allowed the seven members of the CRQA Monitoring team to ensure focused oversight of more than 300 different studies and more than 1,000 study participants per year, providing an additional layer of oversight of participant safety and data quality. Additionally, the findings identified during these reviews have helped direct education efforts across MSK, further increasing the reach of the CRQA Monitoring team.

5. Lessons Learned and Future Directions

A multidisciplinary approach to monitoring can reduce the need for extensive visits and increase efficiency tailoring monitoring activities to the areas of highest risk. While some automation of processes has already been achieved, a true integration between the electronic medical record (EMR) and case report forms (CRFs) will furthermore streamline monitoring activities.

Memorial Sloan Kettering Cancer Center

Innovative Approaches to Clinical Research Monitoring: The Power of Ingenuity at Memorial Sloan Kettering Cancer Center

Soraya Sanchez-Molero Perez, MD, Adrian Granobles, Kamala Mantha-thaler, Lauren Bello-Matricaria, Karima Yataghene, MD

BACKGROUND

The Risk-Based Monitoring (RBM) approach prioritizes oversight of clinical trials based on potential risk to study data quality and patient safety. At Memorial Sloan Kettering Cancer Center (MSK), the number of active institutional therapeutic and diagnostic studies has increased one hundred and seventy-nine percent (179%) in the last three (3) years, accruing over four thousand-seven hundred (4,700) participants in 2022.

It is crucial to design strategies that maximize the power of monitoring to increase the reach of monitors to identify and mitigate risks to data quality and patient safety, while improving the efficiency of monitoring.

GOALS

1. Maximize the efficiency of an RBM strategy to ensure proper oversight of Investigator Initiated Trials (IITs).
2. Streamline the review of critical study areas such as eligibility and informed consent procedures by optimizing the process to reach as many participants as possible.

METHODS

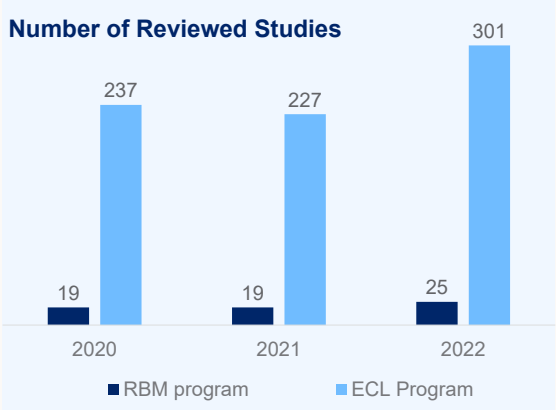
The Clinical Research Quality Assurance (CRQA) Monitoring team developed and implemented a multidisciplinary RBM strategy aimed to identify areas that pose the highest risk to participant safety and data quality while minimizing low yield monitoring activities through process automation. The following priorities have been established.

1. High-risk studies – RBM of IIT portfolio: A risk assessment tool selects single-center IITs for which a customized RBM plan is developed. Study participants are reviewed based on a targeted source data verification (TSDV) calendar focused on primary and secondary study endpoints.
2. High-risk processes – Eligibility Checklist (ECL) Verification Review: A randomized sample of research participants undergo an independent review to ensure that registration and eligibility procedures are followed and are compliant with internal and federal regulations.
3. Low-yield monitoring activities: Process automation minimizes the possibility of deficiencies and the need for broad monitoring, focusing on compliance areas instead of transcription errors.

Method #1: RBM Program

Method #2: ECL Program

Method #3: Process Automation



RESULTS

Our strategy has allowed prioritization of monitoring activities, selecting high risk studies for customized RBM monitoring, and broad oversight of high-risk processes shared by clinical trials, such as eligibility and informed consent. Additionally, process automation has helped identify areas where monitoring can be reasonably waived without impacting safety.

This innovative approach to RBM has allowed the seven (7) members of the CRQA Monitoring team to oversee more than three hundred (300) different studies and more than one thousand (1,000) study participants in one year, providing an additional layer of oversight of participant safety and data quality.

Additionally, the findings identified during these reviews have helped direct education efforts across MSK, further increasing the reach of quality assurance compliance.

CONCLUSION

A multidisciplinary approach to monitoring can reduce the need for extensive visits and increase efficiency tailoring monitoring activities to the areas of highest risk. While some automation of processes has already been achieved, a true integration between the Electronic Medical Record (EMR) and Case Report Forms (CRFs) will furthermore streamline monitoring activities.

ACKNOWLEDGMENTS

Allan Paras, Yuliya Fridman, Tori Velez, Dana Horton

The Impact of Having a "Quality" Quality Assurance System on Audit Findings From 2020-2022

J. Brown, M. Martinez, N. Surana, P. Seo, E. Dawkins
Sylvester Comprehensive Cancer Center, University of Miami

1. Background

Clinical research monitoring and auditing are an important element of any clinical research quality assurance (QA) program. They are conducted to determine adherence with federal regulations, and to focus on preventing questionable practices. The main goal of QA is to prevent problems. This requires the selection of competent and responsible investigators who can recruit and train proficient staff on the importance of ethical reporting. However, in clinical research there may be deviations. Therefore, a sound QA system should detect issues through routine monitoring and auditing that recognizes both random and systemic errors. When problems are detected, it is necessary to act quickly and effectively to correct and prevent them via education and training.

2. Goals

The Clinical Research Services Quality Assurance Unit (CRS-QAU) partnered with the institutional monitoring and auditing departments to provide ongoing monthly education and training for staff focusing on how to prevent, identify/detect, and ethically report any issues. Individualized and group training was provided as needed to support continuous learning so that staff were always audit-ready. Findings from audit reports received from the University of Miami's (UM) internal clinical research auditing body, sponsors, and cooperative groups were collected. CRS-QAU sought to determine if the quality assurance system in place was effective in reducing audit findings from 2020-2022. Audit findings were grouped into eight categories, and differences were analyzed comparing 2020 to 2021, and 2021 to 2022 data using the chi square test.

3. Solutions and Methods

There were 8 areas that we investigated: subject accountability; informed consent; test article; sponsor-related; protocol compliance; regulatory; documentation and data; and subject protection and adverse events. The greatest improvements in compliance occurred in test article and sponsor-related (-38- to -75 percent) from 2020-2021. The only areas of increase from 2020-2021 were protocol compliance (+30 percent), regulatory (+83 percent), documentation and data (+70 percent), and subject protection, adverse events (+22 percent). Substantial improvement occurred in several categories (-9 to -64 percent) from 2021-2022; and test article remained stable year over year from (-60 percent). A 10 percent increase in the total number of findings was found in 2021 compared to 2020 [$\chi 2$ (7) = 31.65, P <.001]; and there was no increase nor decrease in the total number of findings in 2022 compared to 2021, [$\chi 2$ (7) = 36.03, P <.001].

4. Outcomes

Audit findings increased from 2020 to 2021 due to various factors such as reduced training, transitioning from onsite to remote monitoring, and staff turnover due to the coronavirus pandemic. However, when remote monitoring stabilized, and training increased to support the rate of new hires, we found that providing competency-based clinical research education and training, performed in greater frequency, and on an individualized or group basis (as needed), was effective in reducing audit findings in key categories, and kept them stable over a short period of time.

5. Lessons Learned and Future Directions

The focus of quality assurance should be prevention, not on the data being error-free, because some errors may remain undetected despite QA and auditing. The aim of QA is to prevent, identify, train, and report problems in a prompt and effective manner to avoid audit findings that could result in fines and/or sanctions.

THE IMPACT OF HAVING A 'QUALITY' QUALITY ASSURANCE SYSTEM ON AUDIT FINDINGS FROM 2020-2022

Authors: J. Brown, M. Martinez, N. Surana, P.H. Seo, E. Dawkins
Institutions: Sylvester Comprehensive Cancer Center – Clinical Research Services Quality Assurance Unit (CRS-QAU)

SYLVESTER COMPREHENSIVE CANCER CENTER
UNIVERSITY OF MIAMI HEALTH SYSTEM

UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

Background

Clinical research monitoring and auditing are an important element of any clinical research quality assurance program. They are conducted to determine adherence with federal regulations, and to focus on preventing questionable practices. The main goal of quality assurance (QA) is to prevent problems. This requires the selection of competent and responsible investigators who can recruit and train proficient staff on the importance of ethical reporting. However, in clinical research there may be deviations. Therefore, a sound QA system should detect issues through routine monitoring and auditing that recognizes both random and systemic errors. When problems are detected, it is necessary to act quickly and effectively to correct and prevent them via education and training.

Goals

Clinical Research Services Quality Assurance Unit (CRS-QAU) partnered with the institutional monitoring and auditing departments to provide ongoing monthly education and training for staff focusing on how to prevent, identity/detect, and ethically report any issues. Individualized and group training was provided as needed to support continuous learning and audit-readiness. Findings from audit reports received from the University of Miami's (UM) internal clinical research auditing body, sponsors, and cooperative groups were collected. CRS-QAU sought to determine if the quality assurance system in place was effective in reducing audit findings from 2020-2022. Audit findings were grouped into eight categories, and differences were analyzed comparing 2020 to 2021, and 2021 to 2022 data using the chi square test.

Solutions and Methods

There were 8 areas that we investigated: subject accountability, informed consent, test article, sponsor-related, protocol compliance, regulatory, documentation and data, subject protection and adverse events. The greatest improvements in compliance occurred in test article and sponsor-related (-60 - to -75%) from 2020-2021. The only areas of increase from 2020 -2021 were protocol compliance (+30%), regulatory (+83%), documentation and data (+ 70%), and subject protection, adverse events (+22%). Substantial improvement occurred in several categories (-9 to -64%) from 2021-2022; test article remained stable year over year from (-60%). A 10% increase in the total number of findings was found in 2021 compared to 2020 [χ^2 (7) = 31.65, P <.001]; and there was no increase nor decrease in the total number of findings in 2022 compared to 2021, [χ^2 (7) = 36.03, P <.001].

Outcomes

Audit findings increased from 2020 to 2021 due to various factors such as reduced training, transitioning from onsite to remote monitoring and auditing processes, and staff turnover due to the coronavirus pandemic. However, when remote monitoring and auditing processes stabilized, and training increased to support the rate of new hires, we found that providing competency-based clinical research education and training, performed in greater frequency, and on an individualized or group basis (as needed), was effective in reducing audit findings in key categories, and kept them stable over a short period of time.

Results

Table 1: Number of Audit Findings 2020 vs. 2021 vs. 2022

Category	Number of Findings by Yr.			Percent Increase / Decrease by Category[a]	
	2020	2021	2022	2020 vs 2021	2021 vs 2022
Subject Accountability	6	4	2	-33%	-50%
Informed Consent	8	5	11	-38%	+54%
Regulatory	6	11	4	+83%	-64%
Protocol Compliance	10	13	14	+30%	+8%
Documentation and Data	10	17	17	+70%	-
Subject Protection, Adverse Events	9	11	10	+22%	-9%
Test Article	5	2	2	-60%	-
Sponsor Related	4	1	4	-75%	+75%
	58	**64**	**64**	**+10%*** (0.000)**	**-**

p-value is in parentheses
***p < 0.001
Abbreviation: Yr., Year.
[a] Percent increase/decrease (+/-) in audit findings by category

Lessons Learned and Future Directions

The focus of quality assurance and auditing should be on prevention, not on the data being error free because some errors may remain undetected despite QA, and auditing. The aim of QA is to prevent, identify, train, and report problems in a prompt, and effective manner to avoid audit findings that could result in fines and/or sanctions.

Creating a Robust Quality Assurance Program to Ensure Compliance in Research

S. Achberger, K. McCaffrey, M. Kilbane
Cleveland Clinic Cancer Center

1. Background

To mitigate risks in a fast-changing environment, the Cleveland Clinic (CCF) Taussig Cancer Institute (TCI) Quality Assurance (QA) team has expanded to a multi-faceted and specialized team that focuses on random audits for standard operating procedure (SOP) compliance, a transition team that handles studies during staff vacancies, a clinical process auditor, Data Safety and Toxicity Committee (DSTC) coordinator, dedicated trainers, clinical trial monitors, and QA coordinators.

2. Goals

Elevate clinical research conduct by expanding the QA team and incorporating SOP compliance review, mitigating risk due to staff transitions, ensuring clinical processes are consistent, closing the feedback loop from QA by incorporating department quality deficiencies into standard training, increasing DSTC standardization and department transparency, and expanding overall monitoring and QA.

3. Solutions and Methods

The TCI QA team is organized and works to maintain compliance in the following ways:

- Three study monitors: routine monitoring of high risk (IND/IDE) investigator-initiated trials (IITs), external sites, or any studies deemed needing an internal monitoring plan
- Three QA reviewers organized by specialty: responsible for routine QA reviews of low risk IITs and audit preparation
  - SOP compliance, deviation, and comprehensive cancer center (CCC) integration specialist:
    - Conducts random clinical documentation audits for SOP compliance and provides re-education following findings
    - Tracking observations and reporting findings via a Tableau dashboard
    - Reviews CCC database for accuracy/completeness
  - Data safety and toxicity committee (DSTC) coordinator:
    - Compiles data and report forms for CCC DSTC meeting across 12 unique disease programs
    - Monitors and tracks outstanding required IIT data
  - Cooperative group study QA coordinator:
    - Implemented routine QA reviews for cooperative group studies
    - Averages reviewing two studies per month in addition to cooperative group audit preparation
- Clinical process auditor: clinically trained QA coordinator specializing in the review, auditing, and compliance of our clinical processes and procedures conducted across the clinical research department
- Transition trial managers
  - Hybrid QA/trial management roles that simultaneously manage, review, and clean up a trial when a research coordinator leaves a role at TCI
- Trainers:
  - Two department trainers were moved under the QA team for better alignment and to provide a better closed feedback loop of department deficiencies into updated training and re-education initiatives
  - Hold a minimum of quarterly for-need education sessions, directly built on information provided from QA reviews

4. Outcomes

In 2022, we launched an interactive deviation dashboard reviewed monthly with department leadership. In 2022, 147 monitoring visits were performed for IITs; 16 were for external sites. A total of 52 QA reviews were performed by the team, including 18 IITs, 27 cooperative group studies, and seven industry-sponsored studies were reviewed for audit preparation. This is an increase from 2021 in which 133 monitoring visits and 15 total QA reviews were performed. Five SOPs are reviewed for compliance monthly in addition to any updated or changed SOPs.

5. Lessons Learned and Future Directions

Efficient and standard outcomes-reporting creates expedited solutions and re-education for the department. Specialized QA positions offer a higher level of auditing and review. Expansion and adjustment of team roles is necessary to keep up with compliance in a changing environment.

Cleveland Clinic

Creating a Robust Quality Assurance Program to Ensure Compliance in Research

Susan Achberger, MS, MBA, Kate McCaffrey, MBA, Megan Kilbane, MBA
Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH

BACKGROUND

To mitigate risks in a fast-changing environment, the Cleveland Clinic (CCF) Taussig Cancer Institute (TCI) Quality Assurance (QA) team has expanded to a multi-faceted and specialized team that focuses on random audits for standard operating procedure (SOP) compliance, a transition team that handles studies during staff vacancies, a clinical process auditor, Data Safety and Toxicity Committee (DSTC) coordinator, dedicated trainers, clinical trial monitors, and QA coordinators.

GOALS

Elevate clinical research conduct by expanding the QA team, incorporating SOP compliance review, mitigating risk due to staff transitions, ensuring clinical processes are consistent, incorporating department quality deficiencies into standard training, increasing DSTC standardization and department transparency, and expanding overall monitoring and QA.

OUTCOMES

In 2022 we launched an interactive deviation dashboard reviewed monthly with department leadership and within Program Research Group (PRG) meetings.

In 2022, 147 monitoring visits were performed for IITs; 16 were for external sites. A total of 52 QA reviews were performed by the team, including 18 IITs, 27 cooperative group studies, and seven industry-sponsored studies were reviewed for audit preparation. This is an increase from 2021 in which 133 monitoring visits and 15 total QA reviews were performed. Five SOPs are reviewed for compliance monthly in addition to any updated or changed SOPs.

The Transition Trial Manager roles were created in Q3 of 2022. The Transition Trial Managers rate studies on a scale of 1 to 5 (1 = Poor, 2 = Fair, 3 = Good, 4 = Very Good, 5 = Excellent) to report the condition of the study upon receipt from the departing Research Coordinator. To-date, 26 studies have been transitioned to the trial management team and the average rating for these studies at the time of transition is 3.3. Of the 26 studies transitioned, there have been 10 major findings to date. Corrective actions have been developed for each of the findings.

METHODS

The TCI QA team is organized and works to maintain compliance in the following ways:

- Three Study Monitors: routine monitoring of high risk (IND/IDE) investigator-initiated trials (IITs), external sites, or any studies deemed needing an internal monitoring plan
- Three QA Reviewers organized by specialty: responsible for routine QA reviews of low risk IITs and audit preparation
  - SOP Compliance, Deviation, and Comprehensive Cancer Center (CCC) integration specialist
    - Conducts random clinical documentation audits for SOP compliance and provides re-education following findings
    - Tracking observations and reporting findings via a Tableau dashboard
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- Clinical Process Auditor: clinically trained QA coordinator specializing in the review, auditing, and compliance of our clinical processes and procedures conducted across the clinical research department
- Transition Trial Managers
  - Hybrid QA/trial management roles that simultaneously manage, review, and clean up a trial when a Research Coordinator leaves a role at TCI
- Trainers
  - Two department trainers were moved under the QA team for better alignment and to provide a closed feedback loop of department deficiencies into updated training and re-education initiatives
  - Hold a minimum of quarterly for-need education sessions, directly built on information provided from QA reviews

LESSONS LEARNED AND FUTURE DIRECTIONS

Efficient and standard outcomes-reporting creates expedited solutions and re-education for the department. Specialized QA positions offer a higher level of auditing and review. Expansion and adjustment of team roles is necessary to keep up with compliance in a changing environment.

Reduced Research Patient Wait Times Using Automated Dispensing Cabinet (ADC) Technology for Oral Investigational Drug at an NCI-Designated Comprehensive Cancer Center

E. Waalkes, C. Spalink, J. Scagliola, A. Joshi, B. Pothuri, J. Mehnert, D. Ayoubi
Laura and Isaac Perlmutter Cancer Center at NYU Langone

1. Background

Many multicampus cancer centers face the complex challenge of timely dispensation and administration of investigational drug from a central investigational pharmacy (IP). Before utilizing the automated dispensing cabinet (ADC), investigational oral drug dispensation and administration averaged 96.5 minutes, median 84 minutes (n=122, min: 41, max: 298), from provider order signature to patient administration at a satellite site 0.3 miles from IP in an urban setting. A solution to improve patient wait times and infusion center efficiency was critical while maintaining a safe, standardized research clearance process.

2. Goals

The goal was to utilize the satellite site ADC for dispensation and administration for oral investigational drug administration in order to reduce patient wait times. A multidisciplinary workflow was implemented for safe ADC treatment clearance and for sponsor approval of early vial assignment, when applicable.

3. Solutions and Methods

The ADC workflow was piloted in two oncology disease groups for studies that only utilized oral investigational product. Of 13 studies, two required vial assignment and sponsors granted approval for early dispensation. The following workflow was established for safe clearance (T-0 is day of administration): signed orders in electronic health record (EHR) T-8 to T-2; dispensation email sent T-2, vials assignment (if applicable) and release of orders in EHR by infusion T-2; IP dispenses oral drug to ADC at satellite site T-1; treatment clearance smartphrase is placed in EHR by CRC/CRN and co-signed by investigator T-0; infusion nursing confirms note is cosigned in EHR via a smartphrase T-0; and lastly, IP drug dispensed to patient. Of note, a workflow is in place if a patient requires a dose hold/reduction.

4. Outcomes

Since utilizing the ADC workflow for dispensing oral investigational drug from October 2022-January 2023, the average patient wait time decreased to 27.1 minutes, median 29.5 minutes (n=12, min: five, max: 41) from the time of treatment clearance in Epic to administration at satellite site. The ADC workflow saves patients an average of 69.5 mins, and decreases wait times by 71.9 percent. When comparing paired data for patients dispense times for those that utilized the old vs. new workflow, the average time decreased significantly from 88.3 mins to 28 mins (p=0.0001) and improving efficiency by an average of 362.7 percent (n=7, min: 52; 17, max: 105; 39). This was achieved with a process that maintained the integrity of the research clearance process for safety and quality.

5. Lessons Learned and Future Directions

We plan to initiate the next stages of the pilot:

- Stage 2: include all disease groups at satellite site, expand to include clinical trials that have oral IP drug combined with SOC medications
- Stage 3: expand project to the central IP site, as the overall wait time at all campuses is 85.5 mins (n=409)
- Step 4: implement the process to span all campuses/sites with wait time for Oral IP under 30 minutes and perform a patient satisfaction survey

Reduced Research Patient Wait Times Using Automated Dispensing Cabinet (ADC) Technology for Oral Investigational Drug at a NCI- Designated Comprehensive Cancer Center

Erika Waalkes, Christy Spalink, DNP, Joan Scagliola, MSN, Ankeeta Joshi, Bhavana Pothuri, MD, Janice Mehnert, MD, Doaa Ayoubi, PharmD

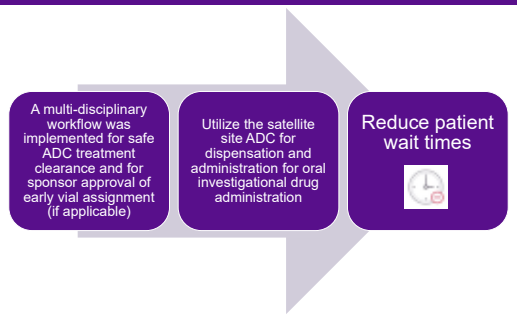
Perlmutter Cancer Center
An NCI-designated Comprehensive Cancer Center

NYU Langone Health

Background:

Many multi-campus Cancer Centers face the complex challenge of timely dispensation and administration of investigational drug from a central Investigational Pharmacy (IP). Before utilizing the Automated Dispensing Cabinet (ADC), investigational oral drug dispensation and administration averaged 96.5 mins, median 84 mins (n=122, min: 41, max 298) from provider order signature to patient administration at a satellite site 0.3 miles from IP in an urban setting. A solution to improve patient wait times and infusion center efficiency was critical, while maintaining a safe, standardized research clearance process.

Goals:



Solutions and Methods:

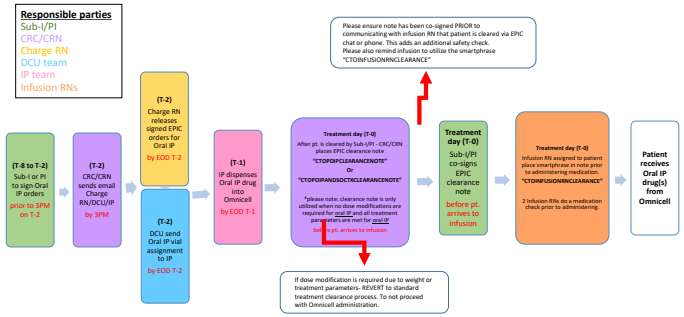


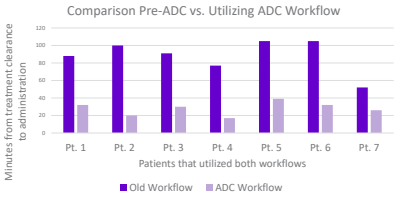
Figure 1. ADC ("Omnicell") Workflow & Responsible Parties

The ADC workflow was piloted in two oncology disease groups for studies that only utilized oral investigational product. Of 13 studies, two required vial assignment and sponsors granted approval for early dispensation. The following workflow was established for safe clearance (T-0 is day of administration): signed orders in electronic health record (EHR) T-8 to T-2, dispensation email sent T-2, vials assignment (if applicable) and release of orders in EHR by infusion T-2, IP dispenses oral drug to ADC at satellite site T-1, treatment clearance smartphrase is placed in EHR by CRC/CRN and co-signed by investigator T-0, infusion nursing confirms note is cosigned in EHR via a smartphrase T-0, and lastly IP drug dispensed to patient. Of note, a workflow is in place if a patient requires a dose hold/reduction.

Outcomes:

Since utilizing the ADC workflow for dispensing oral investigational drug from October 2022- January 2023:

- Average patient wait time decreased to 27.1 mins, median 29.5 mins from the time of treatment clearance in Epic to administration at satellite site (n=12, min: 5, max: 41).
- The ADC workflow saves patients an average of 69.5 mins, and decreases wait times by 71.9 percent.
- When comparing paired data for patients dispense times for those that utilized the old vs. new workflow, the average time decreased significantly from 88.3 mins to 28 mins (p=0.0001).
- Improving efficiency by an average of 362.7 percent (n=7, min: 52; 17, max: 105; 39).



This was achieved with a process that maintained the integrity of the research clearance process for safety and quality.

Future Directions:

Stage 2: Include additional disease groups at satellite site, expand to include clinical trials that have oral IP drug combined with SOC medications***

Stage 3: Expand project to the central IP site, as the overall wait time at all campuses is 85.5 mins (n=409)

Step 4: Implement the process to span all campuses/sites with wait time for Oral IP under 30 minutes and perform a patient satisfaction survey

***Currently expanded to five disease groups and we allow for the ADC process for IP oral medications with or without SOC medications.

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Keeping an Eye on RNI: Frequent Monitoring to Eliminate Preventable Reportable New Information

E. O'Donovan, P. Patel, E. Yepes, A. Joshi, C. Spalink, A. Goutzinopoulos, B. Pothuri
Laura and Isaac Perlmutter Cancer Center at NYU Langone

1. Background

Responsible handling of reportable new information (RNI) is essential to the conduct of clinical trials. RNI reporting addresses unanticipated adverse events, protocol changes to prevent apparent immediate hazards, or additional potential risk and/or harm to which research subjects are exposed. Certain types of RNI cannot be prevented because, by their nature, trials produce experiential data that was previously unknown or cannot be predicted. Other types of RNI result from the action or inaction of members of the study team and may have been prevented by changes to the workflows, procedures, or policies of the institution conducting the trial. The Perlmutter Cancer Center Clinical Trials Office (CTO) has sought to eliminate preventable harm and provide the highest standard of care and safety to our patients by reducing instances of preventable RNI.

2. Goals

- Define preventable versus non-preventable RNI
- Regularly monitor RNI to identify trends
- Adjust workflows, procedures, and policies to mitigate emerging trends and eliminate preventable RNI

3. Solutions and Methods

- The CTO worked with Information Technology (IT) to develop an RNI database; a report of all RNI submitted in the week prior is pulled from the database and sent to CTO leadership for review, enabling leadership to make prompt alterations to workflow and policies
- We expanded and frequently revised trainings for new and current clinical staff each year since 2019 and changed our policies and procedures to incorporate lessons learned from audits; training sessions were an opportunity to obtain timely feedback from staff most familiar with the workflows contributing to RNI
- In 2021, we initiated CTO high reliability organization (HRO) huddles which are attended by the entire CTO staff; this weekly forum enabled communication of urgent changes to our policies/procedures and explanation of the circumstances leading to these changes and provided a platform for staff to share safety stories, near-misses, and concerns
- We initiated assembly of an RNI Committee to meet regularly with a focus on eliminating preventable RNI with representation from every unit and position within the CTO, from research data associate to director

4. Outcomes

The CTO effected a 75 percent reduction in preventable RNI arising from our clinical care of trial patients, from 20 instances in 2019 to five in 2022, including an elimination of preventable RNI related to adverse event reporting and our investigational pharmacy. During this same period, we experienced an increase in the size of our portfolio, activating an average of 14 percent more trials year-over-year, and growth to the complexity of our trial portfolio (42 percent more subjects accrued to Phase I/II trials from 2018-2022 versus 2013-2017).

5. Lessons Learned and Future Directions

The centralization of RNI review has been successful and has demonstrated the potent synergy between regular oversight by leadership and collaboration with staff who have expertise on how best to close gaps in workflows and policies. There is no simple way to account for human error in all forms; no workflow or policy is impervious to inadequate execution. We will continue our weekly review of RNI indefinitely, and our diverse committee will continually refine our workflows and practices with the goal of mitigating preventable harm.

Perlmutter Cancer Center

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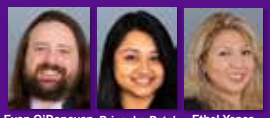
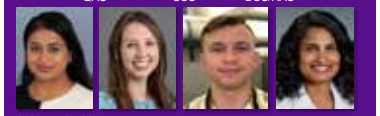
Keeping an on RNI: Frequent Monitoring to Eliminate Preventable Reportable New Information



Evan O'Donovan, QAU
Priyanka Patel, CCU
Ethel Yepes, DCU/RAU



Ankeeta Joshi, Administrative Director
Christy Spalink, DNP, Administrative Director
Angelo Goutzinopoulos, QAU
Bhavana Pothuri, MD, Medical Director

NYU Langone Health

BACKGROUND

Responsible handling of Reportable New Information (RNI) is essential to the conduct of clinical trials.

The Perlmutter Cancer Center Clinical Trials Office (CTO) has sought to eliminate preventable harm and provide the highest standard of care and safety to our patients by reducing instances of preventable RNI.

RNI reporting addresses unanticipated adverse events, protocol changes to prevent apparent immediate hazards, or additional potential risk and/or harm to which research subjects are exposed. Certain types of RNI cannot be prevented because, by their nature, trials produce experiential data that was previously unknown or cannot be predicted. Other types of RNI result from the action or inaction of members of the study team, and may have been prevented by changes to the workflow, procedures or policies of the institution conducting the trial.

GOALS

Define preventable versus non-preventable RNI → **Monitor** RNI to identify trends regularly → **Adjust** workflows, procedures and policies

SOLUTIONS AND METHODS

Worked with IT to develop an RNI database where all RNI submitted in the week prior is pulled and sent to CTO leadership for review

Expanded and frequently revised trainings for clinical staff each year since 2019. Training sessions were an opportunity to identify trends and obtain timely feedback from staff most familiar with the workflows

Initiated weekly CTO high reliability organization huddles attended by the entire CTO staff. Enabled communication and explanation of urgent policies/procedure changes

We initiated assembly of an RNI Committee to meet regularly with a focus on eliminating preventable RNI with representation from every unit and position within the CTO.

Perlmutter Cancer Center/ NYU Langone Website

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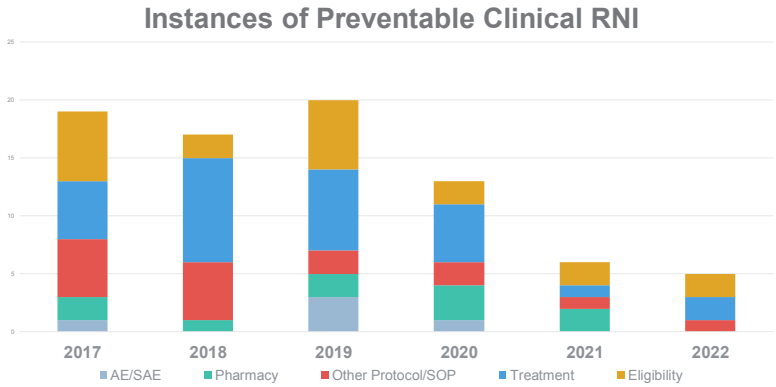
OUTCOMES

75% reduction in preventable RNI arising from our clinical care of trial patients, from 20 instances in 2019 to 5 in 2022.

Elimination of preventable RNI related to adverse event reporting and our investigational pharmacy.

During this same period we experienced an increase in the size of our portfolio:

- ***Activating an average of 14% more trials year-over-year***
- ***42% more subjects accrued to Phase I/II trials from 2018-2022 vs 2013-2017***



LESSONS LEARNED AND FUTURE DIRECTIONS

The centralization of RNI review has been successful and has demonstrated the potent synergy between regular oversight by leadership and collaboration with staff who have expertise on how best to close gaps in workflows and policies. There is no simple way to account for human error in all forms; no workflow or policy is impervious to inadequate execution. We will continue our weekly review of RNI indefinitely, and our diverse committee will continually refine our workflows and practices with the goal of mitigating preventable harm.

Meeting a National Need: Implementing an NCTN Quality Assurance Program

R. Selle, C. Gill, S. Zindars, K. Schroeder, B. George
Medical College of Wisconsin Cancer Center

1. Background

Coordinating Cooperative Group/National Clinical Trials Network (NCTN) studies has long been a challenge for cancer centers as they are typically trials that are not monitored regularly, with only a sampling of subjects audited every three years, routinely. This can be a challenge for data quality and timeliness. The Medical College of Wisconsin (MCW) Cancer Center Clinical Trials Office (CTO) recognized this limitation and began exploring solutions in 2021.

2. Goals

The goals of this work were to improve data timeliness, reduce missing data forms, and educate staff on the expectations of NCTN trials.

3. Solutions and Methods

The solution proposed by the MCW Cancer Center CTO was to introduce a NCTN Quality Assurance (QA) coordinator to focus QA efforts on the goals previously outlined. This QA coordinator runs monthly expectancy reports for all teams; contacts study teams directly about data that is overdue or nearing the due date; and performs QA reviews on the first subject enrolled on all NCTN studies. An NCTN clinical research assistant was also hired in 2022 who can be assigned to work on at-risk data to assist teams with meeting data entry timelines.

4. Outcomes

Since implementing this program, we have seen improvements in Alliance and NRG data timeliness. Our on-time data percentages have improved for Alliance and delinquent data and outstanding query numbers have fallen.

5. Lessons Learned and Future Directions

With new hires always joining the CTO, it is important to continuously convey the importance of quality regardless of the sponsor type. These frequent reminders and internal quality assurance reviews have been valuable learning experiences for staff of all experience levels. An additional hire is being made to the Education and QA team, which will hopefully improve the NCTN QA coordinator's capacity by offsetting other responsibilities that are unrelated to NCTN. We hope to soon have capacity to review more subjects on each study, with a future goal being to review the first subject on each treatment arm at minimum.

Meeting a National Need: Implementing an NCTN Quality Assurance Program

Cassandra Gill, BA, CCRP; Rebecca Selle, BS, CCRP; Katy Schroeder, BSN, RN, OCN, CCRP; Stacey Zindars, MS, CCRP; Ben George, MD
Medical College of Wisconsin Cancer Center

Background

Cancer centers find coordinating National Clinical Trial Network (NCTN), or "cooperative group", studies challenging because they are not monitored as frequently as their industry counterparts. NCTN trial auditors routinely only examine a sample of subjects from a handful of trials every three years, and this is only if the previous audit was rated acceptable. If rated an unacceptable audit, monitoring increases only to yearly until improvement or suspension occurs. This has proved to be problematic for data quality and timeliness. Factors compounding this issue include the recent advent of COVID. As well as the overall increase in staff turnover and NCTN trial complexity. Combined with a decrease in staff experience exacerbates the situation. Thus, the MCW Cancer Center Clinical Trials Office (CCCTO) began exploring solutions to these issues starting in 2021.

Goals

This initiative began to improve data timeliness, reduce missing data, improve quality and audit outcomes, as well as educate staff involved with NCTN trials on expectations.

Solutions and Methods

MCW CCCTO created an NCTN Quality Assurance (QA) and Education (Ed) Coordinator role to focus on the goals outlined above. The QA/Ed coordinator reviews institutional performance reports (including form/query delinquency) and upcoming data due. They complete bi-weekly team check-ins regarding their overdue data and discuss resolutions. This is for all MCW CCCTO teams involved with NCTN trials, including any affiliate sites. They also perform QA reviews on the first subject and regulatory work on all CCCTO NCTN trials. Meetings modeled after an audit exit interview are held following each review to analyze findings and discuss corrective actions to prepare staff for future audits.

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A floating NCTN Clinical Research Assistant (CRA) was additionally hired in 2022. The CRA addresses overdue and at-risk data to assist teams with meeting data entry timelines.

Outcomes

Since implementing this program, we have seen more stability and improvements in data timeliness overall. Specifically, two NCTN groups, Alliance and NRG, had enough data available for analysis. **Figure 1** details notable improvement regarding on-time data and Institutional Performance Evaluation Committee (IPEC) scores since February 2022. **Figure 2** outlines NRG audit deficiencies prior to and after the implementation of the NCTN QA/Ed Program.

Figure 1. Change in Recent Data Scores

ALLIANCE	Feb 2022	Sept 2022	Dec 2022
Percentage of on-time data	72.60%	82.80%	94%
IPEC Reporting Period Score	87.60%	89.10%	91.70%

NRG	Dec 2018	Jul 2022
Delinquent Data	12.60%	1.30%
Outstanding Queries	2.50%	0.30%

Lessons Learned

With new staff regularly joining the CCCTO, it is important to continuously convey the importance of quality data regardless of the sponsor type. These frequent reminders and internal quality assurance reviews have been valuable learning experiences for staff of all experience levels. Teams have become accustomed to receiving monthly expectancy reports and responding to them, just as they would typically do for an industry sponsor.

Figure 2. Audit Findings before and after implementation of NCTN Quality Assurance Program

NRG	(Routine audit) 2019	(Reg Reaudit) 2020	(Routine audit) 2022
Major Deficiencies	**12**	**0**	**1**
-Regulatory	(10)	(0)	(1)
-Patient Cases	(1)	N/A	(0)
-Pharmacy	(1)	N/A	(0)
Lesser Deficiencies	**2**	**4**	**3**
Regulatory	(1)	(4)	(0)
Patient Cases	(1)	N/A	(3)
Pharmacy	(0)	N/A	(0)

All of the factors that may have contributed to the improvements in the NRG audit outcomes from 2019 to 2022 are not entirely clear yet. We presume it is multifactorial. The NCTN QA Program, increased staff education, and mentorship from experienced staff all contributed to this success. The NCTN QA/Ed Coordinator has a presence at twice annual NCTN Lead Protocol Organization (LPO) group meetings and also serves on the Alliance Clinical Research Professionals (CRP) and Research Operations Initiative (ROI) committees. The latter of which is multi-institutional nationwide and focuses solely on reducing sites burden with NCTN trials. Updates from these meetings are regularly shared with staff.

Future Directions

The MCW Cancer Center CTO Education and Quality Assurance Team established and filled another role to expand the NCTN Quality Assurance coordinator's capacity by offsetting other unrelated responsibilities. We hope to soon have capacity to review additional subjects on each NCTN trial, with a future goal to review the first subject on each treatment arm at minimum.

Acknowledgement
Special thanks to Ms. Carrie O'Connor for her technical writing assistance on this poster.

Path to Improved Trial Management and FDA Inspection Readiness

G. Grimaldi, M. Reynolds, P. Chada, C. Luk, F. Yeh, K. Yataghene, C. Houston, A. Drilon, M. Gounder
Memorial Sloan Kettering Cancer Center

1. Background

In January 2023, the Early Drug Development (EDD) service was alerted to trial and data management concerns from the sponsor that could lead to an FDA inspection. Preparation revealed deficiencies in existing service-wide workflows and study tools. The EDD is an exceptionally high accruing service, with 113 open protocols and 282 patients accrued in 2022. Due to high patient volume and rapid accrual, it is of the utmost importance that study teams have workflows and tools in place to ensure protocol compliance and favorable patient outcomes. In response to deficiencies identified, we are working with senior leadership to ensure real-time quality management of our rapidly accruing trials.

2. Goals

1. Utilize sponsor monitoring follow-up letters and implement new tracking methods to ensure findings are collaboratively addressed in real time

2. Refine existing workflows for SAE and deviation reporting to ensure accountability, accuracy, and adherence to reporting timelines

3. Optimize principal investigator (PI) involvement in operational and regulatory trial aspects through a revamped PI meeting format

3. Solutions and Methods

While preparing for the inspection, we observed the lack of continuous oversight during monitoring visits and the delay in reconciliation of follow-up letter findings. Subsequently, we are developing a templated response to monitoring letters and a standardized tracking system to ensure thorough documentation and timely resolution of findings.

Similarly, the team is developing a centralized SAE tracking system to promote wider accessibility to documentation of safety events and follow-up reports. To ensure timely deviation reporting, we are streamlining our workflows to simplify the reporting process while allowing greater visibility to PIs and management staff throughout the reporting process. Prior to the FDA audit, PI meetings prioritized patient reviews over regulatory issues, monitoring findings, and other operational items. We are working to improve the overall quality of trial management during PI meetings. This includes an increase in time spent with the study team, a more equitable review of operational aspects of the trial, and the rollout of a modified meeting minute template to emphasize operational items.

4. Outcomes

After refining these operating procedures, we expect the service-wide trial portfolio to be better maintained and more compliant with protocol requirements, which will in turn ensure high quality FDA inspections. After fully implementing these changes, our plans to evaluate outcomes—which will be included in a poster presentation—include:

- Routine checks of deviation and SAE reports to ensure adherence to reporting timelines

- Comparisons of the number of deviations reported to evaluate whether new monitoring workflows and tracking methods improve overall compliance

- Survey study staff and PIs to assess familiarity with the operational aspects of the protocol and open action item

5. Lessons Learned and Future Directions

- The need to continuously evaluate and adapt procedures based on the success of existing workflows

- The importance of centralization and standardization of tools to track all study related items, including safety events and deviations

- The need for consistent review of pending operational items during time with the PI

Memorial Sloan Kettering Cancer Center

Path to Improved Trial Management and FDA Inspection Readiness

Margaret Reynolds, Grace Grimaldi, Puja Chadha, Carly Luk, Fiona Yeh, Karima Yataghene, MD, Collette Houston, Alexander Drilon, MD, and Mrinal Gounder, MD.

BACKGROUND

In January 2023, the Early Drug Development (EDD) service was alerted to trial and data management concerns from the sponsor that could lead to an FDA inspection. Preparation revealed deficiencies in existing service-wide workflows and study tools. The EDD is an exceptionally high accruing service, with 113 open protocols and 282 patients accrued in 2022. Due to high patient volume and rapid accrual, it is of the utmost importance study teams have workflows and tools in place to ensure protocol compliance and favorable patient outcomes. In response to deficiencies identified, we are working to ensure real-time quality management of our rapidly accruing trials.

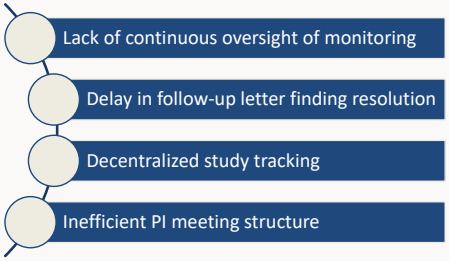

Figure 1: Areas for Departmental Improvement Identified in 2022

GOALS

- Utilize sponsor monitoring follow-up letters and implement new tracking methods to ensure findings are collaboratively addressed in real-time.
- Refine existing workflows for SAE and deviation reporting to ensure accountability, accuracy, and adherence to reporting timelines.
- Optimize Principal Investigator (PI) involvement in operational and regulatory trial aspects through a revamped PI meeting format.

METHODS

- Develop a templated response to monitoring letters and a standardized tracking system to ensure thorough documentation and timely resolution of findings.
- Create a centralized SAE tracking system, thus promoting wider accessibility to documentation of safety events and follow-up reports.
- Streamline deviation workflows to ensure timely reporting. The workflow will also provide greater visibility to PIs and management staff throughout the reporting process.

Prior to the FDA audit, PI meetings prioritized patient reviews over regulatory issues, monitoring findings, and other operational items. We are working to improve the overall quality of trial management during PI meetings. This includes an increase in time spent with the study team, a more equitable review of operational aspects of the trial, and the rollout of a modified meeting minute template to emphasize operational items.

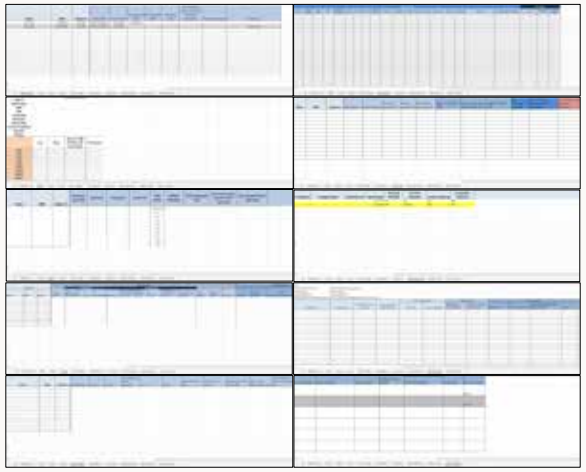

Figure 2: Sample Tabs from EDD Master Study Tracker

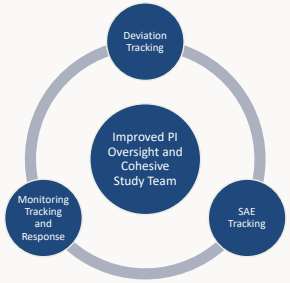

Figure 3: Overview of Workflow Improvements

RESULTS

After fully implementing these changes, our plans to evaluate outcomes include:

- Routine checks of deviation and SAE reports to ensure adherence to reporting timelines.
- Compare the number of deviations reported to evaluate whether new monitoring workflows and tracking methods improve overall compliance.
- Survey study staff and Principal Investigators to assess familiarity with the operational aspects of the protocol and open action items.

LESSONS LEARNED

The need to continuously evaluate and adapt procedures based on the success of existing workflows.

The importance of centralization and standardization of tools to track all study related items, including safety events and deviations.

The need for consistent review of pending operational items during time with the PI.

Implementation of an Audit Assessment Category Guidance System to Define Audit Deficiencies as Critical, Major, or Minor

M. Storms, K. Bogaard
The University of Texas MD Anderson Cancer Center

1. Background

Internal protocol audits conducted by MD Anderson's Clinical Research Audit Group consist of reviewing and evaluating the regulatory documents and the individual patient records for compliance with the study. All deficiencies are identified and recorded on a report during the audit review process and then discussed with the study principal investigator (PI) and research team. We define a deficiency as any incomplete, incorrect, or missing item that is not in keeping with the investigational plan, institutional requirements, or federal regulations. This definition is in line with the National Institute of Health (NIH) and National Cancer Institute (NCI) monitoring and auditing guidelines. While our audit process is very consistent, we were lacking a standardized method to categorize the severity of each audit deficiency.

2. Goals

Our primary goal was to come up with a systematic way to label and categorize each audit deficiency by degree of severity to be in line with industry and federal guidelines/processes. By developing an internal reference chart to define the severity of each deficiency, this would standardize the way that each auditor captures audit deficiencies. We believe these labeling categories provide a means of making the audit process more impactful for the principal investigator (PI) study team and our internal Data Safety Monitoring Committee (DSMC).

3. Solutions and Methods

An "Audit Assessment Category Guidance Process" was initiated in September 2021 to provide standardized categories that the auditors could use to grade the severity of each audit deficiency. The auditors now assess and label each audit deficiency as "critical," "major," or "minor" per a reference chart within the guidance document. The audit deficiencies are further broken down into the following categories: regulatory documents, informed consent, eligibility, protocol compliance, treatment administration, disease outcome, toxicity, and data quality. If critical or major deficiencies are noted in the audit, the PI may also be asked to complete and return a Corrective and Preventive Action Plan (CAPA).

4. Outcomes

The feedback has been positive on the initiation and usefulness of the audit deficiency categories. This has been a very effective method for both the auditor and the PI in understanding which audit deficiencies are more serious in nature. Since this process was initiated, CAPAs for major deficiencies have been requested and completed for 28 studies out of the 171 total protocol audits conducted representing approximately 16 percent of all audits conducted. For internal studies with DSMC oversight, the review categories have assisted the DSMC in determining the severity of the audit. Additionally, the PI and study team are now encouraged to take internal research topic educational courses for any repetitive audit deficiencies categorized as major or critical.

5. Lessons Learned and Future Directions

We plan to continue updating this process and the reference chart as more data and different audit situations arise. Over the last six months, we have started tracking additional audit metrics and trends on the number of major and critical audit deficiencies. We plan to use this data to better identify PIs and departments who have repetitive major findings within the same audit categories. We will also share this information with our research education team so that they can assist with re-education needs as identified through the audit deficiencies.

Implementation of an Audit Assessment Category Guidance System to Define Audit Deficiencies as Critical, Major or Minor

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The University of Texas at MD Anderson Cancer Center, Houston, TX

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center Making Cancer History®

Background

Audits conducted by MD Anderson Cancer Center (MDACC) audit team consists of reviewing and evaluating the regulatory documents and individual patient records for compliance with the study. While our audit process has been consistent, we previously did not have a standardized method to categorize the severity of each audit deficiency recorded on the audit summary report. Deficiencies are identified as any incomplete, incorrect, or missing item that does not comply with the investigational plan, institutional requirements, or federal regulations.

Goals

- Develop a systematic method to categorize audit deficiencies by degree of severity to be in line with industry and federal guidelines
- Standardize the categories to ensure each auditor uses the same grading method
- Provide a more impactful audit report for the PI, study team, and our internal Data Safety Monitoring Committee (DSMC)

Solutions and Methods

Our team developed an "Audit Assessment Category Guidance process" document that standardized categories that are used to grade the severity of each audit deficiency. The deficiencies will then be labeled as either critical, major or minor per a reference chart within the guidance document. If critical or major deficiencies are noted in the audit, the PI may also be asked to complete and return a Corrective and Preventive Action Plan (CAPA).

Audit Deficiency Categories

Informed Consent	Toxicity	Compliance	Treatment Administration
Disease Response	Eligibility	Data Quality	Regulatory Documents

Grading Scale

Critical
- Any event that adversely affects the well-being of the participant and/or study integrity. This includes any intentional misrepresentation of data.

Major
- A deviation from study procedures, practices, or schedule that is severe and/or compromises patient safety
- Impacts data integrity
- Repetitive events
- Involve multiple participants

Minor
- Minimal impact on the outcome or interpretation os the study and not described as a major deficiency

Outcomes

Since this process was initiated, Corrective and Preventive Action plans (CAPAs) for major deficiencies have been requested and completed for 28 out of the 171 protocol audits conducted, representing approximately 16% of all audits in that timeframe.

Additionally, the PI and study team are encouraged to take internal research topic educational courses for any repetitive deficiencies categorized as a 'major' or 'critical' deficiency. For internal studies with DSMC oversight, the review categories have assisted the DSMC in determining the severity of the audit.

The DSMC chair has indicated there is high value in the categories, especially for significant issues like informed consent and protocol eligibility.

Lessons Learned and Future Direction

We will continue updating this process and refining the reference chart as more data and different audit situations arise. Over the last 6 months, we began tracking additional audit metrics and trends on the number of major and critical audit deficiencies. We will use this data to better identify PIs and departments that have repetitive major findings within the same audit categories. We will also share this information with our clinical research training team so that they can assist with education needs as identified through the audit deficiencies.

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A Formal Dose Escalation/Safety Lead-In Request and Approval Process

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UCSF Helen Diller Family Comprehensive Cancer Center

1. Background

Each year at UCSF, approximately 6,500 adults and children are newly diagnosed with cancer. The UCSF Helen Diller Family Comprehensive Cancer Center Data and Safety Monitoring Committee (HDFCCC DSMC) is responsible for ensuring participant safety and data integrity for all cancer related clinical research trials conducted at UCSF. For both Phase I and II trials, the DSMC monitors are tasked with monitoring source documents and conducting source document verification for participants in each dosing cohort prior to granting approval of enrollment in the next dosing cohort as per protocol. The HDFCCC DSMC has developed this distinctive dose escalation and safety lead-in review approval process that is unique to comprehensive cancer centers (CCCs).

2. Goals

- Provide improved oversight to ensure participant safety and data integrity
- Provide a streamlined process for the preparation/submission by the study team and the review/approval by the DSMC for all dose escalation and safety lead-in requests for applicable Phase I and II studies, respectively

3. Solutions and Methods

Two types of reviews are performed to ensure the safety of participants in their current cohort prior to moving to the next stage:

1. Dose escalation reviews prior to enrollment in the next higher dosing cohort
2. Safety lead-in reviews prior to opening the phase II study for further enrollment

These reviews verify that all participants in each dosing cohort are consented according to IRB regulations, meet all eligibility criteria, receive Investigational Product as per protocol, all serious adverse events and protocol violations are reported, and any undocumented dose-limiting toxicities are identified. In advance of a dose escalation/safety lead-in request, the study team communicates when the final participant of a cohort initiates treatment so the DSMC monitor can ensure the timely completion of monitoring the current cohort. Monitoring must be completed, and all significant safety issues addressed by the study team prior to the approval of the dose escalation/safety lead-in request to enroll in the next dosing cohort. Once monitoring concludes, the study team completes a Dose Escalation/Safety Lead-in Report that provides a summary of all safety data for the dosing cohort. The report is forwarded to the DSMC chair or vice chair for review and approval. Once approval is granted, the study team is formally notified that they may begin enrolling participants in the next dosing cohort. If approval is not granted, the reason for disapproval will be communicated to the PI with required action items (e.g., replacement of non-evaluable participants). Once these items have been addressed, the study team will then resubmit the amended Dose Escalation/Safety Lead-in Report for review and approval by the DSMC.

4. Outcomes

A novel, independent dose escalation/safety lead-in approval process improved data integrity and protocol compliance by identifying 4.1 percent of participants as non-evaluable and requiring replacement per protocol definitions. This process was feasible with a turnaround time of approximately two business days from request to approval by the DSMC.

5. Lessons Learned and Future Directions

Future directions include refining dose escalation/lead-in approval request templates according to study phase/design, soliciting feedback from study teams across site committees, and benchmarking with other CCCs.

UCSF Helen Diller Family Comprehensive Cancer Center

A Formal Dose Escalation/Safety Lead-In Request and Approval Process

Melody Gawliu, CCRP

Background

Each year at UCSF, approximately 6,500 adults and children are newly diagnosed with cancer. The UCSF Helen Diller Family Comprehensive Cancer Center Data and Safety Monitoring Committee (HDFCCC DSMC) is responsible for ensuring participant safety and data integrity for all cancer related clinical research trials conducted at UCSF. For both phase I and II trials, the DSMC Monitors are tasked with monitoring source documents and conducting source document verification for participants in each dosing cohort prior to granting approval of enrollment in the next dosing cohort as per protocol. The HDFCCC DSMC has developed this distinctive dose escalation and safety lead-in review approval process that is unique to Comprehensive Cancer Centers (CCCs).

Goals

- Provide improved oversight to ensure participant safety and data integrity
- Provide a streamlined process for the preparation/submission by the study team and the review/approval by the DSMC for all dose escalation and safety lead-in requests for applicable phase I and II studies, respectively.

Solutions and Methods

Two types of reviews are performed to ensure the safety of participants in their current cohort prior to moving to the next stage:

- Dose escalation reviews prior to enrollment in the next higher dosing cohort
- Safety lead-in reviews prior to opening the phase II study for further enrollment

These reviews verify that all participants in each dosing cohort are consented according to IRB regulations, met all eligibility criteria, received Investigational Product as per protocol, all serious adverse events and protocol violations are reported, and any undocumented dose-limiting toxicities are identified.

In advance of a dose escalation/safety lead-in request, the study team communicates when the final participant of a cohort initiates treatment so the DSMC Monitor can ensure the timely completion of monitoring the current cohort. Monitoring must be completed, and all significant safety issues addressed by the study team prior to the approval of the dose escalation/safety lead-in request to enroll in the next dosing cohort. Once monitoring concludes, the study team completes a Dose Escalation/Safety Lead-in Report that provides a summary of all safety data for the dosing cohort. The report is forwarded to the DSMC Chair or Vice Chair for review and approval. Once approval is granted, the study team is formally notified that they may begin enrolling participants in the next dosing cohort. If approval is not granted, the reason for disapproval will be communicated to the PI with required action items (e.g., replacement of non-evaluable participants). Once these items have been addressed, the study team will then resubmit the amended Dose Escalation/Safety Lead-in Report for review and approval by the DSMC.

Outcomes

A novel, independent dose escalation/safety lead-in approval process improved data integrity and protocol compliance by identifying 4.1% of participants as non-evaluable and requiring replacement per protocol definitions. This process was feasible with a turnaround time of approximately 2 business days from request to approval by the DSMC.

	Approved Safety Lead-Ins	Approved Dose Escalations	Approved Interim Analysis	Patients Reviewed
2020	3	2	1	34
2021	2	2	0	18
2022	1	5	0	21
Total Reviews	**6**	**9**	**1**	**73**

Future Directions

Future directions include refining dose escalation/lead-in approval request templates according to study phase/design, soliciting feedback from study teams across Site Committees, and benchmarking with other CCCs.

Contact

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Taking Data Validation to the Next Level: Automating Data Validation Using CDASH-Standardized Global eCRFs

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UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

1. Background

A high volume of clinical trial data is generated daily. Data management staff then ensure the data's accuracy, reliability, and consistency and prepare high-quality datasets for safety and efficacy analysis by biostatisticians. Hence it is essential to have the data validated from the initial stages of the clinical trial to avoid risks to patient safety and data quality. Data validation is a tedious and time-consuming process highly susceptible to human error, resulting in lower data quality. Therefore, there is a necessity for automating the data validation process, which is time-saving and more efficient than manual data validation. This automation helps in understanding multivariate data relations.

2. Goals

This project aims to implement an automated data validation process using CDASH-standardized global electronic case report forms (eCRFs) to maintain data quality and integrity by automatically detecting non-compliant data. Further goals include:

- Expediting data review by directly reviewing the targeted data
- Increased accuracy of the data validation by eliminating human-prone errors and increasing query volume
- Developing a user interface to execute the data validation programming checks by entering the study reporting parameters that will run the Statistical Analysis System (SAS) program and output the data into the study folder

3. Solutions and Methods

For each study, the clinical data management associate (CDMA) provides the Data Validation Plan (DVP) to the programmer in an Excel sheet. The automation uses the SAS programming language, whereby the checks within and across the CRFs are programmed into separate SAS code files. After executing the programs, data issue reports are generated as Excel workbooks containing multiple sheets corresponding to each CRF. Each Excel sheet contains tables of observations for each issue with titles describing them. The CDASH eCRF global library enables a standardized SAS program file that can be used across studies.

4. Outcomes

The data review process is faster and easier as all the targeted data is in one place. We will collect metrics to assess the number of discrepancies and data review time using the new process. Automated results made a significant difference when there were many records where the issues could be easily missed in manual reviews. This new process also increases frequency of clinical data reviews. The creation of cross-form checks enabled the assessment of multivariate data relationships. Evaluating standard data checks and queries to streamline the eCRF build increased the database build efficiency. Success is contingent on improving the data review time.

5. Lessons Learned and Future Directions

Some checks cannot be automated and require manual intervention. We successfully standardized the checks for forms, wherein we reduced programming time by coding individual reusable forms common for various studies. However, we still need to write new code exclusively for study-specific forms. Phase 2 of the project will aim to build and host a website where authorized users can choose an Advarra EDC protocol from a list. Upon execution, it connects to the EDC backend and builds a SAS initialization program that generates the validation reports without the involvement of the SAS programmer.

Taking The Data Validation To Next Level: Automating Data Validation Using CDASH-Standardized Global eCRFs

Shreya Rachuri, MSc; Mary O'Dwyer, MRP, CCRP; Kathe Douglas, BA; Leilani Logan, MSc; Josh Tewell, BA; Saianand Balu, MS;
Carrie Lee, MD, MPH; J. Kaitlin Morrison, PhD; Erin Crecelius, MA
[Lineberger Comprehensive Cancer Center]

Background

A high volume of clinical trial data is generated daily in Investigator-Initiated trials(IITs) at Lineberger Comprehensive Cancer Center. Data management staff then ensure the data's accuracy, reliability, and consistency and prepare high-quality datasets for safety and efficacy analysis by biostatisticians. Hence it is essential to have the data validated from the initial stages of the clinical trial to avoid risks to patient safety and data quality. Data validation is a tedious and time-consuming process highly susceptible to human error, resulting in lower data quality. Therefore, there is a necessity for automating the data validation process, which is time-saving and more efficient than manual data validation. This automation helps in understanding multivariate data relations.

Goals

This project aims to implement an automated data validation process using CDASH-standardized global Electronic Case Report Forms (eCRFs) to maintain data quality and integrity by automatically detecting non-compliant data. Further goals include:

- Expediting data review by directly reviewing the targeted data
- Increasing accuracy of the data validation by eliminating human-prone errors and increasing query volume
- Decreasing the programming time by standardizing the checks for global forms used across all the studies and reusing the same code
- Developing a user interface to execute the data validation programming checks by entering the study reporting parameters that will run the SAS program and output the data into the study folder

Solutions & Methods

For each study, the Clinical Data Management Associate (CDMA) provides the Data Validation Plan (DVP) to the programmer in an Excel sheet. The automation uses the Statistical Analysis System (SAS) programing language, whereby the checks within and across the eCRFs are programmed into separate SAS code files. After executing the programs, data issue reports are generated as Excel workbooks containing one sheet corresponding to each eCRF. Each Excel sheet contains tables of observations where issues are color code and titles describe issues programmed. The CDASH eCRF Global library enables a standardized SAS program file that can be used across all studies.

Fig1: Flow Diagram Of Events In Automating Data Validation

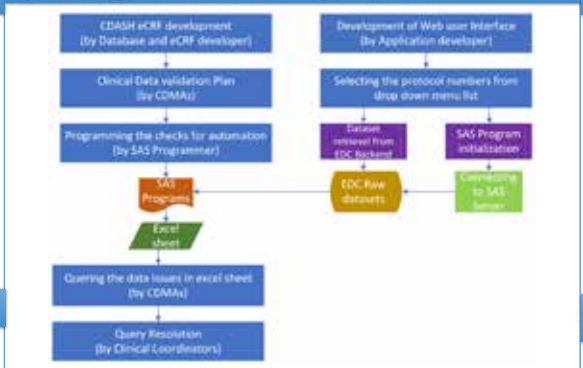
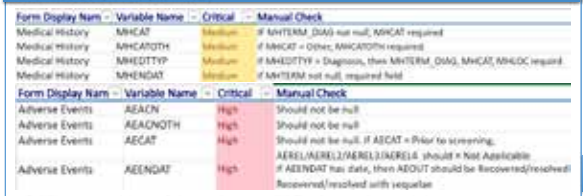


Fig 2: DVP Spreadsheet Prepared for SAS Programmer. All Variables for All Forms are Listed. The CDMA Indicates How Critical The Form Data is And Validation to be Programmed



Form Display Nam	Variable Name	Critical	Manual Check
Medical History	MHCAT	Medium	if MHTERM_DIAG not null, MHCAT required
Medical History	MHCATOTH	Medium	if MHCAT = Other, MHCATOTH required
Medical History	MHEDITYP	Medium	if MHEDITYP = Diagnosis, then MHTERM_DIAG, MHCAT, MHLOC require
Medical History	MHENDAT	Medium	if MHTERM not null, required field
Form Display Nam	Variable Name	Critical	Manual Check
Adverse Events	AEACN	High	Should not be null
Adverse Events	AEACNOTH	High	Should not be null
Adverse Events	AECAT	High	Should not be null. if AECAT = Prior to screening, AEREL/AEREL2/AEREL3/AEREL4 should = Not Applicable
Adverse Events	AEENDAT	High	if AEENDAT has date, then AEOUT should be Recovered/resolved/ Recovered/resolved with sequelae

Fig 3: User Interface to Select Protocol From Drop Down Menu to Connect to The EDC Backend. The Connection Initializes The SAS Program to Generate The Validation Reports

Outcomes

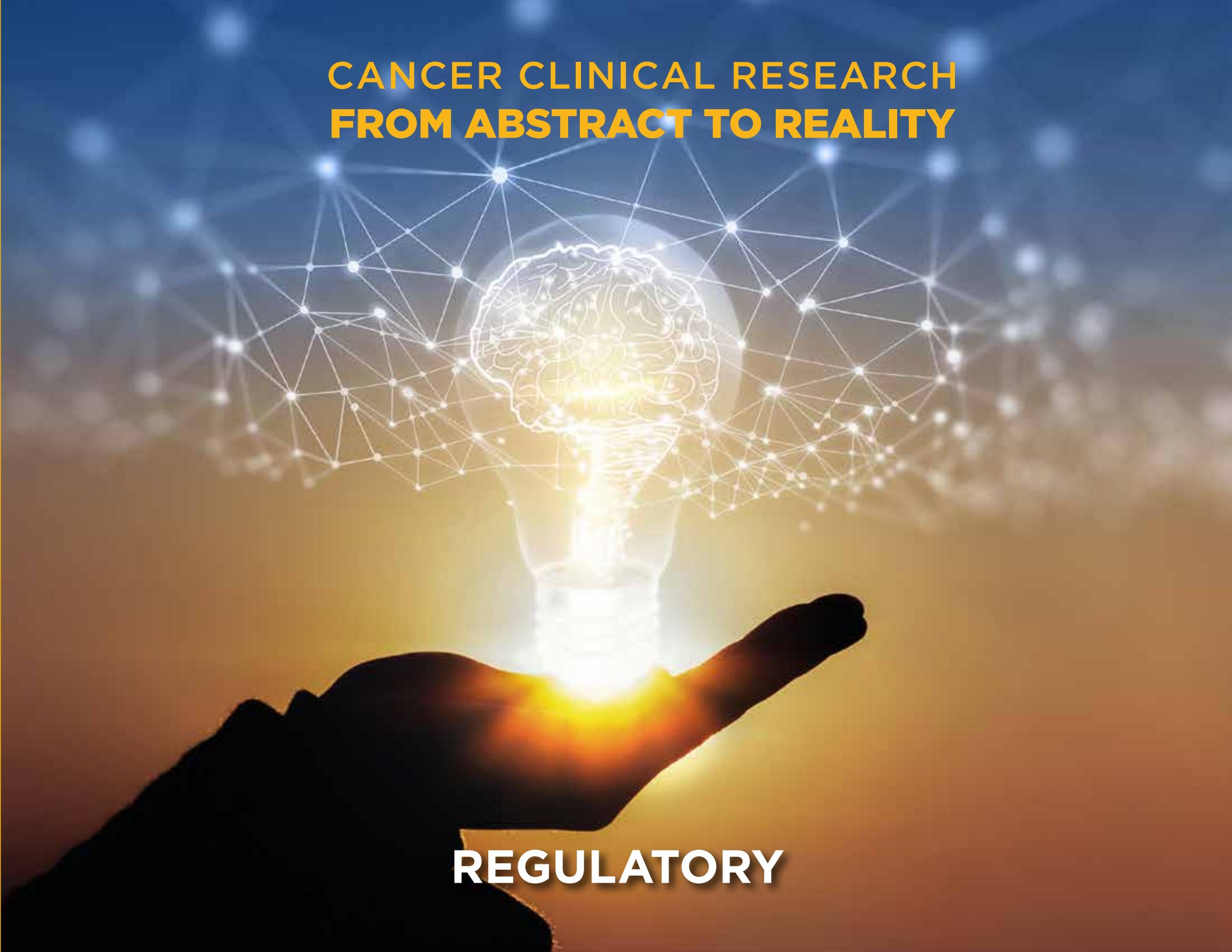
The data review process is faster and easier as all the targeted data is in one place. We will collect metrics to assess the number of discrepancies and data review time using the new process. Automated results made a significant difference when there were many records where the issues could be easily missed in manual reviews. This new process also increases frequency of clinical data reviews. The creation of cross-form checks enabled the assessment of multivariate data relationships. Evaluating standard data checks and queries to streamline the eCRF build increased the database build efficiency. Reusing the code for standardized checks for global forms has decreased the programming time by approximately 50-60%. Success is contingent on improving the data review time.

Fig 4: Validation Outcome in Excel Sheet Listing The Data Issues And Missing Data is Color Coded for Immediate Identification.

Lessons Learned & Future Outcomes

Some checks cannot be automated and require CDMA review. We successfully standardized the checks for forms, wherein we reduced programming time by coding individual reusable forms common for global studies. New coding will only be required for less common study-specific forms. Phase two of the project will aim to build and host a website where authorized users can choose an Advarra EDC protocol from a list. Upon execution, it connects to the EDC backend and downloads the SAS datasets and then builds a SAS initialization program file. This SAS file has the program that generates the validation reports. Upon invocation of SAS on web application server and executing the SAS initializing file, validation reports are generated. Once all this process is built, Validation reports can be run at any time without the involvement of SAS Programmer.

CANCER CLINICAL RESEARCH
FROM ABSTRACT TO REALITY



REGULATORY

Implementation of a Dashboard to Improve Protocol Oversight and Data and Safety Monitoring Committee (DSMC) Reviews

C. Kolenut, K. Napolitano, X. Lekperic, C. Zamore, A. Bijwe, D. Caron, S. Hanley, J. Chaft, S. Slovin
Memorial Sloan Kettering Cancer Center

1. Background

The Data and Safety Monitoring Committee (DSMC) requires submission of a database report for review. Historically, the database report came from the study's primary database(s); however, there were no standards or requirements for how data was provided, and integration of multiple data sources was manual. Additionally, raw data was typically submitted, which made the review of data challenging. With over 690 reviews conducted in 2022, the current process was not efficient for staff or DSMC reviewers. Thus, a report to automatically summarize large amounts of complex data in a consistent and tabulated way was needed.

2. Goals

Create an electronic database report that:

- Eliminates the submission of raw unorganized data
- Provides real-time data visualization from multiple sources
- Tabulates data to enhance review and monitoring
- Streamlines the data reporting process

3. Solutions and Methods

In collaboration with DSMC Leadership and Clinical Research Information Technology (CRIT), the Protocol Review Core (PRC) implemented the Protocol Overview Dashboard (POD) using the data visualization software Tableau. Careful project management using the following steps was required to achieve our goals:

1. Confirmed goals with stakeholders (e.g., DSMC, investigators, study teams, regulatory groups, institutional leadership) and created working groups

2. Finalized dataset needed to conduct monitoring oversight
   a. Protocol details: high-level overview of trial characteristics to provide a snapshot of protocol for users (e.g., PI, accrual target(s), protocol phase/type/risk)
   b. Participant summary: detailed overview of participant status for users to monitor study conduct and progress (e.g., enrollment by cohort/arm, demographics, disease/survival details, evaluability, and participating site accruals)
   c. S/AE details: list of S/AEs organized by organ system and grouped by cohort, grade, and intervention for users to monitor safety and identify trends

3. Identified data sources needed to provide consistent summary data in one location
   a. Clinical Trial Management System (CTMS)
   b. Protocol Information Management System (PIMS)
   c. Clinical research databases

4. Chose functionality that supports use at DSMC
   a. Designed visualization and report requirements to be visually pleasing and user-friendly (e.g., tables/graphs, data export, and download)
   b. Finalized data field terminology and settings to provide data requested by DSMC (e.g., information overlays, default filters, and custom views)
   c. Customized access to secure participant data (e.g., investigator, study team, DSMC)

5. Prepared the institution for use at DSMC
   a. Piloted across a diverse set of departments/services for inclusive feedback
   b. Provided multi-session trainings for study teams and DSMC
   c. Publicized use to investigators (e.g., institution-wide announcement, advertisements)
   d. Updated requirements and resources (e.g., How To, decision tree)

4. Outcomes

Following the pilot, use of the dashboard became a submission requirement for the majority of the DSMC portfolio (300+ studies). Implementation of the dashboard leverages data from multiple systems, creates a standard way of viewing trial data, and ensures more accurate submissions and better monitoring by the DSMC.

5. Lessons Learned and Future Directions

Use of the dashboard cannot be a mandatory requirement for all studies based on data requirement changes (e.g., older studies) and complexities with multicenter protocols. Future directions will include further refinement of data (e.g., laboratory toxicity, toxicity heat map) and use beyond the DSMC.

Implementation of a Dashboard to Improve Protocol Oversight and Data and Safety Monitoring Committee (DSMC) Reviews

Memorial Sloan Kettering Cancer Center

Christina Kolenut, MPH, Krista Napolitano, MA, Xhenete Lekperic, Aditi Bijwe, Dawn Caron, Sara Hanley, MSW, Jamie Chaft, MD, Susan Slovin, MD, PhD

Background

- The Data and Safety Monitoring Committee (DSMC) requires the submission of a database report.
- Historically, the database report came from the study's primary database(s); however, there were no standards or requirements for how data was provided, and integration of multiple data sources was manual.
- Raw data was often submitted which made the evaluation of data challenging. With over 690 reviews conducted in 2022, improvements to the current process were necessary.

Goals

Create an electronic database report that:

- Provides visualization of real-time data from multiple sources
- Eliminates the submission of raw unorganized data
- Automates and streamlines the data reporting process

Methods

In collaboration with DSMC Leadership and Clinical Research Information Technology (CRIT), the Protocol Review Core (PRC) implemented the Protocol Overview Dashboard (POD) (Figures 1-3) using the data visualization software, Tableau.

Careful project management using the following steps was required to achieve our goals:

Confirmed goals with stakeholders and created working groups

- Stakeholders included: DSMC, investigators, study teams, regulatory groups, and institutional leadership

Finalized dataset needed to conduct monitoring oversight

- **Protocol Details:** high-level overview to provide a snapshot of the study (e.g., study type, phase, risk level, status, target accrual)
- **Participant Summary:** in-depth overview of participant data to monitor study progress (e.g., demographics, disease/survival details, enrollment/evaluability status, site accrual details)
- **Serious Adverse Event (SAE) / Adverse Event (AE) Summaries:** organized by organ system and grouped by cohort, grade, and intervention in order to monitor safety and identify trends

Identified data sources

- Clinical Trials Management System (CTMS)
- MSK's Protocol Information Management System (PIMS)
- Clinical Research Electronic Data Capture Systems (EDCs)

Chose functionality that supports use at DSMC

- Designed aesthetically appealing and user-friendly data visualization (Figure 2)
- Finalized data field terminology, filter settings, and custom views (Figure 3) requested by DSMC
- Customized access and security script to secure participant data
- Granted DSMC members access to view and filter data directly

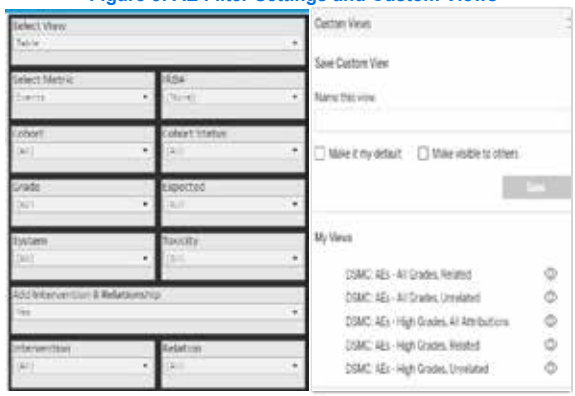
Prepared the institution for use at DSMC

- Piloted a diverse set of departments/services for inclusive feedback
- Provided multiple training sessions for study teams and DSMC
- Publicized to investigators (e.g., institution-wide announcement, advertisements)
- Updated requirements and instructional resources

Figure 1: Dashboard Landing Page

Figure 2: Adverse Event (AE) Example

Figure 3: AE Filter Settings and Custom Views



Outcomes

- Following the pilot, use of the dashboard became a submission requirement for the majority of the DSMC portfolio (300+ studies).
  - Note the AE tab cannot be used for certain older studies and for external sites of multicenter studies.
- Implementation of the dashboard enhances the submission and monitoring of trial data:

Leverages data from multiple systems that updates daily and exports data into PDF format

Creates a standard way of viewing trial data across all study types

Replaces raw data with tabulated data tables and graphs

Ensures more accurate submissions and improves monitoring by the DSMC

Facilitates interpretation of data by Principal Investigators with potential to enhance patient safety with improved data integrity

Future Directions

- Incorporate additional data into the dashboard:
  - Laboratory toxicity
  - Toxicity heat map
  - External toxicity data from multicenter studies
- Better track outcomes to demonstrate the impact of the dashboard:
  - Collect committee review data in support of the hypothesis that fewer administrative comments and more substantive comments are a result of clear data being provided for review
- Extend use of the dashboard to other key committees (e.g., MSK's Pediatric-specific DSMC)
- Broaden use of dashboard by investigators to oversee their data:
  - Monitor trial data
  - QA data entry
- Use dashboard data to produce graphs and figures for presentations and publications

Creation of the Performance Monitoring Committee: Optimizing Review of the MSK Clinical Research Portfolio

X. Lekperic, K. Napolitano, C. Kolenut, S. Hanley, A. Rodavitch, C. Houston, D. Rathkopf
Memorial Sloan Kettering Cancer Center

1. Background

Memorial Sloan Kettering's (MSK) Protocol Review and Monitoring System (PRMS) provides rigorous internal oversight of our scientific portfolio in accordance with Cancer Center Support Grant (CCSG) guidelines. Historically, our Research Council (RC) conducted PRMS second stage and performance monitoring reviews. To optimize the management of our expanding portfolio, the Performance Monitoring Committee (PMC) was created as a PRMS sub-committee in 2021.

2. Goals

- Create PRMS sub-committee to oversee performance monitoring
- Streamline institutional performance monitoring process

3. Solutions and Methods

- Created the PMC and transferred performance monitoring oversight from RC:
  - Ensured multidisciplinary membership (PRMS/institutional leadership and department/service representatives)
  - Provided multi-session training for members on CCSG guidelines and review process/tools
  - Defined mission/scope: To monitor MSK's research portfolio, appropriately identify underperforming studies, and terminate studies that do not demonstrate scientific progress or potential for completion
- Enhanced performance monitoring processes:
  - Expanded existing underperforming definition (estimated time to completion > five years) to include studies with zero accruals in the last 12 months and/or open for accrual > five years
  - Improved principal investigator (PI) submission template to capture information PMC needs to assess potential for completion and facilitate goal setting (accruals/progress, importance, goals)
  - Increased transparency with presentations, announcements, and trainings
  - Created and circulated department/service metrics to facilitate portfolio management decisions; metrics included past monitoring summary and distribution of protocols:
    - In activation
    - Open to accrual
    - Closed to accrual
    - Underperforming
- Created and implemented PMC review tools:
  - Performance Monitoring Tableau dashboard:
    - Real-time visual of portfolio's performance (by department/service/PI) available to PMC reviewers and clinical research leadership
    - Leverages data from multiple systems and visualizes comprehensive metrics including protocol lifespan and accrual rates
  - Decision tree
    - Facilitates PMC decision-making using a point system to quantify likelihood of study completion
- Leveraged home-grown Protocol Information Management System (PIMS) functionality:
  - Algorithm to identify underperforming studies
  - System-generated notifications to PIs/study teams
  - Electronic PI submissions and PMC reviews (including structured review form, meeting agendas, minutes, and review letters)
    - PMC review letters and/or closure recommendations drafted in/sent from system. Stored for future reference by PMC and other institutional committees (e.g., IRB, DSMC)
  - Submission and review "user work" for tracking protocols
  - Reporting features and Tableau integration
- Implemented accrual reminders for studies with zero accruals in six months

4. Outcomes

- Increased transparency with investigators fosters the shared institutional mission to close underperforming studies and reallocate resources towards trials with greatest scientific importance and likelihood of completion
- Expansion of underperforming criteria doubled the number of underperforming trials identified and broadened PMC's oversight
- PMC reviews resulted in a 230 percent increase in study closures in 2021-2022; this was vital due to increased number of protocols and decreased resources/staffing during and after the COVID-19 pandemic
- Implementation of the 0-accrual in 12 months metric was successful as these studies accounted for 43 percent of 2022 closures

5. Lessons Learned and Future Directions

- Implement continuous review process for studies with 0 accruals in 12 months
- Create SOPs
- Expand membership expertise
- Customize monitoring for rare disease, pediatric, and National Group studies
- Explore options to "stop the clock" for planned holds/amendments

Creation of the Performance Monitoring Committee: Optimizing Review of the MSK Clinical Research Portfolio

Memorial Sloan Kettering Cancer Center

Xhenete Lekperic, Krista Napolitano, MA, Christina Kolenut, MPH, Sara Hanley, MSW, Ann Rodavitch, MA, Collette Houston, Dana Rathkopf, MD

Background

- Memorial Sloan Kettering's (MSK) Protocol Review and Monitoring System (PRMS) provides rigorous internal oversight of the clinical research portfolio in accordance with Cancer Center Support Grant (CCSG) guidelines.
- Historically, the Research Council (RC) conducted PRMS second stage and performance monitoring reviews.
- To optimize the management of our expanding scientific portfolio (>2,000 prospective trials), a separate committee and streamlined processes were needed.

Goals

- Create PRMS sub-committee to oversee performance monitoring.
- Streamline institutional performance monitoring process.

Methods

Created the Performance Monitoring Committee (PMC) as a sub-committee of our PRMS and delegated performance monitoring oversight to PMC in 2021:

- Multidisciplinary membership (PRMS/institutional leadership and department/service representatives).
- Members received multi-session training on CCSG guidelines and review process/tools.
- Defined mission/scope: ***To monitor MSK's research portfolio, appropriately identify underperforming studies, and terminate studies that do not demonstrate scientific progress or high potential for completion.***

Expanded underperforming definition and enhanced performance monitoring processes:

- Expanded existing underperforming definition **(Estimated Time to Completion ≥5 years)** to include studies with **0 accruals in the last 12 months** and/or **Open for Accrual ≥5 years.**
- Improved **Principal Investigator (PI) submission template** (Figure 1) to facilitate goal setting.
- Created and circulated department/service metrics to facilitate portfolio management decisions.
- Increased transparency with institutional presentations, announcements, and trainings.

Created and implemented PMC review tools:

- **Performance Monitoring Tableau Dashboard** (Figure 2): Visual of portfolio's real-time performance (by department/service/PI) available to PMC reviewers and clinical research leadership. Leverages data from multiple systems and visualizes comprehensive metrics including protocol lifespan and accrual rates.
- **PMC Reviewer Decision Tree** (Figure 3): Facilitates PMC decision-making using a point system to quantify likelihood of study completion.

Leveraged home-grown Protocol Information Management System (PIMS) functionality:

- Modified existing system to separate PMC as a sub-committee.
- Built search **algorithm** to identify underperforming studies.
- System-generated notifications to PIs/study teams.
- Electronic PI submissions and PMC reviews.
- **Reporting** features and **Tableau** integration.

Implemented monthly monitoring:

- Accrual reminders for studies with **0 accruals in previous 6 months**; no response required.
- Started in March 2023.

Figure 1: Performance Monitoring Form

Figure 2: Performance Monitoring Tableau Dashboard

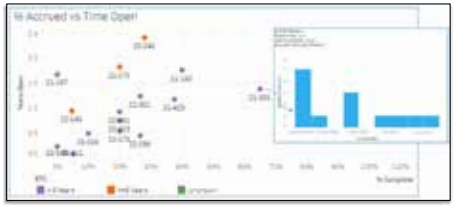


Figure 3: Reviewer Decision Tree

Outcomes

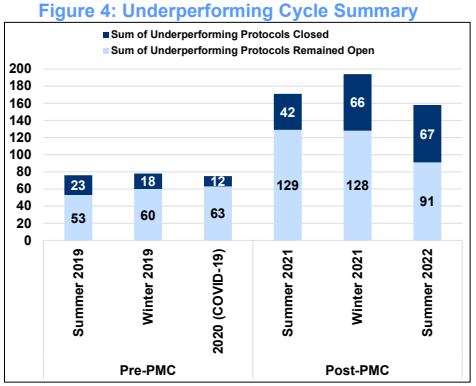
Creation of the PMC and expansion of the underperforming criteria doubled the number of underperforming trials identified. This broadened PMC's oversight and average per-cycle reviews from 76 pre-PMC to 174 post-PMC (Figure 4).

Multidisciplinary PMC membership and increased transparency fosters the shared institutional mission to close underperforming studies and reallocate resources towards trials with the greatest scientific importance and likelihood of completion.

PMC reviews resulted in a 230% increase in study closures (Figure 4) with 175 in 2021-2022 vs. 53 in 2019-2020. This was vital due to increased number of protocols and decreased resources/staffing during and after the COVID-19 pandemic.

Implementation of the 0 accruals in 12 months metric was successful as these studies accounted for 43% of 2022 closures.

Figure 4: Underperforming Cycle Summary



Future Directions

- Assess effectiveness of monthly accrual reminders for studies with 0 accruals in previous 6 months.
- Expand monthly monitoring to include continual monitoring and formal reviews for studies with 0 accruals in 12 months.
- Revise Standard Operating Procedures and incorporate customized monitoring for rare disease, Pediatric, and NCI National Group studies.
- Explore options to "stop the clock" for planned holds and amendments.

A Review and Recommendations for Implementing eRegulatory Investigator Site File Systems (eBinder, eISF)

M. Blair, C. Trani, L. McHugh, K. Tang, V. Chan
Abramson Cancer Center of the University of Pennsylvania

1. Background

Investigators are required to maintain adequate and accurate source documents and records to support the validity/reproducibility of human subjects. These documents are collectively referred to as a "regulatory binder" or "investigator site file (ISF)." In a digital world, additional requirements are imposed to ensure the infrastructure managing electronic information is trustworthy, reliable, and generally equivalent to process execution in a paper environment (21CFR11). The Abramson Cancer Center Clinical Research Unit, Office of Regulatory Affairs (ACC-CRU-ORA) has adopted an eISF infrastructure utilizing a commercially available cloud-based document management system. This eISF contains the administrative regulatory documentation required by law and as associated with the conduct of human subject research. Historically, the ACC-CRU-ORA maintained regulatory documentation in a paper format. Beginning in 2019, a program was initiated to migrate paper ISF information from the digital representations housed on a department shared server to the eISF cloud-based format.

2. Goals

The goals of the project were to implement of a cloud-based document management system fully addressed the compliance concerns associated with 21CFR11, streamlined process, and promoted continued support of best practices in clinical research document storage. Implementation, in advance of any formal enforcement action by an inspection agency, would allow us to resolve compliance issues with minimal impact on day-to-day operations.

3. Solutions and Methods

University of Pennsylvania (UPenn) allocated experts in the fields of information systems (IS), institutional policy, and the conduct of human subject research. Vendor resources, technical support, and ongoing maintenance of the system is overseen by vendor and IS partners. End-user account creation and account maintenance, with associated role-directed technical training is supported by UPenn central resources. Best practices for end-user adoption and function within the system are established through shared institutional governance in partnership with departments.

4. Outcomes

Implementation of this system has enhanced efficiency across both the site and exchanges with external collaborators (such as sponsors and monitors) and forced real-time health authority inspection readiness – overall improving the quality and efficiency of our systems. Further, we improved our ability to assess and report out important key performance indicators about the research portfolio, including: reports on product utilization; inpatient vs. outpatient services; partner organizations; person profile documents; compliance with protocol specific training documentation requirements; time to and outstanding e-signatures documenting investigator oversight; and quality assurance measures for supervisor oversight.

5. Lessons Learned and Future Directions

Acquiring and implementing an eISF regulatory document management system requires a significant upfront investment and translates to increased economies with efficiencies over time. A clear vision including scope of documentation for migration and/or decision to begin with only new research projects is essential. Sites must consider future utilization across departments/divisions and ensure unified acceptance of best practices while working within the system. Guard rails should be established for aligned quality control and quality systems management. Centralization of key resources for IS and institutional policy including infrastructure for supporting processes such as account creation and shared document management is essential. Efficiencies demonstrated are offset by the need for resources supporting change control, frontend data entry, and quality assurance maintenance.

A Review and Recommendations for Implementing eRegulatory Investigator Site File Systems (eBinder, eISF)

Meghan Blair, MS, CIP , Christine Trani, PhD, CIP, Kathy Tang, Vincent Chan
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Abstract

Investigators are required to maintain adequate and accurate source documents and records to support the validity/reproducibility of human subjects. These documents are collectively referred to as a 'regulatory binder' or 'investigator site file (ISF).' In a digital world, additional requirements are imposed to ensure the infrastructure managing electronic information is trustworthy, reliable, and generally equivalent to process execution in a paper environment [21CFR11]. The Abramson Cancer Center Clinical Research Unit, Office of Regulatory Affairs (ACC-CRU-ORA) has adopted an e-ISF infrastructure utilizing a commercially available cloud-based document management system.

Introduction

This e-ISF contains the administrative regulatory documentation required by law and as associated with the conduct of human subject research. Beginning in 2019, the ACC-CRU-ORA initiated a program to migrate legacy documentation stored on the department shared server to the e-ISF cloud-based application. There was no best practice for how an e-ISF should be created nor maintained; our use of a share departmental drive introduced 21CFR11 vulnerabilities. Implementation of the cloud-based document management system fully addresses the 21CFR11 compliance concerns associated with the shared servers.

Methods

- Performed landscape analysis to make scoping decisions about what trials to migrate, which types of human subjects research to include, and expected timeline for completion.
- Allocated experts and resources in the fields of information systems (IS), institutional policy, and site related regulatory affairs.
- Developed best practices for site based electronic document management leveraging parallels from the TMF DIA reference model.
- Beta-tested team based portfolio migration to inform process and timeline (Figure 1).
- Orchestrated change management control and end-user training to enhance adoption.
- Projected portfolio migration roadmap (Figure 2).
- Consolidated person profile documents comprising credentials and qualifications into the cloud-based application (Figure 3).

Figure 1 Trial Migration Process Map

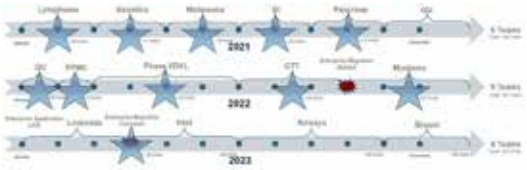
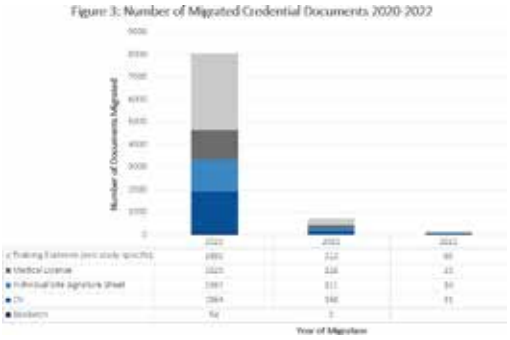
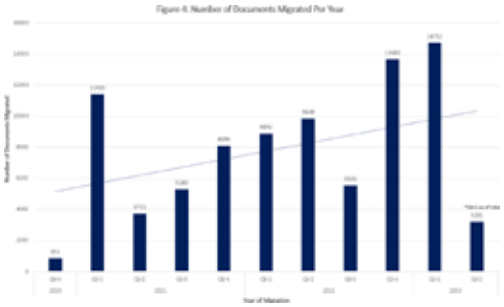


Figure 2: Trial Migration Roadmap:





Results

- A central repository of 7000+ person credential and qualification documents was created and immediately leveraged in advance of team based migration events (Figure 3).
- Entirety of ACC-CRU-ORA portfolio will be migrated by end of CY2023 addressing 21CFR11 compliance vulnerabilities. Efficiencies and economies of scale were leveraged to increase number of migrated overtime (Figure 4).
- Implementation enhanced efficiency across both the site and exchanges with external collaborators and forced real-time health authority inspection readiness.
- Improved ability to assess and report out important key performance indicators about the research portfolio including: reports on product utilization, in-patient vs out-patient services, partner organizations, person profile documents, compliance with protocol specific training documentation requirements, time to and outstanding e-signatures documenting investigator oversight, and quality assurance measures for supervisor oversight.

Discussion / Future Directions

A clear vision including scope of documentation for migration and/or decision to begin with only new research projects is essential. Acquiring and implementing an e-ISF regulatory document management system requires a significant upfront investment and translates to increased economies with efficiencies over time, including forced health authority inspection readiness.

Sites must consider future utilization across departments/divisions and ensure unified acceptance of best practices while working within the system. Guard rails should be established for aligned quality control and quality systems management. Centralization of key resources for IS and institutional policy including infrastructure for supporting processes such as account creation and shared document management is essential. Efficiencies demonstrated are offset by the need for resources supporting change control, frontend data entry, and quality assurance maintenance.

Research team portfolios based in the e-ISF cloud-based application can be analyzed for volume and complexity which guides workload management and staffing allocations.

Acknowledgements

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Arti Patel, Ralph Johnson
Special thanks to Research Team Regulatory Specialists, Program Managers,
and Clinical Team Faculty and Staff.

Penn Medicine

Development and Implementation of a Research Study Regulatory Complexity Assessment Tool

M. Blair, C. Trani, L. McHugh
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1. Background

There is an abundant amount of research on complexity of clinical trial design that suggests that clinical trials have become increasingly more complex over the years for a variety of reasons, including recording more patient-reported outcome measures, biomarker studies, and refined eligibility criteria. However, limited information is available on the impact of increased trial design on the regulatory complexity of a clinical trial. Regulatory complexity assessment tools can be utilized to collect and evaluate relevant clinical trial factors to effectively manage workload distribution, perform quality assurance review, and calculate future portfolio projections. In the Abramson Cancer Center Clinical Research Unit, Office of Regulatory Affairs (ACC-CRU-ORA), we previously would have to do a manual review of multiple systems to obtain an assessment of research portfolio demographics. In 2019, the ACC-CRU-ORA adopted an e-ISF infrastructure utilizing a commercially available cloud-based document management system. Information about study organizations and product information is a required data point for the study creation in the system. As a result, the ACC-CRU-ORA is now capable of running a report in the system on the composition of the center's research portfolio.

2. Goals

Our goal was to leverage a cloud-based eRegulatory investigator site file system to create a regulatory complexity assessment tool, thereby increasing understanding of each research teams' and the unit's portfolio so that appropriate resources are allocated to maintain regulatory compliance.

3. Solutions and Methods

Partnering with the vendor and IS collaborators, we leveraged information on the study factors in the cloud-based system to create research team-specific study level reports based on trial phase, study status, and organizations such as IRB of record, regulatory sponsor, CRO, etc. From the report, we implemented a weighting scale from "less" to "most" complex on a regulatory basis and graded each trial in the portfolio accordingly to obtain an overall average assessment of the research portfolio.

4. Outcomes

Leveraging the regulatory complexity assessment tool assisted in addressing concerns about equitable distribution of resources within the ACC-CRU-ORA supporting the unit. It has increased transparency between ACC-CRU-ORA staff and managers in meeting compliance expectations as there can now be a real time report of regulatory complexity for the portfolio which a staff member manages. Not only is this useful for current staff, but also when onboarding and training new staff to determine which types of trials are most appropriate for training purposes. Users can now review an entire portfolio of work on an equal rating scale. As new studies are approved or old studies are terminated, a user can see in real time portfolio complexity.

5. Lessons Learned and Future Directions

Developing and implementing the system required an intradepartmental collaboration with subject matter experts on creating reports and those who will utilize the reports. Report creators must have a robust understanding of the items which would contribute to regulatory complexity within the specific portfolio. In the future, we aim to use the compilation of assessments to track trends and create more precise projections to ensure the ACC-CRU-ORA is appropriately resourced to manage the unit's research portfolio.

Development and Implementation of a Research Study Regulatory Complexity Assessment Tool

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University of Pennsylvania, Philadelphia, PA

Abstract

Oncology clinical trials are among the most active and longest in duration in the area of drug trials. Research suggests, trials are becoming more complex with varying designs, objectives, and endpoints. Regulatory affairs is crucial to the success of these trials to ensure adequate regulatory document maintenance throughout the conduct of the trial. However, limited information is available on the impact of increased trial design on the regulatory complexity of a clinical trial. Regulatory complexity assessment tools can be utilized to collect and evaluate relevant clinical trial factors to effectively manage workload distribution, perform quality assurance review, and calculate future portfolio projections. Understanding the scope of regulatory complexity is essential to ensuring there is appropriate regulatory support and infrastructure to demonstrate the trial's compliance.

Introduction

In the Abramson Cancer Center Clinical Research Unit, Office of Regulatory Affairs (ACC-CRU-ORA) is capable of running a report in a cloud based application on the composition of the Center's research portfolio as a result of adopting an e-regulatory system. Study demographics are a required data point for the study creation in the system.
Our goal was to leverage a cloud-based eRegulatory investigator site file system to create a regulatory complexity assessment tool thereby increasing understanding of each Research Teams' and the Unit's portfolio so that appropriate resources are allocated to maintain regulatory compliance, protect human capital, and best match staff expertise with portfolio complexity.

Methods

- Developed stakeholder consensus as to factors which contribute to regulatory complexity.
- Partnered with the vendor, Office of Clinical Research (OCR), and Information System (IS) collaborators to leverage information on the study details in the cloud-based application to create Research Team specific study level reports based on trial phase, study status, and organizations such as IRB of record, regulatory sponsor, CRO, number of products.
- Developed and implemented generalizable weighting scale from least to most regulatory effort based on factors list above.
- Analyzed and reviewed research team portfolios undertaken within the Unit.

Research Team A: Portfolio Complexity Report

Research Team B: Portfolio Complexity Report

Results

- Utilizing stakeholder feedback, a weighting scale was created based on column headers in the figures. Highest (most complex) achievable score is 55 based on the weighting scale.
- A total of 9 complexity reports were created using the reporting function in the e-regulatory system; 2 example complexity reports shown at left.
- Research Team A had a total of 43 studies and average complexity is 33.8.
- Research Team B had a total of 16 studies and average complexity is 34.5.

Discussion / Future Directions

Leveraging the regulatory complexity assessment report as part of the toolkit in portfolio oversight assisted in addressing concerns about equitable distribution of resources within the ACC-CRU-ORA supporting the Unit. It has increased transparency between ACC-CRU-ORA staff and managers in meeting compliance expectations as there can now be a real time report of regulatory complexity for the portfolio which a staff member manages. Not only is this useful for current staff, but also when onboarding and training new staff to determine which types of trials are most appropriate for training purposes and to match regulatory skill sets with portfolio. Users can now review an entire portfolio of work on an equal rating scale. As new studies are approved or old studies are terminated, a user can see in real time portfolio complexity.
Developing and implementing the system required an intradepartmental collaboration with subject matter experts on creating reports and those who will utilize the reports. Report creators must have a robust understanding of the items which would contribute to regulatory complexity within the specific portfolio. Report users should pair this tool with other tools in the assessment kit such as annual submission metrics to obtain a full scope of understanding for both regulatory complexity and associated submission volume.
In the future, we aim to use the compilation of assessments to track trends and create more precise projections to ensure the ACC-CRU-ORA is appropriately resourced to manage the Unit's research portfolio and keep pace with the rapidly developing oncology clinical trial landscape.

Acknowledgements

Special thanks to Kathy Tang and Vincent Chan for expert guidance and support in generating the demographic reports.

Eliminating Unnecessary Review of Offsite Adverse Event (Expedited IND Safety) Reports: Departmental Collaboration Leading to Institutional Position

M. Blair, S. Mercado, M. Hendricks, D.T. Vogl
Abramson Cancer Center of the University of Pennsylvania

1. Background

FDA guidance indicates the sponsor is responsible for evaluating individual safety reports, assessing significance, performing aggregate analysis, and communicating actionable concerns to sites. OHRP has taken the position that it is neither useful nor necessary for reports of individual adverse events (AEs) in subjects enrolled in multicenter studies to be distributed to all investigators or IRBs [Unanticipated Problems (UPs)]. Individual AEs should be reported to investigators and IRBs after the sponsor has made a determination that the events meet specific criteria and are deemed actionable at the site. Sponsors and sites have not yet reached consensus on the process for distribution of individual reports. Most sponsors send all safety reports regardless of assessment and including those lacking action at the site. The University of Pennsylvania, Perelman School of Medicine (PSOM)'s Office of Clinical Research and the Abramson Cancer Center Clinical Research Unit (ACC CRU) have adopted an approach intended to limit administrative burden associated with unnecessary event report reviews.

2. Goals

Reporting AEs that are not serious, unexpected, and related to the study product creates administrative burdens for all site stakeholders including staff, faculty, and review committee members. The intention of the unified position was to reduce the number of uninformative AE reports being received, processed, and reported, unnecessarily, at the site.

3. Solutions and Methods

We aligned practice for review of events to only those meeting a clear definition for action at the site and those communicated outside of bulk automated systems. A guidance document delineating this best practice was developed, in addition to supportive tools explaining the position; language has also been added to contracts between PSOM and sponsors. Since the position was not specific to oncology programs, and the ACC CRU focuses heavily on sponsored projects, the ACC CRU served as lead in developing the position which could later be applied more broadly across the institution. ACC CRU (department) and PSOM (institution) continue to collaborate to message the position, train faculty/staff, and collect stakeholder feedback.

4. Outcomes

The ACC CRU has seen drastic (nearly complete) reduction in administrative burden as most reports previously received were not actionable. Actionable events continue to be communicated in alignment with "Dear Investigator" letters, protocol amendments, and/or updates to the investigator's brochure. Sponsors have provided generally positive feedback on the position; negative feedback served to present an opportunity for discussion and education. Our confidence has been bolstered by three FDA inspections of trials employing the position with no related findings upon review of safety reports/IRB submissions.

5. Lessons Learned and Future Directions

Sites will gain momentum in pushing back on undesirable, inefficient processes by banding together to communicate a consistent message supported by regulation. Institutions can seek inspiration for broad policy from internal departments as operational workflows and system requirements are realized during the day-to-day conduct of human subject research. As the ACC CRU continues to improve efficiency through review of process and implementation of new electronic systems, sustained enhanced communication and collaboration with PSOM will afford future opportunity for alignment with institutional policy.

Eliminating Unnecessary Review of Offsite Adverse Event (Expedited IND Safety) Reports: Departmental Collaboration Leading to Institutional Position

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University of Pennsylvania, Philadelphia, PA

Abstract

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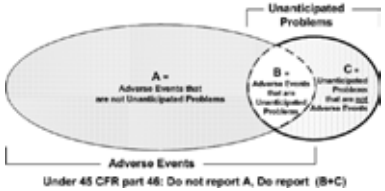
Introduction

Reporting AEs that are not serious, unexpected, and related to the study product creates administrative burdens for all site stakeholders including staff, faculty, and review committee members. The intention of the unified position was to reduce the number of uninformative AE reports being received, processed, and reported, unnecessarily, at the site allowing for focus on informative reports which promotes patient safety. We sought to realize our goal by first provide a framework for those principal investigators conducting clinical trials regarding the processing of external IND safety reports upon receipt from an external sponsor that is consistent with US Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP) regulations.

We chose to take these steps at the current time to realign practice with regulations ensuring the responsibility of analysis and communication of qualifying reports remains with the regulatory sponsor. Our desire was to reduce unnecessary, over reporting, and uninformative reporting at the site level.

Figure 1: Relationship between Adverse Events and Unanticipated Problems:



Methods

We aligned practice for review of events to only those meeting a clear definition for action at the site and those communicated outside of bulk automated systems. A guidance document delineating this best practice was developed, in addition to supportive tools explaining the position; language has also been added to contracts between PSOM and sponsors. Since the position was not specific to oncology programs, and the ACC CRU focuses heavily on sponsored projects, the ACC CRU served as lead in developing the position which could later be applied more broadly across the institution.

Core Tenets:
Principal Investigators are required to receive, review, report (as applicable), and retain external IND safety reports only when the report meets the following criteria:
AE must be:

- Serious or life threatening; and
- Unexpected; and
- Related to the study drug, as assessed by the sponsor; and
- The report must be accompanied by intentional and directed communication from the sponsor that includes the following information:
  - Clear explanation of why the AE has been determined to be an SUSAR or UP
  - Directives and/or actions required of the investigator (i.e., immediate notification to subjects participating, revised consent forms, revised protocol, revised investigator brochure)

Events meeting these criteria fall into categories 'B' and/or 'C' in Figure 1 and would qualify for Investigator review, reporting and retention in the investigator site files (ISF).

Events NOT meeting above criteria are NOT received, reviewed, reported or retained.

Expectations of External Sponsors:

- Directly notify Investigators of UPs and safety information that has implications for the conduct of the research (21 CFR 312.32, 21 CFR 312.55, 21 CFR 812.46, 21 CFR 812.150).
- Succinctly inform investigators of any UPs for which reporting is required, state the proposed action based on analysis of the UP, provide a report in a format sufficient to fully and accurately inform the IRB.
- Make any reports that are required in a dedicated correspondence.
- Provide an explanation of why an event was determined to be an UP and clearly indicate the implications for the conduct of the study.

Key features of the methods included:

- Definitions utilized in position statement are taken from the FDA to ensure consistency and alignment with federal regulations and across industry/site
- Approach and defined processes comply and align with federal regulations and IRB reporting guidelines to ensure both sponsor/site obligations are fulfilled
- Phased implementation, allowing for current practices to remain for active/already established studies yet reduce burden with implementation on new studies

Results

The ACC CRU has seen drastic (nearly complete) reduction in administrative burden as most reports previously received did not include sponsor provided aggregate analysis and/or were not actionable. Actionable events continue to be communicated in alignment with 'Dear Investigator Letters', Protocol Amendments, and/or updates to the Investigator's Brochure. Sponsors have provided generally positive feedback on the position; negative feedback served to present an opportunity for discussion and education. Our confidence has been bolstered by 3 FDA inspections of trials employing the position with no related findings upon review of safety reports/IRB submissions.

Discussion / Future Directions

Sites will gain momentum in pushing back on undesirable, inefficient processes by banding together to communicate a consistent message supported by regulation. Institutions can seek inspiration for broad policy from internal departments as operational workflows and system requirements are realized during the day to day conduct of human subject research. As the ACC CRU continues to improve efficiency through review of process and implementation of new electronic systems, sustained enhanced communication and collaboration with PSOM will afford future opportunity for alignment with institutional policy.

Acknowledgements

Special thank you to:

- Abramson Cancer Center Department of Compliance and Monitoring
- Perelman School of Medicine Office of Clinical Research
- University of Pennsylvania Institutional Review Board
- Faculty & Staff across participating Research Teams implementing the process

Penn Medicine

Closing Time: Protocol Scoring & Remote Closeout for Portfolio Optimization

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1. Background

Despite the negotiations and arduous work required to activate a trial, the closure of unsuccessful trials remains in the best interest of a clinical research site. Maintaining a heterogeneous portfolio of clinical trials is paramount for a research site to present alternative treatment routes for populations with analogous cancer types who have not responded well to approved treatment options. However, an issue common to many clinical sites is the oversaturation of low-accruing clinical trials. While a promising drug mechanism may seem exciting for patients with a rare mutation at the forefront of activation, slow enrollment in the institution seeking funds to maintain their program has financial ramifications. Further, there is a significant administrative burden in renewing, processing amendments, and providing repeated explanations to internal and external entities for the underperformance of a study. For these reasons, the Herbert Irving Comprehensive Cancer Center (HICCC) has established systems that streamline and amplify trial closures and close-out visit processes to bolster the integrity of clinical trial portfolios across disease teams, offer the most promising investigational agents to our patients, and optimize the financial output of our team efforts.

2. Goals

- Decrease administrative burden
- Bolster integrity of clinical trial portfolios
- Increase rate of close out visit of low/no accrual studies
- Optimize quality of study start-ups

3. Solutions or Methods

In Fall 2020, HICCC deployed the Disease Based Team (DBT) Prioritization scoring process, adapted from an NIH-based scoring system (Andrews, 2013, 5-10), and evaluated during routine DBT meetings, as presented in Figure 1. Prioritization review works with a trial Feasibility review to examine and qualify studies for start-up activities.

Adopting remote monitoring visits in early 2020 catalyzed the rapid innovation of external monitoring visits. In tandem with the DBT Prioritization review, the regulatory team transitioned to LabArchives, a remote Investigator Site File (ISF) sharing platform. The shift to LabArchives further optimized the secure document review process for our site and monitors by facilitating ISF sharing, external accessibility, and expediting close-out visit review.

4. Outcomes

The implementation of the DBT Prioritization Scoring review has led the investigators to select trials that satisfy feasibility deliberately. The process has demonstrated that start-ups are selected thoughtfully.

Concurrently, utilizing LabArchives for close-out visits has enabled faster scheduling. This platform facilitates remote monitoring visits, and in the recent year, 2022, there has been an uptick in closing out studies with poor accruals and inactive studies.

5. Lessons Learned and Future Directions

- Priority scoring has allowed for a more defined evaluation of each study before submission to our review committees. The feasibility process decreased the amount of Protocol Review and Monitoring Committee (PRMC) declined trials as submitted trials are of higher scientific merit and meet clinical needs.
- The PRMC reviews studies annually and issues six-month warnings for studies with no accruals. In Fall 2022, PRMC evolved this oversight to close studies with zero accruals after 12 months. The PRMC intervention is backed by biostatistical analysis suggesting that underperforming studies are unlikely to improve over time.
- LabArchives is being further developed as an eRegulatory platform to eliminate the need for regulatory staff to upload documents for review manually.

Sources:
1. Andrews, Jeff. 2013. "Prioritization Criteria Methodology for Future Research Needs Proposals Within the Effective Health Care Program: PiCMe-Prioritization Criteria Methods" Methods Future Research Needs Reports, no. 10 (Jan). 5-10. Available from: https://www.ncbi.nlm.nih.gov/books/NBK116677/

Closing Time: Protocol Scoring & Remote Closeout for Portfolio Optimization

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Background

Maintaining a heterogeneous portfolio of clinical trials is paramount for a research site to present alternative treatment routes for populations with analogous cancer types who have not responded well to approved treatment options. However, an issue common to many clinical sites is the oversaturation of low-accruing clinical trials. While a promising drug mechanism may seem exciting for patients with a rare mutation at the forefront of activation, slow enrollment in the institution seeking funds to maintain their program has financial ramifications. Further, there is a significant administrative burden in renewing, processing amendments, and providing repeated explanations to internal and external entities for the underperformance of a study. For these reasons, the HICCC has established systems that streamline and amplify trial closures and close-out visit processes to bolster the integrity of clinical trial portfolios across disease teams, offer the most promising investigational agents to our patients, and optimize the financial output of our team efforts.

Goals

- Bolster integrity of clinical trial portfolios.
- Increase rate of close out visit of low/no accrual studies.
- Optimize quality of study start-ups.
- Decrease administrative burden.

Methods

After ramping down research activities due to the COVID-19 pandemic, the Cancer Center needed to define a process for prioritizing start-up studies across the Disease Based Teams (DBTs) portfolios. Statistical analysis of enrollment probability for low accruing studies (Figure 1) was assessed to differentiate which studies would resume and which would be deprioritized. As a result, we developed the prioritization score, which was eventually adapted and incorporated into our feasibility review committee assessment portal.

The Prioritization Scoring review precedes the Feasibility assessment to qualify studies for start-up activities. In Fall of 2020, HICCC deployed the Disease Based Team (DBT) Prioritization scoring process, adapted from an NIH-based scoring system (Andrews, 2013, 5-10), and evaluated during routine DBT meetings. These categories included: scientific merit, clinical need, feasibility, academic output, funding, and resources.

Figure 1. Likelihood of studies with Low/No Accrual to Increase Enrollment Over Time

Subjects Accrued in Year 1	2017-2019 Studies Probability of Accrual in Year 2	2020-2021 Studies Probability of Accrual in Year 2	Change in Probability of Accrual in Year 2
2	16.68 %	7.04 %	- 9.64%
1	4.98 %	2.22 %	- 2.22 %
0	25.89 %	8.75%	- 17.14 %

Post-study activation, the Protocol Monitoring Review Committee (PRMC) annually reviews the predicted study accrual against actual accrual. As of early 2020, studies that do not reach 50% of the anticipated accrual are issued a six-month warning letter by the PRMC. The Principal Investigator is then required to provide a rationale for study continuation.

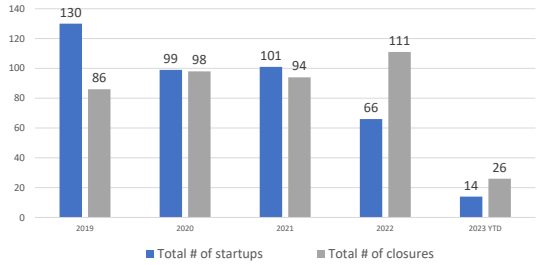
In Fall 2022, the PRMC issued a new initiative to close study enrollment of trials that do not accrue subjects in the first year after study activation. This policy is backed by biostatistical analysis indicating that studies with no accrual or low accrual in the year following activation will not improve enrollment over time (Figure 1).

In tandem with the DBT Prioritization review and PRMC initiative, the regulatory team transitioned to LabArchives, a remote Investigator Site File (ISF) sharing platform. Adopting remote monitoring visits in early 2020 catalyzed the rapid innovation of external monitoring visits. The shift to LabArchives further optimized the secure document review process for our site and monitors by facilitating ISF sharing, external accessibility, and expediting close-out visit review.

Results

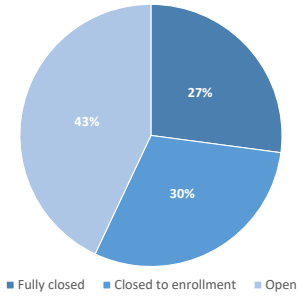
The implementation of the DBT Prioritization Scoring Process has led the investigators to select trials that deliberately satisfy feasibility. The DBT Prioritization Scoring has demonstrated that trials are selected thoughtfully and reduce wasted time and resources, as seen in Figure 2. In the recent year, 2022, the total number of start-ups had reduced by 197% since 2019, when there was no prioritization review, PRMC Warnings, or remote monitoring.

Figure 2. Start-Ups & Closure Comparison



Since enacting the PRMC warning letters, 57% of low-accruing studies have been closed to further enrollment, and about half have been fully closed at our site (Figure 3). Concurrently, utilizing LabArchives for close-out visits has enabled faster scheduling. This platform facilitates remote monitoring visits, and in the recent year, there has been an uptick in closing out studies with poor accruals and inactive studies. In comparison, in 2019, when LabArchives and little to no remote monitoring usage, there was a 77% increase in study closure.

Figure 3. Study Statuses Post PRMC Warnings



Conclusion

The adaptation of the DBT Prioritization Scoring Process has improved the thoughtful selection of start-up trials appropriate for the CUIMC community and within the caliber of the institution. PRMC's initiative of closing underperforming clinical trials has also combatted the oversaturation of low-accruing trials. In combination, the initiatives have reduced administrative burden and, in turn, improved efficiency, quality, and progress toward conducting pivotal cancer clinical trials.

Future Improvements

- LabArchives is being further developed as an eRegulatory platform to eliminate the need for regulatory staff to manually upload documents for external review.
- Optimization of start-up selection during prioritization review is expected to yield increased enrollment in the 2022-2023 period.
- The PRMC reviews studies annually and issues six-month warnings for studies with no accruals. In Fall 2022, PRMC evolved this oversight to close studies with zero accruals after 12 months. PRMC policies will continue to be updated according to the data these policies produce.

Sources:

1. Andrews, Jeff. 2013. "Prioritization Criteria Methodology for Future Research Needs Proposals Within the Effective Health Care Program: PiCMe-Prioritization Criteria Methods" *Methods Future Research Needs Reports,* no. 10 (Jan). 5-10. Available from: https://www.ncbi.nlm.nih.gov/books/NBK116677/

Herbert Irving Comprehensive Cancer Center COLUMBIA

Using HL7-FHIR to Automate Mandatory Reporting of Bone Marrow Transplant Data Decreases Staff Effort and Improves Data Quality

C. Thomas, R. Panchal, J. Konecny, T. Casali, M. Buckley, E. Klein
Memorial Sloan Kettering Cancer Center

1. Background

Memorial Sloan Kettering is required to submit outcomes data on every transplant performed to the Center for International Blood and Marrow Transplant Research (CIBMTR). We have developed an application, BMTVerse, to electronically send data from our electronic health record (EHR) to CIBMTR directly using Health Level 7-Fast Health Interoperability Resources (HL7-FHIR) technology. With this automation, we aimed to decrease the time spent on manual data abstraction from our EHR and manual data entry into CIBMTR and thus reduce data entry errors with this Source-to-Target approach: meet the data where it is.

2. Goals

- Eliminate dependency on data managed in excel spreadsheets
- Develop a user-friendly application to extract and blend data from internal databases and send it electronically to CIBMTR
- Reduce manual data entry burden
- Time savings
- Improve data quality

3. Solutions and Methods

We partnered with CIBMTR on their Data Transformation Initiative (DTI). To facilitate that, we developed BMTVerse, our home-grown application that leverages data from multiple internal databases and presents the cohort of patients, their demographics, and labs to be submitted to CIBMTR. DMs (Data Managers) can now send the patient demographics and labs to CIBMTR with a simple click. The data automation was done in 3 phases:

- Phase 1 (Dec 2021) demographics data automation
- Phase 2 (March 2022) pre-transplant lab automation
- Phase 3 (Nov 2022) post-transplant lab automation

4. Outcomes

DMs (Data Managers) spend on average 16.5 hours per patient on data entry on CIBMTR form completion per year. We have automated 7/27 (26 percent) demographic fields and 290/5,614 lab data fields (5.17 percent) via BMTVerse. Compared to manual methods, BMTVerse saves between three and twenty minutes for labs (depending on disease and form type) and five minutes for demographic data per patient.

5. Lessons Learned and Future Directions

Tools like BMTVerse, with the ability to pull and blend data from the various internal data source decreases the time burden associated with manual data extraction and increases accuracy. The percentage of data errors in the next CIBMTR audit will be used to measure the improvement in data quality. Data automation has already saved time and will continue to reduce this administrative data reporting burden tremendously as we acquire and automate more data sets to CIBMTR.

Using HL7-FHIR to Automate Mandatory Reporting of Bone Marrow Transplant Data Decreases Staff Effort and Improves Data Quality

Memorial Sloan Kettering Cancer Center

Authors: Cenia Thomas, BS; Renata Panchal, M.S.; John Konecny, BS; Timothy Casali, BS; Michael Buckley; Elizabeth Klein, MPH; Joseph Lengfellner

BACKGROUND

Transplant centers are required to submit outcomes data on every transplant performed to the Center for International Blood and Marrow Transplant Research (CIBMTR).

Data is manually abstracted from the Electronic Health Record (EHR) entered by data managers (DM) into an online data capture system, called FormsNet3 (FN3).

PROBLEM

Data staff spend on average 16.5 hours per patient on data entry for CIBMTR form completion per year

Manual data entry is inefficient, time consuming and error prone

METHODS

Data automation planning began in June 2021 and the BMTverse App went into production in December 2021.

Our rollout was conducted in 3 phases:

1) Automation of demographics submissions in December 2021
2) Automation of select pre-transplant labs in March 2022
3) Automation of complete blood count with differential labs at post- transplant in November 2022.

We monitored time and effort savings as our main key performance indicator (KPI).

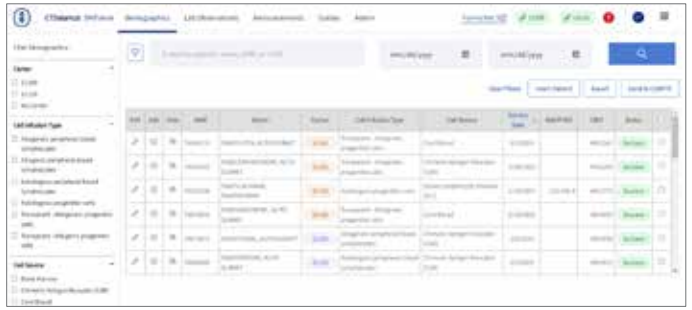
GOAL

Eliminate, manual data entry via automation of data submission to CIBMTR.

[1] Gonzales et al., 2020, "Time-Driven Activity-Based Costing (TDBAC) Identifies Time and Effort Required for Completion of CIBMTR Forms and Can Assist in Resource Planning for HCT Centers", Biol. Blood Marrow Transplant 26:S96-S255

BMTVERSE

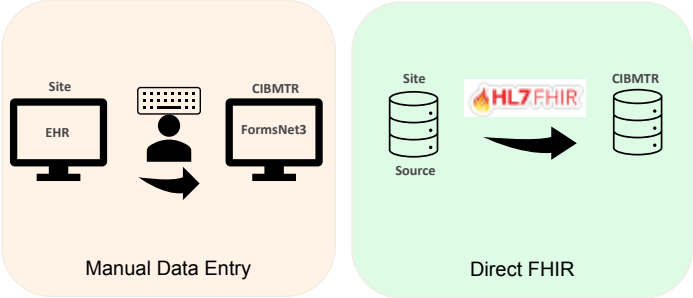
User interface for triggering and monitoring data submission to CIBMTR

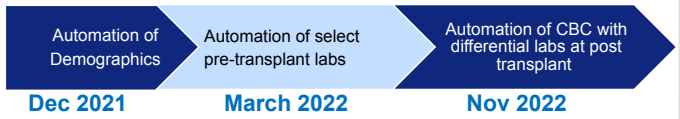


Automatically extracts and sends source data to CIBMTR forms using Health Level 7-Fast Health Interoperability Resources (HL7-FHIR) technology.

MSK was the first center to leverage Direct FHIR and not Epic FHIR.

Facilitate new research opportunities, while reducing the time research staff is required to maintain and report on the data timely.





RESULTS

- Phase 1: Automation of **demographics** data submission to CIBMTR to register a patient saved 5 minutes/patient[1].
- Phase 2: Automation of certain pre-transplant and post-transplant **lab results** data to CIBMTR saved 3-20 minutes/patient[1].

DEMOGRAPHICS

Saves 5 minutes Per patient

LABS

Saves 3-20 minutes per patient

(depending on disease/form type)

CONCLUSIONS

Digital tools like BMTVerse powered by HL-7-FHIR can:

- Decrease the time burden associated with mandatory data reporting requirements
- Improve data management operational efficiencies
- Increase data accuracy
- Reduce data submission latency

FUTURE DIRECTIONS

Partner with CIBMTR to automate other high-value data fields in 2023.

ACKNOWLEDGEMENTS

We would like to thank Dr. Sergio Giralt, Dr. Miguel Perales, Dr. Jaap-Jan Boelens, Dr. Andrew Harris, Dr. Stephanie Terzulli, MSK's Data managers- Elizabeth Hoover, Kelcey Skinner, Olivia Cohen and CIBMTR team for their invaluable guidance and support.

Regulatory Burden of IRB Submissions: Commercial vs. Internal IRBs

E. Sibilsky Enselman, J. Humfleet, D. Bashllari
University of Michigan Rogel Cancer Center

1. Background

The University of Michigan (UM) Health Rogel Cancer Center's Oncology Clinical Trials Support Unit (O-CTSU) primarily has utilized UM's internal IRBMED as the institutional review board (IRB) for industry studies. In second quarter of 2021, a pilot was instituted to increase the utilization of central institutional review boards (cIRB), such as Advarra and WCG, to reduce approval and study activation timelines.

O-CTSU's Regulatory team is separated into two units: Start-up (focus on coordination through initial IRB approval) and Maintenance (focus on coordination after initial approval). The Regulatory team standardized the utilization of IRBMED across the entire portfolio of studies with established guidelines and reporting requirements. In addition, O-CTSU and IRBMED have a collaborative feedback loop in place to address changes, issues, and questions that arise. In comparison, use of cIRBs for O-CTSU was low and without standardized processes. Further, IRBMED does not cede oversight of all aspects of trials and institutional ancillary committees remain linked to the IRBMED application, resulting in duplicative submissions in IRBMED and cIRB systems. While IRB approval and activation timelines showed an improvement, the O-CTSU Regulatory team expressed an increase in effort and resources spent on managing cIRB studies.

2. Goals

- Determine the regulatory effort of utilizing cIRB compared to IRBMED for industry studies

3. Solutions and Methods

Due to our staff recording effort in a web-based research effort tracking application (RETA), we were able to determine the amount of time spent on specific tasks over a standard time frame. We included studies with amendments, other reportable information or occurrence (ORIOs), and continuing renewals. This yielded 41 IRBMED studies and 41 cIRB ceded studies for analysis. For each study, we separated the tasks into Start-up and Maintenance focused. For each category we evaluated total, median, and average time.

4. Outcomes

Upon analysis, the initial application with cIRBs required 32.4 percent less effort on average, with substantial time savings captured in the ICF development and revisions/contingencies. Once the study was transferred to Maintenance, the effort increased for cIRB studies compared to IRBMED studies. On average, a Maintenance RC uses an increased effort of 3.4 percent per protocol amendment, 42 percent per non-protocol amendment, and 3.3 percent per ORIO. The biggest increase in effort was spent on approval notifications and distributions with cIRB studies taking on average an additional 39 percent longer per study to process.

5. Lessons Learned and Future Directions

While the initial application for cIRB studies requires less time, due to a shorter internal application to IRBMED for ceded studies, the overall effort is higher in the maintenance phase. This could be due to our institution still requiring ancillary committee reviews prior to implementation of amendments, unfamiliarity with cIRB web platforms, or lack of a close working relationship with cIRBs. Additional data and time are needed to evaluate why there is an increase in maintenance effort for cIRB studies. We want to evaluate this same group of studies during their lifetime at our institution and compare the time saved at start up to the effort increase in maintenance to help inform our finance team adjust budgets more appropriately.

Regulatory Burden of IRB Submissions: Commercial vs. Internal IRBs

Elizabeth Sibilsky Enselman, MEd, ATC, CCRP; Jennifer Humfleet, BS, CCRP; Daniela Bashllari, MHA
University of Michigan Health Rogel Cancer Center – Oncology Clinical Trials Support Office

Background

The University of Michigan Health Rogel Cancer Center's Oncology Clinical Trials Support Unit (O-CTSU) primarily has utilized UM's internal IRBMED as the Institutional Review Board (IRB) for industry studies. In second quarter of 2021, a pilot was instituted to increase the utilization of Central Institutional Review Boards (cIRB) such as Advarra and WCG to reduce approval and study activation timelines.

O-CTSU's Regulatory team is separated into two units:

- Start-Up- focus on coordination through initial IRB approval
- Maintenance - focus on coordination after initial approval through termination

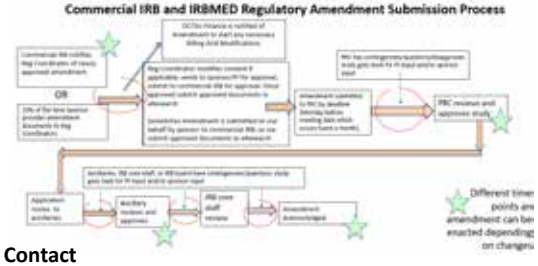
The Regulatory team consists of 1 manager, 3 leads, 1 project coordinator/administrator, 5 start-up coordinators and 10 maintenance coordinators. The team supports over 400 projects at any given time.

The Regulatory team standardized the utilization of IRBMED across the entire portfolio of studies with established guidelines and reporting requirements. In addition, O-CTSU and IRBMED have a collaborative feedback loop in place to address changes, issues, and questions that arise. In comparison, use of cIRBs for O-CTSU was minimal and without standardized processes. Furthermore, when using a cIRB, IRBMED does not cede oversight of all aspects of trials and institutional ancillary committees remain linked to the IRBMED application, thus resulting in duplicative submissions in IRBMED and cIRB systems.

While IRB approval and activation timelines showed an improvement, the O-CTSU Regulatory team expressed an increase in effort and resources being spent on managing cIRB studies.

IRBMED Regulatory Amendment Submission Process

Commercial IRB and IRBMED Regulatory Amendment Submission Process



Contact

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Website: https://octsu.med.umich.edu

Goal

Determine the regulatory effort of utilizing cIRB compared to IRBMED for industry studies.

Methods

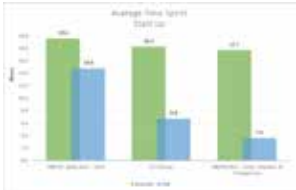
Our staff records effort in a web-based research effort tracking application (RETA). We were able to use RETA tracking to determine the amount of time spent on specific tasks over a standard time frame. We included studies with amendments, other reportable information or occurrences (ORIOs), and continuing renewals. This yielded 41 IRBMED studies and 41 cIRB ceded studies for analysis. For each study, we separated the tasks into Start-up and Maintenance focused. For each category we evaluated total, median, and average time.

RETA Effort Statistics
- Effort Record during a standard timeframe
- Reviewed the following Categories:
  - IRB/PRC Application
  - Initial ICF Develop
  - IRB/PRC Application, Protocol Amendment
  - IRB/PRC Application, Other Amendment
  - IRB/PRC/Anc. Comm. Revisions & Contingencies
  - IRB Application, ORIO
  - IRB Approval Notifications & Distribution
  - IRB SCR & Termination, eResearch

Application Type	Total Number Evaluated	Total # of Studies with Protocol Amendments	Total # of Studies with other Amendments	Total # of Studies with ORIOs	IRB SCR & Termination
Standard	41	28	28	11	14
cIRB	41 (Advarra- 23) (WCG- 18)	34 (Advarra- 8) (WCG- 6)	20 (Advarra- 12) (WCG- 11)	4 (Advarra- 4) (WCG- 2)	16 (Advarra- 10) (WCG- 6)

Outcomes

Upon analysis, the initial application with cIRBs required 32.4% less effort on average with substantial time savings captured in the ICF development and revisions/contingencies.



Once the study was transferred to Maintenance, the effort increased for cIRB studies compared to IRBMED studies. On average, a Maintenance Research Coordinator experienced an increased effort of 3.4% per protocol amendment, 42% per non-protocol amendment, and 3.3% per ORIO. The biggest increase in effort was spent on approval notifications and distributions, with cIRB studies taking on average an additional 39% longer per study to process.

Outcomes Cont.

Application Type	Average minutes per IRB/PRC Application Protocol Amendment	Average minutes per IRB/PRC Application, Other Amendment	Average minutes per ORIO	Average minutes per IRB Approval Notifications & Distribution event	Average minutes per IRB SCR & Termination event
Standard	528	114	54	336	72
cIRB	546	162	72	468	78
WCG	468	84	84	300	54
Advarra	642	234	60	492	90

Discussion

While the initial application for cIRB studies requires less time, due to a shorter internal application to IRBMED for ceded studies, the overall effort is higher in the maintenance phase. While there may be a savings in Start-up as this period can be a relatively short period compared to Maintenance. The difference between some values may appear to be small (e.g., 336 minutes vs. 468 minutes for AMD distributions), this is per event and would compound over time unless a change is made, as the maintenance phase is much longer.

This could be due to our institution still requiring ancillary committee reviews prior to implementation of amendments, or unfamiliarity with cIRB web platforms, or lack of a close working relationship with cIRBs.

Additional data and time is needed to evaluate why there is an increase in maintenance effort for cIRB studies.

Future Directions

We want to evaluate this same group of studies during their lifetime at our institution and compare the time saved at start up to the effort increase in maintenance to help inform our finance team to adjust budgets more appropriately.

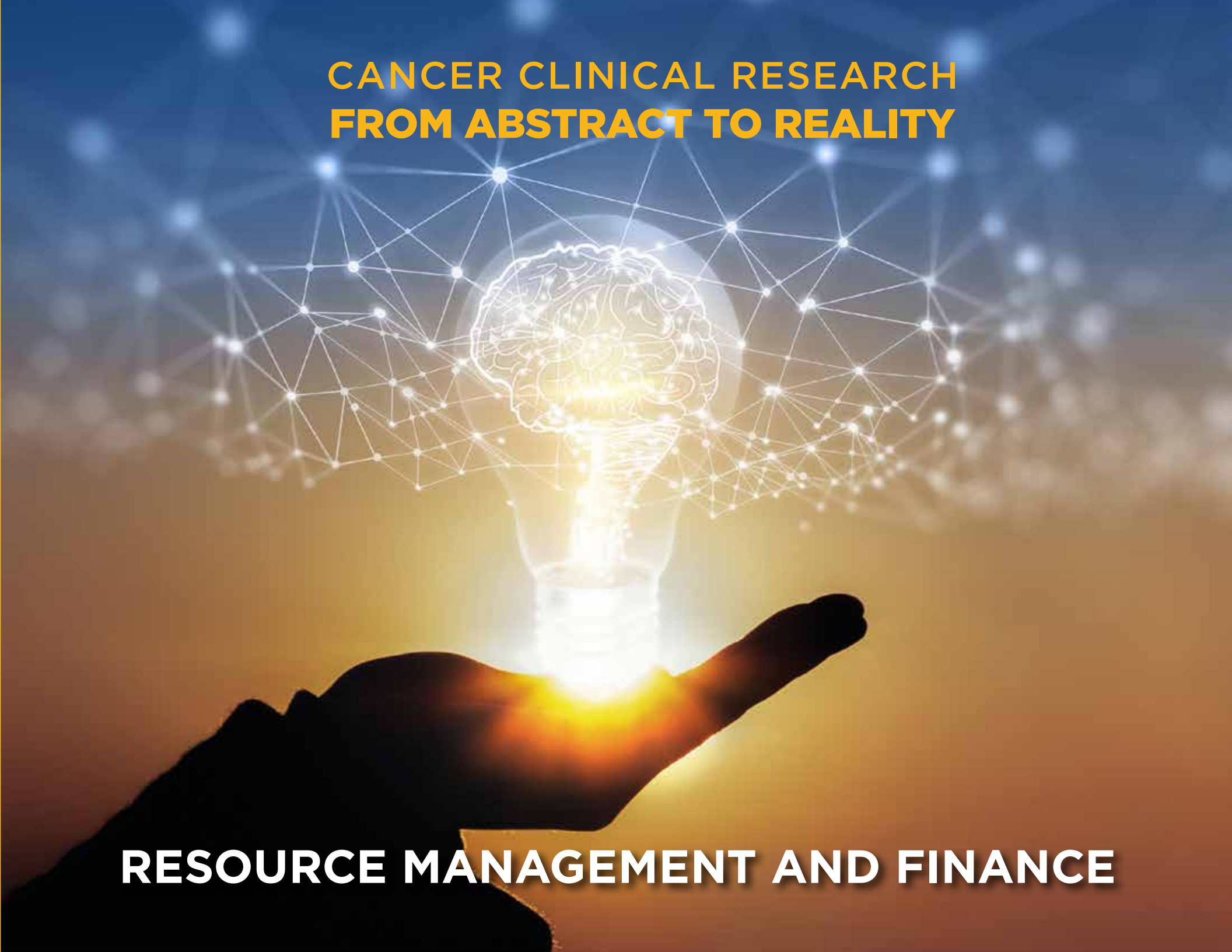
We want to break the studies down further to see if the phase and complexity of the cohorts under the protocol affects the time requirements.

Acknowledgments

Michigan Medicine Oncology Clinical Trials Support Unit SC-Reg for all of their tireless efforts and contributions to Oncology Clinical research studies.

CANCER CLINICAL RESEARCH

FROM ABSTRACT TO REALITY



RESOURCE MANAGEMENT AND FINANCE

Clinical Research Scorecard - Performance Metrics

M. Hendricks
Abramson Cancer Center of the University of Pennsylvania

1. Background

Strategic clinical research management is integral to advancing the science of cancer care and improving clinical outcomes. Often, enrollment to therapeutic studies is the driving metric for signaling productivity and corresponding justification for resource allocation. However, in cancer clinical research, the complexity and acuity of trials continues to increase with innovative advancements. The Abramson Cancer Center (ACC) Clinical Research Unit (CRU) is currently comprised of 12 research teams that support disease/modality/location specific medical oncology/CAR-T cancer programs within the ACC.

2. Goals

- To advance the overall mission of the ACC CRU by driving enrollment, productivity, and quality, while decreasing deviations and operational inefficiencies
- To develop and maintain standardized key performance indicators (KPIs) that link to purpose
- Evaluate metrics, beyond enrollment, to measure performance and productivity transparently, proactively, and objectively
- To provide targeted progress reporting to optimize resource management, justification, and validation of revolutionized staffing models
- In a snapshot, celebrate what is working well and identify opportunities for improvement

3. Solutions and Methods

ACC CRU central and research team leadership identified and uniformly defined KPIs that aligned with our mission, vision, and values. KPIs included enrollments, time to trial activation, time to first enrollment from study activation, reportable deviations, data completion, auditing and monitoring outcomes, pioneering innovative approaches to clinical research operations, stakeholder feedback, and staff attrition. KPI definitions and source of data were defined across research teams. Each resulting KPI was color coded in a stoplight fashion (green, yellow, red).

Data was compiled and measured for quarterly review by each research team's program manager (PM). In a snapshot, PMs assessed for progress, targeted intervention, and strategic planning opportunities. For example, if a program's enrollments were going up, and data submissions rates were going down; or if enrollments and data submission were doing well, but deviations were on the rise, timely and targeted intervention becomes achievable.

4. Outcomes

The research team's scorecard provided transparent objective metrics to support timely review of the team's clinical research portfolio, overall performance, quality, productivity, and staffing. It streamlined data collection and reporting with related justification for resource utilization, staffing, and evaluation of pilot projects (i.e., hybrid remote work) and associated impact on clinical research operations. And it supported identification of opportunities for improvement and intervention.

5. Lessons Learned and Future Directions

- Engagement with PMs, physician investigators, and study team members is essential
- Must provide uniform reporting source for the objective metrics
- Future directions for 2023:
  - Adding a KPI for retention
  - Updating KPI definitions to align with enhanced efficiency post-pandemic

Clinical Research Scorecard- Performance Metrics

Maria Hendricks, MSN, RN – Director Clinical Research Operations
Abramson Cancer Center (ACC) Clinical Research Unit (CRU)
University of Pennsylvania, Philadelphia, PA

BACKGROUND

- Strategic Clinical Research Management is integral to advancing the science of cancer care and improving clinical outcomes.
- Enrollment to therapeutic studies often is the driving metric for signaling productivity and corresponding justification for resource allocation.
- The complexity and acuity of cancer clinical trials continues to increase with innovative advancements.
- The Abramson Cancer Center (ACC) Clinical Research Unit (CRU) is currently comprised of 12 Research Teams (RTs) that support disease/modality/location specific Medical Oncology/CAR-T cancer programs within the ACC.

CLINICAL RESEARCH TEAM SCORECARD

	A	B	C	D	E
1	ACC CRU Example Research Team 2022	Q1 (Jan/Feb/March)	Q2 (Apr, May, June)	Q3 (July/Aug/Sept)	Q4 (Oct/Nov/Dec)
2	**Mission**				
3	Enrollment to Therapeutic Studies	9	10	7	7
4	Total Enrollment	21	30	28	28
5	Time to Trial Activation	165	155	140	130
6	Time to 1st enrollment from study Activation	41	30	29	29
7	**Values- Stewardship**				
8	Studies W/ THOUF Any Enrollments	<5%	<5%	<5%	5%
9	**Values- Quality & Safety**				
10	Reportable Deviations	0	1	0	0
11	Data Completion	94%	96%	95%	95%
12	Audits & Monitoring	Acceptable	Acceptable- Moderate "rating"	Acceptable- Moderate "rating"	Acceptable
13	**Values - Innovation**				
14	Pioneer New Approaches to Clinical Research Operations	ACC CRU Wi	CRN Committee Rep	Spotlight Presentation	CTO Abstract
15	**Values- Accountability**				
16	Stakeholder Feedback	Investigator Feedback	Collaborative Department	Mentor Feedback UPCC 1234	Investigator Feedback
17	**Vision - Engaged Clinical Research Workplace**				
18	Attrition	0	0	0	0

SOLUTIONS/ METHODS

- ACC CRU Central and RT Leadership identified and uniformly defined KPIs that aligned with our Mission, Vision, and Values. Each resulting KPI was color coded in a stoplight fashion (Green, Yellow, Red).
- Data was compiled and measured for quarterly review by each RT's Program Manager (PM).
- In a snapshot, PMs assessed for progress, targeted intervention, and strategic planning opportunities.

OUTCOMES

- Enabled timely identification of opportunities for improvement and intervention.
- Streamlined data and supported justification for resource utilization, staffing, and evaluation of pilot projects (i.e., hybrid remote work) and associated impact on clinical research operations.

GOALS

- To advance the overall mission of the ACC CRU by driving enrollment, productivity, and quality while decreasing deviations and operational inefficiencies.
- To develop and maintain standardized Key Performance Indicators (KPIs) that link to purpose.
- Evaluate metrics, beyond enrollment, to measure performance and productivity transparently, proactively, and objectively.
- To provide targeted progress reporting to optimize resource management, justification, and validation of revolutionized staffing models.
- In a snapshot, celebrate what is working well and identify opportunities for improvement.

KEY PERFORMANCE INDICATORS (KPIs)- DEFINED

	A	B	C	D	E
1	Key Performance Indicator (KPI)	SOURCE/ REPORT	Green	Yellow	Red
2	Therapeutic Enrollments: 3 month average	SBM/DAG	Enrollment @ Target (+/- 20%)	Enrollment (-20%; -30%)	Enrollment (-30%)
3	Total Enrollment: 3 month average	SBM/DAG	Enrollment @ Target (+/- 20%)	Enrollment (-20%; -30%)	Enrollment (-30%)
	Time to activation: average of studies activated in the last 12 months. (Refer to RRS-002 SBM				
4	Work Instruction for definition and corresponding report in OAG	SBM/DAG	Average <= 150 days	Average > 150 days ; < 180 days	Average > 180 days
5	Time to 1st Enrollment from Study Activation: within the last 12 months	SBM/ DAG	< 30 days	>30 days; <90 days	>90 days
	Studies without enrollments: % portfolio studies open to enrollment without any accruals				
6	within the last 6 months, including dose cohort studies	SBM/DAG	<5%	>5%, <10%	>10%
7	Reportable Deviations (current quarter)	Regulatory Tracking Log	None	<2	>2
8	Data Completion: % of studies in portfolio without delinquent data (current quarter)	PM ; Sponsor	100-75%	75-50%	<50%
9	Audits & Monitoring: Internal: OOCM, DOR; External Sponsor GCP; FDA (current quarter)	PM	Acceptable "rating"	Acceptable- Moderate "rating"	Any unacceptable "rating"
	Pioneer New Approaches to Clinical Research Operations. Examples include ACC CRU GO, Wi				
10	Sponsor, Spotlight Presentation, Collaborative Department Projects (current quarter)	PM	Yes, completed	Yes, in draft	No
11	Stakeholder Feedback, including ACC CRU Central - average (current quarter)	PM	Excellent	Making Progress - Moderate	Needs Improvement
12	Attrition (current quarter)	PM	None; staff member <5-2 years	staff member > 2 years; > 15 months	Any staff member <5-15 months

LESSONS LEARNED / FUTURE DIRECTIONS

- Engagement with PMs, Physician Investigators and RT members is essential.
- Must provide uniform reporting source for the objective metrics.
- Plan to add a KPI for retention.
- Plans to update KPI definitions to align with enhanced efficiencies post pandemic.

Special Acknowledgement: ACC CRU: Colleen Redlinger Tabery, Associate Director- Clinical Research Operations and ACC CRU Research Team Program Managers/ Lead Research Nurses, & Physician Leaders

Creation of a Budget Workload Score for Analysis

B. Search, H. Hampton, K. Kaufman, E. Lascu, B. Zakrzewski
Memorial Sloan Kettering Cancer Center

1. Background

Memorial Sloan Kettering Cancer Center's (MSKCC) Clinical Research Finance, Budget Analysis unit is responsible for centralized budget development for new, amended, and feasibility studies. An in-house developed clinical research application, the Budget and Contracts Management System (BCMS), tracks action and status dates of the budget development process. Complexity for these budgets can range based on factors including budget type, protocol type, protocol category, number of treatment arms, company budget, and amendment categories. These variables are tracked across different clinical research applications. Budget work should be distributed to budget analysts evenly based on the complexity of that budget and that analysts' work capacity.

2. Goals

To develop a budget workload score (BWS) to be associated to each budget. This BWS will allow managers to distribute work accordingly, and to develop detailed reporting to continuously monitor budget work completion and pending work items.

3. Solutions and Methods

The Clinical Research Finance team reviewed and identified variables that would be included in the budget workload formula to calculate the BWS. The developed BWS score has a scale of 0 to 10.

Letter of intents (LOIs) are assigned a score of 3.5. Five variables are used to calculate the BWS for new protocol budgets: protocol type, internal budget status, protocol category, company budget status, and number of treatment arms. These variables were sourced within clinical research applications. All other variables are sourced from BCMS. The complexity of the elements within each variable are assigned a score ranging from 0.0 - 1.0, multiplied together, and then multiplied by 10 to calculate the BWS.

Within BCMS, amendments can have one or many categories. These categories range from treatment arms being added (score = 10) to addition of central labs (score = 1). For amendments with multiple categories, the highest score category is declared as the BWS.

Tableau is utilized to blend our data across applications with different database types. Multiple visualizations have been created from the Tableau data source, allowing managers to identify workloads across sponsoring departments, budget analysts, and budget managers.

4. Outcomes

The below Tableau visualization shows one example of data reporting capabilities. We went live with the first reports from the BWS on 3/11/2022. Budget managers have since used this dataset to reassess workload for their staff, and to assign new budget development projects. At the click of a button, budget managers can identify members of the team that have or do not have bandwidth and reassign work accordingly. Managers are also able to view work completed vs. work in progress, in addition to total work for a given period. BWS may be utilized to create benchmarks for progress during onboarding of new budget analysts.

5. Lessons Learned and Future Directions

We will continue to refine the BWS with input from the Clinical Research Finance team and their staff's assessment of the BWS matching to the observed complexity of the budgets they are developing. The count of studies in a budget analyst's queue is not representative of workload due to the complexity of individual studies. The BWS allows mangers to take both the number of budgets and workload score into account when assigning work.

Creation of a Budget Workload Score for Analysis

Memorial Sloan Kettering Cancer Center

Benjamin Search, MPH, Holly Hampton, Kristopher Kaufman, MS, Elena Lascu, MA, Barry Zakrzewski, MS

Background

- Our institution has centralized budget development for new, amended, and feasibility studies within the Clinical Research Finance (CRF) unit.
- Complexity of the budget development is based on many factors.
- The team's leadership wanted to ensure that budget work is distributed to Budget Analysts evenly based on the complexity of each budget assigned and an analyst's current workload capacity.

Goals and Methods

- A budget workload score (BWS) formula was developed to allow managers to distribute work equitably and to develop detailed reporting to continuously monitor budget work completion and pending work items.
- We developed a formula to calculate scores on a 10-point scale per budget, leveraging data from multiple applications. The New Protocol budget type multiplies these 5 inputs together and then standardizes to a 10-point scale

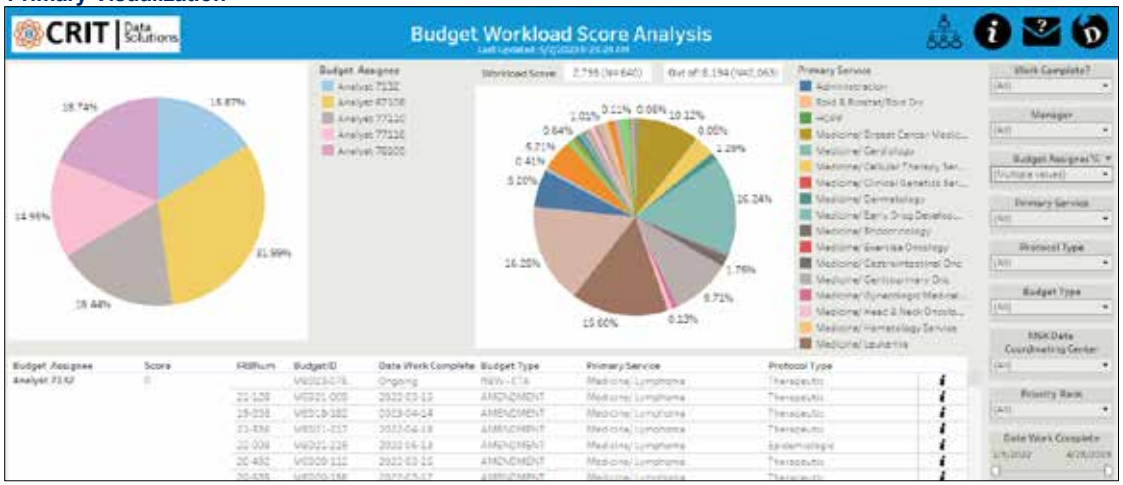
Systems and Data Sources

- An in-house developed clinical research application, the Budget and Contracts Management System (BCMS), tracks budget types as well as action and status dates of the budget development process.
- An in-house developed clinical research application, the Protocol Information Management System (PIMS), manages all steps involved with the regulatory protocol life cycle.
- A vendor product, OnCore by Advarra, is our Clinical Trials Management System (CTMS) for subject tracking and financial management.
- A project management software, Smartsheet, is used by the CRF unit to assign a Budget Analyst to a Budget Manager.

Calculation

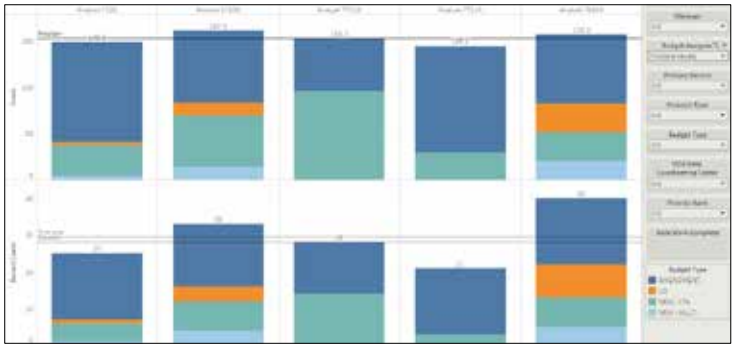
Budget Type	Factors	Data Source
Letter of Intent	Standard 3.5 / 10 score	BCMS
Protocol Amendment	Amendment Category	BCMS
New Protocol	Protocol Type	PIMS
	Protocol Category	PIMS
	Treatment Arm Count	CTMS
	Internal Budget Status	BCMS
	Company Budget Status	BCMS

Primary Visualization



Features

- Managers can review completed work vs. work in progress (WIP).
- Pie chart (L) allows managers to review distribution of work across staff.
- Pie chart (R) allows managers to see a service's volume as a percentage of the institution's total portfolio.
- When service portfolios need to be redistributed, managers can select multiple services in the right graph and the viz will recalculate to show who is currently assigned and what the new combined score would be.
- Budget level details are also provided the bottom portion of the dashboard.



Outcomes and Future Direction

- Complex reporting can be created to manage staff workload. The bar graph presented to the left shows how a manager can assess the current WIP portfolio across analysts to assign incoming budgets.
- The BWS may be utilized to create benchmarks for progress during onboarding of new staff.
- Continuous refinement of the BWS logic, taking into consideration additional criteria as our source systems are enhanced and as we receive feedback from the budget team regarding accuracy and precision of the calculations.

Automation of Clinical Research Administrative Fees for Internal Recovery

B. Search, J. Chen, K. Kaufman, L. Lupkin, J. Yan
Memorial Sloan Kettering Cancer Center

1. Background

Memorial Sloan Kettering's (MSK) Clinical Research program has administrative fees that are recovered internally to support department funds. These fees are typically a component of the budget agreements with the study sponsor(s). There are unique business rules to determine when to apply each fee. The data needed to make these determinations are sourced across applications. The original manual process required significant staff time and effort to access, blend, clean, do quality assurance, and upload the data to our financial systems. Therefore, these fees were typically only recovered on a quarterly basis, and in some scenarios, annually. The delayed recovery often led to additional work to resolve.

2. Goals

Our goal is to automate the internal recovery for all administrative fees in real time. Our secondary goal is to implement a simple reconciliation method for any data quality issues. We chose to implement 24 fees as a subset before expanding.

3. Solutions and Methods

We developed pipelines within our Clinical Research Data Warehouse (CRDW) to stage data across applications, which allows for complex blending of the required data. The initial applications included were our Clinical Trials Management System (CTMS), OnCore by Advarra, and our Protocol Information Management System (PIMS), an in-house developed application. These two applications provide details of subject registrations, protocol rate bases, cost center and funds, and protocol life cycle actions. We created new CRDW tables to record annual pricing of each fee, data errors preventing fee generation, specific protocol exceptions, and the finalized output. The process runs daily at ~1:00 am and stages the data meeting the initial business rules from the last 30 days. CTMS is cross-referenced for the protocol's rate base to calculate the pricing, if applicable. The CC/Fund is then applied from CTMS, and if that fee has not already been written to the final table, the fee is committed. We collaborated with the TIPS development team to access the finalized output table to ingest into their application.

4. Outcomes

The last successful manual upload, for Q4 2022, included 650 events. The average service to upload date was 400.11 days (median: 410). Even after the delay to ensure data quality, 10 more were missing data, and 97 more were rejected due to closed or inactive funds.

In January, we automated 565 events recorded in PIMS, with an average service to upload date of 3.81 days (median: 1). In addition, 3,478 subject tracking events in CTMS were captured (services between 10/1/22 and 1/31/2023).

The manual process of cleaning and uploading the PIMS events accounts for 25 staffing hours each quarter. Additionally, the management of rejected fees within TIPS is an ongoing process, accounting for over 30 hours each year. This automation should significantly reduce the impact of these rejected fees.

5. Lessons Learned and Future Directions

We plan on analyzing if automated fees are rejected due to hitting closed funds, which should no longer be an issue due to the tighter turnaround time. Business owner buy-in for logic definitions is paramount in this development process. We are expanding our set of business cases to automate the internal recovery for as many fees as feasible.

Automation of Clinical Research Administrative Fees for Internal Recovery

Memorial Sloan Kettering Cancer Center

Benjamin Search, MPH, Jennifer Chen, MBA, Kristopher Kaufman, MS, Lawrence Lupkin, MPA, Jun Yan, MS

Background

- Our institution's Clinical Research program utilizes administrative fees for internal recovery to support department funds.
- These fees are typically a component of the budget agreements with the study sponsor(s).
- There are unique business rules to determine when to apply each fee based on data sourced from multiple applications.
- The original manual process required significant staff time and effort to access, blend, clean, do quality assurance, and upload the data to our financial systems (TIPS), which is managed by another department.
- These fees were typically only recovered on a quarterly basis, and in some scenarios annually. The delayed recovery often led to additional work to resolve.
- 24 fees were selected for the initial implementation due to familiarity with the logic and accessibility of the data.

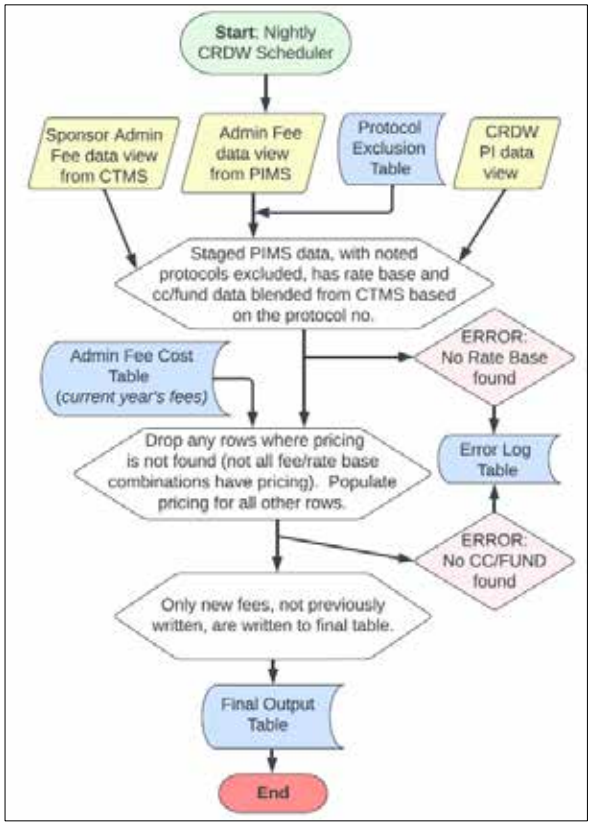
Goals

- Our primary goal was to automate the internal recovery for all administrative fees in real time.
- The secondary goal was to implement a simple reconciliation method for any data quality issues.

Fees for Internal Units

Internal Unit	Fee Type Count
Clinical Research Compliance	1
Department Protocol Development and Planning	1
Developmental Therapeutic Unit	3
Human Research Protection Program	9
Medicare Coverage Analysis	1
Pharmacy Administration	3
Protocol Activation Core	3
Regulatory Oversight and Product Development	3

Methodology



- Our Clinical Research Data Warehouse (CRDW) has pipelines to stage data from multiple applications, allowing for data blending. This allows us to write complex SQL to incorporate business logic into views on top of the data from the source systems.

Methodology (continued)

- Tables were created in CRDW to facilitate additional transformation and logging of annual pricing of each fee type (1), data errors preventing fee generation (2), specific protocol exceptions (3), and the final output recovery records (4).
- The process runs daily ~1am. TIPS ingests new data incrementally from this table each morning. TIPS will then run additional processes to recover the money to the applicable fund.

Systems / Data Sources

- An in-house developed clinical research application, the Protocol Information Management System (PIMS), manages all steps involved with the protocol life cycle.
- A vendor product, OnCore by Advarra, is our Clinical Trials Management System (CTMS) for subject tracking and financial management. This includes protocol specific rate bases and financial cost center / fund numbers (CC/Fund).

Pre and Post Assessment *(Average Days)*

Timeframe	Date of Service to TIPS Upload	Date of TIPS Upload to Processing	Count
2020-2022	158.49	19.57	19,064
2023	6.19	12.47	2,961

- Example: The last manual upload sample, of 2022 annual fees, consisted of 757 fee records. Of those, 10 fees were excluded due to missing data, and an additional 97 were rejected because they hit closed or inactive funds. This accounted for 14% of the sample, providing an example of the degree of manual reconciliation still required.

Time and Effort Savings

- The manual process of cleaning and uploading the PIMS events accounts for **100 staff hours each year**.
- Additionally, the management of rejected fees within TIPS is an ongoing process, accounting for over **30 staff hours each year** (not including study team time and effort). The expectation is that the automation will significantly reduce the impact of these rejected fees.

Lessons Learned and Next Steps

- Business owner buy-in for logic definitions is paramount in this development process.
- Prove our hypothesis that rejected fees will be significantly reduced due to more real time processing.
- Continue to expand the fees associated with internal recovery that are automated.

Fostering Portfolio Stewardship Through a Trial Portfolio Balancing Framework

J. Lebsack, H. Soliman
Moffitt Cancer Center

1. Background

In 2022, Moffitt's Clinical Trials Office (CTO) leadership recognized disease-based programs (DPBs) and their respective clinical research medical directors (CRMDs) were facing challenges with respect to trial portfolio management and maintaining appropriate CTO resource utilization. In response, the center began work on a new initiative to improve DPB/CRMD trial portfolio stewardship, clinical research alignment with institutional goals, and utilization of available resources within the CTO.

2. Goals

1. Establish a new framework for maintaining trial portfolio balance at both the disease-program and enterprise levels

2. Implement new tools and training to aid CRMDs and CTO leadership optimize trial portfolio management

3. Solutions and Methods

Utilizing National Comprehensive Cancer Network (NCCN) survey data, National Cancer Institute (NCI) Cancer Center Support Grant (CCSG) guidance, and Moffitt strategic priorities, essential elements for portfolio balance were established. Based on these essential elements, Moffitt established a portfolio framework that includes four dimensions: (1) trial mix by phase, (2) trial mix by sponsor type, (3) Moffitt scientific leadership role, and (4) financial sustainability (see Figure). Physician leaders critically reviewed the framework and support for this framework was received by stakeholders and center leadership. CRMDs and CTO leaders received a report comparing the current state for each DBP to the portfolio framework guidance during a collaborative retreat. This retreat included education regarding portfolio stewardship, clinical trials financial metrics, and a session on leadership skills (led by Moffitt's Organizational Development Team). Feedback from this session was extremely positive, with a request by CRMDs to hold recurring future collaborative retreats. Following the retreat, a CRMD Resource Guide was developed for current and future CRMDs.

4. Outcomes

All 16 DBPs are actively using the framework to manage their trial portfolios. Adjustments have been made to bring DBP portfolios closer in line with the framework guidance. In addition, the development of this framework has prompted each program to create portfolio dashboards, which are used at program meetings to review portfolio performance and guide portfolio decisions. DBPs now have access to potential subject revenue data, and this is now informing portfolio balancing while providing transparency regarding financial sustainability of the DBPs' clinical research programs. With this information now in one place, several DBPs have initiated creative trial recruitment strategies targeted at both internal and external referral sources to address trial accrual deficiencies. Finally, this framework has provided a platform for forecasting accrual and clinical trial revenue goals for the coming year in a way not previously possible.

5. Lessons Learned and Future Directions

Development and sharing of a trial portfolio framework improved the stewardship of our clinical trial enterprise by providing clinical research leaders with enhanced tools to better understand portfolio performance, alignment with strategic goals, and clinical research financial sustainability.

Moving forward, the tools will be further refined and automated to improve their accessibility to DPBs and CRMDs. Moffitt will use this framework to inform how the institution scales up growth of our clinical trial infrastructure and position us for clinical research excellence in the years to come.

Citation
1. NCCN. "NCCN Best Practices Committee Report on the 2020 NCCN Clinical Research Benchmarking Survey", December 2020.

Fostering Portfolio Stewardship through a Trial Portfolio Balancing Framework

Jay Lebsack MA, Hatem Soliman MD

MOFFITT CANCER CENTER

Background

Disease-based programs (DBPs) and their respective clinical research medical directors (CRMDs) were facing challenges with respect to trial portfolio management and maintaining appropriate CTO resource utilization.

Goals

(1) Establish a new framework for maintaining trial portfolio balance at both the disease-program and enterprise levels

(2) Implement new tools and training to aid CRMDs and CTO leadership optimize trial portfolio management

Methods

Retreat (Dec '22) with CRMDs and CTO Leaders

Agenda

- Strategic Alignment Session by Research Sr Executives
- Portfolio Stewardship Educational Session
- Clinical Trials Finance Primer
- Leadership Skills Session (Leading thru Influence) (Led by Organizational Development Office)

Trial Portfolio Balance Essential Elements

Trial Portfolio Framework

DBPs are asked to align portfolio to these four dimensions, noting where factors are not practical or appropriate for the DBP (ex: Bone Marrow Transplant portfolio will have a larger mix of Cooperative Trials)

CT REV = Clinical Trial Revenue

Refinements and Next Steps

Clinical Research Medical Director Guide v.1

Reference guide developed for current and new CRMDs (and Chairs and CTO Administrative Leaders) to provide clarify on roles & responsibilities and portfolio stewardship principles.

360 Portfolio & Ops Dashboard

GI Program developed a dashboard to manage to portfolio framework. GI Shared w/ other DBPs & tool/ format refined & was adopted across all DBPs

References

NCCN. "NCCN Best Practices Committee Report on the 2020 NCCN Clinical Research Benchmarking Survey", December 2020.

Development of an Enhanced Clinical Trial Workload Assessment Tool – The BC Clinical Trial Complexity Tool

M. Sadiq, S. Sundquist, D. Kato, R. Xu, D. Curman, P. Pollock, K. Sit, K. Halvorsen, J. Clark, M. Abacan, C. Kollmannsberger, B. Eigl

BC Cancer

1. Background

The complexity of cancer clinical trials and the associated workload has significantly increased over time, requiring more research personnel to perform study-related activities. This situation poses human resource challenges for Clinical Research Unit (CRU) leaders to overcome. BC Cancer comprises six regional centers, each with a CRU, that combined, conduct approximately 400 clinical trials of varying complexity, accruing over 800 patients per year. CRU managers do not have validated tools to evaluate the workload and staffing resources required for any given trial, therefore, allocations are made subjectively. A tool that can proactively evaluate, quantify, and document the expected work required to execute a clinical trial effectively would be invaluable to clinical trial sites to determinate appropriate staffing levels and allocations.

2. Goals

The objective of this project was to develop an enhanced workload assessment tool that can reliably evaluate and predict staff workload based on measures of individual trial complexity, enable proper distribution of workload, and be reproducible across clinical trial sites.

3. Solutions and Methods

Clinical research stakeholders who had significant knowledge of this topic were initially engaged. A comprehensive literature review was carried out which confirmed the need for an improved tool to capture clinical trial workload. An online survey was distributed to clinical trial managers across Canada through the Canadian Cancer Clinical Trials Network (3CTN) to understand their current practices for staff workload assessment and gauge their interest in using an enhanced tool.

Prior validated assessment tools, such as IRST Workload Assessment Tool (IWAT), Ontario Protocol Assessment Level (OPAL), 3CTN Academic Cancer Trial Portfolio Complexity Tool, and the National Cancer Institute (NCI)Trial Complexity and Elements Scoring Model, were analyzed for strengths and weaknesses and incorporated into the development of an enhanced tool.

4. Outcomes

Literature review revealed that current workload assessment tools were focused on specific elements or created for another effort and fell short of adequately capturing trial-associated workload. The online survey revealed only 21 percent of CRU managers currently use a tool to measure trial associated workload and 73 percent of CRU managers considered adopting a tool a high-priority need.

Findings from literature, established tools, survey results, and work experience were integrated to develop the BC Clinical Trial Complexity Tool (BC-CT2) in 2022. The BC-CT2 allows for objective measurements of protocol-specific and activity-specific complexity associated with the trial patient caseload. This tool is designed to focus on protocol complexity, administrative workload, data, and patient-related procedures. Trials are assigned low-, medium-, and high-complexity protocol scores and maximum workload capacity scores. The tool is simple and easy to use and allows for electronic completion and auto-calculation of scoring.

5. Lessons Learned and Future Directions

With the increasing complexity of clinical trials, a workload assessment tool was identified as a high-priority need. We attempt to resolve this issue by creating an objective workload assessment tool that is simple and easy to use.

Next steps involve validating the tool by evaluating clinical trial workload across the six BC Cancer CRUs as well as a retrospective comparison of BC-CT2 against other tools, such as OPAL, to determine accuracy in measuring trial workload.

Development of an Enhanced Clinical Trial Workload Assessment Tool – The BC Clinical Trial Complexity Tool

Manahil Sadiq[1,2], Darko Curman[1], Stephen Sundquist[3], Diana Kato[3], Rebecca Xu[3], Phil Pollock[1], Kitty Sit[1], Kelly Halvorsen[1], June Clark[1], Maria Abacan[1], Dr. Christian Kollmannsberger[1], Dr. Bernhard J. Eigl[1]

[1] BC Cancer, British Columbia, Canada, [2] University of British Columbia, British Columbia, Canada, [3] Canadian Cancer Clinical Trials Network (3CTN), Ontario, Canada

Background

The complexity of cancer clinical trials and the associated workload has significantly increased over time, requiring more research personnel to perform study-related activities. This situation poses human resource challenges for Clinical Research Unit (CRU) leaders to overcome. BC Cancer comprises of six regional centers, each with a CRU, that combined conduct approximately 400 clinical trials of varying complexity, accruing over 800 patients per year. CRU managers do not have validated tools to evaluate the workload and staffing resources required for any given trial, therefore, allocations are made subjectively. A tool that can proactively evaluate, quantify, and document the expected work required to execute a clinical trial effectively would be invaluable to clinical trial sites to determine appropriate staffing levels and allocations.

Goals

The key objectives of this project were to develop an enhanced workload assessment tool that:

- Allowed for objective measures of staff workload based on the complexity of clinical trials and patient load.
- Enabled proper distribution of staff workload and ability to redistribute or reallocate trials.
- Is simple to use while also being dynamic and reproducible across cancer centers.

Methods

Clinical research stakeholders who had significant knowledge of this topic were initially engaged. A comprehensive literature review was carried out which confirmed the need for an improved tool to capture clinical trial workload. An online survey was distributed to clinical trial managers across Canada through the Canadian Cancer Clinical Trials Network (3CTN) to understand their current practices for staff workload assessment and gauge their interest in using an enhanced tool. Prior validated assessment tools, such as IRST Workload Assessment Tool (IWAT), Ontario Protocol Assessment Level (OPAL), 3CTN Academic Cancer Trial Portfolio Complexity Tool, and the NCI Trial Complexity and Elements Scoring Model, were analyzed for strengths and weaknesses and incorporated into the development of an enhanced tool.

Outcomes

Literature review revealed that current workload assessment tools were focused on specific elements or created for another effort and fell short of adequately capturing trial-associated workload. The online survey revealed only 21 percent of CRU managers currently use a tool to measure trial associated workload and 73 percent of CRU managers considered adopting a tool as a high-priority need. Findings from literature, established tools, survey results, and work experience were integrated to develop the BC Clinical Trial Complexity Tool (BC-CT^2) in 2022 (Figure 1). The BC-CT^2 allows for objective measurements of protocol-specific and activity-specific complexity associated with the trial patient caseload. This tool is designed to focus on protocol complexity, administrative workload, data, and patient-related procedures. Trials are assigned low-, medium-, and high-complexity protocol scores and maximum workload capacity scores. The tool is simple and easy to use and allows for electronic completion and auto-calculation of scoring.

Figure 1. The BC Clinical Trial Complexity Tool Interface

Future Directions

With the increasing complexity of clinical trials, a workload assessment tool was identified as a high-priority need. We attempt to resolve this issue by creating an objective workload assessment tool that is simple and easy to use. Next steps involve validating the tool by evaluating clinical trial workload across the six BC Cancer CRUs as well as a retrospective comparison of BC-CT2 against other tools, such as OPAL, to determine accuracy in measuring trial workload.

Contact

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"Will They Pay?" Let's Find Out First! Saving Time and Money in Industry-Trial Activation

E. Lebleu, S. Ford, L. Hayes, J. Moehle, H. Soares
Huntsman Cancer Institute at the University of Utah

1. Background

As the number of trials offered to cancer centers is constant, vetting and selection of clinical trials by sites becomes increasingly important. The activation process can be costly from the moment solicitation begins, as compared with the sites' operational budgets. Trial sites have limited funding as compared to sponsors and contract research organizations (CROs). Because of this, the financial consequences associated with incomplete or failed startup are likely much more impactful to sites than to sponsors. If a trial is not successful in getting through activation and achieving a signed contract, it ends in a financial loss for the effort expended. Historically, the feasibility team would do a quick review of the budget to identify any red flags. However, many trials moved forward with activation, incurring significant costs, only to be abandoned once we realized the sponsor would not cover our site fees. These trials often had over six months of budget negotiation time before failing, which negatively impacted activation timelines.

2. Goals

Our goal was to identify significant barriers to a successful budget negotiation, address them at an earlier time in the study lifecycle, and decrease loss incurred by trials that had a high likelihood of failure before activation.

3. Solutions and Methods

The clinical trials office finance team identified non-negotiable fees (i.e., items that if not agreed to "as-is" would ultimately lead to start-up abandonment) as frequent sticking points. They developed a standard listing of these fees and provided them to sponsors ahead of our internal feasibility committee approval. If the sponsor was unable to agree to them, the Feasibility and Administrative Review committee (FAR) would not schedule the study for review as it was strong indication budget negotiations would fail. At this point, the principal investigator would be engaged if a path forward with the sponsor could not be achieved the FAR committee would decline trial activation saving significant effort and resources.

4. Outcomes

- The finance team developed a standard, non-negotiable fee sheet
- Activation administrator sends site fees as early as possible for new sponsors that we have not worked with before
- Studies are not approved by FAR until the non-negotiable fees have sponsor approval
- If the sponsor cannot agree to the fees, the FAR committee deems the trial not feasible, and the trial is declined
- Saved significant start-up effort on at least five trials since implementing this process in July 2022

5. Lessons Learned and Future Directions

We are encouraged by the time and effort saved by our new process. However, further improvements are being made. Additionally, there are some points to be aware of when implementing this. Firstly, because sponsors are unfamiliar with a process like this, it is important to clearly communicate your site's process and expectations. For instance, we let the sponsor know that the fees are not negotiable and that our FAR committee requires approval before proceeding with any other activity. Secondly, we have found that for us the earlier we begin the fee discussion the more time we can save. We are moving towards implementing fee discussions as early as site selection

"Will They Pay?" Let's Find Out First! : Saving Time and Money in Industry-Trial Activation

Emerson Lebleu MS, Shanna Ford, MHA, Laura Hayes, CCRC, Jessica Moehle, CCRP, Heloisa Soares, MD, PhD

BACKGROUND

As the number of trials offered to cancer centers is constant, vetting and selection of clinical trials by sites becomes increasingly important. The activation process can be costly from the moment solicitation begins, as compared with the sites' operational budget. Trial sites have limited funding as compared to sponsors and CROs. Because of this, the financial consequences associated with incomplete or failed startup are likely much more impactful to sites than to sponsors. If a trial is not successful in getting through activation and achieving a signed contract, it end in a financial loss for the effort expended. Historically, the feasibility team would do a quick review of the budget to identify any red flags. However, many trials moved forward with activation, incurring significant costs, only to be abandoned once we realized the sponsor would not cover our site fees. These trials often had over 6 months of budget negotiation time before failing which negatively impacted activation timelines.

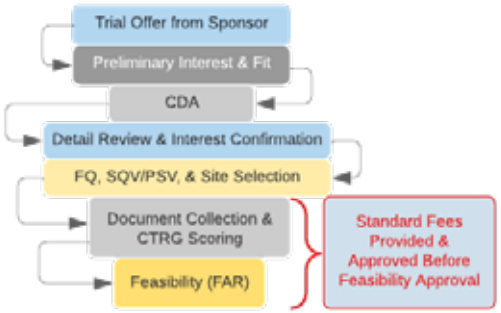
GOALS

- Our goal was to identify significant barriers to a successful budget negotiation, address them at an earlier time in the study lifecycle, and decrease loss incurred by trial that had a high likelihood of failure before activation.

SOLUTIONS AND METHODS

The CTO finance team identified non-negotiable fees (i.e., items that if not agreed to "as-is" would ultimately lead to startup abandonment) as frequent sticking points. They developed a standard listing of these fees and provided them to sponsors ahead of our internal feasibility committee approval (*see Figure 1*). If the sponsor was unable to agree to them, the Feasibility and Administrative Review committee (FAR) committee would not schedule the study for review as it was strong indication budget negotiations would fail. At this point, the PI would be engaged if a path forward with the sponsor could not be achieved the FAR committee would decline trial activation saving significant effort and resources.

Figure 1



OUTCOMES

- The finance team developed a standard, non-negotiable fee sheet.
- Activation Administrator sends site fees as early as possible for new sponsors that we have not worked with before.
- Studies are not approved by FAR until the non-negotiable fees have sponsor approval.
- If the sponsor cannot agree to the fees, the FAR committee deems the trial not feasible, and the trial is declined.
- Saved significant startup effort on at least five trials since implementing this process in July 2022

FUTURE PLANS

We are encouraged by the time and effort saved by our new process. However, further improvements are being made. Additionally, there are some points to be aware of when implementing this. Firstly, because sponsors are unfamiliar with a process like this, it is important to clearly communicate your site's process and expectations. For instance, we let the sponsor know that the fees are not negotiable and that our FAR committee requires approval before proceeding with any other activity. Secondly, we have found that for us the earlier we begin the fee discussion the more time we can save. We are moving towards implementing fee discussions as early as site selection.

UNIVERSITY OF UTAH HUNTSMAN CANCER INSTITUTE

HEALTH UNIVERSITY OF UTAH

Leveraging Automation to Increase Time Savings for Processing Research Non-Billables (RNBs)

S. Siamwalla, R. Panchal, M. Buckley, J. Lengfellner
Memorial Sloan Kettering Cancer Center

1. Background

Memorial Sloan Kettering Cancer Center (MSK) uses its Clinical Trials Management System (CTMS) to manage protocol information and study budgets but relies on an additional system known as Application for Research Charges (ARC) to process RNB information. Both systems require the same input of data to carry out their independent functions, just at different time points. This resulted in hours of repetitive manual data entry by the budgets team, ultimately prolonging the processing of RNBs and introducing risk into the accuracy of the data entered.

2. Goals

For this two-phase initiative, the elimination of double data entry was prioritized by leveraging CTMS as a primary source and pulling its data into a view for automatic injection into ARC. Since the successful go-live of Phase I for new protocols on October 17, 2022, Phase II is currently targeted to automate manual data entry tasks for protocol and budget amendments. The goals of both phases are the same: to improve data quality, reduce errors from manual data entry, increase time savings, and streamline productivity for budget staff.

3. Solutions and Methods

The approach in addressing the challenges above was multifold:

- The triggers: there are three sign-off points within CTMS that indicate when a protocol is ready to have data injected into ARC
- The data view: a view picks up the data when the triggers are entered and makes it available for the injection into ARC
- The injection: a new worksheet is created within ARC based on four integrated fields taken from CTMS: funding source category, budget date, current cost center number and fund number, and the service code; from these four fields, the rate bases are automatically calculated for each RNB procedure within the protocol
- The exceptions report: for every procedure entered on a new protocol, a Tableau dashboard captures the studies with RNBs and assigns it a status according to the integration

The go-live schedule was divided into three different parts for Phase I, each time adding on more services than the previous.

4. Outcomes

Each study pushed from CTMS to ARC saves 45 minutes in manual work for the budgets team and 30 minutes for the study team. Since the first go-live, a total of 116 have been published, amounting to a total of 5,220 minutes for the budgets team and 3,480 minutes for the study team in time savings. In addition, the integration has made an impact from a compliance perspective since the previous process caused errors due to manual data entry.

5. Lessons Learned and Future Directions

We have learned that eliminating steps for manual data entry has benefits that supplement the expected process improvements, such as opening a gateway for future integrations. With the data view, triggers, and mapping created in Phase I of the integration, we have a robust foundation now to introduce amendments within the automated process for Phase II. By Quarter 3 2023, we expect to be live with both phases of the integration and entirely reliant on CTMS as a single point of data entry.

Leveraging Automation to Increase Time Savings for Processing RNBs

Memorial Sloan Kettering Cancer Center

Saif Siamwalla, Renata Panchal, Michael Buckley, Joseph Lengfellner
Memorial Sloan Kettering Cancer Center

Background

MSK uses its Clinical Trials Management System (CTMS) to manage protocol information and study budgets, but relies on an additional system known as Application for Research Charges (ARC) to process and reconcile Research Non-Billable (RNB) information. Both systems require RNB data to be inputted in order to carry out their independent functions, just at different time points. Traditionally, this would require hours of repetitive manual data entry by the budgets team, who would type every single RNB procedure into both CTMS and ARC. Along with prolonging the time in which RNBs would be processed, this method also introduced significant risk of data entry error.

Goals

For this two-phase initiative, the elimination of double data entry was prioritized by leveraging CTMS as a primary source and pulling its data into a view for automatic injection into ARC. Since the successful go-live of Phase I for new protocols on October 17, 2022, Phase II is currently targeted to automate manual data entry tasks for protocol and budget amendments. The goals of both phases are the same:

- to improve data quality
- reduce errors from manual data entry
- increase time savings
- streamline productivity for budget staff

Solutions and Methods

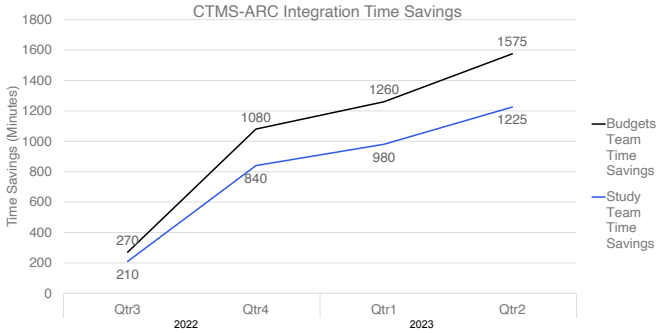
The approach in addressing the challenges above was multifold:

- The triggers: There are three sign-off points within CTMS that indicate when a protocol is ready to have data injected into ARC.
- The data view: A view picks up the data when the triggers are entered and makes it available for the injection into ARC.
- The injection: A new worksheet is created within ARC based on four integrated fields taken from CTMS: funding source category, budget date, current cost center number and fund number, and the service code. From these four fields, the rate bases are automatically calculated for each RNB procedure within the protocol.
- The exceptions report: For every procedure entered on a new protocol, a Tableau dashboard captures the studies with RNBs and assigns it a status according to the integration.

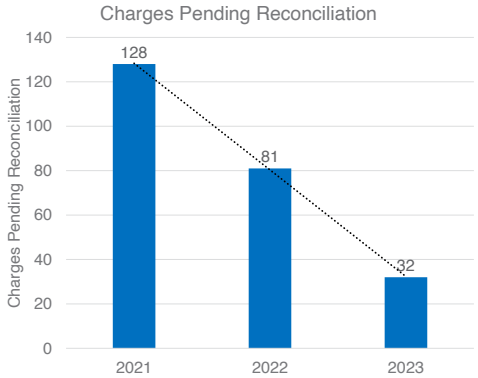
Results

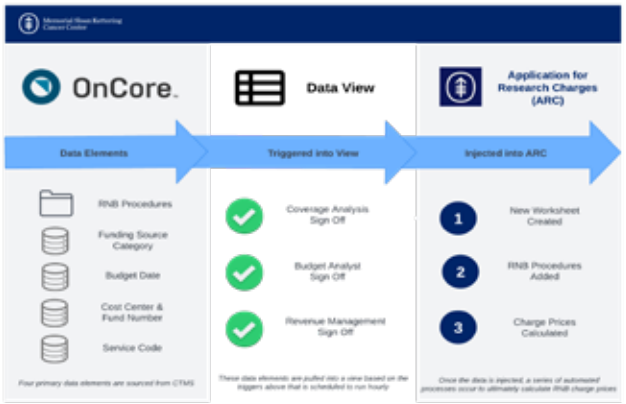
Each study pushed from CTMS to ARC saves 45 minutes in manual work for the budgets team and 30 minutes for the study team. Since the first go-live, a total of 119 studies have been published, amounting to a total of 5,310 minutes for the budgets team and 4,130 minutes for the study team in time savings. In addition, the integration has made an impact from a compliance perspective, since the previous process caused errors due to manual data entry.

Total of 9,440 minutes or 157 hours in time savings for both the budgets and study teams



The total charges that were pending reconciliation reduced following the integration. This indicated that a fewer number of studies required reconciliation due to fewer data entry errors. By selecting a monthly time frame and analyzing the change in charges pending reconciliation, charges requiring reconciliation reduced in line with the implementation of the integration, highlighting that the integration reduced manual data errors.





Future Directions

We have learned that eliminating steps for manual data entry has benefits that supplement the expected process improvements, such as opening a gateway for future integrations. With the data view, triggers, and mapping created in Phase I of the integration, we have a robust foundation now to introduce amendments within the automated process for Phase II. By Q3 2023, we expect to be live with both phases of the integration and entirely reliant on CTMS as a single point of data entry for both new protocols and amendments. Ultimately, this would increase time savings for both the budgets and study teams, as well as simultaneously increase data accuracy and reduce manual data entry errors by fully automating the injection of ARC data based on a triggers within CTMS. Phase II of the integration will include the following components based on budget amendments:

- Adding new RNBs
- Removing previously submitted RNBs
- Updating incorrectly entered service codes
- Updating missing professional charges

Development of a Clinical Research Coordinator Capacity Model

J. Johnson, M. Ugrenovic-Petrovic, E. Royster, B. Jones-Lombard, B. Mack, A. Patel, I. Krupitsky, K. Hulse, J. Lebsack
Moffitt Cancer Center

1. Background

Given the complexity of the clinical research coordinator (CRC) role it is essential to determine a sustainable workload and forecast the number of full-time equivalent employees (FTEs) needed to support clinical research. Currently, in Moffitt Cancer Center's Clinical Trials Office (CTO) team managers have utilized the Clinical Research Effort Study Tool (CREST) (Feb 22, 2016, Onsemble, 2016, Turner) which was derived from the OPAL (Journal of Oncology Practice, 2011, Smuck et al.) to measure CRC activity by measuring protocol complexity. We reviewed literature on previous work such as the Clinical Research Coordinator Workload Estimation and Tracking tool by M. Repede, AACI 2022 abstract.

2. Goals

We sought to design a CRC workload capacity model that is efficient, effective and captures the time it takes a CRC to complete operational tasks at Moffitt. Secondly, the tool will support operational managers' decisions in projecting FTEs needed to coordinate active trials in the portfolio and trials in activation pipeline.

3. Solutions and Methods

Thirty CRCs used an "effort diary" for eight weeks and noted how long it took to complete activities on each study. The diary included the study and subject ID associated with each activity, which was then mapped to the schedule of study activities in Oncore–Clinical Trials Management System (CTMS). CRCs provided additional feedback to a project manager, who aggregated and analyzed data to calculate an average duration for each task per study. For the administrative tasks unrelated to protocol procedures, a weekly average time was given by each CRC. For clinical related tasks, an average duration was calculated and multiplied by the frequency of the tasks, as described in the calendar in Oncore-CTMS. To estimate clinical hours, only patient-facing tasks were mapped, using an Office Data Connection report from Oncore-CTMS.

4. Outcomes

The workload capacity tool can estimate:

- CRC workload hours and capacity percent per calendar week
- FTE support needed in hours per program disease
- Number of hours spent in clinic by disease site-based team per calendar week
- FTE support is shown both prospectively and retrospectively
- The model is based on real time data from Oncore-CTMS

5. Lessons Learned and Future Directions

Staff member engagement is imperative to ensure the data accurately captured the "real world" of the CRC. Reassurance and open communication served to lessen the perception that the tool was a means to monitor personal productivity and efficiency. The estimations for tasks unrelated to the study calendar were challenging as the effort diary data revealed a significant amount of time devoted to tasks related to internal operational processes, which we factored in under administrative tasks. It was identified that coordinators spent more time on administrative tasks due to operational processes and tasks specifically related to a particular disease or the type of trial, for example trials that may have a surgical or in-patient component. Future steps will focus on validation and refinement of the tool to account for the variance in coordinator's capacity based on coordinator level of experience, involvement in projects, and mentorship.

Citations

1- Turner, Rebecca. "Workload Scoring Using OnCore" Onsemble Conference Presentation, February 22, 2016.
2- Smuck B, Bettello P, Berghout K, et al.: Ontario Protocol Assessment Level: Clinical trial complexity rating tool for oncology clinical trials. J Oncol Pract 7:80- 84, 2011.
3- Repede M, Beighley D, Putz K, Fritsche A, Nowakowski G. "Clinical Research Coordinator Workload Estimation and Tracking" Poster Presentation, AACI 2023.

Development of a Clinical Research Coordinator Capacity Model

Jaidit Johnson, Milijana U. Petrovic, Erica Royster, Bucky Jones-Lombard, Brittany Mack, Anita Patel, Igor Krupitsky, Kira Hulse, Jay Lebsack

MOFFITT CANCER CENTER

Background

Given the complexity of the clinical research coordinator (CRC) role it is essential to determine a sustainable workload and forecast the number of full-time equivalent employees (FTEs) needed to support clinical research. Currently, in Moffitt Cancer Center's Clinical Trials Office (CTO) team managers have utilized the Clinical Research Effort Study Tool (CREST) (Feb 22, 2016, Onsemble, 2016, Turner) which was derived from the OPAL (Journal of Oncology Practice, 2011, Smuck et al) to measure CRC activity by measuring protocol complexity. We reviewed literature on previous work such as the Clinical Research Coordinator Workload Estimation and Tracking tool by M. Repede, AACI 2022 abstract.

Goals

(1) To design a CRC workload capacity model that is efficient, effective and captures the time it takes a CRC to complete operational tasks at Moffitt.

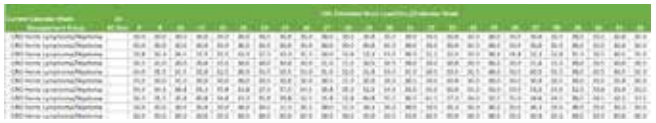
(2) To develop a tool that will support operational managers' decision in projecting FTEs needed to coordinate active trials in the portfolio and trials in activation pipeline.

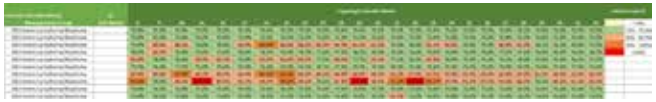
*Oncore–Clinical Trials Management System (CTMS)

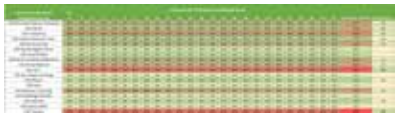
Solutions and Methods

CRCs (n=30) used an "Effort Diary" for 8 weeks and noted how long it took to complete activities on each study. The diary included the study and subject ID associated with each activity, which was then mapped to the schedule of study activities in Oncore*. CRCs provided additional feedback to a project manager, who aggregated and analyzed data to calculate an average duration for each task per study. For the administrative tasks unrelated to protocol procedures, a weekly average time was given by each CRC. For clinical related tasks, an average duration was calculated and multiplied by the frequency of the tasks, as described in the calendar in CTMS. To estimate clinical hours, only patient-facing tasks were mapped, using an Office Data Connection report from CTMS.

CRC Workload Per Week and FTEs Variance







Outcomes

The workload capacity tool can estimate CRC workload per hours of the week and %, number of hours spent in clinic by disease site-based team per calendar week. The distinctive ability of the tool is that it can pull number of hours that are needed to support clinical trial based on schedule of events. The tool pulls 12 weeks of prospective and retrospective capacity assessments based on the real time data from CTMS without the need for additional effort tracking by staff.

Refinements and Next Steps

Future steps will focus on validation and refinement of the tool to account for the variance in coordinator's capacity based on coordinator level of experience, involvement in projects and mentorship. Additionally, development of the reference guide for CTO managers and Supervisors to use for Fiscal Year(FY) FTE planning. Lastly, build out of the capacity model Research Data Coordinators (RDC) is a focus in FY24.

References

Repede M, Beighley D, Putz K, Fritsche A, & Nowaksoki G. (2023). Clinical Research Coordinator Workload Estimation and Tracking. *AACI, Poster Presentation.*

Smuck B, Bettello P, Berghout K, et al. (2011). Ontario Protocol Assessment Level: Clinical Trial Complexity Rating Tool for Oncology Clinical Trials, J Oncol Pract, Mar;7(2):80-84. Doi: 10.1200/JOP.2010.000051.

Turner, R. (2015). Workload Scoring using OnCore. *February 22, 2016: Onsemble Conference Presentation*

Improving PRMC Accrual Monitoring Procedures: Making it Count

S. Osipowicz, R. Dampman Weiss, J. Curry, J. Johnson, M. Kasner
Sidney Kimmel Cancer Center at Jefferson Health

1. Background

Protocol Review and Monitoring Committees (PRMCs) are tasked with ensuring that protocols meet adequate scientific and accrual progress as part of the Protocol Review and Monitoring System at National Cancer Institute (NCI)-Designated Cancer Centers. This responsibility comes with the challenge of ensuring studies are demonstrating progress while also not imposing barriers to important research. Many PRMCs acknowledge that some studies are expected to be slow accruing and therefore a one-size fits all accrual monitoring process can be punitive to study teams and administratively burdensome to the PRMC. Thus, Sidney Kimmel Cancer Center proposed to establish a process that could address unique study circumstances more flexibility, while also encouraging meaningful accrual progress.

2. Goals

- Set minimum accrual expectations and monitoring frequency to be appropriate for different study characteristics
- Reduce administrative burden

3. Solutions and Methods

First, we surveyed AACI members to learn about other centers' minimum accrual expectations and accrual monitoring processes. Based on the information gathered, we revised our policy to change monitoring from a biannual process to a rolling review process based on critical open to accrual milestones (6, 12, 24 months, etc.). PRMC developed three categories outlining minimum annual accrual expectations and committee review frequencies. Investigator-initiated studies (Category A) are expected to accrue at least 50 percent of their annual accrual goal and are monitored every six months. Externally sponsored (Category B) are monitored at least annually and are expected to accrue a minimum of four participants every 12 months. Phase I and rare disease studies (Category C) are given more leniency with an expectation of one participant every 12 months. We developed a custom report that tracks minimum accrual expectations based on assigned category, low accrual status, and upcoming accrual monitoring review dates. An accrual monitoring subcommittee was created to review principal investigator (PI) responses to low accrual notifications and recommend outcomes to the PRMC for consideration during full committee review. We developed a standard form to collect PI responses to low accrual notifications to ensure collection of meaningful information for consideration by the PRMC subcommittee.

4. Outcomes

The revised policy was implemented in June 2022 and was well received by investigators. By recognizing and accepting that certain studies will be low in total accrual numbers but high in scientific validity, we have reduced the administrative burden by monitoring accrual only once per year. By reviewing on a rolling basis, individualized to trial category, the administrative burden has been spread out, reducing stress on staff. Creating the accrual monitoring subcommittee has created additional opportunities for member engagement.

5. Lessons Learned and Future Directions

Short-term goals include automating low accrual notifications and utilizing our Clinical Trial Management System to track outcomes. For the future, PRMC will consider expanding accrual monitoring to non-interventional studies and increasing minimum expectations each year a study is open to accrual. Long-term goals will focus on engagement with disease teams to allow tracking and monitoring of accrual progress compared to minimum accrual expectations independently, so they have access to view this information prior to receiving a low accrual notification from the PRMC.

Improving PRMC Accrual Monitoring Procedures: Making it Count

Sarah Osipowicz, MSEd; Rachael Dampman Weiss, BS; Joseph M. Curry, MD; Jennifer M. Johnson, MD, PhD; Margaret Kasner, MD, MSCE
Sidney Kimmel Cancer Center – Jefferson Health

Background

- Protocol Review and Monitoring Committees (PRMCs) are tasked with ensuring that protocols meet adequate scientific and accrual progress as part of the Protocol Review and Monitoring System at NCI-designated cancer centers.
- Balance between encouraging progress and not creating unnecessary barriers is a challenge.
- Some studies are expected to be slow accruing and a one-size fits all accrual monitoring process can be punitive to investigators and administratively burdensome on support staff.
- Sidney Kimmel Cancer Center proposed a process to address unique study circumstances with a more flexible approach while encouraging meaningful accrual progress.

Goals

1. Set minimum accrual expectations and monitoring frequency to be appropriate for different study characteristics.
2. Reduce administrative burden.

Methods

- We surveyed AACI members to learn about other centers' minimum accrual expectations and accrual monitoring processes.

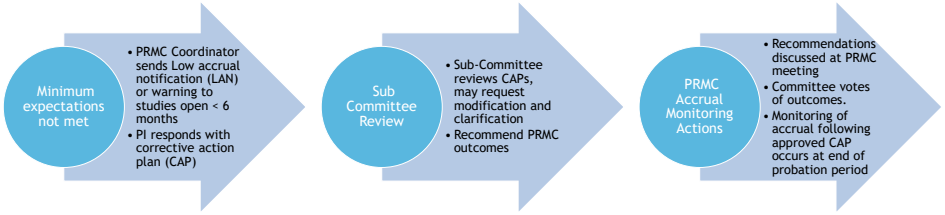
Solutions

- Developed 3 categories tailored to the circumstances of the trial (**Table 1**).
- Revised monitoring policy from bi-annual review for all studies to a rolling review process based on critical accrual milestones (6, 12, 24 months, etc.).
- Developed a custom report that tracks minimum accrual expectations and upcoming monitoring timepoints.
- Implemented a standard form to collect PI responses to low accrual notifications.
- Established an accrual monitoring subcommittee to recommend outcomes to the full PRMC **(Figure 1)**.

Table 1. Accrual Monitoring Categories

Category	Minimum Accrual Expectations	Monitoring Frequency	Studies Typically Assigned to this Category
A	50% of annual accrual goal per year	Every 6 months	Jefferson investigator-initiated studies
B	4 per year	Every 12 months	National, industry, and external investigator-initiated studies
C	1 per year	Every 12 months	Phase I, rare disease, and rare molecular subtypes

Figure 1. Low Accrual Notification and Review Process



Outcomes

- By recognizing and accepting that a subset of studies will be low in total accrual numbers but high in scientific contribution we have reduced administrative burden by monitoring accrual only once per year.
- Reviewing on a rolling basis, individualized to trial category, has spread out the administrative burden, reducing stress on staff.
- The custom report from OnCore eliminates manual tracking of follow up monitoring timepoints, accrual information, and relevant study details.
- The standard form for responding to low accrual notifications has improved the quality of responses from PIs and streamlined communication.
- The accrual monitoring subcommittee has created additional opportunities for member engagement.

Future Directions

- PRMC will consider expanding accrual monitoring to non-interventional studies and increasing minimum accrual expectations each year a study is open to accrual.
- Utilize OnCore's ePRMS console to further improve administrative workflows and streamline reporting.
- Long term goals will focus on engagement with disease teams to allow tracking and monitoring of accrual progress compared to minimum accrual expectations independently, to enhance access to this information prior to receiving a low accrual notification from the PRMC.

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Clinical Research – Following the Money, Phase 4

R. Geary, P. Eggleton, M. Kovak, M. Birrer, A. Smith, Z. Feng, N. Pruss
UAMS Winthrop P. Rockefeller Cancer Institute

1. Background

Prior to the development of the Clinical Research Accounting System (RAS) at UAMS, there was no consistent or efficient method to track incurred clinical trial revenue or expenses. Although in-depth budgets were developed for each clinical trial, there lacked streamlined accounting processes across all clinical research departments for tracking revenue or expenses when they were incurred. We required a system that could efficiently track earned invoiceable, milestone, and start-up revenue while accounting for incurred expenses to allow for appropriate reconciliation of clinical trial accounts. Also needed was an efficient method of comparing earned versus received revenue and incurred versus paid expenses. We needed a system that could help forecast revenue and expenses for a future year for budgeting purposes. Lastly, we had no way to answer campus leadership financial questions without tedious, manual collation of data from multiple systems including the UAMS enterprise finance system (SAP), Clinical Trial Management System (CTMS), and electronic medical record (EMR) system.

2. Goals

We started with the goal of creating a streamlined system to track clinical trial revenue and manage receipt of payments. Our next goal was tracking expenses related to clinical trials. One of the biggest goals we tackled to date is the creation of an income statement. Our current goals include the creation of a balance sheet and the ability to forecast revenue and expenses for a future year to assist in annual departmental budgeting. We also want the ability to track unfunded procedures.

3. Solutions and Methods

Our first goal was achieved by linking our custom developed CTMS with our new accounting system allowing us to track exactly which procedures were completed for which participant. We were also able to link and track study revenue and expenses such as annual continuing reviews. Tracking patient-related expenses was achieved by pulling data from the already-integrated charge master.

4. Outcomes

Since the inception of this software application, we have been able to track successfully and systematically, report and post revenue and expenses for our clinical trials. Comprehensive integration with Workday and the CTMS reduced routine and often duplicative manual processes. We are now financially managing 220 oncology clinical trial accounts (industry, cooperative, and investigator-initiated) and have been able to adequately and comprehensively track revenue and report expenses related to clinical trials. We have an income statement that can be executed per study, disease type, study type, or for all studies with activity in the chosen time range. This has allowed for more accurate and timely reporting of financial reports to leadership.

5. Lessons Learned and Future Directions

Phase 4 of this project is in discussions. This phase will bring balance sheets as well as forecasting abilities that can be run per study, disease type, study type, or for all studies with activity in the chosen time range which will be integral in our communication with campus financial leadership. Enhancements are ongoing and additional features will be implemented as we progress forward.

Clinical Research: Following the Money Phase IV

Ronni Geary, MBA, CPC[1], Philip Eggleton, BBA[1], Matthew Kovak, MS, CCRP[1], Michael Birrer, MD, PhD[1],
Nicholas Pruss, BS[2] , Angela Smith, MS, PMP[2], Zhidan Feng, MS[2]
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[2]IT Research Systems, University of Arkansas for Medical Sciences, Little Rock, AR

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Goals and Metrics

We started with the goal of creating a streamlined system to track clinical trial revenue and manage receipt of payments. Our next goal was tracking expenses related to clinical trials. One of the biggest goals we tackled to date is the creation of an income statement. Our current goals include the creation of a balance sheet and the ability to forecast revenue and expenses for a future year to assist in annual departmental budgeting. We also want the ability to track unfunded procedures.

Methods

Our first goal was achieved by linking our custom-developed CTMS with our new accounting system allowing us to track exactly which procedures were completed for which participant. We were also able to link and track study revenue and expenses such as annual continuing reviews. Tracking patient-related expenses was achieved by pulling data from the already-integrated charge master.

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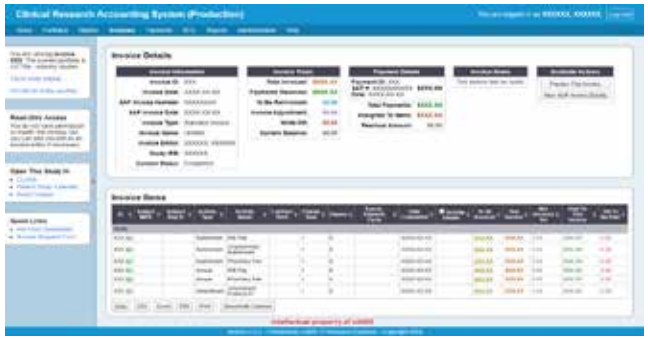

Future Directions

Phase 4 of this project is in discussions. This phase will bring balance sheets as well as forecasting abilities that can be run per study, disease type, study type, or for all studies with activity in the chosen time range which will be integral in our communication with campus financial leadership.
Enhancements are ongoing and additional features will be implemented as we progress forward.

Contact

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Developing a Scoring Tool to Calculate Protocol Acuity for Clinical Research Nurse Workload

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[2] *UAMS IT Research Systems*

1. Background

Nurse managers in our Clinical Trials Office experienced a discrepancy among nurses and their perceived workload. Management requested a tool to assist with human resource management that could apply empirical objective values to face-to-face patient interactions and allow for fair and equitable case assignments. A literature search did not yield a tool that addressed nursing duties specifically. This project began in early 2022 was implemented in Spring 2023.

2. Goals

The quality improvement model used throughout our project was FADE: Focus, Analyze, Develop, Execute, and Evaluate. We are currently in the Execute and Evaluate phases. Our goals continue to be:

1. To improve existing processes used by managers to assign studies to nursing staff
2. To quantify overall staffing needs, by evaluating nursing activities involved per protocol
3. To assign a tangible score based on objective criteria to minimize subjectivity in nurse staffing
4. To improve staff retention and employee satisfaction by defining optimal workload per nurse
5. To allow managers an opportunity to work with individual staff on prioritization and organizational skills as identified

3. Solutions and Methods

Criteria were developed for each aspect of the nursing interactions that occur in each phase of the clinical trial, such as screening, treatment, and follow-up. Values were assigned to each nursing task required and averaged for a score for each arm of the study. The plan was to incorporate the protocol acuity score into our Clinical Trials Management System (CTMS) and provide reports that assess current nurse workload. Once all studies were scored and available in our CTMS, managers were provided access and were able to assess current staff workloads and levelized as needed. Managers then were able to discuss with individual staff nurses to compare actual work performed to the workload measurement tool, determining the tool's reliability and validity.

4. Outcomes

Managers were able to assess current workloads, reassign protocols as needed, and identify the acceptable workload score per nurse. This information proved helpful in projecting staffing needs for studies in the start-up pipeline. This tool has already been used by managers to adjust staffing shortages.

5. Lessons Learned and Future Directions

There is a need for a research nurse specific workload tool. Future development includes scoring studies in the start-up process and anticipate the impact on current staffing, providing objectivity in determining feasibility of existing pipeline. This conference provides opportunity for collaboration with other institutions to further develop and improve this tool.

Developing A Scoring Tool to Calculate Protocol Acuity for Clinical Research Nurse Workload

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[2]University of Arkansas for Medical Sciences IT Research Systems

UAMS Winthrop P. Rockefeller Cancer Institute

Background

Nurse managers in our Clinical Trials Office experienced a discrepancy among nurses and their perceived workload. Management requested a tool to assist with human resource management that could apply empirical objective values to face to face patient interactions and allow for fair and equitable case assignments. A literature search did not yield a tool that addressed nursing duties specifically. This project began in early 2022 was implemented Spring of 2023.

Goals

- Improve existing staffing assignments
- Quantify staffing needs per protocol
- Develop objective scoring criteria
- Improve staff retention and employee satisfaction
- Define optimal FTE workload
- Project future staffing needs

Outcomes

- ☑ Levelized existing workloads
- ☑ Identified manageable baseline nurse workload score
- ☑ Decreased Projected staffing needs for studies in pipeline
- ☑ Adjusted assignments during staffing shortages

Future Directions

- Score studies in the pipeline
- Provide objectivity during feasibility evaluation
- Collaborate with other institutions to further develop this tool

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Methods

Criteria were developed for each aspect of the nursing interactions that occur in each phase of the clinical trial such as Screening, Treatment, and Follow up. Values were assigned to each nursing task required and averaged for a score for each arm of the study. The plan was to incorporate the protocol acuity score into our Clinical Trials Management System and provide reports that assess current nurse workload. Once all studies were scored and available in our CTMS, managers were provided access and were able to assess current staff workloads and levelized as needed. Mangers then were able to discuss with individual staff nurses to compare actual work performed to the workload measurement tool, determining the tool's reliability and validity.

Nurse Workload Report Scoring Grid

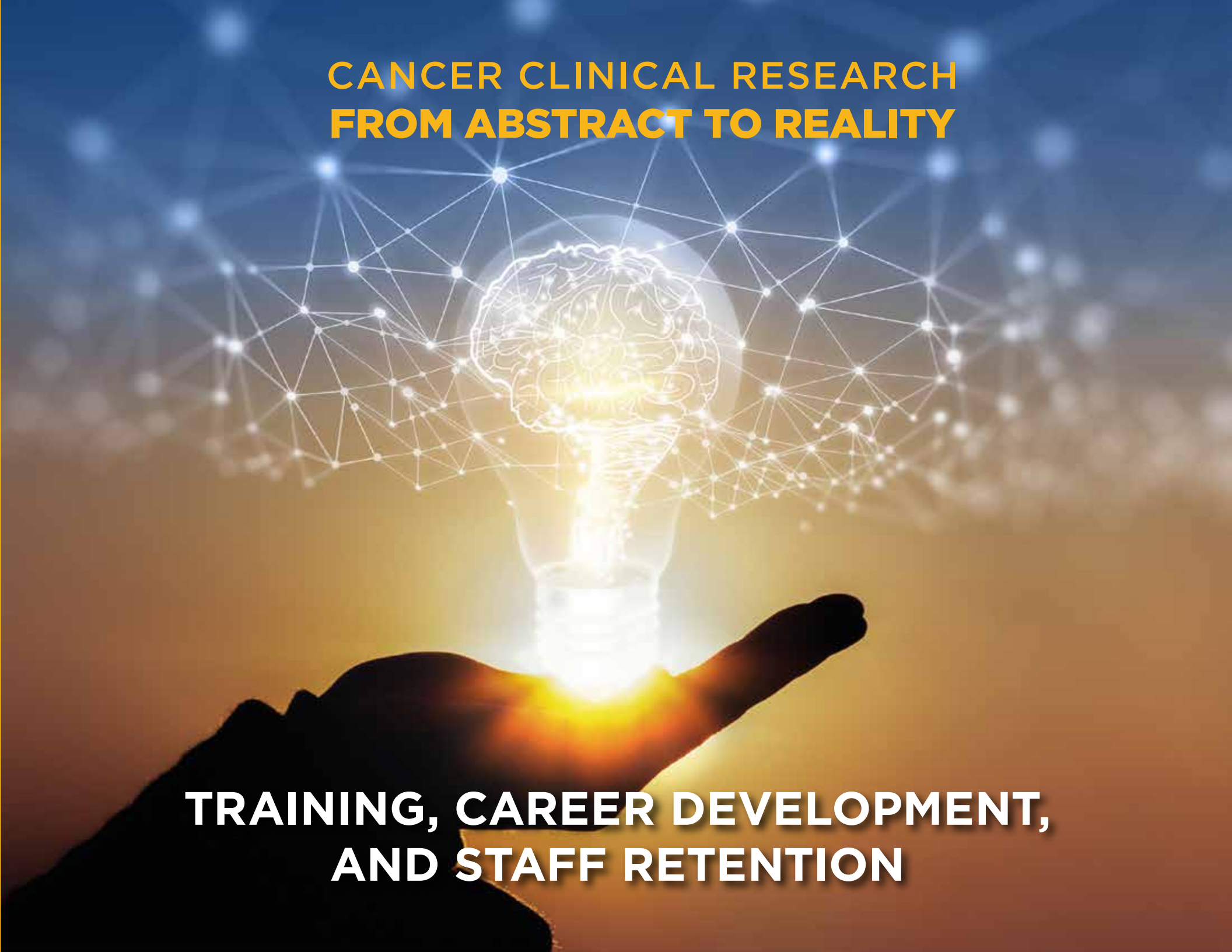
Determine a score for each epoch by determining the score for each epoch item and taking the average for all items in that epoch.

Epochs	Epoch Items	0	1	2	3	4	5
Screening	Pages in Consent	N/A	from 1 to 6	from 7 to 15	from 16 to25	from 26 to 35	36+
	Eligibility Items	N/A	1	from 1 to 10	from 11 to25	from 26 to 35	36+
	Eligibility Testing	N/A	None	(Minimal)-Can be completed the day of consent. No tests require scheduling or a second visit.	(Moderate)-Requires a second visit but can be completed in one visit.	(Extensive)-Require a more than one additional day	(Maximum)-Requires more than one additional visit and an invasive procedure such as a biopsy
Treatment	Number of visits	N/A	from 1 to 2	3-4 Visits OR >4 week intervals	5-8 Visits OR 3-4 week intervals	9+ Visits OR 1-2 week intervals	Multiple visits per week
	Visit Complexity	N/A	(Brief)-QOL or equivalent only	(Focused)-Con meds or AEs. +/- QOL	(Standard)-AEs and Con meds, +/- QOL	(Complex)-Standard plus one or more of the following: Pill Count, Diary, Photos, Measurements, EKG by CRN or Hospitalization (non-Home)	(Intense)-Multiple visits per week or Hospitalization (Hematology)
	Modalities	N/A	N/A	N/A	1	>1	Transplant
Follow-up	Follow-up	N/A	<3 visits per year (5yr average)	>/=3 visits and < 5 visits per year (5yr average)	5+ visits per year (5yr average)	N/A	N/A

Definitions:
Screening--All activites from consent through enrollment.
Treatment-During protocol intervention
Follow-up-Post protocol intervention.
Consent--The IRB approved document excluding the HIPAA section
Modality--Treatment Discipline such as, Medical, Surgical, Radiation

CANCER CLINICAL RESEARCH

FROM ABSTRACT TO REALITY



TRAINING, CAREER DEVELOPMENT, AND STAFF RETENTION

#ResearchOnResearch – A Research Training Initiative for Clinical Research Professionals

T. Waite
Abramson Cancer Center of the University of Pennsylvania

1. Background

Opportunities for independent research by non-physician clinical research professionals (CRPs) from the 12 cancer research teams of the Abramson Cancer Center Clinical Research Unit (ACC CRU) have been limited. No abstracts for independent research by ACC CRU CRPs had been submitted to research conferences, until launching of the #ResearchOnResearch initiative in April 2022. #ResearchOnResearch leverages the clinical research expertise of ACC CRU CRPs, to empower ACC CRU CRPs to pursue and to develop research projects derived from their clinical research experiences and academic interests, and to provide research training and career development opportunities for ACC CRU CRPs.

2. Goals

- Discuss research ideas and mentor ACC CRU CRPs in developing research projects
- Provide training sessions to ACC CRU CRPs on activities supportive of research, e.g., formulating research questions, designing research projects, writing research abstracts, creating research posters, formulating podium presentations, and publishing research
- Identify prospective research conferences for submission of abstracts for poster, podium, and roundtable presentations
- Provide a forum for research collaboration among ACC CRU staff

3. Solutions and Methods

The 14th Annual Conference of the International Association of Clinical Research Nurses (IACRN) in October 2022 stimulated the development of #ResearchOnResearch. Ongoing performance/improvement projects developed by ACC CRU CRPs were identified. Three individuals were contacted and provided intensive training on abstract writing over a two-week period by Terease Waite, as well as two-month intensive training in poster development/writing after acceptance of their abstracts. Maria Hendricks and Terease Waite were trained in the development of abstracts and posters.

4. Outcomes

All four abstracts to the IACRN conference were accepted:

- Evan Anderson (Airways Research Group): "Tracking Physician Attestation of Clinical Research Staff Documentation Using Electronic Health Record Reporting Tools"
- Maria Hendricks (Central CRU): "Clinical Research Scorecard – Performance Metric"
- Philip Seger/Alexandra Torres (DVL Research Group): "Use of Pre-screening Demographic Data to Target Recruitment Resources for Underrepresented Populations"
- Terease Waite (Central CRU): "Creation of an Ethics Journal Club for Clinical Research Staff"

The "Clinical Research Scorecard – Performance Metrics" abstract/poster was accepted to the 31st Annual Society of Clinical Research Associates (SOCRA) in the category of Clinical Research Management in September 2022. "Use of Pre-screening Demographic Data to Target Recruitment Resources for Underrepresented Populations" won third place in the IACRN 14th Annual Conference Poster Contest. Also, the posters by Evan Anderson, Maria Hendricks, and Philip Seger/Alexandra Torres were submitted and accepted to the 10th Annual Penn Medicine Nursing Research and Evidence-Based Practice Conference. The first #ResearchOnResearch training session, titled "What is Research," occurred on November 4, 2022. Subsequent training sessions have included: "Quantitative Research" and "Five Phases of Quantitative Research." Through #ResearchOnResearch, three abstracts have been submitted to the 2023 Association of American Cancer Institutes (AACI) Clinical Research Innovation (CRI) conference.

5. Lessons Learned and Future Directions

#ResearchOnResearch's success has resulted in the identification of forthcoming annual research conferences for submission of abstracts and more rapid identification of ongoing quality/performance improvement projects. The training sessions will continue with an initial focus on quantitative research and research methods. The projects underlying the IACRN abstracts have continued data collection and have plans for publication of their results.

#ResearchOnResearch—A Research Training Initiative for Clinical Research Professionals

Terease S. Waite, PhD, RN – Program Manager, Education and Training
Abramson Cancer Center (ACC) Clinical Research Unit (CRU)
University of Pennsylvania, Philadelphia, PA

BACKGROUND

- Opportunities for independent research by non-physician clinical research professionals (CRPs) from the 12 cancer research teams of the Abramson Cancer Center Clinical Research Unit (ACC CRU) have been limited, to non-existent, until the launching of the #ResearchOnResearch initiative in April 2022.
- #ResearchOnResearch leverages the clinical research expertise of ACC CRU CRPs, empowers ACC CRU CRPs to pursue and to develop research projects derived from their clinical research experiences and academic interests, and provides research training and career development opportunities for ACC CRU CRPs.

GOALS

- Discuss research ideas and mentor ACC CRU CRPs in developing research projects.
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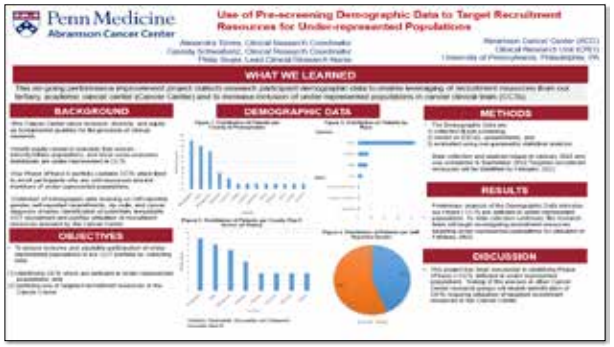
- Identify prospective research conferences for submission of abstracts for poster, podium, and round-table presentations.
- Provide a forum for research collaboration among ACC CRU Staff.

2022 IACRN #ResearchOnResearch Posters

"Tracking Physician Attestation of Clinical Research Staff Documentation Using Electronic Health Record Reporting Tools"

"Use of Pre-screening Demographic Data to Target Recruitment Resources for Under-represented Populations"



SOLUTIONS/ METHODS

- The 14th Annual Conference of the International Association of Clinical Research Nurses (IACRN) in October 2022 stimulated the development of #ResearchOnResearch and the submission of four abstracts.
- On-going performance/improvement projects developed by ACC CRU CRPs were identified. Two research groups were contacted, and CRP authors/co-authors were provided intensive training on abstract writing over a two-week period, as well as two-month intensive training in poster development/writing after acceptance of their abstracts.

OUTCOMES

- All four abstracts submitted to the IACRN were accepted.
- "Use of Pre-screening Demographic Data to Target Recruitment Resources for Underrepresented Populations" won third place in the IACRN 14th Annual Conference Poster Contest.
- The first #ResearchOnResearch training session, entitled "What is Research," occurred on November 4, 2022. Subsequent training sessions have included: "Quantitative Research" and "Five Phases of Quantitative Research."

LESSONS LEARNED / FUTURE DIRECTIONS

- #ResearchOnResearch's success has resulted in the more rapid identification of on-going quality/performance improvement projects.
- The projects underlying the IACRN abstracts have continued data collection and have plans for publication of their results.

Special Acknowledgement: Erica L. Dahlmeier, MPH; Liudmila L. Mazaleuskaya, PhD; Maria Hendricks, MSN, RN, Colleen Tabery, BA, Christina Vikingstad, HSE, MS,

CROSS to CRES: The Evolution of a Clinical Research Operations Supplemental Series to an Accredited Clinical Research Education Series

T. Waite, C. Redlinger-Tabery, E. Dahlmeier
Abramson Cancer Center of the University of Pennsylvania

1. Background

The COVID-19 pandemic resulted in attrition of non-physician research staff, or clinical research professionals (CRPs), across all levels of experience and roles within the 12 oncology research groups in the Abramson Cancer Center (ACC) Clinical Research Unit (CRU). ACC CRU central leadership assessed orienting/onboarding CRPs and determined additional clinical operations (OPS) training was necessary. In May 2021, the Clinical Research Operation Supplemental Series (CROSS) was launched to bridge the gap between the knowledge and experience of orienting/onboarding CRPs, as well as to engage and to provide OPS continuing education for current CRPs working hybrid schedules. The success of CROSS for education and career development for ACC CRU CRPs resulted in the evolution to an accredited education activity for ACC CRU clinical research nurses, coordinators, pharmacists, advanced practice providers, other credentialed CRPs, and physicians.

2. Goals

- Provide OPS educational opportunities for ACC CRU CRPs and ACC CRU physicians relevant to clinical research
- Ensure content relevance by basing CROSS sessions on perceived CRU research needs, issues identified by CRPs, and drawing presenters from ACC CRU physicians and ACC/University of Pennsylvania (Penn) collaborating departments
- Stimulate information-sharing and collaboration among the ACC CRU oncology research groups, ACC CRU physicians, and collaborating with Penn through engagement and participating in CROSS activities
- Continue to improve the knowledge, skills/strategies, and competencies of CRPs, while supplementing preexisting OPS with Quality Assurance (QA), and Regulatory Affairs (RA) research knowledge and skills

3. Solutions and Methods

The ACC CRU central leadership identified the initial CROSS topics and engaged ACC CRU oncology physicians and Penn collaborating department (e.g., pharmacy, fertility preservation, radiology) subject matter experts (SMEs). Accreditation of CROSS was acquired in recognition of the continuing education and career development opportunities for CRPs and to stimulate physician SMEs' interest in presenting CROSS educational sessions. Presentations were recorded to support future learning opportunities for CRPs and orienting/on-boarding training for CRPs.

4. Outcomes

- Attendee direct feedback from initial CROSS sessions inspired future topics and encouraged physician SMEs to provide educational sessions ("Jehovah's Witnesses—The Medical and Ethical Challenge in Clinical Research," "Hallmarks of Cancer," and "Immune Toxicities")
- Approximate attendance of the CROSS sessions averaged 50-80 of the 140 ACC CRU CRPs and physicians
- The increasing intersection of OPS, QA, and RA research landscapes in the ACC CRU necessitated CROSS's incorporation of an existing RA education series in January 2023—CROSS became the accredited Clinical Research Education Series (CRES)

5. Lessons Learned and Future Directions

- Incorporation of recorded CROSS sessions into the ACC CRU Orientation/Onboarding program provides early introduction to OPS, QA, and RA clinical research activities
- Increase topics in future CRES sessions to reflect the expanding relevance of QA and RA
- Continued engagement from physician and Penn collaborative department SMEs have resulted in upcoming presentations concerning Financial Toxicity in Cancer Treatment (Penn Center for Health Incentives and Behavioral Economics) and Cardio-Oncology (Penn Thalheimer Center for Cardio-Oncology)

CROSS to CRES: The Evolution of a Clinical Research Operations Supplemental Series to an Accredited Clinical Research Education Series

Terease S. Waite, PhD, RN; Colleen Tabery, BA; Erica Dahlmeier, MPH, CCRP; Christina Vikingstad, HSE, MS
Abramson Cancer Center, Clinical Research Unit
University of Pennsylvania, Philadelphia, PA

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- Stimulate information-sharing and collaboration among the ACC CRU oncology research teams, ACC CRU clinicians, and collaborating Penn departments through engagement and participating in CROSS activities.
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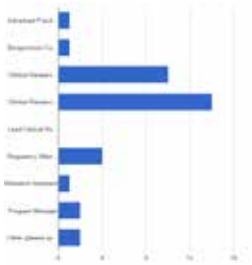
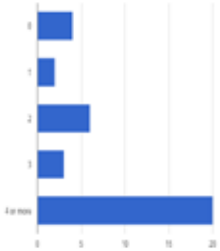
PARTICIPATION

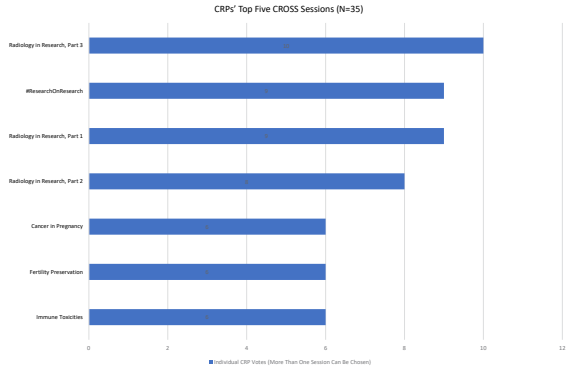


Participation by Role (N=35)



CROSS Sessions Attended (N=35)

CROSS PRESENTATIONS



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FUTURE DIRECTIONS

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Special Acknowledgement: Maria Hendricks, MSN, RN; ACC CRU Clinical Research Professionals

New Employee Orientation – Joining the 21st Century

F. Kerr, S. Asche, C. Bucks
Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. Background

At the Indiana University Melvin and Bren Simon Comprehensive Cancer Center (IUSCCC), the Quality and Education Team is responsible for the training of newly hired and promoted employees; as well as mentoring, writing, and updating Guidance Documents and Standard Operating Practices (SOPs); and managing continuing education, quality improvement projects, and routine data checks and audit preparedness.

In 2019, the Quality and Education Team recognized the need for a solution to increasing numbers of new hires in orientation cohorts and the burden in-person orientation training was placing on the team. In mid-late 2019 the Quality Assurance Coordinators (QAC) had transitioned 18 of the 46 training modules into a web-based Content Management System (CMS), Canvas.

As 2020 emerged, and the COVID-19 pandemic drove the United States to a halt, the IUSCCC Clinical Trials Office (CTO) was uniquely positioned to have already begun integrating virtual orientation topics. While other centers stumbled to learn and catch up, the IUSCCC was able to quickly transition remaining in-person topics to the remote platform and continue onboarding staff remotely.

2. Goals

1. Transition lower priority training modules to a virtual platform
2. Create quizzes and assignments within the CMS to evaluate trainee retention
3. Provide existing staff a platform to self-retrain on any topic at any time
4. Relieve the orientation burden on QACs so focus can switch to mentoring and other quality tasks
5. Allow for near continuous onboarding despite QAC staffing fluctuations

3. Solutions and Methods

Indiana University had an existing contract with the Canvas CMS.

- QACs created a simple CTO portal and outlined a syllabus for orientation
- All topics, regardless of delivery method, are represented in the Canvas portal
- Subject Matter Experts (SME) and PowerPoint slides were attached to all presentations so staff could take notes, review on their own, or reach out to a SME for additional help
- Scripts and multimedia recordings were made for each topic identified as lower priority
- High priority topics (e.g., informed consent, eligibility verification, adverse event assessments, SAEs, etc.) continue to be taught in-person
- Quizzes and in-depth exercises for both virtual and in-person trainings were built in Canvas

4. Outcomes

- Twenty-six modules currently in Canvas
- Ten quizzes currently in Canvas
- Six in-depth exercises currently in Canvas
- CTO annual onboarding rates have continued to increase with Canvas meeting the demand. Automated videos, quizzes, and exercises allow the QACs to focus on mentoring, process improvement, audit readiness, and implementation of new processes, such as eConsent.

5. Lessons Learned and Future Directions

The addition of Canvas as part of the IUSCCC CTO orientation onboarding has been integral for the growth of the Clinical Trials Office. With the burden of in-person training now eased by Canvas modules, the Quality and Education Team has had time to focus on new training topics, one-on-one mentoring of newly hired staff, guidance document and SOP creation, process improvement, and future project goals.

Quizzes within Canvas can be set to auto-grade; however, exercises still need hand-grading. This is still a time-saving benefit, as all assessments were hand-graded prior to the implementation. Reports can be run within Canvas to see student scores and topics where students struggle are addressed with them one-on-one in mentoring.

QACs have noticed that some of the less exciting modules do not maintain student attention. Future goals for the Quality and Education Team are to revise videos with knowledge assessments embedded within the content of the video and to increase the number of quizzes. There is also a minimal increase in workload for updating videos. Slides, scripts, and recordings all need to be updated whenever there is a change to a process, but while the effort is heavy on the front end, it is a one-time effort that makes up for the weekly presentation time.

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Fyalon Kerr, BA, CCRP; Sarah Asche, MS, CCRP; Chelsea Bucks, BA, ACRP
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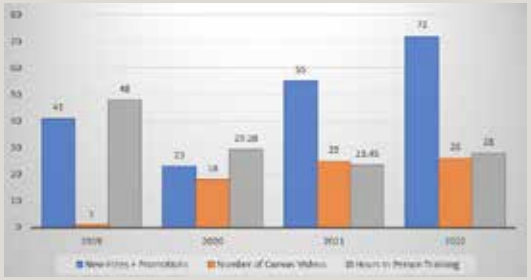

Outcome

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Lessons Learned

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INDIANA UNIVERSITY MELVIN AND BREN SIMON COMPREHENSIVE CANCER CENTER

2

Strategies to Improve Clinical Research Staff Engagement, Retention, Career Development and Performance at an NCI-Designated Cancer Center

C. Spalink, A. Joshi, A. Husni, P. Patel, A. Haegler, E. Waalkes, N. Chowdhury, B. Pothuri, J. Mehnert
Laura and Isaac Perlmutter Cancer Center at NYU Langone

1. Background

In 2019 the clinical unit of the NYU Langone Health (NYULH) Perlmutter Cancer Center (PCC) Clinical Trials Office (CTO) had an annual turnover rate of 34.4 percent, retention rate of 59.3 percent, promotion rate of 2.9 percent, vacancy rate of 13.9 percent and a NYULH Human Resource (HR) employee engagement survey index of 56 percent engagement or favorable responses (80 percent response rate, 12/15 staff). A clinical research staff satisfaction survey was conducted in 2019 showing 30 percent of staff not feeling supported in their role, 55.2 percent not feeling valued, 34.5 percent without a formal orientation, 55.2 percent expressing overwork, and 77.8 percent expressing a need for more standard operating procedures (SOPs). Survey themes included a lack of standardized policies, orientation, and mentorship, understaffing, and a perceived lack of leadership support, lack of role delineation between clinical research coordinators (CRCs) and nurses (CRNs), and pay disparities. Clinical leadership sought a partnership style approach with clinical staff and management to systematically address each theme.

2. Goals

Taking an incremental and multipronged approach the goal was to decrease the CCU turnover rate to <25 percent, increase the retention rate to >75 percent and promotion rate to (>10 percent) and maintain the vacancy rate at <15 percent while increasing the employee engagement to greater than 70 percent as assessed independently by NYULH HR.

3. Solutions and Methods

Interventions to improve the metrics included: targeting culture change by establishing a High Reliability Organization (HRO) program (2021-2023), creating clinical career ladders for CRCs and CRNs with market analyses and pay increases (2019, 2021, 2022); implementing an evidence-based clinical orientation program (2019); developing career promotional tracks to clinical management (2021); creating a CTO staff-led mentorship program (2021); forming CRN and CRC unit practice counsels to support staff problem identification; solution generation and communication with management (2022); increasing internal CTO SOPs and establishing a formal orientation program; and maintaining a hybrid and flexible work-model post-pandemic.

4. Outcomes

In 2022 the clinical unit annual turnover rate reduced to 24.6 percent (decrease 9.8 percent; p=0.15), retention rate 77.1 percent (increased 17.8 percent; p=0.033), promotion rate 39.9 percent (increased 37 percent; p=0.001) and maintained a vacancy rate of 14.7 percent (p=0.46) despite increasing positions from 40 in 2019 to 65 (63 percent increase). The NYU HR employee engagement index increased to 73 percent (increase 14 percent; p=0.12) with an 83 percent response rate (52/63). Starting in 2020 all internal and external audits were passed and internal audit findings decreased by 80 percent. In 2022 a central review for preventable Reportable New Information submissions showed a 30 percent decrease. SOPs increased from 14 in 2018 to 33 in 2022.

5. Lessons Learned and Future Directions

Tackling clinical research operational challenges requires an innovative and systematic approach in partnership with staff, management, and HR. Future directions include: creating a novel partnership with the NYU School of Nursing Masters of Research Program to support training new research RNs, collaborating with NYU HR to augment the CRN and CRC ladders to include a fourth and most senior step, and further reducing the turnover rate to <15 percent and increasing the engagement index to >80 percent.

Strategies to Improve Clinical Research Staff Engagement, Retention, Career Development & Performance

Christy Spalink, DNP, Angelica Husni MS, Nadia Chowdhury, Alison Haegler, Priyanka Patel, Erika Waalkes, Ankeeta Joshi, Bhavana Pothuri MD & Janice Mehnert MD

Perlmutter Cancer Center
An NCI-designated Comprehensive Cancer Center

NYU Langone Health

Background 2019

- High turnover rate (34.4%)
- Low retention rate (59.3%)
- Low promotion rate (2.9%)
- Vacancy rate (13.9%)
- Low NYULH HR employee engagement survey score 59% (12/15)

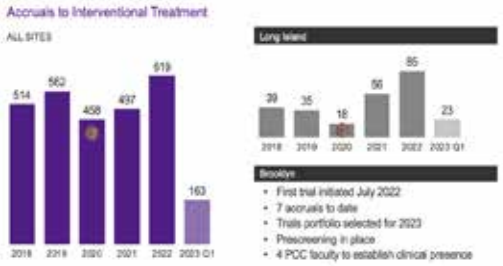
Clinical Staff Survey 2019

- Lack of support for the role (30%)
- Not feeling valued in the role (55.2%)
- Lack of formal orientation (34.5%)
- Feeling of overwork (55.2%)
- Desire for more SOPs (77.8%)

Goals

- Incremental and multi-pronged approach
- Collaborate with NYU Human Resources
- Decrease turnover rate by > 10%
- Increase retention rate and promotion rate by > 10%
- Maintain vacancy rate (goal <15%)
- Increase employee engagement to > 70%

The NYULH PCC Context



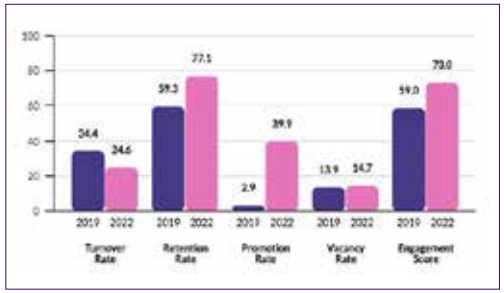
Outcomes

- Turnover rate decreased 9.8% (p = 0.15)
- Retention rate increased 17.8% (p = 0.03)
- Promotion rate increased 37% (p = 0.00003)
- Vacancy rate maintained at 14.7% with FTE increase from 40 (2019) to 65 (2022) (63% increase)
- NYULH HR engagement results increased to 73% (goal >70%) (p = 0.17) (89% response rate 58/65)
- All internal and external audits passed 2020-2022
- Internal audit findings decreased by 80% 2020 to 2022
- Central review of reportable events showed a 30% decrease in 2022
- SOPs increased from 14 to 33 (2018 to 2022)

Solutions

- Create and maintain an evidence-based, competency driven orientation program for clinical research staff (2019)
- Create clinical research career ladders and perform market analysis (2019 & 2022)
- Develop career promotional tracks to clinical management (2021)
- Institute an employee-lead mentorship program (2021)
- Establish a High Reliability Organization (HRO) program (2021)
- Form unit practice counsels (2022)
- Evaluate and address need for internal clinical research SOPs (2019-2022)

Outcome Measures



Next Steps?

- Partner with NYU Rory Meyers College of Nursing Research MSN to establish a training pathway
- Create additional licensed management positions
- Add a project management steps to the clinical research ladder

The Dynamic Duo: Dyad Mentorship of Cancer Clinical Trials Office (CCTO) Leadership

A. Fritsche[1], G. Nowakowski[1], J. Moehle[2], T. Werner[2]
[1]*Mayo Clinic Comprehensive Cancer Center*
[2]*Huntsman Cancer Institute at the University of Utah*

1. Background

A Cancer Center Clinical Trials (CCTO) leadership role can often feel like drinking from a firehose, and it does not come with a reference manual. Mentorship is needed for both medical directors and their administrative directors to assure successful leadership in arguably one of the most complex areas of a cancer center. Within a single institution, expertise and critical mentorship can be lacking and direct effort is needed to find identify a compatible mentor outside the institution. The Association of American Cancer Institutes (AACI) facilitates listservs for both leadership roles along with an annual meeting. Through these venues, a new dyad leadership team from Mayo Clinic Comprehensive Cancer Center (MCCCC) reached out to a dyad leadership team at the Huntsman Cancer Institute for key mentorship of newly appointed CCTO medical and administrative directors.

2. Goals

1. To understand the historical experiences that provided key lessons learned in the dyad leadership team

2. To share best practices, problem solving, and operational efficiencies for CCTO, PRMS, National Cancer Institute site visits and reporting structures

3. To foster a safe place for mentorship, trust, and collaboration on challenging topics

3. Solutions and Methods

Using virtual connections, the dyad leadership teams met as a group on at least two occasions within the year and separately as medical and administrative directors. The administrative partners met monthly during the first year for best practice sharing and mentorship on a variety of topics. Establishing trust, confidence, and a historical perspective of operations, during the first encounter the dyad leadership shared their lessons learned, and identified areas that could be quick, successful wins at the institution versus topics and areas that would take longer and were political, but that would have the greatest operational success. Between the monthly meetings, frequent emails were used for questions and answers and planned sessions in person were accomplished with AACI Clinical Research Innovation (CRI) and Cancer Center Administrators' Forum (CCAF) in-person conferences. Best practices were shared, including feasibility committee, cancer-related definitions, definition of rare cancer, staff reporting structures, and revised PRMS operations.

4. Outcomes

The mentored dyad partnership has successfully onboarded into their CCTO leadership roles and have been successful implementing several items from their dyad mentors including:

- Successful implementation of a trial feasibility committee

- Approval of an IRB hard-stop for cancer-related trials

- Implementation of the following policies: rare cancer definition and cancer-related definition

5. Lessons Learned and Future Directions

The dyad partnership is a critical component to the success of cancer clinical trial office operations. In addition, mentorship by a dyad partnership from another cancer center can lead to successful onboarding of these critical roles, further dissemination of best practices, and knowledge sharing between both cancer centers. It is recommended that AACI work on building a mentorship community with sign-ups from interested cancer center leaders that kicks off during the AACI CRI annual meeting.

The Dynamic Duo: Dyad Mentorship of Cancer Clinical Trials Office (CCTO) Leadership

Authors: Angela Fritsche, MPA[1], Grzegorz Nowakowski[1], MD, Theresa Werner, MD[2], Jessica Moehle, CCRP[2]
[1]Mayo Clinic Comprehensive Cancer Center; [2]Huntsman Cancer Institute

BACKGROUND

Cancer Center Clinical Trials (CCTO) leadership role can often feel like drinking from a firehose, and it does not come with a reference manual.

Mentorship is needed for both medical directors and their administrative directors to assure successful leadership in arguably one of the most complex areas of a Cancer Center. Within a single institution, expertise and critical mentorship can be lacking and direct effort is needed to find identify a compatible mentor outside the institution.

The American Association of Cancer Institutes (AACI) facilitates listservs for both leadership roles along with the annual meeting. Through these venues, a new dyad leadership team from Mayo Clinic Comprehensive Cancer Center (MCCCC) reached out to a dyad leadership team at the Huntsman Cancer Institute for key mentorship of newly appointed CCTO medical and administrative directors.

GOALS

- To understand historical experiences that provided key lessons learned in the dyad leadership team.
- To share best practices, problem solving and operational efficiencies for CCTO, Protocol Review Monitoring System (PRMS), National Cancer Institute (NCI) Site Visits and reporting structures.
- Foster a safe place for mentorship, trust and collaboration on challenging topics.

SOLUTIONS AND METHODS

VIRTUAL CONNECTIONS

- Using virtual connections, the dyad leadership teams met as a group on at least 2 occasions within the year.

ADMINISTRATIVE CONNECTIONS

The administrative partners met monthly during the first year. This was to establish:

- Best practice sharing and mentorship on a variety of topics.
- Establishing trust, confidence and a historical perspective of operations,
- Shared their lessons learned,
- Identified areas that could be quick, successful wins at the institution versus topics and areas that would take longer, were political, but that would have the greatest operational success.

ADMINISTRATIVE BETWEEN CONNECTIONS

- Between the monthly meetings communications included:
- Frequent emails to address questions
- Planned sessions in-person when possible- i.e., AACI CRI and CCAF in-person conferences.

FIGURE 1

Administrative connections were vital to creating a trusting and confident mentorship

Visits were completed over virtual connections, but in-person was also considered when applicable.

Figure 1 represents the communication interactions that took place during the mentorship.

OUTCOMES

DYAD SUCCESS

The mentored dyad partnership has had multiple successes, including:

- Best practices were shared including feasibility committee, cancer-related definitions, definition of rare cancer, staff reporting structures and revised PRMS operations.
- Onboarded into their CCTO leadership roles.
- Implemented several endeavors form their dyad mentors.

IMPLEMENTED ENDEAVORS:

Implemented endeavors include:

- Successful implementation of a trial feasibility committee.
- Approval of an Institutional Review Board (IRB) hard-stop for cancer-related trials.
- Implementation the following policies:
  - Rare Cancer definition
  - Cancer-Related definition

LESSONS LEARNED

The dyad partnership is a critical component to the success of Cancer Clinical Trial Office operations. In addition, mentorship by a dyad partnership from another cancer center can lead to successful onboarding of these critical roles, further dissemination of best practices and knowledge sharing between both cancer centers.

FUTURE DIRECTION

It is recommended that AACI work on building a mentorship community with sign-ups from interested cancer center leaders that kicks off during the AACI CRI annual meeting.

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Retaining Staff through Surveys: 6-Month, Stay and Exit

J. Ludescher, G. Nowakowski, T. Halfdanarson, A. Fritsche, C. Griffin, R. Platou, M. Wrenn, K. Croghan
Mayo Clinic Comprehensive Cancer Center

1. Background

The retention of staff has been under constant surveillance over the past few years due to the Great Resignation. Mayo Clinic Comprehensive Cancer Center (MCCCC) encompasses four regions, including Arizona (ARZ), Florida (FLA), Mayo Clinic Health System (MCHS), and Rochester (RST). To help ensure retention oversight, we established a data collection feedback loop (surveys) that highlights various time points in the study coordinator continuum.

2. Goals

Retention surveys are used across four regions to assess trends; act share regional best practices; address staff frustration; and address gaps in training and continuing education.

3. Solutions and Methods

The retention surveys were built into REDCap and included times points such as 1) 6-month new staff assessment to further enhance training; 2) Stay interviews were structured to understand the "why" staff stay to further magnify these reasons for all staff; and 3) exit interviews, which were conducted by a human resource (HR) representative or People Strategy Program Manager (PM) to understand why staff are departing. REDCap reports were then sent to the PM, who reviews the feedback and forwards to regional leadership; and provides regular updates to senior leadership.

This feedback is used to:

- Modify training programs
- Schedule discussion forums with staff
- Improve processes
- Provide continuing education
- Provide feedback to leadership and Principal Investigators (PIs) on actions to help create a better environment for new and existing staff

4. Outcomes

The surveys have led to the development of a robust people strategy for the Cancer Clinical Trials Office (CCTO) to advise recruitment and retention strategies. The continuous surveys allow leadership to track success of process improvements and identify "stay interventions" earlier on in the process. Leaders were also able to identify opportunities to enhance communication within their teams and units. Staff who are positively highlighted in a survey (good mentor, trainer, co-worker, supervisors) receive an "Above and Beyond" recognition certificate. In reference to the transfer/exit surveys, we can predict when we will have staff turnover which helps inform the staffing to attrition plan.

5. Lessons Learned and Future Directions

The voice of our most precious resource needs to be heard. By understanding opportunities throughout the employment cycle, we can use this information to continue to create an improved environment with meaningful impact. For the future, the supervisors requested to move the new staff survey to 3 months in addition to the 6-month point for earlier intervention with onboarding and training. Departments and divisions across the institution have requested demonstrations of the process and REDCap due to the value of this level of data.

Mayo Clinic Exit, Stay and 6-Month New Hire Survey Process for Allied Staff (Research)

Jay Ludescher, M.B.A. Comprehensive Cancer Center – Cancer Clinical Trials Office
Angie Fritsche, M.H.A. Comprehensive Cancer Center – Cancer Clinical Trials Office

ABSTRACT

BACKGROUND
The retention of staff has been under constant surveillance over the past few years due to the 'Great resignation'. At Mayo Clinic Comprehensive Cancer Center (MCCCC) encompasses four regions, including Arizona (ARZ), Florida (FLA), Mayo Clinic Health System (MCHS), and Rochester (RST). To help ensure retention oversight, we established a data collection feedback loop (surveys) that highlights various time points in the study coordinator continuum.

OBJECTIVE
To collect better feedback during the Exit interview process, to automate the Stay interview process for established staff and introduce a 6-Month New Hire survey.

METHODS
RedCap is the preferred method to collect the feedback.

RESULTS
The surveys have led to the development of a robust people strategy for the Cancer Clinical Trials Office (CCTO) to advise recruitment and retention strategies. The continuous surveys allow leadership to track success of process improvements and identify "stay interventions" earlier on in the process. Leaders were also able to identify opportunities to enhance communication within their teams and units. Staff who are positively highlighted in a survey (good mentor, trainer, co-worker, supervisors) receive an 'Above and Beyond' recognition certificate. In reference to the transfer/exit surveys, we can predict when we will have staff turnover which helps inform the staffing to attrition plan.

CONCLUSIONS
Implementation of the surveys in research has provided more accurate feedback on what is happening in the units and departments. This information has become more actionable for leadership. Other departments in Mayo Clinic are considering implementing these surveys.

INTRODUCTION

Mayo Clinic leadership did not feel like managers and operations managers were receiving accurate information from staff in Exit Interviews. And Stay Interviews took an enormous amount of time and effort to complete and rarely conducted. Lastly, leadership was not hearing from our new hires.

OBJECTIVES

To collect better feedback during the Exit interview process, to automate the Stay interview process for established staff and introduce a 6-Month New Hire survey. The People Strategist partnered with Human Resources to assist in the Exit interview process creating an open space for the departing staff member to share what is working well and what needs to be addressed.

METHODS

The retention surveys were built into REDCap and included times points such as 1) 6-month new staff assessment to further enhance training. 2) Stay interviews were structured to understand the "why" staff stay to further magnify these reasons for all staff; and 3) Exit interviews, which were conducted by a Human Resource (HR) representative or People Strategy Program Manager (PM) to understand why staff are departing. REDCap reports were then sent to the PM, who reviews the feedback and forwards to regional leadership; and provides regular updates to senior leadership.

RESULTS

- Provide feedback to leadership and Principal Investigators (PIs) on actions to help create a better environment for new and existing staff.
- Modify training programs.
- Equip managers with feedback to address needs of employee.
- Exit trends help leadership plan for vacancies (see below).
- Themes are easily identifiable for leadership.
- Schedule discussion forums with staff.
- Provide continued education.
- Improve processes.
- Ability to look at feedback for all sites and identifying trends.
- Success was shared with Nursing leadership who are adopting the Stay Interview process in Florida.
- Identify why staff are leaving Mayo Clinic (see below).

FIGURE 1: EXIT TRENDS (2019-2023)

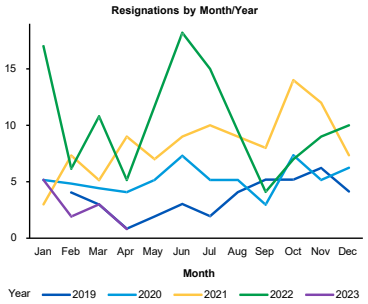
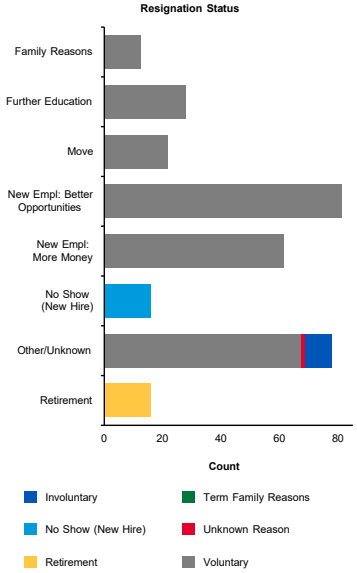


FIGURE 2: REASONS FOR LEAVING MAYO CLINIC



CONCLUSION

The successful implementation of the surveys has had a dramatic effect on managers and staff. Managers receive more tangible feedback and staff feel leadership are listening.

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A Cancer Clinical Trials Office (CCTO) Orientation Course Reduces Insufficiencies Among Study Coordinators

K. Croghan, G. Boe, J. Zbacnik, A. Youssef, A. Holland, G. Nowakowski, A. Fritsche
Mayo Clinic Comprehensive Cancer Center

1. Background

The Mayo Clinic Comprehensive Cancer Center (MCCCC) CCTO serves the clinical investigators and research participants across the MCCCC's academic medical centers in Arizona (ARZ), Florida (FLA), Mayo Clinic Health System (MCHS), and Rochester (RST). The complexity and geographic distribution of staff has led to a lack of standardization among training programs and available resources. While numerous training materials and onboarding processes were developed, the utilization of these resources by CCTO staff was inconsistent and ineffective. In 2019, an RST MCCCC All Staff Survey indicated 33 percent of study coordinator (SC) staff requested a standardized training for new hires. This led to the development of the CCTO SC Orientation in October 2020.

2. Goals

The goal was to establish a MCCCC New Hires Orientation course that would help establish expectations and resources available for study teams, address the decline in retention, and increase familiarity with resources among SC staff.

3. Solutions and Methods

The course covers general topics relating to conducting studies within the CCTO and expands specifically on the requirements and resources available to staff, along with providing examples and walkthrough scenarios. The course utilizes institutional course materials along with CCTO resources housed in the Quality Management System (QMS).

The course is covered over 6-weeks at 3-times/week for 2-hour intervals. A feedback mechanism was also established to capture information from the new hires pre and post course to help identify educational and procedural gaps in the course and/or resources. The gaps would then be fed back to the CCTO Leadership teams to help establish and revise resources and educational material as needed.

Feedback Mechanism includes:

- Chat cohort communication- where anyone can ask questions and the preceptors and supervisors help address in real-time
- REDCap surveys issued pre- and post-orientation course
- Post-orientation assessments at 6-weeks and 6-months via one-on-one sessions between preceptor and attendee
- A 30-question quiz assessment at course completion

4. Outcomes

As of March 2023, the course has completed 12 cohorts with ~130 attendees over multiple units within MCCCC and beyond.

The post-assessment data revealed on average, the attendees feel comfortable with the resources available. They are also reaching out to CCTO team staff with questions, and concerns. This can also be illustrated in our quality review findings in RST and MCHS, where there has been a decline in major findings across delayed SAE reporting and deviation timeline reporting.

5. Lessons Learned and Future Directions

Orientation has become an effective tool and resource for attendees. A focus on establishing continuous resources, course tools and expansion to MCCCC enterprise is underway.

Cancer Clinical Trials Office (CCTO) Orientation Course Reduce Insufficiencies Among Study Coordinators

Authors: Katrina Croghan, M.S., CCRP, Gwen Boe, M.A.N, R.N., Jade Zbacnik, Amanda J Youssef, M.S., Adam Holland M.S., Grzegorz Nowakowski, MD, Angela Fritsche, MPA
Comprehensive Cancer Center, Mayo Clinic

BACKGROUND

The Mayo Clinic Comprehensive Cancer Center (MCCCC) CCTO serves the clinical investigators and research participants across the academic medical centers in Arizona (ARZ), Florida (FLA), Mayo Clinic Health System (MCHS), and Rochester (RST).

The complexity and geographic distribution of staff has led to a lack of standardization among training programs and available resources. While numerous training materials and onboarding processes were developed, the utilization of these resources by CCTO staff was inconsistent and ineffective.

In 2019, an RST MCCCC All Staff Survey indicated 33% of study coordinator (SC) staff requested a standardized training for new hires. This led to the development of the CCTO SC Orientation in October 2020.

TABLE 1: General topic development for CCTO Orientation course

	Topic		
	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

GOALS

Implement a MCCCC New Hires Orientation course that would help:

- Establish expectations and resources available for study teams
- Address the decline in retention
- Increase familiarity with resources among SC staff

SOLUTIONS AND METHODS

ENTERPRISE ASSESSMENTS

A 10-day Orientation to Research course, completed by all study teams new to research.

Competency exam, completed by all SCs at the one-year mark.

CCTO COURSE SETUP

The Orientation course occurs over 6-weeks, 3-times/week in 2-hour intervals.

Covers general topics relating to conducting studies within the CCTO and expands specifically on the requirements and resources available to staff, along with providing examples and walkthrough scenarios.

Resources and Course Materials housed in the CCTO Quality Management System (QMS), which are sustained, and maintained by the MCCCC Quality Management Coordinators.

FEEDBACK MECHANISM

Established to capture information from the new hires pre and post CCTO Orientation course to help identify educational and procedural gaps in the course and/or resources.

The gaps would then be fed back to the CCTO Leadership teams to help establish and revise resources and educational material as needed.

Feedback Mechanism includes:

- Chat cohort communication- where anyone can ask questions and the preceptors and supervisors help address in real-time
- Included Pre- and post-orientation anonymously REDCap surveys.
- Post orientation assessments at 6-week and 6-months via one-on-one sessions between the Preceptor and attendee.
- 30-question review sent to each attendee at the 6-week mark.

OUTCOMES

DEMOGRAPHICS

- As of March 2023, the course has completed 12 cohorts with ~130 attendees over multiple units within MCCCC and beyond.
- The post-assessment data revealed on average, the attendees feel comfortable with the resources available.
- They reach out to CCTO team staff with questions, and concerns. This can also be illustrated in our quality review findings in RST and MCHS, where there has been a decline in major findings across delayed SAE reporting and deviation timeline reporting.

FIGURE 1

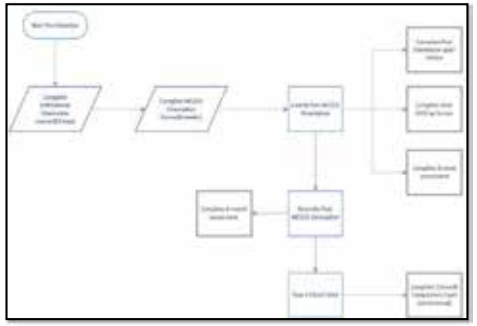

Figure 1 represents the CCTO new Hires Orientation course assessment flow

TABLE 2: Post Survey Confirmation regarding the Preceptors and the Orientation Course

	Survey score (1-5) (see footnotes for key)		
	Preceptors presented constant information	**I had opportunities to ask questions and speak up**	**Preceptors were accommodating to the individual needs**
Average (n=79)	4.74	4.94	4.83
Standard Deviation	0.47	0.30	0.37

Footnotes:

- N=79 included the 65 SC required attendees and a few additional members who wanted to participate in the post-assessments.
- Table 1 Key:
  - 1 & 2 = Strongly disagree/Disagree with the statement
  - 3 = Neutral
  - 4 & 5 = Agree/Strongly agree with the statement.

LESSONS LEARNED

Orientation has become an effective tool and resource for attendees.

A focus on establishing continuous resources to help shift seasoned staff mind set on new and updated Standard Operating Procedures (SOP) is vital.

FUTURE DIRECTION

Focus on education will now turn to:

- Expanding to ARZ, FLA and MCHS where possible
- Continuous education resources and materials for all SC staff using the Quality Management System (QMS)- implementation pending June 2023
- Mentor Training to help guide mentors through the mentorship process
- Disease Education

ACKNOWLEDGMENT

Special thank you to the Rochester study coordination teams and supervisors for participating and precepting the orientation course since cohort 1 (October 2020). In addition, a huge thank you to MCCCC Leadership and Quality Management System (QMS) for all the support and resources to keep the course moving forward.

This work was funded by the Mayo Clinic Comprehensive Cancer Center.

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Going From an In-Person to Remote Training Program: How to Ensure Engagement

V. Tomaselli, M. Nicola
Memorial Sloan Kettering Cancer Center

1. Background

The COVID-19 pandemic confronted us with the challenge of having to quickly convert our highly interactive on-site clinical research training program to a fully remote instructor-led training (ILT) program. Our on-site training program consisted of:

- A series of required pre-requisites (self-paced, web-based courses) to attend in-person, instructor-led learning sessions
- Highly interactive ILTs consisting of exercises utilizing various training environments of various clinical research systems

2. Goals

1. Research available online training platforms that were compatible with our Learning Management System (LMS)

2. Research system requirements for staff to be able to participate remotely

3. Train the trainers in the new methodology (remote vs. in-person)

4. Redesign content, while keeping the sessions highly interactive
   a. Modify content presentation to make it more dynamic and keep staff engaged
   b. Adapt the exercises utilizing training environments so that they can be accessed and completed remotely

3. Solutions and Methods

1. Worked with LMS administrators and clinical research system owners to ensure proper integration of learning platforms

2. Informed managers and supervisors of system requirements staff needed to participate remotely

3. Required all trainers to complete a Facilitating Virtual Training Certificate

4. Reformatted training content to make it suitable for remote trainings: added interactions utilizing various learning tools and assessments offered by the LMS to increase engagement and retention

4. Outcomes

2019: 84 in-person ILTs, 436 total attendees
2020: 86 trainings (18 in-person ILTs, 68 remote), 409 attendees

Learner feedback:
"I felt like I was at an in-person course training. I enjoyed that there were live trainers available to guide me through all of the training guides and information. I also enjoyed how the students were able to remain engaged by doing in-class activities and quizzes."

"Remote training allows for information and practice in clinical systems to be accessible during a time where many of us are not able to be on site."

5. Lessons Learned and Future Directions

The COVID pandemic forced a complete restructuring of our clinical research training program; a program that serves ~900 staff. We faced multiple challenges in ensuring our new remote training program was as highly interactive as our in-person trainings. To avoid disruption to the training program and continue to meet the training needs of an ever-growing and changing training population, we had to make the changes in a two-week period.

1. Assessments of our new remote trainings based on learner feedback and trainer observations allowed for us to make required revisions; additional interactions with the learners were included to address the difficulty of retaining attention and interest that can occur with remote trainings

2. We created instructional materials on how to address/troubleshoot technical issues; delivering a highly interactive session remotely added new technical challenges, therefore, providing additional instructions on how to address potential technical issues allowed the sessions to run more efficiently

As we move forward with our fully remote training program, we are continuously implementing changes to meet current demands and challenges. As we train, we learn how to better deliver content to increase engagement and retention.

Memorial Sloan Kettering Cancer Center

Going from an in-person to remote training program: how to ensure engagement

Tomaselli, Veronica; Nicola, Mayra

Background

The COVID-19 pandemic confronted us with the challenge of having to quickly convert our highly interactive in-person clinical research training program to a fully remote instructor-led training (ILT) program. Our on-site training program consisted of:

- A series of required pre-requisites (self-paced, web-based courses) to attend in-person, ILT sessions
- Highly interactive ILTs consisting of exercises utilizing various training environments of various clinical research systems

Goals

1. Research available online training platforms that were compatible with our Learning Management System (LMS)
2. Research system requirements for staff to be able to participate remotely
3. Train the trainers in the new methodology (remote vs in-person)
4. Redesign content, while keeping the sessions highly interactive
   a. Modify content presentation to make it more dynamic and keep staff engaged
   b. Adapt the exercises utilizing training environments so that they can be accessed and completed remotely

Solutions and Methods

1. Worked with LMS administrators and clinical research system owners to ensure proper integration of learning platforms
2. Informed managers and supervisors of system requirements staff needed to participate remotely
3. Required all trainers to complete a Facilitating Virtual Training Certificate
4. Reformatted training content to make it suitable for remote trainings: added interactions utilizing various learning tools and assessments offered by the LMS to increase engagement and retention

Outcomes

1. **Technology enhancements.** Expanded use of the remote functions of our LMS, including implementation of its Virtual Classroom platform. Created instructional videos and handouts to ensure staff could log in and participate remotely. Although the logistics involved in our trainings became more complex once we went fully remote, we saw an increase in the satisfaction regarding logistics (see Table 2).
2. **Leadership support.** Received approval and support from leadership to restructure the training program to become fully remote.
3. **Developed internal capacity.** To ensure our Trainers met the requirements of remote trainings, they completed a Facilitating Virtual Training Certificate. This certificate, now a requirement for all Trainers, provides skills and tools that foster and maintain engagement within remote trainings.
4. **Interactive Learning Environment.** In order to maintain a highly interactive learning environment that we applied with our in-person trainings, training exercises were re-formatted to fit the remote format. Changes included required participation among all learners (e.g., called on all learners throughout training, use of chat feature), required use of virtual classroom tools (whiteboard, arrows, text boxes, etc.) to respond to exercises and contribute to discussions, and continued use of clinical research systems, but now via remote log-in.

Table 1. "Core" ILT Trainings, 2019-2021

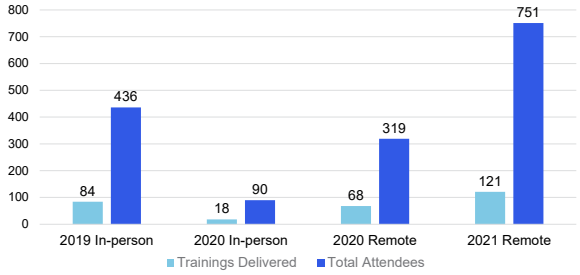
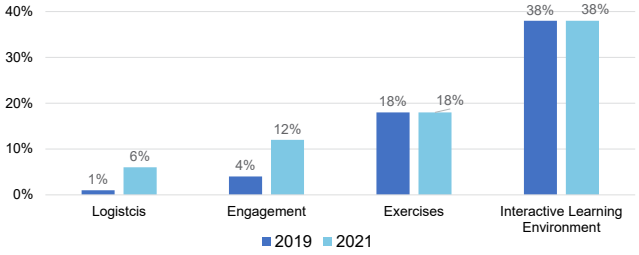


Table 2. What did you like most about the training?



Learner Feedback, Remote Trainings, 2021

> *I liked the varied forms of participation to keep engagement up.*
>
> *I liked that we were kept engaged throughout and had several activities to test out knowledge.*
>
> *I thought this was very well done and easy to stay engaged, which can be hard for online courses.*

Lessons Learned and Future Directions

The goal of the training program for ~900 clinical research staff at MSK is to provide immersive and engaging training experiences to ensure staff retain information and can apply the information in appropriate situations/procedures. Our well-established training program was forced to quickly adapt to the changes brought upon the COVID pandemic. Restructuring from a fully on-site to remote program required various technology enhancements, guidance and approval from leadership, and internal capacity building.

COVID changed the landscape of training, making remote training a necessity. Although we continue to experience new demands that come with providing flexible and adaptable remote trainings, our commitment to providing an interactive and engaging training program remains our guiding principle and reason for our continued success.

The Great Rebound: Successful Clinical Trials Office Staffing Recovery Strategies

K. Morrison, S. Ladd, J. Huamani-Bundy, C. Hilliard, L. Schreiner, N. Whitman, M. Roxas, S. Scott, B. Adams, E. Moore, J. Maccarone, E. Kelly, J. Mayfield, E. Riley, M. Laffan, C. Tew, P. Derebail, S. Rego, L. Kiefer, T. Conrad, B. Marini, G. Harrison, W. Sarratt, V. Bae-Jump, L. Carey, C. Lee

UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

1. Background

The Great Resignation affected all industries, leading to a record-breaking turnover rate. As a result of this trend, the University of North Carolina (UNC) Lineberger Comprehensive Cancer Center (LCCC) experienced an unprecedented staffing shortage. This was further exacerbated by pre-existing local, regional, and industry factors such as UNC LCCC's location in the Research Triangle Park where competition for clinical research professionals is fierce and pharmaceutical pay, benefits, and flexibility historically far exceeded academic research centers. LCCC's staffing crisis was further compounded by a hold on raises for state employees during this time frame, and a lack of a commensurate increase in staff to support substantial portfolio growth in 2019 during which the number of open to accrual studies and interventional accruals increased by 58 percent and 34 percent, respectively. In May 2021, LCCC hit its staffing low with 62 vacancies out of 174 positions. By spring 2022, clinical and regulatory vacancies led to accrual and clinical trial activation holds.

2. Goals

The goal of this initiative was to quickly onboard qualified staff and to increase office capacity while also retaining current staff to enable the LCCC Clinical Trial Office (CTO) to fulfill our mission: Extraordinary Research. Exceptional Care.

3. Solutions and Methods

Staff recruitment: to address immediate staffing needs, several initiatives were put into effect. 1. Increased use of contracting agencies 2. Expanded use of direct reach out as a recruitment tool 3. Creation of remote/hybrid roles to allow for nationwide recruitment 4. Development of roles that required no prior research experience which created an entry point for undergraduate students to join the workforce 5. Development of a workforce pipeline through internships 6. Realignment of salaries to appropriate benchmarks

Staff retention: to retain research staff, several initiatives were put into effect. 1. Metered enrollment based on staff morale and bandwidth 2. Creation of a trial activation slot system based on CTO capacity 3. New/expanded career ladders in key functional groups 4. Salary increases via formal human resources job reclassifications 5. Transition to remote work for non-patient facing staff and hybrid work for patient facing staff 6. In-person and remote teambuilding activities to reshape office culture 7. New career growth opportunities outside of personnel management 8. Professional development offerings for CTO leadership

4. Outcomes

Key outcomes metrics are provided in Table 1.

5. Lessons Learned and Future Directions

The most successful recruitment efforts were the increased use of contractors from a variety of agencies and the creation of entry-level positions allowing for recruitment of undergraduate students. Salary increases and career ladders were the most successful retention methods when coupled with a positive workplace culture. Building workplace culture was driven by teambuilding activities; decreasing the staff to manager ratio, allowing for increased staff support; and creating subject matter expert training positions to alleviate the training burden placed on managers and staff. To ensure the continuation of staff recruitment and retention efforts, LCCC clinical research conducted strategic planning in 2022. Strategic planning led LCCC to initiate organizational structure optimization including hiring a Director of Workforce Development & Administration to lead and sustain focus on staff recruitment, development and belonging.

UNC LINEBERGER COMPREHENSIVE CANCER CENTER

The Great Rebound: Successful Clinical Trials Office (CTO) Staffing Recovery Strategies

UNC CANCER CARE

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Background & Goals

Great Resignation affected all industries, leading to a record-breaking turnover rate. As a result of this trend, the University of North Carolina (UNC) Lineberger Comprehensive Cancer Center (LCCC) experienced an unprecedented staffing shortage. This was further exacerbated by pre-existing local, regional and industry factors such as UNC LCCC's location in the Research Triangle Park where competition for clinical research professionals is fierce and pharmaceutical pay, benefits and flexibility historically far exceeded academic research centers. LCCC's staffing crisis was further compounded by a hold on raises for state employees during this timeframe, and a lack of a commensurate increase in staff to support substantial portfolio growth in 2019 during which the number of open to accrual studies and interventional treatment accruals increased by 58% and 34%, respectively. In May 2021, LCCC hit its staffing low with 62 vacancies out of 174 positions. By spring 2022, clinical and regulatory vacancies led to accrual and clinical trial activation holds.

The goal of this initiative was to quickly onboard qualified staff and to increase office capacity while also retaining current staff to enable the LCCC Clinical Trial Office (CTO) to fulfill our mission: ***Extraordinary Research. Exceptional Care.***

Solutions & Methods

Staff Recruitment: To address immediate staffing needs several initiatives were put into effect: 1. Increased use of contracting agencies (**Figure 1**), 2. Expanded use of direct reach out as a recruitment tool, 3. Development of roles that required no prior research experience which created an entry point for undergraduate students to join the workforce (**Figure 2, 3 and 4**), 4. Creation of remote/hybrid roles to allow for nation-wide recruitment (**Figure 3**), 5. Development of a workforce pipeline through internships (**Table 1**), and 6. Realignment of salaries to appropriate benchmarks (**Figure 5**).

Figure 1. Contract Agencies

2019	2022
Advanced Group	Advanced Group
Actalent	Actalent
Medix	Medix
Piper	Piper
Procom	Procom
University Temporary Services	University Temporary Services
	Astrix
	Insight Global
	WCG
	Medasource

Figure 1. The CTO increased use of contracting agencies expanding from 6 to 10 agencies tasked with recruiting contract staff to join the CTO in a variety of positions ranging from study coordinators (SC) to regulatory associates (RA) to OnCore™ pre-award financial analysts. These contracting agencies recruited for both direct placement and 6-12 month contract roles. This substantially increased the # of contractors hired into the CTO in 2022.

Senior staff with the CTO also focused on recruiting former peers and friends to join the CTO, with one staff member recruiting a remarkable 7 applicants leading to 3 permanent hires for senior-level positions within a 9-month period.

Staff Retention: To retain research staff, several initiatives were put into effect: 1. Metered enrollment based on staff morale and bandwidth, 2. Creation of a trial activation slot system based on CTO capacity, 3. New/expanded career ladders in key functional groups (**Figure 4**), 4. Salary increases via formal HR job reclassifications (**Figure 5**), 5. Transition to remote work for non-patient facing staff and hybrid work for patient facing staff (**Figure 3**), 6. In-person and remote teambuilding activities to re-shape office culture (**Figure 6**), 7. New career growth opportunities outside of personnel management (**Figure 3 and 4**), and 8. Professional development offerings for CTO leadership (**Figure 7**).

Figure 2. Entry-Level Assistant Study Coordinators

Figure 2. An Assistant Study Coordinator role was developed and 6 FTEs were hired as a solution to offset coordinator burnout and create a feeder pool of employees who would spend a year gaining incrementally more advanced experience within the office. Two dedicated training roles were developed to support the training of 50 staff hired in 2022 alone. A dedicated on-site trainer bridged the gap for employees unfamiliar with our campus due to being hired in a hybrid work environment. A SME professional track was created and serves as an alternative to the previously established management professional track for advancement.

Table 1. Building the Pipeline Internships

Internship Name	UNC Lineberger & North Carolina Central University (NCCU)-Building Oncology Workforce Summer Internship	UNC Lineberger Clinical Development ImPACT Internship	Office of Clinical Translational Research Internship
Brief Description	2-year longitudinal summer internship for 5 North Carolina Central University (NCCU) undergraduate students that focuses on longitudinal mentorship as well as exposure to cancer clinical research, clinical care of cancer patients, and professional development activities.	Internship offered through the UNC Training Initiatives in Biomedical and Biological Sciences (TIBBS) Program, which provides PhD students with internships that allow career exploration and professional development opportunities.	The TSHS Clinical Research Internship is a semester-long program that is designed to provide undergraduate students with an introduction to clinical research and healthcare.
Target Interns	BIPOC Undergraduate Students, from NCCU, an HBU	UNC Life Science PhD Candidates	UNC Undergraduate Students
Paid/Unpaid	Stipend	Salary Support	1st Cohort Paid
Curriculum Description	• Clinical research courses • Career panels • Lecture series • Clinical rotations • SC shadowing • 1:1 Mentorship • Professional development seminars	• Asynchronous clinical development/regulatory courses • Clin dev/regulatory shadowing • Training on medical writing with assigned projects to complete • Oversight Committee/IRB meeting attendance • 1:1 Mentorship	• SC, lab & provider shadowing • Clinical research workshops

Table 2. Pipelines of future clinical research staff were developed by training students at UNC and NCCU in clinical research

Solutions & Methods

Figure 3. Functional Group Recruitment/Retention Methods

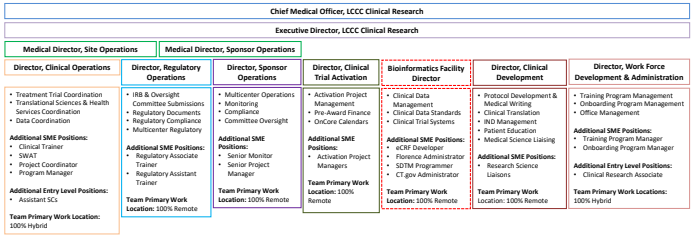

Figure 3. Additional subject matter expert (SME) positions were added within each functional group to allow for continued growth and development of staff outside of management of direct repots. In response to the pandemic, UNC's School of Medicine (SOM) added flexibility in staff primary work locations, increasing the CTO's ability to create hybrid and remote roles. Each functional group was re-evaluated by the CTO to determine the business needs for onsite presence resulting in all non-patient facing teams being transitioned to remote work . Clinical teams remained hybrid work with additional flexibility to work from home more frequently. To meet the business needs, each disease group is required to have 1 member of the clinical team onsite and readily available to consent newly identified patients. Furthermore, for all in person visits, clinical staff come on site to support study subjects. These onsite SCs with scheduled visits are in addition to the onsite consenting support for the disease group. Not only did transitioning to more flexible work improve the work/life balance and satisfaction of the CTO team, creating an inducement for clinical research staff interviewing for CTO roles to accept them, it also enabled nation-wide searches for high quality and hard to find talent.

Figure 4. New/Expanded Career Ladders

Figure 4. Career ladders were created in key functional groups, such as (A) Clinical Operations, and (B) Sponsor Operations. This allowed for incremental growth and development of staff in-house and recognition for their step-wise growth of expertise. Furthermore, new growth opportunities outside of personnel management were development such as the Clinical Trainer & SWAT SC in Clinical Operations and Senior Monitor and Senior Project Manager in sponsor operations.

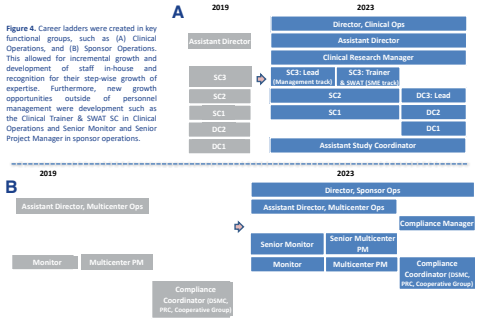

Figure 5. CTO Salary Growth

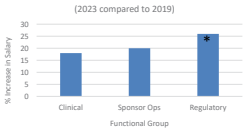

Figure 5. CTO salaries were realigned to appropriate benchmarks to recruitment new talent and retain current talent. *2023 projected increases.

Figure 6. CTO Teambuilding

Types of Activities	• Lunch & Learns • Meal (Breakfast, Lunch, Happy Hour) • Games (Bowling, Drive Shack, Baseball, Trivia) • Art& Crafts (Wine & Design) • Retreats
Goal	Connect teams in fun ways. Driving in-person connection for teambuilding. Creating a culture of gratitude.
Groups	1. Each disease group, 2. Leadership, 3. Behind-the-scenes staff
Funding	Yes, amounts based on group size
Frequency	Quarterly
Owner	Disease Groups: Disease Group Leader Leadership: Executive Director Behind-the-Scenes Staff: Rotates functional groups
Required Attendance	No
Timing	Preference- during work, after work, weekends

Figure 6. Teambuilding events balance in-person connection with not requiring staff to come back to the office. Overwhelmingly these events have received positive feedback from staff who love working at home, but miss the connection with their peers.

Figure 7. CTO Leadership Development

Goal	Provide professional development to the super stars to keep them in-house. Grow strong leaders to support retention of staff.
2022 Activities	• SME Conferences (e.g., AACI CRI) • Leadership Conferences (Workhuman Live) • Workshops (How to Conduct a 1:1 Bootcamp) • Leadership Coaches
2023 Plans	• Crucial Conversations 2-day Workshop • Leadership Books (Multipliers by Liz Wiseman & Reality-Based Leadership by Cy Wakeman) • Leadership Playing Cards (Management Mess to Leadership Success by Scott Miller • UNC-Based Leadership Development Program (ULead) • SME Conferences (e.g., AACI CRI) • Leadership Conference (Workhuman Live) • Leadership Onboarding Program

Executive Director discretionary funds outside of the CTO budget to dedicate to leadership development.

Outcomes

Figure 8. CTO Vacancies, Growth, Attrition & Re-staffing

Remote work allowed for recruitment from new talent pools. For example, as of May 2023, the regulatory team has 18% out of state employees & 9% in-sate employs living ≥2 hours from the cancer center (27% overall)

99 new staff members onboarded January 2022 to December 2022

96% (24 of 25) contractors converted in 2022.
7 resigned prior to completing their contractions & being invited to apply for permanent positions.
Contractor conversion rate = % of individuals invited to convert to permanent positions who ultimately accepted a permanent position

Activation Capacity (2023 compared to 2019 & 2022) Increased
23 additional interventional treatment trial slots

Figure 8. 2019 was a banner year for the CTO, with the number of open to accrual studies and interventional treatment accruals increasing by 58% and 34%, respectively leading to the need to increase the workforce to support this additional workload. (A) The number of positions within the CTO grew from 137 to 199 from 2019 to 2022. % vacancy increased from 2019 to 2021 before reducing to an all-time low in 2022, with only new leader-level positions needing to be filled. (B) The % increase in the # of positions in the CTO (2029 compared to 2022) as a whole and each functional group to cover the increased workload and provide further opportunity for CTO portfolio and accrual growth. (C) Vacancies due to increasing the size of the office were further compounded by an increase in the attrition rate. Attrition rate is defined as the # of staff leaving the CTO for an external opportunity ÷ total staff in CTO. Attrition rate was high (12%) in 2019 due to the increase in workload without the subsequent increase in staffing leading to burnout. Attrition rate decreased in 2020 due to the covid-19 pandemic, but then skyrocketed to a 4-year high of 13% during the Great Resignation. The attrition rate was then substantially decreased in 2022 by 4.5% (8.5% attrition).

Learns Learned & Future Directions

The most successful recruitment efforts were the increased use of contractors from a variety of agencies and the creation of entry-level positions allowing for recruitment of undergraduate students. Salary increases and career ladders were the most successful retention methods when coupled with a positive workplace culture. Building workplace culture was driven by teambuilding activities, decreasing the staff to manager ratio allowing for increased staff support, and creating subject matter expert training positions to alleviate the training burden placed on managers and staff. To ensure the continuation of staff recruitment and retention efforts, LCCC clinical research conducted strategic planning in 2022. Strategic planning led LCCC to initiate organizational structure optimization including hiring a Director of Workforce Development & Administration to lead and sustain focus on staff recruitment, development and belonging.

Innovative and Inclusive Approach to Clinical Research Pharmacist Development

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Yale Cancer Center, Yale School of Medicine

1. Background

Investigational pharmacists are responsible for the proper maintenance, preparation, and documentation of hundreds of investigational drugs, yet post-graduate pharmacists typically do not have access to an in-depth cross-training environment with collaborating research-focused departments. Yale New Haven Hospital (YNHH) is currently one of the leading institutions in the nation for the development and implementation of research pharmacy training, which allows for an opportunity to standardize post-graduate research pharmacy training and cultivate a stronger partnership across all involved in the research endeavor, including integration with the Human Research Protection Program, Institutional Review Board, Yale Cancer Center Clinical Trials Office, Yale Center for Clinical Investigation, and sponsors. Focusing on a more comprehensive, hands-on, and inclusive research-based training for incoming research pharmacy residents will increase interest and engagement of research pharmacists. Additionally, integration and training across ancillary research groups will also improve the collaboration and communication between investigational pharmacists and research teams, thereby improving protocol compliance and patient safety.

2. Goals

There is a need to standardize the pharmacy residency training related to practical application of research. All existing research pharmacists have had onsite training but have not had access to a robust, comprehensive post-graduate program to support safe and compliant research practice. The goal of this partnership is to provide focused, post-graduate Research Pharmacy training with practical application of research, protocol compliance, and patient safety that will further cultivate relationships between researchers and YNHH.

3. Solutions and Methods

The Investigational Drugs and Research Post Graduate Year-2 (PGY-2) Residency offers a year-long, systematic education and training through the American Society for Health-System Pharmacy (ASHP) for new graduates to integrate into research pharmacy services, enabling them to provide highest quality of pharmaceutical care. Standard competencies from ASHP were utilized to address key areas of development for PGY-2 Residents and were addressed via a cross-functional, integrative approach with various stakeholders. Each resident in the year-long rotation spent four weeks in collaborative dedicated areas. At the end of the program, the resident completed an exemplar highlighting the work completed and lessons learned, demonstrating an "expert working knowledge of the clinical research study process, human subject protection, and national and local regulations governing drug research. They are responsible for providing information to the appropriate health care team members including pharmacy staff that may be unfamiliar with the investigational drug product, enabling them to correctly dispense it as described in the clinical protocol and ensure its safe use." The cumulative experience was captured in PharmAcademic.

4. Outcomes

The pharmacy resident was able to adequately demonstrate a robust understanding of the research endeavor. The resident continued to support and guide study team members following the completion of the program, regularly integrating with the team. Of the two graduates of the program to date, both have accepted permanent research pharmacy roles utilizing their experiences from this program.

5. Lessons Learned and Future Directions

The PGY-2 Residency Program has been successful at our site thus far and plans for future pharmacy residents continue. Given the wide integration of the residents with the research teams, our site recommends implementing this program at other sites where available.

Yale NewHaven Health
Yale New Haven Hospital

Innovative and Inclusive Approach to Clinical Research Pharmacist Development

Kira Pavlik, Ruta Sawant, Linda Coleman, Stephanie Brogan, Thomas Ferencz, Prashant Patel

Yale Cancer Center; Yale Center for Clinical Investigation; Yale University School of Medicine &
Department of Pharmacy Services; Smilow Cancer Hospital at Yale New Haven Health, New Haven, CT

Yale NewHaven Health
Smilow Cancer Hospital

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Objective

There is a need to standardize the pharmacy residency training related to practical application of research. All existing research pharmacists have had onsite training but have not had access to a robust, comprehensive post- graduate program to support safe and compliant research practice. The goal of this partnership is to provide focused, post-graduate Research Pharmacy training with practical application of research, protocol compliance, and patient safety that will further cultivate relationships between researchers and YNHH.

Method and Results

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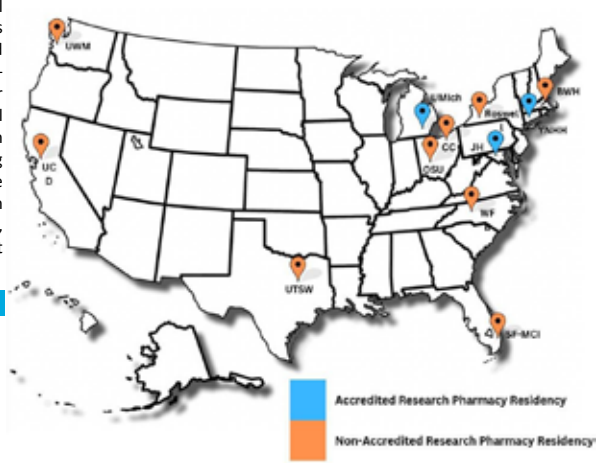

Discussion & Recommendations

The pharmacy resident was able to adequately demonstrate a robust understanding of the research endeavor. The resident continued to support and guide study team members following the completion of the program, regularly integrating with the team. Of the two graduates of the program to date, both have accepted permanent research pharmacy roles utilizing their experiences from this program.

This PGY-2 residency program has been granted full accreditation by the American Society of Health System Pharmacists. Each former graduate and this year's current graduate have accepted employment positions in this chosen specialty in academic practice settings.

Conclusions

The PGY-2 Residency Program has been successful at our site thus far and plans for future pharmacy residents continue. Given the wide integration of the residents with the research teams, our site recommends implementing this program at other sites where available.

In addition, there is a need for standardized ongoing continuing education related specifically to research pharmacy. We recommend an accreditation program similar to SOCRA or ACRP for research pharmacists to assist with education, training, development, and retention.

Acknowledgements

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Training for Excellence in Clinical Research: 5 Years of Growth

M. Guy, M. Kilbane, K. McCaffrey
Cleveland Clinic, Taussig Cancer Institute

1. Background

A training program was established in February 2019 to provide standardized onboarding to research coordinators. The structure was designed with a monthly rotating curriculum of 33 modules to introduce new caregivers to data and regulatory during live training sessions. The modules are enriched by connecting the new hire with a mentor and increasing supervisor engagement. This model was the springboard for future enhancements.

2. Goals

- Maintain positive morale
- Implement a competency log for the new hire to take ownership of their growth, assist the mentor with task delegation, and show the supervisor areas of success and where improvement is needed
- Add interactive polls to enhance discussion during live training sessions
- Launch MyLearning Assessments to provide metrics on retention and development

3. Solutions and Methods

The feedback revealed that new hires desired hands-on experience outside of the six (one-hour) weekly training sessions. The trainer designed one of the weekly sessions to be collaborative for research coordinators to ask questions, provide demonstrations, share experiences, and discuss current tasks. Additionally, the mentorship involvement increased to scheduling standing meetings once or twice a week, instead of an as needed basis. Initiating a routine, released the burden of new hires feeling like they were constantly "bothering" their mentor(s), peer(s), supervisor, and/or trainer. A new attendance requirement for the rotating curricula was set to two rounds instead of one, to strengthen knowledge of tasks and responsibilities.

4. Outcomes

Currently, 104 research coordinators have completed the training program. A continuous improvement team of new hires was created in November 2021 to enhance the tools and resources available during onboarding. In February 2022, a committee was created to review and update the Clinical Trial Management Tool (CTMT) in real time, offloading this responsibility from one individual to a self-sustaining working group. In 2019, "I get the training I need to do a good job" was listed as a concern on the Press Ganey Survey with a score below the national health care average. Most recent survey results (2022) to the equivalent question, "I get the tools and resources I need to provide the best care/service for our patients" was a strength, scoring above the national average.

5. Lessons Learned and Future Directions

- Introduce improvements to the multifaceted training
  - Collaborate with the clinical research trainer to provide mandatory education sessions each quarter to both clinical and non-clinical team members
  - Offer quarterly quality assurance (QA) training to all research coordinators
  - Standing weekly new hire/mentor discussions to review competency log
  - Interactive polls highlight key tasks while adding valuable engagement
  - Dedicate one training session a week to collaborative review of new hires experience
  - Require two rounds of attendance to reinforce awareness of responsibilities
- Supervisor engagement remains vital to the success of the program
  - Trainer provides feedback to the supervisor for 90 day review
- Trainer shifted to the Quality Assurance Team to ensure findings are incorporated (preventative measures) in the educational material
- Scheduled to launch MyLearning Assessments in April 2023 for each module to confirm retention of key information
- Future development of standing support meetings for trainer/mentor touch base

Cleveland Clinic

Training for Excellence in Clinical Research: 5 Years of Growth

Makenzie Guy, MBA, Megan Kilbane, MBA, and Kate McCaffrey, MBA
Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH

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GOALS:

- Obtain feedback from new hires on the training program and maintain department engagement in its success
- Implement a competency log for the new hire to take ownership of their growth, assist the mentor with task delegation, and show the supervisor areas of success and where improvement is needed
- Add interactive polls to enhance discussion during live training sessions
- Launch MyLearning Assessments to provide metrics on retention and development

SOLUTIONS AND METHODS:

New hire feedback revealed the need for a more hands-on experience outside of the six 1 hour weekly training sessions

- The trainer designed a new collaborative weekly session designed for new research coordinators to ask questions, provide demonstrations, share experiences, and discuss current tasks

New hires commented they felt they were constantly “bothering” their mentor(s), peer(s), supervisor, and/or trainer

- Mentorship involvement improved by requiring a once a week meeting between new hire and mentor
- A new attendance requirement for the rotating curricula was set to two rounds instead of one, to strengthen knowledge of tasks and responsibilities

OUTCOMES:

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“I get the training I need to do a good job” was listed as a concern on the 2019 Press Ganey Survey with a score below the national healthcare average. Most recent survey results (2022) to the equivalent question, “I get the tools and resources I need to provide the best care/service for our patients” was a strength, scoring above the national average.

LESSONS LEARNED AND FUTURE DIRECTIONS:

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- Trainer position was moved to the Quality Assurance Team to provide closer communication and to ensure findings/re-education opportunities are incorporated (preventative measures) in the educational material
- MyLearning Assessments were launched in May 2023, onboarding research coordinators will complete each module to confirm retention of key information
- Future development of standing support meetings for trainer/mentor touch base

Investing in the Future: Protocol Review Mentorship Program for Oncology Fellows at the Duke Cancer Institute

C. Riggan, A. Bender, A. Armstrong
Duke Cancer Institute, Duke University Medical Center

1. Background

Scientific peer review is critical for pre-IRB oversight of protocols involving cancer patients, but this process is presently not formally taught to trainees. We sought to overcome this unmet need and to develop future academic oncology faculty with expertise in protocol review and oversight, the Duke Cancer Institute's PRMC and the Office of Cancer Research Training & Education Coordination (CRTEC) designed a PRMC Fellows Program for rising third year Duke medical oncology fellows.

2. Goals

1. Create a mentorship program for rising third year Duke medical oncology fellows
2. Give fellows the skills, training, and confidence to participate as full members in the PRMC
3. Collect metrics on this pilot program to improve its efficacy and expand to other trainee groups

3. Solutions and Methods

In 2022, the PRMC and CRTEC offices created and administered a survey to fellows to gauge their interest in participating in a PRMC mentorship program. Following positive responses, we developed and pilot tested a 6-month long curriculum.
Each fellow attended a virtual welcome training with the lead PRMC chair, the associate director of CRTEC and PRMC staff. Fellows completed an electronic IRB training with PRMC staff to learn how to navigate the system and review protocol assignments. They were then paired with an existing PRMC medical reviewer mentor for six months.
In this initial pilot, three mentors and three mentees were matched based on availability, not fields of interest. Mentees attended one PRMC meeting per month with their mentor for six total meetings. Mentors/mentees met before the meeting (virtually or in person) to discuss assignments and conduct review training. During months 1-3 the mentor presented the review; during months 4-6 the mentee presented the review to the full committee with the mentor review in parallel. Following each meeting, the pairs were encouraged to debrief. Additional mentee training opportunities included 30-minute virtual trainings with PRMC statistician, pharmacist and patient advocate roles and a program mid-point meeting with lead PRMC chair.

4. Outcomes

At the program mid-point, mentors and mentees were surveyed regarding the program and opportunities for improvement.

Overall, mentee and mentor responses were positive. All three fellows indicated that they were "likely" or "extremely likely" to join a PRMC like committee once they became faculty. One mentee wrote, "The valuable opportunity to participate in engaged discussions about clinical trial design with experienced faculty has been the highlight of the program."

At the conclusion of the 6-month program, the fellows were presented with a certificate of completion for their own file.

5. Lessons Learned and Future Directions

The mid-point survey and the check in with the lead PRMC chair allowed fellows to express any concerns or critiques that they had of the program. Based on this feedback, the PRMC staff edited the initial interest survey, to include detailed information about program requirements. This program is ideal for future academic oncologists, including medical, radiation, surgical, and pathology fellows or residents or non-physician trainees who will be conducting clinical research involving patients with cancer.

Investing in the Future: Protocol Review Mentorship Program for Oncology Fellows *at the Duke Cancer Institute*

Colleen Riggan, BSN, RN, CCRP, Ali Bender, MAEd, Andrew Armstrong, MD, ScM, FACP
Duke Cancer Institute, Duke University, Durham, NC

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DCI PRMC/CRTEC Fellows

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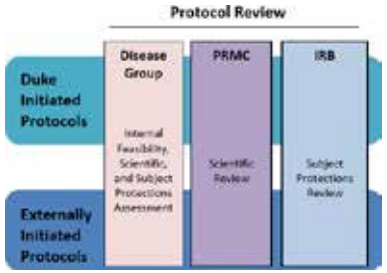
In this initial pilot, three mentors and three mentees were matched based on availability, not fields of interest. Mentees attended one PRMC meeting per month with their mentor for six total meetings.

Mentors/mentees met before the meeting (virtually or in person) to discuss assignments and conduct review training. During months 1-3 the mentor presented the review; during months 4-6 the mentee presented the review to the full committee with the mentor review in parallel. Following each meeting, the pairs were encouraged to debrief. Additional mentee training opportunities included 30-minute virtual trainings with PRMC statistician, pharmacist and patient advocate roles and a program mid-point meeting with Lead PRMC Chair.



Outcomes

At the program mid-point, mentors and mentees were surveyed regarding the program and opportunities for improvement.

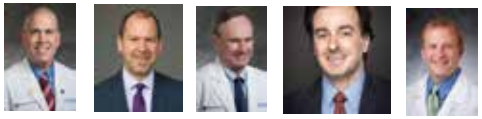
Overall, mentee and mentor responses were positive. All three fellows indicated that they were "likely" or "extremely likely" to join a PRMC like committee once they became faculty. One mentee wrote "The valuable opportunity to participate in engaged discussions about clinical trial design with experienced faculty has been the highlight of the program."

At the conclusion of the 6-month program, the fellows were presented with a certificate of completion for their own file.

Lessons Learned & Future Directions

Based on fellow feedback, the PRMC Staff edited the initial interest survey to include detailed information about program requirements.

This program is ideal for future academic oncologists, including medical, radiation, surgical, and pathology fellows or residents or non-physician trainees who will be conducting clinical research involving patients with cancer.



DCI PRMC/CRTEC Faculty Mentors

"The valuable opportunity to participate in engaged discussions about clinical trial design with experienced faculty has been the highlight of the program."

-DCI PRMC/CRTEC Fellow

Narrowing the Gap – The Synergistic Effect of the Clinical Trials Nurse Liaison

L. Lujan, S. Sharry, J. Moehle, R. Doering, A. Emett, J. Jones, C. Kotobalavu, M. Dolim, T. Werner, H. Soares
Huntsman Cancer Institute at the University of Utah

1. Background

Scientific peer review is critical for pre-IRB oversight of protocols involving cancer patients, but this process is presently not formally taught to trainees. We sought to overcome this unmet need and to develop future academic oncology faculty with expertise in protocol review and oversight, the Duke Cancer Institute's PRMC and the Office of Cancer Research Training & Education Coordination (CRTEC) designed a PRMC Fellows Program for rising third year Duke medical oncology fellows.

2. Goals

1. Create a mentorship program for rising third year Duke medical oncology fellows
2. Give fellows the skills, training, and confidence to participate as full members in the PRMC
3. Collect metrics on this pilot program to improve its efficacy and expand to other trainee groups

3. Solutions and Methods

In 2022, the PRMC and CRTEC offices created and administered a survey to fellows to gauge their interest in participating in a PRMC mentorship program. Following positive responses, we developed and pilot tested a 6-month long curriculum.
Each fellow attended a virtual welcome training with the lead PRMC chair, the associate director of CRTEC and PRMC staff. Fellows completed an electronic IRB training with PRMC staff to learn how to navigate the system and review protocol assignments. They were then paired with an existing PRMC medical reviewer mentor for six months.
In this initial pilot, three mentors and three mentees were matched based on availability, not fields of interest. Mentees attended one PRMC meeting per month with their mentor for six total meetings. Mentors/mentees met before the meeting (virtually or in person) to discuss assignments and conduct review training. During months 1-3 the mentor presented the review; during months 4-6 the mentee presented the review to the full committee with the mentor review in parallel. Following each meeting, the pairs were encouraged to debrief. Additional mentee training opportunities included 30-minute virtual trainings with PRMC statistician, pharmacist and patient advocate roles and a program mid-point meeting with lead PRMC chair.

4. Outcomes

At the program mid-point, mentors and mentees were surveyed regarding the program and opportunities for improvement.

Overall, mentee and mentor responses were positive. All three fellows indicated that they were "likely" or "extremely likely" to join a PRMC like committee once they became faculty. One mentee wrote, "The valuable opportunity to participate in engaged discussions about clinical trial design with experienced faculty has been the highlight of the program."

At the conclusion of the 6-month program, the fellows were presented with a certificate of completion for their own file.

5. Lessons Learned and Future Directions

The mid-point survey and the check in with the lead PRMC chair allowed fellows to express any concerns or critiques that they had of the program. Based on this feedback, the PRMC staff edited the initial interest survey, to include detailed information about program requirements. This program is ideal for future academic oncologists, including medical, radiation, surgical, and pathology fellows or residents or non-physician trainees who will be conducting clinical research involving patients with cancer.

Narrowing the Gap – The Synergistic Effect of the Clinical Trials Nurse Liaison

Lujan, Leanne, BS, CCRP; Sharry, Susan, BS, CCRP; Moehle, Jessica, BS, CCRP; Doering, Ryan, MSN, RN, OCN; Emett, Amanda, BSN, RN; Jones, Jen, RN, BSN, OCN; Kotobalavu, Cassidy, MS, RN, OCN; Dolim, Megan, MS, RN, OCN; Werner, Theresa, MD; Soares, Heloisa, MD, PhD
Huntsman Cancer Institute, University of Utah

BACKGRO UND

Research participants can be seen in multiple inpatient and outpatient settings across the cancer institute as a part of their treatment and care on a clinical trial. The clinical research coordination team is largely comprised of non medically trained staff with a heavy administrative focus. Implementing strategies to bridge the gap between research administration and clinical care professionals in these key service areas across the research enterprise is imperative to ensure participant safety, satisfaction, and protocol compliance. In support of this, we identified the need for a supportive link to aid in strengthening our collaborative efforts where we could more formally establish clear lines of communication, improve education related to the care and treatment of trial participants, as well as define and implement shared work practices and a delineation of duties between the research team and clinical staff members.

GOALS

- Create a new clinical trials nursing liaison position(s) (CTL) to act as a supportive link between the CTO and the Infusion and Inpatient service lines to share institutional knowledge, provide nursing expertise and ongoing education to team members, in both research and clinical patient care teams, from trial prescreening through activation and trial conduct.
- Improve compliance by reducing deviations in the Infusion and Inpatient areas.
- Establish formal shared work practice guidance documents to ensure consistency and more seamless continuity of patient care.

UNIVERSITY OF UTAH HUNTSMAN CANCER INSTITUTE

2017
- The first CTL position funding approved, posted, and filled to support the Infusion center.

2018
- Established complex trials team of Infusion nurses to work under the direction of the CTL. Further refined job description to better accommodate research efforts based on experience from the previous year.

2020
- Discussions to add an additional CTL with a focus on Inpatient service areas to support the growing cellular immunotherapy portfolio in solid and Hematologic malignancies.

2021
- 2nd CTL position funding approved, posted, and filled to support Inpatient service areas.

SOLUTIONS AND METHODS

- Collaboration between key CTO and clinical stakeholders to establish funding mechanisms, reporting structure, and a detailed job description for the new CTL position/s.
- CTLs added as members of the Feasibility Administrative Review (FAR) Committee to vet all new research protocols for the feasibility of clinical integration.
- Involvement in SIV and logistics meetings to ensure appropriate resources and education is provided to the study team/s.
- Monthly connection meetings with CTLs and their respective leaders to ensure ongoing process improvement.

OUTCO MES

Established new shared work practice guidelines: resulting in improved communication, education, and an overall reduction of protocol deviations.

- After-hours care: Transition from Infusion to the Huntsman Acute Care clinic (HAC)
- Notification of Consent and Enrollment communication workflow.
- Collaboration on Fast Fact Sheets, Nursing Instruction Sheets, and Drug Administration Sheets.

FUTURE PLANS

Collaboration and communication to ensure continuous process improvement.
Ongoing consideration of additional CTL positions to support the growth of clinical trials.

HEALTH UNIVERSITY OF UTAH

Adding to the Career Ladder of Clinical Research Staff at IUSCCC

L. Haney, F. Kerr, J. Spittler, L. Rohn, J. Corman, L. Sego, C. Nelson, S. Bailey, M. Contreraz, T. Lautenschlaeger
Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. Background

The original staffing model disease-oriented teams (DOT) of the IU Simon Cancer Center (CC) prior to its distinction of Comprehensive Cancer Center included patient facing research staff consisting of physicians and clinical research nurses (CRN). Within each DOT other research roles were non-patient facing focused. The Clinical Trials Office (CTO) has grown in the number of clinical trials overall for which the former staffing model of direct patient facing staff was no longer sustainable.

Staffing shortages and budget constraints during the COVID-19 pandemic left the CTO like many other institutions – short on qualified research nurses. IUSCCC CTO leadership met with leaders across multiple cancer centers across the United States and research units within IU to construct a solution for the use of non-nursing staff within the scope of subject care. The Clinical Research Patient Specialist (CRPS) model was created with the focus of relieving CRN tasks, dividing workload efforts, providing comprehensive care for subjects and efforts to improve staff retention.

2. Goals

- Have CRPS be protocol experts for non-therapeutic and therapeutic clinical trials in the clinical setting
- The CRPS and physician work together to accomplish study related assessments in real time
- Allow CRN to focus on high-risk, Phase I, and early development clinical trials
- Increase overall accruals to both non-therapeutic and therapeutic trials

3. Solutions and Methods

- Work closely with physicians, CRNs and CRPS to establish expectations and designated responsibilities of each role
- Office-wide source documents were updated to emphasize requirements of both CRPS and CRN/MD
- Standard operating practices (SOPs) were updated to include role-specific information
- Guidance documents and training materials were created for the CRPS role
- A CRPS-specific mentor was added to the Quality and Education Team with experience in the role to enable faster troubleshooting
- Collaborated with IU Health for training specific to the electronic medical record system
- Provide disease specific training and basic assessment skills for the CRPS

4. Outcomes

- Twenty CRPS positions have been integrated into DOT
- Over the past two years averaging an increase in accruals
- Successfully integrated the CRPS role into the daily workflow of multiple therapeutic trials at our satellite site
- CRPS managing research patients on non-therapeutic trials

5. Lessons Learned and Future Directions

The CRPS model has shown to be effective in relieving responsibilities of CRNs when implemented effectively. Education, training, and trust are imperative for a smooth transition. Across several DOTs the CRPS model have demonstrated to be effective in managing non-treatment/non-therapeutic studies. Managing workload and integration of CRPSs into existing teams does have some difficulty. Many of the CRPSs have never been patient facing and therefore physicians and nurses must be preceptors. Existing CRNs who are used to managing every aspect of a subject's care are sometimes hesitant to delegate more than menial tasks to a CRPS. There are also limitations to what degree of documentation CRPSs are allowed to complete (collect adverse events [AEs], but not grade or assign relatedness of AEs). Teams who are reluctant to use CRPSs to their full potential will not see more than administrative relief, while teams who fully embrace these collaborations in workflow have a partner in the subject's care rather than an administrative assistant.

Adding to the Career Ladder of Clinical Research Staff at IUSCCC

LaTrice Haney, R.N.; Fyalon Kerr, CCRP; John Spittler, R.N.; Liz Rohn, MS, CCRC; Jessica Corman, CCRC; Lina Sego, CCRP; Christina Nelson, GS, CCRP; Suzanne Bailey, CRTM; Mario Contreraz, MBA, MSN, RN.; Tim Lautenschlaeger, MD.

Indiana University School of Medicine

Background

The original staffing model disease-oriented teams (DOT) of the IU Simon Cancer Center (CC) prior to its distinction of Comprehensive Cancer Center included patient facing research staff consisting of physicians and clinical research nurses (CRN). Within each DOT other research roles were non-patient facing focused. The CTO has grown in the number of clinical trials overall for which the former staffing model of direct patient facing staff was no longer sustainable.

Staffing shortages and budget constraints during the COVID-19 pandemic left the CTO like many other institutions – short on qualified research nurses. IUSCCC CTO leadership met with leaders across multiple cancer centers in the United States and research units within IU to construct a solution for the use of non-nursing staff within the scope of subject care. The Clinical Research Patient Specialist (CRPS) model was created with the focus of relieving CRN tasks, dividing workload efforts, providing comprehensive care for subjects and efforts to improve staff retention.

Goals

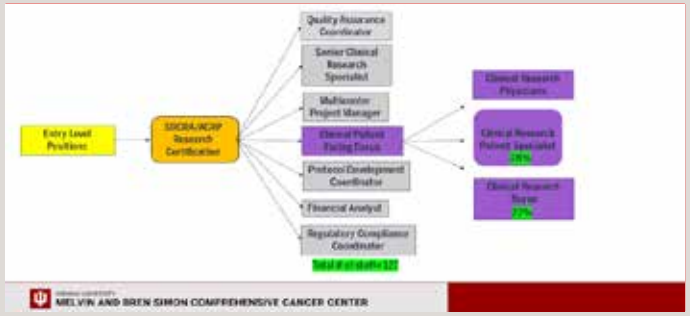
- Have CRPS be protocol experts for non-therapeutic and therapeutic clinical trials in the clinical setting.
- The CRPS and physician work together to accomplish study related assessments in real time.
- Allow CRN to focus on high-risk, Phase I, and early development clinical trials.
- Increase overall accruals to both non-therapeutic and therapeutic trials.

Methods

- Work closely with physicians, CRN's and CRPS to establish expectations and designated responsibilities of each role.
- Office-wide source documents were updated to emphasize requirements of both CRPS and CRN/MD
- SOPs were updated to include role-specific information
- Guidance Documents and training materials were created for the CRPS role
- A CRPS-specific mentor was added to the Quality and Education Team with experience in the role to enable faster troubleshooting
- Collaborated with IU Health for training specific to the Electronic Medical Record system.
- Provide disease specific training and basic assessment skills for the CRPS.

Results

The addition of CRPS became a new staffing model in providing a career extension to clinical research. Twenty-two positions have been integrated into DOTs; making up 28% of CTO staff and close to a 1:1 ratio of CRPS to CRN. Over the past two years there has been a notable increase to patient accruals for non-therapeutic trials.



Conclusions

- The CRPS model has shown to be effective in relieving responsibilities of CRN when implemented effectively.
- Education, training, and trust are imperative for a smooth transition.
- Across several DOTs the CRPS model have demonstrated to be effective in managing non-treatment/non-therapeutic studies.
- There are limitations to what degree of documentation CRPS are allowed to complete (collect AEs, but not grade or assign relatedness of AEs).
- Teams who are reluctant to use CRPSs to their full potential will not see more than administrative relief, while teams who fully embrace these collaborations in workflow have a partner in the subject's care rather than an administrative assistant.

INDIANA UNIVERSITY MELVIN AND BREN SIMON COMPREHENSIVE CANCER CENTER

Development and Implementation of Micro-Trainings as Part of Continued Education for Clinical Research

K. Croghan, G. Boe, J. Zbacnik, A. Youssef, A. Holland, G. Nowakowski, A. Fritsche
Mayo Clinic Comprehensive Cancer Center

1. Background

This Quality Improvement Project addresses the need for continued education for clinical research coordinators (CRCs) within the Mayo Clinic Comprehensive Cancer (MCCCC). While the course has been successful for new hires, the next step is to ensure that established study teams are re-educated as workloads increase and trials become more complex. Additionally, there is a lack of process to share updates to Quality Management System (QMS) documents and resources while still outlining the fundamentals of research in an accurate, yet "quick" manner center. In late 2020, MCCCC established a Cancer Clinical Trials Office (CCTO) New Hire Orientation to help establish expectations and resources available for CRCs and other study team members. While the course has been successful for new hires, the next step is to ensure that established study teams are re-educated as workloads increase and trials become more complex. Additionally, there is a lack of process to share updates to QMS documents and resources while still outlining the fundamentals of research in an accurate, yet "quick" manner.

2. Goals

Our goal was to develop a monthly micro-training program that can be continuously updated throughout the year and can help communicate and sustain training among CCTO CRCs. These micro-trainings can also be used during the CCTO New Hire Orientation as additional resources, and utilized to address additional re-education, if needed.

3. Solutions and Methods

Create a fixed monthly continuing education program that revolves around one or two general topics that can be emphasized in 5-15 minutes. These micro-trainings use the fundamentals of change management to establish the need for and importance of topic education, location of topic resources, and a high-level overview of the process with an example. They are kept high-level to help reduce the maintenance for these modules, while pointing staff to the specific resources that will be updated per QMS needs.

These trainings are then placed into the institutional learning program to be sent out to staff at scheduled intervals. The learning program also maintains an attestation of completion that is auditable.

4. Outcomes

Outcomes are pending; however, general feedback from both new hires (who are piloting the modules) and CRCs has been positive.

5. Lessons Learned and Future Directions

At this time, we are continuing to develop the topics with a targeted implementation of the full program scheduled for June 2023.

Monthly Micro-Training Continued Education

Authors: Katrina Croghan, M.S., CCRP, Gwen Boe, M.A.N, R.N., Jade Zbacnik, Amanda J Youssef, M.S., Adam Holland M.S., Grzegorz Nowakowski, MD, Angela Fritsche, MPA
Comprehensive Cancer Center, Mayo Clinic

BACKGROUND

This Quality Improvement Project addresses the need for continued education for clinical research coordinators (CRCs) within the Mayo Clinic Comprehensive Cancer Center (MCCCC).

In late 2020, MCCCC established two successful programs:

1) A Cancer Clinical Trials Office (CCTO) New Hire Orientation to help establish expectations and resources available for CRCs and other study team members.
2) A Quality Management System (QMS) to help create, implement, sustain and maintain policies, procedures and other resources while still outlining the fundamentals of research in an accurate, yet 'quick' manner.

Both programs have had major success, but a gap remains:

How do we continue to educate established study teams as workloads increase and trials become more complex?

GOALS

Develop a program that can be:

- 5-15minute trainings = Micro-training
- Easy to revise when needed
- Can help communicate and sustain training among CCTO CRCs when revisions are made to QMS
- Resource for Cancer-related programs that are not housed within CCTO but follow MCCCC QMS requirements.
- Resource for the CCTO New Hire Orientation as additional resources.
- Utilized to address re-education, as needed, i.e.: as part of Corrective and Preventative Action (CAPA) Plan

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SOLUTIONS AND METHODS

THE FIXED MONTHLY PLAN

Create a fixed monthly continuing education program that revolves around 1 or 2 general topics that can be emphasized in 5-15 minutes.

Kept the trainings high-level to help reduce the maintenance need for these modules, while pointing staff to the specific resources that will be updated per QMS needs.

Once complete, the micro-trainings are then placed into the institutional learning program to be sent out to staff at scheduled intervals. The learning program also maintains an attestation of completion that is auditable.

MICRO-TRAINING ANATOMY

The micro-trainings utilize the fundamentals of change management to establish the need of topic education.

- Attention Getter:
- Why is this topic important?
- Where to find the topic resources,
- A high-level overview of the process
- Emphasize the training with a summary- typically in the form of a walk-through.
- Some require multiple small videos to emphasize all the aspects of a topic, such as reportable events. Thus, we add these to one module called a mini-series.

TABLE 1: General Fixed Topic Monthly Plan for continued education

FIGURE 1

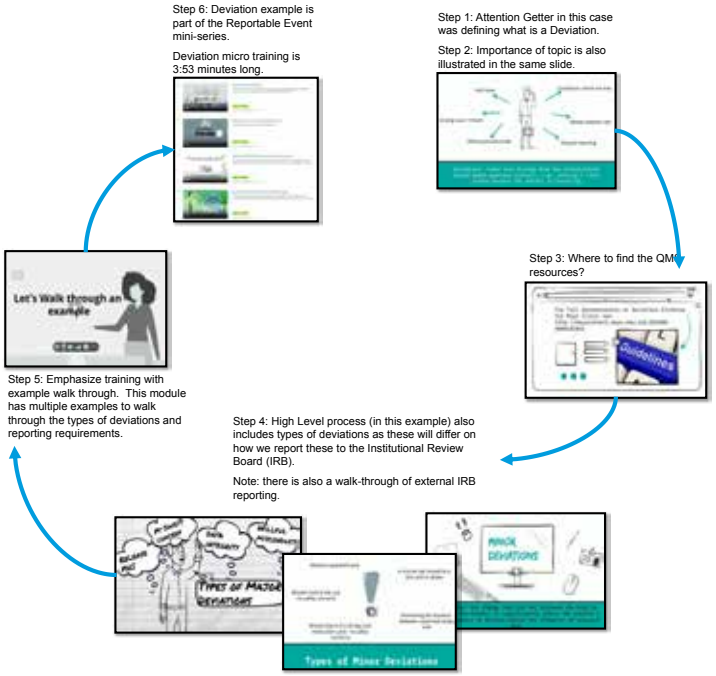


Figure 1 represents the micro-training anatomy throughout the deviation training.

OUTCOMES

Outcomes are pending; General feedback from both new hires and seasoned CRCs who have been reviewing the micro-training is positive. They have emphasized their excitement for continued education through a 'different platform'.

LESSONS LEARNED

Lessons Learned are still pending, as course has not been fully implemented yet (June 2023). Some take aways while creating these trainings include:

- Hour courses are not feasible.
- The same information in a 60-minute course can be emphasized using different platforms in a quarter of the time.
- The 'end users' know what they need, and we listen to them.

FUTURE DIRECTION

We are continuing to develop the 11 topic units (Table 1) with a targeted implementation of the full program scheduled for June 2023 release.

ACKNOWLEDGMENT

Special thank you to the CCTO study coordination teams and Supervisors for participating and emphasizing the need for continued education. In addition, a huge thank you to MCCCC Leadership and Quality Management System (QMS) for all the support and resources to keep our education moving forward.

Managing Flexible Work Schedules Within a Disease Specific Team

C. Dwight, S. Zindars, H. Heaviland
Medical College of Wisconsin Cancer Center

1. Background

In June 2022 the Medical College of Wisconsin (MCW) began formalizing flexible work arrangements. The Clinical Trials Office (CTO) understood that flexible work arrangements were a job satisfier and a benefit that helped with staff retention. MCW CTO created a baseline that "patient facing staff" were required to be onsite three out of five workdays and non-patient facing staff were required to be onsite two out of five workdays. The composition of the 40-hour work week for hourly and salaried staff followed the options available per institutional guidelines (ex. five – eight-hour days, four- ten-hour days, etc.) Guidelines from cancer center leadership included that these were options and that each team needed to determine what would work best given individual team business needs. Leadership wanted the teams to design the option that worked best for them. The goal was to provide maximum flexibility without undue stress, while meeting business needs.

2. Goals

By providing greater work schedule flexibility the institution hoped to be able to increase job satisfaction and retain clinical research coordinators and clinical research assistants.

3. Solutions and Methods Methods:

The clinical research coordinators and clinical research assistants met independently of the team manager and determined what minimum in-office staffing was needed for each day of the work week. Individual team members' wish lists were then compiled into a proposed schedule and the team worked together to problem solve any discrepancies between the required coverage and the individual requests.

Solutions: The clinical team developed two separate schedules. One for fall/winter and one for Spring/summer as the team recognized the desire for more flexible schedules during the warmer months. schedules are re-evaluated quarterly summer/fall/winter/spring. staff often like to do something different for about three months, and then try something new or revert to conventional work schedules with changing work/clinic/home/school year needs.

4. Outcomes

Flexible schedules were implemented in July of 2022. We have seen an increase in satisfaction among staff and increased communication.

5. Lessons Learned and Future Directions

The flexibility in work schedules required staff to view the group more as a team with one mission as opposed to focus primarily on individual studies and a more collaborative approach to patient visits and cross-coverage of studies. Increased communication amongst the team related to workload and tasks was observed.

We are planning on compiling results of a staff survey in May/June of 2023 to investigate if flexible schedules have increased staff job satisfaction and retention.

Managing flexible work schedules within a disease specific team

Cindy Dwight, RN, ND, CCRC Haley Heaviland, ALB, CCRP Stacey Zindars, MS, CCRP
Medical College of Wisconsin Cancer Center

Background

In June 2022 the Medical College of Wisconsin (MCW) began formalizing flexible work arrangements. The Cancer Center Clinical Trials Office (CCCTO) understood that flexible work arrangements were a job satisfier and a benefit that helped with staff retention. MCW CCCTO created a baseline that "patient facing staff" were required to be on-site three out of five workdays and non-patient facing staff were required to be on site two out of five workdays. The composition of the 40-hour work week for hourly and salaried staff followed the options available per institutional guidelines (ex. Five – eight-hour days, four- ten-hour days, etc.) Guidelines from Cancer Center leadership included that these were options and that each team needed to determine what would work best given individual team business needs. Leadership wanted the teams to design the option that worked best for them. The goal was to provide maximum flexibility without undue stress, while meeting business needs.

Goals

By providing greater work schedule flexibility the institution hoped to be able to increase job satisfaction and retain clinical research coordinators, clinical research nurses and clinical research assistants.

Contact:
Name: Cindy Dwight, RN, ND, CCRC
Email: cdwight@mcw.edu

Solutions and Methods

Methods: The Clinical Research Coordinators (CRC), Clinical Research Nurses (CRN) and Clinical Research Assistants (CRA) met independently of the team manager and determined what minimum in-office staffing was needed for each day of the work week. Individual team members' wish lists were then compiled into a proposed schedule and the team worked together to problem solve any discrepancies between the required coverage and the individual requests.
Solutions: The clinical team developed two separate schedules. One for Fall/Winter and one for Spring/Summer as the team recognized the desire for more flexible schedules during the warmer months. Schedules are re-evaluated quarterly Summer/Fall/Winter/Spring. Staff often like to do something different for about three months, and then try something new or revert to conventional work schedules with changing work/clinic/home/school year needs.

Week 1

	Monday	Tuesday	Wednesday	Thursday	Friday
CRC 1	8	8	8	8	8
CRC 2	8	8	WFH 8	8	WFH 8
CRC 3	NPF 10*	8	8	8	10*
CRC 4	WFH 8	8	WFH 8	8	8
CRC 5	WFH 8	8	8	WFH 8	8
CRC 6	WFH 8	8	8	WFH 8	8
CRC 7	8	8	WFH 8	8	8
CRA 1	8	8	8	WFH 8	WFH 8
CRA 2	WFH 8	8	WFH 8	8	8
CRA 3	9	9	9	9	WFH 4
Minimum Office/ Working	3	4	3	2	4

Week 2

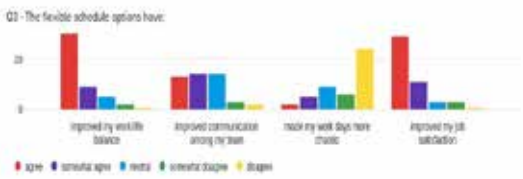
	Monday	Tuesday	Wednesday	Thursday	Friday
CRC 1	8	8	8	8	8
CRC 2	8	8	WFH 8	8	WFH 8
CRC 3	NPF 10*	8	8	8	10*
CRC 4	WFH 8	8	WFH 8	8	8
CRC 5	WFH 8	8	8	WFH 8	8
CRC 6	WFH 8	8	8	WFH 8	8
CRC 7	8	8	WFH 8	8	8
CRA 1	8	8	8	8	8
CRA 2	9	9	9	9	WFH 4
CRA 3	9	9	WFH 4	9	9
Minimum Office/ Working	3	4	3	2	4

Notes:
WFH/OFF days can still be moved around amongst each other, respecting the minimum in office each day.
*Off/Out/Away days also need to be mindful of the minimum in office each day, and someone may have to cancel a WFH day to accommodate vacations/sick days of co-workers.
*People in blue responsible for making sure late coverage is covered between themselves.
*Continue putting all WFH, OUT/OFF/AWAY in Team calendar

Figure 1: sample team schedule

Outcomes

Flexible schedules were implemented in July of 2022. Not all Disease Oriented Teams were able to implement full flexibility due to staffing issues. In early May 2023, CRCs, CRAs and CRNs across the Cancer Center CTO were sent an anonymous survey asking questions about how the flexible schedules have impacted their work and job satisfaction. 47 responses were generated, of the 47 46 were working on teams that have implemented flexible schedules. Over all results show an increase in job satisfaction and better communication within teams. We do not have retention data currently.



Lessons Learned

The flexibility in work schedules required staff to view the group more as a team with one mission as opposed to focus primarily on individual studies and encouraged a more collaborative approach to patient visits and cross-coverage of studies. Increased communication amongst the team related to workload and tasks was observed.

Peer Support for Second Victim Syndrome

S. Eberhardt, A. Pilarski, T. Klatt, S. Babe, H. Nestle, K. Schroeder, M. Lingongo
Medical College of Wisconsin Cancer Center

1. Background

Second Victim Syndrome (SVS) is when a health care team member becomes traumatized by an adverse medical event; the patient is the primary victim, but the clinician is affected secondarily. SVS is known to affect the entire clinical team; however, it also impacts research professionals. Research professionals are patient-facing and share patients' experiences, including patient deaths. SVS can lead to stress, burnout, anxiety, and potentially staff resignations. In more extreme cases, SVS can result in depression, post-traumatic stress disorder, and/or suicidal thoughts/attempts. Our Clinical Trials Office (CTO) internal advisory committee identified the need for emotional first aid to support our teams and mitigate the risk of SVS.

2. Goals

We sought to implement a Peer Support Program (PSP) to provide emotional aid in the CTO.

3. Solutions and Methods

The first step was to provide easy access for staff to be trained as Peer Supporters (PSs). Online trainings were explored; however, we chose the internal PSP training offered for personnel through our partnering hospital, Froedtert, because it was free and conveniently scheduled. Thirteen CTO staff members obtained formal training as PSs. This training began with online videos explaining second victim syndrome, including real stories from hospital staff about their experiences with second victim syndrome. Then, an in-person training allowed staff to explore different tactics and language that peer supporters can use to assist their colleagues through potentially distressing experiences. The PSP program includes certified counselors (CC) if further emotional aid is necessary, beyond PS intervention. To access the PSP in the CTO, a Qualtrics submission form was created that allows staff to choose either a PS or CC; it is received by the CTO PSP lead and triaged to the applicable PS/CC no later than one business day. This form inquires how urgently they need support, and the general topic. These topics may include distressing medical events/notes, disease progression, or a patient's death. Since the staff member's needs can change over time, the PS reaches out the next day, and one and two weeks after the event.

4. Outcomes

Establishing this program within the CTO is an ongoing process. We plan to follow metrics through originating Qualtrics submission forms. These metrics will allow us to track the number of staff members that ask for support, what topics were discussed, and if escalated aide is required.

5. Lessons Learned and Future Directions

While PSPs are utilized often by clinicians, there is a need among non-clinician staff, such as research professionals. As this CTO PSP is used, PSs will meet monthly to critically review metrics and identify potential changes to this clinician-focused PSP that may be helpful in a CTO setting. We hope that providing research professionals with emotional aid will lead to decreased stress amongst staff and a more supportive work environment. Our innovative journey to implement this hospital-based PSP in a CTO setting has potential applications among other research medical centers for oncology.

Peer Support for Second Victim Syndrome

Sydney Eberhardt[1], Alicia Pilarski MD[2], Timothy Klatt MD[3], Stephanie Babe[4], Hannah Nestle[1], Katy Schroeder[1], & Melissa Lingongo[1]

Medical College of Wisconsin: Cancer Center Clinical Trials Office[1], Department of Emergency Medicine[2], Department of Obstetrics & Gynecology[3]; Froedtert Hospital[4]

Background

- Second Victim Syndrome (SVS) is when a health care team member becomes traumatized by an adverse medical event; the patient is the primary victim, but the clinician is affected secondarily. [1]
- SVS can lead to stress, burnout, anxiety, and potentially staff resignations. In more extreme cases, SVS can result in depression, post-traumatic stress disorder, and/or suicidal thoughts/attempts. [1]
- SVS is known to affect the entire clinical team; however, it also impacts research professionals. Research professionals are patient-facing and share patient's experiences, including patient deaths.
- Two separate research organizations conducted studies regarding stress levels within research teams and found there was a high level of burnout for clinical research professionals[2, 3]
- Our Clinical Trials Office (CTO) internal advisory committee identified the need for emotional first aid to support our teams and mitigate the risk of SVS.
- Similar programs have been established and found to have improved burnout in clinical professionals within NCI centers[2, 3]

Innovative Approach

- Pier 1 includes entire care team
- Optimal patient care, optimal support & recovery requires a team
- Promotes team recovery
- Promotes future team functioning and culture of safety

Tier 3:
Expedited Referral Network:
Employee Assistance Program
Mental Health Services
Spiritual Services

Tier 2:
Trained Peer Supporters
Patient Safety and Risk Management Resources

Tier 1:
Local Support:
(Unit/Departmental)
Peer-to-Peer Support:
Clinical Research Assistants, Coordinators, Nurses

Goals

We sought to implement a Peer Support Program (PSP) to provide emotional aid in the CTO. This program aims to provide staff with mental health support when they experience potential effects of SVS.

Solutions and Methods

- PSP offered through CTO partnering hospital, Froedtert; the program was developed by Dr. Alicia Pilarski and Dr. Timothy Klatt based on the work of Dr. Susan Scott (University of Missouri)[1]
- 13 staff were trained to be Peer Supporters (PSs)
- Training consisted of two parts:
  - online training included videos with personal accounts from hospital staff about their experiences with SVS
  - in-person training allowed staff to explore different tactics/language that PSs can use to assist their colleagues through potentially distressing experiences
- Qualtrics submission form was created to access the PSP in the CTO; it is received by the CTO PSP Lead and triaged to the applicable PS no later than one business day
- Since the staff member's needs can change over time, the PS reaches out the next day, and one and two weeks after the event

Submission Form: Scan to view

Supporting Our Staff

Outcomes

Establishing this program within the CTO is an ongoing process. We plan to follow metrics through originating Qualtrics submission forms. These metrics will allow us to track the number of staff members that ask for support, what topics were discussed, and if escalated aide is required.

Lessons Learned

- While PSPs are utilized often by clinicians, there is a need among non-clinician staff such as research professionals.
- As this CTO PSP is used, PSs will meet monthly to critically review metrics and identify potential changes to this clinician-focused PSP that may be helpful in a CTO setting.
- We hope that providing research professionals with emotional aid will lead to decreased stress amongst staff and build a more supportive work environment.

Future Directions

- We would like to optimize a streamlined process where research staff can request mental health support and be provided with resources within the same business day if necessary.
- Our innovative journey to implement this hospital-based PSP in a CTO setting has potential applications among other academic medical centers.
- This program has the potential to grow and become more personalized to each research department depending on what each team needs.

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Integrating Technology to Support Data Management Abstraction of Adverse Events (AE) and Concomitant Medications (ConMed) from the Electronic Health Record (EHR) to Sponsor Electronic Data Capture (EDC) Systems Using Design Thinking Methodology to Increase Efficiency and Help Reduce Staff Turnover

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Memorial Sloan Kettering Cancer Center

1. Background

Manual abstraction of data from a site's EHR to pharmaceutical sponsor's EDC system is labor intensive, error prone and frustrating which results in data manager (DM) burnout and staff turnover.

2. Goals

To reduce the time and effort of this process for data managers, a web-based application, Clinical Trials Data Hub (CTDataHub), was developed using design thinking methods. It extracts and consolidates AE and ConMed data from the EHR and displays it in a user friendly, automated, and consolidated view for easy entry into EDC forms.

3. Solutions and Methods

Following design thinking methodology to develop CTDataHub, we interviewed 12 DMs to identify data entry bottlenecks, and ideated solutions. To evaluate CTDataHub's value, we built a functioning prototype using Splunk and conducted pilot A/B testing with 6 DMs for 2 use cases (Case 1: basic easy to find ConMed linked to the AE, and Case 2: complex, where the ConMed linked to the AE was buried in a 33-page document) using their current workflow (A) versus CTDataHub (B) where a five-minute training occurred prior to testing. We hypothesized that CTDataHub would outperform current workflows across three primary outcomes: 1) correct data identification, 2) time to identify data, and 3) using a modified Single Ease Question (SEQ) rating scale to assess how difficult users found the task. This study was conducted in Jan-Aug 2022 at a large single-center cancer hospital.

4. Outcomes

DMs spend ~20 hours/week on data entry; the majority of which is spent searching the EHR for which ConMeds are associated with an AE. A/B testing results are noted in Table I (shown in the uploaded file).

Use case two showed that DMs using CTDataHub reduced the time to find one ConMed linked to an AE by 148 percent, saving ~five minutes in one task. Five of six participants preferred CTDataHub to existing clinical systems.

5. Lessons Learned and Future Directions

Our pilot findings suggest that CTDataHub allows DMs to 1) identify AE and ConMed data required for EDCs more quickly than in current workflow, 2) identify data more accurately to be entered in sponsor EDCs, and 3) perceive the task of identifying this data to be easier. CTDataHub reduces the time DMs spend searching clinical systems and documents and has the potential to save meaningful time per patient per study. CTDataHub will launch into production in May 2023.

Digital tool product development using design thinking methodology has the potential to improve operational efficiency and the clinical staff user experience. This is particularly important in an industry that has struggled with burnout, cost containment, and high turnover.

Integrating Technology to Support Data Management Abstraction of Adverse Events (AE) and Concomitant Medications (ConMed) from the Electronic Health Record (EHR) to Sponsor Electronic Data Capture (EDC) Systems Using Design Thinking Methodology To Increase Efficiency and Help Reduce Staff Turnover

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Leemor Yuravlivker, Nancy Bouvier, Michael Buckley, Sundar Jeevarathnam, Steve Lazan, Mairi McKellop, Renata Panchal, Joseph Lengfellner, Stephanie Terzulli, Paul Sabbatini

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Background

Manual abstraction of data from a site's EHR to pharmaceutical sponsor's EDC system is labor intensive, error prone and frustrating which results in Clinical Research Coordinator (CRC) burnout and staff turnover. To reduce the time and effort of this process for data managers, a web-based application, Clinical Trials Data Hub (CTDataHub), was developed using design thinking methods. It extracts and consolidates AE and ConMed data from the EHR and displays it in a user friendly, automated, and consolidated view for easy entry into EDC forms.

Understanding the CRCs and Their Painpoints

We first conducted user research to interview 12 CRCs at MSK to understand their current workflows and painpoints. We ran 12 1-hour remote sessions – 30-minutes for observation of their current workflow followed by a 30-minute interview. We used those insights to build empathy with the coordinators and understand their data management journeys.

Figure 1 - Clinical Research Coordinator Persona

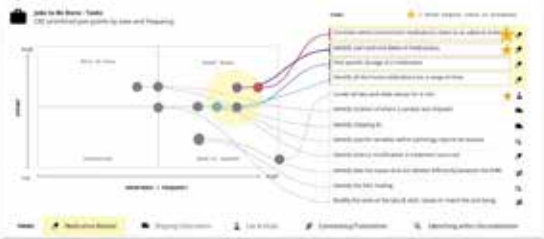
Our research found that CRCs oversee between 4-8 protocols at one time and spend approximately 2-15 minutes finding adverse event (AE) data, such as nausea or fever, and 30-90 minutes finding medication data per patient on a protocol each week using current clinical systems. The results from this initial user research found that CRCs spend up to 50% of their week doing data entry and that a primary, time-consuming painpoint for them is the time it takes to identify which medications are given to a patient in response to an AE.

Figure 2 - Data Entry Journeymap

Defining our Focus, Together

We ran a Design Thinking workshop to prioritize which painpoint to focus on solving first. Participants included 13 representatives across Design, Engineering, Research, Product, and CRCs. Prior to the workshop, we conducted a Jobs-To-Be-Done survey to understand the greatest unmet needs and help prioritize the scope of the new solution. Participants agreed that most valuable goal of the solution would be to reduce CRC data entry time for medications and AEs by at least 25%, keep the same rate of accurate data identification, and be preferable to current clinical systems.

Figure 3 - Jobs-To-Be-Done Outcomes



Testing our Hypothesis

We developed a working proof-of-concept application, CTDataHub, using Splunk [2] as a pilot to test whether it could help reduce the time it takes to find the right medication and AE data. CTDataHub enabled CRCs to look up patients on the protocols they oversee and aggregated a single view of adverse events and medication data for those patients.

Figure 4 - Pilot of CTDataHub Developed with Splunk

To inform the desirability of features within CTDataHub, we ran a KANO [1] survey to validate which needs must be met for our tool to provide value. We then conducted A/B testing with 6 CRCs for 2 use cases (use case 1: basic easy to find medication linked to the AE, and use case 2: complex, where the medication linked to the AE was buried in a 33-page document) using their current workflow (A) versus CTDataHub (B) where a 5-minute training occurred prior to testing. We hypothesized that CTDataHub would outperform current systems across 3 primary outcomes: 1) correct data identification, 2) time to identify data, and 3) using a modified Single Ease Question (SEQ) rating scale to assess how difficult users found the task.

Results

The results of A/B testing are below in Figure 5.

	Use Case 1		*Use Case 2 (more complex)*	
	Current clinical systems	CTDataHub	Current clinical systems	CTDataHub
Correct data identification rate	83%	80%	50%	75%
Time to identify data (minutes)	10.25	7.25	8.37	3.38
SEQ (1 = difficult, 5 = easy)	2.9	4	2	4.25

Figure 5 - Results of A/B Testing

Use case 1 showed that CRCs using CTDataHub reduced the time to find a medication linked to an AE by 41%. The rate of correct identification was 3% higher for current clinical systems, and the easiness for which they completed the use case scored higher by 1.1 points for CTDataHub. Use case 2 showed that CRCs using CTDataHub reduced the time to find one medication linked to an AE by 148%, saving ~5 minutes in one task. The accuracy of the data identified increased by 25%, and CTDataHub scored 2.25 points higher on ease of use than current clinical systems. 5 of 6 participants preferred CTDataHub to existing clinical systems. CTDataHub shows higher likelihood to decrease time spent finding medication and adverse event data for patients with more complex use cases, such as having a longer medication history or higher-than-average volume of medication and AE documents within the EHR. This research was conducted in Jan-Aug 2022.

Limitations and Confounding Factors

The first limitation for the A/B testing was the small sample size of 6 participants. Our survey and behavior data are subject to positive experience bias due to experiencing CTDataHub one time for < 1 hour through curated use cases which were chosen based on completeness of data. Working with live data created minor variability between test sessions.

Conclusion and Future Direction

Our pilot findings suggest that CTDataHub allows CRCs to 1) identify AE and ConMed data required for EDCs more quickly than in current workflow, 2) identify data more accurately to be entered in sponsor EDCs, and 3) perceive the task of identifying this data to be easier. CTDataHub reduces the time CRCs spend searching clinical systems and documents and has the potential to save meaningful time per patient per study. This type of time-saving data abstraction can expand beyond ConMed and AE data to other clinical data such as lab results, shipping IDs and biospecimen data. CTDataHub will launch into production in July 2023.

Figure 6 - Screenshot of CTDataHub

Digital product development using design thinking methodology has the potential to improve operational efficiency and the clinical staff user experience. This is particularly important in an industry that has struggled with burnout, cost containment, and high turnover.

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Meeting the Demands of a Growing Team: How Making a Multifaceted Onboarding Program Helped Protocol Activation Move Forward in a Remote Environment

K. Gary, M. Kehoe, J. Larkin, J. Anopa, T. Schulte, E. Valentino, A. Rodavitch
Memorial Sloan Kettering Cancer Center

1. Background

Since the unit opened for business in 2018, onboarding study start-up managers (SSUMs) into the Protocol Activation Core was achieved through a combination of on-the-job training, peer mentoring, and training by the supervising manager. When the team expanded in early 2020, onboarding was forced to shift to a fully remote environment due to the global pandemic. This made the previous onboarding approach more challenging, leading to knowledge gaps and inconsistencies within the group.

2. Goals

Our 2022 goal was to develop a comprehensive onboarding package covering all core activation topics and tasks, as well as facilitate a motivational environment. This was critical as the team size was expanding by 47 percent due to new positions while also backfilling open positions. The keys goals included:

- A multifaceted onboarding and training program for new staff that is comprehensive, consistent, caters to different learning styles, and facilitates integration into the team.
- Training tools and resources for all staff to refer to after training
- A welcoming and team-centric atmosphere

3. Solutions and Methods

- The multifaceted training program consisted of:
- Leveraging 16 self-paced institutional e-learnings
- Creating 15 remote facilitator-led trainings
- Developing 23 real work experience activities
- Organizing 20 meet and greets with team members and collaborating groups
- Coordinating observations of the IRB and scientific review committee
- Developing team building exercises and continued education

4. Outcomes

Ten new team members hired over seven months completed the program. The onboarding program provided a framework of trainings, tasks, and meetings to be completed within four weeks. This provided a definitive timeline for when new staff would be ready for assigned work while allowing for training activities that mimic work to be done at the pace of the individual. The program developed resources which ensured staff received consistent information and were trained on all the topics relevant to the SSUM role.

Through an anonymous questionnaire of the 10 individuals who participated in the program and seven individuals who had staff who participated, the program was deemed successful.

- Sense of confidence in employees
  – 100 percent reported
- A positive experience
- Pace was just right
- Balance of e-learnings, e-meetings, meet and greets and activities
  – 80 percent felt
- Onboarding program catered to different learning styles
- SSUM's felt prepared to take on their first protocol
- Sense of confidence from managers
  - The onboarding program prepared their new SSUMs to receive their first protocol
  - SSUMs regularly reference the training materials

The team building exercises, inclusive of at home scavenger hunt and a coffee break reality TV check-in have been very successful and staff have requested these more frequently.

5. Lessons Learned and Future Directions

The large amount of complex content is best absorbed when learned in a variety of ways and reinforced throughout the onboarding process. Continuing education modules are being developed in a two-pronged approach. First to reinforce onboarding program materials in an individual setting. Second to explore complex topics in a group setting that fosters discussion, allowing team members to express their ideas and questions while learning form their peers to better understand the Memorial Sloan Kettering network.

Memorial Sloan Kettering Cancer Center

Meeting the Demands of a Growing Team: How Making a Multifaceted Onboarding Program Helped Protocol Activation Move Forward in a Remote Environment

Kristen Gary, BS, Marissa Kehoe, MS, Joe Larkin, BS, Jenny Anopa, MA, Taylor Schulte, MS, Emily Valentino, MPH, Ann Rodavitch, MA

BACKGROUND

Since the Protocol Activation Core (PAC) was initiated 2018, onboarding study start-up managers (SSUMs) into the PAC was achieved through a combination of on-the-job training, peer mentoring and training by the supervising manager. When the team expanded in early 2020, onboarding was forced to shift to a fully remote environment due to the global pandemic. This made the previous onboarding approach more challenging, leading to knowledge gaps and inconsistencies within the group. As PAC activates over 300 prospective protocols each year, it was critical that the onboarding program close that gap.

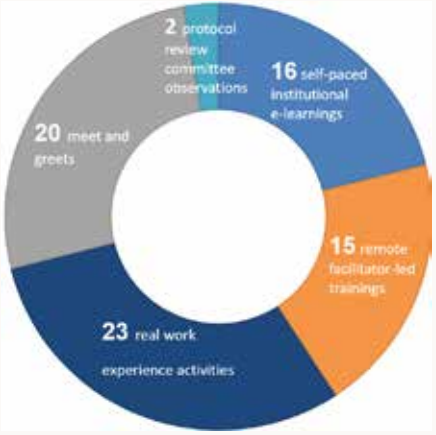
GOALS

Our goal was to develop a comprehensive onboarding package covering all core study start-up topics and tasks, as well as facilitate a motivational environment. This was critical as the team size was expanding by 47% due to new positions while also backfilling open positions. The key goals included:

- A multifaceted onboarding and training program for new staff that is comprehensive, consistent, caters to different learning styles and facilitates integration into the team.
- Training tools and resources for all staff to refer to after training.
- A welcoming and team centric atmosphere.

SOLUTIONS AND METHODS

The multifaceted 4-week training program consisted of 76 training elements including:



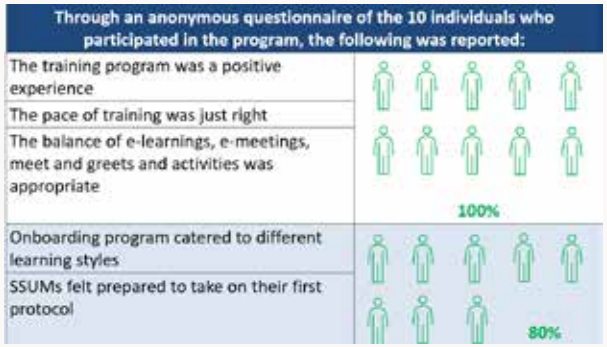
In addition to the training program outlined above, the following were also developed:

- Team building exercises inclusive of
  - Home scavenger hunt
  - Virtual themed coffee breaks
  - Virtual yoga sessions
- Continued education modules

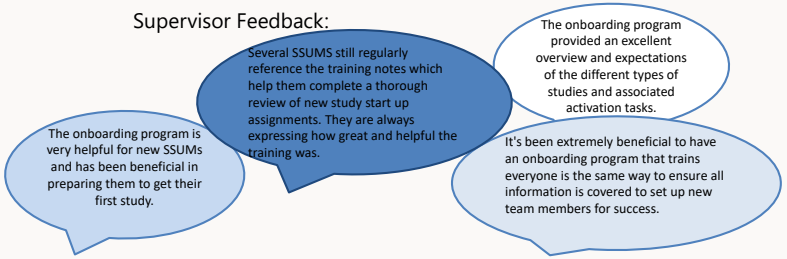
OUTCOMES

Ten new team members hired over seven months in 2022 completed the onboarding program.

The program provided a framework for all elements to be completed within four weeks. This provided a definitive timeline for when new staff would be ready for their first study assignment while also allowing for training activities to be done at the pace of the individual. Resources were developed which ensured staff received consistent information and were trained on all the topics relevant to the SSUM role.



Supervisor Feedback:



LESSONS LEARNED AND FUTURE DIRECTIONS

The large amount of complex content is best absorbed when learned in a variety of ways and reinforced throughout the onboarding process. Continuing education modules are being developed in a two-pronged approach. First to reinforce onboarding program materials in an individual setting. Second to explore complex topics in a group setting that fosters discussion, allowing team members to express their ideas and questions while learning from their peers to better understand the MSK network.

Implementation of Small Group Trainings to Expedite Initial Onboarding for Clinical Research Staff and Increase Connection Between New Employees – One Year Review

D. Kreitner, M. Wanchoo, D. Castro, R. Lewis, C. Burgin
OHSU Knight Cancer Institute

1. Background

OHSU Knight Cancer Institute (KCI) provides individual onboarding for new clinical research staff, consisting of ~50 topics over ~30 sessions. The target timeline for completion is 150 days, requiring one to two training sessions per week. When fully staffed, KCI employs two full-time trainers, who can each conduct ~20-25 sessions per week.

In late 2019, there was a trainer vacancy. In early 2020, due to COVID-19 and uncertain financial projections, OHSU implemented a hiring freeze. When the hiring freeze ended in August 2020, numerous staff were hired to backfill vacancies. This trend continued into 2021. A second trainer was hired in January 2021. By then, the average time to complete onboarding had increased to 297 days. In addition, COVID-19 modified operations required remote work that hindered staff connection.

2. Goals

Primary goal: to decrease onboarding completion time by increasing trainer touchpoints per employee
Secondary goal: to increase staff connection and engagement.

3. Solutions and Methods

Small group trainings were implemented in August 2021, consisting of two to four trainees (based on start date, role, availability) and meeting weekly for 12-16 weeks. Trainers identified ~30 topics amenable to group trainings, with the remainder covered during one-on-one sessions.

4. Outcomes

Since implementation, the average time to complete onboarding has drastically decreased, from 297 days for those who started in 2021-Q1 to 146 days for those who started in 2022-Q3.

We requested formal feedback in November 2022 from trainees who had completed initial onboarding and finished their first year at KCI. Survey recipients included a mix of those who did and did not participate in small group training.

We received eight responses from those who participated in small groups (six clinical research coordinators, one data manager, and one regulatory project manager).

The survey asked six questions regarding the small group cohort trainings, as summarized below:

1. The small group cohort training was an effective approach:
   Extremely effective (3), very effective (1), Moderately effective (1), Slightly effective (2)

2. How well did you like the small cohort sessions with CRQA trainer:
   Like a great deal (4), like somewhat (2), neutral (1), dislike somewhat (1)

3. The group trainings introduced me to other team processes:
   Strongly agree (5), neutral (1), somewhat disagree (1), strongly disagree (1)

4. I felt comfortable asking questions during group session:
   Strongly agree (4), somewhat agree (3), neutral (1)

5. I felt comfortable reaching out to members on the group outside of sessions: disagree (1)

6. I interacted with group members outside of group sessions:
   Strongly agree (3), somewhat agree (2), somewhat disagree (2), strongly disagree (1)

5. Lessons Learned and Future Directions

Overall, the feedback regarding the small groups has been positive. Moving forward, we will continue to utilize small group trainings, as appropriate, in conjunction with one-on-one trainings.

Currently, the average duration of onboarding includes a mix of trainees who did and did not participate in small groups. A future direction of this project will be to delineate the two averages for a direct comparison and specifically track/measure individual touch points per trainee.

Implementation of Small Group Trainings to Expedite Initial Onboarding for Clinical Research Staff and Increase Connection Between New Employees – One Year Review

Dustin Kreitner, MS; Mihir Wanchoo, MBBS, MHA; David Castro, Phd; Rebecca Lewis, BS; Christina Burgin, BA

Background

OHSU Knight Cancer Institute (KCI) provides individual onboarding for new clinical research staff, consisting of ~50 topics over ~30 sessions. The target timeline for completion is 150 days, requiring one to two training sessions per week. When fully staffed, KCI employs two full-time trainers, who can each conduct ~20-25 sessions per week.

In late 2019, there was a trainer vacancy. In early 2020, due to COVID-19 and uncertain financial projections, OHSU implemented a hiring freeze. When the hiring freeze ended in August 2020, numerous staff were hired to backfill vacancies. This trend continued into 2021. A second trainer was hired in January 2021. By then, the average time to complete onboarding had increased to 297 days. In addition, COVID-19 modified operations required remote work that hindered staff connection.

Goals

1. Decrease onboarding completion time by increasing trainer touchpoints per employee.
2. Increase staff connection and engagement, in light of increased remote work.

Methods Implemented

- Implemented small group cohorts in August 2021, consisting of 2-4 trainees.
- Approximately 30 topics identified as amenable to group trainings.
- Trainers continued to meet with each trainee for 1:1 training sessions to ensure all initial onboarding training topics were covered.
- Each group was scheduled to meet weekly for 12-16 weeks.

Outcome

- The average time to complete onboarding has decreased from 297 days for those who started in 2021-Q1 to 146 days for those who started in 2022-Q3.
- Formal feedback was solicited in November 2022 from trainees who had completed onboarding and finished their first year at KCI. Six questions were asked regarding the small group cohort trainings, as summarized below *(responses in italics)*:

Q1. The small group cohort training was an effective approach:
Extremely effective (3), Very effective (1), Moderately so (1), Slightly so (2)

Q2. How well did you like the small cohort sessions with CRQA trainer:
Like a great deal (4), Like somewhat (2), Neutral (1), Dislike somewhat (1)

Q3. The group trainings introduced me to other team processes:
Strongly agree (5), Neutral (1), Somewhat disagree (1), Strongly disagree (1)

Q4. I felt comfortable asking questions during group session:
Strongly agree (4), Somewhat agree (3), Neutral (1)

Q5. I felt comfortable reaching out to members on the group outside of sessions:
Strongly agree (5), Somewhat agree (1), Neutral (1), Strongly disagree (1)

Q6. I interacted with group members outside of group sessions:
Strongly agree (3), Somewhat agree (2), Somewhat disagree (2), Strongly disagree (1)

Lessons Learned and Future Direction

- Due to the positive response and efficiency of the small group cohort, we will continue to utilize the group trainings, as appropriate, in conjunction with 1:1 trainings.
- Currently, the average duration of onboarding includes a mix of trainees who did and did not participate in small groups. A future direction of this project is to delineate the two averages for a direct comparison and specifically track/measure individual touch points per trainee.

Moving From a Single Educator to an Office of Research Education and Professional Development at an NCI-Designated Comprehensive Cancer Center in Under Five Years

G. Watkins-Keller
Rutgers Cancer Institute of New Jersey

1. Background

In the five years since presenting to AACI-CRI, many changes have occurred.

- Now part of an Academic Health System (AHS) with 11 oncology clinical trial sites
- Provide training to over 196 full time equivalents (FTEs) with over 20 distinct roles
- Moved from single educator to office with four educators and program coordinator
- Training is done at various locations, both remote and in-person

In addition to training, the education department is part of other projects.

- Development of clinical trial internship programs
- Collaboration with a local university in the creation of a clinical research coordinator (CRC) badge
- Clinical site for master and undergraduate students
- Creation of clinical trial education in the community

Throughout this growth, the department maintained a positive learning environment that supported staff, looked at ways to allow them to grow in their professional role, and assisted in retaining staff for delivering high-quality oncology clinical trials.

2. Goals

To coordinate and enhance clinical trial education, training, and career development activities throughout AHS.

3. Solutions and Methods

Clinical Trials Education involves a multifaceted approach. Examples of solutions and methods to meet our educational mission are below:

- Increase education team – education specialist, educators, program coordinator
- Improve orientation program through web-based platforms – Microsoft Teams and Planner
- Develop content for educating staff in a variety of different ways – in person and remotely
- Expand curriculum to other roles (i.e., protocol activation, data management, budget analysis, etc.)
- Update the two-day Fundamentals of Clinical Trials Course
- Implement an Anatomy and Physiology course geared toward the oncology clinical trial staff
- Investigator training through a web-based clinical trial toolkit
- Pilot a clinical trial internship program for college students
- Create CRC badging program with a university partner based on national guidelines
- Provide clinical trial practicum experience for students
- Health educators out in the community educating diverse populations about clinical trials

4. Outcomes

- 94 staff onboarded in 2022
- Orientation checklist created for 20 distinct clinical trial roles
- Since 2019, over 100 have attended a two-day clinical trial course
- Since 2022, five topics in the Anatomy and Physiology course have been presented, with over 30 staff attending each topic
- Intern transitioned to a staff role (recruitment specialist) in 2022
- Since the summer of 2022, health educators have presented over ten clinical trial community education programs

5. Lessons Learned and Future Directions

In the last five years, we have learned valuable lessons, one being the art of resiliency. Working on the east coast and in one of the first states to be hit with the pandemic, we maintained clinical trial operations and even had a 10 percent enrollment increase. We took advantage of the pandemic's challenging time and devised creative ways to work, such as remote work, utilizing web-based platforms such as Microsoft Teams, streamlining clinical trial roles, and collaborating with local colleges.

Our future directions include a stand-alone training center to open in early 2023. Other initiatives include expanding intern positions to other clinical trial departments. Our ongoing growth and success are due to the support of our organization's leadership. With this continued leadership support and the education department's hard work, seeing what the future brings will be exciting.

Moving From a Single Educator to an Office of Research Education and Professional Development at an NCI-Designated Comprehensive Cancer Center in Under Five Years

Ginnette Watkins-Keller, DNP, RN, OCN, NEA-BC
watkingm@cinj.rutgers.edu

BACKGROUND

In the five years since presenting to AACI-CRI, many changes have occurred.

- Part of an Academic Health System (AHS) with eleven oncology clinical trial sites
- Provide training to over 196 FTEs with over twenty distinct roles
- Moved from single educator to office with four educators and program coordinator
- Training is done at various locations, both remote and in-person

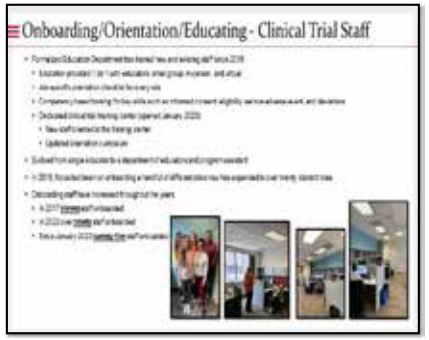
Additionally, the education department is part of other projects.

- Development of clinical trial internship programs
- Collaboration with a local university in the creation of a clinical research coordinator (CRC) badge
- Clinical site for master and undergraduate students
- Creation of clinical trial education in the community

METHODS

Multifaceted approach to clinical trials education. Examples include:

- Increase education team – education specialist, educators, program coordinator
- Improve orientation program through Web-based platforms – Microsoft Teams & Planner
- educating staff in a variety of different ways – in-person and remotely
- Expand curriculum to other roles (i.e., protocol activation, data management, budget analysis, etc.)
- Two-day Fundamentals of Clinical Trials Course
- Implement an Anatomy and Physiology course geared toward the oncology clinical trial staff.
- Investigator training through a web-based clinical trial toolkit
- Clinical trial internship for college students
- CRC badging program with a university partner based on national guidelines
- Clinical trial practicum experience for students
- Educating diverse populations about clinical trials with Health Educators



GOALS & OBJECTIVES

To coordinate and enhance clinical trial education, training, and career development activities through Academic Health System.

OUTCOME

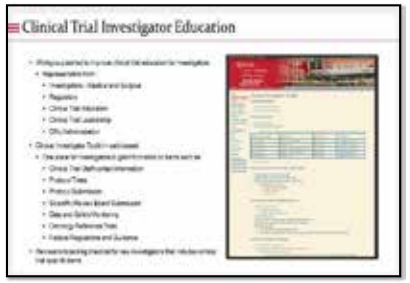
Outcomes include:

- 94 staff onboarded in 2022
- Orientation checklist created for 20 distinct clinical trial roles
- Since 2019, over 100 attended a two-day clinical trial course
- Since 2022, five topics in the Anatomy and Physiology course have been presented, with over 30 staff attending each topic
- Intern transitioned to a staff role (recruitment specialist) in 2022
- Since summer of 2022, health educators have presented over ten clinical trial community education programs

LESSONS LEARNED AND FUTURE DIRECTIONS

In the last five years, we have learned the art of resiliency. Working on the east coast and one of the first states to be hit with the pandemic, we maintained clinical trial operations and even had a 10 percent enrollment increase. We took advantage of the pandemic's challenging time and devised creative ways to work, such as remote work, utilizing web-based platforms such as Microsoft Teams, streamlining clinical trial roles, and collaborating with local colleges.

Future directions include a stand-alone training center (now open!), expanding intern positions to other clinical trial departments (this is done, too!), and building upon our clinical trial investigator education. In addition, we are thankful for the cancer center leadership support that has allowed us to grow within the education department. Through their support, we have continued to develop a robust clinical trial educational program. It will be exciting to see what the future brings us and to report all the impactful things we have accomplished in another five years.



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Righting the Ship: Addressing Staff Turnover

K. Herman, C. Gifford-Hollingsworth, T. Newhall, S. Osipowicz, C. Jerome, C. Hubert, J. Frazier, M. Kasner, M. Brose, P. O'Connor, M. Huesser, A. Khariton, K. Kelly
Sidney Kimmel Cancer Center at Jefferson Health

1. Background

Like many Clinical Trials Offices (CTOs) across the country, our Sidney Kimmel Cancer Center (SKCC) CTO has been impacted by higher rates of staff turnover since the start of the 2020 COVID-19 Pandemic. The impact of turnover has led to decreased site and subject matter expertise across teams, increased the workload of staff burdened with coverage responsibilities, and decreased staff morale. A well trained and engaged clinical trials staff is essential to the success of clinical trials.

2. Goals

1. Identify the factors contributing to staff turnover (survey)
2. Identify and implement correction action measures to address the factors contributing to turnover (staff retreat and follow-up)
3. Collect staff feedback on corrective action measures (survey)

3. Solutions and Methods

In December 2021, the SKCC distributed a survey to identify factors contributing to increased CTO staff turnover. Following the survey, a virtual All Staff Retreat was held in January 2022 in an effort to connect with staff, discuss results of the survey, and identify corrective action measures to best address staff concerns. Following the retreat, several corrective action measures were initiated to address staff engagement (including staff training, career ladder development, team communication measures, and salary benchmarking). An interim survey to further assess staff engagement preferences was conducted in September 2022, which highlighted additional opportunities for improvement (including professional development, staff recognition, team building needs, and salaries). A CTO Engagement Committee was formed to further address staff engagement needs. A second All Staff Retreat was held in February 2023. Pre-retreat and post-retreat surveys were conducted, and dedicated monthly All Staff meetings will further address goals/opportunities identified and discussed during the 2023 All Staff Retreat.

4. Outcomes

The SKCC CTO has seen a decline in staff turnover and an improvement in staff morale (as seen in HR employee retention data, as well as SKCC CTO surveys from 12/2021 and 1/2023). An increased number of staff attended the All Staff Retreat in 2023, and feedback from the surveys has shown improvement in staff morale from 2021 to 2023. Several corrective action measures remain in-progress related to career ladder benchmarking and salaries. These measures require significant time and collaboration with organizational stakeholders outside of the SKCC CTO including human resources and other non-cancer clinical research leaders.

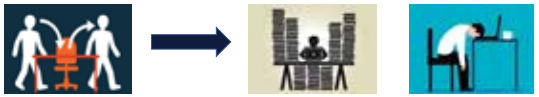
5. Lessons Learned and Future Directions

The issues impacting staff turnover, retention, and engagement are multifaceted and involve multiple institutional stakeholders. Maintaining an ongoing pulse of issues most pertinent to engagement is essential to staff retention and ultimate success of the clinical trials office in meeting individual trial goals, as well as broader institutional goals. Mid- and long-term goals include further development of onboarding and training programs, introduction of additional professional development opportunities, more frequent salary benchmarking, and exploration of alternative staff models to fill gaps in staffing during times of turnover.

Righting the Ship: Addressing Staff Turnover

Kristin Herman, MBA, Cynthia Gifford-Hollingsworth, DrNP, Tracey Newhall, MSN, Sarah Osipowicz, MSEd, Christine Jerome, MS, Christine Hubert, Jennifer Frazier, MPH, Margaret Kasner, MD, Marcia Brose, MD, PhD, Pete O'Connor, Matt Huesser, DBA, Alex Khariton, MBA, Kevin Kelly, DO

Background



Like many Clinical Trial Offices (CTOs) across the country, our SKCC CTO has been impacted by higher rates of staff turnover since the start of the 2020 Covid-19 Pandemic. The impact of turnover has led to decreased site and subject matter expertise across teams, increased the workload of staff burdened with coverage responsibilities, and decreased staff morale. A well trained and engaged clinical trials staff is essential to the success of clinical trials.

Goals

1. Identify the factors contributing to staff turnover (CTO staff survey and 2022 AACI Staff Retention Task Force Findings).
2. Identify and implement correction action measures to address the factors contributing to turnover (staff retreat and follow-up).
3. Collect staff feedback on corrective action measures (survey).

CTO Staff Survey

	VERY DISSATISFIED	SOMEWHAT DISSATISFIED	NEUTRAL	SOMEWHAT SATISFIED	VERY SATISFIED
Training and Onboarding: CRO Onboarding	0.00% 0	7.84% 8	15.69% 16	26.47% 27	50.00% 51
Training and Onboarding: Role Specific/On-the-job Training	2.94% 3	12.75% 13	12.75% 13	28.42% 29	43.14% 44

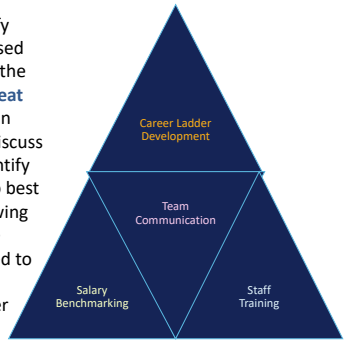
AACI CRI Association of American Cancer Institutes Clinical Research Innovation

2022 CTO Staff Retention Task Force Findings and Recommendations

Below are the recommendations and findings developed by the AACI CTO Staff Retention Task Force to help reduce staff turnover. (Please note, numbering is included for review and referencing and does not indicate priority.)

Solutions and Methods

In December 2021 the SKCC distributed a survey to identify factors contributing to increased CTO staff turnover. Following the survey, a virtual **All Staff Retreat** was held **in January 2022** in an effort to connect with staff, discuss results of the survey, and identify corrective action measures to best address staff concerns. Following the retreat, several corrective action measures were initiated to address staff engagement (including staff training, career ladder development, team communication measures, and salary benchmarking).



An interim survey to further assess staff engagement preferences was conducted in **September 2022**, which highlighted additional opportunities for improvement (including professional development, staff recognition, team building needs, and salaries). A CTO **Engagement Committee** was formed to further address staff engagement needs. A second All Staff Retreat was held in February 2023. Pre-retreat and post-retreat surveys were conducted, and dedicated monthly All Staff meetings will further address goals/opportunities identified and discussed during the 2023 All Staff Retreat.

- Walking Club
- Music Therapy
- Recognition Events
- All Staff Retreat
- New Employee Checklist
- New Employee Team Lunch
- Virtual Trivia
- Ways to say thank you
- Knitting Club

Outcomes

The SKCC CTO has seen a **decline in staff turnover** and an improvement in staff morale (as seen in HR employee retention data, as well as SKCC CTO surveys from 12/2021 and 1/2023). An increased number of staff attended the All Staff Retreat in 2023, and feedback from the surveys has shown improvement in staff morale from 2021 to 2023. Several corrective action measures remain in-progress related to career ladder benchmarking and salaries. These measures require significant time and collaboration with organizational stakeholders outside of the SKCC CTO including Human Resources and other non-cancer clinical research leaders.

Lessons Learned

The issues impacting staff turnover, retention, and engagement are multifaceted and involve multiple institutional stakeholders. Open communication with staff about measures taken to address areas of concern is essential.

Future Directions

Maintaining an ongoing pulse of issues most pertinent to engagement is essential to staff retention and ultimate success of the Clinical Trials Office in meeting individual trial goals, as well as broader institutional objectives. Mid and long term goals include further development of onboarding and training programs, introduction of additional professional development opportunities, more frequent salary benchmarking, and exploration of alternative staff models to fill gaps in staffing during times of turnover.

@ResearchAtJeff

Training Program: From No Experience to Clinical Research Coordinator

S. Annis, J. de Jong, J. Smith
The University of Kansas Cancer Center

1. Background

The Clinical Trials Office is challenged to innovate and meet the demand to recruit, hire, and retain experienced Clinical Research Coordinators (CRC).

2. Goals

To hire individuals with little or no research experience as a Clinical Research Assistant (CRA) to train and provide oncology research experience for a period of 6 months to 1 year with a plan to place them into a permanent CRC role.

3. Solutions and Methods

- Three CRA positions are filled at a given time
- A Project Manager with oncology CRC experience is assigned to hire and manage the CRAs and to develop the CRA training curriculum and program
- The Project Manager conducts weekly one on one meetings to assess CRA development, completion of training onboarding requirements and perform mock informed consent training
- The CRA and Program Manager perform weekly mock informed consent training, review documentation criteria and discuss methods to improve consenting style and efficiency; this training is done using actual consents from a variety of disease, trial types, and complexity levels
- Role playing is conducted as if the CRA is consenting an actual study participant
- Role play scenarios are practiced preparing for solutions before they occur; these include interactions with providers and sponsors, email etiquette, correction of errors, good clinical practice documentation, completion of pill counts, drug diary preparation, and administration of quality-of-life questionnaires
- 4-week immersion training is rotated with a CRC from different disease working groups; this immersion period will provide the opportunity to experience the full lifecycles of events such as informed consent completion through screening, screen fail, or to the enrollment and start of cycle 1 day 1, to observe and perform scheduling of activities, adverse event and serious adverse event submission and lifecycle, in clinic and out of clinic tasks. and how to maintain an efficient desk and clinic schedule
- Routinely include CRAs in challenging projects to develop problem solving skills to navigate database systems, electronic medical records, and other platforms; and learn to manage a working CRCs workload and requirements

4. Outcomes

- 10 CRAs hired and trained as of April 2021
- 7 placed into a CRC position
- 1 moved out of state
- 2 pending completion of training period

5. Lessons Learned and Future Directions

- The need for the assigned immersion phase was implemented to provide varied observation, coordination experiences and perform duties
- The immersion phase is successful as it creates a working bond with staff members, develops CRC knowledge, training and leadership skills and ensures the CRAs real time clinic exposure and trial coordination experience with actual oncology CRCs
- CRA success is subjective and with continued program adjustments, role play activities and observation with many CRC team members has resulted in successful placement into a CRC role
- Expand CRA immersion training to our remote community sites
- Develop a CRA program within other departments such as regulatory and data management

THE UNIVERSITY OF KANSAS CANCER CENTER

Clinical Research Assistant to Clinical Research Coordinator

Sandy Annis[1]; Jilliann de Jong[2]; Jeffrey Smith[3]

NCI Comprehensive Cancer Center

BEST HOSPITALS USNews

Background

The Clinical Trials Office (CTO) is challenged to recruit, hire and retain experienced Clinical Research Coordinators (CRC) to the University of Kansas Cancer Center. The ongoing demand for CRCs did not slow during the COVID-19 pandemic and the need to fill vacant positions continues.

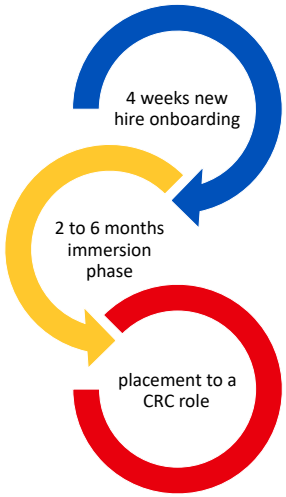
Goals

Due to the ongoing demand for experienced CRCs the Clinical Operations team, Training Department and Human Resources leadership proactively implemented a program to develop candidates to fill open CRC positions. The goal is to hire individuals with little or no research experience as a Clinical Research Assistant (CRA) with a focus to train and provide cancer center research experience for a period of 6 months to 1 year with a plan to place them into a permanent CRC role.

Solutions and Methods

- CTO leadership collaborated with HR to determine the number of CRA positions and develop the job description. Maximum of 3 CRA positions based on open positions.
- A Project Manager was hired to develop the CRA training curriculum and program and manage all CRAs during the training phase.
- The CTO training team onboards each CRA following the CRC training competency to ensure all new hires have the same baseline knowledge
- The CRA and Program Manager meet weekly for consent lab to practice how to consent, review documentation criteria and discuss methods to improve consenting style and efficiency. This role playing is conducted as if the CRA is consenting an actual participant using actual consents from a variety of disease, trial types and complexity levels
- Improvisation activities are practiced to prepare for the CRC role. These include:
  - ✓ How to effectively communicate with providers and sponsors, correction of errors, Good Clinical Practice documentation, completion of pill counts, drug diary preparation, and administration of quality-of-life questionnaires
- 4-week immersion training is rotated with a CRC from different disease working groups.

Lifecycle of Training



Immersion Phase Focused Activities

Informed consent process through enrollment

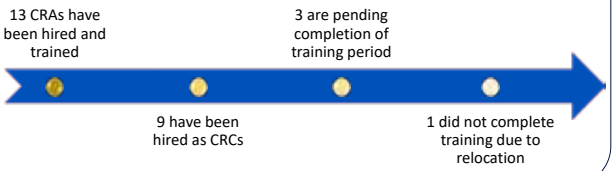
Observe scheduling, adverse event collection and serious adverse event submission, & drug accountability

Off study procedures and follow-up

Lessons Learned

- Initially the CRA was to complete their onboarding period, followed by an announcement to all staff of the new CRAs availability to shadow and assist CRCs and it was anticipated that CRCs would utilize the CRA for support and knowledge sharing. The need for focused immersion training was determined as the CRAs were not being called upon for actual coordination duties, rather only to complete administrative tasks such as redacting documents and sorting paperwork.
- The CRA Program Manager developed the 4-week immersion plan with an effort for all teams to mentor the learning of all CRC responsibilities. The immersion phase is a success as it creates a working bond with staff members, develops training and leadership skills for current CRCs and ensures the CRAs real time clinic exposure and trial coordination experience with actual CRCs.
- Daily check ins, bi-weekly one on one meetings, and administration of stay questions by the program manager allows the CRA to confirm their learning and request more training. This creates the opportunity to customize the training, or to provide the CRA additional training to reinforce their competency and escalate placement to a CRC position.
- The prediction of each CRAs success is subjective and continual open-ended questions and mentorship by many team members can assist in the successful, long-term placement of a CRA to the CRC role.
- Continuation of the CRA program is successful through consistent and frequent adjustment of the program to improve the experience through hands on learning.

Outcomes



Future Directions

- Expand CRA immersion training to our various remote community sites for exposure to those locations.
- Develop a CRA program within other departments such as regulatory and data management.

Addressing the Clinical Research Staffing Shortage: Clinical Development ImPACT Internship

S. Rego, N. Babadi, L. Kiefer, A. Camp, M. Roxas, K. Morrison
UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

1. Background

Staffing Shortages Persist in Clinical and Translational Research (CTR)

Record high turnover in CTR staff during COVID resulted in significant staffing shortages in health care workers. Turnover rates of clinical research professionals (CRPs) were especially high in academic medical centers (AMCs). Several issues contribute to the staffing issues for CTR in AMCs, including outdated institutional practices and lack of awareness of the career.

PhDs Offer an Untapped Pool of Potential new CRPs

PhDs possess valuable knowledge and skills in communication, ethical research design, and problem solving that make them excellent candidates as CRPs. Learning about careers in CTR is difficult because there are few dedicated educational pathways, especially in graduate schools. Programs are needed to introduce potential CRPs to the field and provide valuable hands-on experience. AMCs are ideally positioned to offer these programs to PhD students.

Clinical Development Immersion Program to Advance Career Training (ImPACT) Internship

The ImPACT Internship offered through the UNC Training Initiatives in Biomedical and Biological Sciences (TIBBS) program provides PhD students with internships that allow career exploration and professional development opportunities. In 2022, the UNC Lineberger Comprehensive Cancer Center (LCCC) partnered with TIBBS to deploy the inaugural Clinical Development ImPACT Internship. The internship offered an immersive nine-week paid program, with dedicated time away from the bench, designed to inform students on different careers in CTR at LCCC.

2. Goals

1) Create an immersive nine-week internship in CTR for UNC graduate students. Topics to cover include:
   a. Protocol development
   b. Amendments and administrative letters
   c. Institutional review boards (IRBs)
   d. Informed consent form (ICF) development

2) Expose interns to different CRPs, such as protocol development and regulatory associates

3) Connect interns to mentors

4) Conduct surveys to assess knowledge gained by intern

3. Solutions and Methods

The internship covered multiple clinical trials and regulatory projects. The intern learned about the development of clinical documents and participate in review meetings of protocol and/or consent forms. Furthermore, medical/regulatory writing strategies to complete compliant data of sponsor trials submitted to the FDA were covered. A primary mentor was assigned to the intern who met at least weekly and other staff were shadowed during the course of the internship.

4. Outcomes

To measure the success of the program both quantitative and qualitative data collection via an electronic survey as well as interviews were performed. At the end of the program the intern presented their experience at the ImPACT Internship Showcase.

Deliverables (Inaugural Program): Over the nine-week program the intern: attended > 40 meetings (advocacy council, IRB, etc.), reviewed > 10 training resources, assisted with three concept development projects, reviewed 10 clinical protocols, reviewed/drafted four protocol amendments, reviewed/drafted five ICFs, and reviewed two FDA submissions. Based on pre- and post-knowledge surveys (using a five-point Likert scale) the intern improved their knowledge of several clinical research related concepts (Figure 1).

5. Lessons Learned and Future Directions

The inaugural program demonstrated the importance of collaborative approaches in development and implementation. Future iterations of the internship will identify areas of improvement based on survey results and modularize the program to provide flexibility to the interns.

Addressing the Clinical Research Staffing Shortage: Clinical Development ImPACT Internship

Stephen Rego, Ph.D.; Nasrin H. Babadi, Ph.D., RAC; Leila Valanejad Kiefer, Ph.D.; Allison Camp, Ph.D.; Michael Roxas; J. Kaitlin Morrison, Ph.D.

Background

Staffing Shortages Persist in Clinical and Translational Research (CTR): Record high turnover in CTR staff during COVID resulted in significant staffing shortages in healthcare workers. Turnover rates of clinical research professionals (CRPs) were especially high in academic medical centers (AMCs). Several issues contribute to the staffing issues for CTR in AMCs, including outdated institutional practices, lack of awareness of the career, and unclear progression pathways. Learning about careers in CTR is difficult because there is low recognition and few dedicated educational pathways. Institutions restrict the candidate pool by requiring previous experience. Programs are needed to introduce potential CRPs to the field and provide valuable hands on experience.

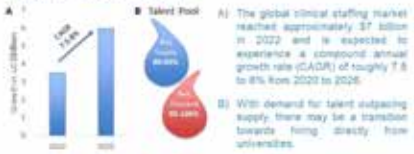


Figure 1: Clinical trial staffing market (Source: Beroe Analysis, 2022).

PhDs Offer an Untapped Pool of Potential new CRPs: PhDs possess valuable knowledge and skills in communication, ethical research design, and problem solving that make them excellent candidates as CRPs. Learning about careers in CTR is difficult because there are few dedicated educational pathways, especially in graduate schools. Programs are needed to introduce potential CRPs to the field and provide valuable hands on experience. AMCs are ideally positioned to offer these programs to PhD students.

Clinical Development Immersion Program to Advance Career Training (ImPACT) Internship: The ImPACT Internship offered through the UNC Training Initiatives in Biomedical and Biological Sciences (TIBBS) program provides PhD students with internships that allow career exploration and professional development opportunities. In 2022, the UNC Lineberger Comprehensive Cancer Center (LCCC) partnered with TIBBS to deploy the inaugural Clinical Development ImPACT Internship. The internship offered an immersive nine week paid program, with dedicated time away from the bench, designed to inform students on different careers in CTR at LCCC.

Goals

The clinical development ImPACT internship had 4 primary goals:

1) Create an immersive nine week internship in CTR for UNC graduate students. Topics to cover include:
   a. Protocol development
   b. Amendments and administrative letters
   c. Institutional review boards (IRBs)
   d. Informed consent form (ICF) development
2) Expose interns to different CRPs, such as protocol development and regulatory associates
3) Connect interns to mentors
4) Conduct surveys to assess knowledge gained by intern

Solutions, and Methods

The internship covered multiple clinical trials and regulatory projects. The Intern learned about the development of clinical documents and participated in review meetings of protocol and/or consent forms. Furthermore, medical/regulatory writing strategies to complete compliant data of sponsor trials submitted to the FDA were covered. A primary mentor was assigned to the intern who met at least weekly and other staff were shadowed during the course of the internship to provide cross-functional training.

Design of the inaugural program

Description: The internship covered multiple clinical trials and regulatory projects in the LCCC clinical development team. The intern learned the development of clinical **protocols**, **consent forms**, and investigational new drug (**IND**) applications. The Intern reviewed IND applications and protocol/protocol amendments of sponsored clinical research of investigational products from UNC, new treatments given by external pharma, and CAR-T cell therapies. The Intern participated in review meetings of protocol and/or consent forms as opportunities present, including the **Patient Advocacy for Research Council**, **Protocol Review Committee**, and **Protocol Review Meetings** with the operational study team. The Intern also completed an initial IRB application with guidance from regulatory personnel. In addition, the intern attended lectures on clinical trial development, sponsor responsibilities, IND, clinical operations, and the process of investigator initiated trials (IITs). The Intern shadowed staff in different positions to gain the big picture of protocol development.

Schedule: This internship lasted 9 weeks and consisted of a combination of presentations, collaborative and individual activities, and assignments. Each week will began with a 1-2 hour meeting between the intern and Senior Protocol Development Associate to go over the topics and expectations for the week. The intern also had biweekly touch points meeting with the Director of UNC Lineberger Sponsored Clinical Research.

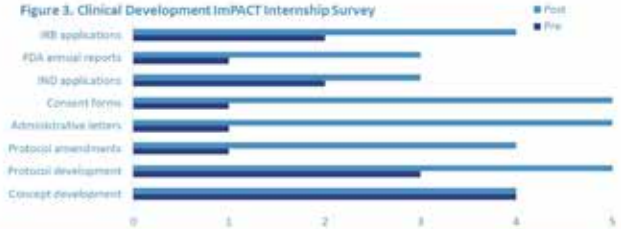
Outcomes

To measure the success of the program both quantitative and qualitative data collection via an electronic survey as well as interviews were performed. At the end of the program the intern presented their experience at the ImPACT Internship Showcase.

Deliverables (Inaugural Program): Over the nine week program the intern completed activities that spanned the course of IIT development including (**Figure 2**); attended > 40 meetings (advocacy council, IRB, etc.), reviewed > 10 training resources, assisted with three concept development projects, reviewed 10 clinical protocols, reviewed/drafted four protocol amendments, reviewed/drafted five ICFs, and reviewed two FDA submissions.

Figure 2. The process of Investigator Initiated Trials (IIT) (https://unclineberger.org/iit/)

Based on pre- and post-knowledge surveys (using a five-point Likert scale) the intern improved their knowledge of several clinical research related concepts (**Figure 3**).



Conclusion

The inaugural program demonstrated the importance of collaborative approaches in development and implementation of these types of programs. Future iterations of the internship will identify areas of improvement based on survey results and modularize the program to provide flexibility to interns.

The Importance of a Dedicated Clinical Trainer in the Hybrid Environment

C. Tait, S. Ladd, J. K. Morrison, D. Wallack
UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

1. Background

University of North Carolina (UNC) Lineberger Comprehensive Cancer Center (LCCC) Clinical Trial Office (CTO) transitioned to a hybrid environment in 2020, limiting onsite support and training for study coordinators (SCs). Training needs were further exacerbated by onboarding 87 clinical staff from 2020 to 2023 to replace losses from the Great Resignation and to grow the clinical team by 34.4 percent from 2019 to 2023.

2. Goals

To address these challenges, LCCC needed to develop a productive method to provide training for new clinical staff and to retrain existing clinical staff. The goals of this project were to create a subject matter expert clinical trainer position; assess the current training structure; address the challenges of training in a hybrid environment; ease the training burden for other roles; and create a robust, structured clinical training program.

3. Solutions and Methods

The clinical trainer role was developed with the following responsibilities: provide hands-on onboarding and training to clinical research staff to ensure safe and efficient conduct of oncology clinical trials, provide expert level knowledge in clinical trial practices and regulations, serve as a frontline expert to develop the performance and expertise of new staff and support the assessment of existing staff in ensuring compliant clinical trial coordination, and champion a collaborative relationship with staff and other departments. The clinical trainer implemented the following training solutions:

1. Resources and Remedies Club, including lectures and hands-on practical curriculum
2. One-to-one mentorship program for junior-level positions (assistant SCs)
3. Onsite training support for study visits followed by an assessment and action plan
4. Lecture-based training classes for the CTO
5. Established workload threshold of five SCs and two data coordinators paired with one trainer to prevent overload and burnout
6. A biweekly communication plan between managers and clinical trainers to share training progress, induct new staff into the training program, and request re-training of current staff

4. Outcomes

The Resources and Remedies Club has improved our culture by creating a sense of community in a hybrid environment, encouraging shared learning, and focusing on training new coordinators to be successful in their role. The Assistant Study Coordinator Mentorship Program has provided a global viewpoint of clinical research for employees and enables them to gain experience to advance their careers. An onsite presence improved the office culture, eased the training burden on other employees, and led to the discovery and resolution of office-wide training gaps. Biweekly assessments have increased collaboration and ensured harmonious communication amongst leadership to best aid new staff. In part due to the success of the clinical training program, since 2020, 60 staff were hired as contract, 30 converted to permanent positions, and 12 are in the process of being invited to convert to permanent positions.

5. Lessons Learned and Future Directions

The success of the clinical trainer subject matter expert training role led to the expansion of trainers into other units (e.g., regulatory). Future directions include recruitment of a training program manager to oversee the subject matter expert trainers and program within each functional group, and to educate trainers on best practices for training adult learners.

UNC LINEBERGER COMPREHENSIVE CANCER CENTER

The Importance of a Dedicated Clinical Trainer in the Hybrid Environment

UNC CANCER CARE

Crissey Tait, MPH; Stephanie Ladd, BS, CCRP; J. Kaitlin Morrison, PhD; Diana Wallack, BS, CCRC

Introduction

University of North Carolina (UNC) Lineberger Comprehensive Cancer Center (LCCC) Clinical Trial Office (CTO) transitioned to a hybrid environment in 2020, limiting onsite support and training for study coordinators (SCs). Training needs were further exacerbated by onboarding 87 clinical staff from 2020 to 2023 to replace losses from the Great Resignation and to grow the clinical team by 34.4% from 2019 to 2023.

Solutions/Methods

To address these challenges, LCCC needed to develop a productive method to provide training for new clinical staff and to re-train existing clinical staff. The goals of this project along with the responsibilities of the new role of a Clinical Trainer were established (**Figure 1**).

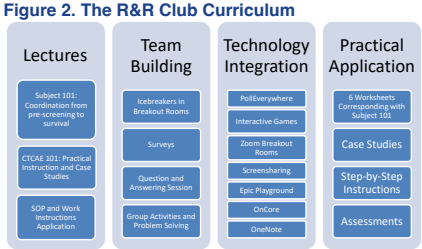
Figure 1. Goals and Responsibilities

Goals
Create a subject matter expert clinical trainer position
Assess the current training structure
Address the challenges of training in a hybrid environment
Ease the training burden for other roles
Create a robust, structured clinical training program
Clinical Trainer Responsibilities
Provide hands-on onboarding and training to clinical research staff to ensure safe and efficient conduct of oncology clinical trials
Provide expert level knowledge in clinical trial practices and regulations
Serve as a frontline expert to develop the performance and expertise of new staff
Support the assessment of existing staff in ensuring compliant clinical trial coordination
Champion a collaborative relationship with staff and other departments

The clinical trainer implemented multiple training solutions. The Resources and Remedies Club (The R&R Club) is a biweekly meeting where new staff members can get to know colleagues at various training stages, receive practical training, and ask questions. New staff members' attendance is required but all staff are welcome to participate in lectures and hands-on practical curriculum (**Figure 2**). There has been 60 members, including 40 new staff members.

The trainer provides onsite training support for study visits followed by an assessment and action plan. The role incorporates lecture-based training classes for the CTO, including creation of a new course (**Figure 4**). A workload threshold of five SCs and two data coordinators paired with one trainer was established to prevent overload and burnout. A biweekly communication plan was implemented between managers and clinical trainers to share training progress, induct new staff into the training program, and request re-training of current staff (**Figure 5**).

Figure 2. The R&R Club Curriculum



Solutions/Methods

Figure 3. ASC Mentorship Program

Monday	Tuesday	Wednesday	Thursday	Friday
Chat with Mentor and check-in regarding today's tasks.	Chat with Mentor and check-in regarding today's tasks.	Chat with Mentor and check-in regarding today's tasks.	Chat with Mentor and check-in regarding today's tasks.	Chat with Mentor and check-in regarding today's tasks.
Update OnCore for today's patient visits	Update OnCore for today's patient visits	Update OnCore for today's patient visits	Update OnCore for today's patient visits	Update OnCore for today's patient visits
Reach out to team regarding which patients need kits for the upcoming week and deliver and/or build those kits	Binder maintenance (new consents that need new binders built, what from the hoteling space can be filed?)	Add patient visits to the POD Outlook calendar	Review patients for the upcoming week and determine assessments needed per protocol and prepare/complete documents.	Ensure all required assessments are performed per protocol
Enter any deviations into OnCore	Enter any SAEs into OnCore	Add patient visits to the lab Outlook calendar	Submit archival tissue requests to TPF if applicable	Submit CPR-OR requests if applicable
Redact source documents	Maintain kit inventory lists/Order kits	Complete long term follow up survival phone calls & document telephone encounter in Epic	Specimen and QOL completion for cooperative groups	Request outside records as needed
Potential Patients: 1. Maintain protocol-specific lists of potential patients 2. Obtain medical records for eligibility review 3. Review UNC medical chart for eligibility 4. Pre-screen patients	Assist in any upcoming monitor visits: 1. Schedule with CPO Admin 2. Submit Epic request for monitor 3. Take monitors to IDS and PI appointments if onsite	Assist in study activation: 1. Second check of lab flowsheets 2. Participate/attend SIV and start up meetings 3. Ensure delivery of kits and equipment 4. Work on site-readiness 5. Participate in Beacon build validation meetings	Request imaging discs	Request imaging uploads to sponsors from Rad Core

The Assistant Study Coordinator (ASC) Mentorship Program provides structure and one-to-one mentorship for junior-level positions who wish to advance their careers. Competencies, evaluations, resources, and group training are provided for both ASCs and mentors (**Figure 3**).

Figure 4. CTCAE 101 Case Study Examples

DOS: 6/10/2022

Ms. Applegate returns to the clinic today for consideration of C7D1 on the A70154 trial. She reports that loss of appetite and nausea began the day after C6D1 (5/20/22) and has not improved. She has lost 10 pounds since her last visit due to this. Baseline weight is 180 lbs., and she is 170 lbs. today. She states that most food taste bad, and she must force herself to eat. She has been supplementing with Ensure. She had one episode of vomiting on 5/21/22 which resolved with Zofran. She also reports increased diarrhea that began around 5/25/22. She is having 7 stools per day (baseline is 2 per day). Fatigue has remained about the same, and she states that it does not limit any of her activities if she takes a nap in the afternoon. She does continue to get out of breath with moderate exertion but is still able to walk her dogs for 2 miles. She reports getting moderate migraines, worse when she is not able to eat much, and reports this has been occurring intermittently since 3/10/22.

Adverse Event Log

AE	Date Started	Date Ended	Grade	Attribution	Clinically Significant? (Y / N)
Fatigue	2/3/22		1	Possibly Related	N
Dyspnea	2/6/22		1	Unlikely Related	N

Date	5/17/2022		
Cycle/Day	C7D1	Normal Range	Grade
WBC	3	3.6-11.2	
RBC	4.34	3.95-5.13	
Hemoglobin	9.9	11.3-14.9	
Hematocrit	36.5	34.0-44.0%	
Platelet Count	49	150-450	
ANC	1.4	1.8-7.8	
Abs Lymphocytes	2.1	1.1-3.6	
Abs. Monocytes	0.4	0.3-0.8	
Abs. Eosinophils	0	0.0-0.5	
Abs. Basophils	0.1	0.0-0.1	
Sodium	153	135-145	
Potassium	3.1	3.4-4.8	
Chloride	104	98-107	
CO2	29	20.0-31.0	
BUN	12	9.0-23.0	
Creatinine	0.96	0.60-0.80	
Glucose	114	70-179	

Using CTCAE v.5.0, perform a lab check on the values listed. Some may not be listed in the CTCAE but try seeing if you can find them regardless. CrtrlF is a great way to quickly search. You can either use the medical term or search the provided test (hyponatremia vs sodium). If you do not know the medical term, you can look it up in your search engine. Only grade what is outside the normal range. Keep track of the grades so you can check your work.

Helpful Hints: Remember your symbols! >,<,≥,≤ Write down your work if that helps you: write down the formula and see which grade range the test value falls into. Remember that there are different ways to calculate the grade for ALT, AST, Alk. Phos, creatinine.

Figure 5. Biweekly Training Assessment Template

Please use the template below to assess training needs for your team members every other week. This can be completed for each member and emailed to Crissey and Diana. Thanks for your collaboration to ensure all staff members are being supported.

Name:

Area(s) of improvement since last update:

Area(s) that are in process, but independent status has not been reached:

Area(s) that need training:

Priority level for training (Red-ASAP, Yellow-within 1 week), (Green-within 2 weeks), (Blue-greater than 2 weeks):

Date/time requested for in-person training:

Results

The Resources and Remedies Club has improved our culture by creating a sense of community in a hybrid environment, encouraging shared learning, and focusing on training new coordinators to be successful in their role (**Figure 6**). The Assistant Study Coordinator Mentorship Program has provided a global viewpoint of clinical research for employees and enables them to gain experience to advance their careers. An onsite presence improved the office culture, eased the training burden on other employees, and led to the discovery and resolution of office-wide training gaps. Biweekly assessments have increased collaboration and ensured harmonious communication amongst leadership to best aid new staff. The Clinical Trainer role has supported the training of 80 staff members since initiation of the role, including 57 new staff members (**Figure 7**). In part due to the success of the clinical training program, since 2020, 60 staff were hired as contract, 30 converted to permanent positions, and 12 are in the process of being invited to convert to permanent positions (**Figure 8**).

Figure 6. R&R Club Impact

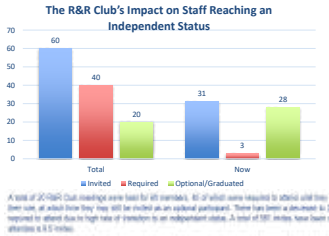


Figure 7. Staff Trained During First Year of Role

Figure 8. Clinical Operations Talent Recruitment

Conclusions

The success of the clinical trainer subject matter expert training role led to the expansion of trainers into other units (e.g., regulatory). Future directions include recruitment of a training program manager to oversee the subject matter expert trainers and program within each functional group, and to educate trainers on best practices for training adult learners.

Contact

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Research Certification Prep Study Groups: Encouraging Professional Certification for CRO Staff

J. Thomas, A. Anderson, T. George, E. Monari, A. Ivey
University of Florida Health Cancer Center

1. Background

As part of professional development expectations, all University of Florida Health Cancer Center (UFHCC) Clinical Research Office (CRO) staff are required to attain ACRP and/or SOCRA certification within two years of eligibility. In 2022, the UFHCC CRO implemented Research Certification Test Preparatory (RCP) sessions for eligible staff. These sessions offer opportunities to explore exam options, identify study resources, and discuss professional goals. These sessions are also open to other interested UF staff.

2. Goals

- Increase first-time pass rate of CRO staff taking a clinical professional certification exam
- Increase staff knowledge of certification opportunities, providing resources and tips
- Connect eligible staff for co-mentoring and professional networking

3. Solutions and Methods

UFHCC RCP sessions are offered biannually in early spring and fall to coincide with testing windows. Sessions meet weekly for 1 hour over 4 weeks. CRO staff are invited based upon their eligibility status. Other UF research community members may attend.

Sessions begin with an overview of professional certification options and how to determine which certification best fits employee goals. Curriculum includes:

- Session 1: Introductions, meet others with similar professional goals
- Session 2: Studying strategies and creating a study plan while working full-time
- Sessions 3 and 4: Sourcing available resources for studying and practice questions
- Recently certified guest speakers (SOCRA or ACRP) attend meetings to discuss studying methods and useful resources

A Canvas (Learning Management System [LMS]) course was created. Six online practice quizzes based on exam topics were created. These quizzes offer test-taking in the same modality as the actual exam. Tips are provided for successful practice-exam setups to de-stress test-takers inexperienced with online exams. These practice quizzes were reviewed during the live sessions.

4. Outcomes

In 2022, 12 eligible staff members were identified, and four others requested to join. Fourteen attended at least one of the sessions. Seven enrolled in the online course, with 2 completing all offered quizzes and 2 completing 0 quizzes. The others completed 1-2 quizzes each. Of the 14 attendees, 3 UFHCC staff members took a certification exam, and 100 percent passed.

Attendees received a poll after the sessions (27 percent response rate) to gather information about their experience with the RCP. Seventy-five percent of respondents attended the fall session, and 25 percent attended both. Fifty percent of the respondents attended all 4 sessions, 25 percent attended 3 sessions, and 25 percent attended 1.

Attendee feedback suggested offering sessions at different dates/times and to “advertise” by including endorsements from previous attendees in the invitations. While manager support for these sessions was evident in the invitation stage, it was suggested that supervisors advocate for participation.

Reasons for not taking the exam included feeling unprepared or no time to study. Sixty-seven percent of respondents indicated that sharing study tips was most helpful while 33 percent felt access to practice questions was most beneficial.

5. Lessons Learned and Future Directions

Based on feedback, future RCP sessions will focus on time management tips to prepare for the certification examination along with supervisor encouragement for participation. Program feedback will be solicited following each session to improve completion compliance.

Research Certification Prep Study Groups: Encouraging Professional Certification for CRO Staff

Julie Thomas, M.Ed., Ashley Anderson, MBA, ACRP-CP, Thomas George, MD, F.A.C.P, Erin Monari, Ph.D, CCRP, Alison Ivey, RN, MS, MBA, OCN, CCRP

BACKGROUND

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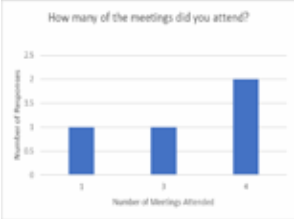
OUTCOMES

In 2022, 12 eligible staff members were identified, and four others requested to join. 14 attended at least one of the sessions. Seven enrolled in the online course, with two completing all offered quizzes and two completing zero quizzes. The others completed 1-2 quizzes each. Of the 14 attendees, three UFHCC staff members took a certification exam, and 100% passed.

Attendees received a poll after the sessions (27% response rate) to gather information about their experience with the RCP. 75% of respondents attended the fall session, and 25% attended both. 50% of the respondents attended all 4 sessions, 25% attended 3 sessions, and 25% attended 1.



CONTACT

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Request a pdf of this poster by email using this QR code.

Attendee feedback suggested offering sessions at different dates/times and to "advertise" by including endorsements from previous attendees in the invitations. While manager support for these sessions was evident in the invitation stage, it was suggested that supervisors advocate for participation.

Reasons for not taking the exam included feeling unprepared or no time to study. 67% of respondents indicated that sharing study tips was most helpful while 33% felt access to practice questions was most beneficial.

FUTURE DIRECTIONS

Based on feedback, future RCP sessions will focus on time management tips to prepare for the certification examination along with supervisor encouragement for participation. Program feedback will be solicited following each session to improve completion compliance.

The Utilization of Microsoft Teams for Clinical Research Operations Team Management

M. Russell, D. Kitterman
University of Illinois Cancer Center

1. Background

The clinical research operations team (clinical research coordinators and data coordinators) grew quickly between 2018 and 2022 and this created the need for increased standardization, structure, and oversight. Communication and standardized procedure management was further hampered by institutional network constraints on clinical research coordinators requiring them to be on a separate network from the rest of the team. The need for increased organization, standardization of practices, and seamless communication led us to review many systems to support our workflows.

2. Goals

- Increase information dissemination while decreasing the need for one-on-one messaging
- Process standardization of processes across a staff of 20+ individuals
- Increased workload and performance measurement transparency
- Consistent access to process documentation and decision history

3. Solutions and Methods

We implemented Microsoft Teams to create various "teams" that centralized CRC screening, agenda items for meetings, management discussions, pathology report review, coverage requirements, and disease flowchart access. We also created disease specific groups such as "Breast Team" that included any members that worked on that disease to all have central discussions. Discussions are cataloged and kept in a searchable knowledgebase for future retrieval and reference. We also utilize Teams to make weekly schedule assignments. Please see associated graphic for a visual representation of the dashboard created.

4. Outcomes

This tailored implementation of Microsoft Teams has greatly increased our productivity and ability to oversee the clinical research operations of a larger team. Coordinators started having smaller targeted group discussions. The exclusion we have found is just as important as the inclusion. Too many people were involved in discussions that they did not need to be, resulting in decreased concentration and message fatigue.

5. Lessons Learned and Future Directions

The importance of targeted communication is vital, and the visibility and standardization of clinical research coordinator and data coordinator tasks helps both the staff perform their jobs in an efficient and effective way while also giving management a way of overseeing a steadily growing team.

The Utilization of Microsoft Teams for Clinical Operations Team Management

Meredith Russell, BS, CCRP; Darlene Kitterman, MBA
University of Illinois Cancer Center

UNIVERSITY OF ILLINOIS CANCER CENTER

Background

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Objectives

- Increase information dissemination while decreasing the need for one-on-one messaging.
- Process standardization of processes across a staff of 20+ individuals
- Increased workload and performance measurement transparency.
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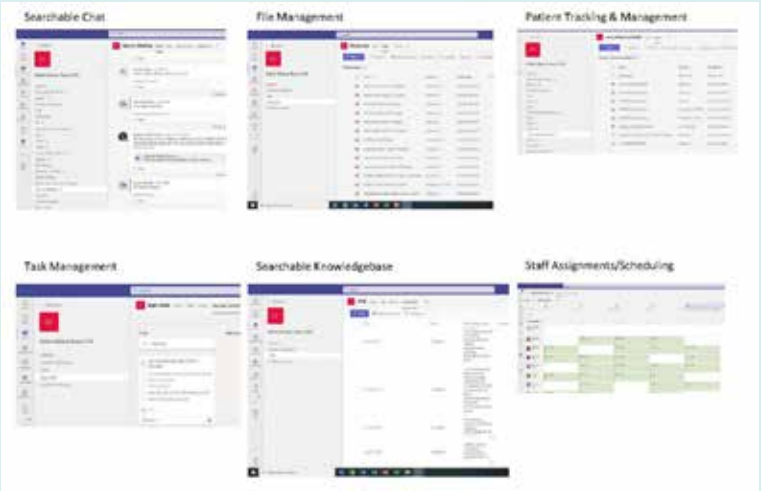
Methods

We implemented Microsoft Teams to create various "teams" that centralized CRC screening, agenda items for meetings, management discussions, pathology report review, coverage requirements, and disease flowchart access. We also created disease specific groups such as "Breast Team" that included any members that worked on that disease to all have central discussions. Discussions are cataloged and kept in a searchable knowledgebase for future retrieval and reference. We also utilize Teams to make weekly schedule assignments. See Figure 1 for an overview of the dashboard created.

Results

Figure 1: UICC CTO Microsoft Teams Clinical Research Operations Management



Conclusions

This tailored implementation of Microsoft Teams has greatly increased our productivity and ability to oversee the clinical research operations of a larger team. Coordinators started having smaller targeted group discussions that only the right people. The exclusion we have found is just as important as the inclusion. Too many people were being involved in discussions that they did not need to be, resulting in decreased concentration and message fatigue. The importance of targeted communication is vital and the visibility and standardization of clinical research coordinator and data coordinator tasks helps both the staff perform their jobs in an efficient and effective way while also giving management a way of overseeing a steadily growing team.

Acknowledgements

We would like to acknowledge the support of the University of Illinois Cancer Center for this project.

CANCER CLINICAL RESEARCH

FROM ABSTRACT TO REALITY

TRIAL RECRUITMENT AND STUDY CONDUCT (IITs)

Early Termination for Multicenter IUSCCC Sites With No Accruals

A. Bauchle, M. Contreraz, K. Miller, T. Lautenschlaeger
Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. Background

Indiana University (IU) has a well-established and robust multicenter program. Trials managed within this program are IU-led investigator-initiated trials with outside participating sites. The goal of the team is to expand research and provide oversight while maintaining a competitive workload that allows the team to effectively manage a large number of protocols and sites; essentially, we are IU's own Clinical Research Organization (CRO). As we all can attest, study start-up and overall trial management take a significant amount of time and resources for all parties. The multicenter team has several policies, procedures, and templates in place to streamline trials and make it possible for IU investigators and sites to participate in IU-led multicenter trials. Low-performing sites are evaluated continuously and those not contributing to overall trial data will receive a warning letter and be considered for early termination.

2. Goals

The goal of the policy is to identify low-performing sites and remove them from the workload. Sites that are not contributing to the overall study accrual goals are recommended for closure to allow other sites to participate in the trial. Closing participating sites also allows the team to take on additional sites and trials to better serve the Investigators in meeting their enrollment goals.

3. Solutions and Methods

A standard operating procedure (SOP) was created, and all principal investigators were notified by email. This SOP is discussed during the site initiation visit (SIV) with each site ensuring clear expectations are set for all parties. Depending on risk level, shown below, sites are given a timeline to accrue their first subject. If a site has not accrued in the allotted time, a warning letter will be issued with a deadline to accrue a subject. If the deadline is missed, sites are subject to termination. Sites have up to one month to appeal the warning letter, which is reviewed by the IU investigator, multicenter manager, and multicenter project manager. If an appeal is awarded, the site will be allowed to remain open and will be re-evaluated depending on the risk level.
High-Risk Trials: Sites must accrue within one year of site activation (open to enrollment); if no subjects are accrued after nine months of activation, a warning letter will be issued to the site PI
Moderate and Low-Risk Trials: Sites must accrue within six months of site activation; if no subjects are accrued after three months of activation, a warning letter will be issued to the site PI.

4. Outcomes

Since rolling out this policy, one site has received a warning letter and was subsequently terminated which allowed the multicenter team to take on an additional site that is now accruing therefore contributing to trial endpoints, outcomes, and goals.

5. Lessons Learned and Future Directions

We will continue to utilize this SOP. As always, we remain open to suggestions and improvements as we all continue to work towards a cure. We hope this process will continue to encourage site participation while also allowing effective workloads that contribute to research goals.

Early Termination for Multicenter IUSCCC Sites with No Accruals

Amber Bauchle; Mario Contreraz; Kathy Miller, Tim Lautenschlaeger
Indiana University Melvin and Bren Simon Comprehensive Cancer Center

Background

Indiana University (IU) has a well-established and robust Multicenter program. Trials managed within this program are IU-lead Investigator-Initiated Trials with outside participating sites. The goal of the team is to expand research and provide oversight while maintaining a competitive workload that allows the team to effectively manage a large number of protocols and sites; essentially, we are IU's own Clinical Research Organization (CRO). As we all can attest, study start-up and overall trial management take a significant amount of time and resources for all parties. The multicenter team has several policies, procedures, and templates in place to streamline trials and make it possible for IU Investigators, and sites to participate in IU Lead multicenter trials. Low- performing sites are evaluated continuously and those not contributing to overall trial data will receive a warning letter and be considered for early termination.

Goals

- Establish an SOP that clearly defines accrual expectations and consequences for sites who do not accrue within specified timeframe.
- Identify low-performing sites and remove them from workload.
- Close low-performing sites to allow team to take on additional sites and trials to better serve the Investigators in meeting their enrollment goals.

INDIANA UNIVERSITY
MELVIN AND BREN SIMON
COMPREHENSIVE CANCER CENTER

Month x, 2023

RE: Protocol number and title

Dear Dr. XXX,

We would like to thank you for your participation in CTO-IUSCCC-0000. Per IU Simon Comprehensive Center's policy, all sites will be monitored for accrual. For High/moderate/low risk trials, sites must accrue within 6 months of site activation. Institution X was OPEN TO ACCRUAL on MM/DD/YYYY. As no accruals have taken place, your site is subject to termination. Please note, your site will have one month to accrue a subject or close out procedures may begin.

You may appeal to the IU Sponsor-Investigator and provide justification to remain active as a site. The appeal will be discussed with the Sponsor-Investigator, CTO Multicenter Team Manager, and Multicenter Project Manager until a decision is reached. You will be notified by email on the appeal decision. If the appeal is denied and your site has not accrued, closeout procedures will begin.

Please do not hesitate to contact us with any questions or concerns.

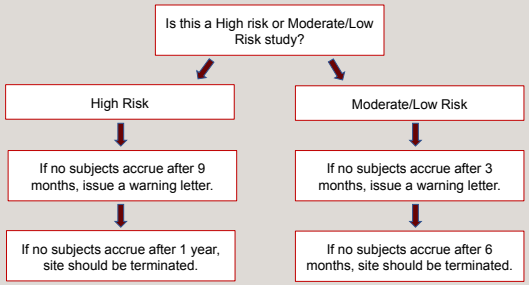
Best Regards,

Dr. XXXXXX

Cc: IU PI
Site PI
Site SC

Methods

- An SOP was created, and all PIs were notified.
- This SOP is discussed during the SIV with each site therefore clear expectations are set for all parties. Depending on risk level, sites are given a certain number of months to accrue a subject.
- If a site has not accrued in the allotted time, a warning letter will be issued with a deadline to recruit a subject.
- If the deadline has past, sites are subject to termination. An appeal process is also discussed in the SOP.



Results and Future Directions

- Since implementation, one site has been terminated allowing high-performing sites to onboard.
- We plan to continue adhering to this SOP while remaining open to suggestions and improvements as we remain working towards a cure.

INDIANA UNIVERSITY MELVIN AND BREN SIMON COMPREHENSIVE CANCER CENTER

Measuring the Impact of Multiple Strategies to Increase Enrollment in Molecular Targeted Trials

L. Wall, K. Paydary, W. M. Stadler, K. Kipping-Johnson, V. Seseri, K. Cabrera, B. Pieke, A. Larkin, M. D'Souza, D. Sulakhe, S. Moellering, A. Spratt
The University of Chicago Medicine Comprehensive Cancer Center

1. Background

Optimal patient accrual to cancer clinical trials is increasingly hampered by molecular inclusion criteria that characterize rare populations. Furthermore, patients may have internal molecular testing (IMT), or external molecular testing (EMT) through a third-party vendor (i.e., Foundation One, Tempus, etc.) at various time points in their care. EMT results are uploaded into the electronic medical records (EMR); however, results are difficult to extract in a meaningful way.

2. Goals

Given the complexity of the trial design and the data siloes, we implemented multiple strategies to increase enrollment to molecularly targeted trials and measured the impact of each strategy.

3. Solutions and Methods

Strategy 1- Matching based on External Molecular Testing (EMT)

We partnered with Tempus to increase enrollment in a rare SETD2 mutation trial. Ordering providers that had a patient identified as having an applicable mutation who resided within 50 miles from our center or were receiving treatment at pre-specified clinical sites received written notification regarding the potential trial eligibility. Additional outreach, including reasons for not pursuing the trial, was conducted.

Strategy 2 – Matching based on Internal Molecular Testing (IMT)

We partnered with our internal Clinical Research Informatics (CRI) team to develop an algorithm that would identify potentially eligible patients with IMT testing and other select criteria (i.e., age, prior treatments, last visit, etc.).

Strategy 3 – Integration of trial eligibility into standard-of-care pathways

We partnered with our hospital to integrate specific clinical trials into our electronic standard of care pathways (Clinpath) that clinicians need to utilize for documenting any change in therapy and compliance with peer-reviewed standards of care.

Strategy 4 – Clinical Research Staff Manual Pre-Screening

The fourth strategy included a manual process where our Gynecology Oncology Clinical Research Coordinators (CRCs) pre-screened patients who presented to the clinic on a weekly basis. All new patients or patients who progressed and needed a new treatment plan recommendation were flagged and manually screened for molecularly targeted trial eligibility.

4. Outcomes

We looked at 34 protocols that required genomic variants as part of eligibility. The variants included SET2, EGFR, ERBB2, ERBB3, ERBB4, KRAS, NRAS, BRAF, V600E, V600K, MRE11, NBN, RAD50, HER2, HER3, MSI, MSS, TnMUC1+, MAGEA4, WEE1, FGFR2, B7H4, and FRα _positivity. A total of 290 patients were identified and pre-screened across the four strategies, and 31 patients were enrolled (Table). The primary factor leading to non-enrollment was clinical situations precluding trial participation. Other factors comprised unresponsiveness from healthcare providers, lack of interest from the patient, and the dynamic nature of the trials, including cohort closures and protocol amendments that revise the eligibility criteria.

5. Lessons Learned and Future Directions

The four strategies represented an independent approach to augmenting enrollment in molecularly targeted trials. To effectively increase enrollment in these trials, a comprehensive approach that incorporates multiple strategies is necessary. These strategies require an investment in specialized oncology bioinformatics personnel, the establishment of a robust data warehouse, and dedicated clinical research staff. Future directions include enhancing the data warehouse to obtain access to IMT and EMT uniformly, training additional research staff to perform manual pre-screening, and increasing the number of trials and the number of physicians using the integrated pathways tool. The role of enhanced patient outreach in order to minimize dependency on physician-based trial recruitment is also being investigated.

AT THE FOREFRONT
UChicagoMedicine
Comprehensive Cancer Center

Measuring the Impact of Multiple Strategies to Increase Enrollment in Molecular Targeted Trials

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BACKGROUND

Optimal patient accrual to cancer clinical trial is increasingly hampered by molecular inclusion criteria that characterize rare populations. Furthermore, patients may have internal molecular testing (IMT), or external molecular testing (EMT) through a third-party vendor (i.e., Foundation One, Tempus, etc.) at various time points in their care. EMT results are uploaded into the Electronic Medical Records (EMR); however, results are difficult to extract in a meaningful way. Given the complexity of the trial design and the data siloes, we implemented multiple strategies to increase enrollment to molecular targeted trials and measured the impact of each strategy. We looked at 34 trials that required genomic variants as part of eligibility. The variants included SET2, EGFR, ERBB2, ERBB3, ERBB4, KRAS, NRAS, BRAF, V600E, V600K, MRE11, NBN, RAD50, HER2, HER3, MSI, MSS, TnMUC1+, MAGEA4, WEE1, FGFR2, B7H4, and FRα _positivity.

SOLUTIONS IMPLEMENTED

Strategy 1- Matching based on External Molecular Testing (EMT)

We partnered with Tempus to increase enrollment to a rare SETD2 mutation trial. Ordering providers that had a patient identified as having an applicable mutation who resided within 50 miles from our center or were receiving treatment at pre-specified clinical sites received a written notification regarding the potential trial eligibility. Additional outreach, including reasons for not pursuing the trial was conducted.

Strategy 2 – Matching based on Internal Molecular Testing (IMT)

We partnered with our internal Clinical Research Informatics (CRI) team to develop an algorithm that would identify potentially eligible patients with IMT testing and other select criteria (i.e., age, prior treatments, last visit, etc.).

Strategy 3 – Integration of trial eligibility into standard of care pathways

We partnered with our hospital to integrate specific clinical trials into our electronic standard of care pathways (Clinpath) that clinicians need to utilize for documenting any change in therapy and compliance with peer reviewed standards of care.

Strategy 4 – Clinical Research Staff Manual Pre-Screening

We implemented a manual process where our Gynecology Oncology Clinical Research Coordinators (CRCs) pre-screened patients who presented to clinic on a weekly basis. All new patients or patients who progressed and need a new treatment plan recommendation were flagged and manually screened by review of EMR for molecular targeted trial eligibility.

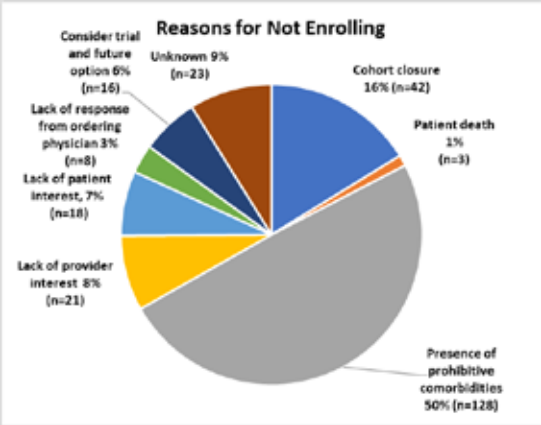
RESULTS

A total of 290 patients were identified and pre-screened across the 4 strategies and 31 patients were enrolled as a result (Table 1). The primary factor leading to non-enrollment was clinical situations precluding trial participation. Other factors comprised unresponsiveness from healthcare providers, lack of interest from the patient, and the dynamic nature of the trials, including cohort closures and protocol amendments that revised the eligibility criteria (Figure 1).

Table 1: Enrollment Results

	# of Patients Identified and Pre-Screened w/Genomic Variant	# of Patients w/Genomic Variants Consented	# of Patients w/Genomic Variants Enrolled	% of Patients Enrolled w/ Genomic Variants
Strategy 1	38	0	0	0%
Strategy 2	83	1	1	1%
Strategy 3	113	18	18	16%
Strategy 4	56	13	12	21%
Total	290	32	31	11%

Figure 1: Reasons for Not Enrolling



FUTURE DIRECTIONS

The four strategies represented independent approaches to augmenting enrollment in molecularly targeted trials. To effectively increase enrollment in these trials, a comprehensive approach that incorporates multiple strategies is necessary. These strategies require an investment in specialized oncology bioinformatics personnel, the establishment of a robust data warehouse, and dedicated clinical research staff. Future directions include enhancing the data warehouse to obtain access to IMT and EMT results uniformly, training additional research staff to perform manual pre-screening, and increasing the number of trials and the number of physicians using the integrated pathways tool. The role of enhanced patient outreach in order to minimize dependency on physician based trial recruitment is also being investigated.

Accelerating Cancer Patient Recruitment Through a Mobile Application (Clinical Trial Finder)

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1. Background

Engagement of both of patients and physicians is a central aspect of clinical trial recruitment. Without sufficient engagement and recruitment, clinical trials are frequently terminated early due to poor accrual or are unable to achieve results that are statistically significant. An estimated 19 percent of Phase II and Phase III clinical trials in Canada are terminated due to inadequate enrollment. Significant factors associated with research centers that suffer from poor recruitment include low physician referral rates, lack of awareness of clinical trials in patients, and a lack of available information regarding clinical trials. Cancer clinical trials (CCTs) face a particular challenge in engaging and recruiting patients. Only 55 percent of cancer trials in the United Kingdom were able to reach their originally specified recruitment goals. Among cancer patients CCT participation is as low as 3 to 5 percent. Only 10 percent of cancer survivors reported being aware that CCT participation was a possibility during their treatment. Additionally, among cancer patients made aware of potential CCT participation, 73 percent were made aware by their physician. This suggests that measures to foster physician and patient engagement and raise awareness of ongoing CCTs could provide access to a previous untapped source of participants in CCTs.

2. Goals

The University of Kansas Cancer Center (KUCC) at The University of Kansas Medical Center sought to accomplish this by developing a clinical trial finder application (app) that could be used by both patients and physicians. The design of the app centered on ease of use, a fluid referral process, and quick access to technical support. After researching features in clinical trial navigators that were commonly requested by physicians, the KUMC team landed on three such features to focus on.

Firstly, physicians desired for clinical trial information to be easily accessible. This desire was addressed through designing our in-house clinical trial navigator as a mobile app. The second desire was an efficient means for physicians to filter trials by treatment circumstance as well as a simple means to weigh risks and benefits. This was addressed by having clinical trials be filtered in the app design from disease group all the way to treatment modality within cancer types. Lastly, physicians wanted to be able to easily find clinical trials by location. This last point led the KUCC team to restrict displayed trials to our health system. This decision was made because traditional clinical trial navigation systems typically include trials from all over the country and require extensive time or experience to navigate. A clinical trial application limited to trials from a local health system streamlines that process for local and regional physicians. The ability to use the application on a portable device further encourages engagement in physicians by allowed them to browse clinical trials while on the move.

3. Solutions and Methods

In order to encourage physician engagement in clinical trials, our team focused primarily on addressing physician concerns regarding the process of making a referral. As previously mentioned, physicians desired information on clinical trials that were local, could be easily assessed for risks and benefits, and were internet accessible.

We included several secondary aims in development based on physician feedback. The first of these was to allow physicians to access clinical trial information on the go or at the bedside, as many physicians expressed that they often did not have time to search for clinical trials at a desk. The second of these was allowing physicians to find trials without manual searching. This aim ties in to the first, where usability without manual searching would allow physicians to search for trials while on the move. The third of these was allowing physicians to differentiate between first line and second line treatment trials. The last of these was building a tool that would promote discussions of clinical trials at the patient bedside.

Very few universities have built a trial searching app, among those applications most of them are web-based and restricted to just a few research personnel. Others are specific to health systems such as Stanford's SCI Cancer Clinical Trials app. However, most of these apps and other trial search functions are designed for both patient and physician use. When designed this way, these systems typically do not provide much benefit to healthcare professionals for their medical expertise and lead to physicians spending similar amounts of time to laymen searching for trials before finding the information they need.

In designing the clinical trial application for physician referral use, The University of Kansas Cancer Center's aim was to capitalize on physician expertise to lead them more quickly to trials and minimize manual text searching.

4. Outcomes

The figure below demonstrates a sample search process, which narrows available trials by disease working groups, then further by cancer type in that system, and lastly by first-line or second-line treatment.

These options follow a line of logic that is consistent with physician considerations in researching potential clinical trials, while still being accessible to laypeople. These options were also implemented according to the secondary aims of development.

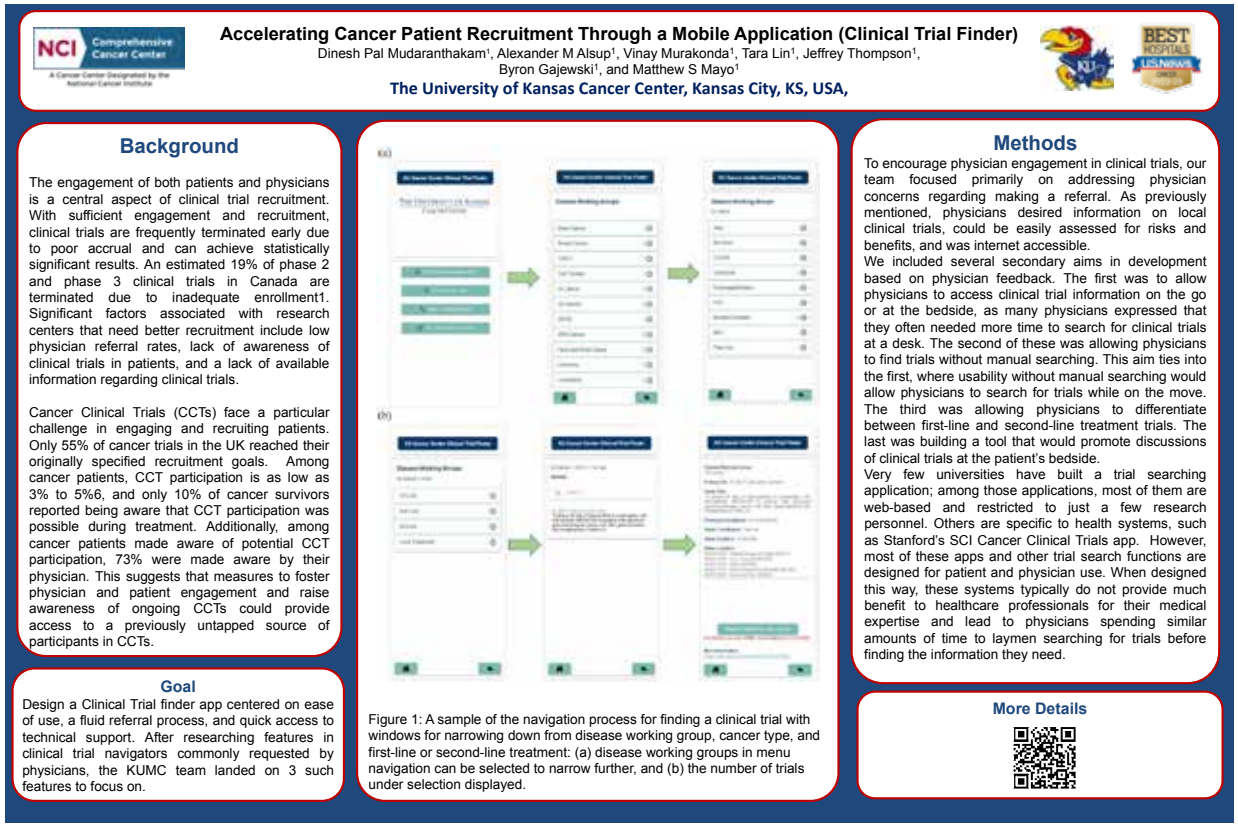
To allow physicians to access information on the go, options were laid out in a clear progression with full utility available through single button presses. A filtering system was implemented to allow physicians to find trials without searching by name. The first- and second-line filtering after trial type selection allows physicians to make those differentiations. This filtering process allows users to filter the available trials for display by broad characteristics, such as cancer type, as well as more specific characteristics like whether the treatment is first or second line. Lastly, the broad availability of the app would allow physicians to guide patients and families through the process at the bedside to provide a tailored list of available trials. All trials present on the app are currently open to recruitment at KUCC. With these features a physician will no longer need to find a workstation and manually search through trials to narrow results using national-level web-based trial finders. Instead, they can use the mobile app at the bedside or in a free moment to find trials quickly and easily. Additionally, because the information contained within the app is derived from clinical trial data that is captured daily, the app will consistently be updated with new trials or the removal of trials which have ceased recruitment.

5. Lessons Learned and Future Directions

The KUCC Clinical Trial Finder app streamlines the physician referral process and can accelerate the process of enrolling eligible patients in the correct study for them. The simplification of this first step in patient enrollment can lead smoothly into the next steps, such as pre-screening tests. The trust that these patients have in their physicians can make a collaborative discussion tool such as this particularly beneficial. Considering that 73 percent of oncology recruitment is done through physician referral, it is crucial to develop clinical trial engagement tools that facilitate this process.

Currently over 600 users have downloaded the CT finder app since its launch in December 2020. The informatics team continues to work closely with physicians and the clinical teams across KUCC to solicit feedback that would help further optimize the application and streamline the data flow. Some of the feedback from the usability survey suggested that we should allow users to search using the study titles, as these contain key words which are familiar to clinicians. The informatics team was able to incorporate this feature in only a few weeks and it is currently available in the version that is deployed in the app store.

Future developments to the app would include the option to prioritize studies within the CT Finder. Through this feature, primary investigators would be able to easily collaborate and refer or recruit patients for prioritized studies. The other feature we anticipate including in the near future is to index studies based on current accrual rates. These indexes could then be displayed for primary investigators to track the progression of their studies through the app.



NCI Comprehensive Cancer Center

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Accelerating Cancer Patient Recruitment Through a Mobile Application (Clinical Trial Finder)

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The University of Kansas Cancer Center, Kansas City, KS, USA,

Background

The engagement of both patients and physicians is a central aspect of clinical trial recruitment. With sufficient engagement and recruitment, clinical trials are frequently terminated early due to poor accrual and can achieve statistically significant results. An estimated 19% of phase 2 and phase 3 clinical trials in Canada are terminated due to inadequate enrollment1. Significant factors associated with research centers that need better recruitment include low physician referral rates, lack of awareness of clinical trials in patients, and a lack of available information regarding clinical trials.

Cancer Clinical Trials (CCTs) face a particular challenge in engaging and recruiting patients. Only 55% of cancer trials in the UK reached their originally specified recruitment goals. Among cancer patients, CCT participation is as low as 3% to 5%6, and only 10% of cancer survivors reported being aware that CCT participation was possible during treatment. Additionally, among cancer patients made aware of potential CCT participation, 73% were made aware by their physician. This suggests that measures to foster physician and patient engagement and raise awareness of ongoing CCTs could provide access to a previously untapped source of participants in CCTs.

Goal

Design a Clinical Trial finder app centered on ease of use, a fluid referral process, and quick access to technical support. After researching features in clinical trial navigators commonly requested by physicians, the KUMC team landed on 3 such features to focus on.

Figure 1: A sample of the navigation process for finding a clinical trial with windows for narrowing down from disease working group, cancer type, and first-line or second-line treatment: (a) disease working groups in menu navigation can be selected to narrow further, and (b) the number of trials under selection displayed.

Methods

To encourage physician engagement in clinical trials, our team focused primarily on addressing physician concerns regarding making a referral. As previously mentioned, physicians desired information on local clinical trials, could be easily assessed for risks and benefits, and was internet accessible.

We included several secondary aims in development based on physician feedback. The first was to allow physicians to access clinical trial information on the go or at the bedside, as many physicians expressed that they often needed more time to search for clinical trials at a desk. The second of these was allowing physicians to find trials without manual searching. This aim ties into the first, where usability without manual searching would allow physicians to search for trials while on the move. The third was allowing physicians to differentiate between first-line and second-line treatment trials. The last was building a tool that would promote discussions of clinical trials at the patient's bedside.

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More Details

Pan-Screening to Improve Patient Identification for Targeted and Disease Agnostic Trials

A. Anderson, A. Kukulka, A. Ivey, T. George, D. Deremer, E. Monari
University of Florida Health Cancer Center

1. Background

In November 2020, the University of Florida Health Cancer Center (UFHCC) expanded the previous Phase I program to include management of disease agnostic and/or genetically targeted clinical trials. It quickly became evident that this portfolio presented unique challenges for patient recruitment and enrollment which historically relied heavily on clinician awareness of disease-specific trial options and engagement with disease-specific facing coordinators.

2. Goals

Key goals were to: 1. Provide individual patient to comprehensive trial matching, representing all enrollment options to clinicians 2. Improve communication efficiency between clinical providers and the research team 3. Improve screening efficiency within the early phase team.

3. Solutions and Methods

Our first step established a single intake process for all trial referrals, a unique email address whereby providers could submit referrals to the entire research team with a single email communication. Requests received through the intake email are managed by a designated member of the early phase team, who confirms receipt and performs an initial, high-level eligibility review. This initial review establishes general trial suitability criteria (e.g., RECIST measurable disease, performance status, organ function, etc.). Referrals failing to pass the initial high-level review are returned to the referring provider with feedback and for clarification regarding identified issues. A subject referral form capturing general demographic and diagnostic information is created for referrals that pass initial review and is disseminated to the full early phase team for completion. Referral forms are electronically stored in a secure, web-based library that enables team members to simultaneously access, update, and autosave.

Completed forms provide a synopsis of subject eligibility across all available trials and are provided to the referring provider for consideration. All screening referrals are reviewed weekly within team meetings that include the program leaders and contributing investigators to verify all options accurately considered and to provide recommendations regarding trial prioritization when more than one enrollment option is available. Referral forms facilitate and verify capture of screening metrics into the Clinical Trial Management System (CTMS), improving overall portfolio surveillance and informing future trial selection.

4. Outcomes

Implementation has been well received by both the research and clinical team members with a 74 percent increase in referrals (245 to 332) from 2021 to 2022. This referral increase was associated with a threefold increase in enrollments (18 to 61) despite a 15 percent reduction in the number of trials in the portfolio. The centralized process eliminated the need for clinicians to know in advance which trials are available and improved efficiencies in referring patients. The consolidation of all potential trial options into a single communication and weekly team review ensured comprehensive reporting and reduced time from referral to informed consent presentation, critically important with dynamic trial slot availability.

5. Lessons Learned and Future Directions

Future directions include development of automated dashboard reporting to identify gaps in patient referrals relative to no trial availability for better trial selection.

Pan-Screening to Improve Patient Identification for Targeted and Disease Agnostic Trials

Anna Kukulka, RN, BSN, CCRC, Alison Ivey, RN, MS, MBA, OCN, CCRP, Thomas George, MD, F.A.C.P., David Deremer, Pharm.D., BCOP, FCCP, FHOPA, Erin Monari, PhD, CCRP, Ashley Anderson, MBA, ACRP-CP

BACKGROUND

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GOALS

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- Improve communication efficiency between clinical providers and the research team.
- Improve screening efficiency within the early phase team.

CONTACT

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METHODS

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Patient Screened:
MRN:
DOB:
Treating Physician:
Primary Disease:
Race/Ethnicity:

Open Studies	Potentially Eligible	Not Eligible	N/A	Reason Ineligible	Comments
Trial 1					
Trial 2					

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FUTURE DIRECTIONS

Future directions include development of automated dashboard reporting to identify gaps in patient referrals relative to no trial availability for better trial selection.

Data Management in Clinical Research: Streamlining, High-Quality Data, and Subject Matter Experts

E. Nelson, A. Ivey, L. Pettiford, A. Anderson
University of Florida Health Cancer Center

1. Background

In March 2020, the University of Florida Health Cancer Center (UFHCC) Clinical Research Office (CRO) formed the Data Management Unit (DMU) to focus on improving the quality of data curation and entry. Previously, data entry was performed by CRO assigned study coordinators or clinical research assistants. Due to the rapidly increasing complexity of trials and impact to workloads, it was discovered that coordinators were deprioritizing data to meet the clinical needs of subjects. This led to lengthened data entry timelines, less precise data entry, and a higher volume of queries. CRO leadership quickly identified the need to intervene as data is a CRO's principal work product. This initiative was implemented at the start of a pandemic, which posed unique challenges and opportunities.

2. Goals

The primary goal of improving data quality was accomplished via two approaches: 1. Streamline the upload and curation of research source documents 2. Train subject matter experts for each disease site group.

3. Solutions and Methods

The initial implementation of the Data DMU was at the start of the COVID-19 pandemic, where CRO staff quickly moved to full or partially remote working assignments and establishment for streamlined methods for source documentation upload to the data unit was necessary. We determined Microsoft Teams was the best platform since clinical units had familiarity with the software and IT Risk Management determined it was appropriate for storage of protected health information. Digitizing and centralizing source documents provided the data unit with remote work options and continuous access to the documents. This simultaneously created an effective means for the UFHCC to go fully electronic and further eliminate the need for paper documents. It's expected that documentation from the clinical staff be available to the DMU within one week of subject visits, thereby helping to facilitate DMU improved data entry timeliness. All documents were uploaded with the same nomenclature into subject folders using the same organization across all trials. It was also decided to separate workloads by disease site groups, thereby allowing the data coordinator to become an expert in their assigned disease area(s). Knowledge was bolstered by inclusion in disease specific trainings, tumor boards, and other clinical meetings.

4. Outcomes

Based on scoring by the NRG Oncology Performance Reports, this new process increased our data entry scores by 15-20 percent, created fewer data delinquencies, and improved the quality of the data being entered.

The inception of electronic source documents has impacted multiple units within the CRO in a positive way. It's allowed the clinical teams to effectively interact with the DMU and others across the CRO, despite physical separation. By creating work assignments based on disease site groups, the quality of the data extraction and entry has increased, resulting in fewer data entry errors, which are now more quickly identified and addressed by the assigned DMU coordinator.

5. Lessons Learned and Future Directions

As the CRO grows, we hope to continue improving data entry scores, offer more trainings for subject matter experts within each disease site group, and provide high-quality data that's ready for statistical analysis without significant data clean-up.

Data Management in Clinical Research: Streamlining, High-Quality Data, and Subject Matter Experts

Elena Nelson, BA, CCRC, Alison Ivey, RN, MS, MBA, OCN, CCRP, Leslie Pettiford, RN, MS, CCRC, Ashley Anderson, MBA, ACRP-CP

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2. Train subject matter experts for each disease site group

CONTACT

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Adverse Events Logs: Transformation From Paper Forms to an Electronic Health Record Integrated Platform

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University of Wisconsin Carbone Cancer Center

1. Background

Adverse events (AE) reporting is an integral part of clinical trials. Conventional paper forms are commonly used for AE documentation, but the process is labor-intensive, time-consuming, and prone to error, as the medical information needs to be manually extracted from the electronic health records (EHR) and again transferred into the study-specific databases. Here we report our transition to an EHR-based AE reporting platform.

2. Goals

With the emergence of COVID-19 pandemic, we decided to transition to an electronic EHR-based AE log to reduce touchpoints, allow remote access for research teams and study monitors, and improve documentation accuracy and workflow efficiency.

3. Solutions and Methods

Initially, developing EHR-based templated notes, which resembled the conventional tables in paper logs, provided a quick but temporary solution. Preparation of these templated notes was time-consuming, and identifying new or changed AEs in the tables was difficult. In the second phase, we implemented the Epic foundation AE activity within the research module of our EHR. However, as we were one of the early adopters of this platform, we had to devise creative ways to modify the customizable parts of the original build to achieve our desired functions. In the first released version, discrete attributions (using multiple-choice buttons) were only available for investigational drugs. Therefore, the initial workflow heavily depended on using pick lists (SmartListsTM) within the comments section to document required datapoints including attributions to anything other than the investigational drugs. This laborious workflow required reactivation of every pick list by the investigator to select the appropriate attribution. The next Epic upgrade of the AE activity allowed discrete attributions for procedures. Using this opportunity, we created a customized list of categories (e.g., “disease under study,” “hormonal therapy,” “radiotherapy,” etc.) which significantly enhanced the usability of this platform. In addition, we created EHR-based reports to monitor the latest status of the AE logs (reviewed by the investigator, pending review, etc.). We designed a survey to assess user satisfaction and identify areas for improvement. We asked our team members about their preferred AE reporting method regarding 16 activities, including finding the appropriate AE term and grade, time spent creating and reviewing AE logs, identifying AE changes over time, accessing patient’s chart for clinical review, and risk of error
.

4. Outcomes

This presentation will share our experience and details of the optimization and implementation process. We received input from 106 research team members (Investigator=26, Research staff=53, Study monitor=27). Survey participants preferred the EHR-integrated AE activity in all 16 surveyed categories and reported higher satisfaction rates using this method when compared to paper forms and templated notes in EHR.

5. Lessons Learned and Future Directions

EHR-integrated AE logs can improve accuracy and efficiency, eliminate paper access and storage issues, provide remote access to study teams and monitors, and facilitate reporting and monitoring of AEs during trials. Although some customization and functionality enhancements were necessary, our investigators and research staff preferred the EHR-integrated AE logs over paper forms and other AE reporting methods.

Adverse Events Logs: Transformation from Paper Forms to an Electronic Health Record Integrated Platform

Hamid Emamekhoo, MD; Marissa Weiss, BS, MBA; Ann Weiben, MS, BSN, RN-BC; Megan Braden, BSN, OCN; Jennifer Collins, BS; Mike Thompson, AAS; Jill Kubiack, BS; Sarah Stewart, BS

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SCHOOL OF MEDICINE AND PUBLIC HEALTH

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Goals

With the emergence of COVID-19 pandemic, we decided to transition to an electronic EHR-based AE log to reduce touchpoints, allow remote access for research teams and study monitors, and improve documentation accuracy and workflow efficiency.

EHR-Integrated AE Activity

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Solutions

V.1 Research Notes in EHR

- Templated notes mirrored format of paper logs
- Allowed for rapid implementation and required minimal training
- AE report preparation was still manual and time consuming
- Tracking changes was very difficult

V.2 Foundational EHR-integrated AE Activity

- Study-level set up of term set version and study medications for attributions minimized errors
- Multiple required data fields had to documented in the comments section (heavily text dependent and laborious)
- Required extensive training via multiple modalities
- Users struggled with identifying areas that required editing prior to finalizing the AE report review

V.3 Optimized EHR-integrated AE activity

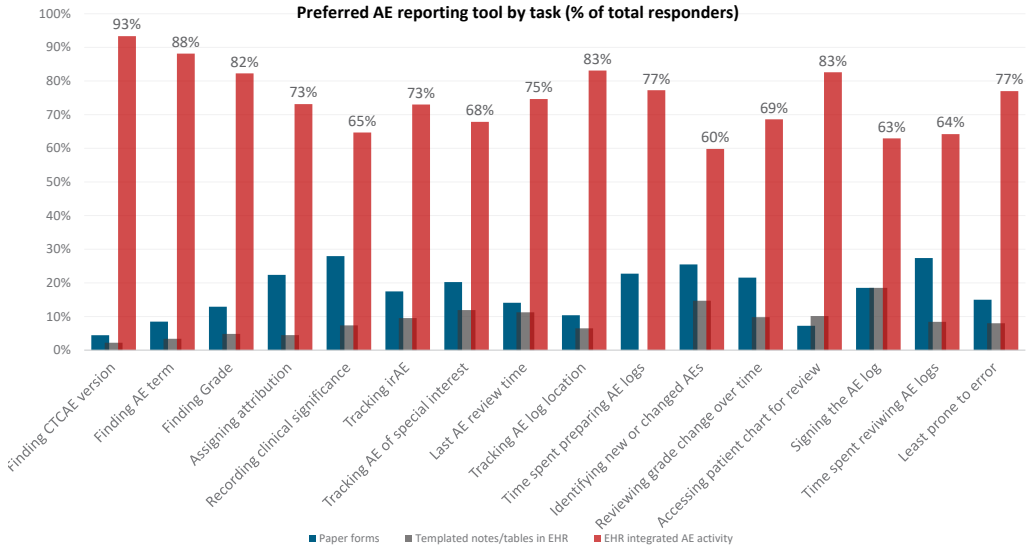
- Repurposed discrete data fields to capture the data items of interest (i.e. IRAE, AESI)
- Created placeholder procedure records to enable easier attribution to more general categories (i.e. hormonal therapy, surgery, radiotherapy)
- Created customized reports to track the latest status of the report and those pending review by the investigator

Survey Methods

- Cross-sectional survey design
- Survey items queried users' preferred AE log tool when preforming 16 AE report related tasks.

Outcomes

We received input from 106 research team members (Investigator=26, Research staff=53, Study monitor=27). Survey participants preferred the EHR-integrated AE activity in all 16 surveyed categories and reported higher satisfaction rates using this method when compared to paper forms and templated notes in EHR optimization and implementation process.



Lessons Learned & Future Directions

EHR-integrated AE logs can improve accuracy and efficiency, eliminate paper record and storage issues, provide remote access to study teams and monitors, and facilitate reporting and monitoring of AEs during trials.

Although some customization and functionality enhancements were necessary, our investigators and research staff preferred the EHR-integrated AE logs over paper forms and other AE reporting methods.

EHR-integrated platforms provide the potential for automated and system identified AE instances and ultimately direct transfer of the discrete data into the sponsors' databases.

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Automated Patient Pre-Screening Using a Clinical Trials Patient Matching Algorithm

C. Wiess, G. Gong, P. Kunz
Yale Cancer Center, Yale School of Medicine

1. Background

Effective participant recruitment is key to the success of clinical trials. To optimize recruitment of participants, pre-screening patient electronic health records is essential. Pre-screening has become increasingly burdensome due to the growing breadth of clinical trials and limited staffing resources to dedicate to this endeavor. Current health care information technology systems are typically limited in their ability to support the development of automated information extraction methods, and this is particularly true in oncology, where specific clinical vocabularies are needed to capture semantic meaning and temporal context of clinical findings. In this pilot study, a clinical trials patient matching (CTPM) algorithm was created using artificial intelligence (AI) and natural language processing (NLP) to filter patients based on defined eligibility criteria, extract relevant patient data, and export the data in an easily reviewable format for research staff.

2. Goals

This pilot study aimed to develop and test an CTPM designed to pre-screen GI Oncology patients for an interventional clinical trial, while simultaneously increasing the efficiency of review by research staff.

3. Solutions and Methods

This pilot study consisted of retrospective and prospective use of the CTPM for pre-screening. In the retrospective cohort, patients seen previously in GI Oncology clinics were reviewed to validate the accuracy and efficiency of the CTPM algorithm. In the prospective cohort, patients who had future visits to the GI Oncology department were pre-screened using the CTPM weekly in advance of the participant's scheduled visit.

4. Outcomes

For the retrospective cohort, research staff conducted chart review without use of the CTPM for the randomly selected week of September 14-20, 2020, during which 161 patients visited Yale New Haven Hospital GI Oncology. Six patients were deemed eligible for consent. When the CTPM was applied it successfully excluded 146 patients, narrowing the pool to 15 patients for manual chart review, resulting in 100 percent sensitivity, 94.2 percent specificity, 40 percent precision, and overall accuracy of 94.4 percent. The time for eligibility review per subject with and without the use of the CTPM was tracked, taking an average of 1.82 and 3.11 minutes respectively, showing an improved efficiency of 41 percent.

For the prospective cohort, the week of June 14-20, 2021 was analyzed. Research staff conducted chart review for this week without use of the CTPM during which 193 patients visited GI Oncology with 14 patients deemed eligible for consent. When the CTPM was applied it successfully excluded 156 patients, narrowing the pool to 37 patients for manual chart review, resulting in 100 percent sensitivity, 87.2 percent specificity, 37.8 percent precision, and overall accuracy of 88.08 percent.

5. Lessons Learned and Future Directions

Takeaways from this pilot study included the importance of thoughtful selection of the eligibility criteria used for patient filtering to increase specificity while not compromising sensitivity. Additionally, this pilot provided insight into future applications, such as pre-activation feasibility assessments and improving pre-screening for rare disease and biomarker driven trials. Scalability testing of the CTPM is ongoing. This expansion includes using the CTPM with additional trials across oncologic specialties and geographic oncology clinic locations within the Yale Cancer Center.

Automated Patient Pre-Screening Using a Clinical Trials Patient Matching Algorithm

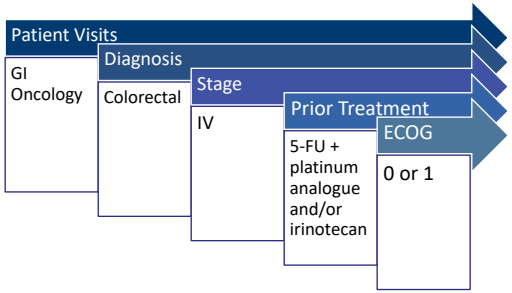
Christina Wiess, BA, CCRP, Pamela L. Kunz, MD, Guannan Gong, PhD

Goals

Develop and test a Clinical Trial Patient Matching (CTPM) algorithm designed to pre-screen patients with GI cancers for an interventional clinical trial, while increasing the efficiency of review by research staff.

Background

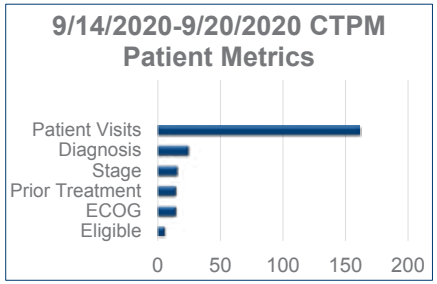
- Effective participant recruitment is key to the success of clinical trials. To optimize recruitment of participants, pre-screening patient electronic health records prior to their scheduled oncology clinic visit is essential.
- Pre-screening has become increasingly burdensome due to the increasing complexity of clinical trials and limited staffing resources. This challenge is further compounded when pre-screening is required across multiple geographic oncology clinic locations.
- Current healthcare information technology systems are typically limited in their ability to support the development of automated information extraction methods, and this is particularly true in oncology, where specific clinical vocabularies are needed to capture the meaning and context of clinical findings.

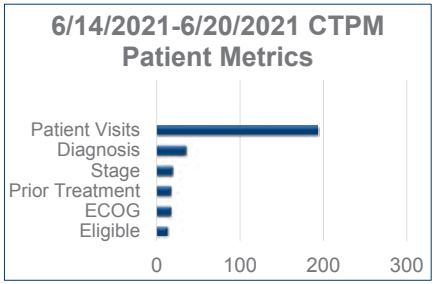


Solutions and Methods

In this pilot study, a clinical trials patient matching (CTPM) algorithm was created using artificial intelligence (AI) and natural language processing (NLP) applied to the electronic medical record in order to filter patients based on defined eligibility criteria, extract relevant patient data, and export the data in an easily reviewable format for research staff. The study consisted of retrospective and prospective use of the CTPM for pre-screening. In the retrospective cohort, patients seen previously in GI Oncology clinics were reviewed to validate the accuracy and efficiency of the CTPM algorithm. In the prospective cohort, patients who had future visits to the GI Oncology department were pre-screened using the CTPM weekly in advance of the participant's scheduled visit.

Outcomes





For the retrospective cohort, research staff conducted chart review without use of the CTPM for the randomly selected week of 9/14/2020-9/20/2020 during which 161 patients visited YNHH GI Oncology. Six patients were deemed eligible for consent. When the CTPM was applied it successfully excluded 146 patients, narrowing the pool to 15 patients for manual chart review, resulting in 100% sensitivity, 94.2% specificity, 40% precision, and overall accuracy of 94.4%. The time for eligibility review per subject with and without the use of the CTPM was tracked, taking an average of 1.82 and 3.11 minutes respectively, showing an improved efficiency of 41%.

For the prospective cohort, the week of 6/14/2021-6/20/2021 was analyzed. Research staff conducted chart review for this week without use of the CTPM during which 193 patients visited GI Oncology with 14 patients deemed eligible for consent. When the CTPM was applied it successfully excluded 156 patients, narrowing the pool to 37 patients for manual chart review, resulting in 100% sensitivity, 87.2% specificity, 37.8% precision, and overall accuracy of 88.1%.

Lessons Learned and Future Directions

- Matching eligible patients with clinical trials requires thoughtful selection of the eligibility criteria used for patient filtering to increase specificity while not compromising sensitivity. Additionally, a thorough understanding of the clinical data is required to optimize the technology used to establish the filters.
- There is an unmet need to explore future applications of the CTPM algorithm, such as pre-activation feasibility assessments and improving pre-screening for rase disease and biomarker driven trials.
- Use of the CTPM algorithm is being expanded to additional trials across oncologic specialties and geographic oncology clinic locations within the Yale Cancer Center.

Contact

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Expansion of Oncology Clinical Trials in the Indianapolis Suburban region

J. Spittler, M. Contreraz, L. Haney
Indiana University Simon Comprehensive Cancer Center

1. Background

The availability of cooperative group and investigator-initiated clinical trials is a major differentiator in the local oncology market. The goal is to expand oncology statewide research within the Indianapolis Suburban region hospitals. Patients will have not only standard-of-care treatment options but will have access to the latest clinical trials. Providing research options locally will prevent the leakage of patients to external systems and out of state providers.

In collaboration with Indiana University Melvin and Bren Simon Comprehensive Cancer Center (IUSCCC) it will provide more treatment options than are available at competing facilities in the region. The IUH Schwarz Cancer Center includes a 20-bay infusion center, compounding pharmacy, phlebotomy/lab processing and dedicated research space. Oncology specialties include Breast, Gynecological, Thoracic, Head & Neck, Gastrointestinal, Radiation Oncology, Surgery, and Hematology Malignancy, all staffed by IUSCCC physicians.

2. Goals

- Providing patients access to IU Simon Comprehensive Cancer Center trials without having to drive to the downtown locations
- Support a clinical trial portfolio that offers options to patients with a variety of cancer diagnoses
- Build a comprehensive research team that manages all aspects of clinical trial research (screening, consenting, eligibility, treatment, correlative sample processing, data management, and follow-up)

3. Solutions and Methods

- In collaboration with the IU Health system, we developed a milestone-dependent accrual mechanism; the clinical research infrastructure continues to grow as accruals are met
- Developed a mechanism to identify clinical trials feasible for the surrounding sites
- Dedicated research office space and a research laboratory for correlative sample processing
- Established a courier system for transporting samples and Investigational products
- Dedicated site-specific research staff (CRN, CRPS, CRS, DC) to support clinical research and allow for real-time data entry
- Ensured physicians have access to the clinical trials portfolio and can access trials through the website
- Developed strong and supportive relationships with IU Health leadership and the site's physicians and staff
- Integrated research staff into the daily workflow of the Schwarz Cancer Center
- Screened physician schedules to identify potential study patients

4. Outcomes

The IU Health Schwarz Cancer Center opened in January 2020 and is supported by 2.4 FTE (1 Clinical Research Coordinator and part-time CRN, regulatory, finance, and manager support). A milestone- dependent achievable plan to increase support is approved with 6.4 FTE as of January 2023. Thus far, all milestones have been met. The Schwarz Cancer Center has enrolled 85 patients in its first year, 99 in its second year, and 146 patients in the third year.

5. Lessons Learned and Future Directions

- We are in our third year of a five-year plan and will need to prepare to renegotiate our budget with the IU Health System
- It is critical to have the research infrastructure in place to support clinical research
- The Schwarz Cancer Center is our model of success and plan to expand research operations to the West region of Indianapolis
- We have hired an Oncology Statewide Research Administrator to provide operational oversight for the expansion of the Indianapolis suburban regional sites
- Health System Leadership and site physician buy-in are essential for success

IUSCCC Expansion of Oncology Clinical Trials in the Indianapolis Suburban Region

A. John Spittler RN, BSN; Mario Contreraz, MBA, MSN,RN; LaTrice Haney RN, BSN
Indiana University School of Medicine

Background

The availability of cooperative group and investigator-initiated clinical trials is a major differentiator in the local oncology market. The goal is to expand oncology statewide research within the Indianapolis Suburban region hospitals. Patients will have not only standard- of- care treatment options but will have access to the latest clinical trials. Providing research options locally will prevent the leakage of patients to external systems and out of state providers.

In collaboration with IU Melvin and Bren Simon Comprehensive Cancer center it will provide more treatment options than are available at competing facilities in the region. The IUH Schwarz Cancer Center includes a 20-bay infusion center, compounding pharmacy, phlebotomy/lab processing and dedicated research space. Oncology Specialties include Breast, Gynecological, Thoracic, Head & Neck, Gastrointestinal, Radiation Oncology, Surgery, and Hematology malignancy all staffed by IUSCCC physicians

Goals

- Providing patients access to IU Simon Comprehensive Cancer Center trials without having to drive to the downtown locations.
- Support a clinical trial portfolio that offers options to patients with a variety of cancer diagnoses.
- Build a comprehensive research team that manages all aspects of clinical trial research (screening, consenting, eligibility, treatment, correlative sample processing, data management, and follow-up).

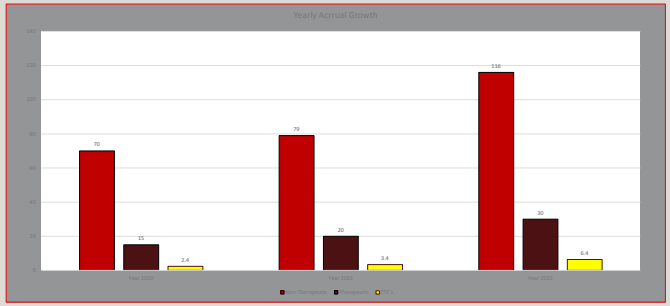
Methods

- In collaboration with the IU Health system, we developed a milestone-dependent accrual mechanism. The clinical research infrastructure continues to grow, as accruals are met.
- Developed a mechanism to identify clinical trials feasible for the surrounding sites.
- Dedicated research office space and a research laboratory for correlative sample processing.
- Established a courier system for transporting samples and Investigational products.
- Dedicated site-specific research staff (CRN, CRPS, CRS, DC) to support clinical research and allow for real-time data entry.
- Developed strong and supportive relationships with IU Health leadership and the site's physicians and staff.
- Integrated research staff into the daily workflow of the Schwarz Cancer Center.
- Screen physician schedules to identify potential study patients.
- Ensured physicians have access to the clinical trials portfolio and can access trials through the website using QR code.

Complete satellite trial portfolio QR code.

Results

The IU Health Schwarz Cancer Center opened in January 2020 and is supported by 2.4 FTE (1 Clinical Research Coordinator and part-time CRN, regulatory, finance, and manager support). A milestone- dependent achievable plan to increase support is approved with 6.4 FTE as of January 2023. Thus far, all milestones have been met. The Schwarz Cancer Center has enrolled 85 patients in its first year, 99 in its second year, and 146 patients in the third year



Conclusions

- We are in our third year of a 5-year plan and will need to prepare to renegotiate our budget with the IU Health System.
- Critical to have the research infrastructure in place to support clinical research.
- The Schwarz Cancer Center is our model of success and plan to expand research operations to the West region of Indianapolis.
- We have hired an Oncology Statewide Research Administrator to provide operational oversight for the expansion of the Indianapolis suburban regional sites.
- Health System Leadership and site physician buy-in are essential for success.

INDIANA UNIVERSITY MELVIN AND BREN SIMON COMPREHENSIVE CANCER CENTER

Improving Data Entry for Clinical Trials: A Review of REDcap's Clinical Data Pull in the Clinical Research Setting

Y. Lean, V. Pohl, N. Chowdhury, F. Davies
Laura and Isaac Perlmutter Cancer Center at NYU Langone

1. Background

In investigator-initiated trials (IITs), the online software, Research Electronic Data Capture (REDCap), is a common data collection tool. Entering clinical data parameters such as laboratory results and vitals into REDCap can be time-intensive, inefficient, and error-prone. Clinical data pull (CDP) is a REDCap feature that uses Fast Healthcare Interoperability Resources to automatically retrieve these clinical data parameters from the electronic medical record and import these results into data capture forms within REDCap.

2. Goals

Our project demonstrates CDP's ability to increase the speed and accuracy of data collection for IITs.

3. Solutions and Methods

The investigators compared the speed of data entry into a CDP-enabled database to two similar databases without CDP functionality. The metric for speed was the time taken to complete the visit's data entry divided by the number of data points entered per study visit. All databases were for IITs at the Perlmutter Cancer Center and required similar data entry. Staff entered 75 different patient visits (N=36 with 1409 data points for CDP enabled, and N=39 with 862 data points for manual entry) with an average of 30.28 data points of clinical laboratory results per visit. A one-tailed Wilcoxon Rank Sum Test tested our hypothesis that CDP increases data entry speed.

To determine accuracy, we checked a random sample of 1126 data points from the CDP-enabled database against the original values displayed in the EMR. A binomial test ensured our measured amount of error was less than 5/1000, one-tenth of our error of five percent in non-CDP enabled databases. We used R Studio enabled with R Version 4.2.2 and GGPlot2 for statistical analysis and data visualization.

4. Outcomes

The mean time per data point with CDP was 1.58s as opposed to 5.41s without CDP (Plot 1). The Wilcoxon Sum Rank Test showed that this difference of 3.83 was significant with a p-value of less than 2 x 10-16. Furthermore, CDP also reduced the standard deviation of time spent inputting lab results from 1.56s in databases without CDP to 0.58s in databases with CDP. We found zero errors in the 1126 data points we randomly sampled, and our binomial test was significant with a p-value of 0.003538 and a 95 percent confidence interval of 0 percent to .26 percent error for the CDP-enabled database.

5. Lessons Learned and Future Directions

Informatic tools like CDP will improve clinical data collection in future IITs. We have seen that CDP is superior to manual input due to its increased speed and accuracy. In 2022, our research team entered approximately 90,000 data points into manual entry REDcaps. CDP usage would have eliminated 4200 data errors and reduced the time spent on data collection by 25 hours (i.e., approximately $1000 salary support) across 3 active studies.

As we continue implementing CDP, we will compare it to manual data entry and validate our results in other disease groups and studies. We will also investigate how CDP collects data outside the parameters used in this abstract, including demographic and medication data.

Improving Data Entry for Clinical Trials:

A Review of Redcap's Clinical Data Pull in the Clinical Research Setting

Yonatan Lean, Virginia Pohl, Faith Davies M.D., Nadia Chowdhury

Perlmutter Cancer Center
An NCI-designated Comprehensive Cancer Center

NYU Langone Health

Background

In Investigator Initiated Trials (IITs), the online software, Research Electronic Data Capture (REDCap), is a common data collection tool. Entering clinical data parameters such as laboratory results and vitals into REDCap can be time-intensive, inefficient, and error-prone. Clinical data pull (CDP) is a REDCap feature that uses Fast Healthcare Interoperability Resources to automatically retrieve these clinical data parameters from the Electronic Medical Record and import these results into data capture forms within REDCap.

Methods

The investigators compared the speed of data entry into a CDP-enabled database to two similar databases without CDP functionality. The metric for speed was the time taken to complete the visit's data entry divided by the number of data points entered per study visit. All databases were for IITs at the NYU Langone Health Perlmutter Cancer Center and required similar data entry. Staff entered 75 different patient visits (N=36 with 1409 data points for CDP enabled, and N=39 with 862 data points for manual entry) with an average of 30.28 data points of clinical laboratory results per visit. A one-tailed Wilcoxon Rank Sum Test tested our hypothesis that CDP increases data entry speed.

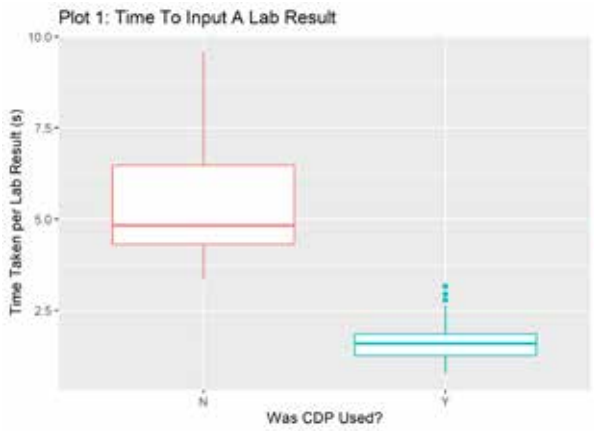
To determine accuracy, we checked a random sample of 1126 data points from the CDP-enabled database against the original values displayed in the EMR. A binomial test ensured our measured amount of error was less than 5/1000, one-tenth of our error of five percent in non-CDP enabled databases.

Goals

Our project demonstrates Clinical Data Pulls's ability to increase the speed and accuracy of data collection for Investigator Initiated Trials.

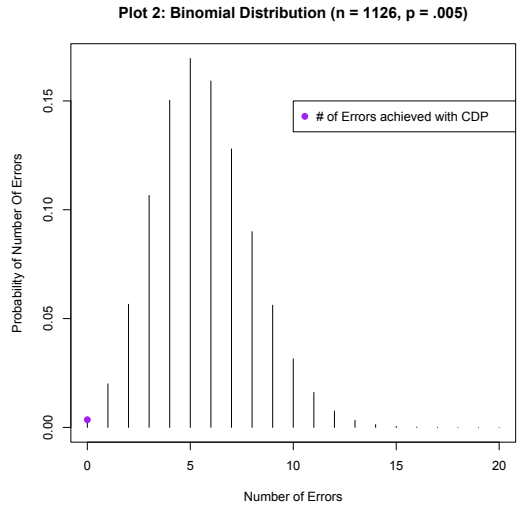
Outcomes: Speed

The mean time per data point with CDP was 1.58s as opposed to 5.41s without CDP. The Wilcoxon Sum Rank Test showed that this difference of 3.83 was significant with a p-value of less than 2 x 10-16. Furthermore, CDP also reduced the standard deviation of time spent inputting lab results from 1.56s in databases without CDP to 0.58s in databases with CDP.



Outcomes: Accuracy

We found zero errors in the 1126 data points we randomly sampled from the CDP-enabled database, and our binomial test was significant with a p-value of 0.003538 and a 95 percent confidence interval of 0 percent to .26 percent error for the CDP-enabled database. This indicates that the results are significant, and the true error rate of a CDP-enabled database is less than half a percent.



Impact of Revised SRC Accrual Monitoring Policy on Closure of Zero-Accruing Trials

L. Ekins
Medical College of Wisconsin Cancer Center

1. Background

Low-accruing trials require substantial staff support and may prevent other, potentially more successful trials from opening due to concerns about limited resources. Underperforming trials should be identified and closed early to minimize their negative impact.

At the Medical College of Wisconsin Cancer Center (MCWCC), the Scientific Review Committee (SRC) is responsible for monitoring accrual to active trials, ensuring adequate progress. Previously, a formal accrual review was not conducted until 12 months following study activation, and low-accruing studies were allowed an additional six months to improve. This resulted in underperforming studies remaining open 18 months before SRC recommended closure. In 2021, the SRC implemented a new policy with a revised review timeline, allowing earlier intervention in those studies with low accrual.

2. Goals

- Earlier closure of underperforming trials, reducing the timeline from approximately 18 months to 12 months
- Increased communication between SRC and Disease-Oriented Teams (DOTs)

3. Solutions and Methods

The 2021 MCWCC SRC policy introduced an earlier initial accrual review at six months following study activation. At this timepoint, studies meeting the minimum annual accrual goal are scheduled for annual review and one-year approval at 12 months. Studies not meeting the goal are issued a letter requesting a corrective action plan (CAP) and are scheduled for subsequent review at nine months. If the goal is still not met at the nine-month review, a warning letter is issued and the study is reviewed at 12 months, with zero- and low-accruing studies recommended for closure by the SRC at that time.

The addition of the six- and nine-month review timepoints allows the PI and DOT to reevaluate a study early in its timeline and either make changes to enrollment strategy or close the study if deemed to have low enrollment potential.

4. Outcomes

We evaluated studies that opened under the new policy with at least 12 months of data available and compared them to studies that completed their initial 12-month reviews under the old policy in the previous year. Our data includes a total of 48 studies monitored under the new policy, 11 of which have at least 12 months of data, and 72 studies under the old policy. Rare disease studies were exempted from this dataset as they are monitored under different criteria.

The new policy has led to the earlier closure of low-accruing studies by the PI/DOT, taking an average of 214 days compared to 615 days under the old policy. The number of zero-accruing studies open at 12 months is now zero, compared to 12 percent under the old policy. We had hoped to see an improvement in the response rate to CAP requests; however, this has remained roughly the same at about 64 percent.

5. Lessons Learned and Future Directions

While it is early in policy implementation, the preliminary results are encouraging. Under the new policy, the number of studies with zero accrual at 12 months has decreased, as these studies have thus far been voluntarily closed by the DOTs. Our sense is that the increased communication at the additional timepoints appears to be drawing focus to accrual issues at the DOT level.

Impact of Revised SRC Accrual Monitoring Policy on Closure of Zero-Accruing Trials

Lauren Ekins, BA, CCRP, Jennifer Bollmer, PhD, William Bradley, MD, Ben George, MD, Razelle Kurzrock, MD, Kathryn Bylow, MD
Medical College of Wisconsin Cancer Center

Background

Low-accruing trials require substantial staff support and may prevent other, potentially more successful trials from opening due to concerns about limited resources. Underperforming trials should be identified and closed early to minimize their negative impact.

At the Medical College of Wisconsin Cancer Center (MCWCC), the Scientific Review Committee (SRC) is responsible for monitoring accrual to active trials, ensuring adequate progress. Previously, a formal accrual review was not conducted until 12 months following study activation, and low-accruing studies were allowed an additional 6 months to improve. This resulted in underperforming studies remaining open 18 months before SRC recommended closure. In 2021, the SRC implemented a new policy with a revised review timeline, allowing earlier intervention in those studies with low accrual.

Goals

- Earlier closure of underperforming trials, reducing the timeline from approximately 18 months to 12 months
- Increased communication between SRC and Disease-Oriented Teams (DOTs)

Solutions and Methods

The 2021 MCWCC SRC policy introduced an earlier initial accrual review at six months following study activation, with subsequent reviews scheduled based on review outcomes:

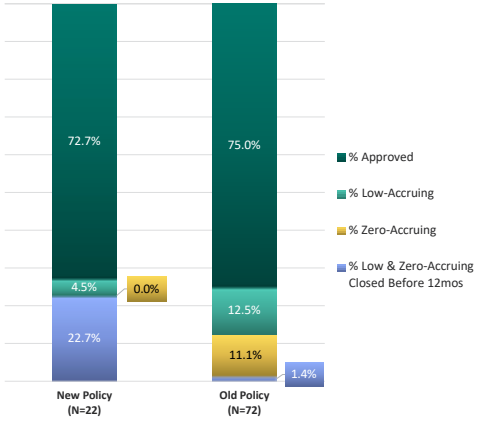
- 6 months: if minimum annual accrual goal is met, study is scheduled for annual review at 12 months; if goal is not met, a corrective action plan (CAP) is requested and study is reviewed again at 9 months.
- 9 months: if study remains below minimum, a warning letter is issued and study is reviewed again at 12 months.
- 12 months: if study remains zero- or low-accruing, recommended for closure by the SRC; if accrual minimum is met, study is approved for 1 year and then reviewed annually.

Outcomes

We evaluated studies that opened under the new policy with at least 12 months of data available and compared them to studies that completed their initial 12-month reviews under the old policy in the previous year. Our dataset includes a total of 62 studies monitored under the new policy, 22 of which have at least 12 months of data, and 72 studies under the old policy. Rare disease studies were exempted from this dataset as they are monitored under different criteria.

The number of zero-accruing studies open at 12 months is now zero, compared to 12% under the old policy (Fig. 1). The new policy has also led to the earlier closure of low-accruing studies by the PI/DOT, taking an average of 283 days compared to 615 days under the old policy (Fig. 2). We have seen a slight improvement in the response rate to CAP requests, now at about 68% compared to 64% previously.

Fig. 1: Study Status at 12 Months - New Policy vs. Old Policy

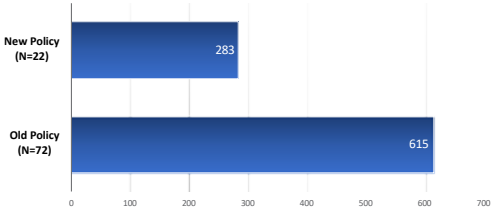


Lessons Learned

The addition of the six- and nine-month review timepoints allows the PI and DOT to reevaluate a study early in its timeline and either make changes to enrollment strategy or close the study if deemed to have low enrollment potential.

While it is early in policy implementation, the preliminary results are encouraging. Under the new policy, the number of studies with zero accrual at 12 months has decreased, as these studies have thus far been voluntarily closed by the DOTs. Our sense is that the increased communication at the additional timepoints appears to be drawing focus to accrual issues at the DOT level.

Fig. 2: Average Number of Days to Close Low-Accruing Trials



Future Directions

As part of the new policy, we have also transitioned from a uniform minimum accrual threshold based on trial type, to a percentage-based system derived from each study's projected annual accrual. Rare disease studies are now being reviewed for progress every two years, when previously they were exempt from accrual monitoring. The early identification and closure of underperforming studies under the new policy has reduced the amount of effort being expended on studies that are not fruitful, and we will continue monitoring to ensure the MCWCC's study portfolio is productive and that resources are being utilized effectively.

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Streamlined Workflow for Tumor Board Preparation, Presentation, and Documentation Allows for Concurrent Clinical Trial Matching Review

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[1]*Robert H. Lurie Comprehensive Cancer Center of Northwestern University*

[2]*Cancer Insights, Bedford Hills, NY*

1. Background

Newly diagnosed and recurrent cases of head and neck cancer are discussed during weekly multidisciplinary tumor boards at Robert H. Lurie Comprehensive Cancer Center of Northwestern University (Chicago, IL). Case preparation and presentation at tumor board is an opportune time for consideration of clinical trial eligibility. Given that initiation of treatment can discount a patient for clinical trial eligibility, systematic review, and consideration of eligibility status for treatment trials open at the institution during tumor board review ensures that all treating clinicians are aware of and agree to support the patient's consideration of treatment trial enrollment.

2. Goals

Our goal was to systematically consider newly diagnosed and recurrent head and neck cancer cases for eligibility for treatment clinical trials open at the treating institution during multi-disciplinary tumor board meetings.

3. Solutions and Methods

A new artificial intelligence-based technology was piloted to aid the preparation, presentation, and documentation of tumor board case review. Implementation of the technology streamlined the tumor board workflows and allowed time for the screening, consideration, and documentation of clinical trial eligibility concurrently with tumor board review. Cases presented at tumor board were considered for 12 treatment trials open for head and neck cancer at the treating institution. Trial eligibility was recorded within the new tool for presentation. Documentation of the tumor board discussion then captured clinical trial consideration and recommendation based on the multi-disciplinary review.

4. Outcomes

From July 26, 2022 to March 13, 2023, a total of 32 tumor boards were prepared, presented, and documented using the new technology. During this time 267 cases were reviewed, which represented 210 unique patients. Of the 210 patients, 34 (16 percent) were screened eligible for at least one open treatment clinical trial at the treating institution. There has been high user satisfaction reported with the new technology which allowed additional time for clinical trial eligibility screening.

In calendar year 2022, a total of 11 patients were enrolled in head and neck cancer treatment trials. With the new technology in place and completely operational since the beginning of the year, there have been 6 patients enrolled in the first quarter of 2023. Assuming similar accrual over the next 3 quarters, this results in an expected year-end total accrual of 18-24 patients, an increase of 160-220 percent over the prior year.

5. Lessons Learned and Future Directions

Systematic review of newly diagnosed and recurrent patients for clinical trial eligibility during tumor board review can give patients optimal opportunity for participation. Future expansion of the new technology to also assist with trial eligibility evaluation is planned. In addition, the tool will in the future provide aggregate reports that capture and track trial consideration over time.

Streamlined workflow for tumor board preparation, presentation, and documentation allows for concurrent clinical trial matching review

Olivia Dunne[1], Emily Kamen, MD[1], Paris Jasmine Austell, MD[1], Cameron Brawley, MD[1], Muyinat Yewande Osoba, MD[1], Cynthia Riley Duck, MD[1], Philip Duffin[1], Aleksandar Zafirovski[1], Michael Gurley[1], Carolyn Passaglia[1], Sharon Hensley Alford, PhD[2], Tarun Kumar[2], Shilpa Mahatma[2], Sandeep Samant, MD[1]

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Abstract

Background: Newly diagnosed and recurrent cases of head and neck cancer are discussed during weekly multi-disciplinary tumor boards at Robert H. Lurie Comprehensive Cancer Center of Northwestern University (Chicago, IL). Case preparation and presentation at tumor board is an opportune time for consideration of clinical trial eligibility. Given that initiation of treatment can discount a patient for clinical trial eligibility, systematic review and consideration of eligibility status for treatment trials open at the institution during tumor board review ensures that all treating clinicians are aware of and agree to support the patient's consideration of treatment trial enrollment.

Goals: To systematically consider newly diagnosed and recurrent head and neck cancer cases for eligibility for treatment clinical trials open at the treating institution during multi-disciplinary tumor board meetings.

Solutions and Methods: A new artificial intelligence-based technology was piloted to aid the preparation, presentation, and documentation of tumor board case review. Implementation of the technology streamlined the tumor board workflows and allowed time for the screening, consideration, and documentation of clinical trial eligibility concurrently with tumor board review. Cases presented at tumor board were considered for 12 treatment trials open for head and neck cancer at the treating institution. Trial eligibility was recorded within the new tool for presentation. Documentation of the tumor board discussion then captured clinical trial consideration and recommendation based on the multi-disciplinary review.

Outcomes: From July 25, 2022 to March 13, 2023, a total of 32 tumor boards were prepared, presented and documented using the new technology. During this time 267 cases were reviewed, which represented 210 unique patients. Of the 210 patients, 34 (16%) were screened eligible for at least one open treatment clinical trial at the treating institution. There has been high user satisfaction reported with the new technology which allowed additional time for clinical trial eligibility screening.

In calendar year 2022, a total of 11 patients were enrolled in head and neck cancer treatment trials. With the new technology in place and completely operational since the beginning of the year, there has been 6 patients enrolled in the first quarter of 2023. Assuming similar accrual over the next 3 quarters, this results in an expected year-end total accrual of 18-24 patients, an increase of 160-220% over the prior year.

Lessons Learned and Future Direction: Systematic review of newly diagnosed and recurrent patients for clinical trial eligibility during tumor board review can give patients optimal opportunity for participation. Future expansion of the new technology to also assist with trial eligibility evaluation is planned. In addition, the tool will in the future provide aggregate reports that capture and track trial consideration over time.

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Methods

Pilot of the technology began in June 2022 for the head and neck cancer weekly tumor board at Robert H. Lurie Comprehensive Cancer Center of Northwestern University (Chicago, IL). All tumor boards were prepared, presented and documented using the pilot system. Case consideration for open trials was noted, when appropriate, in the case details for presentation.

Data on all the tumor boards was available in the pilot technology and retrieved for analysis and summary. This analysis included cases presented during tumor boards from July 25, 2022 to May 15, 2023.

This project was undertaken as a Quality Improvement project and as such does not constitute human subjects research.

Results

From July 26, 2022 to May 15, 2023, a total of 16 trials were open during the review timeframe. (Table 1) During this period 45 tumor boards were conducted with the new software. In total 334 case reviews representing 264 unique patients were presented. Of these 45 cases were considered suitable for clinical trial consideration. After final eligibility and consent, 12 patients were enrolled in a clinical trial. A summary of the patients reviewed in the tumor board during this time is provided in Table 2.

The new process has increased the number of patients considered and ultimately enrolled in clinical trials. Further studies of the impact of workflow improvements on trial consideration and enrollment are needed to validate the findings.

Results (con't)

Table 2. Summary of patient characteristics for all unique patients presented

Patient Characteristics	N (%)
Age	
Mean (Min, Max)	64 (27, 100)
Identified Sex	
Male	188 (72%)
Female	75 (28%)
Cancer Location	
Nasopharyngeal	32 (10%)
Oropharyngeal	196 (59%)
Laryngeal	35 (11%)
Salivary Gland	2 (1%)
Thyroid	4 (1%)
Unknown primary (w/wo neck node)	37 (11%)
Other (skin, face, eye, ear, etc.)	26 (8%)

Conclusions

- Tumor board review is an optimal time to consider clinical trial eligibility.
- Efforts to decrease administrative burden for clinical teams can facilitate expanded efforts for trial accrual.
- Additional approaches to use artificial-intelligence for clinical trial eligibility review has the potential to further improve site trial enrollment.
- Additional study is needed to also understand the role of trial availability, COVID affects, and provider interest on clinical trial enrollment.

Table 1. Trials considered during tumor board review. (Trial titles provided below for reference.)

Trial	Cancer Focus	Treatment Focus	Trial	Cancer Focus	Treatment Focus
1.	Oropharyngeal	Locally advanced, HPV mediated	9.	HNSCC	Recurrent, Second primary
2.	Salivary Gland	Metastatic, recurrent, AR positive	10.	Sarcoma, Melanoma	Any
3.	Oral Cavity	Early stage	11.	Thyroid Cancer	Locally advanced, Metastatic
4.	HNSCC	Recurrent, Refractory, Metastatic	12.	Oropharyngeal	HPV mediated
5.	HNC, Melanoma	Locally advanced, Metastatic, Recurrent, HPV mediated	13.	Oropharyngeal	Early Stage, HPV mediated
6.	HNC	Locally advanced, Metastatic	14.	Nasopharyngeal	Locally advanced, Metastatic
7.	HNSCC	Recurrent, Metastatic	15.	HNSCC	Locally advanced, Metastatic
8.	HNC	Locally advanced, Metastatic, Recurrent	16.	Salivary Gland	Recurrent, Metastatic

Trial Titles

1. Testing Immunotherapy Versus Observation in Patients With HPV Throat Cancer
2. Androgen Deprivation Therapy (ADT) and Pembrolizumab for Advanced Stage Androgen Receptor-positive Salivary Gland Carcinoma
3. Comparing Sentinel Lymph Node (SLN) Biopsy With Standard Neck Dissection for Patients With Early-Stage Oral Cavity Cancer
4. The BURAN Study of Buparlisib in Patients With Recurrent or Metastatic HNSCC
5. BiCaZO: A Study Combining Two Immunotherapies (Cabozantinib and Nivolumab) to Treat Patients With Advanced Melanoma or Squamous Cell Head and Neck Cancer, an immunoMATCH Pilot Study
6. Testing the Addition of Ipatasertib to Usual Chemotherapy and Radiation for Stage III-IVB Head and Neck Cancer
7. Testing the Addition of an Anti-cancer Drug, Ipatasertib, to the Usual Immunotherapy Treatment (Pembrolizumab) in Patients With Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck
8. Testing the Addition of an Anti-cancer Drug, BAY 1895344, With Radiation Therapy to the Usual Pembrolizumab Treatment for Recurrent Head and Neck Cancer
9. Testing What Happens When an Immunotherapy Drug (Pembrolizumab) is Added to Radiation or Given by Itself Compared to the Usual Treatment of Chemotherapy With Radiation After Surgery for Recurrent Head and Neck Squamous Cell Carcinoma
10. Phase 2 CAB-AXL-ADC Safety and Efficacy Study in Adult and Adolescent Patients With Sarcoma
11. Vudalimab for the Treatment of Locally Advanced or Metastatic Anaplastic Thyroid Cancer or Hurthle Cell Thyroid Cancer
12. A Randomized Phase 2 Study of Cemiplimab ± ISA101b in HPV16-Positive OPC
13. De-intensified Radiation Therapy With Chemotherapy (Cisplatin) or Immunotherapy (Nivolumab) in Treating Patients With Early-Stage, HPV-Positive, Non-Smoking Associated Oropharyngeal Cancer
14. Individualized Treatment in Treating Patients With Stage II-IVB Nasopharyngeal Cancer Based on EBV DNA
15. Testing Docetaxel-Cetuximab or the Addition of an Immunotherapy Drug, Atezolizumab, to the Usual Chemotherapy and Radiation Therapy in High-Risk Head and Neck Cancer
16. Nivolumab and Ipilimumab in Treating Patients With Metastatic/Recurrent ACC of All Sites and Non-ACC Salivary Gland Cancer

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Developing a Melanoma Clinical Trial Accrual Task Force

K. Senter, C. Gantz, N. Hartman, R. Seedor
Sidney Kimmel Cancer Center at Jefferson Health

1. Background

Sidney Kimmel Cancer Center at Jefferson Health is a national referral center for ocular melanoma patients, but protocol-specific accrual across cutaneous melanoma clinical trials is historically lower than for ocular melanoma. To boost clinical trial accrual overall, especially for cutaneous melanoma protocols, representatives from the melanoma clinical trials team, Research Liaison Office, and outpatient medical oncology clinic created the Melanoma Clinical Trial Accrual Task Force in August 2022, under the guidance of a physician lead. The task force meets virtually on a monthly basis.

2. Goals

Task force goals are to brainstorm opportunities across the recruitment and enrollment process for increased patient and provider engagement, to execute strategies that attract more melanoma patients to the cancer center for clinical trials, to ensure a smooth screening and enrollment process, and to monitor the impact of the task force on protocol accrual.

3. Solutions and Methods

Completed strategies include creation of patient clinical trial flyers for display in treatment areas, prescreening and screening training for all clinical trial staff, updates to the organizational Trial Finder website for ease of navigation, establishment of an enhanced scheduling process for new potential trial patients, development of an internal and external referring provider list, implementation of electronic health record (EHR) prescreening for treatment naive melanoma patients, and development of a quarterly provider referral newsletter.

4. Outcomes

To date, pre-task force accrual is virtually identical to post-task force accrual (24 patients vs. 22 patients over a 7.5-month period). However, due to pending distribution of the first provider referral letter and only recent implementation of EHR prescreening, we anticipate improved and updated outcomes prior to final presentation.

5. Lessons Learned and Future Directions

Recruitment strategies beyond prescreening the investigator's practice require extensive collaboration across and outside of the cancer center. Research teams may need to invest several months developing recruitment infrastructure prior to achieving increased yield. However, once established, these efforts become scalable across trials and disease groups to decrease barriers to entry over time.

Developing a Melanoma Clinical Trial Accrual Task Force

Katherine Senter, MPH[1]; Christopher Gantz, MBA, DBA[2]; Nicole Hartman, MPH[1]; Rino Seedor, MD[1]
[1]Sidney Kimmel Cancer Center - Jefferson Health, [2]Takeda Pharmaceuticals

Background

The Cancer Center

- Sidney Kimmel Cancer Center – Jefferson Health in downtown Philadelphia, PA
- NCI-Designated
- National referral center for ocular melanoma patients
  - 1st therapy in metastatic setting FDA-approved in 2022
  - Clinical trials often the only therapeutic option for patients
- Historically lower accrual on cutaneous melanoma clinical trials

The Team

- Physician lead – medical oncologist
- Representatives from Cancer Clinical Research Operations, Clinical Research Outreach and Engagement, and Medical Oncology Outpatient Clinic teams

The Task Force

- Virtual biweekly or monthly meetings
- Development of deliverables between meetings
- Meetings with website, electronic health record (EHR), and marketing teams as needed

Goals

- Brainstorm opportunities across recruitment and enrollment process
- Increase patient and provider engagement around clinical trials
- Execute strategies that attract more melanoma patients to cancer center for clinical trials
- Ensure smooth screening and enrollment process
- Monitor impact of task force on protocol accrual

Solutions and Methods

- **Development of patient clinical trial tear pads**

- **Prescreening and screening training for trial staff**
- **Disease-specific overviews for clinical trial screeners**
- **Internal and external referring provider list**
- **Quarterly provider newsletter**

- **New patient workflow for prospective trial patients**
- **EHR prescreening for 1st line metastatic melanoma patients**

Key Outcomes

EHR Prescreening

- **197** patients screened Jan 2023-present on single protocol
- **53** potential patients forwarded to trial team for review
- **1** patient enrolled on protocol to date, internal referral
- Many "new" diagnoses added in EHR are historical
- Often potential patients have already treatment plan in place before trial team notified of eligibility

Provider Newsletter Distribution

- **61** successful deliveries
- **28** opened (**45.9%** open rate compared to 39.1% average)
- Clicks per unique opens: 10.7%

Current Pre and Post Task Force Yield

- **24** trial patients enrolled in 8.5 months prior to task force development; **24** patients enrolled in 8.5 months post

Lessons Learned and Future Directions

Collaboration is key!

- Dedicated trial recruitment service alleviates burden on disease group
- Expansion of existing marketing, EHR, and web services

Sponsor-suggested strategies may not yield significant outcomes

- Patient and provider outreach require significant initial time investment for potentially low yield
- However, once infrastructure in place, may be scalable; e.g., screen for multiple studies simultaneously
- Also, task force facilitates Sponsor recruitment discussion during site selection and start-up
- Collaboration with pathology may be more effective to capture new diagnoses than EHR problem list

Protocol selection and slot availability tailored to clinic patient population still drive accrual outcomes

Resources

Jefferson Clinical Trial Finder Website:
https://www.jeffersonhealth.org/clinical-specialties/cancer/clinical-trials

Jefferson Melanoma Program:
https://www.jeffersonhealth.org/conditions-and-treatments/melanoma

@ResearchAtJeff

Preliminary Development of Expanded Access Through Telemedicine for Advanced Cancers at Kimmel: E-ATTACK Clinic

M. Crino, K. Kaliqi, T. Newhall, T. Savio, J. Anderson, A. Rogers, D. Stone, S. Gordon, B. Bashir, N. Palmisiano
Sidney Kimmel Cancer Center at Jefferson Health

1. Background

From 2016 to 2020 the Phase I team at Sidney Kimmel Cancer Center (SKCC) has increased total available trials by 190 percent. During this time, Phase I physicians represented the primary source of referrals for Phase I trials. With this increase in the Phase I portfolio, a process to facilitate referrals and screening of potential patients within SKCC from external providers was developed. The Expanded Access Through Telemedicine for Advanced Cancers at Kimmel, or E-ATTACK, was developed to allow patients within and beyond the SKCC catchment area to have access to novel Phase I therapies, including many First in Human clinical trials.

2. Goals

E-ATTACK aims to increase patient accrual via streamlining potential patient information for review by Phase I physicians. The system plans to accomplish this by increasing referral accessibility to internal and external physicians, as well as patients and/or their caregivers. Additionally, the development of this innovation seeks to further contribute to the improvement of the lives of cancer patients and their families.

3. Solutions and Methods

We utilize email as a central way to receive referrals. Requests come from Jefferson physicians, external providers, and patients or their caregivers. We ask that the referral include the patient's oncological history, molecular sequencing reports, and recent imaging and laboratory results. Relevant patient oncology history is compiled in an E-ATTACK form to present to Phase I physicians at a weekly meeting. Patient information is reviewed and assessed for potential eligibility for trials in our portfolio. Referring physicians are made aware of the trials their patients may be eligible for, and we offer a telehealth or in-person evaluation with one of our Phase I physicians.

4. Outcomes

E-ATTACK has demonstrated itself as a viable source of internal and external leads. Internal references have increased by 208.96 percent from 2021 to 2022, while external references experienced a growth of 83.72 percent. Additionally, the internal accrual rate increased by 16.29 percent while the external accrual rate decreased by 46.05 percent. Overall, it is expected that E-ATTACK will continue to grow internal references and accrual. Meanwhile, E-ATTACK will need to go through further iterations to increase external effectiveness.

5. Lessons Learned and Future Directions

Our results demonstrate that despite an overall increase in referral rate, the external accrual rate is decreasing. We hypothesize this decrease is due to external candidates having exclusionary variables. These issues can lead to screen failures or unsuccessful prescreening visits. To increase the external accrual rate, referring providers could benefit from additional education on the ideal Phase I clinical trial candidate.

When following up with an external referral, we can offer a consultation visit to better assess the patient's medical history and provide trial information, followed by a consent visit. Our E-ATTACK program would also benefit from the development of a webform, which would be available to external physicians for submitting the required referral information so we can better assess eligibility. We anticipate this streamline of the referral process will boost our accrual rate, thus expanding the opportunity for novel cancer therapies and improvement of the lives of cancer patients.

Preliminary development of Expanded Access Through Telemedicine for Advanced Cancers at Kimmel: E-ATTACK Clinic

Jefferson
Thomas Jefferson University
HOME OF SIDNEY KIMMEL MEDICAL COLLEGE

Mary Crino, Kledia Kaliqi, Tracey Newhall, Tina Savio, Joanne Anderson, Aliya Rogers, Dennis Stone, Sarah Gordon, Babar Bashir, Neil Palmisiano

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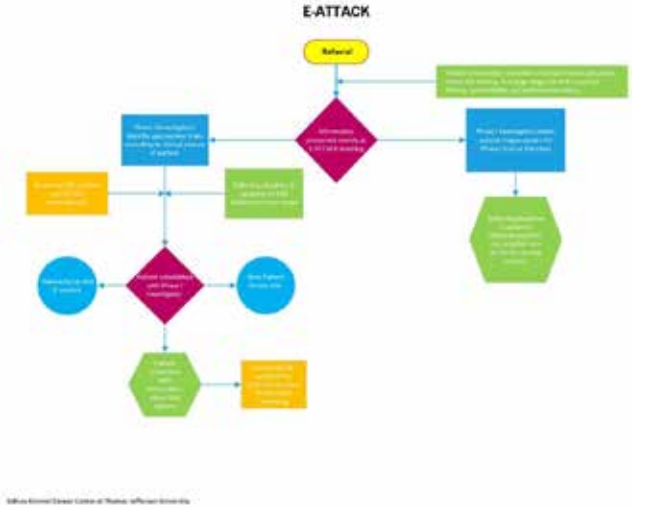

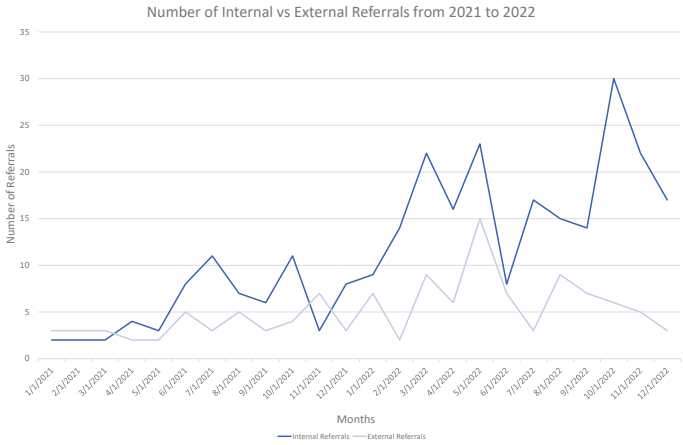

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Lessons Learned

Our results demonstrate that despite an overall increase in referral rate, the external accrual rate is decreasing. We hypothesize this decrease is due to external candidates having exclusionary variables. These issues can lead to screen failures or unsuccessful prescreening visits. To increase the external accrual rate, referring providers could benefit from additional education on the ideal Phase I clinical trial candidate.

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@ResearchAtJeff

Increasing Treatment Accrual in a Diverse Patient Population

M. Russell, D. Kitterman
University of Illinois Cancer Center

1. Background

The University of Illinois Cancer Center (UICC) is planning to apply for National Cancer Institute (NCI) designation. As part of that effort, the UICC Clinical Trials Office (CTO) has been focusing, with great success, on increasing treatment accrual in a diverse patient population.

2. Goals

To increase accrual to interventional treatment trial accruals.

3. Solutions and Methods

We took a three-pronged approach to increase treatment accrual. The first strategy was to hire additional staff to the clinical trials office and, in particular, the clinical research coordinator role. In 2020 there were 12 clinical research coordinators (CRC) and data coordinators total. In 2023, that number has increased to 18, which is a 50 percent increase. This will be expanded further by five positions in early 2023.

The second strategy has been a multi-year project to fine tune our trial portfolio for each disease team to target trials to serve our specific diverse patient population. This has included designing investigator-initiated trials tailored to our patients when externally supported trials did not exist or excluded our population. Disease teams closely examine open trials, identifying portfolio gaps and strategizing ways to fill them. Overlapping and non-enrolling trials are also carefully reviewed monthly and closed as better portfolio options are identified.

The third is to screen all positive pathology reports and all physician clinics for trials. Any pathology report that is positive for cancer gets sent to the clinical research coordinator for that disease site. The CRC screens the patient for their specific trials and if the patient is potentially eligible, the CRC starts an Epic chat to discuss the case. All pathology reports are tracked using Teams so that we can see the success of enrollment over time.

4. Outcomes

The pandemic caused a downshift in enrollment across the world. However, we have recovered and grown treatment accrual significantly past our pre-pandemic numbers. Over the past three years, treatment accrual increased from 85 in 2020 to 146 in 2022 (2020 = 85, 2021 = 95, 2022 = 146). From 2020 to 2022, there was an increase of 78.5 percent despite no increase in analytic cases. Treatment accrual for 2022 was approximately 11 percent of analytic case, 75 percent of which were underrepresented minorities.

5. Lessons Learned and Future Directions

Increasing accrual in a diverse patient population is possible with putting the correct measures in place. We will continue with building our portfolio and have plans to implement clinical trial education to further improve our clinical trial enrollment acceptance rate. However, we are facing a limiting factor of our patient volume, which has been recognized by leadership as needing to increase. Future efforts by the hospital and oncology service line focusing on serving an increased number of patients are needed to achieve our treatment accrual goals.

Increasing Treatment Accrual in a Diverse Patient Population

Meredith Russell, BS, CCRP; Darlene Kitterman, MBA
University of Illinois Cancer Center

UNIVERSITY OF ILLINOIS CANCER CENTER

Background

With the ultimate goal of applying for and achieving NCI designation, the UICC Clinical Trials Office (CTO) over the last five years has implemented a variety of initiatives to increase UICC interventional treatment accrual overall while retaining the diversity of its clinical trial participant population.

Objectives

- Increase interventional treatment accrual
- Preserve the diversity of clinical trial participants

Methods

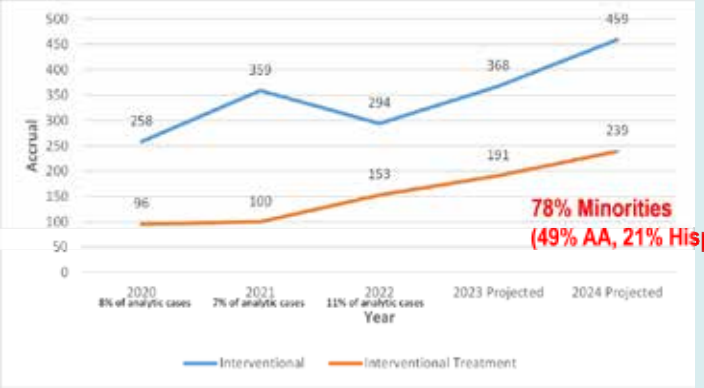
We took a multi-pronged approach to increase treatment accrual:

1. Increase CTO staff numbers: Though we increased staff overall, we particularly focused on our Clinical Research Coordinators. In 2020 there were 12 clinical research coordinators and data coordinators total. In 2023, that number has increased to 23 (almost doubling our clinical research operations staff).
2. Refine our trial portfolio: We have defined for each of our disease teams target trials to serve our specific diverse patient population. This has included designing investigator initiated trials tailored to our patients when externally supported trials did not exist or excluded our population. Disease teams closely examine open trials, identifying portfolio gaps and strategizing ways to fill them. Overlapping and non-enrolling trials are also carefully reviewed monthly and closed as better portfolio options are identified.
3. Screening patients: We implemented screening of all positive pathology reports and all physician clinics for trials. All positive pathology report are sent through Epic to the clinical research coordinator for that disease site. The CRC screens the patient for their specific trials and if the patient is potentially eligible, the CRC starts an EPIC chat to discuss the case. All pathology reports are tracked using Teams so that we can see the status of the patient's enrollment over time.
4. Transportation: Since 2019, UICC began supporting transportation needs for all of its clinical trial participants.

Results

The pandemic caused a downshift in enrollment across the world. However, we have recovered and grown treatment accrual significantly past our pre-pandemic numbers. Over the past three years, treatment accrual increased 78.5 percent despite no increase in analytic cases. Treatment accrual for 2022 was approximately 11% of analytic case, 78% of which were underrepresented minorities. For additional details, see Figure 1 below.

Figure 1: UICC Accrual Over Time



Conclusions

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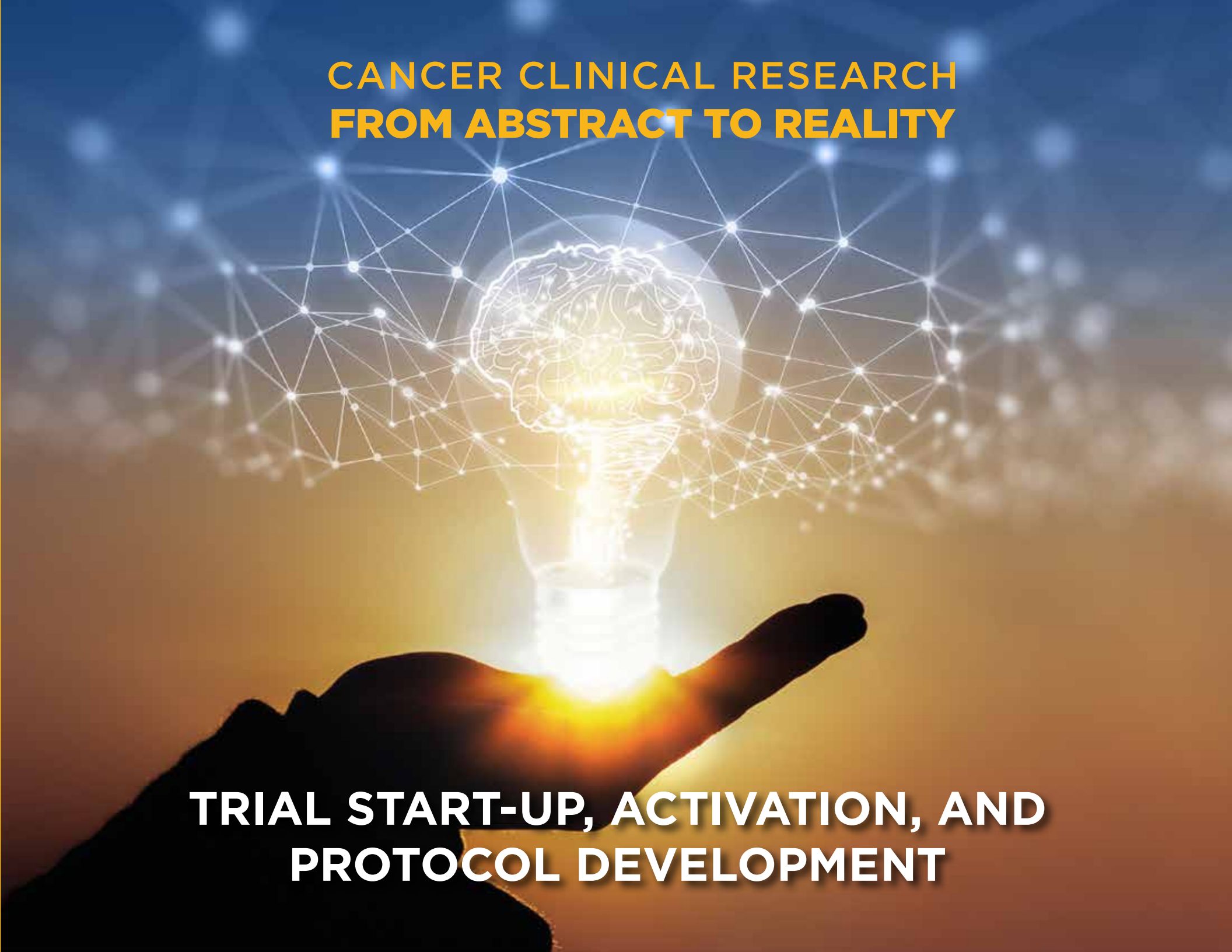
Acknowledgements

We would like to acknowledge the support of the University of Illinois Cancer Center for this project.

CANCER CLINICAL RESEARCH

FROM ABSTRACT TO REALITY



TRIAL START-UP, ACTIVATION, AND PROTOCOL DEVELOPMENT

Timing is Everything! - Reducing Clinical Trial Activation Timelines at an NCI-Designated Comprehensive Cancer Center

A. Joshi, H. Duong, C. Spalink, L. Dhanantwari, R. Robertson, N. Catti, D. Wallach, D. Ayoubi, J. Mehnert, B. Pothuri, J. Weber
Laura and Isaac Perlmutter Cancer Center at NYU Langone

1. Background

The Perlmutter Cancer Center (PCC) at NYU Langone Health (NYULH) is an NCI-Designated Comprehensive Cancer Center. Activating a clinical trial at PCC, a matrix center, is intricate; at a minimum, it involves staff from the Clinical Trials Office (CTO), departments across the institution, and the study sponsor. During the COVID-19 pandemic, the CTO experienced increased study activation times. The median time to activate an interventional treatment study from submission to the Protocol Review and Monitoring Committee (PRMC) was 203 days in 2020, 113 days above our target of 90. Timely activation of trials is critical to offer timely treatment options to patients, maximize time to enroll in the study, and fulfill industry sponsors' rigorous start-up timelines.

2. Goals

The goal was to achieve a median of 90 calendar days by the end of 2022 for all interventional treatment studies prospectively submitted to PRMC in 2022 by the PCC CTO. The timeline started at PRMC submission and ended when the study was opened to enrollment by the PCC CTO.

3. Solutions and Methods

A Study Activation Task Force was assembled to identify bottlenecks and improve processes. The multidisciplinary team included CTO leadership and representatives from the NYULH Office of Science and Research (OSR) and Investigational Pharmacy. Specifically the following interventions were implemented:

1) Developed an internal activation dashboard to monitor and produce reports on study activation timelines
2) Increased staffing for contracts, investigational pharmacy informatics, and pre-activation regulatory
3) Maintained rigorous weekly meetings to review each study in the pipeline and identify any barriers
4) Established Service Level Expectation (SLE) for each activation component and establish an escalation policy when SLE is not being met or at risk for not being met
5) Developed an intake questionnaire for sponsors prior to PRMC submission to identify potential barriers in timely activation and receive sponsor commitment to adhere to PCC CTO SLE
6) Utilized a contract agency to source trained regulatory staff and increase compensation/benefits to stabilize turnover
7) Initiated all sub-processes after the Disease Management Group (DMG) approval instead of after PRMC approval
8) Restructured regulatory management to assign a dedicated pre-activation manager and liaison across the enterprise
9) Limited new studies in Q1 of 2022 to allow for staff stabilization and implementation of new processes and workflows

4. Outcomes

At the conclusion of 2022, our median activation timeline was 71 days, with a range of 28 to 268 days, surpassing our goal by 21 percent. We see a continued downward trajectory in January and February 2023.

5. Lessons Learned and Future Directions

To keep the activation timeline down, rigorous oversight is necessary. This requires a dedicated pre-activation manager with robust escalation policies in place. The intake questionnaire was also critical to identify barriers and engage sponsor commitment. Our future goal is to decrease the time from DMG approval to PRMC submission.

Timing is Everything! Reducing Clinical Trial Activation Timelines at an NCI Designated Comprehensive Cancer Center

NYU Langone Health

Perlmutter Cancer Center
An NCI-designated Comprehensive Cancer Center

Ankeeta Joshi, Huan Duong JD, Christy Spalink DNP, Lalta Dhanantwari, Randi Robertson, Nadia Catti, David Wallach, Doaa Ayoubi Pharm.D. Janice Mehnert MD, Bhavana Pothuri MD, Jeffrey Weber MD

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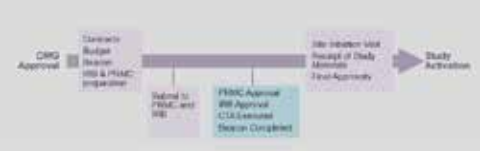
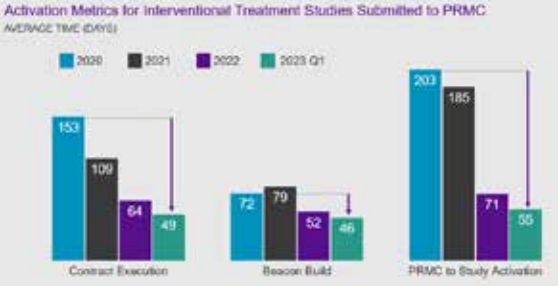
2) Increased staffing for contracts, investigational pharmacy informatics, and pre-activation regulatory
3) Maintained rigorous weekly meetings to review each study in the pipeline and identify any barriers
4) Established Service Level Expectation (SLE) for each activation component and establish an escalation policy to Deputy Director of PCC when SLE is not being met or at risk for not being met
5) Developed an intake questionnaire for Sponsors prior to PRMC submission to identify potential barriers in timely activation and receive sponsor commitment to adhere to PCC CTO SLE
6) Utilized a contract agency to source trained regulatory staff and increase compensation/benefits to stabilize turnover
7) Initiated all sub-processes after the Disease Management Group (DMG) approval instead of after PRMC approval
8) Restructured regulatory management to assign a dedicated pre-activation manager and liaison across the enterprise
9) Limited new studies in Q1 of 2022 to allow for staff stabilization and implementation of new processes and workflows



Outcomes

At the conclusion of 2022, our median activation timeline was **71 days** (range 28-268), surpassing our goal of 90 days by 21 percent. 2023 median number is projecting under 60 days.



Lessons Learned and Future Directions

To keep the activation timeline down, rigorous oversight is necessary. This requires a dedicated pre-activation manager, weekly oversight and robust escalation policies in place. The intake questionnaire was also critical to identify barriers and engage sponsor commitment. Our future goal is to decrease the time from DMG approval to PRMC submission.

Sprinting to the Finish Line: Implementing a "Fast Track" Program to Expedite High Priority Clinical Trials at an NCI-Designated Comprehensive Cancer Center

A. Joshi, H. Duong, L. Dhanantwari, R. Robertson, N. Catti, C. Spalink, D. Wallach, J. Mehnert, B. Pothuri, J. Weber
Laura and Isaac Perlmutter Cancer Center at NYU Langone

1. Background

The Perlmutter Cancer Center (PCC) at NYU Langone Health (NYULH) is an NCI-Designated Comprehensive Cancer Center. Activating a clinical trial at PCC, a matrix center, is complex and involves multiple staff and departments across the enterprise and the study sponsor. In 2022, the CTO implemented several new processes, workflows, and staffing changes, improving the overall median activation timeline to 71 days. During this period, the PCC CTO also launched a "Fast Track" program to expedite the activation of high priority studies. These studies have high accrual potential, are linked to PCC science, PI is an author/on steering committee, or high unmet patient need. Each clinical trial undergoes a two-stage review: 1 – Disease Management Group (DMG) and 2 – Protocol Review and Monitoring Committee (PRMC).

2. Goals

Our goal for all interventional treatment trials is to activate within 90 days of submission to the PRMC. The goal for fast-track studies is to activate interventional treatment trials within 42 to 56 days of submission to PRMC, measured from PRMC submission through the date the study was opened to enrollment by PCC CTO.

3. Solutions and Methods

The CTO met with all internal stakeholders across the enterprise to discuss feasibility, eligibility of trials, capacity, and the need for sponsor commitment to implement this program successfully. Five key components and parameters were identified to achieve this goal: clinical trial agreement (CTA), institutional review board (IRB), site initiation visit, system access, and vendor supplies. In addition, we developed service level expectations (SLE) for NYULH staff and for the sponsor. Before agreeing to fast track a study, we required sponsor commitment to our SLE and evaluated our internal workload and capacity.

4. Outcomes

Our first pilot study was successfully activated 33 days following PRMC submission. Four additional studies were activated. The median time to activate was 59 days, ranging from 33 to 61 days. Two additional studies are in progress and expected to activate in under 42 days.

5. Lessons Learned and Future Directions

While these activation timelines are excellent, some delays could have been avoided (e.g., the study sponsor being unwilling to schedule SIV before CTA execution, the investigator being out of office during a critical time, delayed radiation safety approval, and vendor issues). As a result, we developed a sponsor and investigator intake form and revised specific processes to start earlier to mitigate these potential barriers. The future direction is to develop strategic partnerships with the sponsors we often work with to enable the automatic application of the fast-track program with a master CTA, budget, and informed consent. We will continue to revise our procedures as we learn valuable lessons during this process.

NYU Langone Health

Sprinting to the Finish Line: Implementing a "Fast Track" Program to Expedite High Priority Clinical Trials at an NCI Designated Comprehensive Cancer Center

Perlmutter Cancer Center
An NCI-designated Comprehensive Cancer Center

Ankeeta Joshi, Huan Duong JD, Lalta Dhanantwari, Randi Robertson, Nadia Catti, Christy Spalink DNP, David Wallach, Janice Mehnert MD, Bhavana Pothuri MD, Jeffrey Weber MD

Background

The Perlmutter Cancer Center (PCC) at NYU Langone Health (NYULH) is an NCI Designated Comprehensive Cancer Center. Activating a clinical trial at PCC, a matrix center, is complex and involves multiple staff and departments across the enterprise and the study sponsor. As a NCI Designated Comprehensive Cancer Center, studies are expected to activate under 100 days from submission to the scientific review committee. In 2022, the PCC Clinical Trials Office (CTO) implemented several new processes, workflows, and staffing changes, improving the overall median activation timeline to 71 days from submission to the Protocol Review Monitoring Committee (PRMC). During this period, the PCC CTO also launched a "Fast Track" program to expedite the activation of high priority clinical trials. High priority trials are defined as having high accrual potential, linked to PCC science, PI is an author/on steering committee, or high unmet patient need. Each clinical trial undergoes a 2-stage review: 1 – Disease Management Group (DMG) and 2 – PRMC.

Goals

Our goal for all interventional treatment trials is to activate within 90 days of submission to the PRMC. The goal for fast track studies is to activate interventional treatment trials within 42 to 56 days of submission to PRMC, measured from PRMC submission through the date the study was opened to enrollment by PCC CTO.

Outcomes

We successfully activated our first pilot study **33 days** following PRMC submission. By the end of Quarter 2 in 2023, 8 additional studies have been activated with an overall median of **45 days**, range of 26-61 days. All studies are industry sponsored trials. Of the 6 studies activated within our goal, PCC was able to have the 1st patient enrolled on 4 of these studies; all of which are early phase trials with competitive slot enrollment. 7 of the 9 studies are early phase trials. One of the early phase trials was a solid tumor cellular therapy trial requiring Institutional Biosafety Committee Review. This program has proven to be successful and increases patient access at PCC. The portfolio of these trials also indicate that we can activate a trial of any complexity through this mechanism if it is a high priority and if we have sponsor commitment.

Disease Management Group	Phase	Time from PRMC to Study Activation (Days)
GI	1b/2	33
Thoracic	3	59
Phase I	1/2	61
Hematologic	1/2	59
GU	1	45
GYN	1/2a	26
Melanoma	3	46
Phase I	½	28
Phase I	1	42
Median		**45** (26-61)

Solutions and Methods

The CTO met with all internal stakeholders across the enterprise to discuss feasibility, eligibility of trials, capacity, and the need for sponsor commitment to implement this program successfully. Five key components and parameters were identified to achieve this goal: Clinical Trial Agreement (CTA), Institutional Review Board (IRB), Site Initiation Visit, System Access, and Vendor supplies. In addition, we developed service level expectations (SLE) for NYULH staff and for the sponsor. Before agreeing to fast track a study, we required sponsor commitment to our SLE and evaluated our internal workload and capacity. Once a study is confirmed to go through this mechanism, a timeline with target dates are projected and e-mailed to all responsible parties. A regulatory manager assigned to pre-activation regularly monitors the progress of the trial and escalates when any component is at risk of not meeting target.

Lessons Learned and Future Directions

While these activation timelines are excellent, some delays could have been avoided (e.g., the study sponsor being unwilling to schedule SIV before CTA execution, the investigator being out of office during a critical time, delayed radiation safety approval, and vendor issues). As a result, we developed a sponsor and investigator intake form and revised specific processes to start earlier to mitigate these potential barriers. The future direction is to develop strategic partnerships with the sponsors we often work with to enable the automatic application of the fast track program with a master CTA, budget, and informed consent. We will continue to revise our procedures as we learn valuable lessons during this process. Additionally, with high demand for the fast track program, we are planning for a dedicated fast track manager in the next fiscal year.

3

Protocol Prioritization Scores: Are They Predictive?

J. Bollmer, J. Thomas, B. George, M. Larson, K. Schroeder, S. Zindars, R. Kurzrock
Medical College of Wisconsin Cancer Center

1. Background

Cancer centers assign prioritization scores to new trials to assess the study's position and value in the overall trial portfolio. At the Medical College of Wisconsin Cancer Center (MCWCC), our scoresheet considers scientific impact, accrual potential, and alignment with MCWCC strategic goals, among other aspects. Trials are initially scored by the Disease-Oriented Teams (DOTs), and these scores are confirmed/edited by the Feasibility Review Committee (FRC) before approving the study to continue with activation. Scores are entered into OnCore, our clinical trial management system, along with other standard data elements.

We have not explored whether prioritization scores impact downstream processes (e.g., activation times) or whether they are predictive of trial success (e.g., accrual).

2. Goals

We want to better understand the relationship between prioritization scores and key trial metrics:

- Are high priority trials activated more quickly?
- Do high priority trials enroll patients faster?
- Do high priority trials have higher overall accrual?

3. Solutions and Methods

We compiled prioritization score, activation, and accrual data on adult interventional treatment trials that opened since 2020 and had at least 365 days of active accrual time. Activation times were defined as Scientific Review Committee submission to open to accrual. We pulled each trial's total accrual at the 12-month timepoint, to get a standardized annual accrual rate. We also pulled the time to first patient enrolled, which was defined as the number of days from study activation to first patient on, minus any intervening days that the protocol was suspended to accrual.

4. Outcomes

Priority scores ranged from 3 to 21, with a median of 9 points. Lower-priority trials (scores <9, n=51) opened in an average of 264 days, while higher-priority trials (scores >9, n=39) opened a little faster (250 days). Activation times vary by sponsor type, so we looked at industry trials alone. Higher-priority industry trials (n=21) opened 23 percent faster than lower-priority (n=24), 245 versus 320 days, respectively.

Lower-priority trials averaged 3.1 accruals during their first year open, while higher-scoring trials averaged 4.9 accruals. Of the trials that accrued, higher-scoring trials accrued their first patient faster (mean of 58.4 days) than lower-scoring (mean of 153.7 days). Among industry trials only, higher-scoring accrued their first patients within an average of 61.5 days compared to 182.7 days for lower-scoring, but their first-year total accrual averaged only slightly higher (3.2 versus 2.8 patients, respectively).

5. Lessons Learned and Future Directions

At MCWCC, we assign prioritization scores but do not make purposeful use of them in activation or accrual processes. Nevertheless, higher-scoring trials tend to open faster, which suggests staff recognize their importance. Higher-scoring trials accrue earlier and have higher accrual their first year than lower-scoring trials, even though the score is only partially based on accrual potential.

We are piloting a FastTrack process for select trials to reduce activation times. When we expand this process, we could use prioritization scores to choose which trials are able to take advantage. Also, we would like DOTs to make better use of the scoresheet as another tool for determining whether to pursue a trial and perhaps institute a minimum threshold score for activation.

Protocol Prioritization Scores: Are They Predictive?

Jennifer Bollmer, PhD, James Thomas, MD, Ben George, MD, Marilyn Larson, MBA, Katy Schroeder, RN, CCRP, Stacey Zindars, MS, CCRP, Razelle Kurzrock, MD
Medical College of Wisconsin Cancer Center

Background

Cancer centers assign prioritization scores to new trials to assess each study's position and value in the overall trial portfolio. At the Medical College of Wisconsin Cancer Center (MCWCC), our scoresheet (**Fig. 1**) considers scientific impact, accrual potential, and alignment with MCWCC strategic goals, among other aspects. Trials are initially scored by the Disease-Oriented Teams (DOTs), and these scores are confirmed/edited by the Feasibility Review Committee (FRC) before approving the study to continue with activation.

While we spend a lot of time generating these scores, we have not explored their accuracy as predictive indicators of trial success.

Goals

We wanted to better understand the relationship between prioritization scores and key trial metrics such as:

- Overall accrual
- Time to first patient enrolled
- Activation time

Solutions and Methods

We compiled prioritization score, activation, and accrual data on adult interventional treatment trials that opened since 2020 and had at least 365 days of active accrual time. Activation times were defined as Scientific Review Committee approval to open to accrual. We pulled each trial's total accrual at the 12-month timepoint, to get a standardized annual accrual rate. We also pulled the time to first patient enrolled, which was defined as the number of days from study activation to first patient on, minus any intervening days that the protocol was suspended to accrual.

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Outcomes

Prioritization scores ranged from 3 to 21, with a median of 9 points. Lower-priority trials (scores <9, n=51) averaged 3.1 accruals during their first year open, while higher-scoring trials averaged 4.9 accruals. Of the trials that accrued, higher-scoring trials tended to accrue their first patient faster (mean of 58.4 days) than lower-scoring trials (mean of 153.7 days; **Fig. 2**).

Overall, activation times did not differ between low- versus high-priority trials; however, this is confounded by sponsor type. Looking at industry trials alone, higher-priority trials (n=21) opened 23% faster than lower-priority (n=24), 245 versus 320 days, respectively (**Fig. 3**).

Figure 1. Prioritization Scoresheet

Evaluation Factor	Categories	Points	Earned
Funding Source/Sponsor	NIH-funded IIT/NCTN trial with MCW PI	6	
	Institutionally funded interventional IIT	5	
	Industry-funded IIT	3	
	NCTN or BMT CTN trial	2	
	Industry trial	1	
	External Institutional/Consortium Trial	1	
Clinical/Scientific Impact	Likely to be a breakthrough drug/treatment modality	4	
	Phase I first in class/FIH having potential impact across multiple tumor types/preclinical data support	3	
	Phase I-III trial with possible practice changing implications	2	
	Phase I-III trial with few practice changing implications	1	
	Post-marketing study	0	
Annual Accrual Potential	>10	4	
	5-10	2	
Competing Trials	No competing trials (same eligibility/similar mechanism) open or pending	1	
Academic Value	First/Last authorship	3	
	Middle authorship	1	
Local PI is junior investigator (<5 yrs out from fellowship)	Yes	1	
MCW Lab Correlates (Hypothesis-driven)	Yes	3	
Uniquely Addresses Underserved Populations in Catchment Area	Yes	3	
Alignment with MCWCC Strategic Goals (scored by Feasibility Committee)		0-3	
		Total:	

Figure 2. Days to First Patient Enrolled by Trial's Prioritization Score

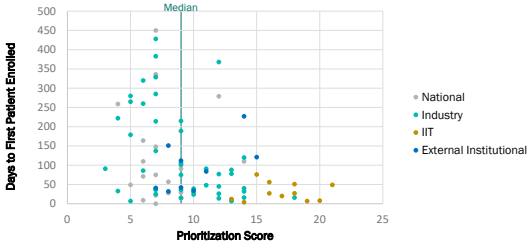
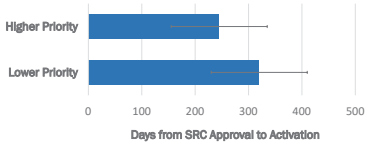


Figure 3. Average Days to Activation by Trial's Prioritization Score



Lessons Learned and Future Directions

Individual trial metrics varied within the lower- and higher-scoring groups, so calling the prioritization scores "predictive" would perhaps be an overstatement. However, as a group, higher-scoring trials more consistently enrolled their first patients quickly and tended to accrue more patients overall. They also tended to open faster, which suggests staff recognized their importance.

With this information, we plan to encourage disease teams to make better use of the scoresheet as another tool for determining whether to pursue a trial and perhaps institute a minimum threshold score for activation. We also hope to better integrate the scores into our activation process, to get higher-priority trials open more quickly.

Protocol Categorization System to Improve Activation Timelines of Mission Critical Research

J. Migliacci, E. Valentino, M. Kehoe, C. Ryan, R. Cambria, A. Rodavitch, S. Hanley
Memorial Sloan Kettering Cancer Center

1. Background

Memorial Sloan Kettering Cancer Center (MSK) activates over 300 prospective trials each year. Improvements to the time it takes to activate trials has always been our priority. In the past few years, increased volume and complexity of protocols coupled with the pandemic in 2020 and "The Great Resignation" of staff throughout the institution placed an additional strain on our system. It became apparent that our volume surpassed resources, resulting in ineffective management of our activation goal for all protocols.

2. Goals

Given our finite resources and expanding portfolio, a protocol categorization system was proposed by leadership to focus our efforts for quick activation on a more manageable volume of studies critical to MSK's mission. The goal was to categorize protocols as: • Mission Critical (MC): studies critical to our mission, for which our goal was to activate in a reduced amount of time • Priority: all priority studies were expected to activate according to our standard institutional goal for activation o Time sensitive: began activation at the time of submission o Not time sensitive: began activation when institutional resources were available.

3. Solutions and Methods

To operationalize this categorization system, leadership determined the monthly number of studies permitted to begin activation, based on the monthly number of studies successfully opened to accrual using our current resources. Each service (disease group) was given an allocation of slots for MC. MC protocols were prioritized by all teams (i.e., finance, legal, research operations, study start-up, protocol review, etc.). Detailed communication plans were developed between groups, starting when a protocol was accepted for activation. Bi-weekly meetings were established with stakeholders of study start up to escalate potential barriers to activation early in the process. Our team created workflows and dashboards to track protocol allocations by disease group and time to activation timelines.

4. Outcomes

Since the rollout of the categorization system, 186 studies were IRB approved, 123 of which have been activated. Our data indicate that the categorization of studies was proven successful in effectively managing our activation timelines. Time to IRB approval was reduced by 56 days and time to activation was reduced by 86 days for MC protocols, compared to all priority protocols.

5. Lessons Learned and Future Directions

After a year of categorizing protocols, we identified limitations which instructed our future goals: 1) MC investigator-initiated protocols (IITs) are unlikely to meet reduced activation goals due to factors specific to IITs (i.e., FDA submission requirements which add at least 30 days, etc.); we are developing guidelines and adjusted goal timelines for certain IIT protocols 2) Obtaining commitment from sponsors and PIs is critical for our MC timelines; we will continue to enhance this process
3) Implementing MC specific activation requirements, such as finalized study manuals, to prevent delays in developing study tools and overall activation

Protocol Categorization System to Improve Activation Timelines of Mission Critical Research

Memorial Sloan Kettering Cancer Center

Jocelyn Migliacci, MA, Emily Valentino MPH, Marissa Kehoe, MS, Carly Ryan, BS, Roy Cambria, BS, Ann Rodavitch, MA, Sara Hanley, MSW

Background

- Memorial Sloan Kettering Cancer Center (MSK) activates over 300 prospective protocols each year. Improvements to the time it takes to activate protocols has always been our priority.
- In the past few years, increased volume and complexity of protocols coupled with the pandemic in 2020 and "The Great Resignation" of staff throughout the institution placed an additional strain on our system. It became apparent that our volume surpassed resources, resulting in ineffective management of our activation goal for all protocols.

Goals

Given our finite resources and expanding portfolio, a protocol categorization system was proposed by leadership to focus our efforts for quick activation on a more manageable volume of protocols critical to MSK's mission.

The goal was to categorize protocols as:

- **Mission Critical (MC):** protocols critical to our mission, for which our goal was to activate in a reduced amount of time
- **Priority:** All priority protocols were expected to activate according to our standard institutional goal for activation.
  - **Time Sensitive:** began activation at the time of submission
  - **Not Time Sensitive:** began activation when institutional resources were available.

Methods

- To operationalize this categorization system, leadership determined the monthly number of protocols permitted to begin activation, based on the monthly number of protocols successfully opened to accrual using our current resources.
- Each service (disease group) was given an allocation of slots for MC. MC protocols were prioritized by all teams (i.e., finance, legal, research operations, study start up, protocol review, etc.) (Figure 1)
- Detailed communication plans were developed between groups, starting when a protocol was accepted for activation.
- Bi-weekly meetings were established with stakeholders of study start up to escalate potential barriers to activation early in the process.
- Our team created workflows and dashboards to track protocol allocations by disease group and time to activation timelines.

Figure 1: Protocol Allocations by Disease Group

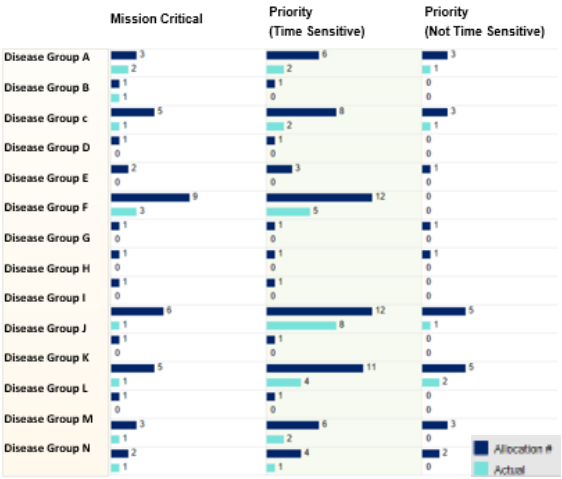
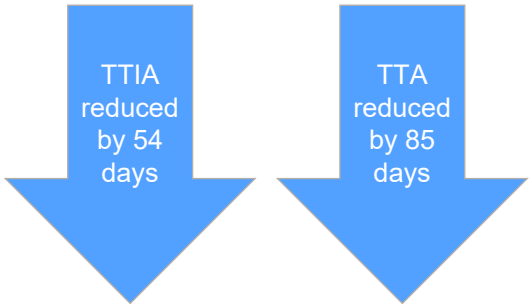


Figure 2: TTIA & TTA Reduction in Mission Critical protocols when compared to Priority protocols



Outcomes

- Since the roll out of the categorization system (as of 5/11/2023), **246** protocols were **IRB approved**, **180** of which have been **activated**.

	# of Categorized Protocols Accepted for Activation	# of IRB Approved Categorized Protocols	# of Open to Accrual Categorized Protocols
Mission Critical (MC)	74	59	49
Priority (Time Sensitive)	194	134	93
Priority (Not Time Sensitive)	65	53	38

- Time to IRB approval (TTIA) was reduced by **54 days** and time to activation (TTA) was reduced by **85 days** for MC protocols, compared to all Priority protocols.
- Our data indicates that the categorization of protocols was proven successful in effectively managing our activation timelines by allowing us to focus our efforts on the activation of MC protocols.
- In 2022, only 1 disease group went over their 2022 MC allocations.

Future Direction

After a year of categorizing protocols, we identified limitations which instructed our future goals:

1. MC investigator-initiated protocols (IITs) are unlikely to meet reduced activation goals due to factors specific to IITs (i.e., FDA submission requirements which adds at least 30 days, etc.). We are developing guidelines and adjusted goal timelines for certain IIT protocols.
2. Obtaining commitment from sponsors and PIs is critical for our MC timelines. We will continue to enhance this process.
3. Implementing MC specific activation requirements, such as finalized study manuals, to prevent delays in developing study tools and overall activation.

Harmonious Activation of Oncology Protocols Across an Integrated Academic Health System

R. Kurz, C. Messick, T. Saunders
Rutgers Cancer Institute of New Jersey

1. Background

In January 2019, Rutgers University (RU) and the RWJBarnabas Health (RWJBH) system entered into an agreement to form an academic health system (AHS). As a result, we had an extraordinary opportunity to expand Rutgers Cancer Institute of New Jersey (CINJ) clinical research to nine of the 14 hospitals of RWJBH. In this newly integrated, unified "one site" model, CINJ has unprecedented numbers of patients at its disposal for clinical research activities to positively impact our catchment areas priorities and needs.

2. Goals

To promote and simplify access and implementation of clinical trials to increase accrual and engagement at CINJ and RWJBH sites.

3. Solutions and Methods

The Office of Protocol Activation (four FTEs) was established in December 2021 to streamline, standardize, and support feasibility and clinical trial activation activities across the organization. Our process beyond the regulatory, budget, and contracting start-up activities focuses on engaging investigators at our system sites and their research staff. Upon SRB approval, the office sends a study interest form (SIF) to all health system sites. Interested investigators complete the form with the number of anticipated enrollments and then each of these interested RWJBH sites is added to a single IRB application. The team tracks other activation tasks such as Epic Beason order set drafts, investigational drug and labs kit availability, and documentation of IRB approval. Once the trial is IRB approved, the office schedules one SIV, which is now conducted remotely and universally. Attendance and training are documented in the electronic regulatory binder (eREG®).

4. Outcomes

The Office of Protocol Activation has had substantial impact in CY2022.

- Reduced time from SRB submission to trial activation from 167 to 72 days (↑232 percent)
- Model allows OHRS the ability to open trials simultaneously at up to eleven clinical sites with a single IRB approval and systemwide SIV process
- Reduced open to accrual to first subject enrolled from 45 to 41 days (↑9 percent)
- Ninety-four unique investigators enrolled 600 subjects to interventional treatment trials in CY2022; overall accrual increased 33 percent (n=423) with a significant 300 percent increase in RWJBH system enrollments from CY2021
- Interventional treatment accruals to underrepresented populations within our catchment area has increased from 38.3 percent to 45 percent in CY2022

5. Lessons Learned and Future Directions

Educating sponsors on the value and strength of our system took a significant investment in time up front but facilitated our ability to open trials at multiple locations. Centralizing protocol activation activities allowed streamlined communication with sponsors, legal, finance, and regulatory, which was critical to getting studies activated quickly. Future directions include:

- Continuing to enhance operational efficiencies in order to increase accrual and reduce time to activation to meet our goal of < 60 days
- Utilizing Deep 6 AI and Epic to assist ensure catchment area needs and priorities are appropriately captured on feasibility assessments
- Focus on promoting more Phase III trials, particularly from NCTN, to meet the needs of the patients treated by a large number of primary oncology providers practicing across the RWJBH System; we continue to promote the "culture" of clinical research at all sites

Harmonious Activation of Oncology Protocols Across an Integrated Academic Health System

Renee Kurz RN, DNP, FNP-BC, AOCNP
Carol Messick RN, BSN
Tracie Saunders RN, MS, CCRC

BACKGROUND

In January 2019, Rutgers University (RU) and the RWJBarnabas Health (RWJBH) system entered into an agreement to form an Academic Health System (AHS). As a result, we had an extraordinary opportunity to expand Rutgers Cancer Institute of New Jersey (CINJ) clinical research to nine of the fourteen hospitals of RWJBH.

GOALS & OBJECTIVES

To promote and simplify access and implementation of clinical trials to increase accrual and engagement at CINJ and RWJBH sites.

METHODS

In order to streamline activating studies at all our locations, we formed an integrated, unified "one site" model. The Office of Protocol Activation was established to streamline, standardize and support feasibility and clinical trial activation activities across the organization. Our unifed research structure included:

- One IRB
- One CTMS (OnCore)
- One Contract/Budget
- One Protocol Activation Office

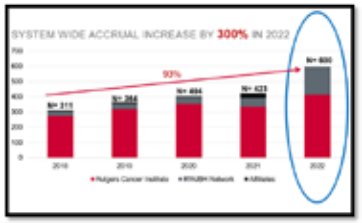
OUTCOMES

Protocol Activation Metrics

(MEDIAN DAYS)

Metric	2021	2022	Improvement
IRB Submission to IRB Approval	30	21	30%
Contract Turnaround	80	60	25%
Budget Turnaround	86	60	30%
SRB Submission to Open to Accrual	167	72	232%

- Primary outcome:
  - Opened 80 clinical trials across 11 sites. *Including Cooperative Group, IITs, Industry Sponsored and BIG Ten Consortium studies*
- Secondary outcomes:
  - 300% increase in enrollment across the Robert Wood Johnson Barnabas Health System.
  - 94 unique investigators contributed to annual accrual of 600 subjects to interventional studies.
  - Minority accrual percentage has increased from 27.6% in 2017 to 45% in 2022.



LESSONS LEARNED AND FUTURE DIRECTIONS

CINJ was able to access unprecedented numbers of patients for clinical research activities as well as improve representation of our catchment area. By deploying the one site model across 11 locations throught the state, we were able to improve access to studies while reducing activation time lines. Our ability to open trials at multiple locations was facilitated by educating sponsors on the value and strength of our one site model which took a significant time investment up front. Centralization of protocol activation activities allowed streamlined communication between sponsors, legal, finance and regulatory which was critical to getting studies activated quickly.

Future directions include:

- Continuing to enhance operational efficiencies in order to increase accrual and reduce time to activation to meet our goal of < 60 days.
- Utilizing Deep6 and EPIC to assist ensure catchment area needs and priorities are appropriately captured on feasibility assessments.
- Focus on promoting more phase III trials, particularly from NCTN, to meet the needs of the patients treated by a large number of primary oncology providers practicing across the RWJBH System. We continue to promote the "culture" of clinical research at all sites.

cinj.org

Prioritizing and Submitting Studies for Scientific Review

J. Gay, L. Gruschkus
The University of Texas at MD Anderson Cancer Center

1. Background

Research is an integral element in the care of patients and the mission of The University of Texas MD Anderson Cancer Center (MD Anderson) and is conducted across multiple divisions and over 43 departments specializing in various cancers. Due to the organization's size and volume of trials, it is a challenge to prioritize and track trials competing to enroll similar patient populations. Historically, study prioritization took place at the individual department level, where a list of trials was maintained and reviewed only within the department.

2. Goals

1. To create disease/discipline focus groups for aid in prioritization of trials

2. To create and implement a web-based platform which would allow for a central location for multidisciplinary review and prioritization

3. Solutions and Methods

In March 2021, MD Anderson formed a standardized process for the Stage 1 review process. Disease/discipline focus groups were created to improve collaboration and prioritization of trials thus bringing together experts from multidisciplinary teams, including, medical oncologists, surgeons, radiation oncologists, and others depending on cancer type and intervention needed.

The Stage 1 Review process at MD Anderson also incorporates a web-based questionnaire collecting the name of the principal investigator (PI), the title of the study, sponsorship, scientific interest, novelty of the investigational product, whether the trial targets a rare disease, estimated enrollments, and targeted trial completion dates. The answers to a subset of questions are automatically scored to assist the disease site review team with a uniform and equitable way to assist with the prioritization of trials. The web-based platform allows for a central location for multidisciplinary review and prioritization across our large institution.

4. Outcomes

Since implementation, 925 concepts/trials were entered into the new online system. Of these, 815 were approved. Ninety-nine were rejected at the disease site level. Reasons for rejection included competing portfolios, limited resources, operational difficulties, lack of early clinical effectiveness, limited academic opportunities, and lack of scientific interest.

5. Lessons Learned and Future Directions

Utilizing a uniform method accessible to all stakeholders allows for transparent prioritization and review of studies, and better use of the institution's resources which benefits our investigators, research teams, and participants.

Multidisciplinary selection and prioritization of trials during Stage 1 review allows for elimination of trials that show little to no accrual promise, trials that are low on the prioritization list when compared to others, and studies that would not be feasible to conduct at the institution. Thus, this process allows for quicker review and mobilization of resources to those trials approved to be conducted at the institution.

Future directions include evaluating metrics to see the impact on the number of trials rejected at the Scientific Review Committee (SRC) meeting level as well as impact on the number of trials closed annually for lack of scientific relevance or accrual.

Prioritizing and Submitting Studies for Scientific Review

Jenny L Gay, BS, CCRP; Lisa Gruschkus, MA, CCRP

The University of Texas at MD Anderson Cancer Center, Houston, TX

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

Making Cancer History®

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Goals

- To create disease/discipline focus groups for aid in prioritization of trials
- To create and implement a web-based platform which would allow for a central location for multidisciplinary review and prioritization

Methods Implemented

In March 2021, MD Anderson formed a standardized process for the Stage 1 Review process. Disease/discipline focus groups were created to improve collaboration and prioritization of trials thus bringing together experts from multidisciplinary teams, including, medical oncologists, surgeons, radiation oncologists, and others depending on cancer type and intervention needed.

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Future Direction

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Reference

https://grants.nih.gov/grants/guide/pa-files/PAR-20-043.html

Clinical Research: Tracking Studies in the Pipeline

J. Migliacci, E. Valentino, M. Kehoe, C. Ryan, R. Cambria, A. Rodavitch, S. Hanley
UAMS Winthrop P. Rockefeller Cancer Institute

1. Background

Prior to the development of Pre-Study Event Tracker at UAMS, there was no consistent or efficient method to track clinical trials in the pipeline. Early steps of clinical trials at our site such as execution of the CDA, Disease Oriented Committee approval, and PRMC (scientific review) approval were not tracked appropriately. Attempted methods of tracking included Word and Excel documents, handwritten notes, and physical folders. Problems with these methods were inconsistency as well as an inability for the whole team to be able to access accurate information pertaining to the pre-study onboarding processes.

2. Goals

Our goal was to create a streamlined process to track clinical trials in the onboarding pipeline. The process should be efficient and accurate, allowing all members of the team to access information quickly.

Metrics used to evaluate Pre-Study Event Tracker were: new study opportunities with the ability to sort by PI, Disease Oriented Committee, or other criteria; open studies including the significant dates from the onboarding process; and, declined studies including reason the clinical trial was declined and by whom.

3. Solutions and Methods

Our Information Technology Research Systems team, through in-depth collaboration with the Cancer Clinical Trials Office, developed Pre-Study Event Tracker with the ability to track clinical trials through the onboarding process beginning with initial interest contact through IRB number assignment. The business development team is able to enter identifying study information, contact information for sponsors and CROs, dates submitted and approved by relevant committees, and additional notes. We can also assign priority to studies and sort the pipeline by priority assigned.

4. Outcomes

Since the inception of Pre-Study Event Tracker, we've been able to successfully maintain tracking of clinical trials through the onboarding process. Pre-Study Event Tracker allows the entire team to access information quickly and accurately. We have also consolidated reports for each Disease Oriented Committee into one Pipeline Report.

5. Lessons Learned and Future Directions

Pre-Study Event Tracker has become integral to our onboarding processes. The Clinical Trials Office uses Pre-Study Event Tracker from initial interest emails to assignment to a study team. All pipeline clinical trials are consistently tracked, easily accessed, and can be sorted by any number of variables. We can also track declined studies and their reasons for National Cancer Institute accreditation. System enhancements are made as necessary.

Clinical Research: Tracking Studies in the Pipeline

Ronni Geary, MBA, CPC[1], Matthew Kovak, MS, CCRP[1], Beth Scanlan, MS, CCRP[1], Michael Birrer, MD, PhD[1],
Emre Ermisoglu, PhD[2], Angela Smith, MS, PMP[2], Zhidan Feng, MS[2]
[1]Cancer Clinical Trials Office, Winthrop P. Rockefeller Cancer Institute
[2]IT Research Systems, University of Arkansas for Medical Sciences, Little Rock, AR

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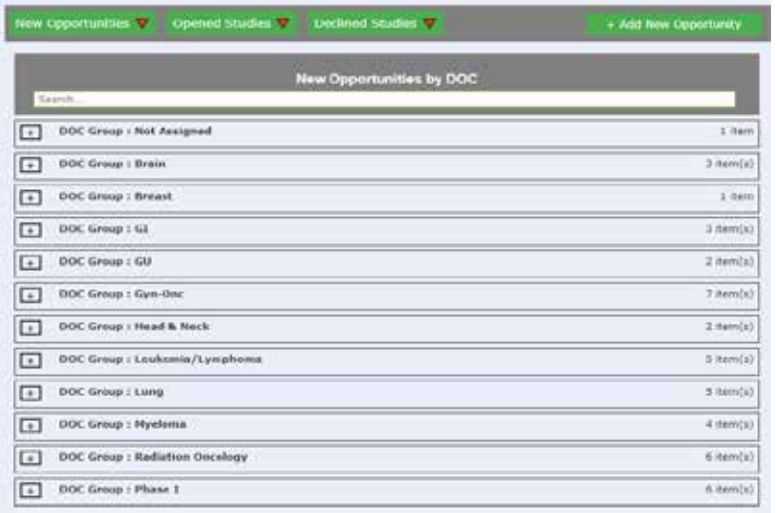

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Future Directions

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System enhancements are made as necessary.

Contact

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Review Week: Promoting Cross-Functional Collaboration During Study Start-up

B. Scanlan, A. Holley, C. Jones, M. Kovak, M. Birrer
UAMS Winthrop P. Rockefeller Cancer Institute

1. Background

The process for clinical trial start-up is complex and involves efforts of many different teams within the Clinical Trials Office (CTO). Previous attempts to convene a single, extended duration meeting at the beginning of the start-up process fell short. The previous method resulted in lack of preparedness and inadequate discussion and protocol understanding, which led to scheduling delays and lack of communication regarding follow-up responsibility. A streamlined process was necessary to shorten the study activation timeline while allowing for cross-functional collaboration across all disciplines of the study team.

2. Goals

- Decrease study start-up time
- Streamline development of the clinical treatment plan and billing procedures
- Efficiently negotiate the budget based on required clinical treatment plan
- Maximize cross-functional collaboration across study teams and study sponsor/Contract Research Organization (CRO)

3. Solutions and Methods

The CTO implemented a process to include the addition of a Review Week during the early stages of the study start-up process. The Regulatory Specialist (RS) assigned to the study is responsible for uploading pertinent documents into a shared file prior to the week. The RS is responsible for scheduling and leading the Review Week, taking minutes, and corresponding with the sponsor/CRO and principal investigator regarding issues that require attention. Attendees include staff from finance, coverage, and clinical teams within the CTO as well as a representative from the research pharmacy. The week consists of daily, virtual meetings that provide opportunity for study staff to review the budget build and discuss aspects of the protocol and treatment plan. During the 30-minute meetings, the teams review the protocol for clinical, financial, and regulatory questions. Internal clinical workflows and processes are discussed and assessed to minimize logistical issues as compared to current standard of care practices. Daily meetings provide opportunity to correspond with the sponsor/CRO to resolve questions that arise and report back later in the week with resolutions. The RS distributes minutes daily including an outline of questions and topics to be resolved during the week.

4. Outcomes

Implementation of the Review Week has aided in increasing collaborative work across different teams within the CTO. Feedback indicates that staff views the Review Week as a vital and productive step in study start-up. More time is given to in-depth discussions of the study treatment plan and order set builds which allows for quicker clinical review, Beacon validation, and EMR activation. The CTO has seen increased efficiency and staff engagement, resulting in decreased study start-up timelines. After implementation of the Review Week, there has been a decrease in the time to activation by an average of 22 days, while simultaneously more than doubling the number of studies activated yearly. Although other changes occurred during the same time period, much of the improvement can be attributed to implementation of the Review Week.

5. Lessons Learned and Future Directions

Future directions for improving the concept of the Review Week include:

- Designating a start-up specific team
- Developing lists/templates to be used by different teams during the week to make sure common, critical questions are answered in advance
- Developing a checklist for the RS incorporating topics that are generally addressed

Review Week: Promoting Cross-Functional Collaboration during Study Start-up

Beth Scanlan, MAP, CCRP; Aaron Holley, BS, CCRP; Cindy Jones MSN, RNP-BC, CCRP;
Matthew Kovak, MS, CCRP; Michael Birrer, MD
Cancer Clinical Trials Office, Winthrop P. Rockefeller Cancer Institute,
University of Arkansas for Medical Sciences

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The process for clinical trial start-up is complex and involves efforts of many different teams within the Clinical Trials Office (CTO). Previous attempts to convene a single, extended duration meeting at the beginning of the start-up process fell short. The previous method resulted in lack of preparedness, inadequate discussion and protocol understanding, which led to scheduling delays and lack of communication regarding follow-up responsibility. A streamlined process was necessary to shorten the study activation timeline while allowing for cross-functional collaboration across all disciplines of the study team.

Goals

- Decrease study start-up time
- Efficiently negotiate the budget based on required clinical treatment plan
- Streamline development of the clinical treatment plan and billing procedures
- Maximize cross-functional collaboration across study teams and study sponsor/Contract Research Organization (CRO)

Methods

The CTO implemented a process to include the addition of a Review Week during the early stages of the study start-up process. The Regulatory Specialist (RS) assigned to the study is responsible for uploading pertinent documents into a shared file prior to the week. The RS is responsible for scheduling and leading the Review Week, taking minutes, and corresponding with the sponsor/CRO and Principal Investigator regarding issues that require attention. Attendees include staff from Finance, Coverage, and Clinical teams within the CTO as well as a representative from the Research Pharmacy. The week consists of daily, virtual meetings that provide opportunity for study staff to review the budget build and discuss aspects of the protocol and treatment plan. During the thirty-minute meetings, the teams review the protocol for clinical, financial, and regulatory questions. Internal clinical workflows and processes are discussed and assessed to minimize logistical issues as compared to current standard of care practices. Daily meetings provide opportunity to correspond with the sponsor/CRO to resolve questions that arise and report back later in the week with resolutions. The RS distributes minutes daily including an outline of questions and topics to be resolved during the week.

Outcomes

- ☑ Increased collaborative work across teams
- ☑ Increased efficiency and staff engagement
- ☑ Quicker clinical review, Beacon validation, EMR activation
- ☑ Decreased start-up timelines by an average of twenty-two days, while simultaneously more than doubling the number of studies activated yearly

Future Directions

- Designating a start-up specific team
- Developing templates to be used by teams to make sure common, critical questions are answered in advance
- Developing a checklist for the Regulatory Specialist incorporating topics that are generally addressed

Contact

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Pilot to Decrease Time-to-Activation for Investigator-Initiated Trials

M. Cases, B. Whalen, A. Yost, A. Skafel, C. Andreadis
UCSF Helen Diller Family Comprehensive Cancer Center

1. Background

The Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) has an increasing number of investigator-initiated trials (IITs): 20 requests for new IITs in 2021 and 29 in 2022. At UCSF, IITs are developed by the Protocol Development (PD) team. Keeping time-to-activation (TTA) as brief as possible while producing quality clinical trial protocols is a central goal of the PD team. Therefore, from February 2022 to February 2023, a pilot project aimed at decreasing TTA for IITs was implemented.

2. Goals

The pilot project aimed to determine the most effective ways to decrease TTA while not compromising protocol quality.

3. Solutions and Methods

The pilot included two categories: 1) new workflows (or services offered), and 2) process improvements to existing workflows.

1) New workflows: to ensure the quality of protocols and ancillary documents and decrease potential slowdowns during reviews, the PD team began working with the PI earlier in the protocol development process, at the initial study concept phase
   a. The PD team retrained on medical writing best practices through a custom-built course
   b. To improve version control and decrease back-and-forth communications between PD and study teams, the PD team became responsible for all protocol-related submissions (PRMC, IRB, FDA)
2) Process improvements to existing workflows: Contract negotiations were initiated earlier to iron out collaboration terms before trial activation begins
   a. Submissions were reorganized for efficiency (i.e., parallel reviews)
   b. Study eCRFs were built in-house
   c. Stakeholder communication was increased to improve project management and accountability

Also, two additional FTE were hired to support these efforts.

4. Outcomes

The pilot demonstrated a decrease in average TTA for IITs of 75 days [average TTA for February 2021 to February 2022 = 196 days (n=5); average TTA for February 2022 to February 2023 = 121 days (n=6)]. Having PIs attend their IRB reviews allowed for more direct communication and decreased timelines, saving an average of 41 days during the IRB review process (average IRB review length when PI did not attend = 84 days; average IRB review length when PI attended = 43 days).

Stronger relationships with improved communications were developed with the UCSF clinical trial activation teams outside the HDFCCC. Workflow changes improved efficiencies by allowing for more parallel processing. Increased FTE for the PD team allowed for better faculty support in the IIT process.

5. Lessons Learned and Future Directions

The pilot has successfully reduced the TTA for IITs and enhanced the support available to HDFCCC investigators who wish to run their own trials. The PD team, UCSF IRB, budgeting, and contracting departments have worked closely together to significantly decrease the amount of back and forth at each activation stage.

The PD team will continue operating under the new set of workflows. In addition, the lessons learned from this pilot will be used to streamline trial activation in industry and cooperative group trials. While successful, the pilot highlighted that this work is resource-intensive, so ways to scale effectively are still being sought.

UCSF Helen Diller Family Comprehensive Cancer Center

Pilot to Decrease Time-To-Activation for Investigator-Initiated Trials

Mallory Cases, PhD, CCRP; Bella Whalen, MPH, CCRP; Arla Yost, MSc, CCRP; Andrea Skafel, MSc, CCRP; Charalambos Andreadis, MD, MS

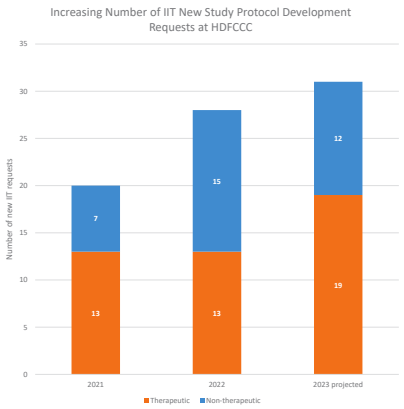
Background

The Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) has an increasing number of investigator-initiated trials (IITs): 20 requests for new IITs in 2021, 28 in 2022, and a projected 31 in 2023.

At UCSF, IITs are developed by the Protocol Development (PD) team. Keeping time-to-activation (TTA) as brief as possible while producing quality clinical trial protocols is a central goal of the PD team. Therefore, beginning February 2022, a pilot project was launched with the aim of decreasing TTA for IITs.

Goals

The pilot project aimed to determine the most effective ways to decrease TTA while not compromising protocol quality.



Solutions and Methods

The pilot included two categories:

- new workflows (or services offered)
- process improvements to existing workflows

New Workflows

- To ensure the quality of protocols and ancillary documents and decrease potential slowdowns during reviews, the PD team began working with the PI earlier in the protocol development process, at the initial study concept phase.
- The PD team also re-trained on medical writing best practices through a custom-built course.
- To improve version control and decrease back-and-forth communications between PD and study teams, the PD team became responsible for all protocol-related submissions (PRMC, IRB, FDA).

Solutions and Methods (cont'd)

Process Improvements

- Contract negotiations were initiated earlier to iron out collaboration terms before trial activation begins.
- Submissions were reorganized for efficiency (i.e., parallel reviews).
- Study eCRFs were built in-house.
- Stakeholder communication was increased to improve project management and accountability.

Misc.

- Two additional FTE were hired to support these efforts.

Pre-Pilot vs. Pilot Time-to-Activation Milestones

Outcomes

The pilot demonstrated a 51% decrease in average TTA for IITs of 165 days [average pre-pilot TTA = 323 days (n=20); average pilot TTA = 157 days (n=9)].

Having PIs attend their IRB reviews allowed for more direct communication and decreased timelines, saving an average of 41 days during the IRB review process (average IRB review length when PI did not attend = 84 days; average IRB review length when PI attended = 43 days).

Stronger relationships with improved communications were developed with the UCSF clinical trial activation teams outside the HDFCCC.

Workflow changes improved efficiencies by allowing for more parallel processing.

Increased FTE for the PD team allowed for better faculty support in the IIT process.

Lessons Learned and Future Directions

- The pilot has successfully reduced the TTA for IITs and enhanced the support available to HDFCCC investigators who wish to run their own trials.
- The PD team, UCSF IRB, budgeting, and contracting departments have worked closely together to significantly decrease the amount of back and forth at each activation stage.
- The PD team will continue operating under the new set of workflows.
- In addition, the lessons learned from this pilot will be used to streamline trial activation in industry and cooperative group trials.
- While successful, the pilot highlighted that this work is resource-intensive, so ways to scale effectively are still being sought.

First Accrual Within 70 Days of Opening Predicts Overall Trial Accrual Success

K. Hoy, A. Gerds, J. Chan, K. McCaffrey, E. Worthing, F. Arnold, L. Masar, M. Kilbane, H. Pounardjian
Case Comprehensive Cancer Center

1. Background

Low- and non-accruing trials consume limited resources while generating little meaningful output, resulting in increased costs and translational timeline for new biomedical discoveries. Comprehensive cancer centers normally use a reactive approach when addressing these studies. Trials that do not accrue at an acceptable rate are flagged for low accrual at 6- or 12-month intervals. This process requires lengthy follow-up and is based on the goals that the study team self-reports during start-up. This inefficient model of monitoring is time intensive and keeps low-accruing studies open for months before poor performance is discovered and mitigated.

In this project we looked to develop a straightforward early predictor of accrual success through the duration of a study. Multifactorial methods to predict and characterize low-accruing protocols have been described (Bennette 2015; Tang 2017). We aim to develop a simple, predictive metric that can identify unsuccessful clinical trials earlier in the study's life cycle. Our hypothesis is that trials that accrue the first participant in 70 days or less will be significantly more likely to reach their accrual goals.

2. Goals

- Characterize trials that will reach accrual goals
- Establish proactive metrics that can be used to identify which trials should receive resources

3. Solutions and Methods

- Share best practices across our consortium partners, ensuring all stakeholders share the same vision and goals
- Descriptive statistics and regression analyses on all trials open to accrual from 2007-2023 Q1

4. Outcomes

- 2183 trials were reviewed from 2007-Q1 2023
- 960 protocols accrued first participant in less than 70 days
- 790 protocols accrued first participant greater than 70 days
- 433 protocols had no accrual at the time of analysis
- Studies with accrual at >70 days average accrual 16, median 6, SD + 42
- Studies with 70+ days average 8, median 4, SD + 19
- Protocols with less than 70 days to first accrual had 100 percent higher average accrual and 50 percent higher median accrual

5. Lessons Learned and Future Directions

Further analysis will examine trends across sponsor type, phase, data table 4 type.

CASE WESTERN RESERVE UNIVERSITY | CASE COMPREHENSIVE CANCER CENTER

First accrual within 70 days of opening predicts overall trial accrual success

Kevin Hoy[1], PhD.; Lydia Masar, BA[1]; Aaron T. Gerds[2], MD, MS; Josephine Chan[3], PhD.; Kate McCaffrey[2], MBA; Emily Worthing[1], MBA; Fearon Arnold[1], BS; Megan Kilbane[2], MBA; H. John Poundardjian[1], MBA

Affiliations: 1) Case Comprehensive Cancer Center 2) Cleveland Clinic Foundation 3) University Hospitals Cleveland

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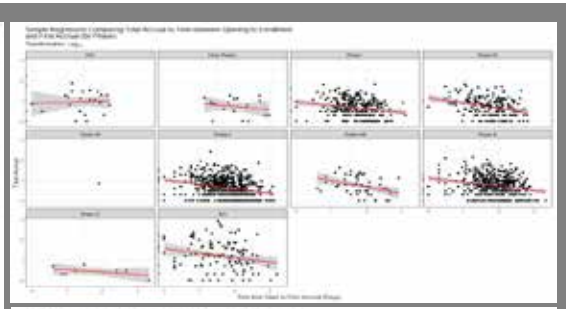
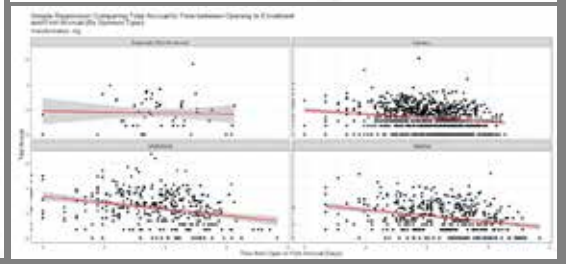
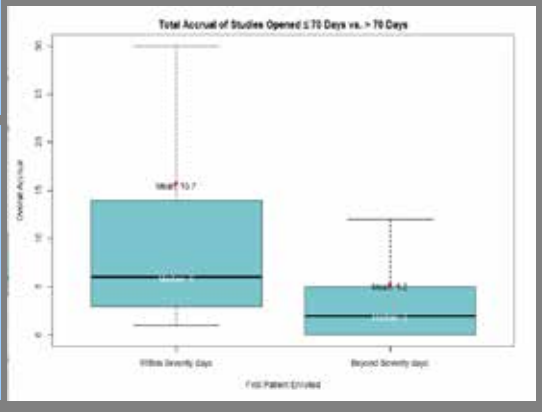
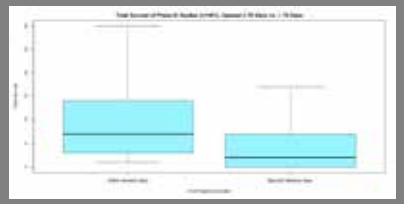
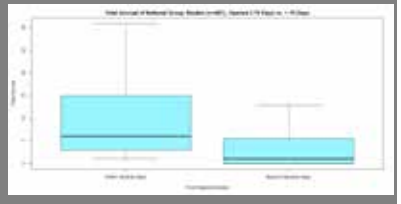
	Within Seventy days (N=953)	Beyond Sevesty days (N=1258)	Overall (N=2211)
Phase			
Pilot	20 (2.1%)	13 (1.0%)	33 (1.5%)
Early Phase I	7 (0.7%)	16 (1.3%)	23 (1.0%)
Phase I	169 (17.7%)	166 (13.2%)	335 (15.2%)
Phase I/II	107 (11.2%)	132 (10.5%)	239 (10.8%)
Phase I/III	0 (0%)	1 (0.1%)	1 (0.0%)
Phase II	330 (34.6%)	474 (37.7%)	804 (36.4%)
Phase II/III	27 (2.8%)	33 (2.6%)	60 (2.7%)
Phase III	217 (22.8%)	344 (27.3%)	561 (25.4%)
Phase IV	5 (0.5%)	5 (0.4%)	10 (0.5%)
N/A	71 (7.5%)	74 (5.9%)	145 (6.6%)
Protocol_Type			
Device Feasibility	1 (0.1%)	0 (0%)	1 (0.0%)
Diagnostic	25 (2.6%)	15 (1.2%)	40 (1.8%)
Prevention	7 (0.7%)	18 (1.4%)	25 (1.1%)
Screening	8 (0.8%)	6 (0.5%)	14 (0.6%)
Supportive Care	64 (6.7%)	91 (7.2%)	155 (7.0%)
Treatment	848 (89.0%)	1128 (89.7%)	1976 (89.4%)
Sponsor_Type			
Externally Peer-Reviewed	35 (3.7%)	31 (2.5%)	66 (3.0%)
Industry	498 (52.3%)	643 (51.1%)	1141 (51.6%)
Institutional	220 (23.1%)	197 (15.7%)	417 (18.9%)
National	200 (21.0%)	387 (30.8%)	587 (26.5%)
Total_Accrual			
Mean (SD)	15.7 (43.6)	5.20 (15.5)	9.73 (31.3)
Median [Min, Max]	5.00 [1.00, 840]	2.00 [0, 291]	3.00 [0, 840]

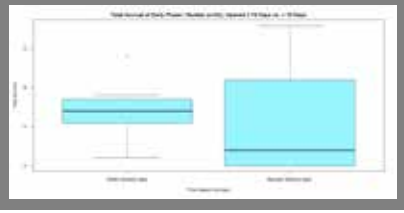


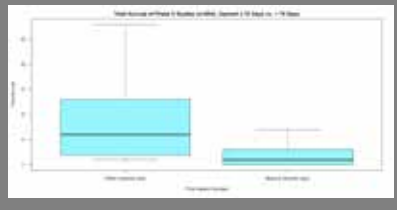












Conclusions

- Studies that accrue their first participant within 70 days of open to accrual had statistically higher overall accrual.
- This observation was also statistically different in : Early Phase I, Phase II, Phase III, and National Group protocols.
- This simple predictor could change the way accrual monitoring is performed.

CTMS Optimization: A Tale of One Platform, Three Clinical Sites, and One Combined Dataset to Improve Trial Activation, Portfolio Management, and Clinical Trials Reporting

M. Mavredes, K. Bouker, M. Marafelias, T. Impallaria, E. Richards
Georgetown Lombardi Comprehensive Cancer Center

1. Background

The Lombardi Comprehensive Cancer Center (LCCC) consists of three clinical sites. Managing harmonized consortium-wide metrics, to measure progress and guide operational decision making for LCCC, requires entering and accessing clinical trials data in two separate accounts from a single CTMS vendor, OnCore. Previously, each site manually generated single-site reports, which were collated to present consortium-wide metrics. To standardize consortium operations, LCCC set consortium-wide data entry and quality assurance practices and data locks to ease the issuance of metrics.

2. Goals

The CTMS Optimization Project goals included:

- Provide at-a-glance metrics via dashboards to LCCC Leadership, Clinical Research Leadership, and Disease Group (DG) Leaders
- Increase efficiency and accuracy of LCCC consortium reporting, measured by a decrease in the person-hours required to provide reports and reproducibility of clinical trials metrics across the consortium
- Harmonize operations across the institutions (e.g., eCRF validation, standardized reporting intervals, monitoring plan)
- Ensure portfolio management via disease group and PRMC activities (e.g., dashboards, reports) and prioritization of institutional, multi-institutional, and national protocols to shift protocol portfolio in alignment with NCI expectations

3. Solutions and Methods

LCCC deployed a multifaceted approach to include: (1) determining and implementing a predictable reporting cadence with standardized dashboards and reports, (2) deploying TIBCO Jaspersoft Studio to create custom coded reports in Java/XML/SQL with dynamic visualizations benchmarked against NCI standards, (3) distributing pilot reports including pipeline activity, time to activation, accruals trends, and portfolio composition to various stakeholders across LCCC, (4) establishing a continuous improvement process to ensure relevance of reports and dashboards, and (5) soliciting stakeholder feedback for additional improvements. These efforts required collaboration across the IT departments within the LCCC consortium for synchronization.

4. Outcomes

There are immediate outcomes and anticipated outcomes (future directions). Immediate outcomes include providing LCCC and Clinical Research Leadership and each DG at-a-glance quick reference dashboards and reports, saving over 200 hands-on person hours via coding and automation, condensing >80 reporting files monthly, and providing customized reports to accurately and efficiently capture data across all modules in OnCore. The quick reference dashboards and reports contain data visualizations, which benchmark LCCC clinical trials data against NCI expectations, for time to activation and accruals progress. Additional custom reports led to aggregating and analyzing consortium accruals data and auto-population of the PRMC Scientific Progress Review Committee agenda, to increase efficiency of review and reduce error.

5. Lessons Learned and Future Directions

There is a gap in services provided by Advarra for managing clinical trials data for NCI-Designated Comprehensive Cancer Centers. Bridging the gap with internal solutions allowed LCCC to provide consolidated consortium reports and dashboards to LCCC and Clinical Research Leadership, along with DG leaders – an essential component to assessing progress and tracking activity. Future directions include deploying consortium-wide task lists to capture additional data points for reporting, customized monthly reports to be uploaded to a cloud environment to feed an interactive dashboard run via automated coding, and conducting a feasibility review to determine automated data transfer to provide fully automated real-time dashboards for consortium-wide access.

CTMS Optimization: A Tale of One Platform, Three Clinical Sites, and One Combined Dataset to Improve Trial Activation, Portfolio Management, and Clinical Trials Reporting

GEORGETOWN UNIVERSITY | Lombardi Comprehensive Cancer Center

Meghan N. Mavredes, MPH[1], Kerrie Briggs Bouker, PhD[1], Michael Marafelias[2], Tessa Impallaria[3], Ernest Richards, PhD, FACN[2]

[1]Georgetown Lombardi Comprehensive Cancer Center, [2]John Theurer Cancer Center, [3]MedStar Health

Background

The Lombardi Comprehensive Cancer Center (LCCC) consists of three clinical sites. Managing harmonized consortium-wide metrics, to measure progress and guide operational decision making for LCCC, requires entering and accessing clinical trials data in two separate accounts from a single CTMS vendor, OnCore. Previously, each site manually generated single-site reports, which were collated, in order to present consortium-wide metrics. To standardize consortium operations, LCCC set consortium-wide data entry and quality assurance practices and data locks to ease the issuance of metrics.

Goals

The CTMS Optimization Project goals included:

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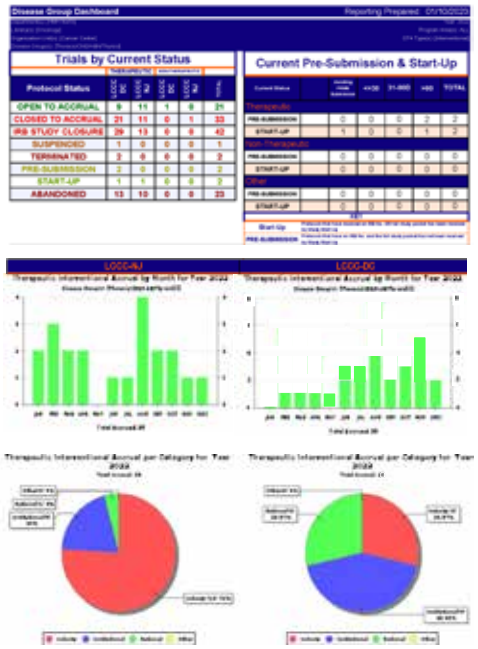
- Increase efficiency and accuracy of LCCC consortium reporting, measured by a decrease in the person-hours required to provide reports and reproducibility of clinical trials metrics across the consortium
- Harmonize operations across the institutions (*e.g.,* eCRF validation, standardized reporting intervals, monitoring plan)
- Ensure portfolio management via disease group and PRMC activities (*e.g.,* dashboards, reports) and prioritization of Institutional, multi-Institutional, and National protocols to shift protocol portfolio in alignment with NCI expectations

GEORGETOWN UNIVERSITY | MedStar Health | Hackensack Meridian John Theurer Cancer Center

Solutions & Methods

1. Determine and implement predictable reporting cadence with standardized dashboards and reports
2. Deploy TIBCO Jaspersoft Studio to create custom coded reports in Java/XML/SQL with dynamic visualizations benchmarked against NCI standards
3. Distribute pilot reports displaying pipeline activity, time to activation, accruals trends, and portfolio composition to LCCC stakeholders
4. Establish continuous process improvement to ensure relevance
5. Solicit stakeholder feedback for additional improvements.

Dashboard Components



Report Keys

Current Pipeline Overview Key

✔	Completed within intended completion window.
✔	Completed not within the intended completion window.
●	Started and still within the completion window.
●	Started and exceeds the intended completion window.
—	Not Started. Protocol has not been submitted to PRMS.
n/a	Not Applicable: One task or multiple tasks have been marked as NA in the task list.

Milestone Completion Windows

60	PRMS (Days)
60	Budget (Days)
90	Contract (Days)
90	IRB (Days)
120	Overall (Days)

Accrual Progress Key

- OPEN TO ACCRUAL AND no enrollment in the last 6 months and < 40% target accrual reached, no enrollment in the last 12 months OR no enrollment life to date
- OPEN TO ACCRUAL AND < 40% target accrual reached and enrollment in the last 6 months OR >=40% target accrual reached with 0 enrollment in the trailing 6 months
- OPEN TO ACCRUAL AND >=40% target accrual reached and active enrollment within the last 6 months

Date Parameters:

MTD = From 12/01/2022 to 12/31/2022

YTD = From 01/01/2023 to 12/31/2022

Outcomes

- LCCC/CR Leadership & each DG received at-a-glance quick reference dashboards & reports
- Saved > 200 person-hrs via coding/ automation
- Condensed monthly report of >80 files
- Provided customized reports to accurately & efficiently capture data across OnCore
- Benchmarked data visualization against NCI expectations for trial activation & accruals
- Increased efficiency & decreased error for PRMC Scientific Progress Review Committee via auto-populated agenda from custom report

Lessons Learned

Gap in services provided by Advarra for managing clinical trials data for NCI-designated Comprehensive Cancer Centers. Bridging the gap with internal solutions allowed LCCC to provide consolidated consortium reports and dashboards to LCCC and CR Leadership, along with DG Leaders – an essential component to assessing progress and tracking activity.

Future Directions

1. Deploy consortium-wide task lists to capture additional data points,
2. Code customized monthly reports & upload to cloud environment to feed interactive dashboard run via automated coding,
3. Conducting feasibility review to determine automated data transfer to fully automate real-time dashboards for consortium-wide access.

Contact

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Cross-Consortium Oversight and Management of Investigator-Initiated Trials at Lombardi Comprehensive Cancer Center

K.Bouker, J. Zenreich, C. Limbad, E. Richards, M. Mavredes
Georgetown Lombardi Comprehensive Cancer Center

1. Background

Lombardi Comprehensive Cancer Center (LCCC) identified a need to more comprehensively support investigator-initiated trials (IITs) consortium-wide. Existing resources dedicated to multisite IITs were insufficient due to lack of centralized single-site IIT oversight, support, and IIT prioritization, and growing investigator interest and IIT portfolio. To address these urgent needs, LCCC developed and implemented an IIT Steering Committee (SC) and a Consortium IIT Office to oversee, prioritize, expand, and adequately support LCCC IITs.

2. Goals

LCCC IIT Steering Committee:

- Ensure appropriate Clinical Trials Office and IIT Office resource allocation in support of LCCC IITs
- Identify opportunities to incorporate LCCC science and LCCC shared resources into IITs

LCCC IIT Office:

- Support investigators in the development, activation, maintenance, reporting, and close-out of IITs across the consortium
- Provide accurate and concise IIT metrics to LCCC Leadership, Clinical Research Leadership (CLR), Program Leaders, and Disease Groups (DG)

3. Solutions and Methods

In 2022, the LCCC CRL established the IIT SC, chaired by LCCC's deputy director and comprised of leaders from across the consortium. The SC meets bi-weekly and accepts nascent LOI concepts to fully developed IIT protocols, and reviews for inclusion of LCCC science, program needs, relevance to LCCC's catchment area, feasibility and alignment with NCI and institutional priorities. The SC ensures appropriate allocation of resources for trial development, activation, and management throughout the consortium.

With cross-consortium institutional investment for twelve additional full-time employees (FTE), the LCCC Consortium IIT Office launched in 2022. The IIT Office provides dedicated resources to support IITs throughout their lifecycle by providing:

- Protocol and budget templates
- Protocol writing support for IIT development and results reporting
- Facilitation of biostatistical support
- All regulatory document submission, maintenance, reporting, and close-out
- Support of trial conduct including multi-site coordination
- Quality control assessments and monitoring

The IIT Office standardized:

- Tracking and reporting on metrics benchmarked against NCI standards (e.g., time-to-activation, accruals)
- Processes and procedures (e.g., role-specific job aids, eCRF validation)
- Templates for investigators (e.g., LOI, protocols, and budgets)
- Trial oversight and monitoring plan, including Data Safety Monitoring Committee compliance

4. Outcomes

LCCC IIT SC:

- Required all new interventional treatment IITs to receive SC review prior to scientific review
- Developed SC submission forms
- Reviewed 12 new IIT concepts, leading to 4 protocol submissions for scientific review
- Identified opportunities to include LCCC science and shared resources and activate protocols consortium-wide

LCCC IIT Office:

- Enhanced metrics reporting via centralized database tracking current portfolio and accruals
- Leveraged medical and protocol writers to ensure high-quality protocols for scientific review
- Effectively ushered IITs through the activation processes to decrease time-to-activation
- Decreased barriers to regulatory management for IITs

5. Lessons Learned and Future Directions

The SC serves a critical role, after DG prioritization, to allocate clinical trials resources. The centralized IIT Office enables efficient conduct of LCCC IITs in support of the LCCC investigator and patient communities. Future directions include: expanding templates and support to interventional non-treatment IITs.

GEORGETOWN UNIVERSITY | Lombardi Comprehensive Cancer Center

Cross-Consortium Oversight and Management of Investigator Initiated Trials at Lombardi Comprehensive Cancer Center

Kerrie Briggs Bouker, PhD[1]; Joshua Zenreich[2]; Chandani Limbad, PhD[2], Ernest Richards, PhD, FACN[2], Meghan N Mavredes, MPH[1]

[1]Georgetown Lombardi Comprehensive Cancer Center, [2]John Theurer Cancer Center

Background

Lombardi Comprehensive Cancer Center (LCCC) identified a need to more comprehensively support Investigator Initiated Trials (IITs) consortium-wide. Existing resources dedicated to multi-site IITs were insufficient due to lack of centralized single-site IIT oversight, support, and IIT prioritization, and growing investigator interest and IIT portfolio. To address these urgent needs, LCCC developed and implemented an IIT Steering Committee (SC) and a Consortium IIT Office to oversee, prioritize, expand, and adequately support LCCC IITs.

Methods

LCCC IIT Steering Committee:

- Ensure appropriate Clinical Trials Office and IIT Office resource allocation in support of LCCC IITs
- Identify opportunities to incorporate LCCC science and LCCC shared resources into IITs

LCCC IIT Office:

- Support investigators in the development, activation, maintenance, reporting, and close-out of IITs across the consortium
- Provide accurate and concise IIT metrics to LCCC Leadership, Clinical Research Leadership (CLR), Program Leaders, and Disease Groups (DG)

Hackensack Meridian John Theurer Cancer Center

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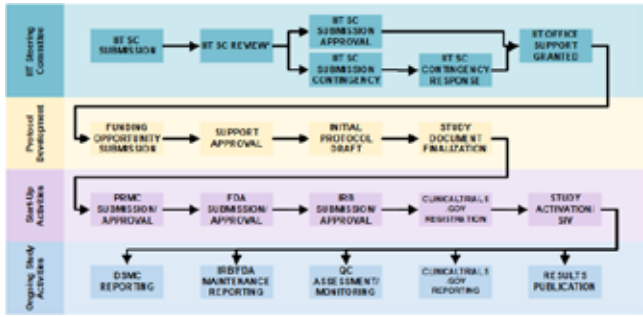
- Tracking and reporting on metrics benchmarked against NCI standards (*e.g.,* time-to-activation, accruals)
- Processes and procedures (*e.g.,* role-specific job aids, eCRF validation)
- Templates for Investigators (*e.g.,* LOI, protocols, and budgets)
- Trial oversight and monitoring plan, including Data Safety Monitoring Committee compliance

IIT Office	Location
Program Manager	DC/NJ
Project Manager	DC
	NJ
Regulatory Specialist Start-Up	DC
	NJ
Regulatory Specialist Maintenance	DC
	NJ
IIT Coordinator	4 (2 DC, 2 NJ)
Medical Writer	2 (DC/NJ)

IIT Workflow



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- Decreased barriers to regulatory management for IITs

Contact

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Georgetown University
3900 Reservoir Rd., NW
Washington, DC 20007
briggsk@georgetown.edu

Smooth Sailing... Cellular Immunotherapy Trials Collaboration and Integration Process

S. Sharry, C. Cromar, L. Lujan, J. Moehle, H. Soares, T. Werner
Huntsman Cancer Institute at the University of Utah

1. Background

The rapid expansion of cellular immunotherapy trials at our institute has required a new operational process involving the clinical trials office, clinical, and cell therapy groups. Cellular Immunotherapy Trials involve CAR T, TIL, BITE and TCR cell therapies. These cellular immunotherapy trials present logistical challenges that require increased communication and planning. Responsibilities, training, and effective communication between all areas were lacking formality and definition. Therefore, focused improvements for these types of trials in particular were necessary.

Compared to the Huntsman Cancer Hospital (HCH) outpatient clinic staff, the HCH inpatient staff assignments frequently rotate shifts and providers, thus communication, education, and training of key personnel was critical to ensure patient safety and trial compliance.

2. Goals

- Provide education on operational processes to involved parties
- Integrate current workflows between the clinical trials office and clinical managers to enable patient care that adhere to protocol requirements
- Appoint clinical research nurse liaison to help facilitate the operational processes

3. Solutions and Methods

- Holding monthly cellular immunotherapy focused meetings with clinical trials office and clinic management to discuss upcoming/active trials, enrollments, issues, positive outcomes, and trends
- Developing a shared, trial specific cellular immunotherapy tracking spreadsheet used by all committee members was especially useful during the COVID-19 pandemic for communication between groups
- Holding clinical logistics meetings prior to a site initiation visit and at the time of first enrollment, attended by investigators, hospital, clinical research, and cell therapy groups
- Providing trial specific nursing instructions, fast fact sheets and contact information provided pre-site initiation visit
- Training clinical trials office clinical research coordinators and clinic nurses on the new process implemented
- Inpatient management identifying a skilled and focused nursing team to care for the clinical research immunotherapy trial patients with ongoing training provided
- Promoting a consistent theme across groups for our clinical trial patients' safety

4. Outcomes

- Increased cohesive, collaborative, and unified environment between all areas that care for patients enrolled to these complex trials
- Meeting regularly alleviates potential exacerbation of issues due to the consistent communication between meeting members
- Having an operational system solidified helps new staff know their role and responsibilities
- Clinical trials office has appointed a solid tumor physician liaison to ensure consistent collaboration and education between the BMT/ inpatient teams and principal investigators

5. Lessons Learned and Future Directions

- Analyze deviation trends pre/post process implementation
- Develop a survey to measure process improvement
- Evaluate Report and Learn* trends since implementation

**Report and Learn = EMR (Epic) application to report issues contemporaneously for resolution, corrective action, and improvements.*

Smooth Sailing . . . Cellular Immunotherapy Trials Collaboration and Integration Process

Susan Sharry, BS, CCRP, Catherine Cromar, BS, Leanne Lujan, BS, CCRP, Jessica Moehle, BS, CCRP, Heloisa Soares, MD, PhD, Theresa Werner, MD *Huntsman Cancer Institute, University of Utah*

BACKGROUND

Cellular Immunotherapy Trials* involve new and complex scientific concepts and procedures. The rapid expansion of these trial types at our institution presented logistical and operational challenges. Care for participants involved in a cell therapy trial spans across multiple disciplines and specialty care areas where staff and providers frequently rotate shifts. Responsibilities and effective routes of communication between the Clinical Trials Office, clinical care teams and the cell therapy group needed to be more clearly defined. Additionally, there was a need for improved training and education for all key personnel involved in the treatment of participants receiving care on a cell therapy trial to ensure patient safety and clinical trial compliance.

** CAR-T (Chimeric Antigen Receptor T-Cell)*
TIL (Tumor Infiltrating Lymphocytes)
TCR (T-Cell Receptor)
NK (Natural Killer) Cells

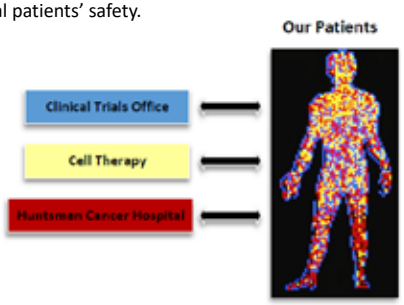
GOALS

- Provide education and training on departmental logistics for cellular immunotherapy trials.
- Define and integrate current workflows between the Clinical Trials Office, clinical care teams and cell therapy group to enable seamless patient care while adhering to the protocol requirements.
- Expand oversight of clinical research nurse liaison to include emphasis and involvement in cell therapy trials.

UNIVERSITY OF UTAH HUNTSMAN CANCER INSTITUTE

SOLUTIONS AND METHODS

- Establish monthly Cellular Immunotherapy focused meetings with Clinical Trials Office and clinical management to discuss updates on upcoming/active trials, enrollments, issues, positive outcomes, and trends.
- Development of a shared, trial specific cellular immunotherapy tracking spreadsheet used by all committee members was especially useful during the COVID pandemic for communication between groups.
- Implemented clinical logistics meetings prior to a Site Initiation Visit and at the time of first patient enrollment; attended by investigators, clinical care teams, clinical research and cell therapy groups.
- Provided trial specific nursing instructions, Fast Fact Sheets and contact information at the pre-Site Initiation Visit.
- Implemented training of Clinical Trials Office clinical research coordinators and clinic nurses on the new process.
- Inpatient management identified a skilled and focused nursing team to treat and care for the clinical research immunotherapy trial patients with ongoing training provided.
- Promote a consistent theme across groups for our clinical trial patients' safety.



OUTCOMES

- Increased cohesive, collaborative and unified environment between all areas that care for patients enrolled to complex treatment trials.
- Meeting regularly alleviates potential exacerbation of issues due to the consistent communication between meeting members.
- Implementation of an operational system which solidified new staff's knowledge of their role and responsibilities.
- Clinical Trials Office has appointed a solid tumor physician liaison to ensure consistent collaboration and education between the BMT/inpatient teams and principal investigators.

FUTURE PLANS

- Analyze deviation trends pre/post process implementation.
- Develop a survey to measure process improvement.
- Evaluate Report and Learn** trends since implementation.

*** Report and Learn = EMR (Epic) application to report issues contemporaneously for resolution, corrective action and improvements.*

HEALTH UNIVERSITY OF UTAH

Collaboration: How Protocol Development and Multi-Center Teams Work to Manage Investigator-Initiated Trials (IITs)

J. Kline, A. Bauchle
Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. Background

Protocol Development (PD) services began in 2005 with a multi-center (MC) team added to the cancer center in 2015. Both teams focus on Indiana University investigator-initiated trials (IU IITs), with PD assisting the investigators in developing/writing protocols and the multi-center team acting as a contract research organization (CRO) for trials wanting to open statewide, nationally, and internationally.

as the multi-center team has grown, cooperation and integration with the Protocol Development team has grown with it. In recent years, the need for PD and MC to work in tandem has led to a better overall experience for our investigators and more opportunities for our investigators to open trials as MC allowing them to include other institutions and geographical locations.

2. Goals

- Continue to expand research; allowing investigators, the opportunity to include additional sites has made meeting accrual expectations that much more accessible
- Integrate study start-up processes with protocol development and multi-center teams to streamline and shorten start-up timelines
- Continue to develop processes to make easier coordination throughout the life of the study, including, but not limited to, amendments, subject safety, FDA reporting, CT.gov, study document creation, etc.
- Streamline study closeout between teams, sites, and investigators

3. Solutions and Methods

Starting at protocol development, investigators are informed of multi-center services and are consulted regarding opening their upcoming trial as a multi-site trial. If the investigators agree, and there is funding available to support the MC team, then the following processes are implemented:

- Protocol is listed on PD pipeline spreadsheet as a MC trial, where the MC team is informed of upcoming project
- Protocol sent to MC Project Manager (MPM) for review and to check MC template language which is included for all multi-site IITs
- MPMs begin start-up processes: initiation of all study documents using templates, initial contact with sites, contracts, feasibility, database builds, logistics, etc.
- MPM works with PD on protocol, manuals, and databases
- MPM coordinates with PD for any safety updates through the life of the study
- PD coordinates with MPM for site-specific updates for FDA reporting, as well as updates for sites in CT.gov

4. Outcomes

Since 2018, there have been 15 studies that have utilized the process listed above and counting, including eight high-, four moderate-, and three low-risk trials. With this process in place, the MC team has been able to initiate trials sooner which has allowed for seamless integration from a single center IIT to a multi-site trial. Both teams are growing as Indiana University investigators are continuing to use this process more and more.

5. Lessons Learned and Future Directions

As the protocol development and multi-center teams grow and expand, the depth, breadth, and complexity of the multi-center trials themselves continues to grow at the same rate. Both teams have hired additional staff and have developed plans and systems in order to accommodate the dozens of trials in our pipeline. We plan to continue our growth through the expansion of the statewide teams, incorporating affiliate sites and navigating the complexities of trials in which manufacturing at IU is included.

Collaboration: How Protocol Development and Multi-Center Teams Work to Manage Investigator-Initiated Trials(IITs)

Jessica Kline and Amber Bauchle
Indiana University Melvin and Bren Simon Comprehensive Cancer Center

Background

Protocol Development (PD) services began in 2005 with a Multicenter (MC) team added to the Cancer Center in 2015. Both teams focus on Indiana University Investigator-Initiated Trials (IU IITs), with PD assisting the investigators in developing/writing protocols and the MC team acting as a Contract Research Organization (CRO) for trials wanting to open Statewide, Nationally, and Internationally. As the MC team has grown, cooperation and integration with the PD team has grown with it. In recent years, the need for PD and MC to work in tandem has led to a better overall experience for our investigators and more opportunities for our investigators to open trials as MC allowing them to include other institutions and geographical locations.

Goals

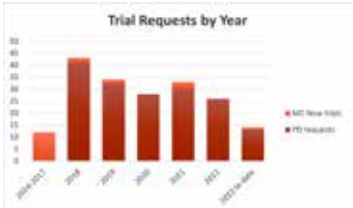
- Continue to expand research. Allow investigators the opportunity to include additional sites has made meeting accrual expectations that much more accessible.
- Additional Integration of study start up that processes with PD and MC teams to streamline and shorten start-up times.
- Continue to develop processes to make easier coordination throughout the life of the study including but not limited to amendments, subject safety, FDA reporting, CT.gov, study document creation, etc.
- Streamline study closeout between teams, sites, and investigators.

Solutions and Methods

Starting at PD, Investigators are informed of MC services and are consulted regarding opening their upcoming trial as a multi-site trial. If the investigators agree and there is funding available to support the MC team, then the following processes are implemented:

1. Protocol is listed on PD pipeline spreadsheet as a MC trial, where the MC team is informed of upcoming project.
2. Protocol is sent to MC Project Manager (MPM) for review and to check MC template language which is included for all Multisite IITs.
3. MPMs begin start-up processes – initiation of all study documents using template, initial contact with sites, contracts, feasibility, database builds, logistics… etc.
4. MPM works with PD on protocol, manuals, and databases.
5. MPM coordinates with PD for any safety updates through the life of the study.
6. PD coordinates with MPM for site-specific updates for FDA reporting, as well as updates for sites in CT.gov.

Outcomes



- With this process in place, the MC team has been able to initiate trials sooner which has allowed for seamless integration from a single center IIT to a multisite trial.

Lessons Learned and Future Directions

- As the PD and MC teams grow and expand, the depth, breadth and complexity of the MC trials themselves continues to grow at the same rate.
- Both teams have hired additional staff and have developed plans and system in order to accommodate the dozens of trials in our pipeline.
- We plan to continue our growth through the expansion of statewide teams, incorporating Affiliate sites, as well as navigating the complexities of trials in which manufacturing at IU is included.

NCI Comprehensive Cancer Center — A Cancer Center Designated by the National Cancer Institute

NCCN National Comprehensive Cancer Network® — Member Institution

Protocol Development Services for Investigator-Initiated Trials (IITs)

J. Kline, M. Contreraz
Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. Background

Protocol Development (PD) services began in 2005 with the intent to provide trial activation, management, and completion services for Indiana University investigator-initiated trials (IU IITs) at the IU Simon Comprehensive Cancer Center. PD assists investigators in developing/writing protocols and all documents required for the conduct of a trial, as well as project managing trials through the initial regulatory processes including scientific, IRB, and FDA reviews. We also provide clinical trials.gov (CT.gov) registration support.

Through the life of the trials, PD provides assistance in amending trial docs when required, all FDA and CT.gov maintenance, including annual reports/updates, amendments, SAE reporting, and results reporting.

2. Goals

- Continue to expand research; allowing cancer center members the opportunity to receive PD services to help meet institutional expectations, regardless of their department on campus
- Continue to develop processes to make easier coordination throughout the life of the study including but not limited to amendments, subject safety, FDA reporting, CT.gov, study document creation, etc.
- Streamline study transition from PD to coordinators actually conducting the research

3. Solutions and Methods

- Protocol development has created a submission portal, to create a better workflow for requests for our services
- PD has begun to engage with other departments on campus earlier to foster relationships and expand our reach outside of just the cancer center for cancer focused research
- PD host monthly “pipeline” meetings with stakeholders in various departments to keep everyone engaged and knowledgeable about upcoming trials
- PD attends monthly disease team meetings to engage with teams throughout trial for amendments and FDA reporting
- PD coordinates with study teams for any safety updates through the life of the study
- PD acts as the liaison for FDA reporting, as well as CT.gov maintenance

4. Outcomes

By engaging with other departments and schools on campus we have been able to facilitate the creation of a new team and trial management connections within our clinical trials office. Our presence in team meetings assists teams with clarifications regarding protocol interpretation and facilitates our ability to capture the need for amendments and any safety reporting in an expedited fashion.

5. Lessons Learned and Future Directions

As the protocol development team grows, the expanse, depth, breadth, and complexity of the trials themselves continues to grow at the same, or faster, rate. PD is in the process of hiring additional staff and has developed plans and systems in order to accommodate the dozens of trials in the pipeline; including utilizing our submission portal more, as well as navigating the complexities of trials in which manufacturing at IU is included.

Protocol Development Services for Investigator-Initiated Trials (IITs)

Jessica Kline and Mario Contreraz
Indiana University Melvin and Bren Simon Comprehensive Cancer Center

Background

Protocol Development (PD) services began in 2005 to provide trial activation, management, and completion services for Indiana University Investigator initiated trials (IU IITs) at the IU Simon Comprehensive Cancer Center. PD assists investigators in developing/writing protocols and all documents required for the conduct of a trial, as well as project managing trials through the initial regulatory processes including Scientific, IRB, and FDA reviews. We also provide clinical trials.gov registration support.

Through the life of the trials, PD provides assistance in amending trial docs when required, all FDA and CT.gov maintenance, including annual reports/updates, amendments, SAE reporting, and results reporting.

Goals

- Continue to expand research. Allowing cancer center members the opportunity to receive PD services to help meet institutional expectations, regardless of their department on campus.
- Continue to develop processes to make easier coordination throughout the life of the study including but not limited to: amendments, subject safety, FDA reporting, CT.gov, study document creation, etc.
- Streamline study transition from PD to coordinators actually conducting the research.

Solutions and Methods

- Protocol development has created a submission portal, to create a better workflow for requests for our services.
- PD has begun to engage with other departments on campus earlier to foster relationships and expand our reach outside of just the cancer center for cancer focused research
- PD host monthly 'pipeline' meetings with stakeholders in various departments to keep everyone engaged and knowledgeable about upcoming trials
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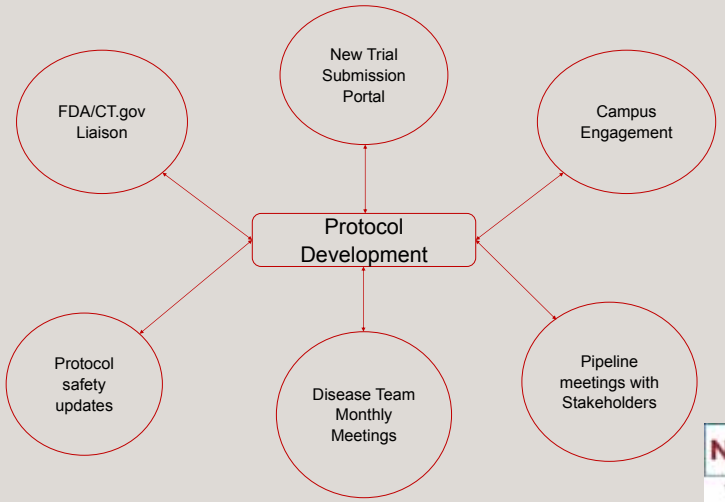
- PD coordinates with study teams for any safety updates through the life of the study
- PD acts as the liaison for FDA reporting, as well as CT.gov maintenance



Outcomes

By engaging with other departments and schools on campus we have been able to facilitate the creation of a new team and trial management connections within our clinical trials office. Our presence in team meetings assists teams with clarifications regarding protocol interpretation, and facilitates our ability to capture the need for amendments and any safety reporting in an expedited fashion

Lessons Learned and Future Directions

As the protocol development team grows, the expanse, depth, breath and complexity of the trials themselves continues to grow at the same, or faster rate. PD is in the process of hiring additional staff and has developed plans and systems in order to accommodate the dozens of trials in the pipeline; including utilizing our submission portal more, as well as navigating the complexities of trials in which manufacturing at IU is included.

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Development of Electronic Logistics Tool to Accelerate Clinical Trial Activation

J. Zbacnik, K. Croghan, A. Youssef, A. Handlogten, G. Nowakowski, A. Fritsche
Mayo Clinic Comprehensive Cancer Center

1. Background

This Quality Improvement Project addresses the extensive time currently invested in establishing internal workflows for new clinical trials (i.e., logistics assessment) within the Mayo Clinic Comprehensive Cancer Center (MCCCC). Logistics assessment occurs early during study development and culminates in the Logistics Meeting, a virtual, interdepartmental gathering lead by a Research Protocol Specialist (RPS). A significant milestone in trial activation, the meeting ensures all involved staff are engaged and in agreement on study conduct prior to Mayo institutional review board (IRB) submission. Many downstream study development activities (e.g., budgets building) are dependent on completion of logistics evaluation before they can continue.

Due to insufficient logistics resources, research staff must devote significant time to navigating the complex multitude of research areas within Mayo Clinic (MC) and establishing efficient working plans for new trials – a frustrating activity that contributes to delayed trial activations.

Recently, the lack of adequate resources has been exacerbated as MCCCC implements a study development/start-up enterprise model called the "Single Research Protocol Specialist" (SRPS). SRPS centralizes all protocol development activities for each participating MC site with a single individual, regardless of the lead site location, to help streamline development. While overall SRPS promotes efficiency, site-specific nuances pose a challenge as RPSs are no longer site experts and must work effectively at all MCCCC locations. Also contributing is a shortage of experienced RPSs. MC is not immune to the increase in staff turnover post-COVID and the resulting loss of experience and knowledge. In addition, to meet increased demands, MCCCC has performed incremental hiring. Both turnover and incremental hiring have created an influx of new staff, which coupled with the SRPS model implementation, has increased urgency for improved logistics resources.

2. Goals

The baseline average time needed to complete logistics assessment activities, established via staff surveys, is 10.9 hours. Our initial target performance is 8.7 hours (20 percent reduction), which would result in increased efficiency at multiple enterprise cancer center sites. The ultimate target performance upon project completion is 2 hours (81 percent decrease).

3. Solutions and Methods

We are using the REDCap (Research Electronic Data Capture) application to create a knowledge base that is accessible to both new staff and staff that are not familiar with site-specific nuances. The pilot project will only address Logistics for the Rochester MCCCC site (selected due to having the most complexity). Eventually, tool functionality will be expanded to use during the Operational Feasibility Committee Review performed for all new cancer-related clinical trials prior to trial development activities.

4. Outcomes

Outcomes are pending; however, general feedback from small testing cohorts has been positive.

5. Lessons Learned and Future Directions

At this time, we are continuing to update the REDCap tool's logic and questioning process. As implementation progresses, we will likely have many lessons to learn. The scope of the project has already changed between ideation and end user testing, which shows that we lacked some staff at the planning stage and MCCCC's needs have continued to evolve. Quality improvement continues to be a priority as we always put the needs of our patients first and above all else.

Development of Electronic Logistics Tool to Accelerate Clinical Trial Activation

Authors: Jade Zbacnik, Katrina Croghan, M.S., CCRP, Amanda J Youssef, M.S., Amy Handlogten, Grzegorz Nowakowski, MD, Angela Fritsche, MPA
Mayo Clinic Comprehensive Cancer Center

BACKGROUND

LOGISTICS ASSESSMENT

This Quality Improvement Project addresses the extensive time currently invested in establishing internal workflows for new clinical trials (i.e., logistics assessment) within the Mayo Clinic Comprehensive Cancer Center (MCCCC). Logistics assessment occurs early during study development and culminates in the Logistics Meeting, a virtual, interdepartmental gathering lead by a Research Protocol Specialist (RPS). A significant milestone in trial activation, the meeting ensures all involved staff are engaged and in agreement on study conduct prior to Mayo Institutional Review Board (IRB) submission. Many downstream study development activities (e.g., budgets building) are dependent on completion of logistics evaluation before they can continue.

CHALLENGES

Due to insufficient Logistics resources, research staff must devote significant time to navigating the complex multitude of research areas within Mayo Clinic (MC) and establishing efficient working plans for new trials—a frustrating activity that contributes to delayed trial activations (Figure 1). Recently, the lack of adequate resources has been exacerbated as MCCCC implements a study development/startup enterprise model called "Single Research Protocol Specialist" (SRPS), which centralizes all protocol development activities for each participating MC site with a single individual, regardless of the lead site location, thus streamlining development. While overall SRPS promotes efficiency, site-specific nuances pose a challenge as RPSs are no longer site experts and must work effectively at all MCCCC locations.

Also contributing is a shortage of experienced RPSs. MC is not immune to the increase in staff turnover post-COVID and the resulting loss of experience and knowledge. In addition, to meet increased demands, MCCCC has performed incremental hiring. Both turnover and incremental hiring have created an influx of new staff, which coupled with the SRPS model implementation, has increased urgency for improved Logistics resources.

FIGURE 1

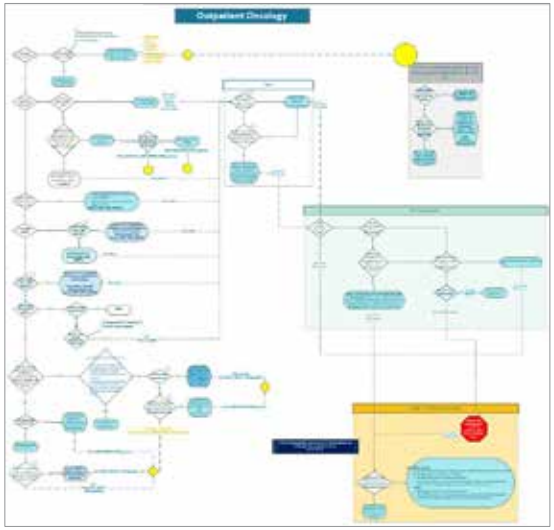

Figure 1. Example workflow for an Outpatient Oncology Trial and basis of REDCap logic Workflow is not intended to be understood, but rather show the complexity, multiple decision points and inter-related outcomes.

GOALS

The baseline average time needed to complete logistics assessment activities, established via staff surveys, is 10.9 hours. Our initial target performance is 8.7 hours (20% reduction), which would result in increased efficiency at multiple Cancer Center enterprise sites.

FIGURE 2

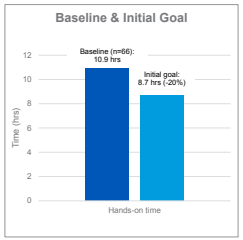

Figure 2. Baseline results and initial goal Survey results and goal based on 20% reduction.

FIGURE 3

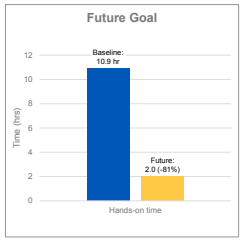

Figure 3. Future milestone The ultimate target performance upon project completion is 2 hours (81% decrease).

SOLUTIONS & METHODS

We are using the Research Electronic Data Capture (REDCap) version 12.4.25 application to create a knowledge base that is accessible to both new staff and staff that are not familiar with site-specific nuances. The pilot project will only address Logistics for the Rochester MCCCC site (selected due to having the most complexity).

OUTCOMES

Outcomes are pending; However, feedback from small testing cohorts has been positive, informative and efficient method to work through a multitude of scenarios.

LESSONS LEARNED & FUTURE DIRECTION

We have implemented the REDCap tool's questioning logic process. As implementation continues, we will likely have many lessons to learn. The scope of the project has already changed between project ideation and end user testing, which indicates the lack of key staff at the planning stage and the evolving needs of MCCCC.

A post implementation survey will be conducted after 6-9 months of use to assess the effectiveness and future enhancements.

Eventually, tool functionality may be expanded to use during the Operational Feasibility Committee Review performed for all new cancer-related clinical trials prior to trial development activities.

ACKNOWLEDGEMENTS

This work was funded solely by Mayo Clinic. Specific thanks to CCTO subject matter experts, beta testers, and leadership who continue to innovate and partner to Quality Improvement continues to be a priority as we always put the needs of our patients first and above all else.

In addition, I'm indebted to MCCCC Leadership and Quality Management System (QMS) for all the support and resources that keep our QMS moving forward.

REFERENCES

REDCap 12.4.25 - © 2023 Vanderbilt University

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Implementation of Operational Feasibility Review During Study Start-up

M. Jacklin, T. Rudnitzki, M. Waggoner, J. Ranous, M. Koceja, B. George, K. Schroeder
Medical College of Wisconsin Cancer Center

1. Background

The clinical trial start-up process presents a myriad of operational challenges that require detailed planning with hospital partners and stakeholders. Since there was a lack of clarity in the process for how and when to include these partners in operational planning, this often led to inconsistency in study feasibility and operational review and ultimately negatively impacted activation timelines. A need was identified for a dedicated clinical trial operations team to develop a well-defined process for obtaining essential documents in a timely manner and involving key stakeholders (hospital partners, sponsors, PI, etc.) earlier in the start-up process.

2. Goals

- To improve feasibility review and operational planning by engaging sponsor and hospital partners early in the start-up process
- To decrease study activation timelines

3. Solutions and Methods

A dedicated clinical trial operations team, including the addition of a new program coordinator and administrative assistants, was created with the purpose of centralizing start-up activities. This team serves as a single point of contact for all parties involved in study start-up activities, including clinical research managers, regulatory, budget/contract, pharmacy, nursing, hospital compliance, and other department leaders as applicable. Having a dedicated team responsible for these activities allows for better tracking of timelines and completion of required submissions. The first step in developing this new process was the creation of an operational feasibility committee and implementation of a review meeting to occur twice monthly. Committee members include the operations team, research managers, investigational pharmacy, nursing, and other departments as required. Once all essential documents are received by the research manager, the operations team is engaged to facilitate review of the protocol. Documents are saved to Florence eBinders electronic regulatory system for central access for partners, which drastically reduces the amount of emails and attachments to keep track of. The study is added to the agenda for the next available review meeting, and committee members are notified two weeks in advance of the meeting so they may complete a thorough operational review. Review comments are added to an operational feasibility tool, which has been developed in partnership with key stakeholders to capture all the operational planning details needed to ensure successful implementation of the protocol. Following the review meeting, outstanding questions are compiled by the operations team and sent to the necessary stakeholders to ensure there are no outstanding operational concerns at the time of final hospital compliance review and activation.

4. Outcomes

- Hospital partners are involved much earlier in the process, and in a consistent way, which leads to more effective operational planning and greater confidence in trial implementation
- Early engagement with sponsor and hospital partners ensures we have all of the required information needed for operational planning

5. Lessons Learned and Future Directions

- The implementation of an operational review meeting has been well-received by all involved, and has demonstrated value in operational planning
- An operational feasibility tool was developed to ensure that all departments receive the information that they need to plan for any study; this tool continues to evolve and now includes specific sections for treatment plan development, inpatient treatment and assessments, expected locations of care that serve to better guide compliance and billing, and additional information specific to cell therapy studies
- Currently, the operations team has grown to include an additional dedicated program coordinator, and the role of the team has expanded to include submission of studies to the hospital compliance oversight office; this is a key step in study activation and includes submission of all study documents received prior to the operational review meeting as well as the completed operational feasibility tool
- Continued engagement of the operations team and compliance office has facilitated faster review and approval of trials and ultimately will serve to lower study activation timelines

Implementation of Operational Feasibility Review During Study Start-Up

Mike Jacklin, BS, CCRP; Theresa Rudnitzki, MS, RN, AOCNS, ACNS-BC; Mindy Waggoner; PharmD, BCOP; Judy Ranous, RN, BSN, OCN; Megan Koceja, BS, CCRP; Ben George, MD; Katy Schroeder, RN, OCN, CCRP
Medical College of Wisconsin Cancer Center

Background

The clinical trial start-up process presents a myriad of operational challenges that require detailed planning with hospital partners and stakeholders. Since there was a lack of clarity in the process for how and when to include these partners in operational planning, this often led to inconsistency in study feasibility and operational review and ultimately negatively impacted activation timelines. A need was identified for a dedicated clinical trial operations team to develop a well-defined process for obtaining essential documents in a timely manner and involving key stakeholders (hospital partners, sponsors, PI, etc.) earlier in the start-up process.

Goals

- To improve feasibility review and operational planning by engaging Sponsor and hospital partners early in the start-up process
- To decrease study activation timelines

Solution

A dedicated clinical trial operations team, including the addition of a new Program Manager, Program Coordinator, and Administrative Assistants, was created with the purpose of centralizing start-up activities. This team serves as a single point of contact for all parties involved in study start-up activities including clinical research managers, regulatory, budget/contract, pharmacy, nursing, hospital compliance, and other department leaders, as applicable. Having a dedicated team responsible for these activities allows for improved consistency, tracking of timelines, and completion of required submissions.

Methods

The first step in developing this new process was the creation of an operational feasibility committee and implementation of a review meeting to occur twice monthly. Committee members include the operations team, research managers, investigational drug pharmacy, nursing, and other departments as required. Once all essential documents are received by the research manager, the operations team is engaged to facilitate review of the protocol. Documents are saved to Florence eBinders electronic regulatory system for central access for partners, which drastically reduces the amount of emails and attachments to track. The study is added to the agenda for the next available review meeting, and committee members are notified two weeks in advance of the meeting (Figure 2) so that a thorough operational review can be completed. Review comments are added to an operational feasibility tool (Figure 1), which has been developed in partnership with key stakeholders to capture all of the operational planning details needed to ensure successful implementation of the protocol (including details for treatment plan builds, imaging capabilities, central labs, etc.). Following the review meeting, outstanding questions are compiled by the operations team and sent to the necessary stakeholders to ensure there are no remaining operational concerns at the time of final hospital compliance review and activation.

Figure 1. Operational Feasibility Tool (Cover Page)

Figure 2. Operational Feasibility Committee (OFC) Email Template

Outcomes

- Hospital partners are involved much earlier in the process, and in a consistent way which leads to more effective operational planning and greater confidence in trial implementation.
- Early engagement with sponsor and hospital partners ensures we have all of the required information needed for operational planning.

Lessons Learned and Future Directions

- The implementation of an operational review meeting has been well-received by all involved, and has demonstrated value in operational planning.
- An operational feasibility tool was developed to ensure that all departments receive the information that they need to plan for any study. This tool continues to evolve and now includes specific sections for treatment plan development, inpatient treatment and assessments, expected locations of care which serves to better guide compliance and billing, and additional information specific to cell therapy studies.
- Currently, the operations team has grown to include an additional dedicated Program Coordinator, and the role of the team has expanded to include submission of studies to the hospital compliance oversight office. This is a key step in study activation, and includes submission of all study documents received prior to the operational review meeting as well as the completed operational feasibility tool. This continued engagement of the operations team and compliance office has facilitated faster review and approval of trials and we anticipate it will further reduce study activation timelines.

Contact:
Mike Jacklin, BS, CCRP
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FastTrack: A Pilot Project to Shorten Activation Times

K. Schroeder, J. Bollmer, B. George, R. Kurzrock
Medical College of Wisconsin Cancer Center

1. Background

At Medical College of Wisconsin Cancer Center (MCWCC), new protocols approved for activation must complete multiple, time-consuming steps before they can be opened to accrual. In addition to the scientific review imposed by MCWCC, trial documents must receive approval from external sponsors and all relevant institutional committees, such as the institutional review board (IRB), safety committees (radiation and biosafety), and the hospital's Office of Clinical Research and Innovative Care Compliance (OCRICC). Our activation times have worsened during the COVID-19 pandemic due to staffing issues within our Clinical Trials Office (CTO) and across our institutional partners.

2. Goals

Our goal was to develop a FastTrack pilot program to open select trials within 60 days of SRC submission. By implementing this pilot, we hope to open high priority trials quickly, reduce our overall activation timeline, and most importantly, identify potential process changes that could create timeline-shortening efficiencies for all the trials in the activation queue.

3. Solutions and Methods

We took a three-pronged approach to implement FastTrack. First, we worked with our hospital and institutional partners to get their buy-in to accelerate their processing of FastTrack protocols. Most notably, the IRB allowed a date for project review to be selected prior to the IRB application being completed and submitted. Second, we introduced the process to our Disease-Oriented Teams (DOTs), who would be nominating protocols for FastTrack. We asked them to choose protocols of high clinical/academic importance, high accrual potential, and commitment from the sponsor and PI to be responsive during the accelerated activation process. DOTs were selected on a rotating basis which allowed all to participate. Lastly, we formed a core CTO group that meets weekly to review where the FastTrack protocols are in activation and troubleshoot delays.

4. Outcomes

The first protocol entered the FastTrack program in March of 2022. Since then, we have opened seven FastTrack protocols with a mean activation time of 98 days (median of 85 days; range of 42 to 193 days) from SRC submission to open to accrual. This includes two cooperative group, three industry, and two institutional trials. Over the same time period, activation of non-FastTrack trials averaged 283 days.

5. Lessons Learned and Future Directions

The importance of having all regulatory and study documents available prior to the initiation of the FastTrack process is critical. This allows all involved to begin review at the same time. Weekly communication between team members allows for quick resolution or escalation of issues. Moving forward, FastTrack trials will only include industry and institutional trials. Since all DOTS have had the opportunity to FastTrack, preference will be given to studies that are high priority and have a high accrual potential. The core CTO group is now meeting twice monthly with every DOT manager to review the entire portfolio in activation for that DOT.

FastTrack: A Pilot Project to Shorten Activation Times

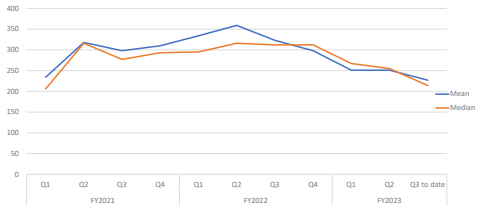
Katy Schroeder RN, OCN, CCRP, Jennifer Bollmer, Phd, Ben George, MD, Razelle Kurzrock, MD

Medical College of Wisconsin Cancer Center

Background

At Medical College of Wisconsin Cancer Center (MCWCC), new trials approved for activation must complete multiple, time-consuming steps before they can be opened to enrollment. In addition to all the sponsor mandated requirements and budget/contract negotiations, trials must receive approval from all relevant institutional committees. This includes review by Scientific Review Committee (SRC), Operational Feasibility Committee (OFC), Institutional Review Board (IRB), safety committees (radiation and biosafety), and the hospital's Office of Clinical Research and Innovative Care Compliance (OCRICC). Not all these reviews are done in parallel. Our activation times worsened during the COVID-19 pandemic due to multiple factors, but most notably related to staffing issues within our Clinical Trials Office (CTO) and across our institutional partners.

Adult CTO activation timelines by quarter



Goals

Our goal was to develop a FastTrack pilot program to open select trials within 60 days of SRC submission. By implementing this pilot, we hoped to open high priority trials quickly, reduce our overall activation timeline, and most importantly, identify potential process changes that could create timeline-shortening efficiencies for all the trials in the activation queue.

Contact:
Name: Katy Schroeder, RN, OCN, CCRP
Email: kbschroeder@mcw.edu

Solutions and Methods

We took a three-pronged approach to implement FastTrack. First, we worked with our hospital and institutional partners to get their buy-in to accelerate their processing of FastTrack trials. Most notably, the IRB allowed a date for project review to be selected prior to the IRB application being completed and submitted. Second, we introduced the process to our Disease-Oriented Teams (DOTs), who would be nominating trials for FastTrack. We asked them to choose trials of high clinical/academic importance, high accrual potential, and commitment from the sponsor and PI to be responsive during the accelerated activation process. DOTs were selected on a rotating basis which allowed all to participate. Lastly, we formed a core CTO group that met weekly to review where the FastTrack trials were in activation and troubleshoot delays.

Outcomes

The first trial entered the FastTrack program in March of 2022. Since then, we have opened seven FastTrack trials with a mean activation time of 98 days (median of 85 days; range of 42 to 193 days) from SRC submission to open to accrual. This includes two cooperative group, three industry, and two institutional trials. Over the same time period, activation of non-FastTrack trials averaged 283 days. The largest impact in timeline was noted in the submission to OCRICC from SRC approval. The average timeline to OCRICC submission of non-FastTrack trials is 134 days. The average timeline to OCRICC submission of the FastTrack trials was 25 days.

Protocol type	Accrual to Date	SRC Approval to OCRICC Submission (Days)	Submission to OCRICC to OCRICC Approval (Days)	Start IRB Submission to IRB Approval (Days)	IRB Approval to Open Accrual (Days)	Total Days in Activation
Industry- Early Phase	8	11	24	50	15	64
Industry-Cell Therapy	19	22	43	69	3	80
Industry-Cell Therapy	0	18	49	75	64	128
NRG-GU	1	22	20	29	1	42
HCRN-Breast	0	31	46	141	32	193
NRG-CNS	0	23	20	75	8	91
IIT-Early Phase	6	49	15	39	1	85

Lessons Learned

The importance of having all regulatory and study documents available prior to the initiation of the FastTrack process was critical. This allowed all involved to begin review at the same time. SRC approval has been the date used to begin all regulatory and budget work in the current workflow. With FastTrack trials, the regulatory team and finance team began this work the moment the study documents were available. Weekly verbal communication between team members(many of which work remotely), including operational and physician leadership, allowed for quick resolution or escalation of issues. The experience of the team members working on the FastTrack trial was also key to the success of activation.

Future Directions

- FastTrack trials will only include industry and institutional trials. The impact of shortening activation timelines in cooperative group trials was not felt to be as significant as those trials generally tend to activate faster.
- Since all DOTS have had the opportunity to FastTrack, preference will be given to studies that are high priority and have a high accrual potential. The institution is considering a tiered approach to trial activation.
- The core activation group (research manager, regulatory coordinator, financial assistant, operations representative, and the OCRICC representative) is now meeting twice monthly to review the entire portfolio in activation for that DOT. This has helped identify gaps, protocol version discrepancies, and operational delays. This has also helped inexperienced staff understand all the steps in trial activation. These meetings have been well received by all groups and will continue.
- Since we have all documents at the onset of the activation process, we are looking at initiating the financial, contractual, and regulatory work prior to the SRC submission.

Evolution of MSK's Protocol Activation Core

J. Migliacci, M. Kehoe, E. Valentino, A. Rodavitch
Memorial Sloan Kettering Cancer Center

1. Background

Memorial Sloan Kettering Cancer Center (MSK) has a high volume of protocols in activation, opening an average of 36 prospective, retrospective, and biospecimen protocols each month. Prior to 2018, protocol activation was managed locally by the principal investigators' (PI) research teams without central oversight of study start-up. MSK identified that activation processes were inefficient and launched the Protocol Activation, Review and Human Research Protection Program centralizing activation and review committee management.

2. Goals

Since our centralized unit included oversight of protocol review committees, it allowed us to seamlessly coordinate protocol review and approval. However, due to the complexity of protocol activation, the Protocol Activation Core (PAC) was tasked with centralizing and streaming other study start-up activities ensuring that all required tools were ready, and tasks were completed at the time of activation so that we can enroll patients to new treatments quickly.

3. Solutions and Methods

PAC has evolved gradually over the last five years. Figure 1.A. illustrates the expansion timeline and added responsibilities. PAC was tasked with facilitating communication between the PI, local study team, and all other key stakeholders in activation, including the sponsor, finance, legal, etc., ensuring that all requirements were fulfilled before opening a study to enroll patients. By the end of 2018, our PAC team included 12 staff members.

In 2020, PAC responsibilities expanded to include creation of key operational tools known to delay activation (i.e., protocol order sets and eligibility checklists). During this time, senior managers were aligned to research departments to provide a "concierge" experience for all PIs participating in study star- up. The additional responsibilities resulted in expanding the team further, with 24 new staff.

In 2022 our team began an "expansion pilot" for five research departments, taking on almost all remaining non-logistical activation activities (e.g., billing harmonization, SIV preparation and facilitation, regulatory document collection, etc.), which resulted in the addition of 17 new staff. While preparing for the pilot, we extensively evaluated the processes of the pilot tasks and focused significant effort to streamline tasks before the rollout, including identification of improvements and system enhancements to reduce task completion time and ensure these tasks were not delaying activation.

4. Outcomes

Forty-seven prospective studies have started activation in the expansion pilot, of which 17 studies have been activated to enroll participants. When comparing activated pilot studies to activated non-pilot studies (N=278) that started activation in the same timeframe, we have seen an improvement at all stages of activation (Figure 1.B). The most notable change was in the stage between IRB approval and open to enrollment (waiting to open) with a 44 percent decrease in median days.

5. Lessons Learned and Future Directions

We plan to gradually add research departments to the pilot throughout 2023 preparing for a full rollout in 2024. The pilot has allowed us to assess the size of the team adequately and ensure we're "right-sized" for the complete rollout. We have been and will continue to identify improvements to streamline our workflows and evaluate our activation metrics to ensure that we're continuing to reduce the time it takes to open studies.

Evolution of MSK's Protocol Activation Core

Jocelyn Migliacci, MA, Marissa Kehoe, MS, Emily Valentino, MPH, Ann Rodavitch, MA
Memorial Sloan Kettering Cancer Center

Background

- Memorial Sloan Kettering Cancer Center (MSK) has a high volume of protocols in activation, opening an average of 36 prospective, retrospective and biospecimen protocols each month.
- Prior to 2018, protocol activation was managed locally by the Principal Investigators' (PI) research teams without central oversight of study start-up.
- MSK identified that activation processes were inefficient and launched the Protocol Activation & Review and Human Research Protection Program (HRPP) centralizing activation and review committee management.

Goals

- Our initial centralized unit, which included oversight of protocol review committees and HRPP, allowed us to seamlessly coordinate protocol review and approval; however, the Protocol Activation Core (PAC) was only responsible for only a portion of all activation activities (shown in Figure 1).
- Due to the complexity of protocol activation, PAC was tasked with gradually streamlining and expanding the number of centralized activities, ensuring tasks were completed at the time of activation so that we can enroll patients to new treatments quickly.

Methods

- PAC was tasked with facilitating communication between the PI, local study team, and all other key stakeholders in activation, including the sponsor, finance, legal, etc., ensuring that all start up. requirements were fulfilled before opening a study to enroll patients.
- Over ~5 years, PAC gradually centralized most activation activities (Figure 1) which resulted in our team's expansion (Figure 2).
- We have extensively evaluated the processes of tasks and focused significant effort to streamline processes, including identification of improvements and system enhancements to reduce task completion time and ensure these tasks were not delaying activation.

Figure 1. Expansion of Protocol Activation Responsibilities over ~5 years

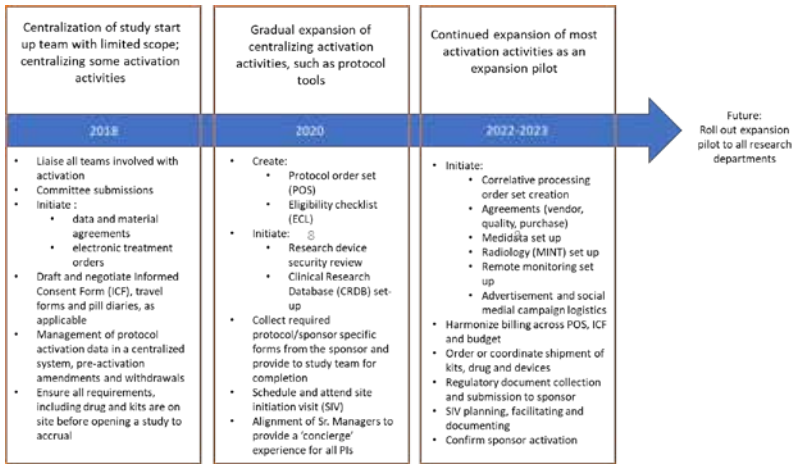
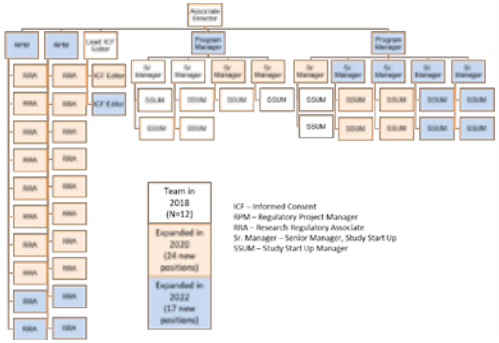


Figure 2. Staffing Expansion over ~ 5 years



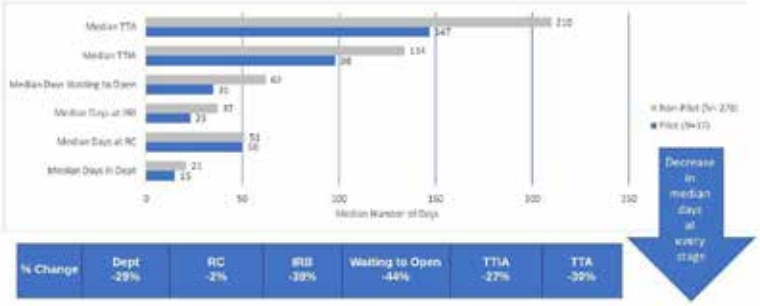
Outcome

- Forty-seven prospective studies have started activation in the expansion pilot, of which 17 studies have been activated to enroll participants.
- When comparing activated pilot studies to activated non-pilot studies (N=278) that started activation in the same timeframe, we have seen an improvement at all stages of activation (Figure 3).
- The most notable change was in the stage between IRB approval and open to enrollment (waiting to open) with a 44% decrease in median days.

Lessons Learn and Future

- We plan to gradually add research departments to the pilot throughout 2023 preparing for a full roll out in 2024.
- The pilot has allowed us to assess the size of the PAC team to ensure we're "right-sized" to expand the pilot across all research departments.
- We have been and will continue to identify improvements to streamline workflows and evaluate activation metrics to ensure that we're continuing to reduce the time it takes to activate studies.

Figure 3. Graphical Depiction of Changes in Medians*



*includes all types of protocols (i.e., investigator initiated, industry, mission critical, etc.)

"Out of Site, Out of Mind" – Visualizing the Study Activation Process Enables the Standardization of Site Initiation Visits

L. Thyssen, K. Williams, Y. Enriquez-Nunez
Sylvester Comprehensive Cancer Center, University of Miami

1. Background

Time to activation (TTA) is a crucial metric for Sylvester Comprehensive Cancer Center (Sylvester) as a matrix NCI-Designated Cancer Center. One of NCI's recommendations is to reduce TTA, ensuring timely activation of studies. As part of a TTA task force, stakeholders detected improvement opportunities by visualizing the overall study activation process through high-level flowcharts. One area that was identified as significantly impacting TTA was the process of scheduling and conducting the site initiation visit (SIV). The SIV plays a mandatory role in trial activation, ensuring that personnel are trained on the protocol and study-related processes.
In 2022, Sylvester's median TTA was 45 days from the time a manager starts the scheduling process to the occurrence of the SIV, which was significantly impacting the overall TTA.
There are 17 site disease groups (SDG) at Sylvester with varying approaches to handling SIVs, leading to lengthy and complex processes. Traditionally, the SIV length and agenda varies by sponsor, burdening the staff and causing inefficient resource allocation.

2. Goals

Reduce TTA through focus on the SIV:

1. Standardization across all SDGs
2. More efficient use of resources

3. Solutions and Methods

The following solutions were implemented to improve scheduling and conduct of the SIV:

1. Standardization across all SDGs:
   a. Trigger to indicate process start for scheduling SIV
   b. Streamline processes:
      i. Step-by-step work instructions with templates
      ii. Assigned roles and responsibilities
      iii. Contact information of required personnel/ departments
2. Sylvester owned SIV agenda - more efficient use of resources:
   a. Four-hour limit including one hour of investigator involvement
   b. Clear delineation of roles and responsibilities per section

4. Outcomes

The standardized process was rolled out to the stakeholders January 31, 2023 and implemented on February 3, 2023. Sylvester's preliminary data and survey collection is based on eight SIVs and shows the following findings:

1. Reduced TTA:
   a. 11 days reduction from notification of trigger to the SIV occurrence, with a median of 34 days
   b. The time between the SIV is scheduled and conducted has reduced to a median of 22 days with three studies taking less than ten days

2. Survey results:
   a. 50 percent agree that the process reduces the SIV scheduling time, while 33 percent selected that a significant reduction is experienced
   b. 100 percent note that this process is preferred
   c. 66.7 percent agree that the process significantly reduces SIVs total time
   d. Managers stated that the standardized process is very smooth, user-friendly, efficient and provides more control of the SIV process
   e. So far, we had 0 percent push back from any sponsor on this standardized process

5. Lessons Learned and Future Directions

The impact of the improvements is tracked with follow-ups to ensure that the process is improving the study activation process and course correcting as needed.

“Out of Site, Out of Mind” – Visualizing the Study Activation Process Enables the Standardization of Site Initiation Visits

Laura Thyssen; Kelly Williams; Yvonne Enriquez-Nunez
Sylvester Comprehensive Cancer center at the University of Miami Miller School of Medicine

SYLVESTER COMPREHENSIVE CANCER CENTER
UNIVERSITY OF MIAMI HEALTH SYSTEM
UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

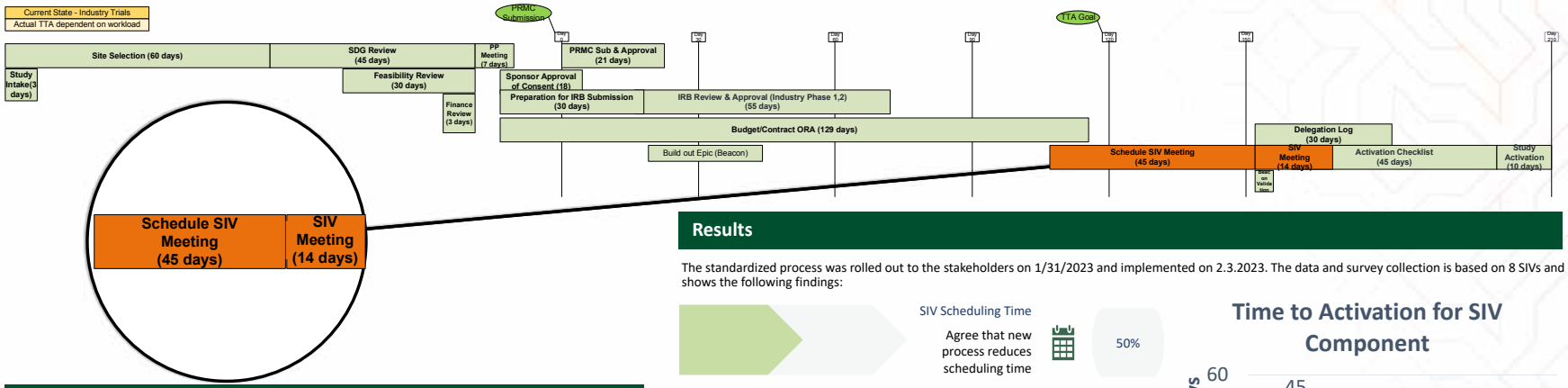
Background

Time to activation (TTA) is a crucial metric for Sylvester Comprehensive Cancer Center (Sylvester) as a matrix, NCI-designated, cancer center. One of NCIs recommendations is to reduce TTA ensuring timely activation of studies. As part of a TTA Task Force, stakeholders detected improvement opportunities by visualizing the overall study activation process through *high-level flowcharts*. One area that was identified as significantly impacting TTA was the process of ***scheduling and conducting the Site Initiation Visit (SIV)***. The SIV plays a mandatory role in trial activation, ensuring that personnel are trained on the protocol and study-related processes.
In 2022, Sylvester’s median TTA was 45 days from the time a manager starts the scheduling process to the occurrence of the SIV, which was significantly impacting the overall TTA. There are 17 Site Disease Groups (SDG) at Sylvester with varying approaches to handling SIVs, leading to lengthy and complex processes.

Goals

Reduce TTA through focus on the SIV:

1. Standardization across all SDGs
2. More efficient use of resources



Solutions Implemented

Standardization across all SDGs

1. Trigger to indicate process start for scheduling SIV in collaboration with Office of Research Administration
2. Streamline of Processes
   a. Step-by-step work instructions
   b. Assigned Roles and Responsibilities
   c. Contact information for required personnel

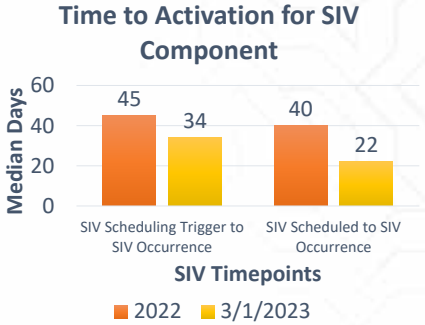
Sylvester owned SIV Agenda - More efficient use of resources

1. 4- hour limit incl. one hour of investigator involvement
2. Clear delineation of roles and responsibilities per section

Results

The standardized process was rolled out to the stakeholders on 1/31/2023 and implemented on 2.3.2023. The data and survey collection is based on 8 SIVs and shows the following findings:

SIV Scheduling Time	Agree that new process reduces scheduling time	50%
Preferred process	New process is preferred	100%
SIV total time reduction	Agree new process significantly reduces SIV total time	66%



Next steps

The impact of the improvements is tracked with follow-ups occurring every 3 months to ensure that the process is improving the study activation process and course correcting as needed.

Still Waiting for Your IIS to Open? Activating Investigator-Initiated Studies at a Matrix Cancer Center

S. Cardona, G. Diaz, L. Thyssen, K. Williams
Sylvester Comprehensive Cancer Center, University of Miami

1. Background

As a National Cancer Institute (NCI)-Designated Cancer Center, Sylvester Comprehensive Cancer Center (Sylvester) faces challenges widely shared among other matrix-modeled cancer centers. One of those challenges is collaborating with the Office of Research Administration (ORA), which holds the signing authority for all budgets and contracts. All studies require an executed budget and contract for activation, thereby necessitating a collaboration between Sylvester's clinical research services (CRS) and ORA.

The NCI recommends that studies are activated within 90-120 days or less, making timely budget and contract execution critical to our overall timeline. To reduce the time it takes to execute a budget and contract for single-site investigator-initiated studies (IIS), the Sylvester project team led a process improvement project including all stakeholders (CRS & ORA) involved in activating IISs.

Using the DMAIC (Define, Measure, Analyze, Improve and Control) model, a lean six sigma process improvement approach, the project started by mapping and Defining the current state. Then the project team Measured the current TTA which resulted in a median of 484 days on what we considered our "CCSG timeline" (from Protocol Review and Monitoring Committee [PRMC] submission until activation). After Analyzing the current state, using tools such as root cause analysis, Pareto graphs, and control charts, we were able to identify the lack of standardization as the primary issue impacting the TTA.

2. Goals

1. Reduce time to activation for single-site IIS to 120 days or less.

3. Solutions and Methods

To address the issue with single-site IIS TTA, we implemented the innovative Improvements outlined below:

1. Rearranged workflow
2. Required key stakeholder communication
3. Established Standard Operating Procedures (SOP) for the improved process of submitting an IIS to ORA, including:
   a. Work instructions
   b. Simplified budget template
   c. Established tracker for SOP

4. Outcomes

Sylvester successfully implemented a future state process map reflecting four adjusted processes impacting TTA for single-site IIS leading to a TTA reduction of 248 days compared to 2022, with a median of 236 days for single-site IIS (2023-YTD).

5. Lessons Learned and Future Directions

Sylvester is currently in the Control phase monitoring the tracker at 30, 60, and 90 days to ensure that studies are reaching TTA quickly and efficiently. To expand this effort, Sylvester is moving to improve tracking with an IIS PowerBi dashboard for increased efficiency. In addition, Sylvester will maintain weekly recurring meetings with ORA to render process improvement initiatives for other study types (such as multisite IIS, industry, and cooperative groups) and ensure a successful collaboration. ORA also implemented this process for single-site IIS submitted by other departments across the institution.

Still Waiting For Your IIS To Open? Activating Investigator Initiated Studies At A Matrix Cancer Center

Sergio Cardona, Gabriel Diaz, Laura Thyssen, Kelly Williams
Sylvester Comprehensive Cancer center at the University of Miami Miller School of Medicine

SYLVESTER COMPREHENSIVE CANCER CENTER
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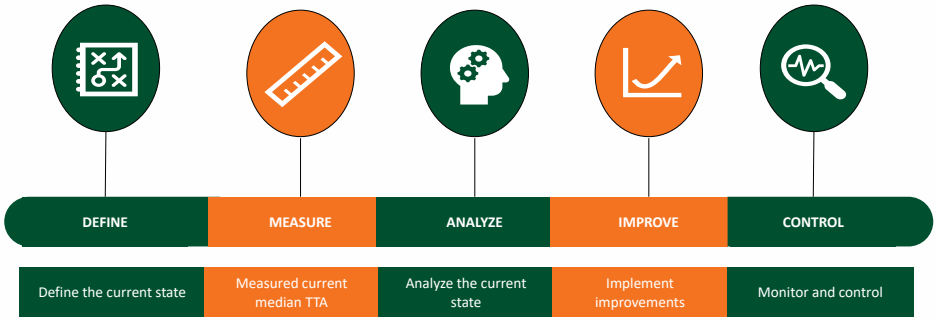
Approach

This project utilized the **DMAIC** (Define, Measure, Analyze, Improve and Control) model, a lean six sigma process improvement tool as shown in figure 1.

Figure 1. DMAIC Model



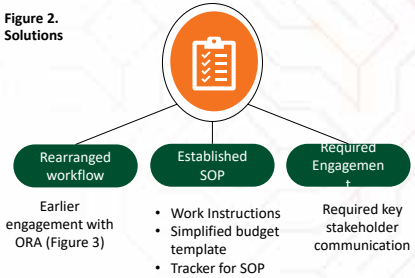
Goal

Reduce time to activation for single-site IIS to 120 days or less.

Solutions Implemented

To address the issue with single-site IIS TTA, we implemented the innovative Improvements outlined in figure 2.

Figure 2. Solutions



Results

Sylvester successfully implemented a future state process map reflecting four adjusted processes (Figure 3) impacting TTA for single-site IIS leading to a TTA reduction of 248 days compared to 2022, with a median of 236 days for single-site IIS (Figure 4).

Figure 3. Workflow

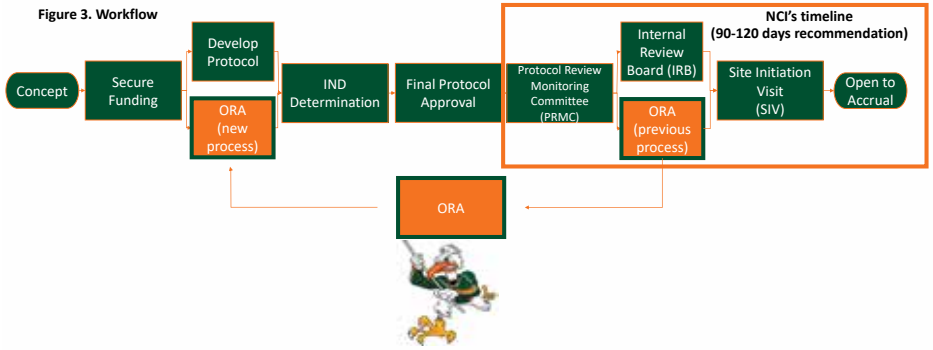
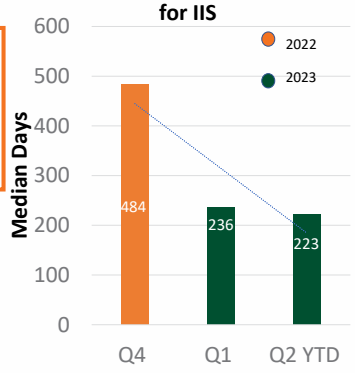


Figure 4. Time to Activation for IIS



Next Steps

Sylvester is currently in the Control phase and will follow the next steps as shown in figure 5.

Figure 5. Next steps

- Monitoring the new process at 30, 60, and 90 days
- Improve tracking with an IIS PowerBi dashboard
- Maintain weekly recurring meetings with ORA to ensure a successful collaboration.

Reducing Burden: The Value of a Research Consent Writer Team

C. Dill, K. Adamick, D. Mitchell IV, A. Zampieri
The University of Texas MD Anderson Cancer Center

1. Background

Each year, thousands of patients participate in clinical trials at MD Anderson Cancer Center. In 2022 alone, 10,074 patients participated in 1,680 research trials.

Each of these trials requires principal investigators and research teams to present the potential subjects with an informed consent document that is comprehensive, meets the required elements of Federal Regulations and Good Clinical Practice Guidelines, and is understandable to the potential trial subjects, parents, and/or legally authorized representatives. Creating and modifying informed consent documents accurately and adequately can be a regulatory burden to research staff, industry sponsors, and reviewers.

2. Goals

MD Anderson has developed a team of clinical research consent writers with goals to:

- Enhance the services offered by a central clinical research office through expertise in research regulations and health literacy
- Remove burden from research departments by preparing new consent documents and modifying existing ones for submission to the institutional review board (IRB)
- Use plain language to make the clinical research process more coherent and accessible to patients and potential subjects
- Facilitate translations of consent documents when necessary
- Work with information technology partners to code and upload electronic consents

3. Solutions and Methods

The consent writing team has created template documents and checklists to guide consent drafting. The team follows a multi-step standard operating procedure to ensure consents contain information that is accurate, adequate, and appropriate. For investigator-initiated trials, the consent writing team begins the process by drafting a consent form utilizing the protocol and collaborating with the research team. For industry-sponsored trials, the consent writers use the consent document provided by sponsors and make edits to meet institutional requirements while negotiating language with appropriate stakeholders and completing a quality assurance process. This allows the team to ensure the submitted consent meets federal standards and is comprehensible to potential trial participants.

4. Outcomes

In Fiscal Year 2022, the consent team assisted the research community by developing 771 new consent documents and providing reviews of 3,193 consent modifications. Through this process, the burden on the central office and on researchers was lessened by having a dedicated team to address the consent requirements. Furthermore, burden on potential participants is reduced through a consent document that is more coherent and comprehensible. In addition, feedback received from study teams regarding the consent services has been positive.

5. Lessons Learned and Future Directions

It has been challenging and time-consuming to navigate the extent of modifications and communication regarding requested modifications between sponsors, study teams, and IRBs in terms of the content of the informed consent document. This back and forth communication process can lead to delays in initial approval and continuing review. Future directions include working with research teams to identify minimum standards that must be in place within protocols to begin drafting an initial consent, collaborating with IRBs to identify common consent document changes needed, and working jointly with sponsors to identify common trends that delay consent reviews.

Reducing Burden: The Value of a Research Consent Writer Team

Corbin Dill, MPH; Kayla Adamick; David Mitchell IV; Adrianna Zampieri

The University of Texas at MD Anderson Cancer Center, Houston, TX

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

Making Cancer History®

Background

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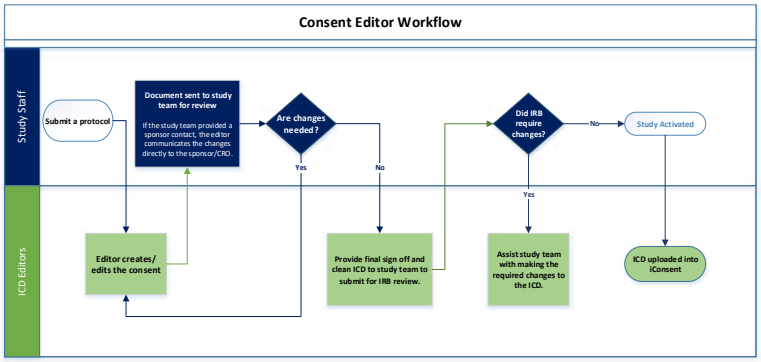
Each of these trials requires principal investigators and research teams to present the potential subjects with an informed consent document that is comprehensive, meets the required elements of Federal Regulations and Good Clinical Practice Guidelines, and is understandable to the potential trial subjects, parents, and/or legally authorized representatives.

Creating and modifying informed consent documents accurately and adequately can be a regulatory burden to research staff, industry sponsors, and reviewers.

Clinical Trial Participation

Based on FY 2022 Data



Solutions and Methods

MD Anderson has developed a team of Clinical Research Consent Writers with goals to:

- Enhance the services offered by a central clinical research office through expertise in research regulations and health literacy.
- Remove burden from research departments by preparing new consent documents and modifying existing ones for submission to the Institutional Review Board (IRB).
- Use plain language to make the clinical research process more coherent and accessible to patients and potential subjects.
- Facilitate translations of consent documents when necessary.
- Work with Information Technology partners to code and upload electronic consents.

The consent writing team has created template documents and checklists to guide consent drafting. The team follows a multi-step standard operating procedure to ensure consents contain information that is accurate, adequate, and appropriate.

For investigator-initiated trials, the consent writing team begins the process by drafting a consent form utilizing the protocol and collaborating with the research team.

For industry sponsored trials, the consent writers use the consent document provided by sponsors and make edits to meet institutional requirements while negotiating language with appropriate stakeholders and completing a quality assurance process. This allows the team to ensure the submitted consent meets federal standards and is comprehensible to potential trial participants.

Outcome

In Fiscal Year 2022, the consent team assisted the research community by developing 771 new consent documents and providing reviews of 3,193 consent modifications.

Through this process, the burden on the central office and on researchers was lessened by having a dedicated team to address the consent requirements. Furthermore, potential participant understanding is improved through a consent document that is more coherent and comprehensible. In addition, feedback received from study teams regarding the consent services has been positive.

Consent Assistance

Based on FY 2022 Data

Conclusions

It has been challenging and time-consuming to navigate the extent of modifications and communication regarding requested modifications between sponsors, study teams, and IRBs in terms of the content of the informed consent document. This back and forth communication process can lead to delays in initial approval and continuing review.

Future directions include working with research teams to identify minimum standards that must be in place within protocols to begin drafting an initial consent, collaborating with IRBs to identify common consent document changes needed, and working jointly with sponsors to identify common trends that delay consent reviews.

Maximizing Efficiency in Managing the Trial Activation Pipeline: Activating High-Priority Trials in a Timely Manner

A. Skafel, R. Aggarwal, E. Small
UCSF Helen Diller Family Comprehensive Cancer Center

1. Background

Time-to-activation is complex and success of clinical trials hinges on the ability to open trials quickly. Studies that take too long to open can close without any patients accrued, thereby wasting activation and coordination resources. In the first quarter of 2022, investigators at the Helen Diller Family Comprehensive Cancer Center (HDFCCC) were on track to submit 152 interventional studies to PRMC. This is substantially more than the annual average of 120 studies activated over the previous three years. Submitting too many studies to PRMC, or opening trials that are unable to accrual, not only strains activation resources, but poses challenges for ancillary services once opened.

2. Goals

The goal of the University of California San Francisco (UCSF) CPDM is to prioritize the activation and coordination of investigator-initiated trials (IITs), NCTN studies, early-stage career faculty, and studies where UCSF plays a key leadership role. Recognizing that industry sponsored studies are a financial necessity to programs, we sought to identify and participate only in industry studies for which robust accrual was likely.

3. Solution and Methods

We implemented a two-stage process to re-evaluate and re-prioritize trials in our activation pipeline. In the first phase, programs were asked to abandon lower priority industry sponsored studies. The second stage prioritized IITs, NCTN studies, trials where an early-stage career faculty was the PI, and industry studies with UCSF leadership. In an effort to ensure that this prioritization schema was uniformly applied across the cancer center, each disease oriented clinical research group was asked to adhere to a specific number of PRMC submission slots for industry studies over the course of a one-year period, which were equal to, or one less than the average annual number of trials activated by each group in the previous three years. There were no restrictions on the number of NCTN trial and IIT submissions. These measures were applied only to trials being submitted to the PRMC; open trials were not affected.

4. Outcomes

In the first stage, 10 percent of industry trials were abandoned during the activation process. In the second stage, 16 percent fewer studies were submitted to PRMC. At the end of the second stage, a similar number of studies, as in prior years, were activated and the number of interventional studies opened to accrual remained constant. The time to activation decreased by 11 percent over the same time period in the year prior. Mid-year survey of faculty demonstrated agreement with ability of site committee chairs to better prioritize PRMC submissions; however, feelings of stress and competition increased among clinical investigators.

5. Lessons Learned and Future Directions

While the number of submissions to PRMC was reduced and resources were focused on high-priority trials, the process initially added stress to faculty and program leaders. As the year concludes, we will survey faculty to determine if the stress changed over-time. Additional analysis is being undertaken to determine if the number of studies closed with zero accruals decreased, and if there was an ongoing impact on time to activation. We will also evaluate the impact on the relative accruals to IIT, NCTN, and industry trials.

UCSF Helen Diller Family Comprehensive Cancer Center

Maximizing efficiency in managing the trial activation pipeline: activating high-priority trials in a timely manner

Andrea L Skafel, Rahul Aggarwal, Eric J Small
Helen Diller Family Comprehensive Cancer Center (HDFCCC), University of California San Francisco

Background

- Time-to-activation is complex. Success of clinical trials hinges on the ability to open trials quickly. Studies that take too long to open can close without any patients accrued, thereby wasting activation and coordination resources.
- The speed with which trials can be activated often hinges on the volume of studies in the protocol development pipeline.
- In Q1 of 2022, HDFCCC investigators were on track to submit 152 interventional studies to Protocol Review and Monitoring Committee (PRMC), substantially higher than the annual average of 120 studies activated over the previous three years.

Goals & Methods

- We sought to normalize the number of studies entering the protocol development pipeline to be more reflective of the yearly average.
- We sought to identify and participate only in industry studies for which robust accrual was likely, in order to successfully manage our overall trial activation pipeline.
- We implemented a one-year pilot with two phases focused on the prioritization of trials in our activation pipeline.

Phase 1 – Low Priority Trials

Disease-oriented clinical research working groups were asked to remove lower priority Industry sponsored studies from the pipeline, including:

- Studies that were likely to be closed or near to closing at the time of projected UCSF activation
- Studies where UCSF was likely to have a limited number of available accrual slots based on the study design or number of centers involved.

Phase 2 – High Priority Trials

- Prioritization of investigator-initiated trials (IITs), NCTN trials, trials where an early-stage career faculty was the PI, and industry studies with UCSF leadership.
- Each disease oriented clinical research group was asked to adhere to a specific number of PRMC submission slots for industry studies over the course of a 1-year period.
- There were no restrictions on the number of NCTN trial and IIT submissions.
- A small number of additional slots for higher priority industry sponsored studies were allocated by a peer-review committee, through an application process.
- These measures were applied only to trials being submitted to the PRMC; open trials were not affected.

Results

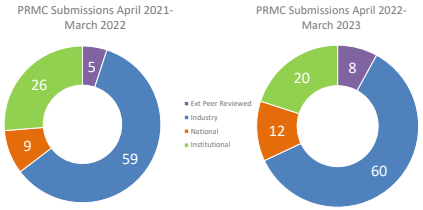
Phase 1 – Low Priority Trials

- 10% of industry trials were abandoned during the activation process.

Phase 2 – High Priority Trials

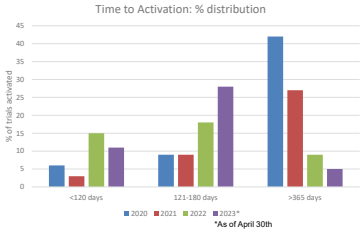
- 16% fewer studies were submitted to PRMC.
- By the 1-year period, only 57.5% of assigned PRMC submission slots were used.
- 6 additional slots were awarded for high priority studies or new faculty members
- At the end of the second phase, a similar number of studies as in prior years were activated.
- The time to activation decreased by 11% over the same time-period in the year prior.

Impact



PRMC submissions portfolio

The percentage of industry and externally peer reviewed trials submitted to remained relatively the same during phase 2 (as compared with the previous 12-month period). NCTN study submissions increased by 33%, where as institutional trials decreased by 23%



Time-to-Activation

- 39% of trials opened in less than 6 months in 2023 (YTD) vs. 12% in 2021
- 5% of trials opened in >1 year in 2023 (YTD) vs. 27% in 2021

Faculty Survey

We sent a survey to HDFCCC investigators, including program leaders at the mid-point and end of the 1-year phase 2 initiative. Although the response rate was small (N=16), faculty were ambivalent regarding the initiatives ability to accurately prioritize trials (38% agreed; 43% disagreed; 19% unsure).

56% of respondents indicated that the initiatives fostered a sense of pressure and competition amongst investigators for the allocated slots.

Conclusions and Future Directions

This pilot was successful in reducing the number of submissions to PRMC and allowed resources to be focused on high-priority trials.

However, the process added stress to faculty and program leaders.

Discussions of industry-sponsored trials at disease oriented clinical research groups now include the likelihood of long-term success of a trial, including the ability to open before national accrual goals are met, and the ability to meet accrual targets.

Future Analysis

Adequately prioritizing trials that are entering the activation pipeline is expected to have downstream effects on the ability of study teams to adequately accrue and operationalize these trials. As we monitor the impacts of the prioritization program, we will:

- Determine if the number of studies closed with zero accruals decreased, and if there was an ongoing impact on time to activation.
- Evaluate the impact on the relative accruals to IIT, NCTN and industry trials.
- Consider the impact on ancillary services at UCSF.

SIV On-Demand: Online Site Initiation Visits for Investigator-Initiated Trials (IITs)

E. Monari, S. Alford, T. George, A. Anderson, A. Ivey
University of Florida Health Cancer Center

1. Background

Scheduling a site initiation visit (SIV) can be challenging due to the coordination of multiple schedules and can result in delayed study activation. Additionally, it is difficult to assess comprehension of critical study processes and it can be challenge to record and collect/maintain a log of participants. Finally, often study processes are embedded in a longer presentation that also contains standard GCP and local SOP information which can dilute important study operational information. To address all of these, the University of Florida Health Cancer Center (UFHCC) Project Management Office (PMO) developed an "on-demand" style site initiation visit process for investigator-initiated trials (IITs).

2. Goals

- Increase efficiency of SIV scheduling and completion
- Improve documentation of SIV attendees
- Enhance understanding of critical study operations with a goal of reducing later protocol deviations

3. Solutions and Methods

Canvas was identified as a promising alternative to live SIVs because it is accessible to all UF staff, allows for automatic tracking of training for each study team member, has the option for "quizzes" that can ensure understanding, and serves as a central resource for new study staff and re-training through the life of the study.

Each study is created as a training module within a larger Canvas "SIV" course, which serves as a portal to access each study. Trainings are created via PowerPoint presentations and recorded by the project manager to be posted in the associated study module. The protocol training is separated into two presentations: one that includes general clinical trial SOPs and GCP and a separate module specific to protocol-specific study operations. A three-question quiz is created by PMO and administered for coordinators as knowledge checks on the most important information from the protocol training presentation.

Once the study module is accessible, a deadline is provided to the study team for completion and an optional meeting time with the PI is set up to discuss any study questions following the SIV. The study module, containing all the training presentations, is active through the life of the study for ease of new staff training. A report using the New Analytics feature can serve as a SIV training log including participants who have viewed the SIV and date of their training. Quiz scores from coordinators are also accessible to identify where special attention may be required for the project manager.

4. Outcomes

PMO developed its first SIV Canvas course in Fall 2021. Since that time, three other IITs have successfully utilized this process.

5. Lessons Learned and Future Directions

Areas for future improvement include being able to post different trainings for different study roles and assign them accordingly. While our current framework does not accommodate this, we are exploring other ways to structure the course so we might implement improvements. Additionally, we'd like to collect metrics on how many times each participant attended the training and track how long they were engaged with each session.

SIV On-Demand: Online Site Initiation Visits for Investigator-Initiated Trials

Erin Monari, PhD, CCRP, Shannon Alford, MPH, CCRP, Thomas George, MD, Ashley Anderson, MBA, ACRP-CP, Alison Ivey, RN, MS, MBA, OCN, CCRP

BACKGROUND

Scheduling a site initiation visit (SIV) can be challenging due to the coordination of multiple schedules, resulting in delayed study activation. Additionally, it is difficult to assess comprehension of critical study processes and it can be challenge to record and collect/maintain a log of participants. Finally, often study processes are embedded in a longer presentation that also contains standard GCP and local SOP information which can dilute important study operational information. To address all of these, the UFHCC Project Management Office (PMO) developed an "on-demand" style Site Initiation Visit process for IITs.

Our primary goals are:

- Increase efficiency of SIV scheduling and completion
- Improve documentation of SIV attendees
- Enhance understanding of critical study operations with a goal of reducing later protocol deviations

METHODS

Canvas was identified as a promising alternative to live SIVs because it is accessible to all UF staff, allows for automatic tracking of training for each study team member, has the option for "quizzes" that can ensure understanding, and serves as a central resource for new study staff and re-training through the life of the study.

Each study-specific SIV is created as a training module within a larger Canvas "SIV" course, which serves as a portal. Trainings are created via PowerPoint presentations and recorded by the project manager to be posted in the associated study module. The SIV is separated into two presentations: (1) one that includes general clinical trial SOPs and GCP and (2) a separate module specific to protocol-specific study operations.

A 3-question quiz is created by PMO and administered for coordinators as knowledge checks on the most important information from the protocol training presentation. Once the study module is accessible, a deadline is provided to the study team for completion and an optional meeting time with the PI is set up to discuss any study questions following the SIV. The study module, containing all the training presentations, is active through the life of the study for ease of new staff training. A report using the New Analytics feature can serve as a SIV training log including participants who have viewed the SIV and date of their training. Quiz scores from coordinators are also accessible to identify where special attention may be required for the project manager.

RESULTS / FUTURE DIRECTIONS

PMO developed its first SIV Canvas course in Fall 2021. Since that time, three other IITs have successfully utilized this process. Areas for future improvement include being able to post different trainings for different study roles and assign them accordingly. While our current framework does not accommodate this, we are exploring other ways to structure the course so we might implement improvements. Additionally, we'd like to collect metrics on how many times each participant attended the training and track how long they were engaged with each session.

CONTACT

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Rapid Release Protocol Activation Via a Just-in-Time Pathway

A. Anderson, T. George, E. Monari, A. Ivey, L. Pettiford
University of Florida Health Cancer Center

1. Background

To minimize the impact of administrative closures for underperforming rare disease trials, the University of Florida Health Cancer Center (UFHCC) Clinical Research Office initiated the Just-in-Time (JIT) activation process in 2021. The pilot program launched with pediatrics given their relatively large portfolio of rare disease studies. The JIT process was designed in response to the SRMC Zero Tolerance Policy (ZTP), which forces the closure of rare disease studies without enrollment at two years following activation. The ZTP was established in 2018 to force the closure of studies previously allowed to remain open without accrual for several years. To deter closing rare disease studies prematurely, the JIT process allows these trials to conduct all activation activities but remain in a "hold" status until a potential subject is identified, and then immediately activate.

2. Goals

- Minimize administrative burden while confirming resource allotment across rare disease portfolios
- Prevent premature ZTP closure of high priority trials expecting slow or limited enrollment
- Activation - ready trials to allow rapid release via the CTMS after subject identification

3. Solutions and Methods

The JIT pathway was created for trials that were both 1) NCTN/ETCTN and 2) Rare disease. Initially, the targeted portfolio was pediatrics; however, this was extended to other disease groups.

Qualifying studies proceed through normal activation processes by our UFHCC Protocol Activation Team; upon completing IRB and budget, trials are placed "on hold" until subject identification. All CTMS signoffs are completed except "open to accrual" to limit delays once a subject is ready to enroll. Routine study maintenance must continue while in JIT "on hold" status, to ensure that the study immediately proceeds to "open to accrual." This includes study calendar, Beacon builds, IDR release, regulatory updates, training and DTLs.

Once opened to accrual, Data Table 4 (DT4) captures the study along with any enrollments. Disease site group (DSG) meetings include JIT studies to maximize enrollment opportunities. Once enrollment begins, study monitoring and continuation reviews are completed per UFHCC SRMC guidelines. SRMC requires JIT studies to move to "open to accrual" by two years, where studies will follow continuation or termination per the ZTP if no accrual within two years of activation.

4. Outcomes

Guidelines were created for activation efficiency, including "Just-in-Time study" must appear in study communications. To date, 13 studies have used JIT pathway, with one study opened to accrual.

DSG portfolios take JIT trials into account as UFHCC limits the number of interventional treatment studies permitted to open. This ensures adequate resources are available since JIT trials may activate at any time.

5. Lessons Learned and Future Directions

The JIT process improved protocol activation communications allowing swift activation for subject enrollment. Analytic review is planned to verify how many studies avoided early SRMC closure due to JIT processes. Modifications may include limits for how many studies a DSG can have a JIT status. Additionally, future plans include enhanced identification of AYA style trials to address required staff and training requirements, as well as gaps in the AYA portfolio for studies that may cross the pediatric/adult clinics.

Rapid Release Protocol Activation via a Just in Time Pathway

Ashley Anderson, MBA, ACRP-CP, Thomas George, M.D., F.A.C.P., Erin Monari, PhD, CCRP, Alison Ivey, RN, MS, MBA, OCR, CCRP, Leslie Pettiford, BSN,RN, MSc, OCN, CCRP

BACKGROUND

To minimize the impact of administrative closures for underperforming rare disease trials, UFHCC Clinical Research Office initiated the Just in Time (JIT) activation process in 2021. The pilot program launched with pediatrics given their relatively large portfolio of rare disease studies. The JIT process was designed in response to the SRMC Zero Tolerance Policy (ZTP), which forces the closure of rare disease studies without enrollment at 2 years following activation. The ZTP was established in 2018 to force the closure of studies previously allowed to remain open without accrual for several years. To deter closing rare disease studies prematurely, the JIT process allows these trials to conduct all activation activities but remain in a 'hold' status until a potential subject is identified, and then immediately activate.

GOALS

- Minimize administrative burden while confirming resource allotment across rare disease portfolios.
- Prevent premature ZTP closure of high priority trials expecting slow or limited enrollment.
- Activation-ready trials to allow rapid release via the CTMS after subject identification.

CONTACT

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METHODS

The JIT pathway was created for trials that were both 1) NCTN/ETCTN and 2) Rare disease. Initially, the targeted portfolio was pediatrics; however, this was extended to other disease groups.

Qualifying studies proceed through normal activation processes by our UFHCC Protocol Activation Team; upon completing IRB and budget, trials are placed 'On Hold' until subject identification. All CTMS signoffs are completed except 'Open to Accrual' to limit delays once a subject is ready to enroll. Routine study maintenance MUST continue while in JIT 'On Hold' status, to ensure that the study immediately proceeds to 'Open to Accrual'. This includes study calendar, Beacon builds, IDR release, Regulatory updates, training and DTLs.

Once opened to accrual, Data Table 4 (DT4) captures the study along with any enrollments. Disease site group (DSG) meetings include JIT studies to maximize enrollment opportunities. Once enrollment begins, study monitoring and continuation reviews are completed per UFHCC SRMC guidelines.

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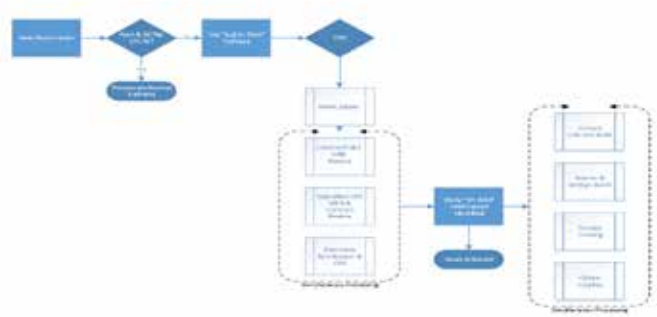

OUTCOMES

Guidelines were created for activation efficiency, including "JUST-IN-TIME study" must appear in study communications. To date, 13 studies have used JIT pathway, with one study opened to accrual.

DSG portfolios take JIT trials into account as UFHCC limits the number of interventional treatment studies permitted to open. This ensures adequate resources are available since JIT trials may activate at any time.

FUTURE DIRECTIONS

The JIT process improved protocol activation communications allowing swift activation for subject enrollment. Analytic review is planned to verify how many studies avoided early SRMC closure due to JIT processes. Modifications may include limits for how many studies a DSG can have a JIT status.

Additionally, future plans include enhanced identification of AYA style trials to address required staff and training requirements, as well as gaps in the AYA portfolio for studies that may cross the pediatric/adult clinics.

Descending the Apex of the Slippery Slope of Kit Management

J. Voyten, J. Urban, M. Horak
UPMC Hillman Cancer Center

1. Background

Clinical trial sponsors deliver supplies based on contracts with the central labs, which often end up as excess trial materials. Automatic resupply from sponsor triggers an apex of trial materials that can quickly become overwhelming. Two disease centers were selected for a pilot study of Slope.io for inventory management at UPMC HCC CRS. One disease center (DC1) is a large and high accruing Phase I center, who opens and closes studies quickly. Disease center 2 (DC2) is long established within the department and opens trials and accrues on a routine and predictable basis.

2. Goals

The plan was to create a snapshot of the current inventory in the department disease centers and provide a method of action to manage kit supply using the Slope.io inventory management application.

3. Solutions and Methods

The department was divided into zones and the cabinets and shelving were labeled accordingly. The CRS Lab (Neutral party) staff members approached each DC by asking for the known location of the kits. Lab staff logged the items in an "as-is" state to determine a snapshot of the center and then completed a walkthrough of the department to locate additional supplies. The lab identified supplies unknown to the DC, for which they tracked separately. Once all the known DC supplies were imported, an item report was generated from Slope. The unknown supply locations and the Slope item report were compiled in Excel and color coded: green (DC known, not expired), yellow (DC known, expired), and grey (DC unknown, mixed). DC Staff were given the task of disposing five kits per day in the yellow area and two hours per week in the gray areas to either dispose or inventory within Slope.

4. Outcomes

DC1 had approximately 68 percent of items either expired or unaccounted for, total amount of usable items where location was known being 2134. Of known items, 760 (26 percent) items were expired on site and occupying space, therefore 43 percent of kit supply items were on site but unaccounted for. DC2 had 3 percent of items expired or unaccounted for, with a total amount of usable items known being 1249. DC1 had 32 percent of allocated space correct and up to date, whereas DC2 had 53 percent of allocated space utilized appropriately. Departmental space was able to be more efficiently distributed due to this data.

5. Lessons Learned and Future Directions

Automatic resupply from sponsor triggers an apex of trial materials that can quickly become overwhelming. The attack position to reach the berm of oversupply is a multiphase approach. DC1 was able to dispose of 1901 kits. DC2 was able to increase allocated space to 96 percent and unused space was given to a disease center in need based on trial volume. The department was inventoried to create a full picture (17,102 known trial supplies, 44 percent of space unusable). The Slope inventory system created a snapshot of the excess within the department and allowed us to target an approach to manage the oversupply across departmental DCs.

Descending the Apex of the Slippery Slope of Kit Management

Jamie Voyten BS, Julie Urban PhD, Mary Horak BS, CCRP
UPMC Hillman Cancer Center, Pittsburgh, PA

Goals

- To create a snapshot of the current inventory in two department disease centers (DC) and provide a method of action to manage kit supply using the Slope.io inventory management application.
- To implement the full department and reallocate space as needed.

Background

Clinical trial sponsors deliver supplies based on contracts with the central labs, which often end up as excess trial materials. Automatic resupply from sponsor triggers an apex of trial materials that can quickly become overwhelming for site staff to sustain in a reasonable amount.

Two disease centers were selected for a pilot study of Slope.io for inventory management at UPMC HCC CRS.

- Disease Center 1 (DC1)
  - Large and high accruing Phase I center
  - Opens and closes studies quickly.
- Disease center 2 (DC2)
  - Long established within the department.
  - Opens trials and accrues on a routine and predictable basis.

Solutions and Methods

The department was divided into zones and the cabinets and shelving were labeled accordingly. The CRS Lab (Neutral party) staff members approached each DC by asking for the known location of the kits. Lab staff logged the items in an "as is" state to determine a snapshot of the center and then completed a walkthrough of the department to locate additional supplies. The lab identified supplies unknown to the DC, for which they tracked separately. Once all the known DC supplies were imported, an item report was generated from Slope. The unknown supply locations and the Slope item report were compiled in Excel and color coded: green (DC known, not expired), yellow (DC known, expired), and grey (DC unknown, mixed). DC Staff were given the task of disposing 5 kits per day in the yellow area and 2 hours per week in the gray areas to either dispose or inventory within Slope.

Data

Space Allocation Across Disease Centers

Outcomes

DC1 Implementation:

- 32% of allocated space utilized appropriately.
- 68% of items either expired or unaccounted for.
- total amount of known usable items was 2134.
  - 760 (26%) items were expired on site and occupying space.
  - 43% of kit supply items were on site but unaccounted for.

DC2 Implementation:

- 53% of allocated space utilized appropriately
- 3% of items expired or unaccounted for.
- Total amount of usable items known being 1249.

At five months post implementation, DC1 had nearly all inventory accounted for and DC2 was fully up to date. Departmental space was able to be more efficiently distributed due to the use of Slope.

Future Outcomes

Automatic resupply from sponsor triggers an apex of trial materials that can quickly become overwhelming. The attack position to reach the berm of oversupply requires a multiphase approach.

- DC1 disposed of 1901 kits in 3 months.
- DC2 increased allocated space to 96%.
- Unused space was given to a disease center in need based on trial volume.
- Department inventoried for full picture (17,102 known trial supplies, 44% of space unusable).

The Slope inventory system created a snapshot of the excess within the department and allowed us to target an approach to manage the oversupply across departmental DCs and proved sustainability over time.

SLOPE

Acknowledgements: The authors would like to acknowledge Alex Yant, Solutions Engineer and Ethan Seville, Manager, Customer Engagement and Strategic Solutions from SLOPE for their continued assistance with creative problem solving and support throughout the implementation process in CRS. We would also like to acknowledge the work of the CRS Research Associate Lab and Disease Center staff members who were involved in the pilot project: Brittini Biddle, Jaclyn Fetes, Courtney Juliano, Jehna Bialowas, Lindsey Smith, Amy King, Thomas Last, Hanna Hetrick, Erin Suderman, Andrew Besselman, Renee Czerwien, Lorenzo Sellitto, Andrew Mikhail, and Nicholas Kerin. Research reported in this poster was also supported by National Cancer Institute of the National Institutes of Health under award number P30CA047904.

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2023 ABSTRACTS

CANCER CLINICAL RESEARCH

FROM ABSTRACT TO REALITY

COMMUNITY OUTREACH AND ENGAGEMENT & DIVERSITY, EQUITY, AND INCLUSION

Telemedicine Electronic Consenting Preference Among Clinical Trial Participants

M. Buckley, S. Chimonas, S. Shah, Y. Redelman-Sidi, C. White, K. Seier, R. Baser, G. Kuperman, R. Panchal, J. Lengfellner, S. Terzulli, P. Sabbatini
Memorial Sloan Kettering Cancer Center

1. Background

Telemedicine disparities in the U.S. during the pandemic are well-reported. However, the use of telemedicine by diverse participants providing electronic informed consent (eIC) for clinical trials in oncology remains unexplored.

2. Goals

To evaluate trial participant characteristics associated with preferences for eIC via telemedicine versus in-person.

3. Solutions and Methods

Clinical trial participants with in-person clinic visits and telemedicine eIC visits from August 2021 to January 2023 received anonymous, uncompensated surveys via patient portal. We assessed age, sex, primary language, ethnicity, race, and three groups of survey questions generated from factor analysis: 1) telemedicine usability; 2) telemedicine satisfaction; and 3) eIC process comfort (comfort using telemedicine for key deliberations in the eIC process) (Figure). A multivariable multinomial regression model evaluated association between factors and eIC preference, a survey item assessing overall preference for eIC via telemedicine or in person or no preference.

4. Outcomes

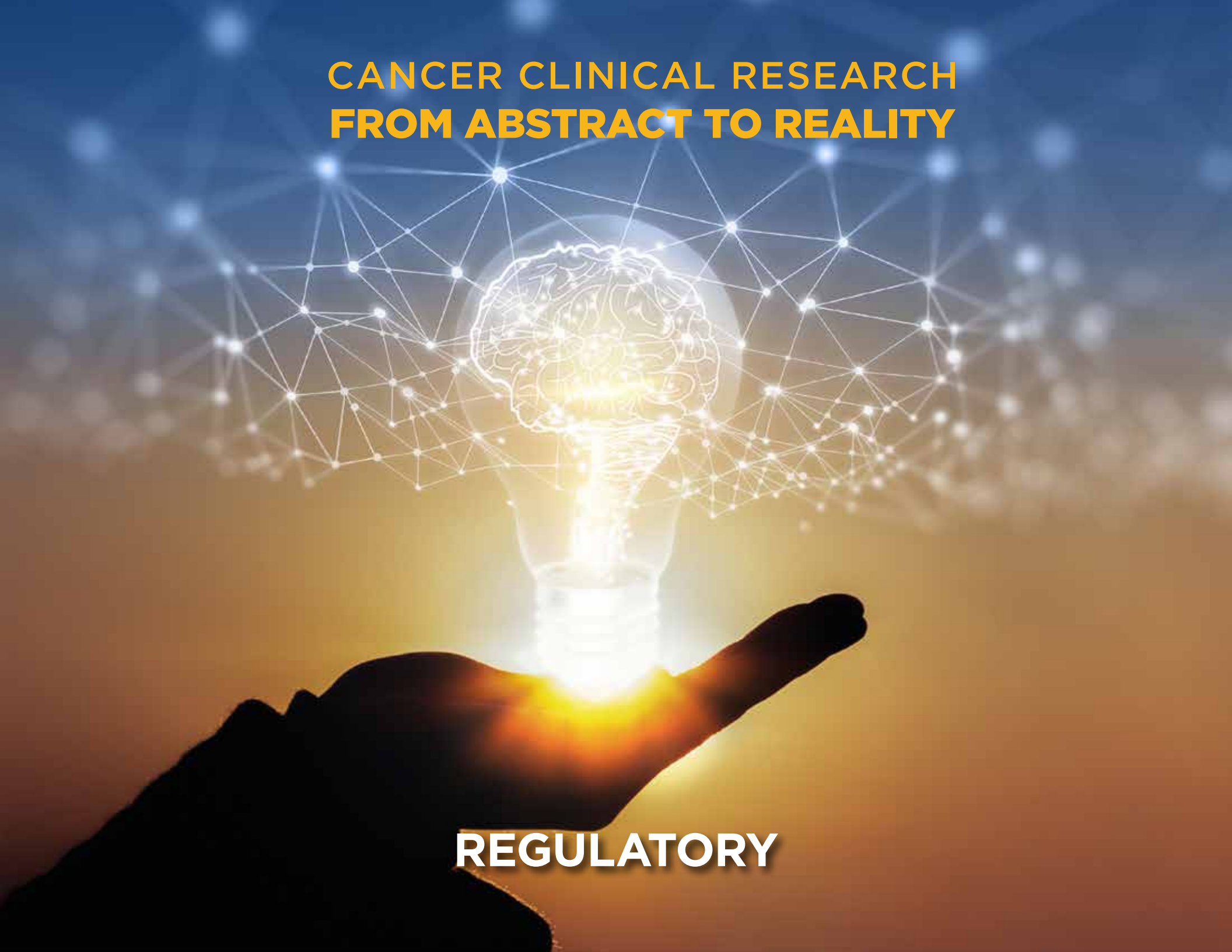
Among 1,154 respondents (28% response rate), 52% preferred telemedicine for eIC, 29% had no preference, and 19% preferred in-person. Respondent median age was 65 (interquartile range 57, 72); 51% (n=591) were male, 49% (n=563) female; 97% (n=1,123) English speaking, 2.7% (n=31) other primary language; 94% (n=1,017) were not Hispanic, 6% (n=65) were Hispanic, and n=72 unknown; 84% (n=928) White, 7.7% (n=85) Asian-Far East/Indian Subcontinent, 5.3% (n=58) Black, 2.6% (n=29) other, and n=54 unknown. Non-native English speakers (odds ratio (OR) 0.31; 95% CI (0.1, 0.93), p=0.037) and Black participants (OR 0.37; 95% CI (0.16, 0.83), p=0.016) had decreased odds of preferring telemedicine to in-person for eIC. Similarly, increased age (OR 0.98; 95% CI (0.96, 0.99), p=0.008) was associated with a decrease in no preference compared to in-person preference for eIC. Increased telemedicine satisfaction (telemedicine [OR 1.04; 95% CI (1.03, 1.05), p<.001] and no preference [OR 1.02; 95% CI (1.01, 1.03), p=.001]) and eIC process comfort (telemedicine [OR 1.07; 95% CI (1.06, 1.09), p<.001] and no preference [OR 1.03; 95% CI (1.02, 1.05), p<.001]) were associated with increased odds of preferring telemedicine or having no preference for eIC.

5. Lessons Learned and Future Directions

In our study nearly all participants preferred telemedicine for eIC or had no preference. However, adjusting for eIC process comfort, telemedicine satisfaction, and other demographics, participants who were Black, older, or non-native English speakers were more likely than others to prefer in-person for eIC. Our future research will target these areas to help support equitable consenting standards and care.

CANCER CLINICAL RESEARCH

FROM ABSTRACT TO REALITY



REGULATORY

Centralized Investigational New Drug (IND) Safety Report Management Within an eBinder System: A Pilot Program

S. Rebar, A. Toulouse, K. Acosta
Fred Hutchinson Cancer Center

1. Background

Management of IND Safety Reports (safety reports) can represent a burden for study teams, from completing timely review and escalation to the principal investigator (PI), to tracking and reporting for financial invoicing. In 2022, our central regulatory team completed a pilot using our eBinder system to permit more efficient processing of safety reports.

2. Goals

1. Standardize a method of receipt for reports, limiting portal access points for study staff
2. Streamline report management workflows to allow more efficient invoice processing
3. Demonstrate increased efficiency to justify the creation of dedicated report management roles within regulatory teams

3. Solutions and Methods

Our pilot involved one disease team with 23 active industry trials. We estimated management of 500- 1,000 reports annually, with an expected average billable rate to sponsor of $75 per report. For efficiency, our team requested emailed safety reports, or direct links from sponsors to access, download, and upload reports into the study eBinder instead of accessing individual sponsor portals. Within the eBinder system, the following process was followed:

- Reports were tagged as “safety report”
- Reports were reviewed according to IRB reporting criteria
- Staff sign as “acknowledged” if the report did not meet reporting criteria
- Staff sign as “reviewed” if the report met escalation criteria to the PI
- A task was assigned to the PI to determine if the report met IRB reporting criteria
- Confirmed PI review and task completion as signed “approved” by the PI

4. Outcomes

1. We were unable to completely move away from accessing sponsor portals, as 10 of the 23 trials required accessing the sponsor portal; however, we limited access to delegated regulatory coordinators only, reducing the burden to study coordinators and PIs
2. By shifting the management of reports into our eBinder system, we streamlined documentation reviews by transitioning from paper tracking systems which also permitted immediate financial reporting
3. Across the 23 trials, 2,741 reports were received, exceeding the expected volumes; the use of our eBinder system, as well as dedicated staff, enables us to support the increase in volume without additional resources

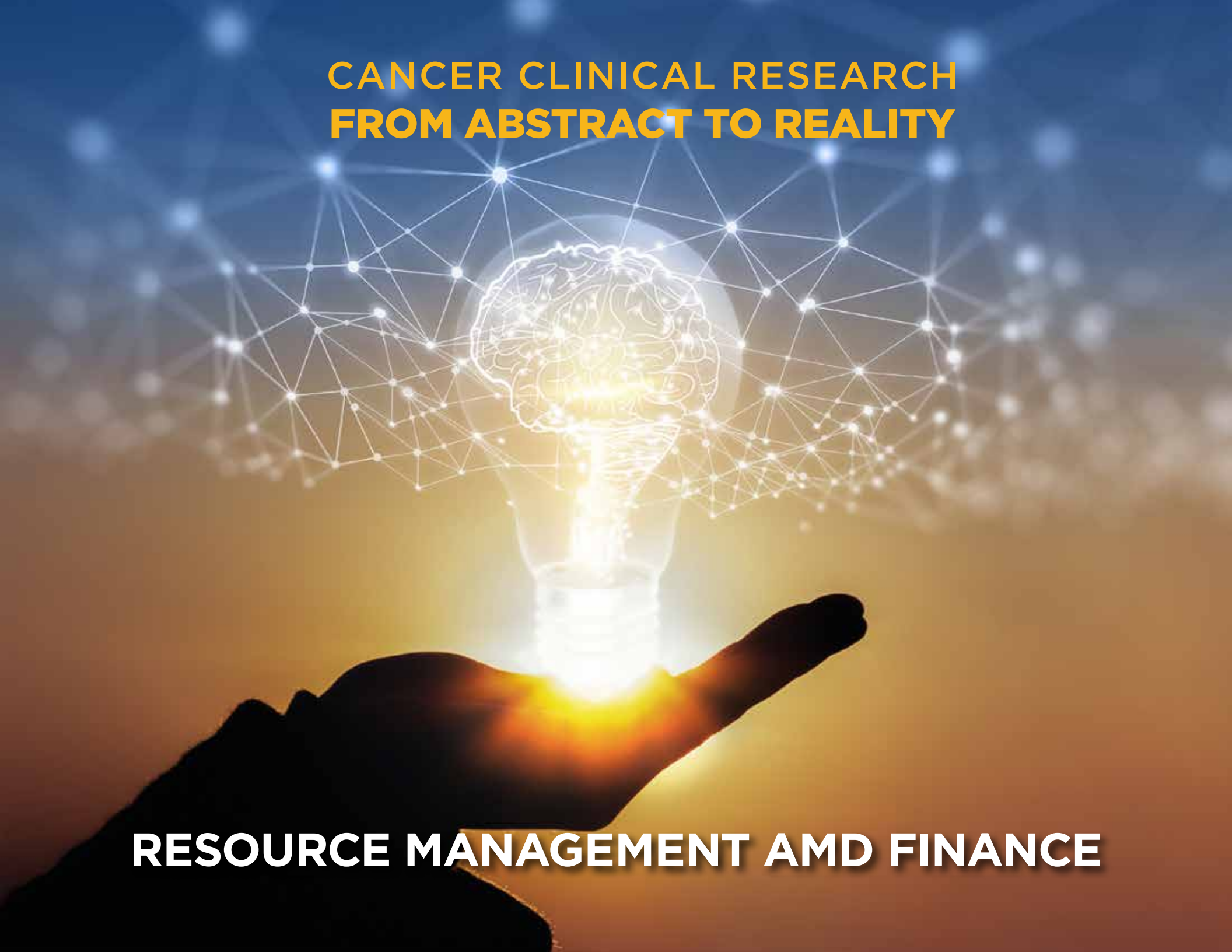
5. Lessons Learned and Future Directions

Two key lessons: we had a much higher volume of reports than predicted, straining staff resources; however, with previously planned staff increases, we balanced this work across an additional centralized resource.

One goal of the pilot was to demonstrate a level of efficiency to justify the centralization of this task across regulatory teams. With these results plus report volumes within other disease teams, we can justify centralizing this effort and removing the burden from disease teams.

CANCER CLINICAL RESEARCH

FROM ABSTRACT TO REALITY



RESOURCE MANAGEMENT AMD FINANCE

Tapping into REDCap Capabilities to Improve Efficiency for PRMC Reviewers and Coordinators

S. Phillips, L. Gross, S. Myles
Siteman Cancer Center

1. Background

Since the Siteman Cancer Center (SCC) transitioned to the OnCore Clinical Trials Management System (CTMS) in 2015, the protocol evaluation process for SCC Protocol Review and Monitoring Committee (PRMC) meetings has occurred exclusively within OnCore. This process involved PRMC coordinators manually creating individual evaluation sheets using Microsoft Word and then uploading them singly to OnCore. Reviewers then downloaded the forms, completed them, saved them locally, and re-uploaded them to OnCore. This proved to be a cumbersome and time-consuming procedure for reviewers and PRMC staff alike and did not allow the aggregation of metrics from the protocol evaluations. Additionally, committee votes for all protocol reviews occurred in-person during meetings pre-pandemic, but the shift to virtual meetings necessitated a new secure electronic system for tabulating committee votes. The SCC PRMC team turned to REDCap (Research Electronic Data Capture) as a means to improve the efficiency and effectiveness of both the protocol evaluation and voting processes for PRMC operations.

2. Goals

- Reduce PRMC reviewer burden for completion of evaluation forms
- Decrease meeting preparation time and workload for PRMC coordinators
- Offer the ability to assess trends from the content of REDCap reviewer forms and voting determinations

3. Solutions and Methods

Immediately after committee meetings transitioned to virtual, a PRMC remote voting survey was deployed in REDCap. Building on this success, a series of REDCap surveys was developed to mimic the questions and comment fields on the existing reviewer forms. PRMC staff created instructions guiding reviewers on form completion. Review status can be monitored at a glance by PRMC staff via the record status dashboard, and prior to meetings, PRMC staff downloads a PDF of all reviews to upload to OnCore to maintain a complete study record. The process was pilot tested over a period of three months for nine meetings by a variety of reviewers from different disciplines, and suggested improvements were then incorporated into the finalized REDCap tool.

4. Outcomes

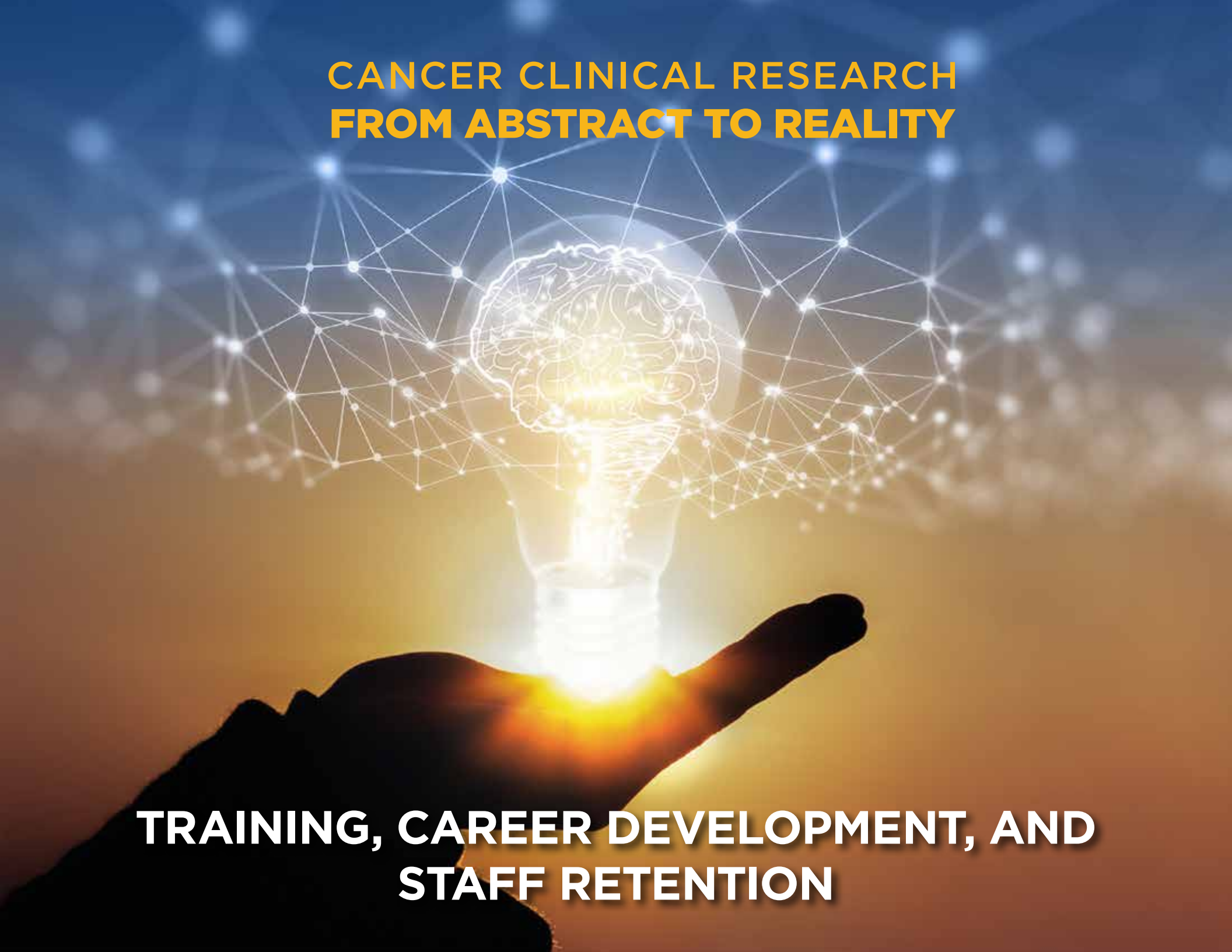
Feedback elicited from PRMC members indicated that they overwhelmingly preferred the REDCap process. Additionally, the meeting preparation procedure for PRMC coordinators has become five times faster. The process has also enabled the PRMC team to generate reports focused on review criteria that are most often marked as “unsatisfactory.”

5. Lessons Learned and Future Directions

Incorporating a pilot testing phase and soliciting feedback from several of the PRMC reviewers in different expertise areas greatly enhanced the ability to improve the REDCap survey prior to rollout to all committees. In the future, reviewer data gleaned from REDCap reports could allow for the creation of targeted educational materials highlighting certain protocol categories most often marked as “unsatisfactory” on contingent/deferred studies.

CANCER CLINICAL RESEARCH

FROM ABSTRACT TO REALITY



TRAINING, CAREER DEVELOPMENT, AND STAFF RETENTION

Launching a Clinical Trial Coordination Team: A 12-Month Report

K. Martinez, P. Panlasigui, F. Ranjbaran
Fred Hutchinson Cancer Center

1. Background

Fred Hutchinson Cancer Center is an NCI-Designated Comprehensive Cancer Center comprised of three organizations that form the Cancer Consortium. The Cancer Consortium has over 650 faculty members and the clinical research is organized into 15 research groups with associated disease-based study teams. Clinical Research Support (CRS), the consortium's CTO, provides central resources, including staffing resources, to investigators in support of their research. Between August 2021 and February 2022, study staff turnover rates exceeded 30 percent with some disease teams experiencing >50 percent vacancy rates. Staffing shortages resulted in decreased accrual and delayed start-up, necessitating a rapid, coordinated response. In March 2022, CRS launched the Clinical Trial Coordination Team (CTC), with the goal of a sustainable, long-term solution for the consortium's clinical research staffing.

2. Goals

To assess the uptake of a clinical research staffing model that provides:

- Clinical research staffing with the flexibility to take on long-term assignments or interim project support
- Rapid hiring, onboarding, and standardized training of clinical research roles (manager, clinical research coordinator, data coordinator, research assistant) to deploy staff within six-weeks of start date
- Standardized workflows and resources that can be integrated into existing teams

3. Solutions and Methods

In Spring 2022, CRS hired the first 14 coordinator staff to be part of the CTC team. Staff were hired in cohorts to streamline onboarding and training, and to create peer groups. Nine of the new staff were assigned to permanent positions within disease teams to address immediate staffing needs and five staff were assigned to teams for interim support. A chargeback model with service agreements was employed with monthly invoices for actual effort with role-based fees.

Based on need, two service models were developed:
1. Portfolio management providing full program support, including a research manager, with staffing hired and/or managed by CTC 2. Project support where team members would be deployed for short-term or long-term assignments

4. Outcomes

One year post launch, CTC has doubled in size from its first hire to 28 team members providing full portfolio management to four disease teams (Breast Oncology, GU Oncology, Neuro Oncology, Nuclear Medicine) and 22 project support deployments to an additional six teams (NCTN, Cancer Genetics, Surgical Oncology, GI, Head & Neck, Public Health Sciences). Rapid onboarding and training with structured mentorship have enabled us to meet our goal of assigning staff to teams within six weeks of their start date.

In addition, increased standardization of roles, including competencies, training, and experience, has led to better-defined career pathways and retention. In this first year, the CTC has promoted six staff members, terminated one for cause, and received one resignation.

5. Lessons Learned and Future Directions

With leadership and its CRS allied service lines' support, the CTC team met the demand for its services. To continue to provide efficient, compliant, and high-quality clinical research team members, we plan to:

- Expand and standardize our onboarding through the addition of a dedicated manager of training and preceptorship
- Focus on team development and retention by offering hybrid/remote work options for eligible roles, education/certification opportunities and promotion pathways
- Increase bandwidth by hiring and training staff prior to new staff being requested/gap in staffing
- Assess the continued adoption of this staffing model and integration challenges

Implementing an Orientation and Training Program for New Investigators

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1. Background

Fred Hutchinson Cancer Center is an NCI-Designated Comprehensive Cancer Center comprised of a tri-institutional consortium. In our matrixed consortium, new faculty investigators are onboarded by multiple people in various departments across the three institutions. Within this framework, a portion of their orientation includes the fulfillment of basic GCP/HSP training, however, knowledge of the central clinical trials office, Clinical Research Support (CRS), resources including staffing and institutional training requirements were lacking.

2. Goals

In September 2021, a clinical research orientation and training program was created to familiarize newly hired faculty investigators with the role of CRS and staffing support, key training, and systems requirements; and to connect them to centralized information resources that support the conduct of oncology clinical research.

3. Solutions and Methods

CRS partnered with the departments and consortium central administrative offices that are involved in the recruitment and onboarding of new faculty including the Medical Staff Office, Faculty Affairs, and the Consortium Office, to raise awareness of our program and to incorporate the CRS training team into their departmental new hire notification processes. An 8-hour online curriculum was created consisting of self-paced eModules and recorded presentations on various topics for study management and oversight such as the Delegation of Authority (DOA) Log, Consenting Non-English Speakers, and Protocol Design. Content was outlined using a comprehensive, self-guided checklist referencing internally developed eModules, required CITI Training courses, protocol templates, policies, and systems training and access. After receiving new hire notifications, the training team oriented new faculty on CRS resources and assigned the curriculum in the center's learning management system for completion within 8 weeks.

4. Outcomes

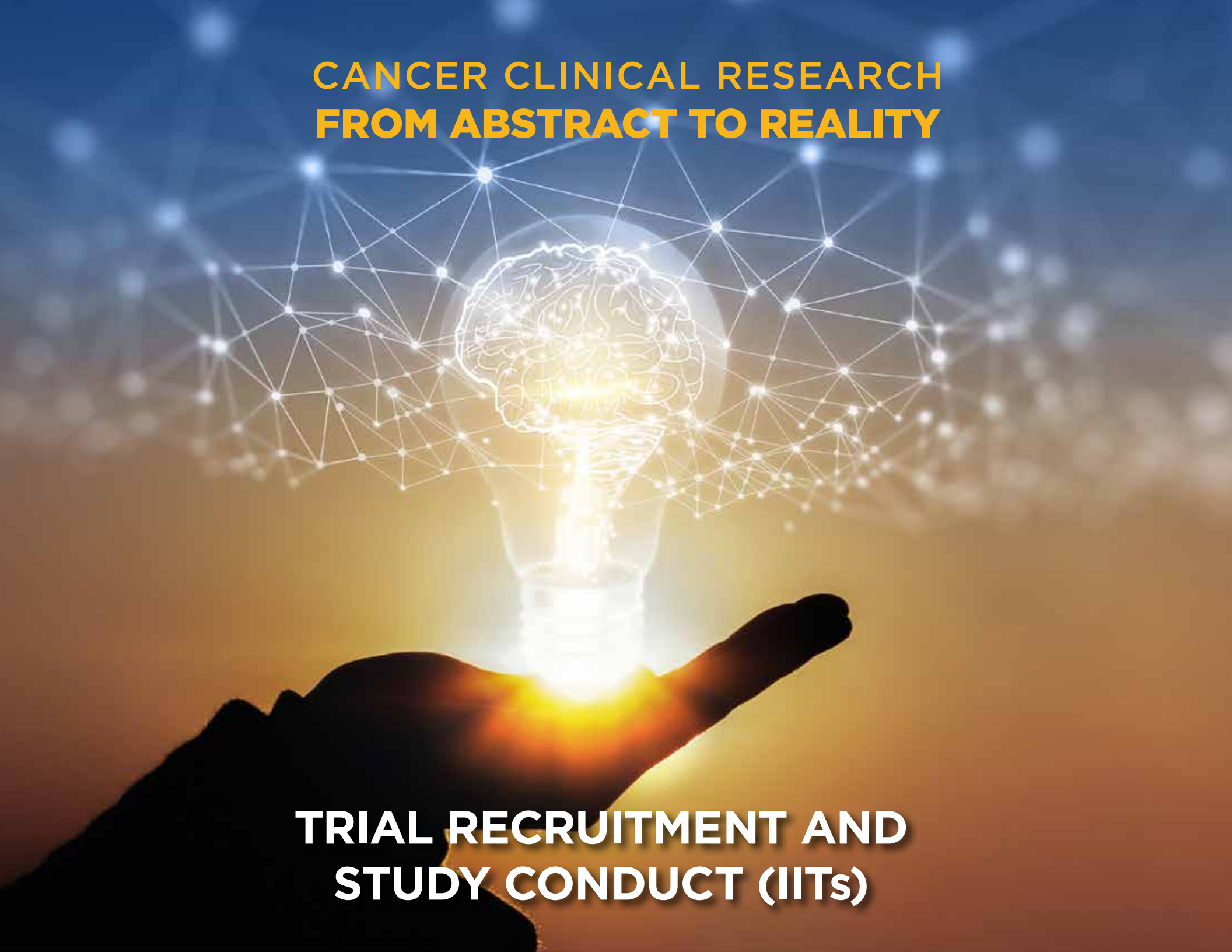
One year after launch, 45 faculty members had been oriented with an additional 9 established faculty members seeking additional guidance. The length of the orientation meeting was reduced from 1hour to 30 minutes and subsequent survey results revealed 77 percent felt the length of the meetings was "about right." Feedback revealed a substantial onboarding burden of new faculty, which impacted nearly half of the faculty members to complete the curriculum within the first 8 weeks. Faculty identified several topics they believed were introduced too soon in their career, such as working with the IRB, site monitors, and the FDA. The resources deemed most useful were related to informed consent and PI responsibility and accountability. The orientation program had established both visibility and support as demonstrated by an increase in referrals from departments across the Consortium.

5. Lessons Learned and Future Directions

There were requests to streamline what was "overall, a very helpful resource." As clinic providers, faculty's focus at hire is to complete onboarding requirements for multiple affiliations along with learning how clinical care is delivered at the Fred Hutchinson Cancer Center. Considering the tremendous training burden on new faculty and time needed for successful clinic integration, we will make the appropriate adjustments to ensure faculty receive the right balance of information over time. We will survey the utility of our orientation program's resources and evaluate training impact through compliance metrics.

CANCER CLINICAL RESEARCH

FROM ABSTRACT TO REALITY



TRIAL RECRUITMENT AND STUDY CONDUCT (IITs)

Electronic Subject Data Collection Within an eBinder System

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1. Background

Our site began implementing a 21 CFR Part 11-compliant eBinder system in 2020 with an initial scope of regulatory binders. We quickly realized the capabilities of the system beyond an electronic Investigator Site File and have since expanded our use of the system to include electronic Subject Data Collection (eSubject Data) management. Electronic Subject Data Collection allows for a fully digital patient record and supports more efficient workflows for data collection and transcription. Following a pilot by our Phase I and COVID clinics, a toolkit was developed and rolled out to support the adoption of eSubject Data by all disease teams within our cancer center.

2. Goals

1. Increase adoption of eSubject ata to improve workflows for data capture and transcription
2. Convert institutional templates into standardized electronic forms
3. Create resources and tools supporting broad adoption of electronic data capture

3. Solutions and Methods

The eSubject Data toolkit provided four types of resources:

1. Guidance documents
2. Standardized electronic forms: institutional templates modified into electronically fillable forms and eLogs
3. Example forms: forms provided with standard structure, allowing study specific customization (i.e., subject eligibility)
4. Tutorial videos: tutorials for modifying templates into electronically fillable forms

In addition, each team was provided a series of trainings from our support team, including guidance on binder setup, side-by-side instruction for their first trial, and assistance with study specific modifications for eLogs.

4. Outcomes

1. Three disease teams are fully utilizing the eSubject Data process with an additional five teams in the process of implementing
2. Data coordinators have been able to remain as remote staff and have real-time access to source data
3. Study teams have centralized access to consolidated research files
4. Monitor visits can occur remotely with access to subject data, without teams having to scan and upload documents to our eBinder system
5. Investigators report increased satisfaction because of real-time access to subjects' research data

5. Lessons Learned and Future Directions

The adoption of eSubject Data across disease teams has been slower than anticipated, from this a few key lessons were identified:

- First, despite being provided an extensive toolkit for eSubject Data adoption, many teams lack the personnel resources to invest the time to learn and transition to new workflows. We identified this as an opportunity to train centralized resources to support the transition work and remove the burden from the teams. We will monitor whether this investment will lead to an increase in the adoption of eSubject Data.
- Second, more change management support is needed, especially with faculty who may be initially resistant to new technology and processes. We will leverage faculty and teams who have deployed eSubject Data to continue to support the change management, training, and education needs for broader adoption.

Measuring the Impact of a Provider Triggered Pre-Screening Workflow on Recruitment

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1. Background

The Genitourinary Medical Oncology (GUMO) Research Group at Fred Hutchinson Cancer Center utilizes a referral-based recruitment system for their 35 actively accruing interventional treatment trials where providers submit patients to clinical research coordinators (CRCs) for pre-screening. The department conducted a retrospective review of participant referrals to assess the effectiveness of the current workflow.

2. Goals

To determine the effectiveness of the current participant recruitment workflow we sought to:

1. Define and document the current system of provider referrals for actively recruiting studies

2. Identify potential points for improvement in the pre-screening process (period prior to informed consent)

3. Solutions and Methods

The department conducted a retrospective review of data from October 2022 to January 2023, looking at encounters, new or recurrent, and research trackers. The team reviewed data from first encounter to screen failure or study enrollment.

4. Outcomes

From October 2022 to January 2023, 1,500 GUMO provider encounters for 1,164 unique patients (215 new and 946 returning patients) were pulled from EMR. Separately, 79 unique patients were recorded on the research team trackers as completing the pre-screening process. Patients were cross-referenced with the encounter list. Of those 79 patients, 54 patients were able to be matched to an encounter and were coded as referred to the study team: 4 percent of new patients and 5 percent of returning patients.

Following the patients through the entire screening process, the most significant point of voluntary drop-off was in the stage of consent where patients opted for alternative treatment (11 out of 51, 22 percent) or declined participation (3 out of 51, 6 percent).

5. Lessons Learned and Future Directions

The 26 pre-screened patients who could not be matched to provider encounters are thought to have originated from external referrals or Advanced-Practice Providers (APPs). In our discussion with the providers, they noted that some patients are considered easily ineligible, and therefore, many patients are not referred to the CRCs for further pre-screening.

The consenting stage was where many patients declined participation in a clinical trial. While the number of treatment options varies between different solid tumor malignancies and stages of disease, prostate cancer, which makes up the diagnosis of approximately 60-65 percent of patients seen by providers, is a disease that has many different FDA-approved treatments and therapies. Given a variety of options, the partial drop at the time of consent makes sense.

While this retrospective review covers only a short time period, the low rate of pre-screening referrals from provider encounters suggests that the research team would benefit from changing its pre-screening referral process. The team will continue to track pre-screening and the process improvement initiatives underway and will include this data in future reports.

PRMS Dashboard for Monitoring Performance & Accrual of Underrepresented Populations

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1. Background

As an NCI-Designated Comprehensive Cancer Center, the Fred Hutchinson Cancer Center operates a two-stage Protocol Review and Monitoring System (PRMS) that ensures rigorous oversight of all cancer clinical trials across three institutions (Fred Hutch, University of Washington, Seattle Children's). The National Cancer Institute (NCI) has reinforced the importance of enhancing diversity, equity, and inclusion in the Cancer Center Support Grant (CCSG) guidelines, including how the PRMS considers and monitors the accrual of underrepresented populations into clinical trials.

2. Goals

The Fred Hutch PRMS has updated its policy for monitoring underperforming trials and is evolving its monitoring process to address the accrual of underrepresented populations into clinical trials. A dashboard is in progress to provide a real-time reporting tool that augments PRMS portfolio reviews and monitoring. The tool also forecasts performance and will provide study teams with an opportunity to preemptively close underperforming trials and prioritize recruitment efforts that address protocol deficiencies.

3. Solutions and Methods

A group from the Fred Hutch PRMS and clinical trials office have created Tableau dashboards that leverage data from OnCore, including the ePRMS console, to display accrual over time, accrual and study duration goals, annual accrual goals defined by the PRMS policy, details of prior second stage monitoring reviews, and accrual demographic data (age, gender, race, and ethnicity). The tool provides two dashboards, a research portfolio overview, and a PRMS monitoring overview for trial-specific performance.

4. Outcomes

The research portfolio overview can be filtered by Research Group and includes a list of open trials available for PRMS monitoring. It provides a performance snapshot with key metrics that highlight trial performance. A heatmap is included to forecast when trials will be monitored by PRMS and indicate performance with red-yellow-green indicators. The Research portfolio overview also displays accrual demographics over time.

The PRMS monitoring overview can be filtered by trial and includes important protocol details. It provides a performance snapshot with key metrics such as study duration, accruals to date, the next PRMS monitoring review date, and forecasted performance outcomes. Trial performance is displayed as both accrual over time (with accrual and study duration targets intersecting a line chart) and accrual at previous monitoring reviews (with accruals and annual targets displayed on a bar chart). Trial accrual demographics are displayed as percentages of total accrual.

5. Lessons Learned and Future Directions

The dashboards will go live in the spring of 2023 and will provide an opportunity to streamline PRMS portfolio and monitoring reviews. Building the dashboards highlighted how some OnCore fields were underutilized and resulted in building new processes to include more data in OnCore that could be electronically accessed. The performance charts will augment PRMS reviews by displaying the multifaceted attributes that influence performance assessments. The dashboards display accrual and demographic trends that will highlight recruitment efforts needing improvement and enhance collaborations with the Office of Community Outreach and Engagement. In the future, we plan to include additional data sources, like catchment area demographics, to highlight the adequacy of recruitment plans and policies. The dashboards will evolve with stakeholder feedback and in conjunction with institutional priorities in diversity and equity.

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