AACI CRI
Clinical Research Innovation

PARTNERING IN PROGRESS

2022 ABSTRACTS AND POSTERS

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Abstracts and posters are organized by category and completion status, then in alphabetical order by cancer center. Abstracts accompanied by posters appear first, followed by abstracts without posters.

CATEGORIES:

- Clinical Trial Operations
- Finance/CCSG/PRMS
- Investigator-Initiated Trials
- Quality Assurance, Remote Monitoring, and Auditing
- Regulatory
- Training and Career Development
- Trial Recruitment & Community Outreach and Engagement
- Trial Start-up and Activation

ABSTRACTS AND POSTERS

Clinical Trial Operations

* *Honorable Mention*

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Finance/CCSG/PRMS

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ABSTRACTS

Clinical Trial Operations

* *Honorable Mention*

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14th Annual AACI CRI Meeting: Partnering in Progress

From July 12-14, 2022, AACI's Clinical Research Innovation (CRI) convened its 14th annual meeting and first in-person meeting since 2019. The 444 in-person attendees (with an additional 117 joining online) included clinical research office leaders, medical directors, cancer center administrators, patient advocates, and representatives from government and industry.

Several meeting sessions focused on diversity, equity, and inclusion (DEI). Other panel discussion topics included barriers to clinical trial participation; technology; clinical trial feasibility; and preparing for the National Cancer Institute's (NCI) Cancer Center Support Grant (CCSG). In addition, breakout sessions covered issues such as trial activation outside the clinical trials office (CTO), trial management, the Cognizant Shared Investigator Platform, investigator-initiated trials, and community trial sites.

During a keynote conversation between Monique Phillips, Bristol Myers Squibb; and Kimberly Richardson, Black Cancer Collective, Phillips and Richardson highlighted the importance of authentically engaging with communities; developing a "shared language" for describing clinical research; and mentoring interns, fellows, and other emerging researchers from diverse backgrounds.

In another session focusing on community outreach, panelists explored social determinants of health, representation of diverse groups in clinical trials, health literacy, and managing misinformation and distrust among potential trial participants. Similarly, two other sessions—"Meeting Our Patients on Their Terms" and "Integrating the CTO With Community Outreach and Engagement"—addressed issues such as obstacles to clinical trial participation and operational aspects of opening clinical trials to the community.

A discussion with the NCI's Dr. Krzysztof Ptak provided a detailed overview of the latest changes to the NCI's CCSG, including efforts to expand DEI activities and the impact of COVID-19 on clinical trial capacity.

Authors from 28 cancer centers submitted 74 abstracts for the meeting. This year's submissions reflected an increase in collaboration between AACI members, vendors, and community partners. Abstract authors Josefina Sanchez, Sylvester Comprehensive Cancer Center, University of Miami Health System; Dr. Erin Hastings Monari, University of Florida Health Cancer Center; and Angela Fritsche, Mayo Clinic Comprehensive Cancer Center, presented their winning abstracts and posters during the meeting. An additional seven abstracts—one from each category—received honorable mentions; all abstracts and posters submitted to this year's meeting are collected in this book.

CRI meeting supporters worked with AACI to create a meeting environment conducive to learning, networking, and strategic innovation. In addition to participating in plenary sessions and poster discussions, this year's CRI meeting attendees also had an opportunity to interact with 16 contracted exhibitors that each demonstrate a strong commitment to working with academic cancer centers to help solve operational challenges.

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PARTNERING IN PROGRESS

2022 ABSTRACTS AND POSTERS

PARTNERING IN PROGRESS

CLINICAL TRIAL OPERATIONS

Clinical Trial Office Response to COVID-19 at an Academic Comprehensive Cancer Center

E. Bentlyewski, F. Brogan, R. Shelton, J. Jurcic, A. Lassman
Herbert Irving Comprehensive Cancer Center, Columbia University Irving Medical Center

1. Background

The COVID-19 pandemic challenged our department to adapt existing workflows to maintain high quality cancer care and clinical trial compliance. Limited patient access to campus altered the way trial procedures were conducted. Clinical research staff, including research nurses, were redeployed to other departments within the institution. Limited hospital bed availability due to COVID-19 proved difficult for our cancer clinical trial patients.

2. Goals

To evaluate practice alterations in response to the COVID-19 pandemic, including redeployment of research staff, decreasing research activities, utilizing telehealth, shipping oral study agents, and coordinating inpatient admissions for patients actively on trial who require hospitalization.

3. Solutions and Methods

Our department has staff of 25 research nurses and research nurse practitioners who work primarily in assigned disease-based teams and assume all clinical care for patients on study. One-third of the nursing staff were redeployed to other clinical departments. In response, remaining nurses filled these gaps in coverage. This was possible because of standardization of policies and procedures throughout our department.

Many of our patients travel from out of state for clinical trial and had difficulties coming to New York. For these patients, we performed remote telehealth visits where feasible. If possible, we performed laboratory and other assessments locally and shipped oral study drugs directly to patients. This involved careful coordination to ensure investigational product stability and maintain patient safety.

Cancer center leadership recognized the continued need to provide excellent cancer care and access to clinical trials during the pandemic while mitigating risk. To reconcile these competing needs, we carefully decreased our study activities while maintaining care of active patients and still offering patients access to trials with potential therapeutic benefit. Enrollment to trials was paused with a review process implemented to request exceptions for accrual of new patients to existing studies. No exception requests were denied.

4. Outcomes

Standardized workflows aided in cross coverage between disease team research nurses and research coordinators.

Obtaining local laboratory and imaging assessments, use of telehealth and direct shipment of oral study agents to patients helped maintain protocol adherence and mitigate COVID-19 exposure risk.

Careful ramp-down of research activities prioritized studies with potential therapeutic benefit. This allowed us to adhere to university research restrictions and maintain patient access to clinical trials with potential benefit.

5. Lessons Learned and Future Directions

The pandemic experience demonstrated that clinical trials offices must remain nimble to adapt to large-scale disruptions. Standardized workflows, training, and competencies allowed the continued conduct of clinical trials while many staff members were redeployed to departments. The use of telehealth and local assessments was beneficial and can be applied more widely to allow patient-centered care closer to their home.

Clinical Trial Office response to Covid-19 at an Academic Comprehensive Cancer Center

Edward Bentlyewski, MSN, APN, NP-C, AOCNP®, CCRP, Fran Brogan, MSN, RN, OCN®, CCRP, Ryan Shelton, BA, Joseph Jurcic MD, Andrew Lassman, MD, MS

INTRODUCTION

The Covid-19 pandemic challenged our department to adapt existing workflows to maintain high quality cancer care and clinical trial compliance.

- Limited patient access to campus altered the way trial procedures were conducted.
- Clinical research staff, including Research Nurses, were redeployed to other departments within the institution.
- Limited hospital bed availability due to Covid-19 proved difficult for our cancer clinical trial patients.

PURPOSE

To evaluate practice alterations in response to the Covid-19 pandemic, including redeployment of research staff, decreasing research activities, utilizing telehealth, shipping oral study agents, and coordinating inpatient admissions for patients actively on trial who require hospitalization

OBSERVATIONS

- 25 Oncology Research Nurses and NPs are assigned to one of 10 disease-based teams and assume all clinical care on study
- 33% were re-deployed to support Covid-19 related research
- Remaining nurses & NPs provided coverage for other disease teams.
- This was possible because of standardization of policies and procedures throughout our department.
- Travel and social distancing restrictions made it difficult for many of our patients to come on site
- Visits converted to telehealth when possible. This posed some medical legal/ technical and reimbursement challenges.
- Where feasible we had laboratory and other assessments performed locally
- Oral study drugs were shipped directly to patients. This involved careful coordination to ensure investigational product stability and maintain patient safety.

OBSERVATIONS, CONT.

Cancer Center leadership recognized the continued need to provide excellent cancer care and access to clinical trials during the pandemic while mitigating risk. To reconcile these competing needs, we carefully decreased our study activities while maintaining care of active patients and still offering patients access to trials with potential therapeutic benefit. Enrollment to trials was paused with a review process implemented to request exceptions for accrual of new patients to existing studies. No exception requests were denied.

CONCLUSIONS

- Clinical Trials Offices must remain nimble to adapt to large-scale disruptions.
- Standardized workflows, training, and competencies are vital to safe conduct of clinical trials .
- Clinical Trial operations may need to be curtailed
- Telehealth and local study assessments can be applied more widely to allow more convenient and patient-centered care

CTO Benchmarking Study

M. Contreraz, T. Lautenschlaeger, K. Lee, K. Miller, B. Hicks, A. Sands, F. Bhimani, M. Gee, T. Hanson, and B. Richardson
Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. Background

At the height of the COVID-19 pandemic, the clinical trials office (CTO) suffered a significant staff shortage (>15 full-time equivalent, or FTE) due to a university-wide hiring freeze preventing replacement of departing CTO staff. After persistent advocacy on behalf of the CTO, a performance review of the CTO was requested.

2. Goals

Key questions were aimed to:

a) Compare staff number and type, trial mix, and funding sources among CTOs
b) Understand collaboration and integration of cancer center CTOs within the larger university/ hospital system, focus on clinical trial site information (CTSI)
c) Understand decision making processes and locus of control

Key hypotheses were that large organizations enjoy economies of scale, less siloed organizations are more efficient, and that high performing CTOs are closely integrated with the rest of the cancer research and institutional infrastructure.

3. Methods and Solutions

We partnered with the Indiana University (IU) Kelley School of Business, enlisting five MBA students to conduct the performance review under Kelley faculty supervision. The study was conducted over a three-month period in the spring of 2021. Nine de-identified NCI-Designated Cancer Center CTOs participated. Data was collected for 2018-2020. The main performance metric was total accrual volume per CTO FTE.

4. Outcomes

Total CTO FTEs ranged from fewer than 80 to over 200, and total yearly accruals ranged from less than 2,000 to over 12,000. Institutions deemed high performing were described as having the following characteristics:

1. Metric-driven management processes
2. High level of financial control over trials with regular review periods
3. Higher number of administrative (versus direct patient/trial management) staff associated with higher performance/accrual efficiency

No correlation was observed between efficiency measures and integration with CTSIs or larger institutional infrastructure. CTO staff composition varied across institutions: 49 to 75 percent trial support staff; 14 to 32 percent regulatory, protocol development, and quality/education staff; and 11 to 19 percent administrative staff. Reliance on dedicated research nurses also varied substantially, ranging from 5 to 40 percent of trial support staff. CTO funding sources varied as well, with industry contracts accounting for <10 to >80 percent and health system support ranging from 0 to >60 percent. All centers faced substantial (+/- 15 percent or more) year to year variance in total funding, limiting financial stability.

5. Lessons Learned and Future Directions

Based on this benchmarking study, institutional leaders' view of the CTO shifted favorably, and the CTO was allowed to resume hiring and request new positions. The CTO plans to shift our staffing model through attrition, relying less on research nurses and more on non-licensed research professionals to support lower complexity trials. Significant fluctuation in yearly budgets complicates long-term financial planning for CTOs.

IUSCCC CTO Benchmarking

Mario Contreraz, MBA, MSN, RN; Tim Lautenschlaeger, MD; Bethany Hicks; Alex Sands; Farrah Bhimani; Megan Gee; Trace Hanson; Blake Richardson; Kelvin Lee, MD, Kathy Miller, MD.
Indiana University School of Medicine, Indiana University Kelley School of Business

Background

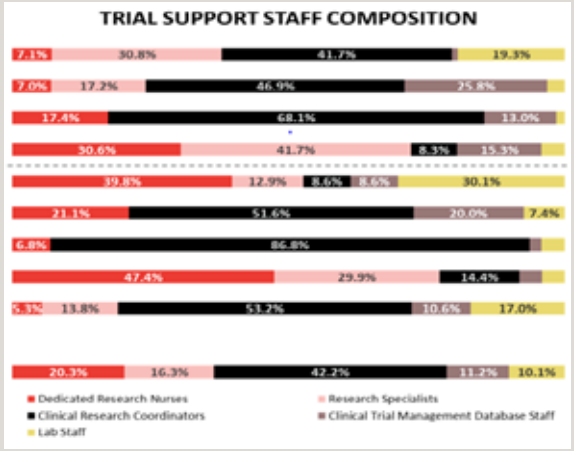
At the height of the Covid-19 pandemic, the Clinical Trials Office (CTO) suffered a significant staff shortage (>15 full-time equivalent FTE) due to a University-wide hiring freeze preventing replacement of departing CTO staff. After persistent advocacy on behalf of the CTO, a performance review of the CTO was requested.

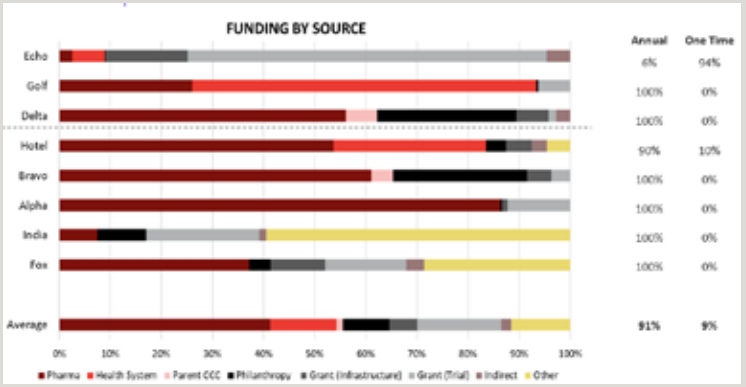
Materials & Methods

IUSCCC partnered with the Indiana University (IU) Kelley business school, enlisting five MBA students to conduct the performance review under Kelley school faculty supervision.

The study was conducted over a three month period in the spring of 2021, and included nine de-identified NCI-Designated Cancer Centers.

Data was collected for 2018-2020.





Results

Total CTO FTEs ranged from less than 80 to over 200, and total yearly accruals ranged from less than 2000 to over 12000. Institutions deemed high performing were described as having the following characteristics:

- Exhibit metric-driven management processes,
- High level of financial control over trials with regular review periods,
- Higher number of administrative (versus direct patient/trial management) staff was associated with higher performance/accrual efficiency.

Results

CTO staff composition varied across institutions:

- 49 to 75% trial support staff, 14 to 32% regulatory, protocol development, and quality/education staff, and 11 to 19% administrative staff. Reliance on dedicated research nurses also varied substantially, ranging from 5 to 40% of trial support staff. CTO funding sources varied as well with industry contracts accounting for <10% to >80% and health system support ranging from 0% to >60%.
- All centers faced substantial (+/- 15% or more) year to year variance in total funding limiting financial stability.

Conclusions

Based on this benchmarking study, institutional leaders view of the CTO shifted favorably, and the CTO was allowed to resume hiring and request new positions.

Single Institution Experience of Integrating Radiation Oncology Clinical Research Into Comprehensive Cancer Center CTO

T. Lautenschlaeger, M. Contreraz, L. Rohn, T. Glendenning, L. Vaughn, R. Zellars, K. Lee, K. Miller
Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. Background

Radiation oncology (RO) clinical research experienced significant growth under new leadership from 2 therapeutic accruals in 2015 to 56 in 2020. This growth was mainly driven through a newly established departmental program supporting development of investigator-initiated trials. Of the 56 therapeutic accruals in 2020, 47 were to investigator-initiated clinical trials and 9 were to NCI's National Clinical Trials Network (NCTN) trials. Corresponding non-therapeutic and non-interventional accruals were 0 in 2015 and 22 in 2020. RO clinical research operations were supported by 5 full-time equivalent (FTE) staff funded by the RO department with some minor cost recovery through grants. The RO office was following most cancer center (CC) clinical trials office (CTO) standard operating procedures (SOPs) but was not under operational control of CTO.

2. Goals

- Provide operational oversight of RO clinical research activity
- Support RO principal investigators (PIs) with existing central CTO services including protocol development, regulatory, and finance support

3. Solutions and Methods

- Discussed rationale and need for radiation oncology research to be under CTO operational control with RO and CC leadership
- Identified stakeholder concerns and financial implications
- Crafted shared vision for expanded support of RO research and combined operations under a unified CTO
- Crafted transition plan in collaboration with RO leadership

4. Outcomes

RO stepwise integration proceeded from January to July 2021. Integration conditions, including funds flow and indirect cost distribution, was modeled based on previous CC CTO integration efforts. The first step was a change in reporting of existing RO staff to an experienced CTO team manager (previously reported to RO department administrator with limited research experience), tasked with review of training and processes to identify differences or deficiencies.

A key element of the second step was providing full access to central CTO resources to RO PIs, requiring use of these services for investigator-initiated trials (IITs) being submitted to the CC's scientific review committee (SRC) starting April 2021. The final step was the full transition of existing RO employees into the CTO, including cost-shifting salary for those employees to the CTO.

5. Lessons Learned and Future Directions

Despite a CC-wide charge back to the PI's department for support of active IITs, clinical research costs for the RO department are estimated to be significantly lower than before the transition. 2021 therapeutic clinical trial accruals were reduced in comparison to 2020 to n=27 (n=25 to IITs, 2 to NCTN), likely secondary due to staff turnover and COVID-19 pandemic. 2021 non-therapeutic and non-interventional accruals were stable at n=19. Of note, 3 out of 5 employees resigned during the transition despite significant efforts to avoid this. Currently 5 FTEs managed by a team manager are assigned to RO trials. In addition, full protocol development, finance, and dedicated regulatory support is in place. No change in number or overall quality of RO PI complaints is noted.

Single Institution Experience of Integrating Radiation Oncology Clinical Research Into Comprehensive Cancer Center CTO

Tim Lautenschlaeger, MD; Mario Contreraz, MBA, MSN, RN; Liz Rohn, MS; Tina Glendenning, BS; LaTrice Vaughn, RN; Amy Graf, RD; James Croop, MD; Bethany Hicks; Richard Zellars, MD; Kelvin Lee, MD; Kathy D Miller, MD.
Indiana University

Background

Radiation Oncology (RO) Clinical Research experienced significant growth under new leadership from 2 therapeutic accruals in 2015 to 56 in 2020. This growth was mainly driven through a newly established departmental program supporting development of investigator-initiated trials (IIT). Of the 56 therapeutic accruals in 2020, 47 were to IITs and 9 to NCI's National Clinical Trials Network (NCTN) trials. Corresponding non-therapeutic and non-interventional accruals were 0 in 2015 and 22 in 2020. RO Clinical Research operations were supported by 5 full-time equivalent (FTE) staff funded by the RO department. The RO office was following most Cancer Center (CC) Clinical Trials Office (CTO) standard operating procedures (SOPs) but was not under operational control of CTO.

Goals

- Provide operational oversight of RO clinical research activity.
- Support RO principal investigators (PIs) with existing central CTO services including protocol development, regulatory, and finance support.

Methods

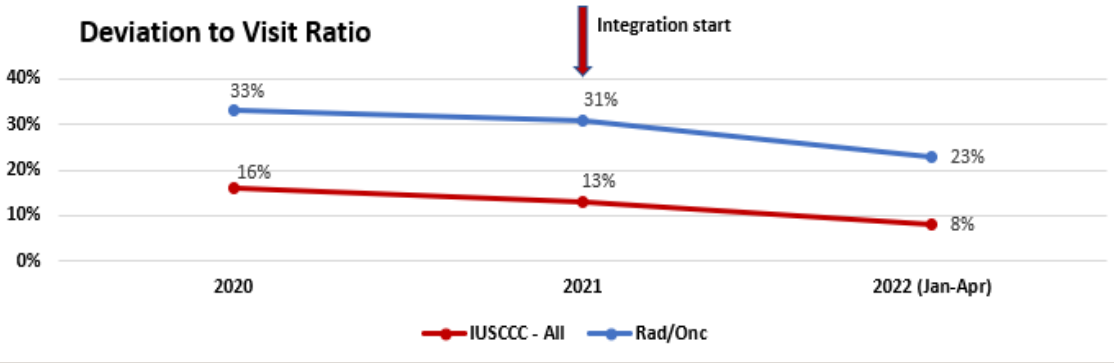
- Discussed rationale and need for radiation oncology research to be under CTO operational control with RO and CC leadership
- Identified stakeholder concerns and financial implications
- Crafted shared vision for expanded support of RO research and combined operations under a unified CTO
- Crafted transition plan in collaboration with RO leadership.

Results

RO integration proceeded from January to July 2021. The first step was a change in reporting of existing RO staff to an experienced CTO team manager, tasked with review of training and processes to identify differences or deficiencies. A key element of the second step was providing full access to central CTO resources to RO PIs, requiring use of CTO services for IITs. The final step was the full transition of existing RO employees into the CTO, including cost-shifting salaries. Despite a CC wide charge back to the PIs department for support of active IITs, clinical research costs for the RO department are lower than before the transition.

2021 therapeutic clinical trial accruals were reduced in comparison to 2020 to n=27 (n=25 to IITs, 2 to NCTN), likely secondary due to staff turnover and Covid-19 pandemic. 2021 non-therapeutic and non-interventional accruals were stable at n=19. Of note, three out of five employees resigned during the transition. Currently 5 CTO FTE plus a shared manager are assigned to RO trials. No change in number or quality of RO PI complaints is noted. Deviations are falling.

	2020		2021		2022 (Jan-April)	
	IUSCCC -all	Radonc	IUSCCC -all	Radonc	IUSCCC -all	Radonc
#total visits	7342	510	6925	440	2415	82
#total deviations	1152	170	892	138	192	19
%deviations to visits	16%	33%	13%	31%	8%	23%



Conclusions:

Longstanding efforts for RO integration led to initiation of integration in 2021. RO integration was successfully completed using a six-month transition plan, with deviations continuing to fall now over 24 months since start of the integration.

INDIANA UNIVERSITY MELVIN AND BREN SIMON COMPREHENSIVE CANCER CENTER

Successful Methods of Addressing Clinical Research Staff Turnover

N. Nahmias, J. Sanchez, A. Olier-Pino, A. Allred, K. Aviles, L. Corrales
Sylvester Comprehensive Cancer Center, University of Miami Health System

1. Background

At the beginning of the COVID-19 pandemic, the University of Miami issued a system-wide hiring freeze that prevented the Sylvester Comprehensive Cancer Center (SCCC) clinical research services (CRS) office from filling vacant positions between March and November 2020. As shown in the poster figure, turnover during this time resulted in a deficit of 24 employees.

2. Goals

Due to the increasing number of resignations from August to November 2020, CRS leadership outlined several proactive measures to combat vacancies in the office. The goal was to quickly identify, recruit, and hire clinical research staff members.

3. Solutions and Methods

To address this challenge, we developed innovative strategies to fill positions as quickly as possible including:

- Hiring Huddles, which met 3 times weekly with our human resource partners to monitor and discuss all open positions in clinical research
  - Through these huddles, the team began tracking data points throughout all stages of the hiring process and was able to identify the followings trends:
    - Delays in the timeline for approval of offers
    - Delays in the timeline for approval of position requests
    - Long timelines for salary negotiations
    - Lag in communication with candidates
- A hiring "SWAT team" to quickly interview and evaluate candidates for high-priority positions and site disease groups (SDGs) within 48 hours of application
  - All interviews with candidates for lower-priority positions were scheduled within 6 days and offers were made within 1 week of initial interview with a maximum of 2 interviews

4. Outcomes

Staff turnover continued into 2021 for a total loss of 73 employees since the start of the pandemic. With the initiation of the new hiring strategies, we have been able to hire 139 new staff members, while recovering from a hiring freeze, and working around multiple staff members being infected with the COVID-19 virus.

Due to the impact of high turnover on clinical research operations, we instituted a 30 percent over-hire model, in which we opened additional positions for all functional areas of the CRS. This method allowed us to provide coverage for staff that resign or are out of the office for extended periods of time without overburdening staff who would otherwise be required to carry the extra workload.

Through the Hiring Huddles and data collection process, we also documented that many of our staff members vacated SCCC positions for roles at our sponsor and CRO partners after being offered 40-100 percent salary increases, fully remote positions, and additional perks. In response, we reviewed existing, and created new, position ladders to increase salaries for the following positions:

- Clinical research coordinators
- Clinical research managers
- Clinical research nurses
- Regulatory staff

5. Lessons Learned and Future Directions

With the support of our clinical research leadership and human resources department, we will continue to restructure the CRS to streamline services, implement additional hybrid/remote work opportunities, and identify perks to offer employees, to ensure a robust clinical research services office for the Sylvester Comprehensive Cancer Center.

Successful Methods of Addressing Clinical Research Staff Turnover

Authors: Nancy Nahmias, BA[1], Josefina Sanchez, BS, CCRC[1], Angela Olier-Pino, DNP, APRN-BC, MBA[1], Angela Allred, BS[2], Katherine Aviles[1], Lindsay Corrales, MPH[1]
Institutions: [1]Sylvester Comprehensive Cancer Center, University of Miami; [2]Huron Consulting Group

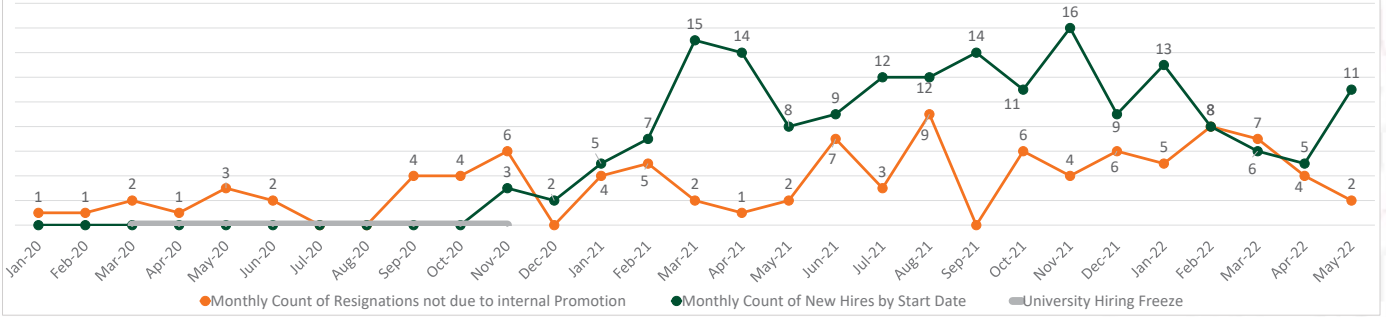
Background

At the beginning of the COVID-19 pandemic, the University of Miami issued a system-wide hiring freeze that prevented the Sylvester Comprehensive Cancer Center (SCCC) Clinical Research Services (CRS) office from filling vacant positions between March and November 2020. As shown in Figure 1, turnover during this time resulted in a deficit of 24 employees.

Goals

Due to the increasing number of resignations from August to November 2020, CRS leadership outlined several proactive measures to combat vacancies in the office. The goal was to quickly identify, recruit, and hire clinical research staff members.

Figure 1. Monthly Count of Resignations (excluding promotions) and New Hires (by start date) as of 5/16/2022



Methods

To address this challenge, we developed innovative strategies to fill positions as quickly as possible including:

- Due to the impact of high turnover on clinical research operations, we instituted a 30% over-hire model, in which we opened additional positions for all functional areas of the CRS.
- Organized Hiring Huddles which met 3 times weekly with our Human Resources partners to monitor and discuss all open positions in clinical research.
- Created a Hiring Task Force team to quickly interview and evaluate candidates for high-priority positions and Site Disease Groups (SDGs) within 48 hours of application. Reviewed all existing and planned position levels.

Outcome

Staff turnover continued into 2022 for a total loss of 99 employees since the pandemic started. Our new hiring strategies facilitated the hiring of 180 staff members while recovering from a hiring freeze and working around multiple staff members being infected with the COVID-19 virus (Figure 1).

This method allowed us to provide coverage for staff that resign or are out of the office for extended periods of time without overburdening staff who would otherwise be required to carry the extra workload.

Through the Hiring Huddles, the team tracked data points throughout all stages of the hiring process and was able to identify the following trends:

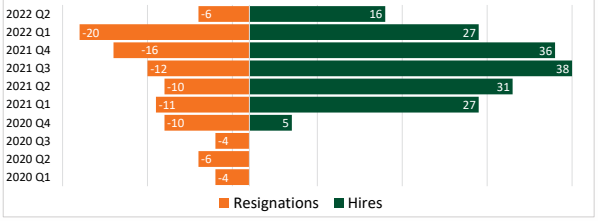
- Delays in offer approval timeline
- Delays in position request approval
- Delays in salary negotiation
- Lag in candidate communication

The Hiring Task Force scheduled all interviews with candidates for high-priority positions within 6 days and made offers within 1 week of initial interview.

We also documented that many of our staff members vacated SCCC positions for roles at our sponsor and CRO partners after being offered 40-100% salary increases, fully remote positions, and additional benefits. In response, we created new position ladders to increase salaries for the following positions:

- Clinical Research Coordinators
- Clinical Research Managers
- Clinical Research Nurses
- Clinical Research Data Specialists
- Regulatory Staff

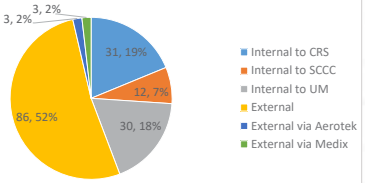
Figure 2. Resignations and Hires by Quarter as of 5/16/2022



Future Plans

With the support of our clinical research leadership and Human Resources department, we will continue to restructure the CRS to streamline services, implement additional hybrid/remote work opportunities, and identify perks to offer employees, to ensure a robust Clinical Research Services office for the Sylvester Comprehensive Cancer Center.

Figure 3. Filled Positions by Origin of Candidate as of 5/16/2022



eRegulatory Process and Software Implementation in Times of Crisis

J. Stern, R. Jones, C. Henrichs
Vanderbilt-Ingram Cancer Center

1. Background

The week of March 16, 2020, the staff of our clinical trials office began a sudden and immediate shift to full time remote work. All our original study documentation was maintained on paper. We were two months away from launching new eRegulatory software, Florence eBinders. There were many reasons to delay the implementation, but one solid reason for us not to: eSignatures (compliant with FDA 21 CFR Part 11 guidelines). This functionality has allowed us to not only continue research administration remotely, but to improve our turnaround times for processing regulatory documents during a pandemic. This is how we worked through those initial months of the pandemic into the present.

2. Goals

- Implement an organization-wide eSignature tool and document workflows
- Facilitate a remote/paperless environment
- Shift to remote monitoring and close-out to keep studies moving forward

3. Solutions and Methods

We paused our initial implementation to develop an interim process for eSignatures. Using Adobe eSignature and forms creation features, we developed processes/education for frequently used forms. We trained staff via video, written instruction sheets, online presentations, and one-to-one support sessions facilitated by our quality assurance and education department (QA&E). This took about two weeks.

It was frequently communicated that we would continue the implementation of our eRegulatory system. Florence staff worked with us to adapt their system training to this remote environment. It was important to not lose the momentum built in the planning phase, so we only paused long enough to assess if and how to move forward.

We provided abundant communication and follow-up when we finally did train for the system and updated processes. We did two weeks of supplemental departmental training developed in collaboration with our regulatory managers and QA&E to help staff clearly understand how these changes would affect them. Training was provided in multiple group sessions and follow-up videos. We also conducted virtual office hours and open group sessions for two weeks following the training to answer questions and provide hands-on demos.

Using this initial comprehensive training and communication model with our data and clinical implementations, we began processing SAEs, uploading eSource, and remote monitoring in Florence with all major implementation completed by April 2021.

4. Outcomes

- 60,000+ signatures (since July 2020)
- Signature receipt times from 3 to 4 weeks to an average of 6 days
- 9500+ eSource documents uploaded (since April 2021)
- 780+ SAEs signed-off (since January 2021)
- 800+ studies remotely managed and monitored (since July 2020)

5. Lessons Learned and Future Directions

- Additional administrative support would have been beneficial; the QA&E team had to de-prioritize quality-related and other educational activities to do low-skilled administrative tasks (i.e., converting documents to fillable forms)
- Clarify goals more than you think is needed; it is easy to lose sight of what needs to be accomplished in a high-stress and chaotic environment
- Follow up with staff to quicken integration into daily workflows

As we move forward with continuous improvement, we hope to focus on adding additional document workflows to Florence for clinical staff and to determine our risk threshold of eliminating paper documentation once it has been converted to eSource.

eRegulatory Process and Software Implementation in Times of Crisis

Jacqueline Stern, M.Ed., PMP; Rebecca Jones; Chelsea Henrichs
Vanderbilt-Ingram Cancer Center Clinical Trials Office, Vanderbilt University Medical Center, Nashville, TN

VANDERBILT UNIVERSITY MEDICAL CENTER

Background

The week of March 16, 2020, the staff of our Clinical Trials Office began a sudden and immediate shift to full time remote work. All our original study documentation was maintained on paper. We were two months away from launching a new eRegulatory software, Florence eBinders. There were many reasons to delay the implementation, but one solid reason for us not to: eSignatures (compliant with FDA 21 CFR Part 11 Guidelines). This functionality has allowed us to not only continue research administration remotely, but to improve our turn-around times for processing regulatory documents during a pandemic. This is how we worked through those initial months of the pandemic into the present.

Goals

- Implement an organization wide eSignature tool and document workflows
- Facilitate a remote/paperless environment
- Shift to remote monitoring and close-out to keep studies moving forward

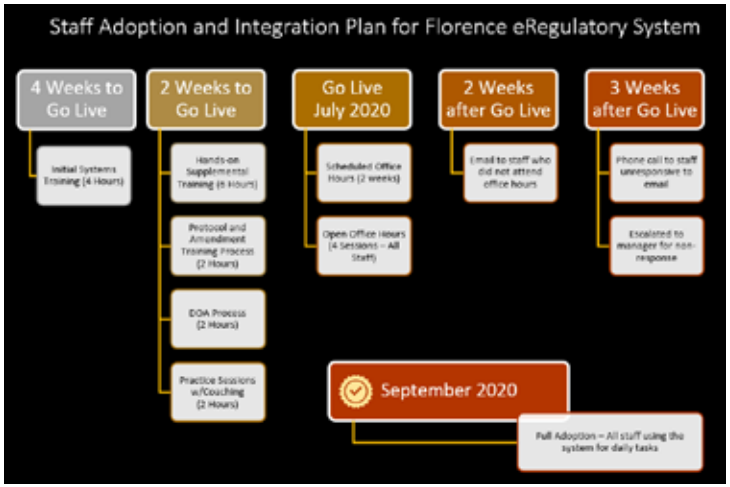


Figure: Training and Communication Model for Staff Adoption of Florence eBinders

Outcomes

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- Signature receipt times from 3 to 4 weeks to an average of 6 days
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Lessons Learned

- Additional admin support would have been beneficial. The QA&E team had to de-prioritize quality related and other educational activities to do low skilled admin tasks (i.e., converting documents to fillable forms).
- Clarify goals more than you think is needed. It is easy to lose sight of what needs to be accomplished in a high-stress and chaotic environment.
- Follow-up with staff to quicken integration into daily workflows.

Solutions and Methods

We paused our initial implementation to develop an interim process for eSignatures. Using Adobe eSignature and forms creation features, we developed processes/education for frequently used forms. We trained staff via video, written instruction sheets, online presentations, and one-to-one support sessions facilitated by our Quality Assurance and Education Department (QA&E). This took about two weeks.

It was frequently communicated that we would continue the implementation of our eRegulatory system. Florence staff worked with us to adapt their system training to this remote environment. It was important to not lose the momentum built in the planning phase, so we only paused long enough to assess if and how to move forward.

We provided abundant communication and follow-up when we finally did train for the system and updated processes. We did two weeks of supplemental departmental training developed in collaboration with our regulatory managers and QA&E to help staff clearly understand how these changes would affect them. Training was provided in multiple group sessions and follow-up videos. We also conducted virtual office hours and open group sessions for two weeks following the training to answer questions and provide hands-on demos.

Using this initial comprehensive training and communication model with our Data and Clinical implementations, we began processing SAEs, uploading eSource, and remote monitoring in Florence with all major implementation completed by April of 2021.

Future Directions

As we move forward with continuous improvement, we hope to focus on adding additional document workflows to Florence for clinical staff and to determine our risk threshold of eliminating paper documentation once it has been converted to eSource.

Contact: jacqueline.stern@vumc.org
Acknowledgements: Special thanks to VICC CTO Team Leads and staff that made this implementation possible during the 2020-2021 pandemic year.

VANDERBILT

VANDERBILT UNIVERSITY MEDICAL CENTER

NCI Designated Comprehensive Cancer Center

NCI National Clinical Trials Network
a National Cancer Institute program

VANDERBILT-INGRAM CANCER CENTER

Automated Reporting for Clinical Trial Operations

M. Rump, M. Kilbane, K. McCaffrey, B. Matia, J. Lindberg
Cleveland Clinic Cancer Center

1. Background

Day-to-day operations of a cancer center requires leveraging multiple sources of data from multiple systems. Data such as clinical trial accrual, start-up tasks and timelines, and protocol and subject deviations must be visible and accessible. Taussig Cancer Institute manages research operations across 12 different sites in northeast Ohio and Florida, with trials conducted across 18 program research groups (PRGs), running 239 active interventional trials (as of March 2022). Previously, reports were generated manually, either on a monthly or ad hoc basis. Automated reporting allows us to view critical operational data in real time.

2. Goals

- Provide cancer center leadership and management with accurate and up-to-date metrics for clinical trial operation, including tracking accruals, start-up times, and deviations
- Increase efficiencies with regard to trial oversight and regulatory management
- Ensure quality of trial data captured for NCI and other reporting purposes
- Free up time and resources for our research informatics team

3. Solutions and Methods

Data is primarily housed in the OnCore clinical trial management system. Oracle SQL is used to query the data, and the data is visualized using Tableau.

4. Outcomes

Currently we have automated three different reporting processes:

- Time to open: using the OnCore Tasklist functionality, we track designated milestones in the pending trial start-up process; teams review this data and are able to highlight barriers and holdups in the process
- Deviations: protocol and subject level deviations are tracked within OnCore, and the data can be reviewed in individual PRG meetings and in a monthly compliance meeting
- Accrual: clinical trial accrual is tracked in near real time by PRG and broken down by enrolling site and trial type

Both accrual and deviation reports have resulted in significant time savings (15 hours per month for accruals, 8 hours for deviations).

5. Lessons Learned and Future Directions

As a matrix style comprehensive cancer center (in collaboration with Case Western Reserve University and University Hospitals Cleveland), we found it difficult to report out data pertaining only to Taussig, and existing applications did not fill this gap. Our automating processes have allowed us to generate data relevant to Taussig clinical trial operations only. Adding visibility to the data has highlighted the need for rigorous QA of data entered into OnCore, and we will be expanding our efforts here. Moving forward we will continue to develop additional reports and visualizations, including expanding our trial start-up analysis, PRG specific dashboards and metrics, and tracking compliance and monitoring results for internal investigator-initiated trials.

Automated Reporting for Clinical Trial Operations

M. Kilbane, J. Lindberg, B. Matia, K. McCaffrey, M. Rump
Taussig Cancer Institute

Background:
Day to day operations of a cancer center requires leveraging multiples sources of data from multiple systems. Data such as clinical trial accrual, startup tasks and timelines, and protocol and subject deviations must be visible and accessible. Taussig Cancer Institute manages research operations across 12 different sites in northeast Ohio and Florida, with trials conducted across 18 Program Research Groups (PRGs), running 239 active Interventional trials (as of March 2022). Previously, reports were generated manually, either on a monthly or ad hoc basis. Automated reporting allows us to view critical operational data in real time.

Goals:
- Provide Cancer Center leadership and management accurate and up to date metrics for clinical trial operation, including tracking accruals, startup times, and deviations
- Increase efficiencies with regards to trial oversight and regulatory management
- Insure quality of trial data captured for NCI and other reporting purposes
- Free up time and resources for our Research Informatics team

Data is primarily housed in the OnCore clinical trial management system. Oracle SQL is used to query the data, and the data is visualized using Tableau.

Currently we have automated three different reporting processes:
- Time to Open: Using the OnCore Tasklist functionality, we track designated milestones in the pending trial start up process. Teams review this data and are able to highlight barriers and holdups in the process
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- Accrual: Clinical trial accrual is tracked in near real time, by PRG and broken down by enrolling site and trial type

Both accrual and deviation reports have resulted in significant time savings (15 hours per month for accruals, 8 hours for deviations)

Lessons Learned and Future Directions:
Being a matrix style Comprehensive Cancer Center (in collaboration with Case Western Reserve University and University Hospitals Cleveland), we found it difficult to report out data pertaining only to Taussig, and existing applications did not fill this gap. Our automating processes have allowed us to generate data relevant to Taussig Clinical Trial Operations only.

Adding visibility to the data has highlighted the need for rigorous QA of data entered into OnCore, and we will be expanding our efforts here.

Moving forward we will continue to develop additional reports and visualizations, including expanding our trial startup analysis, PRG specific dashboards and metrics, and tracking compliance and monitoring results for internal Investigator Initiated trials.

Clinical Research Coordinator Workload Estimation and Tracking

M. Repede, D. Beighley, K. Putz, A. Fritsche, G. Nowakowski
Mayo Clinic Comprehensive Cancer Center

1. Background

The Mayo Clinic Comprehensive Cancer Center clinical research office (CRO) in Rochester, MN employs about 90 clinical research coordinator (CRC) staff to support over 600 active studies including Phase I, II, and III clinical trials. Annually, about 250 trials are proposed for consideration and planning.

Historically, CRO supervisors utilized various tools to manage staffing. Estimating required effort for a trial involved exhaustive review of all support tasks. Conversely, staffing assignments relied on supervisor experience and intuition. Given the CRO's current scale and complexity, a better system was required to align CRC staffing to trial support workload.

2. Goals

The team sought to implement a comprehensive and integrated staffing to workload system. This was broken into three phases, each to be rolled out successively:

- Estimate CRC workload required to support a given study
- Track CRC staffing assignments and actual workload
- Align staffing to workload

3. Solutions and Methods

Two of the above goals have been realized.

First, a sizing tool was developed to estimate the CRC effort required to support a given trial. Based on the study protocol, a supervisor considers four study aspects (screening, active treatment, follow-up treatment, visits) and inputs several numeric values, including the number of trial participants and complexity (on a 1-7 scale) for various tasks. The tool then outputs required effort in per-study, per-patient, and per-visit units.

Next, a tracking tool was created for CRC staff to record the number of patients and visits they supported for each trial. Combined with effort values output from the sizing tool, total monthly efforts are calculated and used for monthly effort certification.

4. Outcomes

Five experienced individuals estimated eight studies utilizing two approaches: the exhaustive line-item tool, and the new sizing tool. The resulting effort estimates were, on average, within 5 percent of each other which confirmed the accuracy of the new tool. The line-item tool took 2-6 hours (depending on protocol complexity), compared to 10-45 minutes with the new tool. This time savings of 85-90 percent demonstrated significant improvement. Aggregated across 250 estimates per year, this saves the team eight person-months annually.

Ninety CRC staff piloted the tracking tool for three months. Compared to the previous system of logging daily how they spent their time, the new tracking tool reduced complexity by instead tracking patients and visits supported. This resulted in time 5-10 minutes saved per person, per day. Aggregated across the team, this is a savings of over 150 hours each month.

5. Lessons Learned and Future Directions

Introducing easy-to-use tools that reduce administrative burden has improved job satisfaction for supervisors creating estimates and CRCs tracking their work. Managers also value objective measures of the team's workload and feel more confident in their staffing decisions. Finally, investigators appreciate rapid estimate turnaround on trials they propose.

Opportunities to improve the existing system include refining workload estimates to better reflect post COVID-19 workflows and expanding the IT infrastructure to support backups and concurrent usage. The primary focus, though, is addressing the third goal of surfacing insights about staffing assignments and team capacity to enable supervisors and managers to effectively align staffing to workload.

Clinical Research Coordinator Workload Estimation and Tracking

Michael Repede, Dawn Beighley, M.S., Kimberly Putz, Angela Fritsche, M.P.A., Grzegorz Nowakowski, M.D. Mayo Clinic Comprehensive Cancer Center

ABSTRACT

BACKGROUND
The Mayo Clinic Comprehensive Cancer Center Clinical Research Office (CRO) in Rochester, MN employs about 90 Clinical Research Coordinator (CRC) staff to support 600+ active studies including Phase I, II, and III clinical trials. Annually, about 250 trials are proposed for consideration and planning.

OBJECTIVE
Historically, CRO supervisors used various tools to manage staffing. Estimating the required effort for a trial involved exhaustive review of all support tasks. Conversely, staffing assignments relied on supervisor experience and intuition. Given the CRO's current scale and complexity, a better system was required to align CRC staffing to trial support workload.

METHODS
A comprehensive and integrated staffing to workload system was broken into 3 phases, each to be rolled out successively:

1. **Sizing Tool:** Estimates CRC workload required to support a given study.
2. **Tracking Tool:** Monitors CRC staffing assignments and actual workload.
3. **Management Tool:** Aligns staffing to workload.

RESULTS
The first two phases are complete. Tooling has been validated, refined, and adopted by the team to size the workload for, and track the effort on, each trial.

CONCLUSION
CRC staff, supervisors, managers, and investigators all benefit from tools that produce results quickly and easily.

SOLUTIONS AND METHODS

Two of the project phases have been realized:

- A Sizing Tool was developed to estimate the CRC effort required to support a given trial. Based on the study protocol, a supervisor considers four study aspects (screening, active treatment, follow-up treatment, visits) and inputs several numeric values, including the number of trial participants and complexity (on a 1-7 scale) for various tasks. The tool then outputs required effort in per-study, per-patient, and per-visit units.
- A Tracking Tool was also created for CRC staff to record the number of patients and visits they supported for each trial. Combined with effort values output from the Sizing Tool, total monthly efforts are calculated and used for monthly effort certification.

SIZING TOOL RESULTS

5 experienced individuals estimated 8 studies utilizing 2 approaches: the exhaustive and incumbent Line-Item Tool, and the new Sizing Tool. Table 1 shows effort estimates were, on average, within ~2% of each other – confirming the accuracy of the new tool. Table 2 shows that staff required ~90% less time to create estimates using the new Sizing Tool (an aggregate savings of 27 hours over 8 studies) – demonstrating significant reduction in administrative burden.

TABLE 1:
Calculated CRC Effort Estimate (hours)

Trial #	Line-Item Tool	New Sizing Tool	Delta
1	3,408	3,375	-1.0%
2	12,316	12,330	+0.1%
3	685	670	-2.2%
4	5,280	5,313	+0.6%
5	2,705	2,835	+4.8%
6	2,315	2,404	+3.8%
7	3,305	3,225	-2.4%
*8	2,795	3361	+20.3%
Average	**32,809**	**33,513**	**+2.1%**

TABLE 2:
Estimate Creation Time (hours)

Trial #	Line-Item Tool	New Sizing Tool	Delta
1	4	0.50	-87.5%
2	6	0.75	-87.5%
3	2	0.15	-92.5%
4	5	0.50	-90.0%
5	3	0.25	-91.7%
6	3	0.25	-91.7%
7	4	0.25	-93.8%
8	3	0.25	-91.7%
Total	**30**	**2.90**	**-90.3%**

*This trial's PI asserted the new Sizing Tool better reflected the actual CRC support required.

DISCUSSION

The third project phase of developing the Management Tool to align staffing to workload is currently under way. The goal is to surface insights about staffing assignments and team capacity, to enable supervisors and managers to effectively align staffing to workload.

Concurrently, the team is exploring opportunities to improve the Sizing Tool and Tracking Tool. Examples include:

- Refine workload estimates to better reflect post COVID-19 workflows.
- Expand the IT infrastructure to support backups and concurrent usage.

CONCLUSIONS

- Introducing easy-to-use tools that reduce administrative burden has improved job satisfaction for supervisors creating estimates and CRCs tracking their work.
- Managers value objective measures of the team's workload and feel more confident in their staffing decisions.
- Investigators appreciate rapid estimate turnaround on trials they propose.

Data Talks: Using Non-Compliance Tracking to Improve Patient Safety

E. Harms, N. Borror, E. Menne
Siteman Cancer Center

1. Background

Since 2012, the division of oncology has tracked reportable non-compliances (also known as major deviations), defined as changes in research made without prior institutional review board (IRB) approval that have the potential to negatively impact the rights, safety, or welfare of a participant. Non-compliance tracking was managed by various teams over the years and tracking terminology was not standardized, resulting in inconsistent categorization and unreliable non-compliance data.

While the reportable non-compliances were reviewed monthly by management, aggregate data was not analyzed for trends, leading to missed opportunities to prevent future non-compliances (i.e., by establishing re-education plans).

2. Goals

- Analyze current categorization to determine areas for improvement
- Update and standardize terminology to eliminate redundant and mislabeled non-compliances
- Re-categorize historical data to increase sample set for analysis
- Establish a method to improve consistent categorization moving forward
- Develop plan for continued aggregate data review
- Identify trends and present to stakeholders

3. Solutions and Methods

After reviewing available non-compliance data, the quality assurance (QA) team found that the current tracking system did not clearly define non-compliance types or include tracking guidelines. User interpretation of non-compliance categories varied, leading to similar non-compliances being tracked differently. Additionally, new categories were created for each unique non-compliance, resulting in 18 different "types" of non-compliances.

In response to these issues, we simplified the possible non-compliance types to seven categories: consent, IRB submissions/approvals, standard operating procedures, study procedures, treatment, and other (to capture one-off situations). We also clarified subtype terminology and created a reference key with examples to ensure all users categorize in a consistent manner.

Utilizing the updated terminology, we re-categorized and analyzed data from 2015-2021. We implemented quarterly management presentations on annual data and team-specific trends.

4. Outcomes

Upon full review of the system and tracking methods, we found areas to improve our tracker and developed strategies to maximize its impact. While we gained insight on historical non-compliances, the plan for how to utilize that knowledge moving forward is still in progress. We expect improved tracking will lead to improved data, which will better inform our priorities for re-education, staffing, standard operating procedures, and protocol development.

5. Lessons Learned and Future Directions

We learned the importance of clear guidelines and consistent execution, especially when it comes to shared tools. We will continue to track non-compliances using the new category system. Quarterly presentation of aggregate data will serve to better inform our leaders and more quickly identify trends in non-compliances. We will partner with our division's education and training team to target areas needing re-education. By collecting clear and consistent data on errors made, we will use the knowledge gained to create tools and training aimed at improving patient safety and clinical trial data.

Division of Oncology

Data Talks:
Using Non-Compliance Tracking to Improve Patient Safety

Emily Harms, MA, CCRP, Nancy Borror, BA, CCRP, Elizabeth Menne, RN, BSN, OCN

Washington University in St. Louis School of Medicine

Background

Reportable non-compliances (also known as major deviations) are defined as *changes in research made without prior IRB approval that have the potential to negatively impact the rights, safety, or welfare of a participant*. Since 2012, non-compliance tracking has been managed by various teams without standardized guidelines or terminology.

This resulted in:

- variation in user interpretation of non-compliance categories, leading to unreliable data and inconsistent tracking (i.e. similar non-compliances were categorized differently)
- creation of new categories for each uncommon non-compliance, resulting in 18 different "types" of non-compliances

Additionally, while the reportable non-compliances were reviewed monthly by management, aggregate data was not analyzed for trends, leading to missed opportunities to prevent future non-compliances (e.g. by establishing re-education plans). To improve the quality of our data and better inform our leadership, we needed to investigate areas for improvement.

Goals

Standardize	terminology to eliminate redundant and mislabeled non-compliances
Create	method to improve consistent categorization
Re-categorize	historical data to increase sample set for analysis
Develop	plan for continued aggregate data review
Present	data analysis and trends to stakeholders

Methods and Outcomes

We simplified the possible non-compliance types to 7 categories.
We now have a reference key with examples to ensure all users categorize in a consistent manner.
We updated data from 2015-2021 with the new standardized terminology.
We will analyze and present data to management on a quarterly basis.
We reviewed historical (2015-2021) and quarter 1 data with management in April 2022.

Standardize Outcome Illustrated

Create Outcome Illustrated

Type	Sub-type	Examples
Treatment	Dosing hold/reduction/ discontinuation error	Two patients were given incorrect dose reductions when resuming treatment after a dose hold. Patient treated beyond progression without medical monitor's approval.
	Infusion administration error	Patient's infusion was restarted at the original infusion rate after an immune-related reaction rather than 50% of the original rate, as mandated per protocol.
	Prescription or dispensing error	Patient was dispensed expired study medication. Study drug was mixed with 50 ml 0.9% Sodium Chloride instead of 100 ml.
	Prohibited meds administered	Two patients took medications known to prolong QT interval, contrary to protocol requirements.

Lessons Learned & Future Directions

We learned the importance of clear guidelines and consistent execution, especially when it comes to shared tools. We expect improved tracking will lead to improved data, which will better inform our priorities for re-education, staffing, standard operating procedures, and protocol development.

We will continue to track non-compliances using the new category system and reference key. Quarterly presentation of aggregate data will serve to better inform our leaders and more quickly identify trends in non-compliances.

The 2022 Q1 analysis has already been presented, with managers utilizing the insights learned to set goals for Q2. We have partnered with our Division's Education & Training Team to target areas needing re-education, starting with an upcoming staff presentation on the types and frequency of non-compliances occurring across all teams.

In conclusion, by collecting, analyzing, and communicating clear and consistent data on errors made, our leaders and collaborators can use the knowledge gained to create meaningful tools and training aimed at improving patient safety and clinical trial data.

SITEMAN CANCER CENTER | Barnes-Jewish Hospital | Washington University in St. Louis School of Medicine

Digital Transformation of Sylvester Comprehensive Cancer Center Research Lab: A Work in Progress

P. Seo, A. Bivin-Martinez, J. Trent
Sylvester Comprehensive Cancer Center, University of Miami Health System

1. Background

Sylvester Comprehensive Cancer Center (SCCC) research lab (RL) is the central hub for research sample processing and shipping. Nearly all documentation is paper based. Previously, every requisition, invoice, and storage record was copied three times to be stored in the lab study folder, invoiced, or long-term stored, respectively. Requests for documentation from the lab were scanned, sent with email reply, and saved on RL staff's local computer. These replicative processes took valuable time from sample processing and shipping. The excessive "paper chase" was overwhelming staff and saving copies on private computers was inefficient. Starting in April 2021, the SCCC RL began a project to transition documentation from paper-based to electronic. We aimed to decrease the paper burden and increase efficiency and accuracy with a "data at your fingertips" model. As metrics, we analyzed the number of sample inquiries and conducted a satisfaction survey.

2. Solutions and Methods

RL conducted a workflow analysis of activities prior to and after sample collection and identified processes to transition to electronic formats. The first workflow change was to provide documentation to the research teams within 24-48 hours of the study visit. In late April 2021, RL started scanning sample documentation (research requisition, sponsor shipping manifests, tracking labels, or RL documents denoting storage for future batch shipping) onto a SCCC RL shared server. This location was selected over proprietary cloud-based storage because SCCC IT can immediately retrieve the twice-daily saved versions in the event of accidental deletion. All research teams were given access to the RL folders identified by protocol number.

3. Outcomes

Sample inquiries from the period of January 2021 until February 2022 were reviewed. From January–April 2021 there were, on average, 28 inquires per month (range 11–41). May–August 2021 averaged 11 inquiries per month (range 7–21). September–December 2021 averaged 3 inquires per month (range 1–5). A comparison of inquires before and after April 2021 reflected a 90 percent decrease in inquiries (28 vs. 3 per month). Although only two months, January–February 2022 averaged 4 inquires per month (range 3–5) perhaps showing plateauing to a steady number of 3–4 inquiries per month. The satisfaction survey revealed that only 25 percent of the 2021 research staff remained employed in February 2022, primarily due to COVID-workforce changes. Therefore, satisfaction survey data was not analyzed because it would not be representative.

4. Lessons Learned and Future Directions

SCCC RL has embarked on a digital transformation and our aim to provide immediate access to data has been very effective. More improvements in 2021 included implementation of a quality control process with an Adobe sign-certified form used for research kit review, creation of an electronic document repository of frequently requested RL documents, and a view-only freezer inventory datafiles. We are presently planning an implementation of a lab management system for ordering requests and an implementation of an inventory system to track equipment, research kits, and shipping supplies. We are developing an electronic medical record research draw order and a customized schedule to view patient appointments.

Digital Transformation of Sylvester Comprehensive Cancer Center Research Lab: A Work in Progress

Pearl H. Seo, MD MPH; Allison Bivin-Martinez, Jonathan Trent, MD PhD
Sylvester Comprehensive Cancer Center, University of Miami, Miami, FL.

Background

Sylvester Comprehensive Cancer Center (SCCC) Research Lab is the central hub for research sample requests and processing. Customized to research requirements, nearly all requests and documentation are on paper. Previously, Research Lab staff would photocopy each paper three times to store in the Research Lab study visit folder, to invoice and long-term storage respectively. When replying to sample queries, Research Lab attached scanned documents to the email reply using the document saved on Research Lab staff's local computer.

These replicative processes took time away from sample processing and shipping; while the feeling of "chasing paper" was overwhelming and saving copies on private computers was counterproductive. Therefore, SCCC Research Lab started a project to transition documentation into electronic formats. We aimed to improve efficiency by decreasing the paper burden and implement a "data at your fingertips" model.

Methods:

Research Lab created a workflow of activities prior to and after sample collection and identified high-impact, paper-based processes to transition to electronic formats.

Since sample information and delivery tracking need to be relayed to the sponsor, the first change was to provide sample information to the research teams within 24- 48 hours of the study visit. In late April 2021, Research Lab incorporated scanning of completed sample documents (phlebotomy collection requisition, sponsor manifest documents and shipping tracking label or Research Lab document denoting storage for future batch shipping) onto a SCCC Research Lab shared server divided into folders by protocol. In addition, Research Lab uploaded logs of temperatures, calibrations and laboratory reference ranges onto the shared server. This location was selected over proprietary cloud-based storage because the server is saved twice a day and the SCCC IT department can immediately retrieve prior saved versions in the event of accidental deletion, which would be difficult with proprietary storage services. All research teams were given access to the Research Lab folders.

Metrics analyzed were the number of queries to the Research Lab sent from the Clinical Research teams over a one-year period and evaluated satisfaction with a survey.

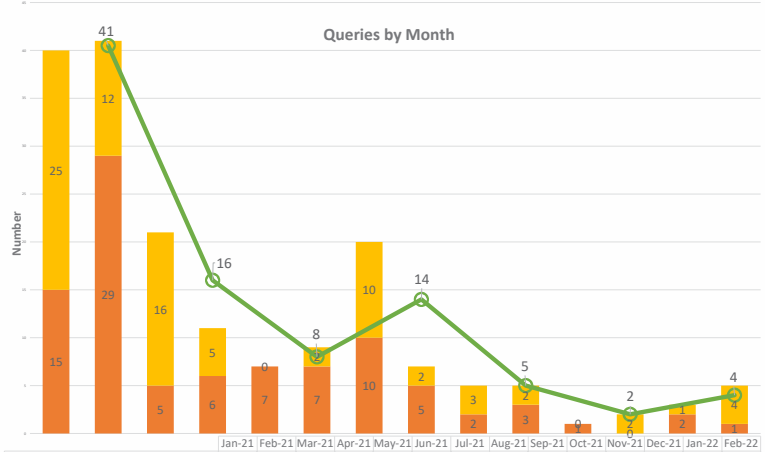
Results

We reviewed the number of queries from January 2021 until February 2022. We combined the query types into two groups. The first group were of queries about sample collection requisitions, Research Lab logs and references (yellow bars) . The second group were of queries related to sample shipping and batch shipping (orange bars)

From January to February 2021 there were a mean of 41 queries sent to Research Lab per month. In March – April 2021: mean 16 queries a month, May – June 2021: mean 8 queries a month, July – August 2021: mean 14 queries a month, September – October 2021: mean 5 queries a month, November – December 2021: mean 2 queries a month and January – February 2022: mean 4 queries a month were sent to Research Lab

Comparing February 2021 to August 2021, there was a 66% decrease in queries. Comparing August 2021 to Feb 2022, there was a 71% decrease in queries. Over the one-year period, February 2021 to February 2022, there was a 90% decrease in queries sent to Research Lab.

With the satisfaction survey, it was discovered only 25% of the 2021 research team remained in March 2022 due COVID-workforce changes, thus it was not analyzed because it would not be representative.



	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22
Collection Requisitions, Logs, References	25	12	16	5	0	2	10	2	3	2	0	2	1	4
Samples Shipping and Batch Shipping	15	29	5	6	7	7	10	5	2	3	1	0	2	1
Bi-Monthly Queries (Average)		41		16		8		14		5		2		4

Discussion and Conclusion

By scanning protocol related paper documents (phlebotomy collection requisitions, sponsor manifests, shipping labels etc.) and uploading them onto an accessible server, the number of queries sent to Research Lab has markedly decreased.

There was a notable uptick of queries in July 2021 because of two monitoring events asking for protocol visit dates in 2019 and 2020 which was prior to the start of Research Lab's scanning processes.

We presume that sponsor queries continue at a steady level every month, but the research personnel can find the answers for these queries themselves by accessing Research Lab documents without forwarding email to Research Lab. This improves the research team's time utilization and efficiency. Our changes to provide immediate data access have been very effective.

Future Efforts

SCCC Research Lab has successfully started its digital transformation and we have already made additional improvements. We have:

- implemented a quality control form with Adobe certified signature to document the research kit reception process.
- created a document repository for frequently requested Research Lab documents.
- provided view-only access to stored samples freezer inventory for the batch samples queries.

In the future, we plan on:

- installing a lab management system for direct scheduling and itemizing Research Lab processes.
- Installing a university-available inventory system to keep track of ordered research kit and supply stockroom.
- Using the electronic medical record for a research draw order and have a customized schedule to view patient appointments and arrivals since we are expanding research process into our Network sites.

* Implementing "Protected Time" to Increase Clinical Research Coordinator Data Entry Efficiency

J. Miller, S. Scheiner, C. Varnadoe-Rothman, S. Lopiano, N. Taylor, P. Garcia
The Tisch Cancer Institute at Mount Sinai

1. Background

Clinical research coordinators (CRC) bear many responsibilities, including, but not limited to, facilitating communications, data entry, sample processing, and regulatory reporting1, 2. CRCs on the genitourinary oncology team at Mount Sinai balance the completion of these tasks across a workload of approximately 30 active clinical trials. The myriad of daily responsibilities that require prolonged efforts are difficult to complete within sponsor-defined timelines. As a result, data delinquency continuously worsens. A literature review revealed that, while data entry is a task frequently performed by CRCs, few interventions to improve the research enterprise have been developed, implemented, and evaluated. Implementing the use of "protected time" was done to increase team efficiency and productivity and to address the outstanding data delinquency.

2. Goals

1. Decrease the number of data delinquencies >90 days old by >50 percent across all trials
2. Identify impact of protected time by comparing quantifying number of query responses and pages completed on days utilizing protected time versus days without for all CRCs for 6 months
3. Each CRC will increase number of queries responded to and pages completed by >25 percent when utilizing protected time for 6 months
4. Create an inclusive environment and empower coordinators by gathering feedback and engaging in weekly team discussions to improve process or incorporate new ideas over 6 months

3. Solutions and Methods

During weekly team meetings, each coordinator identifies and verbalizes their protected time for the upcoming week to their manager and teammates. The purpose of this protected time is to prioritize specific data entry and query resolution and to diminish interruptions. During this time coordinators place an automatic reply on their email and calendar to avoid interruptions. This step provides workload transparency. It also decreases the amount of pressure placed on the CRCs to multitask mitigating distractions and data entry errors. Weekly meetings are scheduled with the CRCs to discuss feedback and suggestions for this quality improvement process.

4. Outcomes

There is a positive change in the quantity of data queries resolved per day as a result of implementing protected time. Data analysis from November 2021 to February 2022 revealed CRC query resolution increases by an average of 42 percent on protected time days. As of February 2022, the delinquent data backlog for all trials in the GU portfolio has improved by 41 percent since November 2021. Positive verbal feedback from the CRCs has been given regarding the protected time workflow change. CRCs feel a decrease in pressure and can fully focus on addressing data delinquencies and find it is a supportive tool in task management.

5. Lessons Learned and Future Directions

Implementation of protected time is an effective method for prioritizing specific tasks and addressing data delinquencies. Consistently implementing weekly protected time for our team is not without challenges. A potential future solution is to determine a consistent day and time for each CRC to implement protected time weekly. Patient study visits are primarily scheduled for Tuesdays and Thursdays. Thus, assigning a time for each of our CRCs on Monday, Wednesday, or Friday would be effective.

Implementing this system may discourage sponsors from contacting or assigning tasks to CRCs during their protected time because this is communicated to them in the CRC's automatic email reply window. Creating a guidance document or SOP may be necessary to help ensure open communication and transparency between site and sponsor teams is preserved.

* *Honorable Mention*

Implementing “Protected Time” to Increase Clinical Research Coordinator Data Entry Efficiency

Justin Miller; Sylvia Scheiner; Sofia Lopiano; Nicole Taylor, MPH; Philip Garcia; Christa Varnadoe-Rothman, MSN, AGNP-C, OCN

Icahn School of Medicine at Mount Sinai

BACKGROUND

Clinical Research Coordinators bear many responsibilities, including, but not limited to, facilitating communications, data entry, sample processing, and regulatory reporting[1, 2].

CRCs on the Genitourinary Oncology team at Mount Sinai balance the completion of these tasks across a workload of approximately 30 active clinical trials. The myriad of daily responsibilities that require prolonged efforts are difficult to complete within sponsor-defined timelines. As a result, data delinquency continuously worsens. A literature review revealed that, while data entry is a task frequently performed by CRCs, few interventions to improve the research enterprise have been developed, implemented, and evaluated.

Implementing the use of “Protected Time” was done to increase team efficiency and productivity and to address the outstanding data delinquency.

METRICS/GOALS

1. Decrease the number of data delinquencies over >90 days old by >50% across all trials.
2. Identify impact of protected time by comparing quantifying number of query responses and pages completed on days utilizing protected time versus days without for all CRCs for 6 months
3. Each CRC will increase number of queries responded to and pages completed by >25% when utilizing protected time for 6 months
4. Create an inclusive environment and empower coordinators by gathering feedback and engaging in weekly team discussions to improve process or incorporate new ideas over 6 months

METHODS

During weekly team meetings, each coordinator identifies and verbalizes their “protected time” for the upcoming week to their manager and teammates. The purpose of this “protected time” is to prioritize specific data entry and query resolution and to diminish interruptions. During this time coordinators place an automatic reply on their email and calendar to avoid interruptions. This step provides workload transparency. It also decreases the amount of pressure placed on the CRCs to multitask mitigating distractions and data entry errors. Weekly meetings are scheduled with the CRCs to discuss feedback and suggestions for this quality improvement process.

RESULTS

There is a positive change in the quantity of data queries resolved per day as a result of implementing “protected time”. Data analysis from November 2021 to February 2022 revealed CRC query resolution increases by an average of 42% on “protected time” days. As of February 2022, the delinquent data backlog for all trials in the GU portfolio has improved by 41% since November 2021. Positive verbal feedback from the CRCs has been given regarding the protected time workflow change. CRCs feel a decrease in pressure and can fully focus on addressing data delinquencies and find it is a supportive tool in task management.

	Outstanding EDC Queries	Outstanding EDC Missing Pages	Outstanding Data Items Total
November 2021	391	80	471
February 2022	225	49	274
Net Change	-166	-31	-197
Percent Change (%)	-42.46	-38.75	-41.83

LESSONS/FUTURE DIRECTIONS

Implementation of “protected time” is an effective method for prioritizing specific tasks and addressing data delinquencies. Consistently implementing weekly “protected time” for our team is not without challenges. A potential future solution is to determine a consistent day and time for each CRC to implement “protected time” weekly. Patient study visits are primarily scheduled for Tuesdays and Thursdays. Thus, assigning a time for each of our CRCs on Monday, Wednesday or Friday would be effective.

Implementing this system may discourage sponsors from contacting or assigning tasks to CRCs during their “protected time” because this is communicated to them in the CRC’s automatic email reply window. Creating a guidance document or SOP may be necessary to help ensure open communication and transparency between site and sponsor teams is preserved.

ACKNOWLEDGEMENTS

We would like to thank the Genitourinary Oncology clinical research team for their hard work and willingness to contribute to this project. We would also like to thank the administration of the Cancer Clinical Trials Office for their support and encouragement.

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Study Start-up Dashboard

D. Mudaranhakam, S. Pepper, A. Tribitt
The University of Kansas Cancer Center

1. Background

The University of Kansas Cancer Center (KUCC) has a large volume of clinical trials that are proposed each year. The sheer variety and amount of these trials required the development of a comprehensive centralized system to track and manage them. This centralized system needs to provide an easy way to track metrics regarding the various studies throughout their lifetime, specifically where they are during the start-up process. The start-up process at KUCC involves many different regulatory committees evaluating prospective trials for feasibility. The metrics gathered from the centralized system regarding the start-up process will allow these management teams to make objective decisions regarding the future of these studies. Currently reports are generated weekly or built on demand regarding these metrics and distributed among the management teams, this project seeks to change that.

2. Goals

This project seeks to develop a dashboard that can generate user reports on demand and provide an easy overall transparent picture of where a study stands in the start-up process. This dashboard will pull data from a centralized database.

3. Solutions and Methods

Study data is entered into the Velos eCompliance system which acts as the centralized database. Automated SQL queries regularly dump the data from Velos where it is used to generate reports which are then distributed to the clinical trials office. Using a Shiny R dashboard users from the clinical trials office are empowered to get near real-time numbers through the dashboard reports instead of getting reports generated weekly.

4. Outcomes

The dashboard provides a level of transparency that was not currently available to study management, it allows for better planning and projection regarding the activation of trials and helps avoids conflicting study initiation, as shown in the poster figure.

5. Lessons Learned and Future Directions

Future projects will involve the development of more dashboards that track other metrics of the studies. Also, further refinements can be made to this by breaking down the start-up process into even more stages.

Bolstering the Study Startup Process and Technology for Oncology Trials

Dinesh Pal Mudaranthakam[1,2,4], Sam Pepper[1,2], Alexander Alsup[1,2], Qamar Khan[2],
Tara Lin[2], Natalie Streeter[2], Byron Gajewski[1,2], Matthew S Mayo[1,2]

The University of Kansas Cancer Center, Kansas City, KS, USA,

Introduction

The study startup process for clinical trial drugs is a long process that involves many different teams. Each team has their own study checklist which verifies that the necessary tasks are done before a study can move on to the next team. This regulation process provides quality assurance and is vital for ensuring patient safety. However, without having the process centralized, study approval can take a very long time as a study passes through many different hands. To facilitate this process the regulatory management, site development, cancer center administration, and the bioinformatics teams came together to build a platform aimed at streamlining the startup process and providing a transparent view of where a study is in the startup process.

GOALS

Develop a Centralized Study Startup System that:

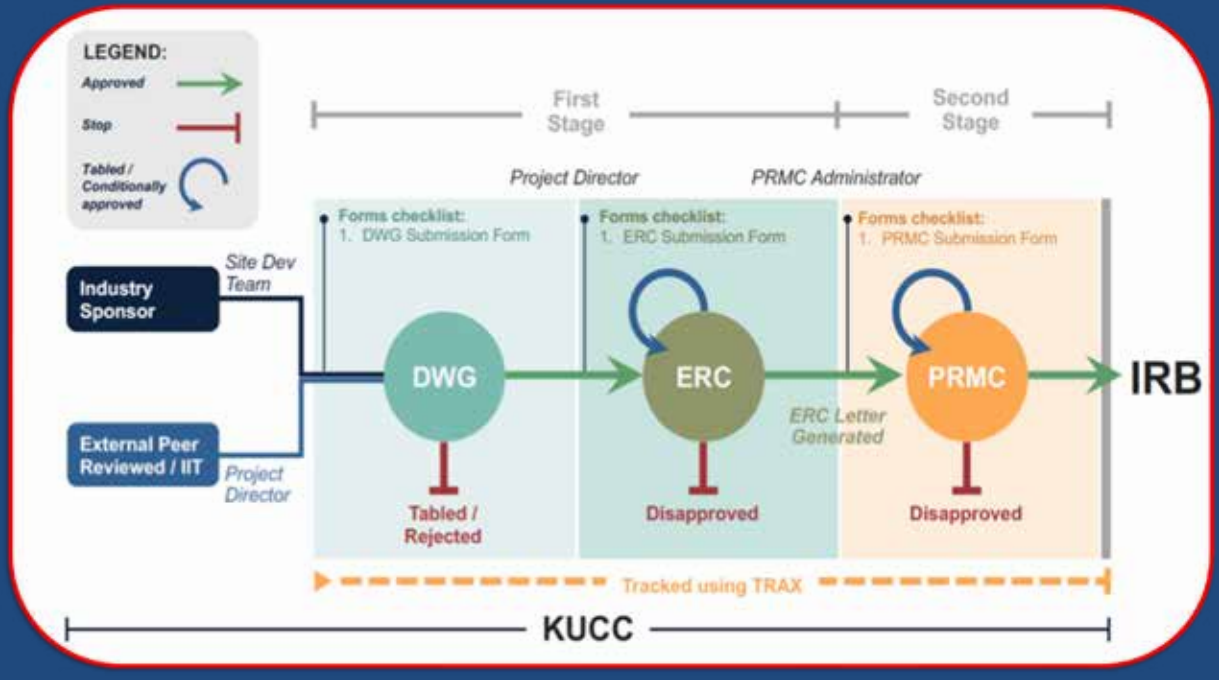
- Incorporates Every Stage of Study Startup
- Has a Scoring Mechanism to allow prioritization
- Generates Automatic Outcome Letters
- Provides Notifications when deadlines are close
- Allows data to be easily exported and analyzed

Methods

In August 2020, the University of Kansas Cancer Center implemented a system that allows review boards to seamlessly review and approve therapeutic trials, thereby ensuring appropriate studies are opened in a timely fashion. This system is referred to as Trial Review and Approval for Execution (TRAX) and was developed through a partnership between the clinical trials office and the Biostatistics and Informatics shared resources. The software base of the TRAX system was built in partnership with WCG Velos.

Results

Tracking all the information within a single system allowed our cancer center to track metrics that allows our operational and regulatory teams to assess the year-by-year trend and plan for the upcoming year. In case of an audit, it makes it easy for the PRMS administrator to review and gather information from the system as all the information through each review is documented electronically. Additionally, the reports allow the cancer center to obtain metrics on the fly.



Establishing a Pre-Screening Process – Creating the Right Tool

S. Panozzo, T. Prichett, B. Carter, K. Allen, D. Steward, M. McAdoo, R. Dooley, K. Smith, L. Cunningham, Z. Feng, A. Smith, M. Birrer
UAMS Winthrop P. Rockefeller Cancer Institute
Information Technology Research Systems, University of Arkansas for Medical Sciences

1. Background

Clinical trial recruitment can be a common struggle for many clinical trials offices. In fact, meeting study accrual goals can become a balancing act of managing resources and staff time. With busy clinics, investigators often rely on research nurses and coordinators to find candidates for clinical trials through pre-screening mechanisms. Historically, the UAMS clinical trials office (CTO) has used spreadsheets, paper logs, and disease-specific databases to track pre-screening activities. However, the lack of an organized process has led to missed study enrollments and a loss of valuable time and effort. Additionally, our office needed a way to identify trends and gaps in underperforming trials to examine barriers to trial recruitment. Collection of this data is important to guide future recruitment efforts. As a growing CTO with 260 studies across 14 disease groups, it was essential to find an efficient tool that could be utilized uniformly across our disease teams.

2. Goals

1. Redesign a previously developed system called the pre-screening system (PSS) to meet the current needs of our operations team
2. Use PSS to document/track pre-screening activities and status of potential study candidates across all studies
3. Create study and disease group reports to monitor pre-screening activities
4. Configure PSS to alert study staff when a candidate is added into the portal

3. Solutions and Methods

In 2015, CTO staff collaborated with the information technology research systems team at UAMS to build an application for prescreening called PSS. Unfortunately, the system went underutilized due to its complexity. Rather than build a new application, the two teams decided to redesign PSS to meet our current needs. Early on, the teams met to outline the desired workflow and define the required data elements for the system rebuild. At each phase of development, PSS underwent user testing to evaluate performance of the product and guide the redesign.

Specifications for the new version of PSS:

- Integrated with the electronic medical record (EMR); to add a patient into PSS, the user can search by patient name, medical record number, or clinic schedule
- Upon entry into PSS, patients are categorized in three pre-screening categories: pending, declined, or accepted
  - Pending status indicates staff are waiting on information to complete the review (e.g., lab/pathology reports, etc.)
  - Declined status indicates the patient was found unsuitable for the trial
  - Accepted status indicates the patient will move forward to sign consent and start screening
- Each category is equipped with dropdown menus and comment fields to allow staff to document details about each status
- Study staff track and communicate the status to investigators

4. Outcomes

With the first phases of the project complete, we are working on our implementation plan. As we begin to implement the system on a broader scale, the operations team has designated a small group of staff to complete additional testing and function as training leads.

5. Lessons Learned and Future Directions

The collaboration with our IT partners is ongoing while we continue developing the reporting and auto-notification mechanisms of PSS and focus on continually improving the system.

Establishing a Pre-screening Process- Creating the Right Tool

S. Panozzo, BS, CCRP[1]; T. Prichett BS, CCRP[1]; B. Carter, BS, CCRP[1]; K. Allen, BA, CCRP[1]; D. Steward, BA, CCRP[1], M. McAdoo, RNP[1]; R. Dooley, BSN, RN, OCN[1]; K. Smith, MS[2]; L. Cunningham, BA[2]; Z. Feng, MS[2]; A. Smith, MS, CCRP, PMP[2] ; M. Birrer, MD, PhD[1]
[1]Winthrop P Rockefeller Cancer Institute, University of Arkansas for Medical Sciences (UAMS);
[2]Information Technology Research Systems, University of Arkansas for Medical Sciences

Background

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Metrics & Goals to be Achieved

Goal 1- Redesign a previously developed system called the Pre-Screening System (PSS) to meet the current needs of our Operations team
Goal 2- Use PSS to document/track pre-screening activities and status of potential study candidates across all studies
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Goal 4- Configure PSS to alert study staff when a candidate is added into the portal

Methods

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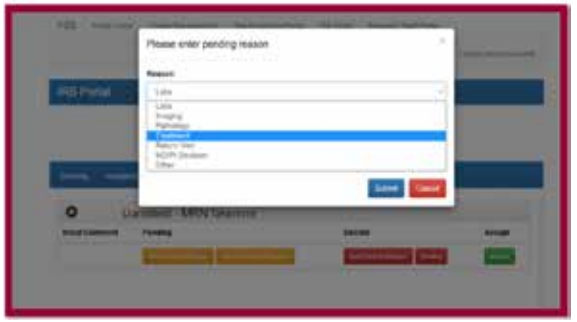

Outcomes

With the first phases of the project complete, we are working on our implementation plan. As we begin to implement the system on a broader scale, the Operations team has designated a small group of staff to complete additional testing and function as training leads.

Lessons Learned & Future Directions

The collaboration with our IT partners is ongoing while we continue developing the reporting and auto-notification mechanisms of PSS and focus on continually improving the system.

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Navigating Oncology Clinical Trials in the Era of COVID-19 – A CRC Perspective

M. Boota, K. Allen, S. Panozzo, M. Kovak, M. Birrer
UAMS Winthrop P. Rockefeller Cancer Institute

1. Background

When COVID-19 was declared a pandemic on March 11, 2020, who would have known the road that lay ahead? Emergency meetings among leadership were called and the clinical trials office (CTO) prepared for all possible scenarios while keeping in mind the best interest of patients and staff.

2. Goals

Our CTO had to immediately pivot our processes to conduct business remotely, with limited in-person contact. At the same time, working with oncology patients, we knew that our trials could not be put on hold. Goals included:

1. Providing staff the tools needed to work remotely
2. Developing alternate workflows for clinical trials operations
3. Revising policies for virtual environment

3. Solutions and Methods

Technology became the backbone of our CTO. Effective almost immediately, the majority of the CTO staff were instructed to work remotely. Only a limited number of staff had supplied laptops which could connect to the university's intranet. Equipment, internet availability, etc., had to be assessed for all staff. Employees worked closely with IT to ensure virtual connectivity. Meetings became virtual, and regular "check-ins" were scheduled to assess morale and employees' ability to manage workload. Clinical research coordinators (CRC), research nurses, specimen technicians, and management continued a presence on campus, as some tasks could only be done on site.

Subjects' treatment on clinical trials and recruitment never stopped during the pandemic. Patient safety was the CTO's first priority. Staff learned how to accommodate ever-changing visitor policies, COVID-19 guidelines, and protocol deviations directly related to the pandemic. A new standard operating procedure (SOP) was created for alternate methods of consent, which detailed consent when meeting face-to-face was not an option. This SOP included fax, email, and mail options, while also incorporating phone or video chat. In-person contact with patients required special personal protective equipment. Introduction of COVID-19 vaccines created new hurdles as investigators worked to ensure patient safety was maintained and study participation interruptions were minimal. Communication with sponsors was integral to ensure subject safety and quality data.

Routine monitoring and audit visits were moved to virtual, with the hospital restricting all visitors. This was an easy transition for CTO, as we already had electronic regulatory binders in use and most (if not all) of the source documents were in a patient's electronic medical record.

4. Outcomes

The CTO continued to operate throughout the pandemic, with minimal disruption in subject treatment. Staff was able to communicate effectively and work as a team to ensure that our participants came first. Now that staff are back on campus 100 percent, we are beginning to expand and restructure our teams to help increase the number of therapeutic clinical trials, with the aim of increasing therapeutic enrollments.

5. Lessons Learned and Future Directions

We learned a lot during the pandemic, which tested every aspect of the CTO. Flexibility and acceptance of change became something our office can easily handle. We survived, and we are on the road to thriving. We have integrated technology in our workflow by conducting meetings virtually and allowing staff flexibility to work virtually. Telehealth and alternate methods of consent are still being utilized.

View all abstracts and posters at **aaci-cancer.org/2022-abstracts**.

Navigating Oncology Clinical Trials in the Era of COVID-19 – A CRC Perspective

Mariam Boota, MD[1], CCRP; Kathryn Allen, BA[1], CCRP; Susan Panozzo, BS[1], CCRP; Mathew Kovak, MS[1] , CCRP; Michael Birrer, MD[1], PhD
[1]Cancer Clinical Trials and Regulatory Affairs, Winthrop P. Rockefeller Cancer Institute, University of Arkansas for Medical Sciences, Little Rock, AR

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CTO had to immediately pivot our processes to conduct business remotely, with limited in-person contact. At the same time, working with oncology patients, we knew that our trials could not be put on hold. Goals included:

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PARTNERING IN PROGRESS

FINANCE/CCSG/PRMS

Creation of a Consort Diagram to Visualize Participant Enrollment and Allocation at the Memorial Sloan Kettering Data and Safety Monitoring Committee

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Memorial Sloan Kettering Cancer Center

1. Background

Memorial Sloan Kettering's (MSK) data and safety monitoring committee (DSMC) requires the submission of a database summary report along with a completed monitoring form with each DSMC submission. Both documents require that enrollment and analysis information be included; however, the numbers generated from different sources are often discordant for a series of different reasons. Thus, an improved process for reconciliation was required.

2. Goals

Our goal was to create a visualization tool that provides study teams and DSMC reviewers with an accurate status regarding overall study flow, including enrollment breakdowns, assignments to arms/cohorts, on-and-off study statuses, number evaluable for key endpoints, and interim analyses results. This document required manual entry and provided an opportunity to clarify enrollment and analysis data.

3. Solutions and Methods

In response to this need, and in collaboration with committee leadership and the department of biostatistics, the protocol review core (PRC) created and piloted two consort diagram templates, one for phase and one for non-phase studies. For the pilot, PRC included protocols for which DSMC, and protocol review and monitoring system (PRMS) committee members were principal investigators (PI). Feedback was provided by investigators, study staff, and DSMC reviewers. The pilot was successful based on demonstrated feasibility, positive feedback, and improved submission quality.

4. Outcomes

Following the pilot, consort diagrams were included as a mandatory submission requirement for studies opened to accrual in 2018 or later. This requirement impacts 67 percent of the current DSMC portfolio (203/305). Of this subset of protocols, 74 percent are therapeutic trials and 60 percent are from the Department of Medicine.

Implementation has positively impacted:

- PRC:
  - Identification of protocols that could be removed from DSMC monitoring (e.g., no active participants)
- PI, study team, statistician:
  - To prospectively track participants and engage biostatistical input throughout the lifecycle of the study, facilitating data analysis and subsequent publication
- DSMC members:
  - Improved monitoring of trials as the schematic depiction indicates withdrawal and dropout rates, missing data and errors in database reports, and enhanced protocol compliance by confirming data matches the trial design (i.e., dose escalation, or treatment arm assignment is proceeding as per protocol specification)
- All:
  - Improved understanding of participant flow within a the trial, and overall study status
  - Clearer understanding of study analyses (i.e., evaluable participants for a specific endpoint and interim analysis details)
  - Validated data integrity by following the numbers (e.g., accrual breakdowns are easy, reproducible, and logistically beneficial)

5. Lessons Learned and Future Directions

Given the success of implementation of these consort diagrams, MSK is exploring transition to a smart form that can account for varied study designs along with integration of the data in our electronic protocol information management system (PIMS) or external consort software. With many different trial designs at the institution, we had to create a general diagram that allows for flexibility among the studies. Creation of a smart form using electronic software could also allow for visual depiction of data from non-traditional study designs. Other future applications of the consort diagrams beyond the DSMC include as part of the annual IRB continuing review, at publication, and summary data for federal reporting requirements.

Creation of a Consort Diagram to Visualize Participant Enrollment and Allocation at the Data and Safety Monitoring Committee (DSMC)

Christina Kolenut, MPH, Krista Napolitano, MA, Xhenete Lekperic, Kay See Tan, PhD, Sara Hanley, MSW, Eileen M. O'Reilly, MD, Susan Slovin, MD, PhD

Memorial Sloan Kettering Cancer Center

Background

- The Data and Safety Monitoring Committee (DSMC) requires a database report and monitoring form with each submission.
- Both documents require the inclusion of enrollment and analysis information; however, the numbers generated from different data sources are often discordant for multiple reasons (Figures 1 and 2).

Figure 1:
Sample Database Report Breakdown

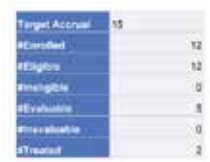


Figure 2:
Sample Monitoring Form Breakdown

Goals

Improve data reconciliation by creating a visualization tool that:

- Provides an accurate status regarding overall study flow, enrollment breakdowns, assignments to arms/cohorts, on-and-off study statuses, number evaluable for key endpoints, and interim analyses results.
- Allows for customized manual entry and an opportunity to clarify enrollment and analysis data.

Methods & Solutions

- In collaboration with Committee Leadership and the department of biostatistics, the administrative team created and piloted two consort diagram templates, one for phase studies (e.g., phase I, I/II, and II therapeutic protocols) and one for non-phase studies (e.g., psychosocial) studies (Figure 3).
- The pilot included protocols for which DSMC members and Protocol Review and Monitoring System (PRMS) committee members were Principal Investigators.
- Feedback regarding the functionality and clarity of the templates was provided by investigators, study staff, and DSMC reviewers.
- The pilot was deemed successful based on demonstrated feasibility, positive feedback, and improved submission quality.
- Feasibility was initially impacted by unclear instructions which resulted in creating a guidance document containing definitions for each diagram category (Figure 4) and hosting trainings.
- Following the pilot and updates to the templates based on feedback, consort diagrams became a submission requirement for studies opened to accrual in 2018 or later.

Example Completed Consort Diagram for a Phase Study

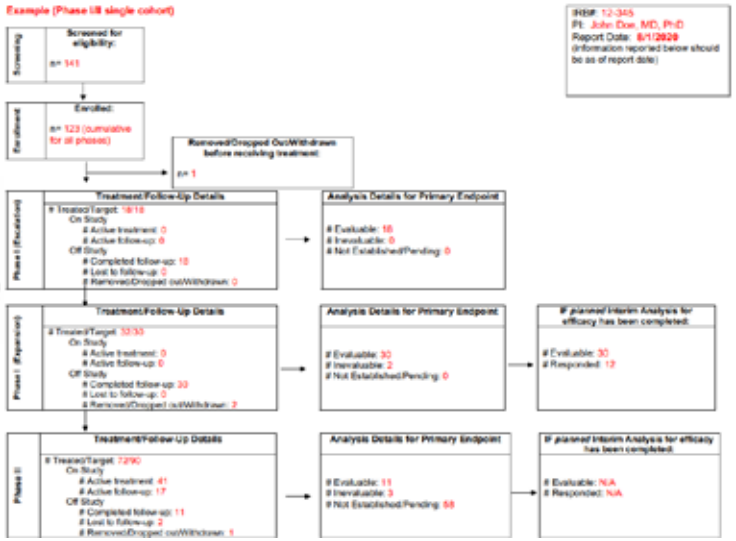
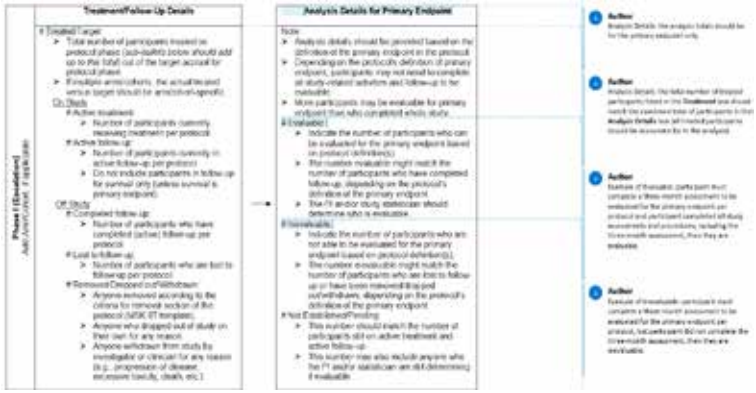


Figure 4: Excerpt of Consort Diagram Guidance Document for Phase Studies



Outcomes

- Implementing the consort diagram has had a positive impact on all stakeholders:

DSMC Administration:
Easily identifies protocols eligible to be removed from monitoring

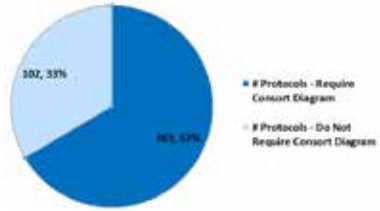
Principal Investigators, Study Staff & Statisticians:
Facilitates data analysis and publication by tracking participants and engaging biostatistical input throughout the lifecycle of the study

DSMC members:
Improves monitoring by highlighting withdrawal and inevaluable rates, data errors, and protocol non-compliance (i.e., following design/analysis plan)

All:
- Fosters data integrity by providing a platform that can be easily followed at each requisite timepoint of monitoring
- Improves understanding of participant flow within a trial, and overall study status
- Clarifies study analyses details (i.e., evaluable participants for a specific endpoint, interim analysis details)

- The requirement impacts 67% of the DSMC portfolio (Figure 5).
- 74% are therapeutic trials and 71% are phase trials.
- 60% are from the Department of Medicine.

Figure 5: Impact of Consort Diagram Requirement on DSMC Portfolio



Lessons Learned and Future Directions

- The consort diagram requires adaptation to fit varied and non-traditional study designs.
- Plan to transition to a 'smart' (electronic) form and potentially pool data from multiple data sources.
- Expand beyond DSMC to other key committees (e.g., IRB, INDC) and as a template for investigators (e.g., accrual monitoring, federal reporting, publication).

Research Portfolio Management: The Protocol Performance Monitoring Dashboard

J. Migliacci, X. Lekperic, B. Seko, K. Kaufman, K. Napolitano, S. Hanley, A. Rodavitch
Memorial Sloan Kettering Cancer Center

1. Background

As an NCI-Designated Comprehensive Cancer Center, Memorial Sloan Kettering (MSK) is required per Cancer Center Support Grant (CCSG) guidelines to have a protocol review and monitoring system (PRMS) that is responsible for monitoring ongoing institutional research. Historically, MSK's PRMS committee (PRMC) was responsible for monitoring the scientific progress of our clinical research portfolio. More recently, MSK's PRMC created a protocol monitoring subcommittee whose sole responsibility is carrying out their mission by evaluating accrual rates, scientific merit, and patient need; and determining trials' potential for completion.

2. Goals

To accomplish its task of closing protocols with low potential for completion, the subcommittee needed a real-time reporting tool to aid in identifying underperforming trials. The tool could be used by department leadership to assess their portfolio and preemptively close underperforming trials that may otherwise be identified by the committee.

3. Solutions and Methods

In collaboration with MSK's clinical research informatics and technology, we sought to develop a user-friendly dashboard to assist with assessing protocol performance. Leveraging data from multiple systems, the dashboard blends comprehensive metrics, including protocol lifespan, estimated time to study completion (ETC), and accrual rates.

4. Outcomes

The protocol performance monitoring dashboard (Fig. 1a) was built with two sections. The upper section shows a graph with percentage of completed accruals on the horizontal axis and years open to accrual on the vertical axis. Each dot on the graph represents a protocol and is encoded by color based on ETC. ETC estimates the amount of time (in years) in which a protocol will complete accrual based on the completed accruals and time open. Protocols with 0 accruals are listed as unknown. Over target protocols have met or exceeded planned accruals.

The bottom section of the dashboard includes important details such as the regulatory sponsor, principal investigator, last accrual date, number of target and actual accruals, ETC, protocol type/category, title, information about prior underperforming notices (i.e., number of NP notices) and when the last notice was issued (i.e., last NP date), etc.

There are multiple filters which make it easy to isolate key protocols. For example, the dashboard can be filtered to isolate protocols that have accrued 0 patients or have been open for an extended period (determined by the user) and may no longer be scientifically relevant.

To provide further understanding, when any protocol on the dashboard is selected, a new graph appears showing the number of accruals by month over the lifetime of a study (Fig. 1b). This provides context, showing a clear picture of accrual performance for patients accrued with MSK oversight (internal locations and participating sites) which can assist the committee when making decisions about closures.

5. Lessons Learned and Future Directions

Spring 2022 will be the first time the new subcommittee is conducting reviews of underperforming protocols and will utilize this new dashboard. We plan to broaden utilization to other institutional leaders (e.g., department heads) and provide education to increase transparency and promote collaboration of portfolio management between PRMS and departments. We plan to reassess the stakeholder needs throughout 2022 to identify improvements or new tools for portfolio management.

View all abstracts and posters at **aaci-cancer.org/2022-abstracts**.

Research Portfolio Management: The Protocol Performance Monitoring Dashboard

Jocelyn Migliacci, MA, Xhenete Lekperic, Brian Seko, Kristopher Kaufman, MS, Krista Napolitano, MA, Sara Hanley, MSW, Ann Rodavitch, MA

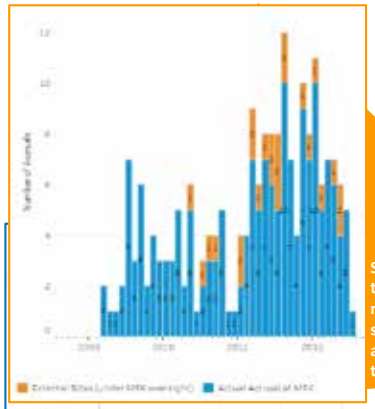
Memorial Sloan Kettering Cancer Center

Background

- As an NCI-designated comprehensive cancer center, Memorial Sloan Kettering (MSK) is required per Cancer Center Support Grant (CCSG) guidelines to have a Protocol Review and Monitoring System (PRMS), responsible for monitoring ongoing institutional research.
- Historically, MSK's PRMS Committee (PRMC) was responsible for monitoring the scientific progress of our clinical research portfolio.
- More recently, MSK's PRMC created a Protocol Monitoring sub-committee whose sole responsibility is carrying out their mission by evaluating accrual rates, scientific progress, and patient need and determining trials' potential for completion.

Goal/Methods

- To accomplish its task of closing protocols with low potential for completion, the sub-committee needed a real-time reporting tool to aid in identifying underperforming trials.
- This tool could be used by department leadership to assess their portfolio and preemptively close underperforming trials that may otherwise be identified by the committee.
- In collaboration with MSK's Clinical Research Informatics and Technology, we developed a user-friendly dashboard to assist with assessing protocol performance.
- Leveraging data from multiple systems, the dashboard blends comprehensive metrics, including protocol lifespan, estimated time to study completion (ETC), and accrual rates.



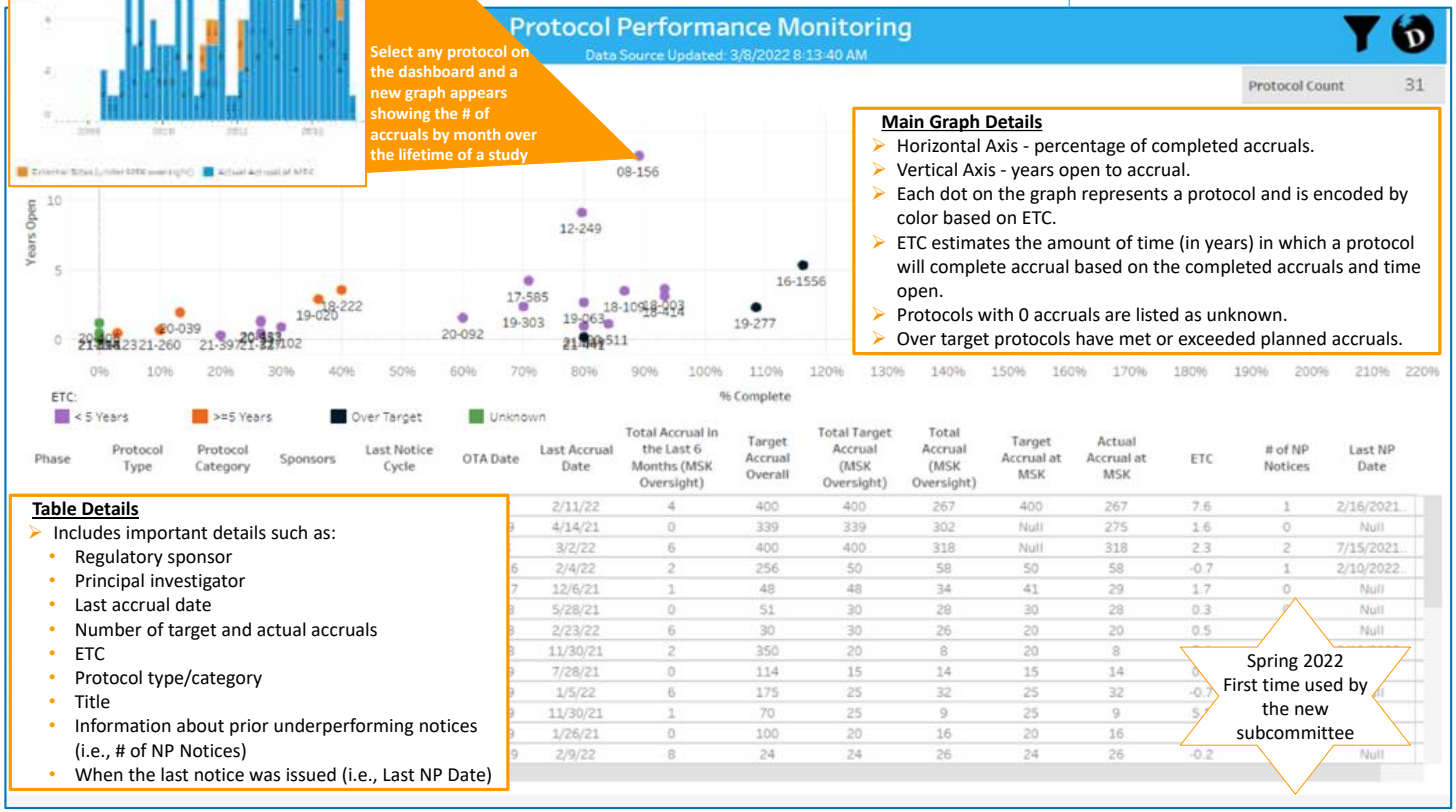
Select any protocol on the dashboard and a new graph appears showing the # of accruals by month over the lifetime of a study

Dashboard Features

- The pop-out provides context, showing a clear picture of accrual performance for patients accrued with MSK Oversight (internal locations and participating sites) which assists the committee when making decisions about closures.
- Multiple filters make it easy to isolate key protocols. E.g., Can isolate protocols that have accrued 0 patients or have been open for an extended period (determined by the user) and may no longer be scientifically relevant.

Next Steps

- Broaden utilization to other institutional leaders (i.e., department heads) and provide education to increase transparency and promote collaboration of portfolio management between PRMS and departments.
- Reassess needs to identify improvements and new tools.



Main Graph Details

- Horizontal Axis - percentage of completed accruals.
- Vertical Axis - years open to accrual.
- Each dot on the graph represents a protocol and is encoded by color based on ETC.
- ETC estimates the amount of time (in years) in which a protocol will complete accrual based on the completed accruals and time open.
- Protocols with 0 accruals are listed as unknown.
- Over target protocols have met or exceeded planned accruals.

Table Details

- Includes important details such as:
  - Regulatory sponsor
  - Principal investigator
  - Last accrual date
  - Number of target and actual accruals
  - ETC
  - Protocol type/category
  - Title
  - Information about prior underperforming notices (i.e., # of NP Notices)
  - When the last notice was issued (i.e., Last NP Date)

Spring 2022
First time used by the new subcommittee

PRMC Member Workload Survey After Charter Alignment With NCI Requirements

B. Hughes, C. Allen, T. Herzog, C. Vollmer, M. Marcum, N. Kurtzweil
University of Cincinnati Cancer Center

1. Background

The University of Cincinnati Cancer Center (UCCC) in 2019 revised its protocol review and monitoring committee (PRMC) charter to optimize the review process of the UCCC PRMC and to align with best practices from existing NCI-Designated Cancer Centers. Critically, the charter was updated to create an expedited administrative review process. In 2022, a survey of PRMC members was taken to obtain insights into the impacts of these changes on members' workloads and PRMC experience.

2. Goals

An anonymous survey was developed in REDCap by the PRMC chair and clinical trials office. The intent was primarily to obtain member's self-reported average time for review completion and member's perceptions of charter updates on their workloads.

3. Solutions and Methods

All 23 current PRMC voting members were provided with a link to the REDCap survey via email one week prior to, and on the day of, the February and March 2022 PRMC meetings. A total of 17 responses were received for a 74 percent response rate.

4. Outcomes

Per the survey, on average a full review takes 67.8, fast-track 48.6, and administrative 45 minutes to complete. There are 753 studies across review types from January 8, 2018 to January 3, 2022 in our dataset (charter change effective May 2019). We took these average review times and multiplied each by the corresponding total number of studies within each review type from pre- and post-change. We normalized these values by dividing by the number of total meetings pre- (16) and post-change (33).

There was a significant time savings of 40 percent (full review) and 35 percent (fast-track) in the average time per PRMC meeting required to complete these reviews across all members. However, 62.5 percent of respondents reported the change had no impact on their own review time; 31 percent reported spending less time; and 6 percent reported spending more time on reviews.

The total number of studies reviewed annually by PRMC were similar (154 in 2018, 123 in 2019, 139 in 2020, 126 in 2021). However, individually, fast-track reviewers experienced an 83-percent increase in the median number of reviews per year and individual full reviewers experienced a 13-percent increase in the median number of reviews per year. Indeed, there were 18 discreet reviewers in 2018 and 2019, 15 in 2020 and 11 in 2021.

5. Lessons Learned and Future Directions

The UCCC PRMC charter changes have aligned UCCC with NCI requirements, while also significantly reducing the workload of members per meeting. However, this time savings has not been experienced by members based on survey responses, which reflect a 39-percent decrease in the number of discreet reviewers since 2018.

Going forward we will use these results to inform how PRMC review assignments are allocated to more evenly distribute reviews across all members. In addition, UCCC will seek to promote incentives at the departmental level to reward and recognize PRMC service as 41 percent of respondents reported not feeling like their service was recognized by their department at all. We hope that by increasing departmental recognition, and more evenly distributing workload as well as right-sizing the committee, we will increase PRMC member engagement and reduce workload.

PRMC Member Workload Survey After Charter Alignment with NCI Requirements

Brittany N. Hughes, BS; Casey L. Allen, MS; Thomas J. Herzog, MD; Christine Vollmer, MBA; Michelle Marcum, MS; Nicky Kurtzweil, JD
University of Cincinnati Cancer Center (UCCC), Cincinnati, OH

Background of the Problem:

The University of Cincinnati Cancer Center (UCCC) in 2019 revised its Protocol Review and Monitoring Committee (PRMC) Charter to optimize the review process of the UCCC PRMC and to align with best practices from existing NCI Designated Cancer Centers. Critically, the Charter was updated to create an expedited administrative review process. In 2022, a survey of PRMC members was taken to obtain insights into the impacts of these changes on member's workloads and PRMC experience.

Goals to be Achieved & Methods:

An anonymous survey was developed in REDCap by the PRMC Chair and clinical trials office. The intent was primarily to obtain member's self-reported average time for review completion and member's perceptions of Charter updates on their workloads.

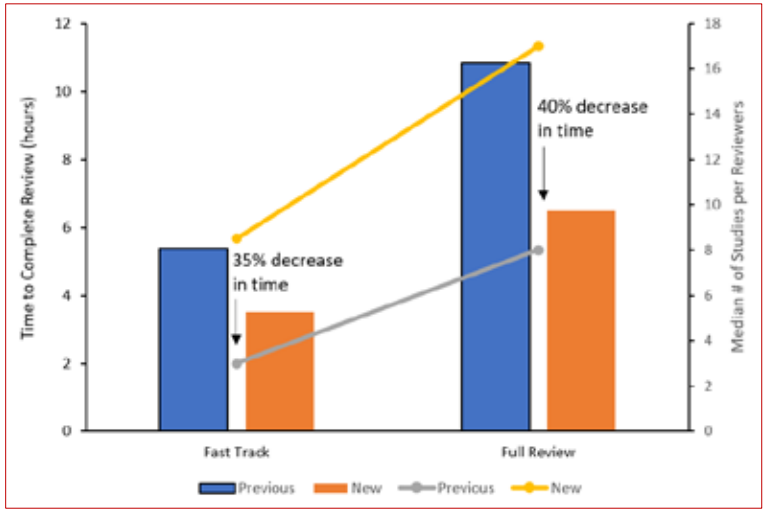
- All 23 current PRMC voting members were provided with a link to the REDCap survey via email one week prior to, and on the day of, the February and March 2022 PRMC meetings.
- A total of 17 responses were received for a 74% response rate.

Contact Casey Allen at allen2cy@ucmail.uc.edu; or Nicky Kurtzweil kurtzwny@ucmail.uc.edu for more information

Outcomes:

Per the survey, on average a Full Review takes 67.8, Fast-Track 48.6 and Administrative 45 minutes to complete. There are 753 studies across review types from 1/8/2018 to 1/3/2022 in our dataset (Charter change effective May 2019). We took these average review times and multiplied each by the corresponding total number of studies within each review type from pre- and post-change. We normalized these values by dividing them by the number of total meetings pre- (16) and post-change (33).

- There was a significant time savings of 40% (Full Review) and 35% (Fast-Track) in the average time per PRMC meeting required to complete these reviews across all members.
- However, 62.5% of respondents reported the change had no impact on their own review time; 31% reported spending less time and 6% reported spending more time on reviews.



Outcomes (cont'd):

The total number of studies reviewed annually by PRMC were similar (154 in 2018, 123 in 2019, 139 in 2020, 126 in 2021). However, individually Fast-Track Reviewers experienced an 83% increase in the median number of reviews per year and individual Full Reviewers experienced a 13% increase in the median number of reviews per year. Indeed, there were 18 discreet Reviewers in 2018 and 2019, 15 in 2020 and 11 in 2021 (39% decrease in the number of reviewers).

Future Directions:

Going forward we will use these results to inform how PRMC review assignments are allocated to more evenly distribute reviews across all members. In addition, UCCC will seek to promote incentives at the departmental level to reward and recognize PRMC service as 41% of respondents reported not feeling like their service was recognized by their department at all. We hope that by increasing departmental recognition, and more evenly distributing workload as well as right sizing the committee, we will increase PRMC member engagement and reduce workload.

University of CINCINNATI CANCER CENTER
University of Cincinnati • UC Health • Cincinnati Children's

Impact of the SRMC Zero Tolerance Policy on DSG Trial Portfolios

J. Walsh, T. Guinn, Jr., T. George, A. Anderson, A. Ivey
University of Florida Health Cancer Center

1. Background

In 2018, the University of Florida Health Cancer Center (UFHCC) scientific review and monitoring committee (SRMC) implemented a zero tolerance policy (ZTP), to raise enrollment expectations among the disease site groups (DSG). The ZTP requires administrative closure of studies without any enrollment within 6 months following activation as historic data demonstrate these studies are unlikely to succeed. The goals of the ZTP are twofold: to lessen the resource burden to maintain trials, and to encourage better trial selection. Once implemented, the policy had differential impacts across UFHCC's 13 DSGs. While several groups flourished under the policy with well-rounded trial selection, some portfolios were greatly reduced, requiring awareness of trial availability outside of their DSG. Additionally, a growing number of rare and pediatric studies were granted exemptions and allowed to continue without accruing for several years.

2. Goals

- Closure of non-performing trials to allow for re-deployment of assigned resources
- Performance metrics of DSG portfolios, focusing on patient needs and feasibility of trials

3. Solutions and Methods

The ZTP targets interventional trials with no accrual activity. Initially demonstrating success by closing studies with 0 accruals by 12 months post-activation, it was subsequently strengthened, placing studies on administrative probation at 3 months and terminating at 6 months if accrual remained at 0. During probation, feasibility is re-assessed to confirm patient population availability, and new recruitment strategies are devised by the clinical research office in conjunction with the community outreach and engagement (COE) office. Investigators must synthesize this information and choose to close the study or submit a corrective action plan (CAP) addressing enrollment. If the CAP fails, studies are administratively terminated per the ZTP and there is no process for appeals.

Previous exceptions to this policy included rare disease studies (modified NIH definition); pediatrics; high-priority investigator-initiated trials; national trials led by UF faculty; and studies experiencing moderate, but temporary, enrollment suspensions. Seeing a rise in study exemptions, the policy was updated in 2021, closing this loophole and requiring that previously exempted trials enroll within 2 years or face termination.

4. Outcomes

The ZTP reduced the number of studies placed on probation. Studies placed on probation initially increased by 16 percent (22 percent vs. 38 percent) between 2017 and 2018, whereas from 2019-2021, only 23 percent of studies reviewed were placed on probation. However, the number of studies closed with 0 accrual in 2021 rose by 27 percent over the previous two years, largely due to the 2021 policy changes.

The ratio of available patients to target accrual is now a key part of the feasibility assessments, with clear expectations for early study enrollment shared across the UFHCC.

This has allowed many DSGs with diminished disease specific study portfolios to focus and increase enrollment onto disease agnostic studies managed by our early-phase and disease agnostic DSG.

5. Lessons Learned and Future Directions

The ZTP improved stewardship of limited resources and provided DSGs with opportunities to better align with patient needs. Future directions include incorporating the COE director for more exhaustive discussions during initial protocol reviews for enhanced recruitment opportunities via COE resources. DSGs and investigators are now better prepared to align studies with patient needs, minimizing wasted resources with non-performing studies.

Impact of the SRMC "Zero Tolerance" Policy on DSG Trial Portfolios

Judy Walsh, CCRP, Timmy Guinn, MS, CCRP, Ashley Anderson, MBA, ACRP-CP,
Alison Ivey, RN, MS, MBA, OCN, CCRP, Thomas George, MD, FACP

BACKGROUND

In 2018, the UFHCC Scientific Review and Monitoring Committee (SRMC) implemented the Zero Tolerance Policy (ZTP), to improve Disease Site Groups (DSG) enrollment accountability. The ZTP requires administrative closure of studies without any enrollment at 6 months following activation as historic data demonstrates these studies are unlikely to succeed. The goals of the ZTP are twofold; lessen the resource burden to maintain trials and encourage better trial selection. Once implemented, the policy had differential impacts across UFHCC's 13 DSGs. While several groups flourished under the policy with well-rounded trial selection, some portfolios were greatly reduced, requiring awareness of trial availability outside of their DSG. Additionally, a growing number of rare and pediatric studies were granted exemptions and allowed to continue without accruing for two years.

GOALS

- Closure of non-performing trials to allow for re-deployment assigned resources
- Performance metrics of DSG portfolios, focusing on patient needs and feasibility of trials

CONTACT

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Associate Director for Clinical Research
University of Florida Health Cancer Center
Clinical Research Office
Thom.George@medicine.ufl.edu

Request a pdf of this poster by email using this QR code.

METHODS

The ZTP targets interventional trials with no accrual activity. Initially demonstrating success by closing studies with zero accruals by 12 months post-activation; it was subsequently strengthened, placing studies on administrative probation at 3 months and terminating at 6 if accrual remained zero. During probation, feasibility is re-assessed to confirm patient population availability, and new recruitment strategies are devised by the Clinical Research Office in conjunction with the Community Outreach and Engagement (COE) office. Investigators must synthesize this information and choose to close the study or submit a Corrective Action Plan (CAP) addressing enrollment. If the CAP fails, studies are administratively terminated per the ZTP. There is no process for appeals.

Previous exceptions to this policy included rare disease studies (modified NIH definition), pediatrics, high-priority IITs, national trials led by UF faculty, and studies experiencing moderate, but temporary, enrollment suspensions. Seeing a rise in study exemptions, the policy was updated in 2021, closing this loophole and requiring that previously exempted trials enroll within 2 years or face termination.

RESULTS

The ZTP reduced the number of studies placed on probation. Studies placed on probation initially increased by 16% (22% vs 38%) between 2017 and 2018 whereas from 2019-2021, only 23% of studies reviewed were placed on probation. However, the number of studies closed with zero accrual in 2021 rose by 27% over the previous 2 years, largely due to the 2021 policy changes for rare disease studies.

The ratio of available patients to target accrual is now a key part of the feasibility assessments, with clear expectations for early study enrollment shared across the UFHCC. This has allowed many DSGs with diminished disease specific study portfolios to focus and increase enrollment onto disease agnostic studies managed by our early-phase and disease agnostic DSG.

FUTURE DIRECTIONS

The ZTP has improved stewardship of limited resources and provided DSGs with opportunities to better align with patient needs, with clear administrative accountability. Future directions include incorporating the COE Director for more exhaustive discussions during initial protocol reviews for enhanced recruitment opportunities via COE resources. DSGs and investigators are now better prepared to align studies with patient needs, minimizing wasted resources with non-performing studies.

* Taking a Closer Look: Standardizing Disease Focus Groups to Strengthen Trial Portfolios

L. Neal
Hollings Cancer Center, Medical University of South Carolina

1. Background

A portfolio of high-performance oncology studies begins with standardizing how disease focus groups (DFGs) select trials. Our 11 DFGs' methods to prioritize clinical trials were subjective and did not prompt the DFG leaders to evaluate trials per our center's mission and patient catchment. DFG leaders did not have appropriate knowledge of the CCSG priorities and did not have the available resources for proper trial selection decisions. Our prioritization form utilized a one-dimensional 5-point scale to report a high impact (1) to low impact (5) score. In FY 2018-2021, our site assessed 35 out of 93 trials, or 38 percent as a moderate to low impact score of 3. This score was not informative to the scientific protocol review committee (PRC) to assess scientific merit, clinical need, and feasibility. There was no correlation between the impact score and ability to meet time to activation and projected accrual goals.

2. Goals

1) Comparison of percentage of trials approved/disapproved by DFG
2) Of trials DFG approved for activation, the overall distribution of prioritization scores and outcome of scientific committee concurrence
3) Analysis of prioritization score and impact on time to activation

3. Solutions and Methods

1) In July 2021, center leadership met individually with each appointed DFG leader to review CCSG goals and outline specific DFG performance expectations; DFG leaders were provided with their patient population tumor registry data from January 2018 to February 2021 and historical trial performance over the last 3 years to improve patient catchment understanding
2) Monthly clinical investigation meetings to present performance metrics and a bi-annual DFG leadership retreat series in November 2021 for ongoing DFG leadership training and strategic planning
3) Created DFG intranet with real-time DFG performance report and a new trial portfolio diagram
4) In November 2021, completed a Six Sigma process improvement project with CTO staff and clinical investigators to determine the success factors for trial performance
5) In February 2022, revised the DFG prioritization form to evaluate the predicted trial success factors identified from the Six Sigma project, and re-engineered the trial start-up process to have multiple prioritization check points

4. Outcomes

Disease focus groups are more discriminatory in their trial selection process, as demonstrated by an increased abandonment rate of 5.75 trials per month in Fiscal Year (FY) 2021 compared to 9.4 trials per month in FY 2022 (up to March 11, 2022). To date, 4 trials have been submitted to the PRC utilizing the new prioritization form. The highest score of 83.1 points out of 100 assessed for a NIH-funded MUSC faculty treatment trial with a high accrual potential, but some financial feasibility concerns. The lowest score was 67.10 for a national screening trial for a small patient population.

5. Lessons Learned and Future Directions

Identifying the patient population catchment groups within the trial portfolio diagram requires investigator time and ongoing reviews. Implementation of the new DFG form required significant communication for buy-in and training. This new prioritization score should create a predictive model of trial success and allow center leaders to implement new policies about prioritization score thresholds for DFG approval and improved utilization of cancer center resources.

* *Honorable Mention*

Taking a Closer Look: Standardizing Disease Focus Groups to Strengthen Trial Portfolios

Lilli Neal, MSc., CCRP

MUSC Medical University of South Carolina | Hollings Cancer Center, An NCI-Designated Cancer Center

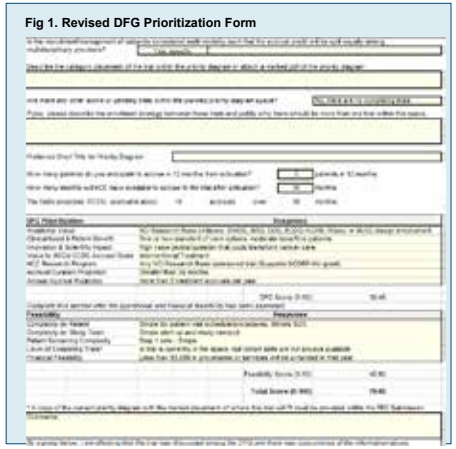
Background

The method to prioritize clinical trials among the eleven Disease Focus Groups (DFGs) was subjective and not consistently aligned with our center's strategic plan and patient catchment. DFG leaders did not have appropriate knowledge of the CCSG priorities and did not have the available resources for proper trial selection decisions. Our DFG prioritization form assigned impact scores via a one-dimensional 5-point scale to report a high (1) impact to low (5) impact score. The score did not correlate to resource allocation levels for meeting time to activation or accrual goals. This score was not informative to the Protocol Review Committee (PRC) relay the value of the trial and predictive success of the trial. To address these issues, DFG leaders engaged in a Lean Six Sigma process improvement project to improve the trial prioritization process.

Method

Each appointed DFG leader reviewed CCSG goals and were outlined specific DFG performance expectations. DFG leaders were provided patient catchment and historical trial performance data and participated in monthly clinical investigations meetings and a bi-annual retreat to stay abreast of cancer center strategic plans. A lean six-sigma process improvement project was completed in November 2021

Fig 1. Revised DFG Prioritization Form



November 2021 that identified key clinical trial success predictors related to scientific merit and feasibility. These predictors were weighted and incorporated into an enhanced DFG Prioritization Form (Fig. 1) that was released for pilot use in March 2022.

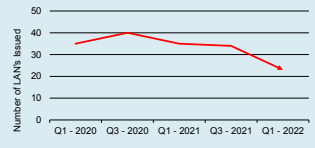
The new form prioritizes trials based on 2 scores: a DFG scientific merit score between 0-50 based on accrual potential, portfolio fit, clinical need, research interest, and institutional value, then an operational and financial feasibility score between 0-50. The final score is the summation of both components. There was no score threshold set for DFG disapproval. The primary aim of the form revision was to improve the decision process for trial selection by DFG and improve communication between DFG and PRC of trial portfolio decisions.

Results

Since these initiatives, DFG leaders and clinical investigators are more discriminatory in their trial selection process, as demonstrated by an increased abandonment rate of 5.75 trials per month in FY21 compared to 8.3 trials per month in FY22 (up to 5/16/22). To date, eight trials have been submitted to the PRC utilizing the new prioritization. The highest score of 85.95 points out of 100 assessed for a NIH funded treatment trial with a high accrual potential, but some financial feasibility concerns. The lowest score was 57.55 for an industry sponsored, high complexity trial with moderate accrual.

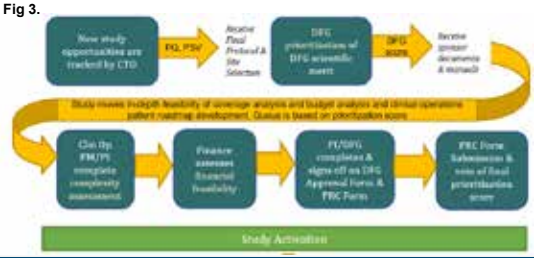
As DFGs became more mindful of trial portfolio performance, the number of PRC issued Low Accrual Notices (LANs) in Q4-2021 decreased (Fig. 2), suggesting by better educating our DFGs and requiring low accruing trials be reviewed monthly, more trials are meeting ≥50% of their accrual goals.

Fig 2. Count of Low Accrual Notices (LANs) by PRC Accrual Review Timepoints



The DFG scientific score is being used by the Clinical Trials Office (CTO) Program Managers (PM) to more objectively assign trials to staff resources. High scoring trials are prioritized first in the queue for feasibility review and coverage analysis. Once feasibility is assessed and scored, the final DFG score is utilized by CTO PMS to assign highest scores to earlier PRC and IRB meeting dates. The modified activation process which includes the points in which the DFG prioritization score is utilized is depicted in Figure 3.

Fig 3.



Conclusion and Future Plans

Identifying the patient population catchment groups within the trial portfolio diagram requires investigator time and ongoing reviews. Implementation of the new DFG form required significant communication for buy-in and training. DFGs are more discerning about trials and trial selection decisions are better communicated to PRC/CTO. This new prioritization score should create a predictive model of trial success and allow center leaders to implement new policies about prioritization score thresholds for DFG approval and improved utilization of cancer center resources.

Automating and Streamlining the 2-Stage Scientific Review Process

T. Baxter, J. Welter, M. Voss, M. Golafshar, T. DeWees, J. Clikeman, A. Fritsche, J. Summer Bolster, A. Dispenzieri
Mayo Clinic Comprehensive Cancer Center

1. Background

In 2020, the Mayo Clinic Comprehensive Cancer Center (MCCC) began planning for implementation of a formal 2-stage scientific review process. This effort was necessary to meet new requirements described in the NCI P30 Cancer Center Support Grant (CCSG) guidelines (PAR-21-321). A review of the current state protocol review and monitoring system (PRMS) process highlighted further opportunities to standardize, automate, and reduce administrative burden.

2. Goals

- Implement a 2-stage scientific protocol review process for MCCC
- Differentiate between first-stage disease group (DG) review and second-stage protocol review monitoring committee (PRMC) review
- Improve communication and flow of data through the 2-stage review process
- Eliminate redundant data entry and improve first time quality
- Develop electronic system to facilitate review process and store documents
- Improve tracking of PRMS metrics

3. Solutions and Methods

MCCC developed a 2-stage scientific protocol review process and defined the elements and criteria to be used by the 22 MCCC DGs and four PRMCs. To support the process, a scientific review e-committee tool was developed. The tool includes a REDCap database enhanced by an independent and interactive online dashboard. The tool features electronic forms for data capture, storage, metrics tracking, branching logic, and automated email communications. The e-committee tool optimizes protocol review through standardization of workflow and process automation while reducing data entry. It applies standardized review criteria for an initial scientific review, feasibility assessment, and prioritization at the DG. Branching logic directs the user to the type of review required (e.g., full, expedited, administrative) and appropriate routing of the protocol for review by one or more committees.

4. Outcomes

The scientific review e-committee tool and 2-stage review process was piloted in three DGs from May to July 2021. As of January 2022, the tool was implemented in 14 of 22 MCCC DGs. One hundred-eighty protocols have been entered with 20 completing the full scientific review process. Prior to implementation, first-time quality on entry of critical PRMS data was: 89 percent for capturing DG review date; 74 percent for PRMC submission date; and 79 percent for PRMC approval date. Leveraging automation, the tool is now capturing these data points at 100 percent.

5. Lessons Learned and Future Directions

Lessons learned through implementation include the value of standardized protocol review forms for data capture as well as DG structure and support to assist study team and committees with a more robust process. A senior program coordinator has been assigned to each DG to support implementation. This additional resource is a main point of contact for investigators and sponsors to help steward protocols from DG submission to PRMC approval. In addition, a protocol review requirement table with definitions was created to aid the entry of protocols into the tool.

Automating and Streamlining the 2-Stage Scientific Review Process

Tiffany L. Baxter MHA[1], Jane C. Welter MBA, Molly M. Voss[2], Michael A. Golafshar, MS, Todd A. DeWees PhD., Jody L. Clikeman, Angela H. Fritsche, MPA, Jolene M. Summer Bolster, MA, Angela Dispenzieri, MD
Mayo Clinic Comprehensive Cancer Center, Division of Biostatistics

BACKGROUND

In 2020, the Mayo Clinic Comprehensive Cancer Center (MCCC) began planning for implementation of a formal 2-stage scientific review process. This effort was necessary to meet new requirements described in the NCI P30 Cancer Center Support Grant (CCSG) Guidelines (PAR-21-321). A review of the current state Protocol Review and Monitoring System (PRMS) process highlighted further opportunities to standardize, automate and reduce administrative burden.

OBJECTIVES/GOALS

- Implement a 2-stage scientific protocol review process for MCCC
- Differentiate between 1st-stage disease group (DG) review and 2nd-stage Protocol Review Monitoring Committee (PRMC) review
- Eliminate redundant data entry and improve first time quality
- Develop electronic system to facilitate review process and store documents

METHODS/SOLUTIONS

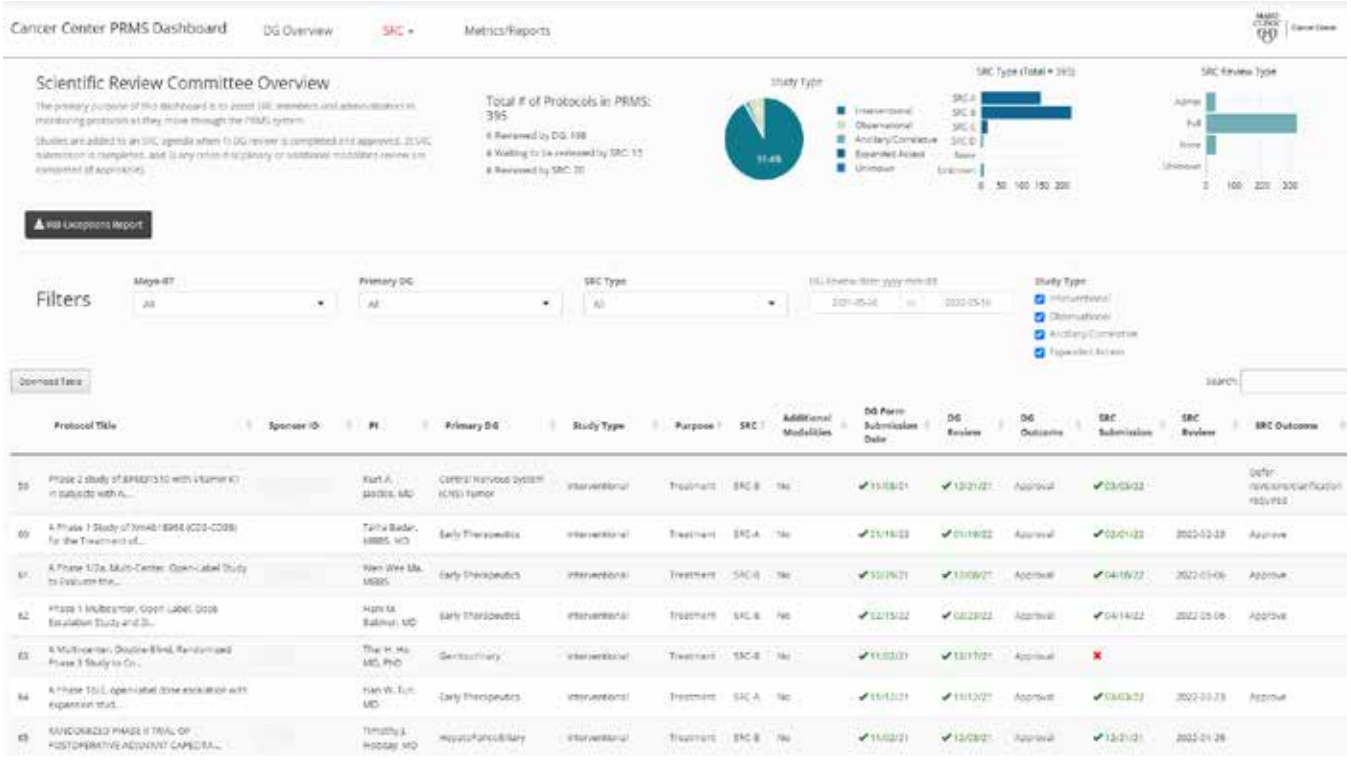
MCCC developed a 2-stage scientific protocol review process and defined the elements and criteria to be used by the 22 MCCC DGs and four PRMCs. To support the process, a scientific review e-committee tool was developed. The tool includes a REDCap database enhanced by an independent and interactive online dashboard as shown in the figure to the right. The tool features electronic forms for data capture, storage, metrics tracking, branching logic and automated email communications. Branching logic directs the user to the type of review required (e.g., full, expedited, administrative) and appropriate routing of the protocol for review by one or more committees.

RESULTS/OUTCOMES

The scientific review e-committee tool and 2-stage review process was piloted in three DGs from May to July 2021. As of January 2022, the tool was implemented in 14 of 22 MCCC DGs. 180 protocols have been entered with 20 completing the full scientific review process. Prior to implementation, first-time quality on entry of critical PRMS data was: 89% for capturing DG review date; 74% for PRMC submission date; and 79% for PRMC approval date. Leveraging automation, the tool is now capturing these data points at 100%.

DISCUSSION

Lessons learned through implementation include the value of standardized protocol review forms for data capture as well as DG structure and support to assist study team and committees with a more robust process. A Senior Program Coordinator has been assigned to each DG to support implementation. This additional resource is a main point of contact for Investigators and sponsors to help steward protocols from DG submission to PRMC approval. In addition, a protocol review requirement table with definitions was created to aid the entry of protocols into the tool.



Clinical Research: Following the Money Phase III

R. Geary, P. Eggleton, M. Kovak, M. Birrer, A. Smith, Z. Feng, N. Pruss
UAMS Winthrop P. Rockefeller Cancer Institute
Information Technology Research Systems, University of Arkansas for Medical Sciences

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. 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 system (EMR).

2. Goals

Our goal was to create streamlined processes for efficiently tracking billable items through robust integration with our CTMS managing receipt of payments, facilitating fund transfers between departments, and reporting clinical trial revenue and expenses on an accrual basis. This function creates a simple notification when a study incurs an expense or earns revenue allowing our financial analysts to create invoices in a timely manner.

Metrics used to evaluate milestones were:

- Revenue from invoiced procedures
- Revenue from milestone procedures
- Revenue from start-up processes
- Institutional expenses posted to the clinical trials
- Unfunded procedures

Based on these five metrics, reports can be generated by a number of criteria.

3. Solutions and Methods

Our information technology research systems team, through in-depth collaboration with multiple research and finance teams, developed the RAS to capture financial activity associated with clinical trials. RAS imports information from our CTMS to provide both study and subject-level clinical trial procedures at the contractual rate for a clinical trial. RAS generates customizable invoices, which can be sent to the sponsor for payment and, through integration with SAP, allows us to track receipt of payment. Incorporation of reporting capabilities allows accurate tracking of clinical trial accounting methods to preserve financial profitability.

4. Outcomes

Since the inception of this program, we have been able to successfully track, report, and post revenue and expenses for our clinical trials in an electronic program. Comprehensive integration with SAP 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 track revenue and report expenses related to clinical trials. This has allowed us to report more accurate figures to campus leadership in a timelier manner.

5. Lessons Learned and Future Directions

Phase III of this project is underway. It brings additional reporting abilities including an income statement that can be run per study, per disease type, per 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 III

Ronni Geary, MBA, CPC[1], Philip Eggleton, BBA[1], Matthew Kovak, MS, CCRP[1], Michael Birrer, MD, PhD[1],
Angela Smith, MS, PMP[2], Zhidan Feng, MS[2], Nicholas Pruss, BS[2]
[1]Cancer Clinical Trials Office, Winthrop P. Rockefeller Cancer Institute
[2]IT Research Systems, University of Arkansas for Medical Sciences, Little Rock, AR

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. 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 system (EMR).

Metrics & Goals to be Achieved

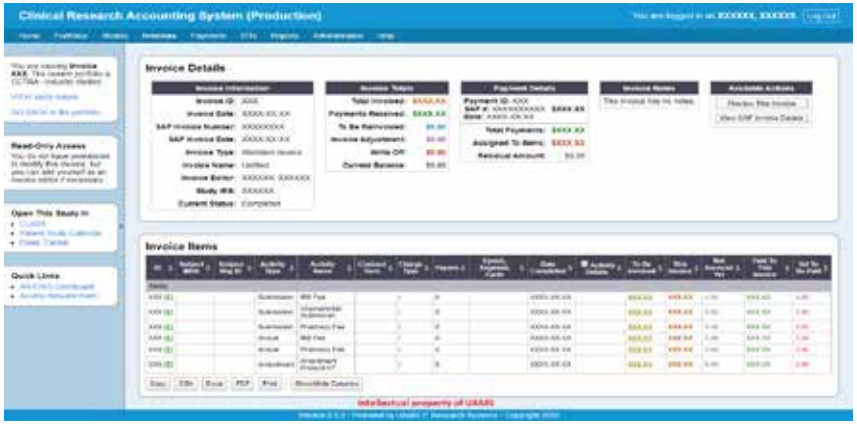
Our goal was to create streamlined processes for efficiently tracking billable items through robust integration with our CTMS managing receipt of payments, facilitating fund transfers between departments, and reporting clinical trial revenue and expenses on an accrual basis. This function creates a simple notification when a study incurs an expense or earns revenue allowing our financial analysts to create invoices in a timely manner.

Metrics used to evaluate milestones were: revenue from invoiced procedures; revenue from milestone procedures; revenue from start-up processes; Institutional expenses posted to the clinical trials; unfunded procedures

Based on these five metrics, reports can be generated by a number of criteria.

Methods

Our Information Technology Research Systems team, through in-depth collaboration with multiple research and finance teams, developed the RAS to capture financial activity associated with clinical trials. RAS imports information from our CTMS to provide both study and subject-level clinical trial procedures at the contractual rate for a clinical trial. RAS generates customizable invoices, which can be sent to the sponsor for payment and, through integration with SAP, allows us to track receipt of payment. Incorporation of reporting capabilities allows accurate tracking of clinical trial accounting methods to preserve financial profitability.



Outcomes

Since the inception of this program, we have been able to successfully track, report and post revenue and expenses for our clinical trials in an electronic program. Comprehensive integration with SAP and the CTMS reduced routine and often duplicative manual processes. We are now financially managing 260 Oncology Clinical Trial accounts (Industry, Cooperative, and Investigator Initiated) and have been able to adequately track revenue and report expenses related to clinical trials. This has allowed us to report more accurate figures to campus leadership in a timelier manner.

Detailed Income Statement
261 Studies
Activities from 7/1/21 to 6/30/22
All Items

Revenue	**$XXX,XXX**
Milestone	$XXX,XXX
Invoiceable	$XXX,XXX
Startup	$XX,XXX
Expenses	**$XXX,XXX**
Cancer Clinical Trials	$XXX,XXX
F&A and Other Adjustments	$XXX,XXX
HB Hospital Billing	$XX,XXX
COM Internal Med	$XX,XXX
Inst Review Board Administration	$X,XXX
PB Professional Billing	$X,XXX
Pharmacy	$X,XXX
Legal	$X,XXX
Net Income	**$XXX,XXX**

Lessons Learned & Future Directions

Phase 3 of this project is underway. It brings additional reporting abilities including an Income Statement that can be run per study, per disease type, per 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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UAMS University of Arkansas for Medical Sciences

Monitoring Study Enrollment Demographics: PRMS-COE Collaboration at University of Colorado Cancer Center (UCCC)

D. McCollister, D. Pacheco, A. Henningham, E. Borrayo, C. Cost
University of Colorado Cancer Center

1. Background

The National Cancer Institute (NCI) is dedicated to ensuring access to clinical trials opened at NCI-Designated Cancer Centers for all demographic populations. In November 2019, the Funding Opportunity Announcement for P30 Cancer Center Support Grants (CCSG) was revised to include additional monitoring responsibilities for the protocol review and monitoring system (PRMS). More specifically, PRMS was newly tasked with evaluating how the inclusion of minorities and other underrepresented populations into clinical trials is considered and monitored in open protocols.

2. Goals

With the new NCI requirements to evaluate the potential for inclusion of underrepresented populations in new clinical trials and to monitor open protocols, PRMS endeavored to roll out a collaborative review process to include key stakeholders, such as the University of Colorado Cancer Center (UCCC) Office of Community Outreach and Engagement (COE).

3. Solutions and Methods

- Input new questions into the scientific review committee form:
  - Are the eligibility criteria broad enough to be inclusive of all demographics?
  - Does the study include satellite/regional hospitals?
  - Does the study provide documents or consents in languages other than English?
- Hold regular meetings between PRMS and COE to determine:
  - Demographic definitions are aligned for race, ethnicity, rurality, and socioeconomic status
  - Areas for enhancement on the PRMS submission form related to potential barriers to enrollment
  - Workflow solutions for relaying PRMS submission requests or identified barriers to COE team
- Revise the PRMS submission form:
  - Input Colorado cancer demographics table for reference
  - Principal investigator (PI) required to indicate whether demographic enrollments are expected to be higher, lower, or the same as Colorado
  - PI able to identify potential barriers for enrolling a diverse population, such as access; language or literacy; cultural or religious; or other barriers
  - PI able to request COE support directly
  - COE list of local resources provided
- Create custom report from our clinical trial management system, OnCore, to review demographic enrollment and study data:
  - Age, Gender, Race, Ethnicity, and Rurality
  - Reports sent to Disease Based Teams (DBTs) biannually

Reports include demographics above; list of studies from which the demographic data was extracted; 6-month trend report; Colorado population demographics; clinic demographics (i.e., who is walking in); a DBT comparison graph for Hispanic/Latino enrollments; and information on how to request English-to-Spanish translation as well as assistance with strategies to make protocol engagement culturally and literacy appropriate

4. Outcomes

New PRMS review and monitoring processes were rolled out in July 2020 to incorporate evaluating newly submitted trials for demographic expectations, ensuring study inclusivity, and providing biannual monitoring reports to DBTs. PRMS has distributed four 6-month reports to DBTs.

5. Lessons Learned and Future Directions

There has been a recent strong push to ensure diversity, equity, and inclusion in cancer clinical trials. Monitoring DBT enrollment demographics has brought awareness of enrollment demographics to UCCC PIs, allowed UCCC to identify areas of need, and informed COE with data to target teams needing more assistance. The ultimate goal is to increase enrollment of underrepresented populations to studies open within the UCCC. Future metrics will determine whether these monitoring efforts have been fruitful.

MONITORING STUDY ENROLLMENT DEMOGRAPHICS: PRMS – COE COLLABORATION AT UNIVERSITY OF COLORADO CANCER CENTER (UCCC)

Deborah McCollister, RN, BSN; Daniel Pacheco, MBA; Anesha Henningham, BS; Evelinn Borrayo, PhD; Carrye Cost, MD

UNIVERSITY OF COLORADO CANCER CENTER

Deborah McCollister, RN, BSN
PRMS Program Director

INTRODUCTION

The NCI is dedicated to ensuring access to clinical trials opened at NCI-Designated Cancer Centers for all demographic populations. In November 2019, the Funding Opportunity Announcement for P30 Cancer Center Support Grants (CCSGs) was revised to include additional monitoring responsibilities for the Protocol Review and Monitoring System (PRMS). More specifically, PRMS was newly tasked with evaluating how the inclusion of minorities and other underrepresented populations into clinical trials is considered and monitored in open protocols.

OVERVIEW

The PRMS established a partnership with the UCCC Office of Community Outreach and Engagement (COE) to provide Principal Investigators and their research teams with data and resources to inform and improve enrollment of underrepresented populations to their clinical trials.

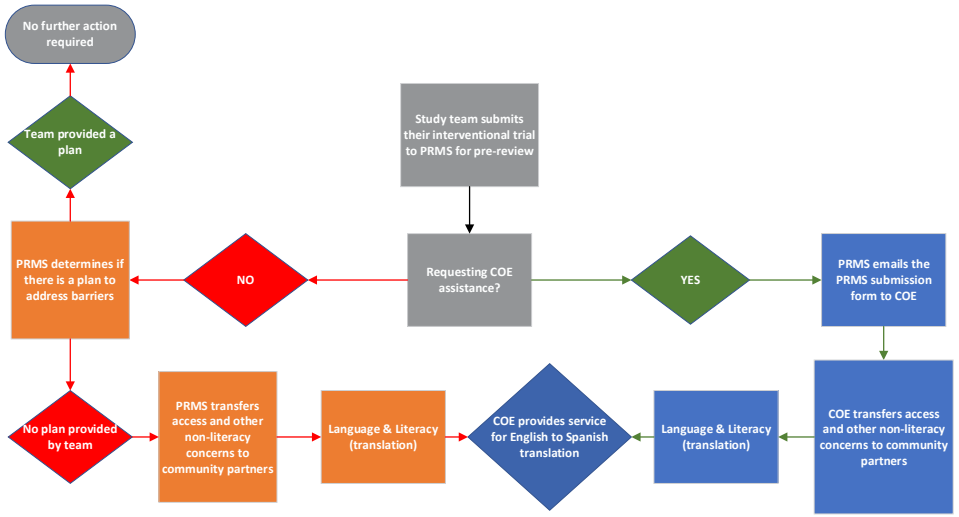
SPECIFIC GOALS

- Evaluate the potential for inclusion of underrepresented populations in new clinical trials and monitor open protocols.
- Roll out a collaborative review process to include key stakeholders, such as the UCCC Office of COE.
- Identify teams needing additional support.

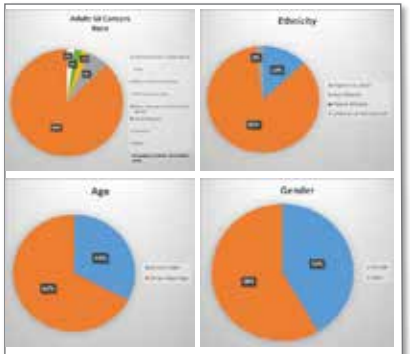
METHODS & SOLUTIONS

PRMS Actions:

- Initiated routine meetings between PRMS and COE to address barriers to diverse enrollment, and created a workflow between the two groups



- Input new questions into the Scientific Review Committee review form
  - Are eligibility criteria broad enough to be inclusive of all demographics?
  - Does the study include satellite/ regional hospitals?
  - Does the study provide documents in languages other than English?
- Revised the PRMS submission form
  - PI indicates anticipated demographic enrollment
  - PI indicates potential barriers to enrollment of diverse populations such as transportation, insurance, cost, languange
- Created a custom demographic report from OnCore, our Clinical Trial Management System



OUTCOMES

Since July 2020

- PRMS distributed four 6-month reports to Disease Based Teams (DBTs)
- PRMS-COE assisted 9 teams with support for identified barriers
- PRMS collaborated with UCHealth hospital on "Who's walking in the door?"
- PRMS and COE partnered on presentations to DBTs to share demographic data enrollment and resources

FUTURE DIRECTIONS

- Continued collaboration with PRMS-COE to monitor enrollment diversity and target teams needing assistance
- Analyze data for changes in enrollment diversity
- Questions?
  Deborah.McCollister@cuanschutz.edu

Prevent and conquer cancer. Together.

PARTNERING IN PROGRESS

INVESTIGATOR-INITIATED TRIALS

* Development of a Multisite Investigator-Initiated Trial Coordinating Center at Cedars-Sinai Cancer

E. Hautamaki, D. Ngo, A. Tan, P. Chang
Cedars-Sinai Cancer

1. Background

In late 2020, the ability to internally coordinate multisite investigator-initiated trials (IITs) at Cedars-Sinai (CS) Cancer became imperative, due to several factors: a growing portfolio of IITs, investigator interest in conducting collaborative research with other institutions, challenges to accrual to existing IITs, and the cost-prohibitive nature of subcontracting with external coordinating centers for IITs with often limited financial resources. Through implementation of a multisite IIT taskforce, CS Cancer has successfully developed the infrastructure to operationalize the coordination of multisite IITs.

2. Goals

- To develop the infrastructure to conduct multisite IITs at CS Cancer, including development of processes, document templates, scope of roles and responsibilities of each team member, and a budget template, for ability to successfully coordinate multisite IITs
- To demonstrate the cost-savings to the investigator/study

3. Solutions and Methods

A task force was convened with weekly meetings over the course of approximately six months in late 2020 to early 2021, with the following objectives:

- Outline the gaps in our documents and processes
- Seek templates from other institutions to modify for application to CS Cancer
- Ensure processes are consistent with CS Cancer institutional and regulatory requirements
- Obtain concurrence with the roles and responsibilities of each team member

The task force included IIT protocol development staff, with input sought from institutional monitors, the institutional IRB, regulatory staff, and finance staff. Staff members were assigned documents or processes to take the lead on, with others providing input at the task force meetings.

4. Outcomes

The task force developed the following processes and document templates relative to multisite coordination:

- Budget
- Protocol
- Manual of operating procedures, lab manual, and pharmacy manual
- Site feasibility and qualification documents,
- Site initiation visit templates
- OnCore and REDCap external user guides
- Regulatory and enrollment trackers
- Site meeting agenda
- Monitoring and close-out checklists

In addition, the scope and expectations of the multisite lead, as well as the role of central regulatory and finance team members contributing their efforts to multisite IITs, were outlined in detail. Whereas, in our experience, the cost of subcontracting to an external coordinating center begins at around $1,000,000, we determined that the cost of internal coordination of multisite trials ranges from around $150,000-$300,000 depending on complexity and duration, based on anticipated number of hours of staff effort and an average hourly rate, making internally coordinated multisite IITs much more feasible to accommodate within a study budget.

5. Lessons Learned and Future Directions

CS Cancer is currently implementing this new infrastructure with two multisite IITs. We anticipate our processes and document templates will continue to evolve as we gain experience and identify areas for improvement. In the future, depending on the speed with which multisite IITs are introduced, it may become necessary to allocate resources for a multisite IIT lead or team.

* *Honorable Mention*

Development of a multisite investigator-initiated trial coordinating center at Cedars-Sinai Cancer

Emily Hautamaki, RN, MPH, CCRP; Diane Ngo; Anamarie Tan, CCRP; Phoebe Chang, PhD
Cancer Clinical Trials Office, Cedars-Sinai Cancer
Cedars-Sinai Medical Center, Los Angeles

Background

In late 2020, the ability to internally coordinate multisite investigator-initiated trials (IITs) at Cedars-Sinai (CS) Cancer became imperative, due to several factors: a growing portfolio of IITs, investigator interest in conducting collaborative research with other institutions, challenges with accrual to existing IITs, and the cost-prohibitive nature of subcontracting with external coordinating centers for IITs with often limited financial resources. Through implementation of a multisite IIT taskforce, CS Cancer has successfully developed the infrastructure to operationalize the coordination of multisite IITs.

Objectives

- To develop the infrastructure to conduct multisite IITs at CS Cancer, including development of processes, document templates, scope of roles and responsibilities of each team member, and a budget template, for ability to successfully coordinate multisite IITs.
- To demonstrate the cost-savings to the investigator/study.

Methods

A taskforce was formed and convened at weekly meetings over the course of approximately six months in late 2020 to early 2021, with the following objectives: outline the gaps in our documents and processes, seek templates from other institutions to modify for application to CS Cancer, ensure processes are consistent with CS Cancer institutional and regulatory requirements, obtain concurrence with the roles and responsibilities of each team member, and to identify roles and reporting responsibilities of the participating sites. The task force included IIT protocol development staff, with input sought from institutional monitors, the institutional IRB, regulatory staff, and finance staff. Staff members were assigned documents or processes to take the lead on, with others providing input at the taskforce meetings.

Figure 1: Manual of Operating Procedures (MOP) Table of Contents

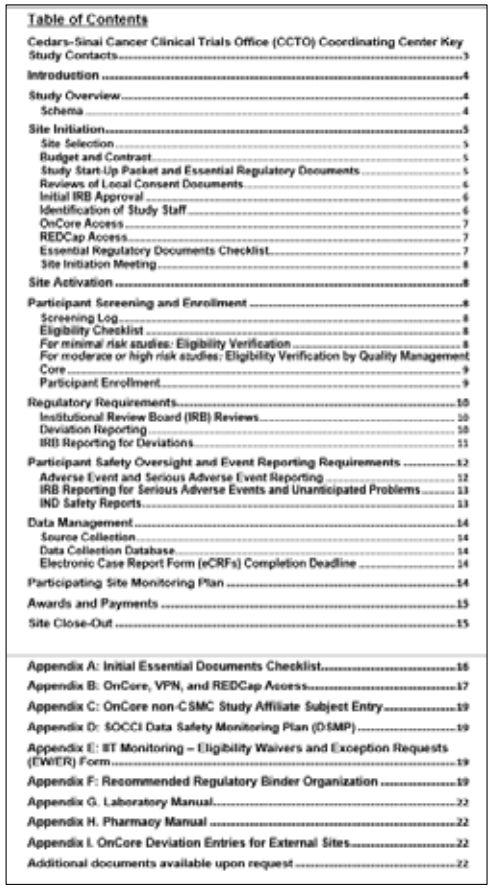


Table of Contents

Outcomes

The taskforce developed the following processes and document templates relative to multisite coordination: budget, protocol, manual of operating procedures, lab manual, pharmacy manual, site feasibility and qualification documents, site initiation visit templates, OnCore and REDCap external user guides, regulatory and enrollment trackers, site meeting agenda, and monitoring and close-out checklists. In addition, the scope and expectations of the multisite lead, as well as the role of central regulatory and finance team members contributing their efforts to multisite IITs, were outlined in detail. An estimate of regulatory and monitoring time and effort based on risk level was developed. Whereas, in our experience, the cost of subcontracting to an external coordinating center begins at around $1,000,000, we determined that the cost of internal coordination of multisite trials ranges from around $150,000 - $300,000 depending on complexity and duration, based on anticipated number of hours of staff effort and an average hourly rate, making internally coordinated multisite IITs much more feasible to accommodate within a study budget.

Lessons Learned and Future Directions

CS Cancer is currently implementing this new infrastructure with two multisite IITs. We anticipate our processes and document templates will continue to evolve as we gain experience and identify areas for improvement. In the future, depending on the speed with which multisite IITs are introduced, it may become necessary to allocate resources for a multisite IIT lead or team.

Development of a Workload Assessment Tool for Investigator-Initiated Trial Protocol Development Based on the Ontario Protocol Assessment Level Scale

E. Hautamaki
Cedars-Sinai Cancer

1. Background

Workload assessment tools provide valuable objective insights into personnel management and workforce planning, which is especially needed for new or rapidly growing teams. Existing workload assessment tools in clinical research, such as the Ontario Protocol Assessment Level (OPAL) scoring tool, are generally intended for application to the role of the clinical research coordinator. Due to a growing portfolio of investigator-initiated trials (IITs) at Cedars-Sinai (CS) Cancer, an objective measure of workload for IIT protocol development specialists was needed to inform equitable new trial assignments and to justify the addition of personnel.

2. Goals

To develop a tool to provide an objective assessment of workload per full-time equivalent (FTE) for IIT protocol development specialists, to provide a basis for tracking ongoing metrics, to inform new trial assignments to protocol development staff members, and to generate baseline data to demonstrate growth over time and to justify the addition of FTEs.

3. Solutions and Methods

Due to its familiarity in the clinical research field, the OPAL tool was selected for modification for application to IIT protocol development staff at CS Cancer. The scope of studies supported by the protocol development team were ranked from 1-8, in order of increasing complexity. Factors contributing to increasing IIT complexity included classification as treatment vs. non-treatment; scope of multi- vs. single-site; Phase I vs. non-Phase I; and trials with an investigator-held IND vs. IND-exempt studies. For single-site studies only, once the trial has opened to accrual, a multiplier of 0.5 was applied. Closed-to-accrual studies did not contribute to the workload assessment. Each trial in the portfolio was categorized according to the tool and assigned a numeric score. A summary score and an average complexity score was generated for each FTE, to provide a snapshot of both the total workload and the average complexity of their portfolio. Per FTE, the average number of studies contributing to the score was 11 (range 9-14); the average summary score was 33 (range 28.5-37.5); and the average complexity score was 3.1 (range 2.7-3.7).

4. Outcomes

These data points, taken into consideration along with the individual's level of experience, administrative responsibilities, existing relationships with investigators and study teams, and career interests and goals, are used to inform equitable future trial assignments, which may contribute to improved staff morale and retention. In addition, when the scope of the protocol development team grew to take on an additional study team portfolio, the newly added trials were scored, which provided objective rationale for increasing the size of the team, and an additional staff member was hired.

5. Lessons Learned and Future Directions

This tool provides objective assessments of workload that resonate with cancer center leadership. In addition, it provides staff members with assurance that new trial assignments are made with objective consideration of existing workload and in the spirit of equity. While the tool reflects the range of trials supported by protocol development staff at CS Cancer, this tool can readily be modified to reflect the scope of other centers. The tool would benefit from additional validation of the categorization as well as correlation of scores to FTEs.

Development of a workload assessment tool for investigator-initiated trial protocol development based on the Ontario Protocol Assessment Level scale

Emily Hautamaki, RN, MPH, CCRP
Cancer Clinical Trials Office, Cedars-Sinai Cancer
Cedars-Sinai Medical Center, Los Angeles

Background

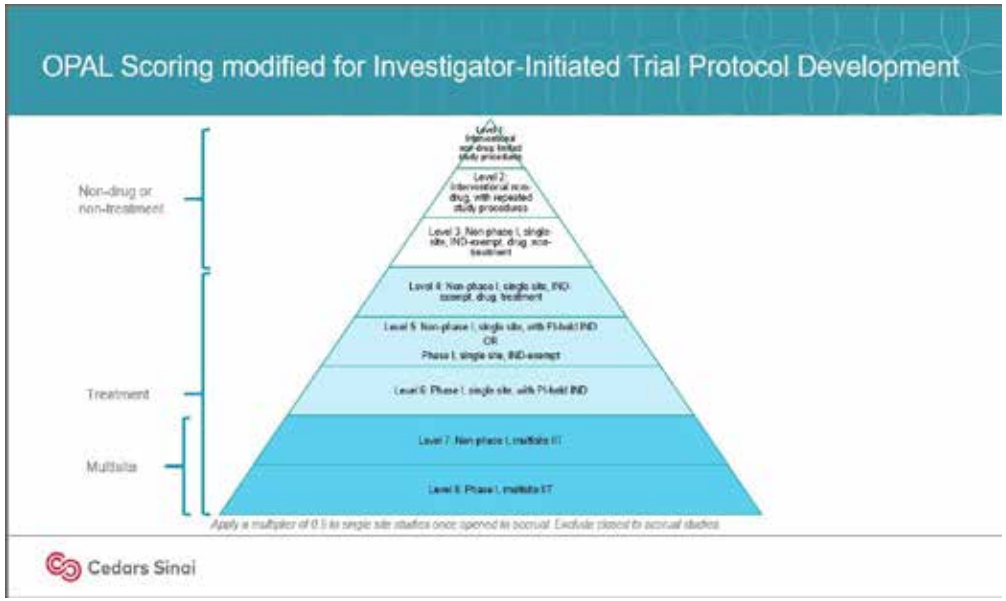
Workload assessment tools provide valuable objective insights into personnel management and workforce planning, which is especially needed for new or rapidly growing teams. Existing workload assessment tools in clinical research, such as the Ontario Protocol Assessment Level (OPAL) scoring tool, are generally intended for application to the role of the clinical research coordinator. Due to a growing portfolio of investigator-initiated trials (IITs) at Cedars-Sinai (CS) Cancer, an objective measure of workload for IIT protocol development specialists was needed to inform equitable new trial assignments and to justify the addition of personnel.

Objectives

- To develop a tool to provide an objective assessment of workload per full-time equivalent (FTE) for IIT protocol development specialists, to provide a basis for tracking ongoing metrics
- To inform new trial assignments to protocol development staff members
- To generate baseline data to demonstrate growth over time and to justify the addition of FTEs

Methods

Due to its familiarity in the clinical research field, the OPAL tool was selected for modification for application to IIT protocol development staff at CS Cancer. The scope of studies supported by the protocol development team were ranked from 1-8, in order of increasing complexity. Factors contributing to increasing IIT complexity included classification as treatment vs. non-treatment, scope of multi- vs. single-site, phase I vs. non-phase I, and trials with an investigator-held IND vs. IND-exempt studies. For single-site studies only, once the trial has opened to accrual, a multiplier of 0.5 was applied. Closed to accrual studies did not contribute to the workload assessment. Each trial in the portfolio was categorized according to the tool and assigned a numeric score. A summary score and an average complexity score was generated for each FTE, to provide a snapshot of both the total workload and the average complexity of their portfolio.



Outcomes

Per FTE, the average number of studies contributing to the score was 11 (range 9-14); the average summary score was 33 (range 28.5-37.5); and the average complexity score was 3.1 (range 2.7-3.7). These data points, taken into consideration along with the individual's level of experience, administrative responsibilities, existing relationships with investigators and study teams, and career interests and goals, are used to inform equitable future trial assignments, which may contribute to improved staff morale and retention. In addition, when the scope of the protocol development team grew to take on an additional study team portfolio, the newly added trials were scored, which provided objective rationale for increasing the size of the team, and an additional staff member was hired.

Lessons Learned and Future Directions

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Building IND Infrastructure to Ensure Compliance and Enable Growth

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

1. Background

IND regulations are complex and require a high level of subject matter expertise to ensure compliance. Historically, Lineberger Comprehensive Cancer Center (LCCC) relied on centralized university resources to submit and maintain its INDs. In 2016, LCCC identified substantial noncompliance with FDA regulations across its IND portfolio and decided to build infrastructure to move IND management in-house.

2. Goals

The goal of this initiative was to develop an IND management system with appropriate checks and balances to ensure LCCC's INDs followed appropriate regulations and to detect early indicators of noncompliance.

3. Solutions and Methods

Root cause analysis identified several contributing factors to noncompliance, including lack of written procedures defining IND management; investigator involvement and awareness; and training at all levels of the organization. The methods implemented were focused on addressing these root causes and ensuring that all management steps relied on a system as opposed to a single individual to ensure compliance. Ten sets of IND-specific SOPs, work instructions, and templates were developed covering topics ranging from IND safety reports to distribution of FDA communication. The SOPs described automated processes that heavily relied on utilization of custom reports generated from OnCore to track submission deadlines. Subject matter experts in protocol development and IND management were hired within LCCC, expanding from 1 FTE solely supporting protocols to 5 FTEs over protocol development and IND management. Their addition was justified by the need to address noncompliance, growth in portfolio, and expansion in IND and protocol development services. Additional FTEs were also added in data management to develop IND reports. Electronic data reports were optimized to ease IND annual report writing and were released under a stringent quality assurance system to ensure the accuracy and completeness of the data. Additionally, a principal investigator (PI) training lecture was launched and covered IND-related hot topics with a focus on lessons learned. Furthermore, a series of lectures targeted to staff were developed and well received.

4. Outcomes

Prior to solution implementation, internal audits revealed that within the 5 years prior there was only 56 percent compliance with submitting IND serial submissions per the regulations. Furthermore, of the serial submissions that were provided to FDA, 64 percent of the submissions were late. This means that LCCC's IND overall compliance rating with FDA regulations was only 20 percent. Internal audits were completed in 2022 of the 5 years after intervention implementation and showed 100 percent compliance with the regulations. Importantly, the IND portfolio grew in complexity within the 5-year period post-intervention with the addition of 10 INDs for internally manufactured products covering 15 clinical protocols. Prior to the transition, LCCC had only 1 IND covering 1 clinical protocol for an internally manufactured investigational product. Therefore, compliance increased significantly despite increased complexity.

5. Lessons Learned and Future Directions

Two major lessons were learned during this process:

1. PI understanding of IND regulations at a high level is key so they know when to reach out with questions
2. Automated systems that are independent of a single individual are necessary to ensure long-term compliant oversight of the IND portfolio

Building IND Infrastructure to Ensure Compliance and Enable Growth

J. Kaitlin Morrison, PhD; Nasrin H. Babadi, PhD, RAC; Erin Crecelius, MA; Shaw Scott, JD; Robin V. Johnson, M.Med.Sc; Susan Boyle; Martha Retter; Allison Camp, PhD; Leila Kiefer, PhD; Carrie Lee, MD, MPH

Introduction

IND regulations are complex and require a high-level of subject matter expertise to ensure compliance. Historically, Lineberger Comprehensive Cancer Center (LCCC) relied on centralized University resources to submit and maintain its INDs. In 2016, LCCC identified substantial noncompliance with FDA regulations across its IND portfolio and decided to build infrastructure to move IND management in-house.

The goal of this initiative was to develop an IND management system with appropriate checks and balances to ensure LCCC's INDs followed appropriate regulations to detect early indicators of noncompliance.

Solutions/Methods

Root cause analysis identified several contributing factors to noncompliance including lack of: written procedures defining IND management, investigator involvement and awareness, and training at all levels of the organization. The methods implemented were focused on addressing these root causes and ensuring that all management steps relied on a system as opposed to a single individual to ensure compliance. Ten sets of IND-specific SOPs, work instructions and templates (**Figure 1A**) were developed covering topics ranging from IND safety reports to distribution of FDA communication. The SOPs described automated processes that heavily relied on utilization of custom reports generated from the clinical trial management system, OnCore™, to track submission deadlines, such as the IND lapse report (**Figure 1B**).

Figure 1. SOPs/Processes for IND Maintenance

A

Templates

-**Protocol** (Biospecimen, Chemotherapy, Health Services, Radiation Therapy, Cellular Therapy, Radiology, Amendment Cover Sheet)

-**Informed Consents** (CAR-T Procurement, CAR T Treatment, CAR-T Biospecimen, Phase 1- Combination, Phase 2, Phase 2- Multi-arm, Biospecimen)

-**IND Initial** (Simple, Complex, CAR-T, eCTD [purchased])

-**IND Report** (1 Study Annual Report, Multiple Studies Annual Report, 1 Study Withdraw, Multiple Studies Withdrawal)

-**IND Cover Letters** (Initial, Protocol Amendment- New Investigator, Updated Form FDA 1572, Protocol Amendment- Change in Protocol, IND Safety Report- Initial, IND Safety Report- Action Letter, IND Safety Report- Initial Aggregate Report, IND Safety Report- Follow-up, Annual Report, Updated Medical Monitor, Acceptance of Transferred IND, IND Transfer to a New Sponsor, PI Transfer, Updated Sponsor Contact Information, IND Withdrawal)

-**Action Letter**

-**IND Exemption Letter**

-**Letter of Authorization**

SOPs/Work Instructions

-Protocol Amendments
-Determining IND Status
-Administrative Letters
-Action Letters
-IND Safety Reporting (single and multicenter)
-Updates for Form FDA 1572
-CAPA Implementation and Oversight
-Drafting and Amending IBs
-Determining IDE Status
-IIT Protocol Review Meetings
-IND Annual Reports
-Distribution of FDA Communication
-Protocol Amendment- Change in Protocol Submissions
-Protocol Amendment- New Investigator Submissions
-Changes in Sponsor, Medical Monitor, and/or PI
-Changes in Multicenter PI
-PI Transfer (with and without an IND)
-IND Withdrawal
-Updating Protocol Templates
-DSMC and IND Data Report Generation
-IND Data Report Review Checklist
-IND Data Report Timelines
-IND OnCore Tracking
-Electronic Submissions through the CDER Portal
-Printing/Binding Paper FDA Submissions
-eCTD Submissions
-Checklist for IND Exemption

B

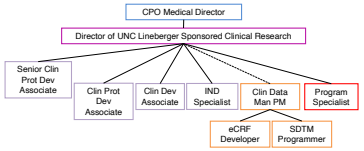
Report generated out of OnCore™ with all upcoming IND submissions:

A. Work Instructions, Standard Operating Procedures (SOPs) and templates for IND and protocol management. B. IND submissions added into the "other external committee" screen in OnCore™ without a submission date, are pulled through custom reports indicating that they still require submission to FDA. INDs requiring annual reporting to FDA are run using a standard OnCore™ (IND lapse report).

Solutions/Methods

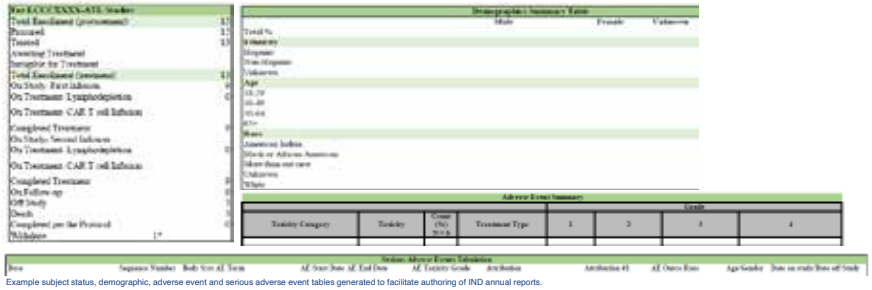
Subject matter experts in protocol development were hired within LCCC expanding from 1 FTE solely supporting protocols to 5 FTEs over protocol development and IND management (**Figure 2**). Their addition was justified by the need to address noncompliance, growth in portfolio and expansion in IND and protocol development services. Additional FTEs were also added in data management to develop IND reports (**Figure 2**). Electronic data reports were optimized to ease IND annual report writing and were released under a stringent quality assurance system to ensure the accuracy and completeness of the data (**Figure 3**). Additionally, a PI training lecture series was launched and covered IND-related hot topics with a focus on lessons learned (**Refer to LCCC Training Poster**). Furthermore, a series of lectures targeted to staff were developed and well received.

Figure 2. IND Infrastructure FTEs



Full-time employees (FTEs) to support IND management and protocol development. Responsibilities for these staff include: 1. Figuring out what regulations apply to the study, 2. Submitting to FDA (IND & IDEs), 3. Drafting/Submitting an IND/IDE exemption to the Protocol Review Committee (PRC), 4. Drafting Letters of Intent (LOIs) & occasionally writing clinical trial grants, 5. Drafting protocols, consent forms & patient education materials, 6. Leading protocol and correlative (lab manual) review meetings, 7. Interacting with the Institutional Conflict of Interest (COI) Board, 8. Facilitating the transition of products from the bench to the clinic, 9. Facilitating access to resources to enable clinical development, 10. Developing FDA compliant data sets and creation of eCRFs in Part 11 compliant systems, 11. Providing guidance to the PRC, Data and Safety Monitoring Committee (DSMC), Compliance Committee, and the COI Committee on FDA regulations, 12. Collaborate with patient advocates on expanding patient education, and 13. Training investigators on their responsibilities.

Figure 3. Example IND Report Data Tables

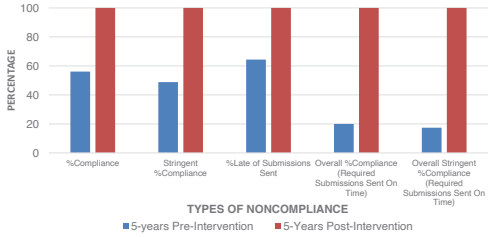


Example subject status, demographic, adverse event and serious adverse event tables generated to facilitate authoring of IND annual reports.

Results

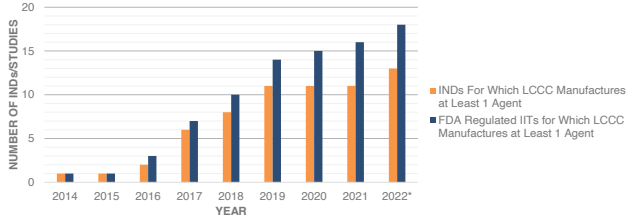
Prior to solution implementation, internal audit revealed that within the 5 years prior there was only 56% compliance with submission IND serial submissions per the regulations (**Figure 4**). Furthermore, of the serial submission that were provided to FDA, 64% of the submissions were late. This means that LCCC's IND overall compliance rating with FDA regulations was only 20%. Internal audits were completed in 2022 of the 5 years after intervention implementation and showed 100% compliance with the regulations. Importantly, the IND portfolio grew in complexity within the 5-year period post-intervention with the addition of 10 INDs for internally manufactured products covering 15 clinical protocols (**Figure 5**). Prior to transition, LCCC had only 1 IND covering 1 clinical protocol for an internally manufactured investigational product. Therefore, compliance increased significantly despite increased complexity.

Figure 4. IND Compliance



% Compliance = Submissions compliant with 21CFR312, Stringent % Compliance = Submissions compliant with 21CFR312 + Community standards (e.g., submission of all protocol amendments to FDA), % Late of Submissions Sent = Submissions sent to FDA, as required, but not submitted within the timeframes specified in 21CFR312, Overall % Compliance = Submissions compliant with 21CFR312 and submitted within the required timeframes, Overall Stringent % Compliance = Submissions compliant with 21CFR312 + Community standards (e.g., submission of all protocol amendments to FDA), and submitted within the required timeframes.

Figure 5. IND Portfolio Complexity



IND complexity increased over time as LCCC focused on development of internally manufactured investigational agents (e.g., CAR-T cells, personalized and adaptive neoantigen dose-adjusted vaccine (PANDA-VAC), C11-AMT, ⁶⁸Ga-PSMA-11) . Several of these INDs focused on a specific investigational agent with multiple clinical protocols managed under the product specific IND spanning multiple indications or phases of development (I, Ib/II, II). *2022 data cut-off 05/13/2022.

Conclusions

Two major lessons were learned during this process: 1. PI understanding of IND regulations at a high-level is key to ensure compliance with regulations and 2. Automated systems that are independent of a single individual are necessary to ensure long-term compliant oversight of the IND portfolio (e.g., OnCore™ and procedural processes).

Development of an Investigator-Initiated Trial Intake Process at Cedars-Sinai Cancer

E. Hautamaki, P. Chang, D. Ngo, A. Tan
Cedars-Sinai Cancer

1. Background

Historically at Cedars-Sinai (CS) Cancer, investigators wishing to conduct an investigator-initiated trial (IIT) would individually engage the protocol development team while seeking funding. However, as the IIT portfolio has grown, at times this has led to IITs that did not have broader support within the disease resource group (DRG); were not feasible or were challenging to accrue to; or did not ultimately receive funding, creating resource challenges among the clinical study teams and administrative teams. As such, a formal IIT intake process was needed to manage the pipeline of IITs, to ensure only the most robust and feasible concepts were approved for implementation.

2. Goals

- Develop an IIT intake process that identified the most scientifically robust and feasible concepts that were of most interest to the DRG and prioritized for support
- Ensure funding was identified early in the protocol development process
- Develop an expedited activation pathway for qualifying studies
- Develop a central contact method for requesting protocol development support

3. Solutions and Methods

Prior to engaging the protocol development team, investigators are required to complete a newly developed concept form, detailing the study summary, resource considerations, ability to accrue to the patient population, and financial considerations. Engagement of a biostatistician and identification of a potential funding source are required at the concept stage.

The investigator presents the concept to the DRG for discussion of the scientific rationale, fit with the overall DRG portfolio, and commitment of staffing resources. If the concept is approved by the DRG, the investigator submits the concept form to the protocol development team via a survey tool, and the concept is assigned to a protocol development specialist and a finance specialist for activation. An expedited activation pathway via ad hoc chair review was developed for non-treatment trials of lower complexity.

4. Outcomes

This process has set forth clear expectations and set a higher standard for selection of IITs that are a better fit for our DRGs and that are more likely to successfully accrue. The goal is that this process will result in fewer study design changes throughout the protocol development process and fewer IITs that are ultimately abandoned for lack of funding after initiation of protocol development, ultimately improving study activation timelines, making the best use of limited staffing resources, and providing the best clinical trial treatment options for our patient populations that yield high accruals. In March 2022, the first study to follow this process entered the pipeline, and in the coming year, we hope to generate metrics to demonstrate effectiveness.

5. Lessons Learned and Future Directions

The success of an IIT depends upon the support of many people at an early stage. Ensuring broad support is obtained prior to investing resources in the concept helps make the best use of limited resources. To be most successful, this process will require active discussion at the DRG level to vet concepts that are brought forth and select for activation only those that are most likely to accrue and diversify the portfolio; objective criteria for disapproving an IIT concept may be needed in the future. As we pilot the process and generate data on its effectiveness, it may continue to evolve to meet the needs of the investigators and the cancer center.

Development of an investigator-initiated trial intake process at Cedars-Sinai Cancer

Emily Hautamaki, RN, MPH, CCRP; Phoebe Chang, PhD; Diane Ngo; Anamarie Tan, CCRP
Cancer Clinical Trials Office, Cedars-Sinai Cancer
Cedars-Sinai Medical Center, Los Angeles

Background

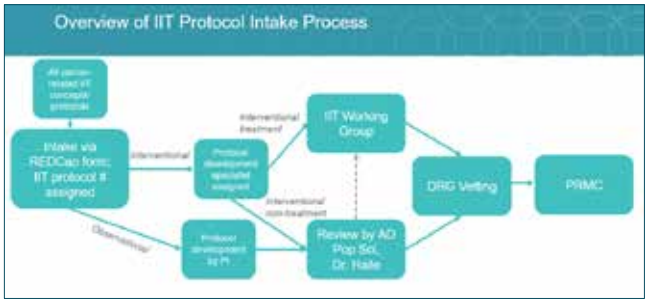
Historically at Cedars-Sinai (CS) Cancer, investigators wishing to conduct an investigator-initiated trial (IIT) would individually engage the protocol development team while seeking funding. However, as the IIT portfolio has grown, this has led to some IITs that did not have broader support within the Disease Resource Group (DRG), were not feasible or were challenging to accrue to, or did not ultimately receive funding, creating resource challenges among the clinical study teams and administrative teams. As such, a formal IIT intake process was needed to manage the pipeline of IITs, to ensure only the most robust and feasible concepts were approved for implementation.

Objectives

- To develop an IIT intake process that identified the most scientifically robust and feasible concepts that were of most interest to the DRG and prioritized for support;
- To ensure funding was identified early in the protocol development process;
- To develop an expedited activation pathway for qualifying studies;
- To develop a central contact method for requesting protocol development support.

Methods

Prior to engaging the protocol development team, investigators are required to complete a newly developed concept form, detailing the study summary, resource considerations, ability to accrue to the patient population, and financial considerations. Engagement of a biostatistician and identification of a potential funding source are required at the concept stage. The investigator presents the concept to the DRG for discussion of the scientific rationale, suitability within the overall DRG portfolio, and commitment of staffing resources. If the concept is approved by the DRG, the investigator submits the concept form to the protocol development team via a survey tool, and the concept is assigned to a protocol development specialist and a finance specialist for activation. An expedited activation pathway via electronic ad hoc chair review was developed for non-treatment trials of lower complexity.



Outcomes

This process has set forth clear expectations and set a higher standard for selection of IITs that are a better fit for our DRGs and that are more likely to successfully accrue. The goal is that this process will result in fewer study design changes throughout the protocol development process and fewer IITs that are eventually abandoned for lack of funding after initiation of protocol development, ultimately improving study activation timelines, making the best use of limited staffing resources, and providing the best clinical trial treatment options for our patient populations that yield high accruals. This process when live in November 2021, and the first study to follow this process entered the pipeline in March 2022. In the coming year, we aim to generate metrics to demonstrate effectiveness, including time-to-activation, rate of abandonment of concepts after initiation protocol development, and ability to meet overall and annual accrual goals.

Lessons Learned and Future Directions

The success of an IIT depends upon the support of many people at an early stage. Ensuring broad support is obtained prior to investing resources in the concept helps make the best use of limited resources. To be most successful, this process will require active discussion at the DRG level to vet concepts that are brought forth and select for activation only those that are most likely to accrue and diversify the portfolio; objective criteria for disapproving an IIT concept may be needed in the future. As we pilot the process and generate data on its effectiveness, it may continue to evolve to meet the needs of the investigators and the cancer center.

Streamlining Data Collection: Implementation of an EDC FHIR Lab Interface

E. Crecelius, M. O'Dwyer, L. Logan, S. Balu, J. Frank, R. Johnson, R. Church, C. Lee, J. Morrison
UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

1. Background

Manual data entry of clinical trial data into electronic data capture (EDC) systems consumes significant time and effort for data and study coordinators. Lineberger Comprehensive Cancer Center (LCCC) initiated a project with the EDC system vendor, Advarra, to establish a patient information link between source system (Epic) and the electronic data capture system (Advarra EDC) for LCCC sponsored investigator-initiated trial (IIT) laboratory result data. Based on effort monitoring, it is estimated data coordinators spend up to 32 hours per week manually entering data into the EDC system. Reducing data entry time can result in effort spent on critical tasks including enrolling and managing research subjects. Manual data entry also introduces the opportunity for transcription errors resulting in an increased risk to data quality.

2. Goals

The goals of this project are to improve data quality by reducing transcription errors and to alleviate a portion of data entry and review burden for staff. Metrics to be used include:

- Decrease in effort tracking hours per month dedicated to data entry for data coordinators (DCs) and data review for clinical data management associates (CDMAs)
- Decrease in data latency and reduction in query rate
- Decrease in query response time for CDMAs and DCs

3. Solutions and Methods

We established a project team comprised of staff from UNC Health, LCCC Bioinformatics Core, and the EDC vendor (Advarra) to plan the implementation of a patient information link between Epic and the EDC system. The lab results interface will pull lab results into electronic case report forms (eCRFs) using SMART on Fast Health Interoperability Resource (FHIR) authentication to the source system. SMART on FHIR together create a standardized way of exchanging data among healthcare systems. The user is temporarily forwarded to the Epic login page to enter their Epic credentials. Once logged into Epic, access to data will be based on their role and permissions within the source system. When users search for subjects using the medical record number, PHI will be displayed for data selection but not saved in the EDC system. The integration was validated by the vendor in test environments and maps FHIR observation codes to Advarra EDC lab codes. Following the UNC FHIR interface build, UNC project team members will validate the integration in the EDC test instance. The laboratory eCRF will be built using clinical data acquisition standards harmonization (CDASH) data standards to enable cross-study implementation.

4. Outcomes

This project is in progress. We will analyze data from protocol data timeliness reports, query metrics, and effort tracking data at baseline and three and six months post integration to determine the success of project outcomes.

5. Lessons Learned and Future Directions

As the LCCC IIT portfolio grows, there will be an even greater need to assess and streamline data collection. The adoption of CDASH data standards and the growth of a global eCRF library will enable future integrations. This includes additional FHIR mappings for demographic, vital sign, adverse event, and concomitant medication eCRFs published in the FHIR to CDISC joint mapping implementation guide.

Streamlining Data Collection: Building a Bridge between the Source and the Electronic Data Capture System

Erin Crecelius, MA; Mary O'Dwyer, MRP, CCRP; Leilani Barry Logan, MSc; Saianand Balu, MS; Jill Frank, MS; Robin V. Johnson, M.Med.Sc.; Randy Church; Carrie B. Lee, MD, MPH; J. Kaitlin Morrison, PhD

UNC LINEBERGER COMPREHENSIVE CANCER CENTER

UNC CANCER CARE

Background & Goals

Manual data entry of clinical trial data into Electronic Data Capture (EDC) systems consumes significant time and effort. A large bulk of the time is spent entering lab result data. A typical investigator-initiated trial includes up to 3 lab eCRFs containing multiple lab assessed at multiple timepoints (figure 1). Lineberger Comprehensive Cancer Center (LCCC) initiated a project with the EDC system vendor, Advarra, to establish a patient information link between source system (Epic) and the Electronic Data Capture System (Advarra EDC) for LCCC sponsored investigator-initiated trial (IIT) laboratory result data. Reducing data entry time can result in effort spent on critical tasks including enrolling and managing research subjects. Manual data entry also introduces the opportunity for transcription errors resulting in an increased risk to data quality.

The goals of this project are to improve data quality by reducing transcription errors and to alleviate a portion of data entry and review burden for staff. Metrics to be used include:

- Decrease in Effort Tracking hours per month dedicated to data entry for Data Coordinators (DCs).
- Decrease in Effort Tracking hours per month dedicated to data review for Clinical Data Management Associates (CDMAs).
- Decrease query rate.
- Decrease in query response time for CDMAs and DCs.

Figure 1. Example Time and Events Table

Preliminary Results

This project is in progress. We will analyze data from protocol data timeliness reports, query metrics, and effort tracking data at baseline and six- and twelve-month post integration to determine the success of project outcomes.

At baseline, data coordinators spend on average 27.5 hours per week manually entering IIT data into the EDC system. Estimates were based on data entry for 11 trials.

The following graphs depict baseline metrics

Figure 2. Baseline Average EDC Query Aging (10/2020-04/2022)

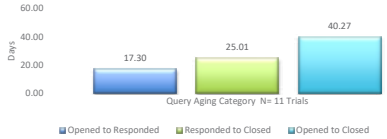


Figure 3. Baseline Data Review Hours (5/1/21-4/30/22)

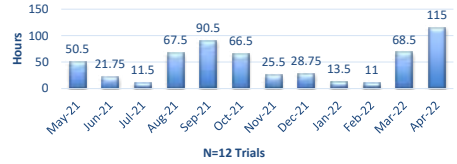
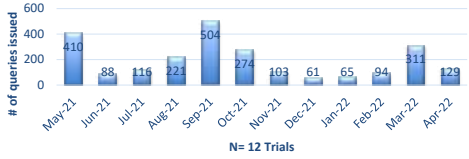


Figure 4. Baseline Query Totals (5/1/21-4/30/22)



Conclusions and Future Directions

As the LCCC IIT portfolio grows, there will be an even greater need to assess and streamline data collection. The adoption of CDASH data standards and the growth of a global eCRF library will enable future integrations. This includes additional FHIR mappings for demographic, vital sign, adverse event, and concomitant medication eCRFs published in the FHIR to CDISC Joint Mapping Implementation Guide. There are a large number of trials that remain in the legacy EDC system and, therefore, are not included. Additionally, the data volumes may be less than typical due to rolling accrual holds related to staffing shortages during the measured time period.

UNC Lineberger Sponsored Clinical Research - Clinical Data Operations

Methodology

We established a project team comprised of staff from UNC Health, LCCC Bioinformatics Core, and the EDC vendor (Advarra) to plan the implementation of a patient information interface between Epic and the EDC System.

The lab results interface will pull lab results into electronic Case Report Forms (eCRFs) using SMART on FHIR authentication to the source system. SMART on FHIR together create a standardized way of exchanging data among healthcare systems. The user is temporarily forwarded to the Epic login page to enter their Epic credentials.

Once logged into Epic, access to data will be based on their role and permissions within the source system. When users search for subjects using the medical record number, PHI will be displayed for data selection but not saved in the EDC system (Figure 5). The integration was validated by the vendor in test environments and maps FHIR Observation codes to Advarra EDC lab codes.

Following the UNC FHIR interface build, UNC project team members will validate the integration in the EDC Test instance. The laboratory eCRF will be built using Clinical Data Acquisition Standards Harmonization (CDASH) data standards to enable cross study implementation.

Figure 5. Example search functionality in EDC (provided by vendor, Advarra)

2 Starting Off on the Right Foot: Elevating the Voice of Community Stakeholders During the IIT Development Process

E. Monari, S. Szurek, A. Ivey, T. George, A. Anderson, E. Shenkman, C. Evans, A. Lawson-Ross
University of Florida Health Cancer Center

1. Background

The IIT Think Tank (I2T3) was established in January 2020 to increase the quality and quantity of UFHCC investigator-initiated trials (IITs) while simultaneously supporting career development for early-stage clinical investigators. In late 2021, the I2T3 was further enhanced through a new partnership using a cohort of community members to increase the patient-centeredness of our concepts to individuals with cancer within our catchment area. To that end, we partnered with UFHCC Office of Community Outreach and Engagement (COE) and their citizen scientist (CS) program to include community member feedback on IIT protocol concepts, as well as recruitment and retention strategies.

2. Goals

Our two primary goals are to:

a) Establish a sustainable collaborative culture between the community and early-stage investigators via an ongoing partnership between I2T3, COE, and CS to meet our community needs
b) Improve the patient-centeredness of IITs through community feedback on interest, recruitment, and impact, from the first discussion of concepts

3. Solutions and Methods

In partnership with UFHCC COE and their CS program, the clinical research office (CRO) invited two community members (citizen scientists, or CS) to I2T3 meetings starting in December 2021 as formal concept reviewers. The CS program was developed as a research partnership model in recognition of the invaluable contributions that citizen scientists make as members of the research team. The CRO's mission in collaborating with this program is to develop research partners who work closely with cancer scientists to address health disparities as partners in the research process. CS receive formal training in health research through general and cancer-specific curricula, including bidirectional communication skills leading to certification as a qualified CS. Each CS is fully integrated into the I2T3 meeting providing verbal and written feedback on all IIT concepts presented. Adequate addressing of any CS concerns by the study team is required, barring documented justification why it cannot, for an IIT to move forward with development. Ongoing partnerships between CS and investigators are encouraged as concepts develop into protocols, including use of CS as a resource and community connection throughout the life of the trial, through support from the UFHCC COE. Beyond assisting with concept and protocol development, CS also assist with reviewing consent forms, patient materials, and grant applications.

4. Outcomes

Implementation of the CS program has yielded positive impact upon cancer research across UFHCC, including feedback on a Patient-Centered Outcomes Research Institute (PCORI) submission for a tobacco cessation study, consulting on responses to FDA queries for a glioblastoma trial, and helping improve feasibility of a head and neck cancer study. To date, CS feedback has centered on innovative strategies to maximize treatment compliance, increase recruitment diversity, and educate subjects about contraindications to treatments and toxicities, across five concepts reviewed.

5. Lessons Learned and Future Directions

We will perform an annual review of feedback provided and track what percentage of CS feedback was ultimately included in protocols, as well as enrollment metrics to assess effects of community feedback on recruitment. We will also collect feedback from investigators and CS to continually improve the program so it can be maximally beneficial to both groups.

Starting off on the right foot: Elevating the voice of community stakeholders during the IIT development process

Erin Monari, PhD, CCRP, Sarah Szurek, PhD, Alison Ivey, RN, MS, MBA, OCN, CCRP, Ashley Anderson, MBA, ACRP-CP, Elizabeth Shenkman, PhD, Christy Evans, Citizen Scientist, Amanda Lawson-Ross, PhD, Citizen Scientist, Thomas George, MD, FACP

BACKGROUND

The IIT ThinkTank (I2T3) was established to increase the quality and quantity of UFHCC investigator-initiated trials (IITs) while simultaneously supporting career development for early stage clinical investigators. In 2021, the I2T3 partnered with the UFHCC Office of Community Outreach and Engagement (COE) and their Citizen Scientist (CS) program to engage community stakeholders at the earliest stages of clinical trial conception. The CS program was developed by COE as a research partnership model, in recognition of the invaluable contributions that citizen scientists make as members of the research team. CS receive formal training in health research through general and cancer-specific curriculum including bidirectional communication skills leading to certification as a qualified CS. These materials are offered as an Open Educational Resource here: https://citizenscientist.ctsi.ufl.edu/

Scan QR code for a direct link to modules

Our two primary goals are:

- Establish a sustainable collaborative culture between the community and early stage investigators via an ongoing partnership between I2T3, COE, and CS to meet our community needs
- Improve the patient-centeredness of IITs through community feedback on interest, recruitment and impact, from the first discussion of concepts.

METHODS

In partnership with UFHCC COE and their CS program, the Clinical Research Office (CRO) invited Citizen Scientists (CS) to I2T3 meetings starting in December 2021 as formal concept reviewers. Each CS is fully integrated into the I2T3 meeting providing verbal and written feedback on all IIT concepts presented. Adequate addressing of any CS concerns by the study team is required, barring documented justification why it cannot, for an IIT to move forward with development. Ongoing partnerships between CS and investigators are encouraged as concepts develop into protocols, including use of CS as a resource and community connection throughout the life of the trial, through support from the UFHCC COE. Beyond assisting with concept and protocol development, CS also assist with reviewing consent forms, patient materials, and grant applications.

Examples of constructive feedback provided by the Citizen Scientists include:

- *"I would encourage staying away from cancer prevention education during the early phases of diagnosis and treatment because that can elicit shame and shut people down."*
- *"Consider giving questionnaires at a different time other than when receiving treatment like chemo. Sometimes they give Benadryl and steroids during treatment and it's very hard to concentrate while receiving treatment."*
- "I am wondering if there needs to be a plan in place to help those randomized in the experimental arm keep track of what they are supposed to take and when they are supposed to take it. I know that when people are very sick or stressed (and older), it can be difficult to keep track of pills. This new treatment regimen looks significantly more complicated than the control regimen."

RESULTS

Implementation of the CS program has yielded positive impact upon cancer research across UFHCC, including feedback on a PCORI submission for a tobacco cessation study, consulting on responses to FDA queries for a glioblastoma trial, and helping improve feasibility of a head and neck cancer study. To date, CS have reviewed 8 concepts and provided largely centered on innovative strategies to maximize treatment compliance, increase recruitment diversity, and educate subjects about contraindications to treatments and toxicities, across five concepts reviewed.

FUTURE DIRECTIONS

We will perform an annual review of feedback provided and track what percentage of Citizen Scientists feedback was ultimately included in protocols, as well as enrollment metrics to assess effects of community feedback on recruitment. We will also collect feedback from investigators and CS to continually improve the program so it can be maximally beneficial to both groups.

CONTACT

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UF's IIT Think Tank Experiment

E. Monari, A. Ivey, T. George, A. Anderson
University of Florida Health Cancer Center

1. Background

To increase investigator-initiated trial (IIT) development and support early-stage clinical investigators (ESIs), monthly IIT Think Tank (I2T3) meetings were initiated in February 2020. Meetings included new concept presentations and discussions about development, feasibility, conduct, and support. Details about how and why this meeting was initiated were presented at the 13th Annual AACI CRI Meeting in July 2021.

2. Goals

During the first year of the program (2020), IIT concept intake increased by nearly 64 percent, supporting our primary goal in establishing I2T3. I2T3 goals for 2021 were to maintain concept intake volume, activate our first I2T3 studies and introduce meeting enhancements.

3. Solutions and Methods

To meet these goals, PMO implemented the following new processes in 2021:

- Identifying extramural funding opportunities, specifically matched for I2T3 concepts
- Documenting concept feedback from a wider range of stakeholders while providing ESIs experience in concept evaluation and review
- Involving Citizen scientists in concept development leveraging community perspective

Ten concepts were received through I2T3 meetings in 2020, and this pace continued with another 10 in 2021, demonstrating sustained new concept volume. Of all concepts presented, only 15 percent have been abandoned, due to lack of funds or feasibility. Three I2T3 studies completed protocol development in 2021 and were opened to accrual, all with current active enrollments.

4. Outcomes

In 2021, the UFHCC project management office (PMO) spearheaded an initiative of grant finding and matching to increase support for I2T3 concepts. As part of this initiative, PMO finds and distributes a summary of available grant opportunities to the I2T3 group. Additionally, PMO looks to match concepts with funding opportunities, and assists with preparation and submission. In 2021, four I2T3 concepts were submitted for grant support, with one awarded (Florida DOH JEK, $1,458,000). In 2020, one grant was submitted and not funded. Three concepts were supported by industry in 2020, and this rate continued into 2021, with two supported and one pending.

PMO updated the existing UFHCC IIT-accelerator process (path for IIT concept approvals to move forward) to include I2T3 feedback from both investigators and newly incorporated citizen scientists (CS). An anonymous Qualtrics survey is distributed to I2T3 members (ESI and senior investigators) to formally collect concept feedback. This survey includes a National Cancer Institute-style scoring rubric on scientific merit, study design, clinical impact, and feasibility. Training on the rubric was provided to assist in providing relevant feedback to presenters and to see firsthand how their own concepts will be reviewed. CS provide separate verbal and written feedback, which is incorporated by PMO into review forms. Survey results and scores are compiled and provided back to concept presenters and used for concept refinement during protocol development.

5. Lessons Learned and Future Directions

In 2021, the pace of I2T3 concept intake continued from its inaugural year (2020), demonstrating sustained volume of new concepts intake. We anticipate this to continue and increase in 2022. We will collect data on which CS feedback components are recurring themes, to look for system-level solutions for protocol incorporation. We plan to collect data from investigators to learn about the usefulness of the Qualtrics feedback received from their peers, as well as CS feedback, and new educational topics desired by the group.

Crowdsourcing Success: UF's IIT Think Tank Experiment

Erin Monari, PhD, CCRP, Alison Ivey, RN, MS, MBA, OCN, CCRP, Ashley Anderson, MBA, ACRP-CP, Thomas George, MD, FACP

BACKGROUND

To increase investigator-initiated trial (IIT) development and support early stage clinical investigators (ESIs), monthly "IIT Think Tank" ("I2T3") meetings were initiated in February 2020. Meetings include new concept presentations and discussions about development, feasibility, conduct, and support.

During the first year of the program, IIT concept intake increased by nearly 64%, supporting our primary goal. I2T3 goals for 2021 were to maintain concept intake volume, activate our first I2T3 studies and introduce meeting enhancements.

METHODS

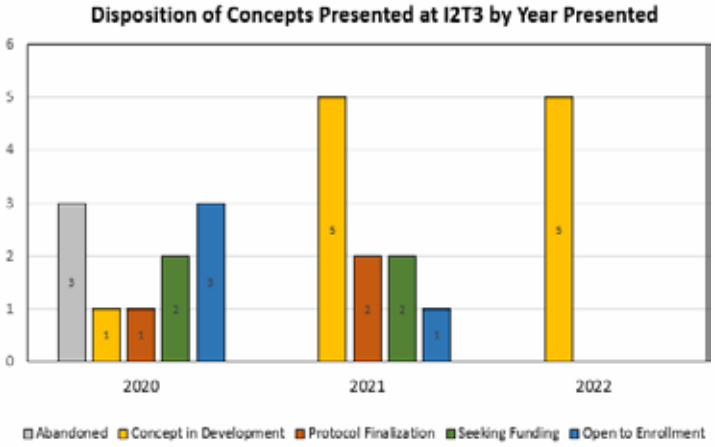
In 2021, the following enhancements were made to the I2T3 meeting process:

- **Grant Finding Initiative**: Identification of extramural funding opportunities, specifically matched for I2T3 concepts.
- **Enhanced Feedback Collection**: I2T3 members provide formal feedback for concepts using an NCI-style scoring rubric on scientific merit, study design, clinical impact, and feasibility. Training was provided and results are provided to the concept presenter as a formal summary document.
- **Citizen Scientist Inclusion:** Two CS have been included in the I2T3. Their feedback is incorporated by PMO into the final feedback document provided to the investigators.

RESULTS

Ten concepts were received through I2T3 meetings in 2020, and this pace continued with another ten in 2021, demonstrating sustained new concept volume. Of all concepts presented, only 15% have been abandoned, due to lack of funds or feasibility. Three I2T3 studies completed protocol development in 2021 and were opened to accrual and one in 2022, all with current active enrollments. 2022 is poised to outpace 2021's concept intake rate, with 5 concepts already in development as of May 2022.

In 2021, four I2T3 concepts were submitted for grant support, with one awarded (Florida DOH JEK, $1,458,000.00). In 2020, one grant was submitted and not funded. Three concepts were supported by industry in 2020, and this rate continued into 2021, with two supported and one pending.



FUTURE DIRECTIONS

In 2021, the pace of I2T3 concept intake continued from its inaugural year (2020), demonstrating sustained volume of new concept intake. We anticipate this to continue and increase in 2022.

We will collect data on which CS feedback components are recurring themes, to look for system-level solutions for protocol incorporation. We also plan to collect data from investigators to learn about the usefulness of the Qualtrics feedback received from their peers, as well as CS feedback, and new educational topics desired by the group. Finally, we will track the number and success of grant submissions associated with the new grant finding initiative.

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PARTNERING IN PROGRESS

QUALITY ASSURANCE, REMOTE MONITORING, AND AUDITING

Proactive Quality Assurance Through Dual Review of Eligibility and Consent

K. Thorne
Huntsman Cancer Institute, University of Utah

1. Background

Enrolling participants on clinical trials that meet protocol specified eligibility criteria not only establishes a homogenous patient population, allowing for adequate data analysis, but it is critical for the safety and well-being of participants. One of the most common U.S. Food and Drug Administration (FDA) Bioresearch Monitoring Program Information (BIMO) audit findings across clinical investigator and sponsor-investigator observations, as assessed by findings on the FDA Form 483, has consistently been "inadequate subject protection; informed consent issues." Research continues to show that protocol complexity continues to rise, despite the awareness that trial complexity adds to the increase in the number of deviations. One area of complexity for oncology trials remains participant eligibility criteria. The ramifications of this can create a perfect storm for enrolling ineligible subjects, as well as subjects not being fully informed of their participation during the consent process.

2. Goals

We took a proactive quality assurance approach to reduce the number of deviations related to consent and eligibility in relation to the number of participants enrolled on therapeutic trials.

3. Solutions and Methods

A standard operating procedure (SOP) was created for dual review of eligibility and consent. This in-depth assessment is performed by experienced study managers and quality assurance professionals. After a new potential participant has provided informed consent, completed all screening procedures, and prior to registration, the dual review process confirms the following:

- Eligibility criteria appear to be met
- Consent forms are complete
- Informed consent process is documented
- Screening procedures have been completed with results
- Regulatory requirements and version control
- General good clinical practice/ALCOA+ standards have been followed

The policy requires that all source documents must be compiled and presented to the reviewer, including medical history assessments, concomitant medication review performed by a trained pharmacist, and any other trial specific checklists. This process complements the review provided by the coordinator and physician by providing an additional level of review. On average, this process takes approximately 60 minutes. Because dual review is required at Huntsman Cancer Institute (HCI), the study team plans for these reviews so that participant registration is not delayed.

4. Outcomes

Although we've had the SOP in place since 2012, we amended the SOP in 2017 requiring the dual review of eligibility process to be performed by a manager or QA professional. The data below indicates the positive trends we've seen since formalizing this process into a requirement performed by senior level management at HCI. The line shows a decrease in percent of patients accrued with deviations entered in OnCore related to consent and eligibility. Overall, we've seen a decrease in the percent of deviations related to consent and eligibility from 7.37 percent in 2016 to 2.56 percent of total accruals in 2021.

5. Lessons Learned and Future Directions

Since implementing an SOP in 2012, HCI has made many adjustments to streamline the process including the following:

- Original SOP allowed another independent coordinator to perform the review
- Added a review for registration/randomization assignments for accuracy prior to enrollment
- Added departmental review of re-consents
- Account for hybrid, virtual setting with reviews, such as confirming witness, Adobe sign is Part 11 compliant, etc.

Proactive Quality Assurance through Dual Review of Eligibility and Consent

Kelli Thorne, MPH, CCRP; Shanon Matkin, BS, CCRP; Janna Espinosa, BS, CCRP
Huntsman Cancer Institute at the University of Utah

BACKGROUND

Enrolling participants on clinical trials that meet protocol specified eligibility criteria not only establishes a homogenous patient population allowing for adequate data analysis, but it is also critical for the safety and well-being of participants. Factors that might impact consent eligibility deviations include:

- Protocol complexity continues to rise.
- Staff turnover.

METRICS/GOALS

- Reduce the number of deviations related to consent and eligibility compared to the number of participants enrolled on therapeutic trials.

METHODS

Dual Review of Eligibility and Consent confirming the following as shown in Figure 1:

- Eligibility criteria appear to be met.
- Consent forms are complete.
- Informed consent process is documented.
- Screening procedures have been completed with results.
- Regulatory requirements and version control.
- Training, delegation, and 1572, if applicable.
- General GCP/ALCOA+ standards have been followed

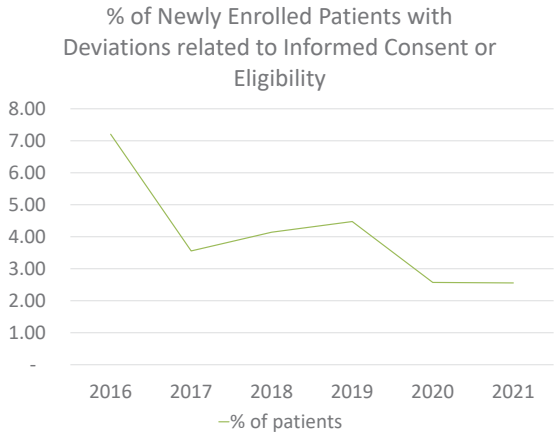
OUTCOMES

Overall, we've seen a decrease in the percent of deviations related to consent and eligibility from 7.5% in 2016 to 2.5% of total accruals in 2021 as shown in Figure 2.

Figure 1


ELIGIBILITY AND CONSENT REVIEW

Figure 2



LESSONS LEARNED

Since implementing an SOP, HCI has made many adjustments to streamline the process including the following:

- Original SOP allowed another CRC to perform the review and we updated the SOP so that dual review must be performed by a Manager or QA professional.
- We added a review for registration/stratification/ randomization assignments for accuracy prior to enrollment.
- Departmental review of re-consents was added.
- Reviews account for hybrid, virtual setting such as confirming witness, Adobe Sign is Part 11 compliant, etc.

Transforming Risk Management: Technological Evolution of MSK's Clinical Research Quality Assurance Program

A. Granobles, M. Satter, S. Puleio, F. Puma, N. Brosnan, K. Yataghene
Memorial Sloan Kettering Cancer Center

1. Background

In 2017, a newly restructured clinical research quality assurance (CRQA) unit at Memorial Sloan Kettering Cancer Center (MSK) was initiated to substantially improve risk management of the clinical research enterprise. At the time, the unit used systems to collect quality assurance data on clinical research in various formats and platforms that were not originally intended to be interconnected and did not follow symmetrical connection points useful in generating a comprehensive overview of clinical research programs. CRQA's strategy was to restructure and strengthen existing systems, leading to dramatic steps in efficiency and effectiveness while producing an improved employee and customer experience.

2. Goals

CRQA set out to consolidate and improve existing systems to facilitate the extraction of useful data for analyses, while reducing system maintenance. This resulted in restructuring these data collection systems to streamline the collection process and reduce variability while improving report outcomes and accountability. In turn, processes and guidelines required standardization for a comprehensive integration. The overall goal of restructuring was to improve the retrieval and analysis of data to further mitigate institutional risks and identify clinical research process improvement opportunities.

3. Solutions and Methods

Standard guides were developed to identify clinical research-related deficiencies consistently across all CRQA. Protocol information management system (PIMS), MSK's main clinical research and information technology system, was identified as the platform to centralize CRQA data and to enhance from a passive tool to an active tool. Finally, operational dashboards were developed to allow clinical research departments to have real-time and direct access to relevant data, significantly reducing CRQA's time and effort as most queries and requests can be addressed quickly.

4. Outcomes

The original strategy for PIMS was to transition it from a passive tool to an active tool. In an innovative manner, CRQA went one step further and transitioned the system into an interactive tool accessible not only to CRQA, but also to clinical research departments. This transformation of PIMS has since shown to increase compliance, communication, transparency, data access, and collaborative relationships between CRQA and clinical research departments. The accessibility of real-time data through the development of dashboards enables CRQA and clinical research departments early identification of deficiencies and trends, while simultaneously identifying potential process improvements. The dashboards have demonstrated to be powerful tools in highlighting gaps, trends, outstanding regulatory tasks, and keeping clinical research departments abreast of these issues.

5. Lessons Learned and Future Directions

Achievement of these successful improvements required a time commitment and collaboration with subject matter experts. Most interim steps for these initiatives needed to be done sequentially to avoid errors and to permit testing. The next goal is to interconnect the data of all CRQA, which consists of four separate programs, into a comprehensive dashboard that can provide a bird's-eye view of all clinical research activities and can forecast and prevent major deficiencies across MSK's clinical research portfolio. Additionally, we will explore inclusion of automation and advanced analytics into our systems to augment and magnify the impact of process redesign, further enhancing both the effectiveness and efficiency of CRQA's risk management for MSK's clinical research enterprise.

Memorial Sloan Kettering Cancer Center

Transforming Risk Management: Technological Evolution of MSK's Clinical Research Quality Assurance Program

Adrian Granobles; Mark Satter; Susan Puleio; Francine Puma; Nancy Brosnan; Karima Yataghene, MD

BACKGROUND: In 2017, a newly restructured Clinical Research Quality Assurance (CRQA) unit at Memorial Sloan Kettering Cancer Center (MSK) was initiated to substantially improve risk management of the clinical research enterprise. At the time, the unit used systems to collect quality assurance data on clinical research in various formats and platforms that were not originally intended to be interconnected and did not follow symmetrical connection points useful in generating a comprehensive overview of clinical research programs. CRQA's strategy was to restructure and strengthen existing systems, leading to dramatic steps in efficiency and effectiveness while producing an improved employee and customer experience.

GOALS

CRQA set out to consolidate and improve existing systems to facilitate the extraction of useful data for analyses, while reducing system maintenance. This resulted in restructuring these data collection systems to streamline the collection process and reduce variability while improving report outcomes and accountability. In turn, processes and guidelines required standardization for a comprehensive integration. The overall goal of restructuring was to improve the retrieval and analysis of data to further mitigate institutional risks and identify clinical research process improvement opportunities.

METHODS

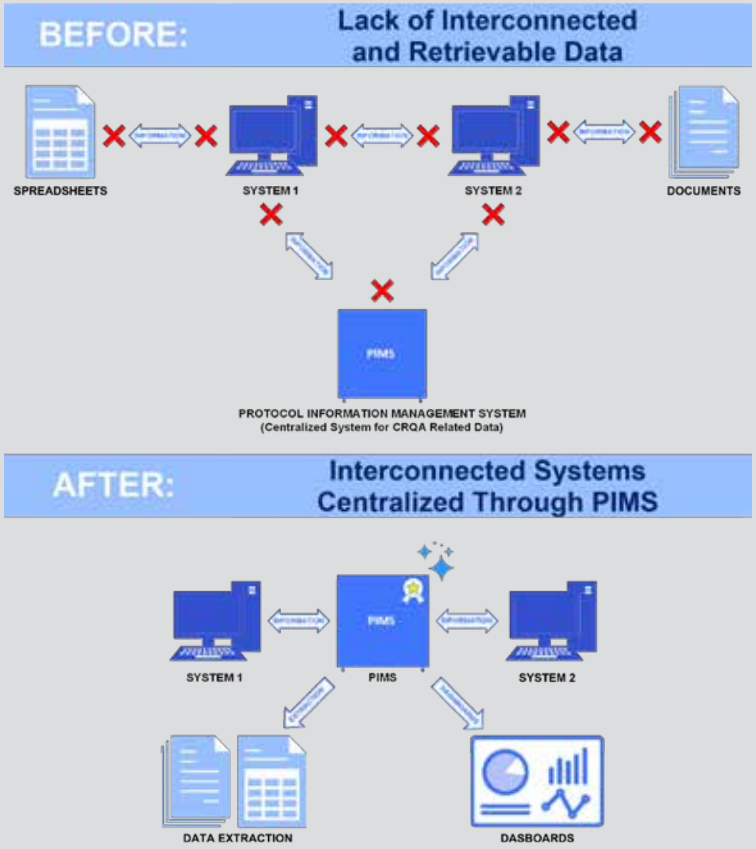
Standardization
Standardized research-related deficiency definitions and other tools were developed for consistency across CRQA

Enhancements
Protocol Information Management System (PIMS), MSK's main clinical research information technology system, was enhanced from passive to active

Dashboards
Developed dashboards for real-time and direct access of data for clinical research departments and CRQA

Interconnections
Systems and resources were centralized through data management in PIMS

Data Extraction
Streamlined data extraction were enabled from enhanced systems for better analysis and reporting



RESULTS

The original strategy for PIMS was to transition it from a passive tool to an active tool. In an innovative manner, CRQA went one step further and transitioned the system into an interactive tool accessible not only to CRQA but also to clinical research departments.

The PIMS transformation has since shown to increase compliance, communication, transparency, data access, and collaborative relationships between CRQA and clinical research departments.

The accessibility of real-time data through the development of dashboards, enables CRQA and clinical research departments early identification of deficiencies and trends, while simultaneously identifying potential process improvements.

The dashboards have demonstrated to be powerful tools in highlighting gaps, trends, outstanding regulatory tasks and keeping clinical research departments abreast of these issues.

COMCLUSION AND FUTURE DIRECTIONS

Achievement of these successful improvements required time commitment and collaboration with subject matter experts.

Most of these initiatives needed to be done sequentially to avoid errors and permit testing.

The next goal is to interconnect the data of all CRQA, which consists of four separate programs, into a comprehensive dashboard that can provide a bird's-eye view of all clinical research activities and can forecast and prevent major deficiencies across MSK's clinical research portfolio.

Additionally, we will explore inclusion of automation and advanced analytics into our systems to augment and magnify the impact of process redesign, further enhancing both the effectiveness and efficiency of CRQA's risk management for MSK's clinical research enterprise.

* Virtual Monitoring and Auditing Digitization in Decentralized Clinical Trials: Source Document Verification, System Scheduling, and Real Time Protocol Performance Feedback

M. Buckley, J. Lengfellner, M. Latif, K. Yataghene, C. Houston, S. Terzulli, N. Cimaglia, P. Sabbatini
Memorial Sloan Kettering Cancer Center

1. Background

Onsite source document verification (SDV) of site clinical trial data is resource intense and inefficient. Our primary objectives were to show return on investment for:

1) Implementing virtual monitoring and auditing (VMA) versus onsite
2) Assessing monitor satisfaction with system performance
3) Using a real time digital feedback monitoring visit form (MVF) to improve clinical research (CR) protocol audit readiness

2. Goals

Our sponsor-site pilot compared virtual to onsite electronic health record (EHR) access for SDV. Side by side comparison of VMA with another comparable site's (accrual, geolocation, etc.) onsite method were captured and analyzed for: 1) productivity, 2) data latency, 3) cost savings, and 4) site and sponsor satisfaction. A 13-question satisfaction survey was sent to all active VMA users. Historical MVF performance was correlated to overall inspection readiness.

3. Solutions and Methods

VMA reclaimed monitor and site research staff productivity by three hour/visit/monitor, decreased query resolution from two to four weeks to five days, and increased sponsor cost savings by reclaiming monitor associated onsite travel costs. In comparison to other sites, survey respondent's overall satisfaction with VMA was 86 percent. Inspection readiness improved with real time MVF feedback and no FDA Form 483s were issued.

4. Outcomes

VMA decreased both data review latency and query resolution and allowed for more efficient use of staff time and effort. Establishing virtual monitoring in 2011 enabled rapid scaling to a completely virtual model during the COVID-19 pandemic. Real time digital MVF feedback lets teams focus efforts on specific areas of protocol compliance, increase data quality, and ensure inspection readiness.

Comparing their experience to other sites, monitors were able to navigate systems and perform their work virtually with high satisfaction rates. Inspection readiness was improved with real time MVF feedback to CRQA and study investigators; with no FDA Form 483s being issued for the 15 protocols inspected in 2019-2020.

5. Lessons Learned and Future Directions

Virtual systems access allowed a nimble response to COVID-19 and will position sites well for protocol compliance continuity in response to any future threats as well as the need to support decentralized or virtual trials as they are developed.

* *Honorable Mention*

Virtual Monitoring & Auditing Digitization in Decentralized Clinical Trials: System Scheduling, Source Document Verification, and Real Time Protocol Performance Feedback

Michael T. Buckley[1], Joseph M. Lengfellner[1], Marcia Latif[1], Karima Yataghene[1], Collette Houston[1], Stephanie Terzulli[1], Nicholas Cimaglia[1], Paul Sabbatini[2]

[1]Memorial Sloan Kettering Cancer Center, New York, NY; [2]Memorial Sloan Kettering Cancer Center and Weill Cornell Medical College, New York, NY

Memorial Sloan Kettering Cancer Center

Background

Traditional onsite source document verification (SDV) of site clinical trial data in the Electronic Health Record and Regulatory binders is resource intense and inefficient.

Primary Objectives

Show return on investment (ROI) for:

1) **Implementing and scaling a virtual monitoring and auditing (VMA) program** versus onsite SDV.
2) **Assessing monitor and staff satisfaction** with Memorial Sloan Kettering Cancer Center's (MSK) VMA system performance.
3) **Using a real time digital feedback Monitoring Visit Form** (MVF) to improve clinical research (CR) protocol audit readiness.

Methods

1) Our sponsor-site pilot compared virtual to onsite Electronic Health Record (EHR) access for SDV.

2) A 13-question satisfaction survey was sent to all active MSK VMA users.

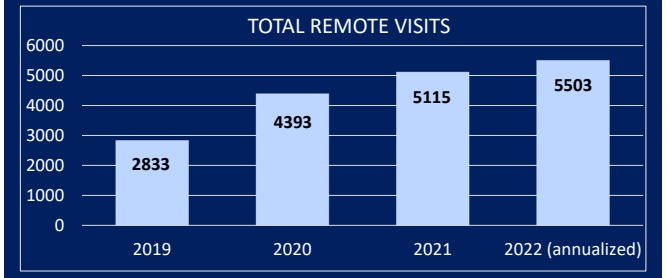
Side by side comparison of VMA with another comparable site's (accrual, geolocation, etc.) onsite method were captured and analyzed for:

a) Productivity
b) Data latency/query response time
c) Cost savings
d) Site and sponsor satisfaction

1) Historical MVF performance was correlated to overall inspection readiness.

Primary Objective Outcomes

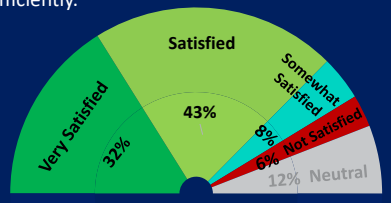
1) **Implementation of VMA started in 2011 with 1 monitor and scaled to a 100% virtual program in 2020.**



2) **Monitor and staff satisfaction with VMA performance,**

- When comparing MSK to other sites' VMA systems, 85% of VMA survey respondents (15% response rate; 959 sent, 144 responses) felt that MSK's training helped them better navigate and use our VMA systems more efficiently.

- **Overall satisfaction of monitors with MSK VMA was 83%**



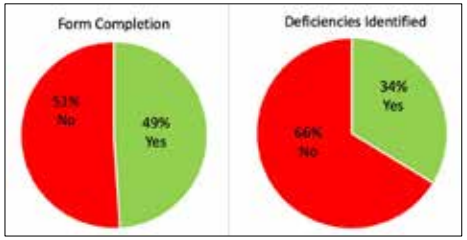
- VMA reclaimed monitor and site research staff productivity by 3 hr/visit/monitor

- Decreased query resolution from 2-4 weeks to 5 days

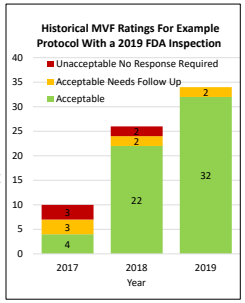
- Increased sponsor cost savings by reclaiming monitor associated onsite travel costs.

3) **Real Time Digital MVFs add transparency and speed to the protocol and data quality feedback loop not possible in a paper-based format.**

Monitoring Visit Feedback Form Completion and Deficiency Rates (2014-April 2021)



- MVFs are reviewed by CR Quality Assurance in a Tableau dashboard, and deficiencies are escalated in real time to the data management team for correction.
- This allows for focused efforts & creation of process improvement that turn around problem areas & ensure inspection readiness.
- For the 15 protocols audited by the FDA at MSK in 2019 to 2020 no FDA 483 letters were issued.



Conclusions

- Establishing VMA in 2011 and eRegulatory in 2015 enabled rapid scaling to a completely virtual model during the COVID19 pandemic.
- VMA decreased both data review latency and query resolution and allowed for more efficient use of staff time and effort.
- Real time digital MVF feedback lets teams focus efforts on specific areas of protocol compliance, increase data quality, and ensure inspection readiness.

Automating Data Safety Monitoring Committee (DSMC) Progress Reports

T. McSpadden, S. Grolnic
University of Colorado Cancer Center

1. Background

For investigator-initiated trials (IITs) not otherwise monitored by a data and safety monitoring board/committee, the University of Colorado Cancer Center (UCCC) DSMC requires study principal investigators to submit a DSM progress report on a regular basis. The DSMC provided a report template which outlined the required elements to be included in the report. Progress reports were manually updated for each review cycle utilizing data from the study database and clinical trials management system (CTMS). Completing the adverse event (AE) component of the progress report required transcription of data from the database into an Excel spreadsheet. This process was extremely time intensive and susceptible to transcription errors. A more efficient process for compiling the DSMC progress reports was needed.

2. Goals

- Decrease the time required to complete the DSM progress reports
- Decrease transcription errors by extracting the required data directly from the CTMS and study database
- Standardize AE listings to improve DSMC review

3. Solutions and Methods

Using the DSMC progress report template, a custom report was created to pull any available data (e.g., enrollments, screen failures, withdrawals, and protocol amendments) from the CTMS. This populated 63 percent of the required elements of the progress report. Remaining information needed for the progress report is manually entered. AE information was exported from the study database and attached to the report for submission to the DSMC. An Excel template was created that included pivot tables and frequently used data "slicers." This provided a standard format for AE listings and allowed DSMC reviewers to easily identify trends and isolate serious adverse events for review.

Following successful pilot by the IIT team, this new process was rolled out to all research teams required to submit DSM progress reports. Completion instructions were embedded in the custom report to aid teams in report completion.

4. Outcomes

The time required to prepare the progress reports significantly decreased (from approximately eight hours to two hours for an average study), allowing for research personnel to focus that time on other work.

DSMC reviewers noted the following impacts to their reviews:

- Standard report format (information located in same place on all reports) has been helpful when reviewing multiple trials
- Standardization to the answers in the reports has improved (e.g., standard language used for reasons behind the screen fails)
- The reviewers can easily review AE data as the information is arranged in a standardized way and they can manipulate the data as needed
  - Prior to the automated report, some AEs would be sent to the committee in PDF format making review difficult
- Increased confidence in the data
  - Since the report pulls bulk of data directly from OnCore, the reviewers can log into OnCore and see where the data is coming from if they have questions

5. Lessons Learned and Future Directions

Pulling the DSMC progress report data directly from the CTMS and study database does require that the clinical teams are consistent in how the data is entered. Therefore, continued guidance documents outlining these components will help ensure we export clear data. Future plans involve export of deviations from CTMS to be included in the DSM progress reports.

AUTOMATING DATA SAFETY MONITORING COMMITTEE PROGRESS REPORTS

OVERVIEW

The Oncology Clinical Research Support Team (OCRST) serves as central resource for Investigator Initiated Trial (IIT) support for CU Cancer Center members. Services provided include regulatory support, project management, data monitoring, and financial management.

The Data Safety and Monitoring Committee (DSMC) provides oversight for the data and safety monitoring for all CU Cancer Center clinical trials. Oversight includes risk assessment of all IITs, auditing, real time review of fatal events, ongoing review of Serious Adverse Events, quarterly DSMC meetings to review progress reports.

OVERSIGHT

KEY STAFF

S. Grolnic: OCRST Program Director

T. McSpadden: OCRST Clinical Project Manager, IIT Program

BACKGROUND

- DSMC requires Principal Investigators to submit regular progress reports on IITs; typically, every 6 months
- Progress Reports include summary of trial design, current status, enrollments to date (inclusive of all participating sites), adverse events (AE), protocol deviation listing, monitoring reports, meeting minutes, FDA reports, and any publications
- Previous DSM progress report template required data to be compiled manually resulting in time consuming process

GOALS

- Decrease time needed to complete DSM Progress Reports
- Standardize AE listing to improve DSMC safety review

METHODS

- Comprehensive review of data elements required for DSM Progress Reports; identified which elements existed in Clinical Trial Management System (CTMS) or available from another source
- Reviewed examples of previously submitted AE listings, gathered feedback from DSMC Director, Chair, and reviewers on key elements needed to facilitate safety review
- Custom report created to pull data from CTMS to populate the DSM Progress Reports; retained original report format that reviewers were accustomed to
- Created standard AE listing export report from EDC (REDCap or other) and Excel template with standard pivot tables and 'slicers'
- Developed instructions for use of new report and AE listing Excel template

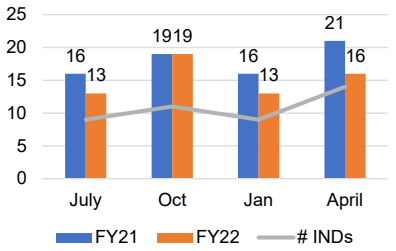
RESULTS

- Custom report pulls 63% of data elements from the CTMS into DSM Progress Report
- Reduced time needed to compile DSM Progress Reports by 75% from approximately 8 hours to 2 hours
- Positive feedback from DSMC reviewers on ease of AE review using the Excel template
- After successful pilot using the custom report and AE listing Excel template by OCRST, implemented across CU Cancer Center teams that compile data and submit DSM Progress Reports

FUTURE DIRECTIONS/LESSONS LEARNED

- Data definitions for consistent entry of information in the CTMS is critical to use of the DSM custom report
- Plans to develop guidelines for improved and standardized entry of deviations in CTMS in order to include in DSM Report are in process
- Report doubles as QA tool for data entry in CTMS (screen failures, withdrawals)

DSMC PROGRESS REPORT VOLUMES FY21-22



Improved AE review and safety oversight

Over 400 hours saved in compiling reports

Introducing a Quality Management System Into the Mayo Clinic Comprehensive Cancer Center Clinical Research Office

K. Alexander, K. Croghan, A. Fritsche, J. Summer Bolster, J. Welter
Mayo Clinic Comprehensive Cancer Center

1. Background

The Mayo Clinic Comprehensive Cancer Center (MCCC) clinical research office (CRO) serves the clinical investigators and research participants across the MCCC's academic medical centers in Arizona, Florida, and Minnesota, as well as throughout the Mayo Clinic Health System in Minnesota and Wisconsin. This organizational complexity and wide geographic distribution of staff contributed to a lack of standardization of training programs and core business processes. While numerous processes and procedures were developed, the utilization of these by CRO staff was inconsistent and ineffective.

A robust quality management system (QMS) was needed to achieve a manageable and sustainable infrastructure for the CRO training, process, and procedure materials. The QMS must be specific and optimized to the needs of the CRO to ensure that it is effective and provides value to the staff. The QMS would cover the following quality system essentials (QSE): organization and leadership; customer focus; personnel and training; standard operating procedures; documents and records; monitoring and assessments; and event management. Development and implementation of these QSEs would ensure effective training of CRO staff. The definition of core business processes, their inputs and outputs, and key performance and quality metrics, will enable better management of operational performance. Once implemented, the cycle of monitoring and continuous improvement will be engaged.

Recommendation was for the MCCC CRO to establish and maintain a stable and living QMS.

2. Goals

The goal is to create a culture of quality for the CRO, an optimized QMS to support the performance and management of core business processes, and their supporting documentation, as well as a system of continuous improvement.

3. Solutions and Methods

- Define governance and oversight for the QMS
- Establish a quality management coordinator (QMC) to be responsible for the development and management of the MCCC QMS
- Define MCCC QMS elements based on ISO 9000/9001 quality management principles
- Train CRO managers and supervisors on QMS
- Perform current state assessment of existing documentation to determine necessary changes- 250 (i.e., archive, update, gap)
- Define core business functions using Supplies Input Process Outcomes Customers/ Requirements (SIPOC/R) methodology
- Establish document control aligned with Mayo Clinic policies
- Develop/revise core business process documentation (i.e., process, procedure, form, training)
- Develop and deliver training
- Develop performance metrics and define maintenance/action plan
- Focus on continuous improvement using metrics to guide education, and documentation

4. Outcomes

- Started implementing QMS:
  - Established awareness, vision, and importance of QMS within MCCC leadership
  - Designated a QMC
  - Confirm subject matter experts
  - Start creation of core business processes
  - Create and reestablish a desire to engage in QMS
  - Develop training

5. Lessons Learned and Future Directions

Creating a culture of quality, and competencies in quality management for our managers, supervisors, and staff is essential. Having an effective system and oversight structure is essential for maintaining a QMS. Our future direction is to continue to mature the QMS and use a change management approach to revision of processes and procedures. We will continue to engage the staff to reinforce the quality management principles and enhance adoption and learning. A dashboard of key performance indicators will be developed in alignment with the core business processes.

Introducing a Quality Management System into the Mayo Clinic Comprehensive Cancer Center Clinical Research Office

Authors: Kellye Alexander,[1] Katrina Croghan, MS, CCRP, M.D.,[2] Angela H Fritsche, MPA,[2] Jolene Summer Bolster, MA[2] Jane Welter, MBA[2]
Division of Research Quality Office, Mayo Clinic; Cancer Center, Mayo Clinic

BACKGROUND

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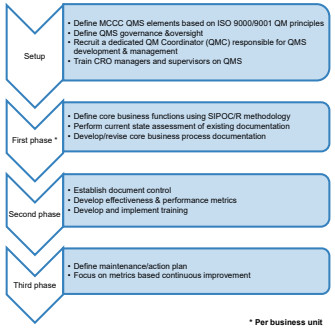
Recommendation was for the MCCC CRO to establish and maintain a stable and living QMS.

GOALS

GOALS TO ACHIEVE

- Create a culture of quality for the CRO.
- Create an optimized QMS to support:
- Performance and management of core business processes,
- Their supporting documentation,
- Support continuous improvement.

SOLUTIONS AND METHODS



*** Per business unit**

OUTCOMES

IMPLEMENTING QMS

- Established awareness, vision, and importance of QMS within MCCC Leadership
- Hired a dedicated QMC
- Confirmed subject matter experts
- Began creation of core business processes
- Reestablished a desire and culture to engage in QMS
- Developed training

QUALITY MANAGEMENT ELEMENTS

- **Leadership Commitment & Culture:**
  - Creating visibility of successes, building coalitions, setting expectations, and navigating barriers are just some of the roles this key partner will need to play.
- **Management System Operations**
  - Leads development and ensures sustainability of the QMS.
- **Process Management**
  - Utilizing SIPOC to ensure all activities work together toward a common goal and achieve results valued by internal and external customers.
- **Documentation System**
  - The foundation supporting all other elements by defining standards, responsibilities and providing consistent resources.
- **Competence, Awareness & Training**
  - Development and implementation of a training and education program built off of the Documentation System, including necessary competencies for personnel performing their work.
- **Measurement & Analysis:**
  - Utilizing metrics to develop evidence-based decisions and assess goal-based tracking.
- **Event Management:**
  - Define process by identifying trends, root causes, and corrective and/or preventative actions, allowing organizations to capture and analyze information from events or activities that do not meet Sponsor or regulatory expectations.
- **Customer Service & Satisfaction:**
  - Identify customer needs and expectations and determine if successful.
- **Continuous Improvement**
  - Ensure continuous and evolving customer expectations are addressed.

FIGURE 1

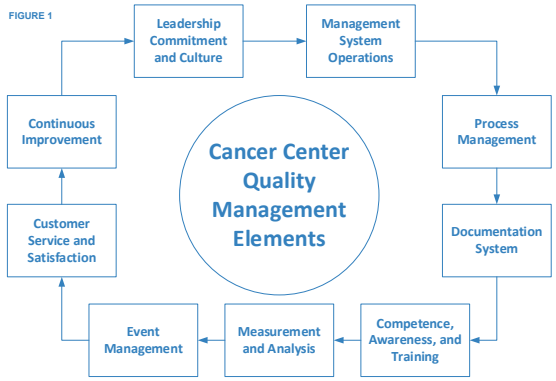


Figure 1 represents the Quality System Elements (QSEs) used to determine and establish the Mayo Clinic Comprehensive Cancer Center Quality Management System (QMS)

LESSONS LEARNED

- Consider the historical context – Failed attempts to implement and sustain QMS in the past may require intentional efforts to build desire and buy-in for the effort among staff
- Set expectations around early success – If negative history exists, much of the early work will involve change management to cultivate engagement; gaining support and creating allies are key successes, in their own right, worth celebrating
- Gain credibility with early wins – Go where the action and need are; focus on pain points and areas of greatest risk to win support of key stakeholders

"Sustained success is now the goal of the standard. Success is the end to be achieved. Quality Management is the means for achieving this end."
- Unknown

FUTURE DIRECTION

- Continue to mature QMS and use a change management approach to evolve processes and procedures.
- Continue to engage staff in reinforcing the quality management principles and enhance adoption and learning.
- Create a dashboard of key performance indicators that aligns with the core business processes.

REFERENCES

- *ISO*, https://www.iso.org/obp/ui/#iso:std:iso:9000:en.

Preparing and Sharing Subject Cases for Remote NCTN Audit

K. Rygalski, M. Russell, D. Kitterman
University of Illinois Cancer Center

1. Background

The COVID-19 pandemic restricted travel and in-person gatherings, prohibiting external audits on campus. The implementation of Epic at the University of Illinois Chicago in 2020 made remote chart review feasible. The University of Illinois Cancer Clinical Trials Office established innovative procedures to support preparation and conduct of remote NCTN audits with Alliance, NRG Oncology, and the Children's Oncology Group in 2021.

2. Goals

Success was measured by the ability of the auditors to easily locate source documents remotely, and the ability to resolve auditor queries in real time during the audit.

3. Solutions and Methods

Each audit group had different requirements for subject case file review. Depending on the group requirements, case files were uploaded to the source document portal in the cancer trials support unit (CTSU), accessed via Epic Care Link, and/or uploaded to a secure PHI box. Document preparation for the CTSU portal required the most work, as all sources needed to be downloaded from Epic, de-identified in Adobe PDF, and organized into packets prior to upload.

Epic Care Link access drastically reduced the amount of de-identification and uploading of documents necessary, as only documents not in the electronic medical record were required to be uploaded (consents, questionnaires, sample tracking, and adverse event logs). Organizing these documents by study, subject ID, and content simplified navigation.

Communication with the auditors during the process was based on their preference. The most intense audit was with Alliance, where we had a Zoom call that lasted through the day with breakout rooms for each auditor. Our site would send a representative to each room to assist in locating documents and answering questions. In the other audits, a point person was designated to receive emails with questions and findings. That person would work with the team to formulate answers and reply in one succinct email chain.

4. Outcomes

Due to the organization and labeling of source documentation and open lines of communication throughout the audit, our site was able to significantly reduce the number of queries or findings on our final reports. In addition, every audit ended with complimentary notes from the reviewers regarding our level of preparation.

5. Lessons Learned and Future Directions

Obtaining information on how the auditor wishes to view documents and conduct the visit is important to define early in the planning stages. This prevented the team from having to re-organize documents or upload multiple times. For future audits we will share a source data identification log with the auditors that will give instructions on where to find data in either Epic Care Link or the secure PHI box.

As we began to rely on the search and redact feature in Adobe PDF, we realized clinicians frequently used nicknames or misspellings of names when referencing patients in documentation. This made de-identification difficult and we re-trained our clinicians to be careful when referencing patients in clinical documentation.

Preparing and Sharing Subject Cases for Remote NCTN Audit

Kayleigh Rygalski, BS, CCRP; Meredith Russell, BS, CCRP; Darlene Kitterman, MBA
University of Illinois Cancer Center

UNIVERSITY OF ILLINOIS CANCER CENTER

Background

The COVID-19 pandemic restricted travel and in-person gatherings, prohibiting external audits on campus. The implementation of Epic at the University of Illinois Chicago (UIC) in 2020 made remote chart review feasible. The University of Illinois Cancer Clinical Trials Office (UICC CTO) established innovative procedures to support preparation and conduct of remote NCTN audits with Alliance, NRG Oncology, and the Children's Oncology Group (COG) in 2021.

Objectives

Create a system to:
- Allow NCTN auditors to efficiently access source documents remotely.
- Give staff the ability to resolve queries remotely during the audit

Methods

Each audit group had different requirements for subject case file review. Depending on the group requirements, case files were uploaded to the source document portal in the Cancer Trials Support Unit (CTSU), accessed via Epic Care Link, and/or uploaded to a Secure PHI Box. Document preparation for the CTSU portal required the most work, as all source needed to be downloaded from Epic, de-identified in Adobe PDF, and organized into packets prior to upload.

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Results

Due to the organization and labeling of source documentation, and open lines of communication throughout the audit, our site was able to significantly reduce the number of queries or findings on our final reports. In addition, every audit ended with complimentary notes from the reviewers regarding our level of preparation.

Conclusions

Obtaining information on how the auditor wishes to view documents and conduct the visit is important to define early in the planning stages. This prevented the team from having to re-organize documents or upload multiple times. For future audits we will share a source data identification log with the auditors that will give instructions on where to find data in either Epic Care Link or the Secure PHI box.

As we began to rely on the search and redact feature in Adobe PDF, we realized clinicians frequently used nicknames or misspellings of names when referencing patients in documentation. This made de-identification difficult and we re-trained our clinicians to be careful when referencing patients in clinical documentation.

From our experience, the following would be helpful changes from CTSU to require from all NCTN groups if remote audits are to continue:

- Standardize the procedures for remote audits: The audits for Alliance, NRG, and COG varied greatly both in respect to preferred methods of accessing source documents (Alliance and NRG accessed the documents directly in the EMR and COG would not work from the EMR directly), as well as preferred communication mechanisms. Standardization would alleviate having to create processes tailored to each audit and create efficiencies both for the auditors and the site.

- Encourage auditors to audit directly from the EMR, where possible: For sites on Epic for audits where the auditor would audit directly from the EMR, Epic Care Link was a very efficient tool for organization the source documentation for the audit and was the most efficient mechanism for source document access for both the site and the auditors.

Acknowledgements

We would like to acknowledge the support of the University of Illinois Cancer Center for this project.

PARTNERING IN PROGRESS

REGULATORY

* Delegation of Authority – A Simplified Process[G]

B. Scanlan, A. Holley, M. Kovak, B. Lehman, P. Newman, R. Perry, D. Wade, M. Birrer
UAMS Winthrop P. Rockefeller Cancer Institute

1. Background

Collecting signatures and maintaining study-specific delegation of authority (DOA) logs has historically been a time-consuming process within our clinical trials office (CTO). With a CTO employing more than 60 staff and working with over 150 investigators, the process was burdensome for all involved. Further, there was no consistent process for DOA completion and maintenance across the approximately 300 research studies managed by the CTO. There were different requirements based on the type of study, whether initiated by a cooperative group, industry sponsor, or a local investigator. The processes were also made redundant due to DOA information required to be submitted in clinical research administration (CLARA), the UAMS electronic system for submission, review, and tracking of research. A simpler process to reduce administrative burden, streamline the procedure for all types of studies, and eliminate duplication of effort was imperative.

2. Goals

- Reduce administrative burden by eliminating requirement for wet-ink signatures on study-specific DOAs
- Streamline procedures by using the same process for all study types and eliminating use of sponsor provided DOAs
- Eliminate duplication of effort by integrating information that is already being captured in CLARA

3. Solutions and Methods

A new authority and delegations of responsibility standard operating procedure (SOP) was implemented to include completion of master signature pages (MSP) by all staff and investigators. At time of completion of the MSP, study staff reviews a central delegation key (CDK) that lists research roles and responsibilities based on credentials and job title. Signature on the MSP indicates agreement to perform delegated responsibilities as assigned based on role, education and training. The roles and responsibilities listed on the CDK are personalized to our site and mirror those listed in CLARA for each study. Staff and investigators are required to complete the MSP once, providing a wet-ink signature. The principal investigator is responsible for ensuring staff lists in CLARA are complete and updated at all times to provide an accurate account of the study specific DOA. Copies of completed MSPs and study specific staff lists are saved electronically for review by auditors and monitors.

4. Outcomes

- MSP completion and review of SOP is now part of our onboarding procedure for new staff and investigators
- Investigator involvement for tedious and redundant paperwork has been limited, allowing them to focus on more meaningful aspects of research
- Monitors have found the centralization of DOA information to be helpful and fewer monitor findings have been received
- Consistency in documentation of DOA across all types of studies has been established

5. Lessons Learned and Future Directions

Initial implementation of the revised process was time consuming for regulatory staff and led to many questions by staff and investigators. Additionally, although study monitors have been receptive to the process, many require additional documentation of our process in addition to the SOP. Overall, the updated DOA SOP has been essential in helping our office meet goals of streamlining procedures and reducing administrative burden.

* *Honorable Mention*

Delegation of Authority – A Simplified Process

Beth Scanlan, MAP, CCRP, Aaron Holley, BS, CCRP, Matthew Kovak, MS, CCRP, Brittany Lehman, BS, CCRP,
Priscilla Newman, Rashad Perry, BA, Daisy Wade, BA, CCRP, Michael Birrer, MD
Cancer Clinical Trials Office, Winthrop P. Rockefeller Cancer Institute,
University of Arkansas for Medical Sciences

Background

Collecting signatures and maintaining study specific Delegation of Authority (DOA) logs has historically been a time consuming process within our Clinical Trials Office (CTO). With a CTO employing more than sixty staff and working with over one hundred fifty investigators, the process was burdensome for all involved. Further, there was no consistent process for DOA completion and maintenance across the approximately three hundred research studies managed by the CTO. There were different requirements based on the type of study, whether initiated by a cooperative group, industry sponsor, or a local investigator. The processes were also made redundant due to DOA information required to be submitted in Clinical Research Administration (CLARA), the UAMS electronic system for submission, review, and tracking of research. A simpler process to reduce administrative burden, streamline the procedure for all types of studies, and eliminate duplication of effort was imperative.

Metrics & Goals to be Achieved

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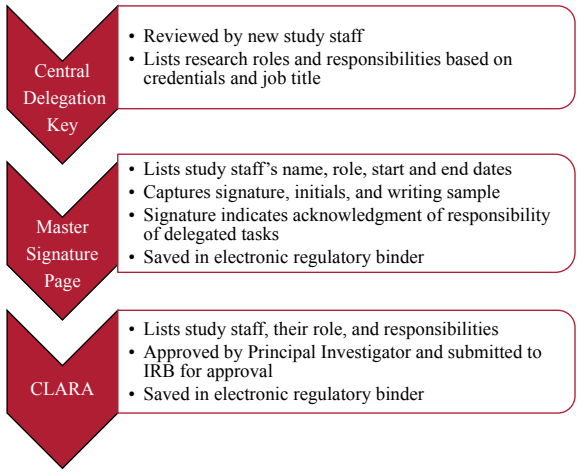
Figure 1: Simplified Workflow



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Simplifying and Improving Training and Delegation Documentation

R. Kingsford, L. Hayes, L. Lujan
Huntsman Cancer Institute, University of Utah

1. Background

Training and delegation are a primary focus of the Code of Federal Regulations and good clinical practice guidelines. The Huntsman Cancer Institute (HCI) clinical trials office (CTO) process for documentation of training and delegation had several problems that needed to be addressed:

- Multiple signatures required from the principal investigator (PI)
- Frequent changes due to staff turnover
- Quality control issues
- No defined process for collecting electronic signatures
- Sponsor overreach due to too much flexibility in our standard operating procedure (SOP)

2. Goals

We identified four major goals for our new process:

- Decrease the signature burden on PIs
- Increase compliance
- Move from wet ink to an electronic platform
- Decrease ambiguity for sponsors

3. Solutions and Methods

One of our senior regulatory coordinators joined our team from another comprehensive cancer center and shared their process for training and delegation documentation. Three of the main components of the process used at this center that we chose to adopt were: 1) the creation of research personnel profile pages for each study role, 2) the creation of a protocol assignment and training log (PATL) to document protocol training, and 3) a PI statement of oversight and delegation. As members of the AACI CRI listserv distribution list, we gleaned additional insight from other cancer centers in regard to SOP language to clarify sponsor expectations of our site. We used all of these components to develop a compliant, comprehensive process that would meet the goals outlined above.

The proposed process was shared with the HCI CTO physician leadership team to garner their support and approval of the new process. HCI CTO leadership drafted a comprehensive SOP and templates for research personnel profiles, PATL, and PI statement of oversight and delegation. We created work practice documents for the study teams to follow to initiate a new study using the revised SOP and how to transition a study that was initiated under our previous SOP to the new process. The new process is 100 percent electronic and compliant with 21 CFR Part 11.

Because the changes were so drastic, we decided to pilot the new process in one of our six research group teams.

4. Outcomes

The pilot began in January 2022 and has been going very well. The study teams have been able to identify and correct several errors in previous delegation and training records that have been transitioned indicating a large improvement in compliance. The study staff involved in the new process have found it to be straightforward and simple. Rather than requiring PI signature for each line on our former delegation of authority logs for every addition, the PI statement of oversight and delegation is signed annually. We are still getting feedback from sponsors on the new process as monitoring visits are occurring for the impacted studies.

5. Lessons Learned and Future Directions

The value of insight gained from the community of cancer research programs cannot be overstated. We felt confident in our new SOP because of the success of other cancer center programs who shared with us. We look forward to making any adjustments to our process based on the feedback we receive as the new process begins to be scrutinized. Once these initial adjustments are made, we plan to implement gradually across the entire department.

Simplifying and Improving Training and Delegation Documentation

Rachel Kingsford, MS, CCRP; Laura Hayes, BS, CCRC; Leanne Lujan, BS, CCRPN
Huntsman Cancer Institute at the University of Utah

BACKGROUND

Training and delegation are a primary focus of the Code of Federal Regulations and Good Clinical Practice guidelines. The Huntsman Cancer Institute (HCI) Clinical Trials Office (CTO) identified several areas for improvement in the current training and delegation documentation process:

- Multiple signatures required by the Principal Investigator (PI).
- Frequent changes due to staff turnover.
- Quality control issues.
- No defined process for collecting electronic signatures.
- Sponsor overreach due to too much flexibility in Standard Operating Procedure (SOP).

METRICS/GOALS

- Decrease the signature burden on PIs.
- Increase compliance.
- Move from wet ink to an electronic platform.
- Decrease ambiguity for sponsors.

METHODS

- HCI CTO leadership reviewed posts from the American Association of Cancer Institutes Listserv.
- Three primary components were developed:
  1. Research Personnel Profile Page for each research role (Figure 1)
  2. Protocol Assignment and Training Log (Figure 2)
  3. PI Statement of Oversight and Delegation (Figure 3)

Figure 1

Figure 2

Figure 3

OUTCOMES

After the SOP and other related documents were drafted, a pilot was begun in January 2022.

- The pilot team was able to identify and correct multiple issues.
- Staff and investigators have found the new process to be more convenient.
- Monitors have provided positive feedback for the new process.

FUTURE PLANS

- After a successful pilot, we will roll out the new process to the entire department.
- Study teams will begin the process of transitioning selected studies to the new process.
- We look forward to full implementation and process adjustments as we move forward.

Acknowledgements: We appreciate the other cancer centers who contribute to the AACI Listserv.

UNIVERSITY OF UTAH HUNTSMAN CANCER INSTITUTE

HEALTH UNIVERSITY OF UTAH

PARTNERING IN PROGRESS

TRAINING AND CAREER DEVELOPMENT

Investing in Investigator Training: Developing Tools to Close the Gap

L. Valanejad Kiefer, N. H. Babadi, M. Robinson, A. Camp, C. Lee, J. K. Morrison
UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

1. Background

Internal feedback from the University of North Carolina Lineberger Comprehensive Cancer Center (LCCC) investigators revealed an unmet need to provide readily available tools and training to educate investigators on the intricacies of developing, obtaining approval, and maintaining investigator-initiated trials (IITs), especially from those with no prior IIT experience. In fact, several investigators voiced concern and frustration during the development of their IITs when their own lack of understanding led to delays in the activation, a multitude of protocol amendments and/or noncompliance with investigational new drug (IND) regulations.

2. Goals

The goal of this initiative was to rebuild the University of North Carolina-LCCC IIT website to create a comprehensive training curriculum to minimize the gap in education between the onboarding of new investigators and the development of their IITs and to prevent noncompliance with FDA IND regulations.

3. Solutions and Methods

An initial lecture on IND management was developed in 2017 and LCCC investigators were invited to attend. An impressive 23 physicians attended despite their clinical schedules and duties, emphasizing the desire for IIT education. All were fully engaged in the discussion, leading the session to run over its allotted 1-hour timeframe as both junior and senior investigators asked questions and shared stories from their IIT experiences. This led to the development of yearly lectures on various IIT topics, with the 2021 lecture maintaining high attendance (34 investigators), and the re-development of the LCCC IIT website to function as a process warehouse where investigators can readily access training and education. Twenty-four webpages were developed to provide education on a variety of IIT topics including: how to identify funding and prepare a letter of intent, how to develop a clinical protocol, and to how work with drug/device regulations. Furthermore, a series of 15 IIT-focused beginner and advanced level lectures are housed on the website which provides a destination for asynchronous learning. Importantly, these trainings highlight the PI responsibilities for an LCCC-sponsored IIT.

4. Outcomes

The investigator-focused lectures and IIT website addressed the unmet need for investigator education. Significant IND noncompliance was identified at baseline, so one of our initial goals was to increase investigator understanding and compliance with IND regulations. In conjunction with other interventions, the implementation of training modules helped improve LCCC's IND overall compliance rating with the FDA regulations from 20 percent to 100 percent compliance despite an increase in IND portfolio complexity due to the addition of internally manufactured products. The informal feedback generated by this endeavor reaffirms that the incorporation of trainings and resources for IITs can significantly increase investigator understanding of the IIT process resulting in improvements in investigator communication, involvement, and compliance.

5. Lessons Learned and Future Directions

The endeavor taught us the importance of introducing investigators to training opportunities early and in a readily available platform to develop a strong foundational understanding of IITs. Our future directions include the adaptation of the website to include guidance on non-treatment trials such as biospecimen, radiology, and health registry protocols, focusing on their unique needs.

Investing in Investigator Training: Developing Tools to Close the Gap

Leila Valanejad Kiefer, Ph.D.; Nasrin H. Babadi, Ph.D., RAC; Mac Robinson, Ph.D.; Allison Camp, Ph.D.; Carrie Lee, M.D., MPH; J. Kaitlin Morrison, Ph.D.

Background

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Solutions and Methods

An initial lecture on IND management was developed in 2017 and LCCC investigators were invited to attend. Discussion from these sessions resulted in the re-development of the LCCC IIT website to function as a process warehouse where investigators can readily access training and education.

Twenty-four webpages were developed to provide education on a variety of IIT topics including the following: how to identify funding and prepare a Letter of Intent, how to develop a clinical protocol, and to how work with drug/device regulations. Furthermore, a series of 15 IIT focused beginner and advanced level lectures are housed on the website which provides a destination for asynchronous learning. Importantly, these trainings highlight the Principal Investigator (PI) responsibilities for an LCCC sponsored IIT, **Figure 1**.

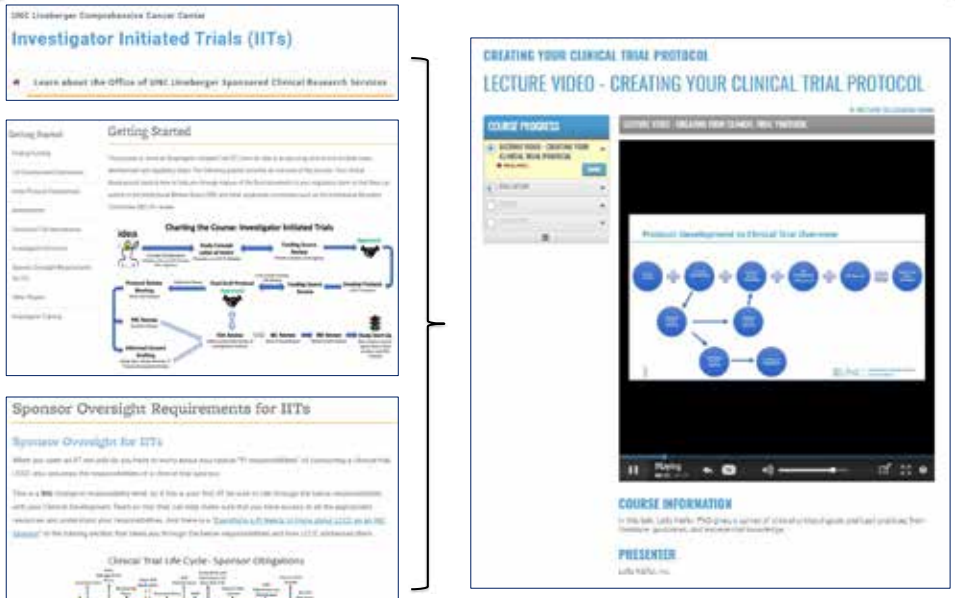


Figure 1: The goal of this initiative was to rebuild the IIT website to create a comprehensive training curriculum with asynchronous lectures that will minimize the gap in education that exists between the onboarding of new investigators and the development of their IITs.

Outcomes

The investigator-focused lectures and IIT website addressed the unmet need for investigator education. For example, noncompliance was noted as a major concern in IND management, and we identified significant noncompliance at baseline (**Figure 2A**). The lectures and website served as tool to increase investigator understanding and compliance with IND regulations. The initial lectures on IND management hosted an impressive 23 physicians in 2017 despite their clinical schedules and duties, emphasizing the desire for IIT education. All were fully engaged in the discussion, leading the session to run over its allotted 1-hour timeframe as both junior and senior investigators asked questions and shared stories from their IIT experiences. This led to the development of yearly lectures on various IIT topics, with the 2021 lecture maintaining high attendance (34 investigators **Figure 2B**),

In conjunction with other interventions, the implementation of training modules helped improve LCCC's IND overall compliance rating with the FDA regulations from 20% to 100% compliance despite an increase in IND portfolio complexity due to the addition of internally manufactured products, **Figure 2A**. The informal feedback generated by this endeavor reaffirms that the incorporation of trainings and resources for IITs can significantly increase investigator understanding of the IIT process resulting in improvements in investigator communication, involvement, and compliance.

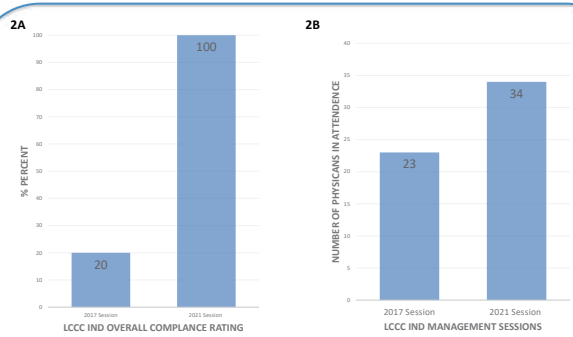


Figure 2: A: FDA compliance has increased from 20% to 100% as a result of the implementation of investigator training tools. B: Increase in demand of Investigator training sessions.

Conclusion

These results highlight the importance of introducing investigators to training opportunities early and in a readily available platform to develop a strong foundational understanding of IITs. Future directions include the adaptation of the website to include guidance on non-treatment trials such as biospecimen, radiology, and health registry protocols, focusing on their unique needs.

The Effectiveness of an Innovative Competency-Based Education and Training Program on Decreasing Audit Findings

E. Dawkins, S. Cole, N. Nahimas, P. Seo, and J. Brown
Sylvester Comprehensive Cancer Center, University of Miami Health System

1. Background

Routine education and training of staff to build their clinical research competencies is crucial to address any gaps related to clinical research practices, compliance, and audit readiness. The industry standard of the "one-size-fits-all" good clinical practice (GCP) training may not fully prepare investigators and other research staff for audits. Clinical Research Services Quality Assurance Unit (CRS-QAU) created an innovative education program consisting of tailored training designed to build greater research competencies.

2. Goals

We sought to determine if the innovative education and training program was effective in reducing audit findings within 1 year.

3. Solutions and Methods

CRS-QAU's education and training program offered GCP training to all new employees on a quarterly basis in 2020. After the audits in 2020, CRS-QAU's education and training administrators reviewed the areas of deficiencies in order to provide tailored training to employees. The innovative, competency-based trainings were offered in 2021 to new and existing employees on a monthly basis. We also provided individualized and group training as needed to support continuous learning and improve performance in their specific roles. Findings from audit reports received from the University of Miami's (UM) internal clinical research auditing body, sponsors and cooperative groups were collected. Audit reports included verification of research compliance, and validation of data submitted by clinical research staff. Audit findings were grouped into eight categories, and differences were analyzed comparing 2020 and 2021 data using the chi square test.

4. Outcomes

Comparing the 2 years, the greatest improvements in compliance occurred in subject accountability, informed consent and subject protection, adverse events reporting (- 91-100%). Substantial improvement occurred in test article, sponsor related, protocol compliance, documentation, and data (- 44-80%). The only area of increase was regulatory (+ 25%). Overall, a 69% decrease in the total number of findings was found in 2021 compared to 2020 [2 (7, 13) = 42.57, P < .001]; [2 (7, 18) = 42.57, P = 0.90, respectively].

5. Lessons Learned and Future Directions

CRS-QAU developed an innovative education and training program for its clinical research teams. Providing ongoing, tailored, competency-based education and training, performed in greater frequency and on an individualized (as needed) basis, is effective for reducing audit findings in key categories and over a short period of time (within 1 year).

THE EFFECTIVENESS OF AN INNOVATIVE COMPETENCY-BASED EDUCATION AND TRAINING PROGRAM ON AUDIT FINDINGS (2020 VS 2021)

Authors: E. Dawkins, S. Cole, N. Nahmias, PH. Seo, and J. Brown
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

Routine education and training of staff to build their clinical research competencies is crucial to address any gaps related to clinical research practices, compliance, and audit readiness. The industry standard of the "one-size-fits-all" Good Clinical Practice (GCP) training may not fully prepare investigators, and other research staff for audits. Clinical Research Services Quality Assurance Unit (CRS-QAU) created an innovative education program consisting of tailored training designed to build greater research competencies. We sought to determine if the innovative education and training program was effective in reducing audit findings within one year.

Design/Methods

CRS-QAU's education and training program offered training to all new employees on a quarterly basis in 2020. After the audits in 2020, CRS-QAU's education and training administrators reviewed the areas of deficiencies in order to provide tailored training to employees. The innovative, competency-based trainings were offered in 2021 to new and existing employees on a monthly basis. We also provided individualized and group training as needed to support continuous learning and improve performance in their specific roles. Findings from audit reports received from the University of Miami's (UM) internal clinical research auditing body, sponsors, cooperative groups were collected. Audit reports included verification of research compliance, and validation of data submitted by clinical research staff. Audit findings were grouped into eight categories, and differences were analyzed comparing 2020 and 2021 data using the chi square test.

Audit Finding Results 2020 vs. 2021

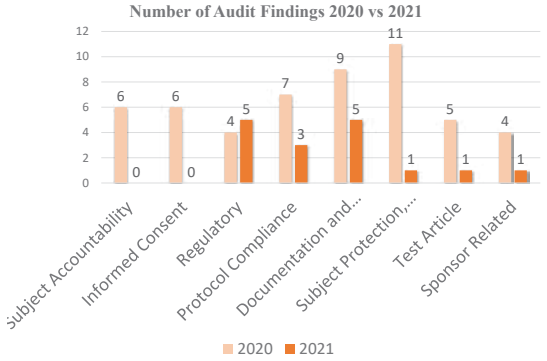


Table 1: Number of Audit Findings 2020 vs. 2021

Category	Number of Findings by Yr.		Percent +/- by Category[a]
	2020	2021	
Subject Accountability	6	0	- 100%
Informed Consent	6	0	- 100%
Regulatory	4	5[b]	+ 25%[c]
Protocol Compliance	7	3	- 57%
Documentation and Data	9	5	-44%
Subject Protection, Adverse Events	11	1	-91%
Test Article	5	1	-80%
Sponsor Related	4	1	-75%
Total	**52**	**16**	**-69%*** (<0.001)**

p-value is in parentheses
*** p < 0.001
Abbreviation: Yr., Year.;
[a] Percent increase/decrease (+/-) in audit findings by category
[b] A cooperative group audit found one item of consent content that impacted several studies
[c] This represents a slight increase in audit findings in the 'Regulatory' category

Results / Conclusions

Comparing the 2 years, the greatest improvements in compliance occurred in subject accountability, informed consent and subject protection, adverse events reporting (- 91-100%). Substantial improvement occurred in test article, sponsor related, protocol compliance, documentation and data (- 44-80%). The only area of increase was regulatory (+ 25%). Overall, a 69% decrease in the total number of findings was found in 2021 compared to 2020 [χ^2 (7, 13) = 42.57, P < .001]; [χ^2 (7, 18) = 42.57, P = 0.90, respectively] (Table 1).

CRS-QAU developed an innovative education and training program for its clinical research teams. Providing ongoing, tailored, competency-based education and training, performed in greater frequency and on an individualized (as needed) basis, is effective for reducing audit findings in key categories and over a short period of time (within 1 year).

Comprehensive Application of Supplemental Phantom Educational Resources (CASPER): a Friendly Phantom Patient to Guide the Way for New Study Coordinators

E. Cunningham, L. Dunham, B. Olsen
Karmanos Cancer Institute, Wayne State University

1. Background

The clinical trials office (CTO) at the Karmanos Cancer Institute, an NCI-Designated Comprehensive Cancer Center, created an enhanced formal orientation program (EOP) in December 2016 for all new employees. This program consists of 22 modules that review the basics of oncology, clinical trials, different research departments, and role-specific topics for eight weeks prior to the coordinators starting their own workloads. So far, 37 groups (over 200 employees) have completed the EOP. Orientees are given a post-orientation survey that asks what they liked about the program and how it can improve. Multiple groups expressed a desire for more interactive modules to reinforce the instruction.

2. Goals

- Address repeated requests from orientees to follow a patient through the trial process
- Allow hands-on practice for new CTO study coordinators (SC), including review of patient documents for study related procedures
- Promote greater familiarity with study processes, which will increase SC proficiency
- Provide examples of tools (adverse event, deviation, and medical history logs, emails to physicians, and note-to-file templates)

3. Solutions and Methods

Three interactive phantom patient modules (PPM) (introduction, informed consent, eligibility review and registration, deviations, tumor tracking, adverse events, source document creation, EMR exposure, and protocol treatments, with all modules reviewing applicable policies) were created to supplement the EOP. The PPM are attended in tandem with the EOP to allow SCs to become familiar with the processes introduced in the modules. To ensure comprehensive exposure, three studies were chosen to represent a broad spectrum of disease types, treatment methods, and sponsor variety. The PPM follows three phantom patients through their respective studies to reinforce the instruction of the EOP. In order for SCs to review the patient specific study procedures, each phantom patient has a corresponding shadow chart that utilizes information from real patients, who have enrolled on these studies. The redacted shadow charts were uploaded into Microsoft Teams and Veeva Site Vault to protect PHI.

4. Outcomes

The PPM were implemented in February 2022 and included employees who recently completed the EOP to gather thorough feedback. Positive feedback was received from participants, indicating they feel more comfortable with the eligibility and registration process and have learned new ways to navigate the EMR. Follow-up with participants and their supervisors is planned in order to determine if there is a greater understanding of the CTO processes once the participant receives their workload. The goal is for SCs to feel more competent and comfortable in their role.

5. Lessons Learned and Future Directions

Initially it was planned to incorporate the phantom patient charts into preexisting modules; however, it was determined that separate PPM would be more beneficial to the orientees.

After presenting the first module, an introduction session was created, which provides more in-depth instructions regarding expectations and the location of documents needed during the PPM. Creating a stand-alone introduction module will also allow more time to be spent on the eligibility and registration process in the first session.

Comprehensive Application of Supplemental Phantom Educational Resources (CASPER): A Friendly Phantom Patient to Guide the Way for New Study Coordinators

Elizabeth Cunningham, MS, CCRP; Leah Dunham, MPH, CCRC; Bradley Olsen, BS, CCRP
Karmanos Cancer Institute

Background

The Clinical Trial Office (CTO) at the Karmanos Cancer Institute, an NCI-Designated Comprehensive Cancer Center, created an enhanced formal orientation program (EOP) in December, 2016 for all new employees. This program consists of 22 modules that review the basics of oncology, clinical trials, different research departments, and role specific topics. The EOP typically spans eight weeks and is designed to be completed prior to the coordinators starting individual study workloads. To date, 38 groups (over 200 employees) have completed the EOP. All orientation groups have been given a Post-Orientation Survey that asks what they liked about the program and allows for suggestions regarding how the program can improve. Multiple groups expressed a desire for more interactive modules to reinforce the instruction. In February 2021, it was decided to create a phantom patient to supplement the original EOP.

Methods Implemented

Three interactive Phantom Patient Modules (PPM) (introduction, informed consent, eligibility review and registration; deviations, tumor tracking, adverse events; source document creation, EMR exposure, and protocol treatments; with all modules reviewing applicable policies) were created. The PPM are attended in tandem with the EOP to allow Study Coordinators (SC) to become familiar with the processes introduced in the modules.

To ensure comprehensive exposure, three studies were chosen to represent a broad spectrum of disease types, treatment methods, and sponsor variety. The PPM follows three phantom patients through their respective studies to reinforce the instruction of the EOP. In order for SC to review the patient-specific study procedures, each phantom patient has a corresponding shadow chart that utilizes information from real patients, who have enrolled on these studies. The redacted shadow charts were uploaded into MS Teams and Veeva Site Vault in order to protect PHI.

Phantom Patient Module	EOP Module
Introduction to the Phantom Patient	Orientation Overview
	Introduction to Clinical Trials
	The Research Team
	Oncology 101 & Assessment of the Patient
	Self-Study: Moving Toward Better Cancer Treatment - Getting Involved with Clinical Trials
Phantom Patient Module #1	The Research Protocol & Review of Eligibility
	Regulatory "Human Research Protection & Review of the Regulatory Coordinator"
	Informed Consent
	Oncore Review
Phantom Patient Module #2	RECIST 1.1
	Shadow Charts & Source Documents
	CTCAE Toxicities
	Serious Adverse Events & Deviations
	Overview of NCI Studies
	Self-Study: Introduction to Vestigo
Phantom Patient Module#3	Central Data Management & The Network
	Quality Assurance & The DSMP
	90 Day Activation
	Pre & Post Awards
	Monitoring Visits
	End of Orientation Wrap Up

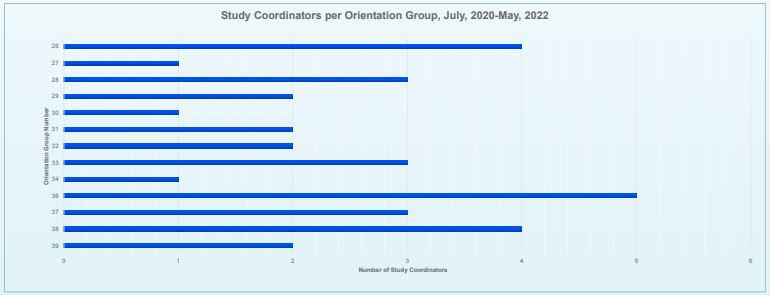
Goals

- Address repeated requests from orientees to follow a patient through the trial process
- Allow hands-on practice for new CTO SC, including review of patient documents for study-related procedures
- Promote greater familiarity with study processes in order to increase SC proficiency
- Provide examples of tools (adverse event, deviation, and medical history logs, emails to physicians, and note-to-file templates) to assist SC with developing personal methods and behaviors to comply with CTO expectations and policies

Recommendations

Segments of the PPM were initially planned to be incorporated into the EOP modules; however, after discussion with EOP module presenters, it was determined that separate PPM would be more beneficial to the orientees.

After presenting the first module, an introduction session was created, in order to provide more in-depth instructions regarding expectations and the location of documents needed during the PPM. The creation of this stand-alone introduction module allows more time to be spent on the eligibility and registration process.



Results

The PPM were implemented in February 2022 with the initial group consisting of employees who recently completed the EOP. Throughout the course of the modules, positive feedback was received from participants, indicating they felt more comfortable with the eligibility and registration process and learned new ways to navigate the EMR. One participant's supervisor reached out in order to make special note of how the program positively impacted the SC comprehension of CTO processes and productivity. Further follow up with participants and their supervisors is planned to determine if there is a greater understanding of the CTO processes once the participant receives their workload.

Conclusion

In April 2022, one series of the PPM was completed. In May 2022, the second series of PPM commenced with SCs currently undergoing the EOP.

Although the PPM is a new addition to the EOP, it does appear that these supplemental modules are making a positive impact on the overall competencies and confidence of the new SC.

In the ever-changing landscape of clinical trials, further follow-up and modifications to the program are planned, in order to keep the program current, beneficial, and relevant to the new orientees.

Implementation of Small Group Trainings to Expedite Initial Onboarding for Clinical Research Staff and Increase Connection Between New Employees

D. Kreitner, M. Wanchoo, D. Castro, C. Burgin
OHSU Knight Cancer Institute

1. Background

The Knight Cancer Institute (KCI) provides 1:1 onboarding for new clinical research staff members. The onboarding program consists of approximately 50 topics, requiring completion of about 30 one-hour individual sessions. The target timeline for initial onboarding completion is approximately five months, which requires one to two training sessions per week to accomplish. When fully staffed, KCI employs two full-time trainers, and each trainer can conduct about 20-25 training sessions per week. Maintaining an ideal pace, each trainer can handle a maximum caseload of 20-25 trainees (40-50 trainees total).

In late 2019, one trainer changed jobs, leaving a vacancy that unfortunately remained unfilled before OHSU implemented a soft hiring freeze in early 2020 due to COVID-19 and uncertain financial projections. Like other medical facilities, KCI experienced high clinical research staff turnover, and the hiring freeze was not lifted until fall 2020. Multiple new clinical research staff members were hired from August to December 2020, and a second trainer was hired in January 2021. Although again fully staffed with two trainers, the number of new trainees had grown to the highest totals the program had ever seen (110 trainees). Due to the imbalanced trainer-trainee ratio, onboarding time increased to approximately 12 months and trainees sometimes went weeks between training sessions. Additionally, COVID-19 modified operations requiring remote work for non-essential workers hindered connection among clinical research staff.

2. Goals

The primary goal was to decrease onboarding completion time by increasing trainer touchpoints per employee. Another goal was to increase staff connection and engagement, in light of increased remote work.

3. Solutions and Methods

Group trainings were implemented in August 2021. Prior to implementation, the trainers discussed small group training with clinical research managers and received buy-in and input. The trainers identified approximately 30 topics as amenable to group trainings, with the remainder to be covered during 1:1 sessions. Each group consisted of two to four trainees based on start date, role, and availability. Each group was scheduled for a weekly recurring meeting for 12 weeks, which could be extended if needed. The trainers continued to meet with each trainee for 1:1 training sessions to ensure all initial onboarding training topics were covered.

4. Outcomes

Thus far, our evaluations indicate positive results following implementation of this new training strategy. Due to trainer touchpoints increasing per employee, trainees in a group are now completing onboarding in about seven months. Trainees are also communicating with their group members for answers to questions and resources. Additionally, group members are showing interest in meeting each other when they are on site.

5. Lessons Learned and Future Directions

The trainers re-reviewed training topics in early 2022. One topic was removed from the group list, three were added, and one was divided up for both individual and group content.

Group training appointments were extended on average from 12 weeks to 14 weeks. Going forward, the recurring group meetings will be scheduled initially for 16 weeks.

Formal feedback from group members is planned and will be solicited in an objective survey in fall 2022.

Implementation of Small Group Trainings to Expedite Initial Onboarding for Clinical Research Staff and Increase Connection Between New Employees

Dustin Kreitner, MS; Mihir Wanchoo, MBBS, MHA; David Castro, Phd; Christina Burgin, BA

Background

The Knight Cancer Institute (KCI) provides 1:1 onboarding for new clinical research staff members. The onboarding program consists of approximately 50 topics, requiring completion of about 30 one-hour individual sessions. The target timeline for initial onboarding completion is approximately five months, which requires one to two training sessions per week to accomplish. When fully staffed, KCI employs two full-time trainers, and each trainer can conduct about 20-25 training sessions per week. Maintaining an ideal pace, each trainer can handle a maximum caseload of 20-25 trainees (40-50 trainees total).

In late 2019, one trainer changed jobs, leaving a vacancy that unfortunately remained unfilled before OHSU implemented a soft hiring freeze in early 2020 due to COVID-19 and uncertain financial projections. Like other medical facilities, KCI experienced high clinical research staff turnover, and the hiring freeze was not lifted until fall 2020. Multiple new clinical research staff members were hired from August to December 2020, and a second trainer was hired in January 2021. Although again fully staffed with two trainers, the number of new trainees had grown to the highest totals the program had ever seen (110 trainees). Due to the imbalanced trainer-trainee ratio, onboarding time increased to approximately 12 months and trainees sometimes went weeks between training sessions. Additionally, COVID-19 modified operations requiring remote work for non-essential workers hindered connection among clinical research staff.

Goals

1. Decrease onboarding completion time by increasing trainer touchpoints per employee.
2. Increase staff connection and engagement, in light of increased remote work.

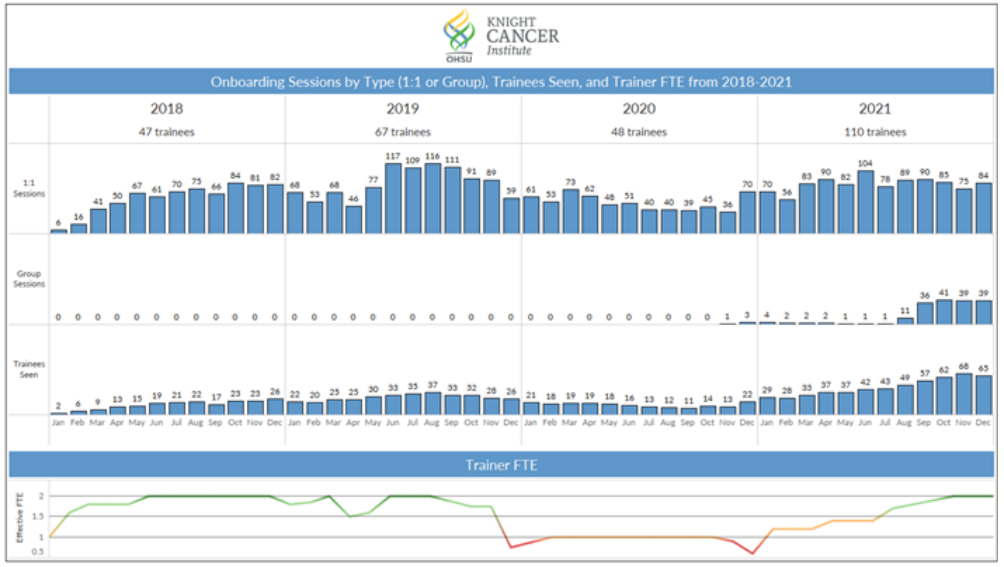
Methods Implemented

- Implemented in August 2021 after buy-in and input from clinical research managers.
- 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 consisted of two to four trainees based on start date, role, and availability.
- Each group scheduled for weekly recurring meeting for 12 weeks.

Outcome

Thus far, our evaluations indicate positive results following implementation of this new training strategy.

- Trainees in groups are completing onboarding in about seven months.
- Trainees are communicating with their group members for answers to questions and resources.
- Group members are showing interest in meeting each other when they are on site.



Lessons Learned and Future Direction

- The trainers re-reviewed training topics in early 2022. One topic was removed from the group list, three were added, and one was divided up for both individual and group content.
- Group training appointments were extended on average from 12 weeks to 14 weeks. Going forward, the recurring group meetings will be scheduled initially for 16 weeks.
- Formal feedback from group members is planned and will be solicited in an objective survey in fall 2022.

* Staffing Pipeline Creation: Clinical Research Internship for Undergraduate BIPOC Students

T. Cummings, A. Walens, A. Leak-Bryant, V. Carlisle, M. Haines, C. Lee
UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

1. Background

During calendar year (CY) 2021, record high rates of seasoned clinical research staff opted to leave their job for a variety of reasons. Also, in CY 2021 the National Cancer Institute (NCI) added a new component to the Cancer Center Support Grant to ensure that all designated centers account for diversity, equity and inclusion among faculty and staff. This has driven NCI-Designated Cancer Centers to critically assess their workforce demographics and develop strategies to engage and attract Black, Indigenous, and people of color (BIPOC) individuals into the workforce.

Collectively, underrepresented racial and ethnic groups make up 30 percent of the population in the United States and in North Carolina (NC), however, there is not an equitable reflection of these groups in health care professions in NC (Kreuter). To ensure adequate representation of BIPOC staff working at Lineberger Comprehensive Cancer Center (LCCC), leadership recognized the need for a more formal program to inform and expose local BIPOC students to clinical research employment opportunities.

The internship program described herein focuses on supporting oncology workforce development among local BIPOC undergraduate students with the intent to attract students to careers in clinical research at LCCC. Our initial effort is a pilot program for students at North Carolina Central University, a Historically Black College/University, designed to expose them to oncology clinical research careers and support professional development.

2. Goals

1) Create a 2-year longitudinal summer internship for 5 BIPOC undergraduate students at NCCU as an avenue for permanent employment at LCCC in the clinical research workforce
2) Connect NCCU undergraduate interns to scientific mentors in cancer clinical research
3) Conduct semi-structured and/or focus groups to explore the lived experiences of the interns and mentors
4) Determine the impact of the internship on students' perceptions of career and graduate opportunities in clinical research
5) Evaluate the strengths, growth opportunities, and barriers to participation in the internship program

3. Solutions and Methods

The curriculum will support years 1 and 2 of the 10-week summer internship. The clinical rotations focus on shadowing oncology care and research activities in outpatient cancer clinics. Students are also given the opportunity to shadow in labs associated with tissue procurement and genomic research. Professional development and mentorship are additional core curriculum components. Every student is assigned a mentor to meet with bi-weekly during the summers and quarterly during the intervening school year.

4. Outcomes

Key metrics used to measure the success of the program include both quantitative and qualitative data collection via an electronic survey as well as semi-structured and/or focus groups. These data will be evaluated in collaboration with the UNC Odum Institute for Research in Social Science, which will provide an in-depth analysis and create a key summary report.

5. Lessons Learned and Future Directions

The inception and development of this internship program underscores the critical importance of a collaborative approach in program development, including the clinical research leadership team, cancer research training and education coordination (CRTEC), community outreach and engagement (COE), and the NCCU leadership.

* *Honorable Mention*

UNC LINEBERGER COMPREHENSIVE CANCER CENTER

Building the Oncology Workforce: Clinical Research Internship for Undergraduate Black, Indigenous, and People of Color (BIPOC) Students

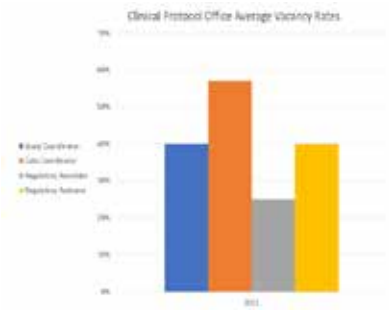
NCCentral UNIVERSITY
Discover what's Central to you.

Theresa Cummings RN, DBA, CCRP, Ashley Leak-Bryant PhD, RN, Andrea Walens PhD, OCN, FAAN, Veronica Carlisle MPH, CHES, Melissa Haines, Carrie Lee MD, MPH

Background

Calendar Year 2021

- Record high rate clinical research staff turnover



- NCI added a new component to the Cancer Center Support Grant, to account for Diversity, Equity and Inclusion among faculty and staff.
- Strategies to engage and attract BIPOC individuals into the LCCC workforce, including a clinical research internship program in partnership with NC Central University. NC Central University is a local Historically Black/Tribal University.

Aims:

1.) To increase the number of BIPOC individuals in the LCCC clinical research workforce.

2.) To assess the impact of more BIPOC individuals in the clinical research workforce on the number BIPOC individuals enrolled on LCCC supported clinical trials.

Design of Summer 1

Two Week Orientation:

- Clinical Resaerch Didactic sessions, GCP, HIPAA
- Individual Development Plan Creation
- Lived Experience Survey (Pre) – mentor and intern
- Intro. To Diversity, Equity and Inclusion, Community Outreach and Engagement, Cancer Center Support Program, Patient Advocacy

Four Week Clinical Rotations:

- Partner with faculty in Lung, Leukemia, Multiple Myeloma, Gynecologic, Genitourinary, and Breast clinics (M-Th, 8:30-12)
- Observe clinical research visit activities
- Daily debrief with Mentor

Four Week Professional Development:

- Creation of a project to present at End of Summer Symposium
- Intro to research administration and grant funded research
- Lived Experience Survey (post) – mentor and intern
- Communication Essentials, resume writing, writing a personal statement

Lessons Learned so far….

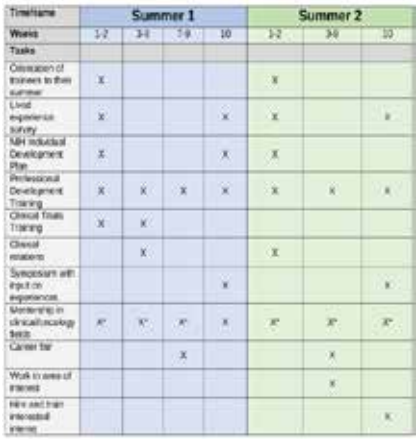
- Student interest was much greater than anticipated – 12 applicants
  Applicant Characteristics:
  - 66% identified as 1st Generation College Student
  - 58% identified as coming from a Low Income background
  - 41% Nursing majors
  - 25% Biomedical Sciences majors
  - 25% Pharmaceutical Sciences mJORS
- Cohort of 5 selected for Inaugural Year – Begins May 17th, 2022.
- Mentor and Faculty interest to participate was also robust

Research funded by: LCCC & V Foundation

Methodology

Cancer Center Collaboration

Create Internship Curriculum



THE V FOUNDATION for Cancer Research

Using Surveys to Evaluate Staff Onboarding Experiences: Pandemic to Present

C.L. Allen, P. Rose, M. Marcum, N. Kurtzweil
University of Cincinnati Cancer Center

1. Background

In 2018 the University of Cincinnati Cancer Center clinical trials office (UCCC CTO) established an onboarding program consisting of an onboarding binder of resources; videos on core research topics; dedicated preceptors for each new employee; and a competency checklist to be verified by a supervisor to exit orientation. As COVID-19 restrictions took effect, it became unclear how well these processes translated into a remote/hybrid setting.

2. Goals

In October of 2020, a REDCap survey for staff in onboarding was implemented by the CTO. The intent was primarily to learn how welcomed employees felt and how satisfied they were with their onboarding. This survey was confidential but not anonymous.

3. Solutions and Methods

All new employees hired between October 2020 and present (n=40) were provided with the survey. Responses from 29 employees were received (73 percent response rate).

4. Outcomes

Survey results were compiled as a summary table of average scores and ratings in aggregate across all respondents. Questions were scored on scales of "1 - not very welcomed" to "5 - very welcomed"; "1 - strongly disagree" to "5 - strongly agree"; and "1 - extremely dissatisfied" to "5 - extremely satisfied."

COVID Onboarding Impact
Comments were received from 62 percent (18/29) of respondents. Of those, 45 percent (8/18) of respondents cited the pandemic or the remote/in-person restrictions/uncertainty as impacting their onboarding.

CTO Culture, Goals & Job Expectations

- 73% (4.59 average) felt "very welcomed" in their team
- 73% (4.64 average) "strongly agreed" that they understand the organization's goals
- 55% (4.32 average) thought they fit into UCCC's culture "very well"
- 41% (3.77 average) "strongly agreed" that they felt like they have all the tools and resources to perform their job successfully
- 36% (3.91 average) "strongly agreed" that this job is what they expected it to be

CTO Onboarding Satisfaction

- 45% (4.14 average) were "extremely satisfied" with resources
- 36% (4.0 average) were "extremely satisfied," with onboarding in general
- 36% (3.95 average) were "extremely satisfied" with trainings
- 36% (3.82 average) were "extremely satisfied" with systems, department, and research overview
- 27% (3.5 average) were "extremely satisfied" with campus tours

5. Lessons Learned and Future Directions

Our survey data demonstrated that new staff felt very welcomed into their teams, understood UCCC's goals and had moderate satisfaction with training/resources/onboarding provided. Unsurprisingly, almost half of respondents who provided comments indicated their experience was impacted by the pandemic, which is also reflected in low satisfaction with campus tours and job expectations scores.

Going forward the CTO will move onboarding resources online (into Canvas) along with developing competency quizzes to better communicate and evaluate training expectations to staff. We are clarifying our career ladder to better define role expectations. We will revise the survey to provide dedicated questions on individuals' prior research experience and work modalities challenges and refine definitions of key terms such as "resources." Finally, we will use employee-driven engagement committees to involve remote/hybrid/in-person staff equally in identifying opportunities to connect and learn from colleagues. We believe these changes will help increase employee satisfaction and effectiveness of onboarding as we continue to work in a mixed modality office.

Using Surveys to Evaluate Staff Onboarding Experiences: Pandemic to Present

Casey L. Allen, MS; Patti Rose, BSN; Michelle Marcum, MS; Nicky Kurtzweil, JD
University of Cincinnati Cancer Center (UCCC), Cincinnati, OH

Background of the Problem:

In 2018 the UCCC Clinical Trials Office (CTO) established an onboarding program consisting of:

- An onboarding binder of resources;
- Videos on core research topics;
- Dedicated preceptors for each new employee;
- A competency checklist to be verified by a supervisor to exit orientation.
- 1 FTE Educator position in CTO

As COVID restrictions took effect, it became unclear how well these processes translated into remote/hybrid setting.

Goals to be Achieved:

- October 2020 UCCC CTO administered a confidential staff onboarding survey using REDCap.
- Goal was to learn how welcomed employees felt and how satisfied employees felt with onboarding

Solutions & Methods Implemented:

- All new employees hired between October 2020 to March 2022 (N = 40) received an invite to participate in the REDCap survey.
- 29 new employees completed a survey (73% response rate)
- Comments were received from 62% (18/29) of all respondents and were used to evaluate pandemic impact.

Outcomes:

- 45% (8/18) of respondents who provided comments cited the pandemic or the remote/in-person restrictions and general uncertainty as impacting their onboarding.

Survey Item - Welcomed	Average Score	5	4	3	2	1
How well do you think you fit in UC Cancer Center's culture?	4.32	55%	23%	23%	0%	0%
How welcomed do you feel in UC Cancer Center?	4.41	64%	18%	14%	5%	0%
How welcomed do you feel in your team?	4.59	73%	18%	5%	5%	0%
I understand my organization's goals.	4.64	73%	23%	0%	5%	0%
I have a clear idea about what is expected of me at this job	4.23	45%	32%	23%	0%	0%
The job is what I expected it to be.	3.91	36%	32%	23%	5%	5%
I feel like I have all the tools and resources to perform my job	3.77	41%	18%	23%	14%	5%
My role so far matches the role description provided to me	4.23	50%	27%	18%	5%	0%
I am feeling productive.	4.00	27%	50%	18%	5%	0%

Survey Item - Resources	Average Score	5	4	3	2	1
UCCC Overview Personal Set Up	3.91	36%	36%	9%	18%	0%
Campus Tours	3.50	27%	32%	18%	9%	14%
Detail Dept. & Research Overview	3.82	36%	32%	9%	23%	0%
Trainings	3.95	36%	32%	23%	9%	0%
Systems (Complion, OnCore)	3.82	36%	27%	18%	18%	0%
Credentialing	3.86	32%	36%	18%	14%	0%
Resources	4.14	45%	32%	14%	9%	0%
Personal	4.14	50%	18%	27%	5%	0%
How satisfied were you with the onboarding in general?	4.00	36%	32%	27%	5%	0%

Contact Casey Allen at allen2cy@ucmail.uc.edu; Patti Rose rosepi@ucmail.uc.edu or Nicky Kurtzweil kurtzwny@ucmail.uc.edu

Outcomes Continued:

- Unsurprisingly impacts of pandemic restrictions were also reflected in low satisfaction with campus tours and job expectations scores (36% & 27%)
- New staff felt very welcome in their teams (73%)
- Most understood UCCC's goals (73%)
- New staff had only moderate satisfaction with the training/resources/onboarding provided (45-36%) it is unclear how much of this is reflective of the pandemic versus the need for program refinements

Going Forward:

To help increase employee satisfaction and improve the effectiveness of onboarding as we continue to work in a mixed-modality office we are:

- Moving onboarding resources online (into Canvas) along with developing competency quizzes to better communicate and evaluate training expectations to staff.
- Clarifying our career ladder to better define role expectations.
- Revising the survey to provide dedicated questions on individual's prior research experience, work modalities challenges and refine definitions of key terms such as "resources."
- Developing employee-driven engagement committees to involve remote/hybrid/in-person staff equally in identifying opportunities to connect and learn from colleagues.

University of CINCINNATI CANCER CENTER
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Piloting a New Investigator E-Learning Onboarding Program

J. Thomas, M. Murphy, T. George, A. Anderson, E. Monari, A. Ivey
University of Florida Health Cancer Center

1. Background

Principal investigator (PI) roles are complex. A formalized onboarding curriculum, created and delivered through the UFHCC clinical research office (CRO) and the research and training core (CaRTECC), was developed for new clinical investigators to provide knowledge and resources to help successfully conduct trials at UFHCC. This curriculum is anticipated to shorten learning curves for administrative and regulatory tasks, improve confidence leading trials, and ultimately decrease deviations. While generalized training exists providing broad coverage of PI competencies, this standardized onboarding will provide investigators instruction on specific research processes at UFHCC.

2. Goals

- Develop standardized clinical research onboarding curriculum for new investigators of varied backgrounds
- Increase new investigators' confidence leading clinical trials
- Assess common knowledge gaps to create focused training modules to reduce errors impacting the institution via CAPAs or data deficiencies

3. Solutions and Methods

In January 2022, the UFHCC new clinical investigator eTraining (NCINET) was piloted with 11 new early-stage faculty. Of these, three completed the entire eight-module course and the remainder are expected to complete training in April. Following Knowles's core principles of andragogy, NCINET has immediate relevance to PI's role in clinical trials; each module is process-centered, using UFHCC policies as core texts. These documents outline clinical trial management, providing learning scenarios to highlight concepts including oversight, compliance, and consent. To maintain engagement and support motivation, learners can monitor individualized progress. By offering NCINET via a learning management system (LMS), investigators can access training and resources 24 hours a day. To ensure successful completion, investigators cannot be added to clinical trials as PI or Sub-I until the minimum passing score of 80 percent is achieved on all module assessments.

4. Outcomes

Five new investigators have initiated training, with three having completed the entire sequence. Initial data shows compliance and oversight domains had the greatest number of outliers. This suggests further module development may be needed, offering more situational practice. Individualized domain progress is also trackable.

The relationship between time spent on NCINET and mean scores across competencies shows a bimodal distribution, suggesting two cohorts working with curriculum. One group spent less time engaged with curriculum (<160 minutes) and the other group spent more time (>420 minutes). Both groups achieved mastery.

We predict more experienced investigators will achieve mastery in fewer hours of engagement than less experienced investigators. Further examination of metadata to link investigator experience with time spent in online training and competency mastery will be needed to study this hypothesis.

The relationship between page views (clicks) and mean scores across competencies was not statistically significant (p=0.29), suggesting number of views does not predict mastery, though the small sample size is a limitation.

5. Lessons Learned and Future Directions

Version 2.0 of NCINET curriculum will include a pre-/post-test, end-of-module surveys, and more interactive content. Assessments will undergo item analysis for outcomes alignment and to identify areas where more support is needed. Metadata will be collected to identify variables associated with investigator experience. A follow-up survey is planned to evaluate level of confidence in trial participation. Audit data will be examined to explore correlations between deviations and training.

Piloting a New Investigator E-Learning Onboarding Program

Julie Thomas, MEd, Martina Murphy, MD, Ashley Anderson, MBA, ACRP-CP, Erin Monari, PhD, CCRP, Alison Ivey, RN, MS, MBA, OCN, CCRP, Thomas George, MD, FACP

BACKGROUND

Principal Investigator (PI) roles are complex. A formalized onboarding curriculum, created and delivered through the UFHCC Clinical Research Office (CRO) and the Research and Training core (CaRTEC), was developed for new clinical investigators to provide knowledge and resources to help successfully conduct trials at UFHCC. This curriculum is anticipated to shorten learning curves for administrative and regulatory tasks, improve confidence leading trials, and ultimately decrease deviations. While generalized training exists providing broad coverage of PI competencies, this standardized onboarding will provide investigators instruction on specific research processes at UFHCC.

GOALS

- Develop standardized clinical research onboarding curriculum for new investigators of varied backgrounds
- Increase new investigator confidence conducting clinical trials at UFHCC
- Assess common knowledge gaps to create focused training modules to reduce errors impacting the institution via CAPAs or data deficiencies

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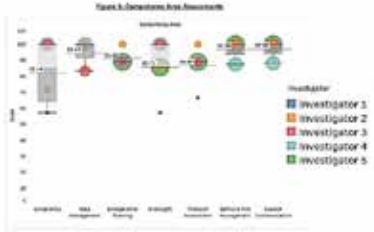
METHODS

In January 2022, the UFHCC new clinical investigator eTraining (NCINET) was piloted with eleven new early-stage faculty. Following Knowles' core principles of andragogy, NCINET has immediate relevance to PI's role in clinical trials; each module is process-centered, using UFHCC policies as core texts. These documents outline clinical trial management, providing learning scenarios to highlight concepts including oversight, compliance and consent. By offering NCINET via a learning management system (LMS), investigators can access training and resources 24 hours a day. To ensure successful completion, investigators cannot be added to clinical trials as PI or Sub-I until the minimum passing score of 80% is achieved on all module assessments.

RESULTS

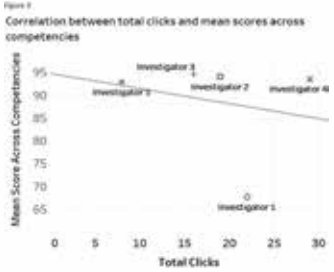
Five investigators initiated training with three completing the entire sequence. Initial data shows Compliance and Oversight domains had the greatest number of outliers [Figure 1]. This suggests further module development may be needed, offering more situational practice. Individualized domain progress is also trackable.

The relationship between time spent on NCINET and mean scores across competencies shows a bimodal distribution, suggesting two cohorts working with the curriculum [Figure 2]. One group spent less time engaged with the curriculum (<160 minutes) and the other group spent more time (>420 minutes). Both groups achieved mastery.



We predict more experienced investigators will achieve mastery in fewer hours of engagement than less experienced investigators. Future examination of metadata to link investigator experience with time spent in online training and competency mastery will be needed to study this hypothesis.

The relationship between page views (clicks) and mean scores across competencies was not statistically significant (p=.29), suggesting number of views does not predict mastery, though small sample size is a limitation [Figure 3]



FUTURE DIRECTIONS

Version 2.0 of NCINET curriculum will include a pre/post-test, end-of-module surveys, and more interactive content. Assessments will undergo item analysis for outcomes alignment and to identify areas where more support is needed. Metadata will be collected to identify variables associated with investigator experience. A follow-up survey is planned to evaluate level of confidence in trial participation. Audit data will be examined to explore correlations between deviations and training.

PARTNERING IN PROGRESS

TRIAL RECRUITMENT & COMMUNITY OUTREACH AND ENGAGEMENT

Community Outreach, Community of Color Accrual: CS-Link Registration and OnCore Enhancements to Capture Ethnic Subgroups, Gender, and Sexual Orientation

J. Gomez, B. Rimel
Cedars-Sinai Cancer

1. Background

Collection of patient demographics for frontline operations and research patients has been standardized at Cedars-Sinai through use of CS-Link (Cedars-Sinai's patient management system) and OnCore (clinical research management system), but there has been a gap in capturing granular demographic data for research participants. This data has been defined as inclusive demographics for research (IDR) and consists of ethnic and racial categories, gender, and sexual orientation and preferred language. Collecting demographics in a comprehensive and inclusive manner provides important insights into populations participating in research at Cedars-Sinai and supports goals of inclusion and equity in research. Historically, the collection of demographics was not inclusive of many populations; this project seeks to correct this deficiency.

2. Goals

By expanding demographic standards, the goal is that historically under-represented populations will be equitably included and better understood in research. The metrics assessed represent an increased focus on the catchment area, targeting the largest communities of color: Latinx, Korean, Filipino, and Black, as well as data on sexual orientation and gender identity (SOGI).

3. Solutions and Methods

An assessment was conducted to review the ability in OnCore to support the collection of the IDR and compare it to CS-Link to determine the opportunity to pull existing IDR data from CS-Link to OnCore. We determined that CS-Link was missing the IDR (which meant information was not being collected at registration or patients were not disclosing the data), and OnCore did not have a location to contain the IDR. The issue was presented to our IRB, which resulted in Cedars-Sinai's IRB reviewing and approving the proposal to allow collection of IDR through a patient questionnaire. OnCore was enhanced to add additional fields to support the addition of the IDR. Through collaboration between Cedars-Sinai's IRB, cancer clinical trials office (CCTO), and health equity and marketing staff, resources were developed. These include an IDR work paper to explain the purpose from a policy perspective, a guidance document which introduces the subject and is a step-by-step guide of the IDR collection process, print versions of the questionnaire, verbal scripts, patient instructions to update their IDR on the patient portal, digital templates for including the questionnaire in research, and recorded presentations explaining resources to staff. Training was conducted for staff in collaboration with the National LGBT Cancer Network to enhance awareness of terminology and to obtain resources for potential challenges when collecting IDR.

4. Outcomes

Data collection for IDR within the CCTO began on February 23, 2022. During the period of February 23-28, there were a total of 12 questionnaires completed. While the numbers are less than 11 at this time, we are unable to share data tables in order to protect patient confidentiality. However, we are seeing positive granular data entries for origin and race, and SOGI.

5. Lessons Learned and Future Directions

Data collection to include historically under- or mis-represented groups requires multiple stakeholders and both electronic medical record and clinical trials software changes. Future work will center on obtaining IDR data directly into the CS-Link data stream which can be shared seamlessly with OnCore.

Community Outreach, Accrual: Epic Registration and OnCore Enhancements to Capture Inclusive Demographics

Cedars-Sinai Cancer Clinical Trials Office
B.J. Rimel, MD
Jose Gomez, MSW
Cedars-Sinai, Los Angeles

Background

While collection of patient demographics for frontline operations and research patients has been standardized at Cedars-Sinai through use of CS-Link (Cedars-Sinai's electronic medical record and patient portal) and OnCore (clinical research management system), there has been a gap in capturing granular demographic data for research participants. This data has been defined as Inclusive Demographics for Research (IDR) and consists of ethnic and racial categories, gender, and sexual orientation (SOGI) and preferred language. Collecting demographics in a comprehensive and inclusive manner provides important insights into populations participating in research at Cedars-Sinai and supports goals of inclusion and equity in research. Historically, the collection of demographics was not inclusive of many populations; this project seeks to correct this deficiency.

Metrics and Goals

By expanding demographic standards, the goal is that historically under-represented populations will be equitably included and better understood in research. The metrics assessed represent an increased focus on the catchment area, targeting the largest communities of color Latinx, Korean, Filipino, Black and data on sexual orientation and gender identity (SOGI).

Solutions and Methods Implemented

An assessment was conducted to review the ability in OnCore to support the collection of the IDR and compare it to CS-Link to determine the opportunity to pull existing IDR data from CS-Link to OnCore. We determined: CS-Link was missing the IDR (which meant information was not being collected at registration or patients were not disclosing the data), and OnCore did not have a location to contain the IDR. The issue was presented to our IRB, which resulted in Cedars-Sinai's IRB reviewing and approving the proposal to allow collection of IDR through a patient questionnaire. OnCore was enhanced to add additional fields to support the addition of the IDR. Through collaboration between Cedars-Sinai's IRB, Cancer Clinical Trials Office (CCTO), Health Equity and Marketing staff, resources were developed: IDR Work Paper to explain the purpose from a policy perspective, a Guidance document which introduces the subject and is a step-by-step guide of the IDR collection process, print versions of the questionnaire, verbal scripts, patient instructions to update their IDR on the patient portal, digital templates for including the questionnaire in research, and recorded presentations explaining resources to staff. Training was conducted for staff in collaboration with the National LGBT Cancer Network to enhance awareness of terminology and to obtain resources for potential challenges when collecting IDR.

Figure 1 Paper Questionnaire

Outcomes and Data / Representing Change

Data collection for IDR within the CCTO began on February 23, 2022. Between the period of 2/23/22 – 4/30/22 there were a total of 18 questionnaires completed representing the following approximate participation in interventional therapeutic trials: 1% for LGBTQ+, 1% for Filipino, 1% for two or more races, 3% Chinese, 5% for Black, and 14% for Latinx communities.

Lessons Learned / Pointing Toward the Future

Data collection to include historically under or mis-represented groups requires multiple stakeholders and both electronic medical record and clinical trials software changes. Future work will center on obtaining IDR data directly into the CS-Link data stream which can be shared seamlessly with Oncore in addition to synthesizing the new data into possible research.

* Implementing Structured Assessments to Determine Research Readiness and Capacity Among Community-Based Clinical Oncology Network Sites

C. Crabtree-Ide, R. Evans, E. Bouchard, K. Noyes, M. Reid, L. Smith, K. Glaser
Roswell Park Comprehensive Cancer Center

1. Background

Our cancer center built a network of community oncology sites across New York State with diverse patient populations and institutional capacities. Disseminating and increasing the reach of clinical research opportunities by bringing research closer to the patients is an institutional priority, and access to diverse patient populations at our community network sites provides a unique opportunity to study cancer care centers and address issues related to disparities and equity. However, community oncology clinics often lack research expertise and infrastructure available at large academic cancer centers, which represents a challenge for intervention fidelity and staffing. Without a formal assessment strategy, research readiness is usually trial and error and takes time to align available research with site capabilities.

2. Goals

In preparation for a broad implementation of the network-wide research programs, we assessed institutional capacities and perceptions of readiness to implement research and identified specific barriers to study participation and patient enrollment among our network of community and affiliate sites.

3. Solutions and Methods

Our survey included: institutional readiness; specific facility and personnel capacity (e.g., CLIA certified laboratory; investigational drug pharmacy, including ability to provide investigational product accountability and storage; systems to identify and randomize patients); IRB system in place; perceived timeline for research readiness; specific gaps and barriers; and interest in different levels of clinical research (e.g. remote, observational, drug interventional CT Phases I-III), as well as a validated tool to assess organizational readiness to implementing change (ORIC). We disseminated this survey to all network sites and assessed capacities at baseline, with the goal to disseminate the survey every 6 months as we work with the sites to monitor and address changes in new or existing barriers.

4. Outcomes

We assessed research readiness and collected survey responses from 13 network sites. Business managers and site staff completed the institutional capacity assessment and the ORIC assessment. Reported institutional/site support of launching new research initiatives (examples: observational studies, behavioral interventions, clinical trials) ranged from somewhat to very strong support [Mean 2.6 (SD=1.2) where 2=Neutral and 3=Strong support].

Most business managers do not know the specific gaps and steps that need to be addressed to launch new research studies (Mean=0.7, where 0=not a clear idea of gaps, 1=somewhat clear idea, 2=clear, 3=very clear, N/A=no gaps, immediately ready). No rural community sites reported being immediately ready to roll out research studies of any kind, indicating an area for further engagement. Reported gaps and barriers included research study staffing, a clearer understanding of the types of research available to the sites, resources, and training.

5. Lessons Learned and Future Directions

Institutional readiness, timelines, and institutional priorities varied by site. Results of the structured assessment provided baseline information to assist clinics with resources needed for different types and phases of research. Disseminating surveys to a single practice champion (e.g., business manager) is an efficient way to assess research readiness of community oncology practice sites. In the future, we plan to create "face pages" or concise site summaries of site descriptions of each site, available for researchers at the central academic oncology center and to create a portfolio of clinical research appropriate for each site for community oncology physician researchers.

* *Honorable Mention*

Implementing structured assessments to determine research readiness and capacity among community-based clinical oncology network sites

Christina R. Crabtree-Ide, PhD, MPH[1], Rachel Evans, PhD, MS, CCRP[2], Elizabeth Bouchard, PhD, MS[1], Katia Noyes, PhD, MPH[3], Mary Reid, PhD[4], Laurie Smith, MA[2], Kathryn M. Glaser, PhD, MA[1]

[1]Department of Cancer Prevention and Control, Roswell Park Comprehensive Cancer Center, [2]Department of Clinical Research Services, Roswell Park Comprehensive Cancer Center, [3]Deparment of Epidemiology and Environmental Health, University at Buffalo, [4]Department of Medicine, Roswell Park Comprehensive Cancer Center

Roswell Park Comprehensive Cancer Center, Buffalo, NY 14263

BACKGROUND

NETWORK

Our cancer center has built a network of community oncology sites

POPULATION

Sites have diverse patient populations and institutional capacities

VALUE

Diverse patient populations at our community network sites provides a unique opportunity to address issues related to disparities and health equity

PRIORITIES

Increasing the reach of clinical research opportunities by bringing research into the network is an institutional priority

THE PROBLEM

Patients from rural and underserved community sites are rarely included in research

THE BARRIERS

Community oncology clinics often lack research expertise and infrastructure available at large academic cancer centers

Research readiness is difficult to assess, is usually trial and error, and takes time to align available research with site capabilities

GOAL AND APPROACH

Standardize the assessments of research readiness in community sites and to identify actionable barriers to research

METHODS: RESEARCH READINESS ASSESSMENT

Survey tools included:

1. Institutional readiness assessment
   a. Specific facility and personnel capacity (e.g. CLIA certified laboratory, investigational drug pharmacy including ability to provide investigational product accountability and storage, systems to identify and randomize patients), IRB system in place
   b. Perceived timeline for research readiness, specific gaps and barriers, interest in different levels of clinical research (e.g. remote, observational, drug interventional CT Phases I-III)
2. Validated tool to assess organizational readiness to implementing change (ORIC)

Research readiness was assessed and survey responses were collected from 13 sites network sites. Business managers and site staff were selected to complete the institutional capacity assessment and the ORIC assessment. Key staff were selected based on their knowledge of site systems and infrastructure.

OUTCOMES

Institutional readiness, timelines, and institutional priorities varied by site. Results of the structured assessment provided baseline information to assist clinics with resources needed for different types and phases of research.

Assessment category	Results
Knowledge of specific steps that need to be addressed to launch new research studies	Most business managers had unclear ideas of gaps and steps to launch research
	Mean=0.7, where 0=not a clear idea of gaps, 1=somewhat clear idea, 2=clear, 3=very clear, N/A=no gaps, immediately ready)
Gaps and barriers	Research study staffing
	Clear understanding of the types of research available
	Resources
	Training
Immediate readiness to roll out studies	Mean=1.7, where 0=Never, 1=More than 1 year, 2=Between 6 months and 1 year, 3=Between 3 and 6 months, 4=Between 1 and 3 months, 5=Immediate ability

LESSONS LEARNED

- No rural or underserved community sites reported being immediately ready to roll out research studies of any kind
- Disseminating surveys to a single practice champion (e.g., business manager) is an efficient way to assess research readiness of community oncology practice sites
- Designated staff and a concrete set of steps for research roll-out may benefit community sites

Contact: Christina.Crabtree-Ide@RowellPark.org

Use of Epic My Reports to Increase Trial Accruals While Decreasing Pre-Screening Time Spent

A. Gatta, A. Kavadas, J. Davenport, K. McCaffrey, M. Kilbane
Taussig Cancer Institute, Cleveland Clinic Cancer Center

1. Background

Identifying potential patients has to occur quickly and efficiently for the success of a clinical trial. At the Cleveland Clinic Taussig Cancer Institute, we use a multi-faceted approach to identify potential patients including physician identification, tumor boards, and schedule screening. This approach is limited due to the manual labor involved and the team is largely reliant on our physicians to communicate new potential patients. Often, providers are unable to reach out to the clinical research team (CRT), leaving many potentially eligible patients without a clinical trial offer. In an effort to identify all potential patients while decreasing time spent screening, we piloted the implementation of Epic My Reports for clinical trials with complex enrollment.

2. Goals

- Create an automated system for the CRT to utilize Epic My Reports across research sites
- Identify potential patients based on clinical trial specific parameters
- Implement a standard operating procedure

3. Solutions and Methods

In the pilot study (Study A) we implemented My Reports in Fall 2021. The CRT was able to gather eligible patient data based on study parameters and quickly identified patients without physician notification. This trial has been successfully enrolling patients and is currently exceeding the accrual goal.

In a second pilot, we recently created a My Reports for a study that has been open to enrollment since June 2021 (Study B). In the study's nine months of enrollment, only six patients have accrued. We launched a My Report screening tool for this study in March 2022 and have determined there are 58 potential patients with upcoming appointments. We plan to compare the accrual data from June 2021-February 2022 to this new phase of enrollment utilizing the My Reports screening method.

4. Outcomes

The number of potential patients for studies not using the My Reports method is unknown. The below data provides the total pre-screen eligible patients for Study A at two sites both using the My Reports screening method.

Chart 1 displays the total potential patients each location identified using My Reports. The subcategories depict the reasons those patients did or did not enroll on Study A. The percent of the total pre-screen eligible patients accrued to trial (Study A) was 27.4 percent at Location 1 and 17.6 percent at Location 2.

5. Lessons Learned and Future Directions

We continue to learn the capabilities of both Epic and the My Reports feature. Using the My Reports filters drives the results for the clinical trial potential patient list. During the pilot Study A, we learned it is critical to perform a quality check on the parameters selected. Additionally, we have found that some eligibility parameters are not available as a filter in Epic, thus making My Reports an ineffective screening tool for certain studies. The CRT is continuing to create effective study specific My Reports and is currently working on ways to enhance patient follow-up through other Epic features.

Use of EPIC My Reports to Increase Trial Accruals While Decreasing Pre-Screening Time Spent

A. Gatta, A. Kavadas, J. Davenport, K. McCaffrey, M. Kilbane
Taussig Cancer Institute

Background:
Identifying potential patients has to occur quickly and efficiently for the success of a clinical trial. At the Cleveland Clinic Taussig Cancer Institute, we use a multi-faceted approach to identify potential patients including physician identification, tumor boards, and schedule screening. This approach is limited due to the manual labor involved and the team is largely reliant on our physicians to communicate new potential patients. Often times, providers are unable to reach out to the Clinical Research Team (CRT) leaving many potentially eligible patients without a clinical trial offer. In an effort to identify all potential patients while decreasing time-spent screening, we piloted the implementation of EPIC My Reports for clinical trials with complex enrollment.

Methods:
In the pilot study (Study A) we implemented My Reports in Fall 2021. The CRT was able to gather eligible patient data based on study parameters and quickly identified patients without physician notification. This trial has been successfully enrolling patients and is currently exceeding the accrual goal.

In a second pilot, we recently created a My Reports for a study that has been open to enrollment since June 2021 (Study B). In the study's 9 months of enrollment, only six patients have accrued. We launched a My Report screening tool for this study in March 2022 and have determined there are 58 potential patients with upcoming appointments. We plan to compare the accrual data from June 2021-February 2022 to this new phase of enrollment utilizing the My Reports screening method.

Goals:
1) Create an automated system for the CRT to utilize Epic My Reports across research sites
2) Identify potential patients based on clinical trial specific parameters
3) Implement a standard operating procedure.

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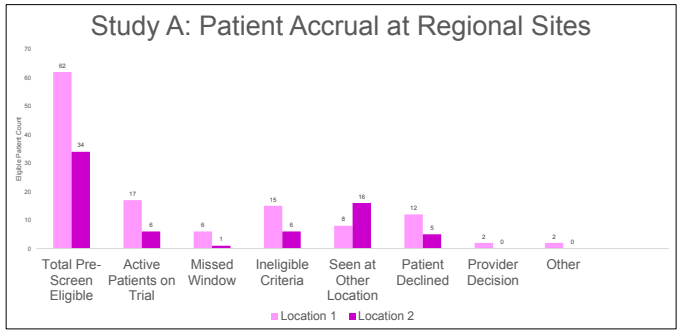

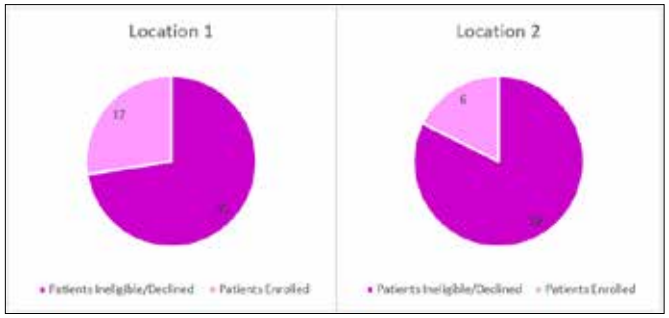

Outcome:
The number of potential patients for studies not using the My Reports method is unknown. The below data provides the total pre-screen eligible patients for Study A at two sites both using the My Reports screening method.

Chart 1 displays the total potential patients each location identified using My Reports. The sub categories depict the reasons those patients did or did not enroll on Study A.

Chart 2 demonstrates the percent of the total pre-screen eligible patients accrued to trial (Study A) at Location 1 (27.4%) and Location 2 (17.6%).

Lessons Learned and Future Directions:
We continue to learn the capabilities of both EPIC and the My Reports feature. Using the My Reports filters drives the results for the clinical trial potential patient list. During the pilot Study A, we learned it is critical to perform a quality check on the parameters selected. Additionally, we have found that some eligibility parameters are not available as a filter in EPIC thus making My Reports an ineffective screening tool for certain studies. The CRT is continuing to create effective study-specific My Reports and is currently working on ways to enhance patient follow-up through other EPIC features.

Machine Evaluation of Catchment Area Relevance Through Text Mining

P. Arlen, J. Chakko, B. Mahal, G. DeGennaro
Sylvester Comprehensive Cancer Center, University of Miami Health System

1. Background

The University of Miami Sylvester Comprehensive Cancer Center (Sylvester) is located in South Florida, with a catchment area that represents the most racially, ethnically, and geographically diverse region in the U.S. Unfortunately, the area's tumor burden is also significant and with many notable disparities, necessitating a prioritization of trials within Sylvester's catchment area. These trials address the needs of the population Sylvester serves by targeting cancers that are locally prevalent, such as prostate and breast; comprise a special population, such as firefighters; are of local concern to those who live in South Florida, such as environmental exposures; or are subject to disparities in treating diverse populations, such as infection with human papillomavirus (HPV). Focusing on these needs of our catchment area is vital to effectively serving our patients.

2. Goals

Our goal is to assess the catchment area relevance of Sylvester clinical trials with a rubric that measures multiple parameters. We plan to automate this process and supply results to investigators, site disease groups (SDGs), and study team members.

3. Solutions and Methods

The rubric ranges in score from 0-8, with higher values indicating greater relevance of trials to catchment area criteria. First, a knowledgeable person assigns a catchment area score to a sample of trials. These scores are used by the machine to evaluate its own performance. The machine searches for key phrases related to each rubric criterion as shown below.

4. Outcomes

Developing an algorithm that assigns catchment score creates a new data point for considering and prioritizing trials. The rubric and automated scoring algorithm perform best on objective and easily accessible signifiers, such as a trial's disease indication. Determining if a trial addresses disparities is the most challenging criterion to score. When evaluating a subjective criterion, human and machine scorers alike benefit from additional scored examples (for example, training) and clearly defined rules.

The scoring algorithm was applied to more than 300 oncology trials available at the University of Miami. Preliminary analysis of the results showed the algorithm correctly flagged trials studying a prevalent cancer in 92 percent of cases (type II error = 8 percent) and correctly flagged trials that do not in 91 percent of cases (type I error = 9 percent). This shows that more training examples are required to capture relevant trials that the algorithm currently mislabels.

5. Lessons Learned and Future Directions

Cancer centers wish to serve the needs of their patient populations by opening trials that are relevant to their catchment areas. Investigators can select or design relevant trials more easily when provided rapid access to appropriate metrics. Text mining can be applied to the eligibility criteria of trials to extract new catchment area score data points. Creating a robust key phrase bank is vital to ensuring the scoring algorithm is objective, fair, and accurate. The scoring process must be clear and understood before any attempts at automation are made.

Machine Evaluation of Catchment Area Relevance

A Text Mining Application

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SYLVESTER COMPREHENSIVE CANCER CENTER
UNIVERSITY OF MIAMI HEALTH SYSTEM
UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

Background and Purpose

The University of Miami Sylvester Comprehensive Cancer Center (Sylvester) is located in South Florida, with a catchment area that represents the most racially, ethnically, and geographically diverse region in the U.S. Unfortunately, the area's tumor burden is also significant and with many notable disparities, necessitating a prioritization of trials within Sylvester's catchment area.

These trials should address the needs of the population Sylvester serves by targeting cancers that are locally prevalent, such as prostate and breast; comprise a special population, including firefighters; are of local concern to those who live in South Florida, such as environmental exposures; or are subject to disparities in treating diverse populations, such as infection with human papilloma virus (HPV). Focusing on these needs of our catchment area is vital to serving our patients effectively.

The purpose of this project is to create a new identifying feature in our trial database. After storing the evaluations, researchers will be able to filter and run metrics on trials that have been labeled as Catchment Area Relevant.

Goals

Create a rubric to standardize the Catchment Area Relevance evaluation process

Evaluating catchment area relevance should be a clearly defined process. Any means of evaluating a study should produce the same score each time. To this end, our goal is to create a rubric that measures multiple parameters and that can be applied by knowledgeable users without additional training.

Automate trial evaluation by implementing a scoring algorithm

The evaluation process will be automatically handled by computers. The logic of the rubric can be coded in programming languages like Java and SQL. The program's execution mimics that of a human evaluator, making it easy to understand and adapt.

Communicate results throughout the organization

The results will be reportable to investigators, study team members, Site Disease Groups (SDGs), protocol review committees, and leadership.

Methodology

- First, a knowledgeable person uses the rubric to assign a catchment area score to each trial in a sample selection. The results of this scoring process are used as a guide when writing and adjusting the program code.
- The machine implementation parses protocol titles and abstracts based on key phrases and awards relevance points. Creating and maintaining a key phrase bank for each rubric criterion is the main driver of the machine evaluator's success.
- The machine parses a trial's title using each criterion's key phrase bank. If the machine finds a match, the trial is awarded points for meeting that criterion.

Catchment Area Relevance Rubric

Criterion	Key Phrase Examples	Points Awarded
Prevalent Cancer	Prostate, Melanoma, Breast	1
Special Population	Firefighters, Haitians, Hispanics	2
Regional Impact	Exposure, Smoking, Microbiome	2
Address Disparity	Community, Outreach, Equity	3

Scoring Examples

Oral Tongue Squamous Carcinoma – Retrospective Study on Gender, Age and Ethnic Disparities
[Addressing Disparity: 3 Points]

Multimodal treatment of Advanced Prostate Cancer using combined local and Systemic Therapy
[Prevalent Cancer: 1 Point]

Examining the Association of Polybrominated Diphenyl Ethers (PBDE) and Thyroid function of South Florida Firefighters
[South Florida: 2 Points; Special Population: 2 Points]

Results

The scoring algorithm was applied to more than 300 oncology trials available at Sylvester. In order to determine accuracy, the output was compared against the score provided by a human evaluator. This comparison of results showed the algorithm correctly flagged trials studying a prevalent cancer in 92% of cases (type II error = 8%) and correctly flagged trials that do not in 91% of cases (type I error = 9%).

Both the rubric and scoring algorithm are most effective when evaluating objective and easily accessible identifiers, such as diagnosis. On the other hand, a subjective criterion, such as whether a trial addresses disparities in the community, is more difficult for all evaluators. In these cases, human and machine scorers alike benefit from additional scored examples (for example, training) and clearly defined rules.

Implementing an algorithm that assigns a score for catchment area relevance creates a new data point for analysis. Database queries can reference the score to filter trials based on catchment area relevance, increasing visibility and establishing a quantifiable metric for strategic planning.

Lessons Learned

The automated scoring algorithm is straightforward enough to adapt to a variety of circumstances. Before any attempts at automation are made, the scoring process must be clearly understood. After all, the scoring algorithm can only be as good as the rubric that serves as its guide.

The algorithm has key requirements that play a large role in achieving accurate results. First is the key phrase bank for each criterion. The phrase banks must be comprehensive and kept current to ensure good performance that is objective, fair, and accurate.

Second is hand-scored examples by experienced evaluators. The algorithm's output is compared to the hand-scored examples to determine the accuracy of the program. These examples are time-consuming to create and should be prioritized.

Process Improvement of the Precision Medicine Program at Sylvester Comprehensive Cancer Center: An Exploration of Different Models to Increase Awareness and Clinical Trial Enrollment

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1. Background

Next-generation sequencing (NGS) tests have mushroomed in type and number of genes assayed with a parallel expansion of reported results. Additionally, precision medicine (PM) clinical trials have very specific, detailed mutation eligibility requirements. The Sylvester Comprehensive Cancer Center (SCCC) PM program implemented different models to provide interpretive scientific support and recommendations on mutation-based clinical trial matching. We will describe lessons learned from a referral PM review and a virtual PM clinic.

2. Goals

Metrics reviewed include the number of clinical trial matches, number enrolled, and the providers' responses to emails.

3. Solutions and Methods

The PM group is comprised of an oncologist, a molecular scientist, and research coordinators. Starting in May 2021, we publicized an inbox account for providers to refer NGS tests for matching to ASCO-TAPUR (7), NCI-MATCH (9), mutation target trials (13) or basket trials (5). When matched to a clinical trial, PM emails the provider and if in agreement, the research coordinators are contacted. Starting in December 2021, PM added a virtual PM (VPM) clinic where all SCCC patients' NGS tests are reviewed with ordering providers emailed clinical trial matches. Data transfer agreements between SCCC and NGS vendors allows for the VPM clinic to have access to web portal results. PM digitalized all information from Referral and VPM cases in a REDCap database, allowing for analyses of the processes implemented.

4. Outcomes

From May to November 2021, the referral PM received 116 NGS requests with 42 patients having clinical trial matches (36 percent); seven enrolled and one consented (Table 1). From December 2021 to February 2022, the referral PM received 52 requests with 14 patients having clinical trial matches (27 percent); one enrolled (Table 2). From December 2021 to February 2022, the virtual PM clinic reviewed 384 NGS tests with 38 having clinical trial matches (10 percent); one patient enrolled, one patient declined, and five providers were interested. For seven patients, the providers would consider PM clinical trials at progression (Table 3).

5. Lessons Learned and Future Directions

The better model to continue is the referral PM review. The greater enrollment rate is likely because this is a pre-selected group of patients who need clinical trial options. With the VPM clinic, much effort was expended for a lower matching rate, likely due to the wider patient mixture of various disease stages and treatment history. However, without the VPM, seven patients would not have been asked about a clinical trial and seven patients will not have the clinical trial considered for subsequent treatment. Our modification of the VPM clinic will be to focus on tumor site mutations with enrolling arms (example: there are no primary brain PM trials, so those NGS tests should not be reviewed in depth). In the future, the PM program will host an all-site disease group monthly molecular tumor board (MTB) meeting to discuss patient cases. Subsequently, PM will invite community SCCC affiliated providers to the MTB to enhance scientific dialog, awareness of clinical trials, and logistics of enrollment. We will continue to capture data and frequently review for process success.

Process Improvement of the Precision Medicine program at Sylvester Comprehensive Cancer Center

An exploration of different models to increase awareness and clinical trial enrollment

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Background

Next-Generation Sequencing (NGS) tests have mushroomed in type and number of genes assayed with a parallel expansion of reported results. Additionally, Precision Medicine (PM) clinical trials have very specific, detailed mutation eligibility requirements.

The Sylvester Comprehensive Cancer Center (SCCC) PM program implemented different models to provide interpretive scientific support and recommendations on mutation-based clinical trial matching. We will describe lessons learned from a Referral PM review and a Virtual PM clinic.

Methods

The PM group comprises of an oncologist, a molecular scientist, and research coordinators.

Referral PM Review:

- Starting May 2021, we publicized an Inbox account for providers to refer NGS tests
- PM group reviewed for matching to ASCO-TAPUR (7), NCI-MATCH (9), mutation target trials (13) or basket trials (5).
- When matched to a clinical trial, PM emails the provider and, if in agreement, the research coordinators are contacted.

Virtual PM Review Clinic:

- Starting December 2021, PM added a Virtual PM (VPM) clinic where all SCCC patients' NGS tests are reviewed.
- Data transfer agreements between SCCC and NGS vendors allows for the VPM clinic to have access to web portal results.
- PM group reviewed for matching to ASCO-TAPUR (7), NCI-MATCH (9), mutation target trials (13) or basket trials (5).
- When matched to a clinical trial, PM emails the ordering provider and, if in agreement, the research coordinators are contacted.

Data:

- PM digitalized all information from Referral and VPM cases in a RedCap database allowing for analyses of the processes implemented.
- Metrics reviewed include the number of clinical trial matches, number consented, enrolled, and the providers' responses to emails.

Results

From May to November 2021, the Referral PM received 116 NGS requests. 42 patients matched to clinical trials (36%); seven enrolled and one was at consent status (total 8 consented) (Table 1).

Table 1: Referral PM (May - November 2021)

Tumor Site	Referrals (Percent of Total Referrals)	Clinical Trial Match (Percent of Tumor Site Referrals / Percent of Total Matches)
Breast	68 (59%)	28 (41% / 67%)
Thoracic	11 (9%)	10 (91% / 24%)
Pancreas	5 (4%)	1 (20% / 2%)
GYO	4 (3%)	1 (25% / 2%)
Skin	2 (2%)	1 (50% / 2%)
Myeloma	1 (1%)	1 (100% / 2%)
Colorectal, Head and Neck	17 (15%)	0
Biliary, GE, Sarcoma	7 (7%)	0
Total	116	42 of 116 (36%)
	Consent for Screening	8 of 42 (19%)
	Enrolled on Trial	7

From December 2021 to February 2022, the Referral PM received 52 requests. 14 patients matched to clinical trials (27%); one enrolled (Table 2)

Table 2: Referral PM (December 2021 - February 2022)

Tumor Site	Referrals (Percent of Total Referrals)	Clinical Trial Match (Percent of Tumor Site Referrals / Percent of Total Matches)
Breast	28 (54%)	7 (25% / 50%)
Thoracic	8 (15%)	4 (50% / 29%)
Gastroesophageal	2 (4%)	1 (50% / 7%)
GYO	1 (2%)	1 (100% / 7%)
Head and Neck	1 (2%)	1 (100% / 7%)
Colorectal, Prostate	8 (15%)	0
Sarcoma, Intestine, Thyroid	4 (8%)	0
Total	52	14 of 52 (27%)
	Consent for Screening	1 of 14 (3%)
	Enrolled on Trial	1

From December 2021 to February 2022, the Virtual PM clinic reviewed 384 NGS tests with 38 patients matched to clinical trials (10%); one patient consented, one patient declined, and five providers were interested. For seven patients, the providers would consider PM clinical trials at progression (Table 3).

Table 3: Virtual PM Clinic December 2021 - February 2022 (Not in Referral PM Group)

Tumor Site	Cases (Percent of Total)	Trial Match Emails (Percent of Site Cases)	Email Responses
Thoracic	63 (16%)	6 (10%)	2 (At progression)
Colorectal	56 (15%)	2 (4%)	1 (Interested)
Breast	42 (11%)	5 (12%)	4 (2 Interested, 2 At progression)
Sarcoma	38 (10%)	4 (11%)	0
GYO	35 (9%)	4 (11%)	2 (1 PI declined, 1 on therapy)
GU	29 (8%)	6 (21%)	1 (Interested)
Pancreas	21 (5%)	2 (10%)	1 (At progression)
Head and Neck	20 (5%)	5 (25%)	4 (1 consent, 2 on therapy, 1 at progression)
GE	10 (3%)	2 (20%)	2 (1 Interested, 1 on therapy)
Melanoma	9 (2%)	1 (11%)	1 (At progression)
Thyroid	7 (2%)	1 (14%)	0
Neuro; Biliary; Liver	41 (11%); 10 (3%); 3 (1%)	0	0
Total	384	38 of 384 (10%)	20
		Consent	1 of 20 (5%)
		Interested	5 (25%)
		Patient declined	1 (5%)
		Already on therapy	4 (20%)
		At progression	7 (35%)
		Deceased	2 (10%)

Discussion and Conclusion

The better model to continue is the Referral PM Review. The greater enrollment rate is likely because this is a pre-selected group of patients who need clinical trial options. With the VPM clinic, much effort was expended for a lower matching rate, likely due to the wider mixture of various disease stages and treatment history. However, without the VPM, seven patients would not have been asked about a clinical trial and seven patients will not have the clinical trial considered for subsequent treatment.

Future Efforts

If we continue the VPM clinic review, we will focus on tumor sites mutations with enrolling arms (ex: there are no brain PM trials, so those NGS tests should not be reviewed).

The PM program will host an all-site monthly Molecular Tumor Board (MTB) meeting to discuss patient cases which will increase awareness of open and enrolling PM trials. Subsequently, PM will invite community SCCC affiliated providers to the MTB to enhance scientific dialog, awareness of clinical trials, and logistics of enrollment. We will continue to capture data and frequently review for process success.

Prescreening GI Cancer Clinic Schedules for Clinical Trial Recruitment – Plan to Make a Difference in Study Accruals

J. Siddiqui, A. Loechtenfeldt, J. Parker
University of Cincinnati Cancer Center

1. Background

Inability to reach site-specific target recruitment goals for clinical trials is a challenge faced by most clinical research institutions. There are various ways to identify potential patients for clinical trial participation: physician's screening while seeing patients; referrals from outside physicians; attending tumor board; and advertising through electronic applications/emails.

At University of Cincinnati Cancer Center (UCCC), our gastrointestinal (GI) clinical research group recently started prescreening physician schedules for potentially eligible patients for available GI cancer trials in attempt to increase accrual.

Prescreening started in September of 2021 with research staff identifying all new patients coming to UCCC with the diagnosis of any GI cancer and looking at eligibility criteria for open clinical trials, so physicians and researchers don't miss any patient due to unforeseeable reasons like a physician's busy clinic.

2. Goals

The goal of this work is to increase patient accrual to open GI cancer trials at UCCC, particularly to trials which have not yet achieved target goal

3. Solutions and Methods

Prescreening activity which included going through each new patient identified on the physician schedules started in September 2021. The UCCC GI research coordinators screen the GI medical and radiology oncology physician schedules for the upcoming week for new patient visits. A list of all potentially eligible patients, and the trial(s) for which they may be a good match, is emailed to the clinical team. Research coordinators prepare to consult/consent the potential patients, should the physician deem the matched clinical trial an appropriate option for the patient. If the eligibility is unclear and the study cannot be immediately offered, the patient is followed via electronic medical record (EMR) review. The rationale behind this method is to offer clinical trials to as many eligible patients as possible before standard of care treatment has begun and, in turn, increase clinical trial accrual.

We are maintaining a database to log our prescreening efforts with patient details including:

1) Which clinical trial(s) patient might fit in
2) After new patient visit, if patient is considered eligible
3) Whether the patient was consulted/consented/enrolled
4) Reasons for being ineligible for clinical trial(s)

4. Outcomes

Prescreening data has been collected from September 2021 through February 2022. There was a total of 62 patients identified from the physician schedules during this period who might fit in one of the open trials, out of 165 new patient charts reviewed.

Eligible patients

Total consented subjects for all open trials between September 2021 and February 2022 (5 months) is 15. Total enrolled patients for all open trials from September 2021-February 2022 (5 months) is 10. We compared it to the previous 5 months (April-August 2021); during that time, total consented were 15 and enrolled were 9. We did notice that for some of the active trials where there was no enrollment since 2020, we have consented at least 1 or more patients during this period.

Ineligible patients

The following are the reasons for ineligibility out of the ones identified on prescreening:

- Incorrect cancer staging in the chart
- Patient plan to pursue care somewhere else
- Started on standard of care treatment
- Poor performance score
- Insurance and transport issues
- Slot unavailable for the study
- Declined participation
- Widespread disease on imaging
- CA-19-9 too low on recent results
- Deranged liver function on recent labs

5. Lessons Learned and Future Directions

On this preliminary data review, we did not find any difference in accrual rates by adding this extra effort of prescreening.

It is too early to say if it has an impact on our overall accrual as we started in September 2021, but it has certainly helped in identifying patients for low accruing trials. This has also definitely increased the engagement between research staff and clinical teams and has increased awareness about the clinical trials available due to communication on a weekly basis.

In the future it will be effective in identifying the causes or some consistent reasoning for ineligibility and will lead to further discussion.

PRESCREENING GI CANCER CLINIC SCHEDULES FOR CLINICAL TRIAL RECRUITMENT-Plan to make a difference in study accruals

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University of CINCINNATI CANCER CENTER
University of Cincinnati • UC Health • Cincinnati Children's

1. Background:

Inability to reach site specific target recruitment goals for clinical trials is a challenge faced by most clinical research institutions. There are various way to identify potential patients for clinical trial participation: Physician's screening while seeing patients, referrals from outside physicians, attending tumor board, and advertising through electronic applications/emails.
At University of Cincinnati Cancer Center (UCCC), our gastrointestinal (GI) clinical research group recently started prescreening physician schedules for potentially eligible patients for available GI cancer trials in attempt to increase accrual.
Prescreening started in September of 2021 with research staff identifying all new patients coming to UCCC with the diagnosis of any GI cancer and looking at eligibility criteria for open clinical trials so physicians and researchers don't miss any patient due to unforeseeable reasons like physician's busy clinic.

2. Goals:

The goal of this work is to increase patient accrual to open GI cancer trials at UCCC, particularly to trials which have not yet achieved target goal

3. Methods:

Pre-screening activity which included going through each new patient identified on the physician schedules started in September 2021. The UCCC GI Research Coordinators screen the GI medical and radiology oncology physician schedules for the upcoming week for new patient visits. A list of all potentially eligible patients, and the trial(s) for which they may be a good match, is emailed to the clinical team. Research Coordinators prepare to consult/consent the potential patients, should the physician deem the matched clinical trial an appropriate option for the patient. If the eligibility is unclear and the study cannot be immediately offered, the patient is followed via electronic medical record (EMR) review. The rationale behind this method is to offer clinical trials to as many eligible patients as possible before standard of care treatment has begun and in turn increase clinical trial accrual.

We are maintaining a database to log our prescreening efforts with patient details including:

1. Which clinical trial(s) patient might fit in
2. After new patient visit if patient is considered eligible.
3. Was the patient consulted/ consented/ enrolled?
4. Reasons for being ineligible for clinical trial(s)

4. Outcomes:

Prescreening Data has been collected from September 2021 through February 2022. There was a total of 62 patients identified from the physician schedules during this period who might fit in the open trials, out of 165 new patient charts reviewed. **Eligible patients:** Total consented subjects for all open trials between the month of Sep2021-Feb2022 (5 months) is **15**. Total enrolled patients for all open trials between the month of Sep2021-Feb2022 (5 months) is **10**. We compared it to the previous 5 months (Apr2021-Aug2021), during that time total consented were **15** and enrolled were **9**. We did notice that for some of the active trials where there was no enrollment since 2020, we have consented at least 1 or more patients during this period.
Ineligible Patients: Following are the reasons for ineligibility out of the ones identified on prescreening: incorrect cancer staging in patient chart, patient plan to pursue care somewhere else, started on standard of care treatment, insurance issues, slot unavailable for the study and many more.

5. Lessons learned:

On this preliminary data review, we did not find any difference in accrual rates by prescreening. It is too early to say if it has an impact on our overall accrual as we started in Sep 2021, but it has certainly helped in identifying patients for low accruing trials. This has also increased the engagement between research staff and clinical teams and has increased awareness about the clinical trials available due to communication on a weekly basis. In the future it will be effective in identifying the causes or some consistent reasoning for ineligibility and will lead to further discussion.

Study Consent Rates and Decline Reasons at the University of Illinois Cancer Center

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1. Background

To address barriers to clinical trial participation, we want to understand clinical trial participation rates and reasons patients decline participation by time (pre/post-COVID pandemic), gender, and race/ethnicity.

2. Goals

The University of Illinois clinical trials office (UICC CTO) analyzed treatment clinical trial participation acceptance rates and reasons for declining clinical trial participation by time, gender, and race/ethnicity.

3. Solutions and Methods

In May 2018, the UICC CTO began collecting demographics and reasons for declining study participation for patients approached for treatment trials. Interim findings from May 2018 through December 2021 were analyzed using 1 logistic regression and 1 multivariable regression model to examine participation and reasons for declining by year (pre/post-COVID), gender, and race/ethnicity.

4. Outcomes

Five-hundred seventy-nine patients were approached to consent to a treatment clinical trial. Sixty-one percent were female, 39 percent were male, 21 percent were Hispanic, 51 percent were Black, 44 percent were white, and the remaining 4 percent were a mix of other races.

The overall acceptance rate was 75 percent (435 patients agreed to participate). Compared with pre-pandemic rates, there was a decline in acceptance rates, post-pandemic, 78% vs. 72%, OR = 0.66, 95%CI [0.44, 0.98], p = .04. Gender and racial/ethnic differences were not statistically significant (ps = 0.15-0.81) across gender (female = 77%, male = 73%), race (white = 79%, black = 74%, other = 60%), and ethnicity (non-Hispanic = 74%, Hispanic = 82%).

Among the 144 patients who declined participation, 52 percent had clinical concerns (e.g., preferred standard treatment, fear of side effects); 27 percent had concerns of experimentation; and 21 percent had logistic/unknown concerns (e.g., transportation, time, insurance). Patients were more likely to decline participation due to mistrust post-pandemic relative to pre-pandemic, 30% vs. 23%, OR = 0.47, 95%CI [0.22, 1.00], p = .05. Male patients were more likely to decline participation due to logistic and unknown concerns, 30% vs. 13%, OR = 0.65, 95%CI [0.28, 1.50], p = 0.31.

5. Lessons Learned and Future Directions

The UICC CTO treatment clinical trial acceptance rate was relatively high, similar across patient gender, race, and ethnicity, though these rates dipped since the COVID-19 pandemic. Burden of participation was not a significant reason for declining trial participation in this study, perhaps due to providing transportation for any clinical trial participants in need of it and UICC's broad financial assistance policy. New interventions need to be developed to address fears of experimentation and clinical concerns in the post COVID-19 pandemic era.

UICC CTO plans to repeat this analysis annually to assure clinical trial participation barriers are minimized and to monitor the success of efforts to address existing barriers. In the short term, together with community members, we are developing and implementing clinical trial educational modules targeting our patients and the community. These interventions will address concerns about clinical trial participation.

Study Consent Rates and Decline Reasons at the University of Illinois Cancer Center

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UNIVERSITY OF ILLINOIS CANCER CENTER

Background

To address barriers to clinical trial participation, we want to understand clinical trial participation rates and reasons patients decline participation by time (pre/post-COVID pandemic), gender, and race/ethnicity.

Objectives

The University of Illinois Clinical Trials Office (UICC CTO) analyzed treatment clinical trial participation acceptance rates and reasons for declining clinical trial participation by time, gender, and race/ethnicity. The objectives of this analysis were:

- To understand the demographic make up of the patients that participate in UICC treatment clinical trials and whether there have been any differences over time (pre/post-COVID pandemic).
- To determine potential barriers to treatment clinical trial participation at UICC, and whether these barriers vary by gender, race, or ethnicity and whether they changed over time (pre/post-COVID pandemic).
- To use this information to address barriers to participation, and thereby maximize both the number and diversity of patients participating in treatment clinical trials at UICC.

Methods

In May 2018, the UICC CTO began collecting demographics and reasons for declining study participation for patients approached for treatment trials. Interim findings from May 2018 through December 2021 were analyzed using 1 logistic regression and 1 multivariable regression model to examine participation and reasons for declining by year, gender, and race/ethnicity.

Results

Table 1: Demographics of Patients Approached For Treatment Clinical Trials

	Year				
	2018	2019	2020	2021	Total
Race					
Asian	0%	4%	6%	1%	3%
Black	43%	46%	51%	63%	51%
Hawaiian	0%	0%	0%	1%	0%
Multiple	0%	1%	0%	0%	0%
Native American	0%	1%	0%	2%	1%
Unknown	2%	1%	0%	1%	1%
White	55%	48%	43%	31%	44%
Ethnicity					
Hispanic	18%	23%	23%	19%	21%
Non-Hispanic	80%	76%	77%	80%	78%
Unknown	2%	1%	0%	1%	1%
Gender					
Female	72%	52%	57%	69%	61%
Male	28%	48%	43%	31%	39%

Table 2: Treatment Clinical Trial Acceptance Rates Across Demographic Categories

	Year				
	2018	2019	2020	2021	Total
Race					
Asian		50%	75%	100%	67%
Black	81%	74%	68%	75%	74%
Hawaiian				100%	100%
Multiple		100%			100%
Native American		0%		33%	25%
White	84%	83%	71%	77%	79%
Ethnicity					
Hispanic	94%	87%	74%	74%	81%
Non-Hispanic	80%	74%	68%	75%	74%
Gender					
Female	85%	80%	72%	71%	77%
Male	71%	73%	66%	82%	73%

The demographics of patients approached to enroll in treatment clinical trials over time is shown in Table 1. 579 patients overall were approached to consent to a treatment clinical trial. 61% were female, 39% were male, 21% were Hispanic, 51% were black, 44% were white, and the remaining 4% a mix of other races.

The acceptance rate broken down by race, ethnicity and gender is presented in Table 2. The overall acceptance rate was 75% - 435 patients agreed to participate. Compared with pre-pandemic rates, there was a decline in acceptance rates post-pandemic, 78% vs. 72%, OR = 0.66, 95%CI [0.44, 0.98], p = .04. Gender and racial/ethnic differences were not statistically significant (ps = 0.15-0.81) across gender (female = 77%, male = 73%), race (white = 79%, black = 74%, other = 60%), and ethnicity (non-hispanic = 74%, hispanic = 82%).

Results (Continued)

Among the 144 patients who declined participation, 52% had clinical concerns (e.g., preferred standard treatment, fear of side effects), 27% had concerns of experimentation, and 21% had logistic/unknown concerns (e.g., transportation, time, insurance). Patients were more likely to decline participation due to mistrust post-pandemic relative to pre-pandemic, 30% vs. 23%, OR = 0.47, 95%CI [0.22, 1.00], p = .05. Male patients were more likely to decline participation due to logistic and unknown concerns, 30% vs. 13%, OR = 0.65, 95%CI [0.28, 1.50], p = 0.31.

Conclusions

The UICC CTO treatment clinical trial acceptance rate was relatively high, similar across patient gender, race, and ethnicity, though these rates dipped since the COVID-19 pandemic. Burden of participation was not a significant reason for declining trial participation in this study, perhaps because UICC provides transportation for any clinical trial participants in need of it, and UICC's broad financial assistance policy. New interventions need to be developed to address fears of experimentation and clinical concerns in the post COVID-19 pandemic era.

UICC CTO plans to repeat this analysis annually to assure clinical trial participation barriers are minimized and to monitor the success of efforts to address existing barriers. In the short term, together with community members, we are developing and implementing clinical trial educational modules targeting our patients and the community. These interventions will hopefully help address concerns about clinical trial participation.

Acknowledgements

We would like to thank the University of Illinois Cancer Center for supporting this work, and the patients at the University of Illinois Cancer Center who participated. This analysis was conducted with approval from the University of Illinois at Chicago Institutional Review Board, IRB# 2022-0242.

Reduction of Days From Referral to Phase I Consultations

J. Bourgeois, T. Goodale, S. Mackoon, D. Arnett, E. Judson, C. Lewis
Winship Cancer Institute of Emory University

1. Background

The Phase I program at the NCI-designated Winship Cancer Institute of Emory University has a consultation process where physicians can easily refer patients for evaluation for early-phase research studies. The patient should be seen by a Phase I provider for clinical trial evaluation quickly. However, this process can take longer than anticipated with communication between the referring physician and the research team about trial selection and patient records. A calendar year's worth of data was reviewed and found the median time between the time of referral till a consult was nine days, and more than 50 percent of patients referred did not have a consult within a week. The longer the delay in consultation, the increased adverse impact on the chances of the patient going on a clinical trial as well as patient and referring physician satisfaction.

2. Goals

The goal is to reduce the median number of days from referral for a Phase I consultation from nine to four days and reduce the percentage of patients who wait longer than a week for a consult for a Phase I provider consultation.

3. Solutions and Methods

The solution implemented is a new workflow leveraging technology to reduce the time from patient referral to a visit with a Phase I provider for evaluation and discussion of clinical trial options within three business days of the referral. This solution utilizes telemedicine visits to remove barriers such as transportation to easily engage the entire catchment area of Emory's Winship NIC-designated cancer center throughout the entire state of Georgia. Two processes occur in tandem once a referral is made to the Phase I program by email. A research nurse reviews the patient's medical record and the Phase I clinical trial portfolio to identify potential clinical trials. A research coordinator will contact the patient within one business day and set up telemedicine or in-person consultation within three business days. The possible clinical trial options are communicated to the Phase I provider conducting the consultation. The expectation of our referring physicians is that at the time of referral, the patient has failed their current line of therapy and is ready to discuss clinical trial options and that the physician has alerted the patient that they have been referred and that the Phase I program will be contacting them to set up a consult. This information is also communicated through an auto-reply from the consultation email address. At the end of the consultation, the Phase I provider contacts the research team to provide the patient with a consent to review. This research team member is also the point of contact for the patient to answer any non-clinical questions, schedule the screening visits and procedures, and relay any clinical questions the patient may have to the Phase I clinical team.

4. Outcomes

N/A

5. Lessons Learned and Future Directions

This new workflow is still a work in progress. However, experiments have proven successful with specific oncology disease groups. This process is being rolled out to internal referrals with the goal of rolling it out to outside referrals within the coming year.

REDUCTION IN DAYS FROM REFERRAL TO PHASE I CLINICAL TRIAL CONSULTATIONS

John Bourgeois MMHC, BSN, RN, OCN, CCRP, NEA-BC; Tracey Goodale RN; Sasha Mackoon RN; Drew Arnett RN; Emma Judson PhD; Colleen Lewis NP

Winship Cancer Institute of Emory University

EMORY WINSHIP CANCER INSTITUTE

BACKGROUND

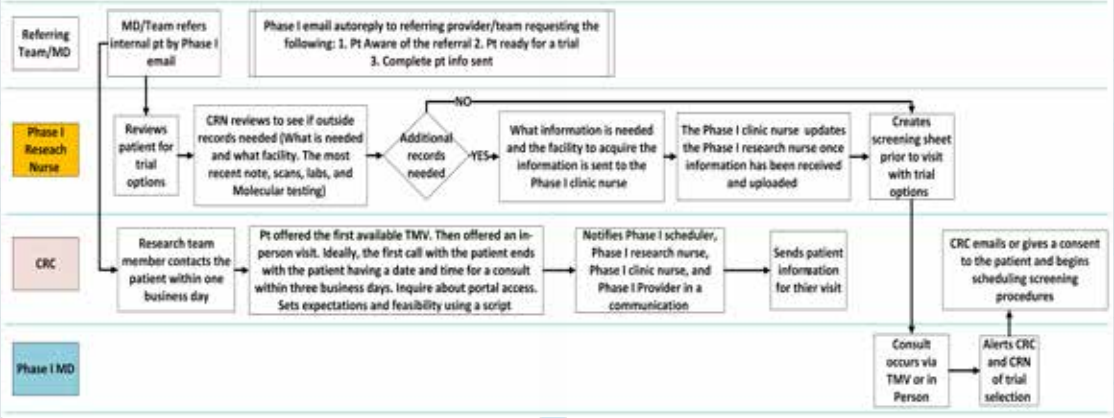
The Phase I program at the NCI designated Winship Cancer Institute of Emory University has a consultation process where physicians can easily refer patients for evaluation for early phase research studies. The patient should be seen by a Phase I provider for clinical trial evaluation quickly. However, this process can take longer than anticipated with communication between the referring physician and the research team about trial selection and patient records. A calendar year's worth of data was reviewed and found the median time between the time of referral until a consult was nine days, and more than 50% of patients referred did not have a consult within a week. The longer the delay in consultation, the increased adverse impact on the chances of the patient going on a clinical trial as well as patient and referring physician satisfaction.

GOALS

- Reduce the median number of days from referral for a Phase I consultation from nine to four days.
- Reduce the percentage of patients who wait longer than a week for a Phase I provider consultation.

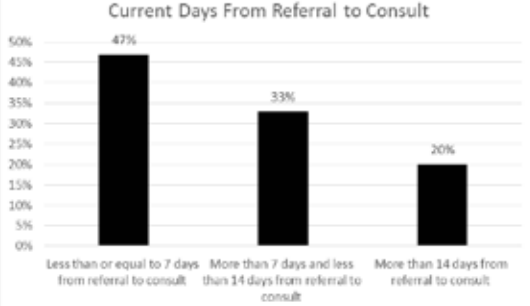
METHODS

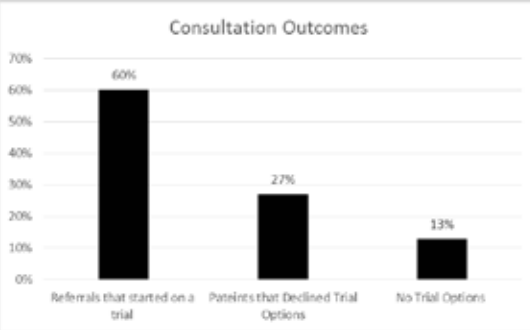
A new workflow leveraging technology was implemented to reduce the time from patient referral to a Phase I provider consultation. The aim was to schedule that clinical discussion visit within three business days of the referral. Telemedicine visits were offered to remove barriers such as transportation to improve access to the catchment area of Emory's Winship NCI-designated cancer center throughout the entire state of Georgia. Two processes occurred in tandem once a referral was made to the Phase I program. A research nurse reviewed the patient's medical record and the Phase I clinical trial portfolio to identify potential clinical trials. A research coordinator contacted the patient within one business day and scheduled a visit within three business days. The possible clinical trial options are communicated to the Phase I provider prior to the consultation. The expectation of referring physicians is that the patient has failed their current line of therapy, is ready to discuss clinical trial options, and that the physician has alerted the patient that they have been referred to the Phase I program and to expect to be contacted.



FUTURE IMPLICATIONS

This new workflow is still a work in progress. However, experiments have proven successful with specific oncology disease groups. This process is being rolled out to internal referrals with the goal of rolling it out to outside referrals within the coming year.





https://winshipcancer.emory.edu/patient-care/clinical-trials/phase1-unit.html

PARTNERING IN PROGRESS

TRIAL START-UP AND ACTIVATION

* Practical Benefits of Defining and Implementing Structured Intake and New Study Assignment in a Centralized Start-up Model

A. McCauley, M. Winkler, M. Poduri, M. Hibbert
Fred Hutchinson Cancer Center

1. Background

The Fred Hutchinson/University of Washington Cancer Consortium implemented a dedicated clinical trial start-up team to reduce historically long start-up times and to improve partnerships with industry sponsors. Start-up timelines were protracted and unpredictable in part due to incomplete and inconsistent new study submissions that were managed by research group start-up teams. Minimum submission requirements were defined for Consortium reviews but variability across sponsor documents and study team vetting of sponsor documents led to downstream delays in the start-up process.

2. Goals

The primary goal of the central start-up team was to achieve reduced start-up times from a median of 204 to 100 calendar days by implementing a comprehensive intake and study assignment process.

3. Solutions and Methods

The central start-up team initiated gatekeeping for new studies using a structured intake process with defined minimum requirements and a robust set of intake questions. The intake process set clear expectations with industry partners and frontloaded a comprehensive package to the assigned central start-up staff.

- The structured intake process included:
  - Collection of minimum required documents
  - Sponsor enrollment projections
  - Relevant regulatory, financial, and clinic implementation questions
  - Site-required pre-approvals
    - Assignment to the central start-up team and initiation of study start-up activity was contingent on industry partners':
  - Readiness to furnish required sponsors' documents
  - Ability to answer preliminary questions that will determine start-up workflow, implementation requirements, and expectations
  - Acceptance of non-negotiable site fees and standard operating procedures
- Completion of the structured intake process resulted in assignment to the central start-up team and initiation of start-up activity

4. Outcomes

The structured intake process reduced median start-up time to a median of 120 calendar days and led to the improved outcomes described below.

- Frontloading key implementation questions prior to initiating start-up activity enabled the centralized start-up team to fulfill regulatory requirements, inform clinic implementation, negotiate and finalize budgets and contracts, secure third-party accesses and site-trainings, coordinate site initiation visits (SIVs), and complete site activations with greater precision and efficiency
- Pre-approval of product/device compatibility with non-negotiable site standard operating procedures, devices, and equipment reduced late-discovery feasibility issues and expense to site and industry partners
- Structured intake managed by dedicated site contact increased transparency and continuity with industry partners
- Status and outcomes of structured intake informed study selection and portfolio prioritization with investigators and research groups
- Utilization of structured intake to gatekeep study assignments allowed for workload planning and equitable distribution to the central start-up team

5. Lessons Learned and Future Directions

The successful implementation of a structured intake process prior to assignment and initiation of start-up led to reduced median start-up time by ensuring needed information and materials were frontloaded and available to the site staff, service areas, and other central offices in advance. The process also increased central start-up team bandwidth, reduced back-and-forth with sponsors, and improved outcomes of budget negotiations.

Central start-up budget and regulatory specialists continue to evaluate other internal start-up processes and opportunities for efficiency gains, including but not limited to budget development and negotiation; negotiation of consent language, essential regulatory documents, and eReg platform utilization.

* *Honorable Mention*

Practical Benefits of Defining and Implementing Structured Intake and New Study Assignment in a Centralized Startup Model

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Fred Hutchinson Cancer Center, Seattle, WA
Clinical Research Support – Study Startup Team – CRSstartup@fredhutch.org

Introduction

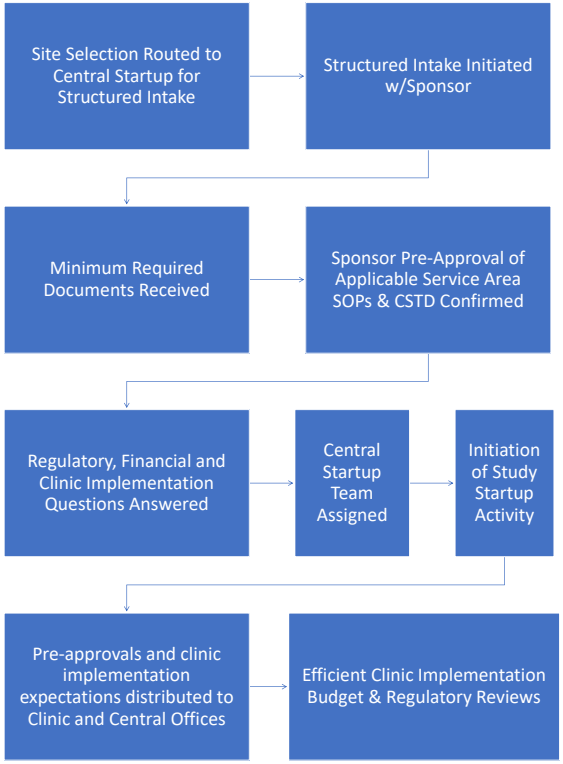
The Fred Hutchinson/University of Washington Cancer Consortium implemented a dedicated clinical trial startup team to reduce historically long startup times and to improve partnerships with industry sponsors. Startup timelines were protracted and unpredictable in part due to incomplete and inconsistent new study submissions that were managed by research group startup teams. Minimum submission requirements were defined for Consortium reviews but variability across sponsor documents and study team vetting of sponsor documents led to downstream delays in the startup process.

The primary goal of the central startup team was to achieve reduced startup times from a median of 204 to 100 calendar days by implementing a comprehensive intake and study assignment process.

Methods

The central startup team-initiated gatekeeping for new studies using a structured intake process with defined minimum requirements and a robust set of intake questions. The intake process set clear expectations with industry partners and frontloaded a comprehensive package to the assigned central startup staff.

- The structured intake process included:
  - Collection of minimum required documents
  - Sponsor enrollment projections
  - Relevant regulatory, financial, and clinic implementation questions
  - Site-required pre-approvals
- Assignment to the central startup team and initiation of study startup activity was contingent on industry partners':
  - Readiness to furnish required sponsors documents
  - Ability to answer preliminary questions that will determine startup workflow, implementation requirements, and expectations
  - Acceptance of non-negotiable site fees and standard operating procedures
- Completion of the structured intake process resulted in assignment to the central startup team and initiation of startup activity.



Results

The structured intake process reduced median startup time to 120 calendar days and led to the improved outcomes described below.

- Frontloading key implementation questions prior to initiating startup activity enabled the centralized startup team to fulfill regulatory requirements, inform clinic implementation, negotiate and finalize budgets and contracts, secure third-party accesses and site-trainings, coordinate site initiation visits (SIVs), and complete site activations with greater precision and efficiency
- Pre-approval of product/device compatibility with non-negotiable site standard operating procedures, devices, and equipment reduced late-discovery feasibility issues and expense to site and industry partners
- Structured intake managed by dedicated site contact increased transparency and continuity with industry partners
- Status and outcomes of structured intake informed study selection and portfolio prioritization with investigators and research groups
- Utilization of structured intake to gatekeep study assignments allowed for workload planning and equitable distribution to the central startup team

Discussion

The successful implementation of a structured intake process prior to assignment and initiation of startup led to reduced median startup time by ensuring needed information and materials were frontloaded and available to the site staff, service areas, and other central offices in advance. The process also increased central startup team bandwidth, reduced back-and-forth with sponsors, and improved outcomes of budget negotiations.

Central startup budget and regulatory specialists continue to evaluate other internal startup processes and opportunities for efficiency gains, including but not limited to budget development and negotiation; negotiation of consent language, essential regulatory documents, eReg platform utilization.

Four Years and Beyond: Progress With the Committee on Radiation

A. Andreatta, C. Ryan, S. Hanley, A. Rodavitch, P. Zanzonico, L. Dauer, M. Williamson
Memorial Sloan Kettering Cancer Center

1. Background

- The protocol review core (PRC) within Memorial Sloan Kettering Cancer Center's (MSK) clinical research administration (CRA) was established in 2018 to provide centralized oversight of protocol review committees, including the committee on radiation (COR), with a goal of decreasing time to activation (TTA) (time from primary department submission to activation)
  - PRC is charged with increasing efficiencies within the review process, while maintaining the quality of protocol reviews
- COR has jurisdiction over all ionizing radiation use in accordance with applicable regulations and MSK's broad scope license, which includes reviewing protocols where participants receive any investigational radiation exposure; COR is also responsible for non-clinical/research uses of radiation
- PRC and COR leadership identified challenges with protocol reviews at COR such as:
  - Ambiguity of criteria identifying protocols requiring COR review resulting in missed reviews
  - Anticipation of an increased submission volume with fixed resources, while supporting the center's TTA goals
  - PRC operating outside of scope since COR is a unique committee reviewing clinical and non-clinical research activities and subject to regulatory oversight

2. Goals

- Streamline COR's review process while ensuring regulatory compliance
- Improve access to COR resources
- Align responsibilities for COR administration

3. Solutions and Methods

- In collaboration with COR leadership, PRC streamlined the review process and ensured regulatory compliance by:
  - Establishing clear criteria to identify protocols requiring COR review
  - Implementing an expedited review process for low-dose, low-radiation risk protocols
  - Collaborating with consent editors to create template informed consent language regarding applicable risks
  - Creating template letter text for review letters
  - Developing an amendment workflow to ensure applicable protocols are routed for COR review
  - Updating COR SOPs to align with expedited review process and other internal workflows
- Improved access to COR resources
  - Updated the clinical research portal page (MSK's intranet) to include resources for the clinical research community (e.g., dosimetry tables, review criteria, consent language, etc.) to improve quality of protocol submissions
- Aligned responsibilities for COR administration
  - PRC offboarded non-clinical research related tasks to a newly created regulatory specialist position in the Medical Health Physics office using the RACI (Responsible, Accountable, Consulted, Informed) matrix to define scope of different teams

4. Outcomes

- 325 percent increase in COR protocol reviews from 2017-2021, demonstrating the improved compliance with institutional and regulatory requirements
- Median days (9 in 2020 and 12 in 2021) for COR review remained consistent despite increase in volume
- Since implementing expedited reviews in July 2019, most protocols are expedited at COR (86 percent in 2020 and 83 percent in 2021)
- 79 percent increase in protocols approved as-is (no comments to investigators) since launching the portal page updates in 2021
- Seamless transition of committee management responsibilities

5. Lessons Learned and Future Directions

- Lessons Learned:
  - Establishing clear review criteria in the initial stage of protocol submissions was effective for ensuring regulatory compliance
  - Incorporating RACI tool was critical for realigning administrative responsibilities
- Future Directions:
  - More effectively manage committee user work and reduce manual tasks (2022) through enhancements with MSK's homegrown protocol information management systems (PIMS)
  - Automate amendment submissions and reviews in PIMS
  - Continue to increase efficiencies within the review process

Four Years and Beyond: Progress with the Committee on Radiation

Ashley Andreatta, Carly Ryan, Sara Hanley MSW, Ann Rodavitch, MA, Pat Zanzonico, PhD, Larry Dauer, PhD, Matt Williamson, MA

Memorial Sloan Kettering Cancer Center

Background

- The Protocol Review Core (PRC) within Memorial Sloan Kettering Cancer Center's (MSK) Clinical Research Administration (CRA) was established in 2018 to provide centralized oversight of protocol review committees, including the Committee on Radiation (COR).
- COR has jurisdiction over all ionizing radiation use in accordance with applicable regulations and MSK's broad scope license, which includes reviewing protocols where participants receive any investigational radiation exposure.
- PRC and COR leadership identified challenges with protocol reviews at COR such as ambiguity of review criteria, increased submission volume, and PRC operating outside of scope since COR is a unique committee reviewing clinical and non-clinical research activities subject to regulatory oversight.

Goals

- Streamline COR's review process while ensuring regulatory compliance
- Improve access to COR resources
- Align responsibilities for COR administration
- Facilitate review at future committee meetings (i.e., IRB)

Solutions Implemented

January 2018
PRC committee management established to standardize review process across institution

May 2019
Clarified and updated COR review criteria to ensure regulatory compliance (Figure 1)

October 2019
Created COR review letter template text to establish consistency and facilitate reviews and PI responses

May 2021
Redesigned COR Clinical Research (CR) Portal Page (Figure 2) to increase transparency and improve access to resources

April 2019
Created Informed Consent template language to ensure COR's vetting of appropriate radiation risk language during review

July 2019
Implemented expedited reviews to facilitate timely activation of protocols

March 2020
Developed amendment workflow (Figure 4) to ensure regulatory compliance

October 2021
SOP revisions and RACI document implemented (Figure 3) to comply with internal workflows and to separate clinical research from radiation safety responsibilities

Figure 1: Review Criteria in the Research Proposal Submission Form (RPSF)

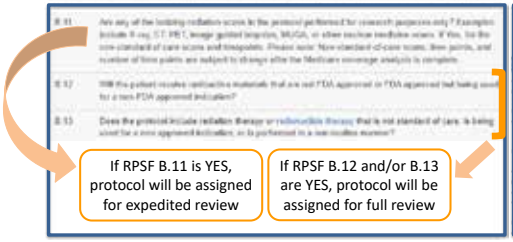


Figure 3: RACI (Responsible, Accountable, Consulted, Informed)

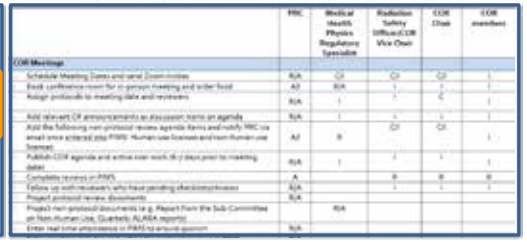


Figure 2: List of Resources Accessible via Clinical Research Portal

COR Review Criteria	Radiation Dosimetry Resources	Additional Resources
• Full • Expedited	• Adults • Pediatrics • Protocol Specific Language	• SOPs • Regulations • Protocol Review Resources

Figure 4: Amendment Review Criteria

Does the amendment include the addition of any of the following that increases radiation exposure for participants?

- ❑ Radioactive materials that are not-FDA approved or FDA approved but being administered for a non-FDA approved indication. Examples include diagnostic molecular imaging scans, radiolabeled antibody drugs (radiopharmaceuticals).
- ❑ Radiation therapy that is not standard of care, is being used for a non-approved indication, or is performed in a non-routine manner

If YES, please specify the radioactive material and/or radiation therapy that is being added

Outcome

325% Increase in COR protocol reviews (2017-2021) as a result of clear review criteria

83% % protocols reviewed via expedited process (2020) compared to 0% prior to PRC management

12 Median days for COR approval, which remained consistent despite significant increase in volume (2020)

79% Increase in protocols 'approved as is' after CR portal redesign, including comprehensive resources, led to improved quality of submissions (2021)

Lessons Learned

- Establishing clear review criteria in the initial stage of protocol submissions was effective for ensuring regulatory compliance
- Incorporating RACI tool was critical for realigning administrative responsibilities

Future Directions

- Leverage technology to improve committee management such as:
  - Automate amendment submissions and reviews in Protocol Information Management System (PIMS)
- Continue to increase efficiencies within the review process

It's About Time: A Simplified Approach to NCI Trial Activation

J. Balletti, L. Gaffney, M. Warren, S. Hanley, E. Valentino, A. Rodavitch, J. Migliacci
Memorial Sloan Kettering Cancer Center

1. Background

As an NCI-Designated Comprehensive Cancer Center, Memorial Sloan Kettering Cancer Center (MSK) is committed to collaborations with NCI-sponsored research organizations to increase clinical trial availability to patients. A multistep review process and extensive list of operational items required to activate a study hindered our investigators' ability to provide new investigational treatments to their patients in a timely fashion.

2. Goals

Through the combined efforts of our local NCI group principal investigators, NCI network program, protocol activation and review cores, human research protection program, clinical research finance, and protocol operations, a plan was developed to simplify the activation process for trials in our NCI portfolio. Our goal was to improve the overall time to activation (OTTA), defined as the number of days from acceptance into the protocol activation and review cores to open to accrual (OTA) date, of NCI-sponsored trials while maintaining our high standards for regulatory compliance.

3. Solutions and Methods

To accomplish our goal, we identified five key study start-up requirements (i.e., eligibility checklist, sponsor-required regulatory documents, sponsor activation, initial protocol training, and study-specific contract, if applicable) needed to OTA. The remaining study start-up requirements (required for non-NCI protocols to OTA) needed to be initiated during the review process and completed within 45 days following OTA (or before the third enrollment). A streamlined review process, bolstered by communication with committees to emphasize short turnaround time, allowed for fast-tracked, concurrent department, committee, institutional review board (IRB) and privacy board (PB) reviews. OTTA was also cut significantly by using simplified standard language highlighting the importance of NCI trial participation in the research proposal submission form, eliminating service chief sign-off, and ensuring all collaborators adopted the new initiative. The goal OTTA using this new process was 15 days for all NCI-sponsored studies, with a "just-in-time" (JIT) mechanism to open trials within 2 to 5 days if an eligible patient was identified.

4. Outcomes

In 2021, following rollout on March 29, 13 trials opened under this initiative. Median OTTA was 14 days, including one study that opened in 4 days via the JIT mechanism, down from 90.5 days in 2020 (n=38 protocols) – an impressive 85 percent decrease in OTTA. The lesser number of protocols activated in 2021 was the intended result of levying a more selective approach to opening NCI-sponsored studies best suited to our patient populations. Overall, this initiative benefits MSK's patients, giving them access to important research studies quickly.

5. Lessons Learned and Future Directions

While we still encounter challenges meeting the 15-day timeline for trials requiring study-specific contracts and those requiring Institutional Biosafety Committee (IBC) review, the majority of our NCI-sponsored trials now open in 15 days or less. In 2022, we will explore ways to shorten the amount of time needed for contract execution and IBC review in order to meet the 15-day turnaround for trials with these more complex requirements.

It's About Time: A Simplified Approach to NCI Trial Activation

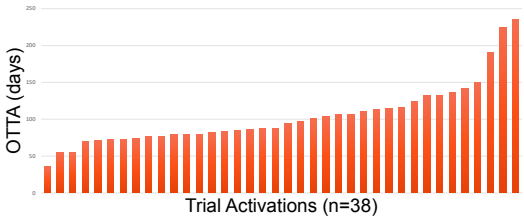
Jennifer Balletti, BS, Leigh Gaffney, MPH, Mary Warren, MSW, Sara Hanley, MSW, Emily Valentino, MPH, Ann Rodavitch, MA, Jocelyn Migliacci, MA

Memorial Sloan Kettering Cancer Center

Background

As an NCI-Designated Comprehensive Cancer Center, MSK is committed to collaborations with NCI-sponsored research organizations to increase clinical trial availability. A multistep review process and extensive list of operational items hindered our investigators' ability to provide timely access to new investigational treatments. In 2020, the median overall time to activation (OTTA) was 90.5 days with a maximum of 235 days.

Overall Time to Activation 2020



Methods

Several departments collaborated on a plan to simplify the activation process for NCI-sponsored trials and decrease OTTA, the number of days from acceptance into the Protocol Activation and Review Cores to open to accrual (OTA) date.

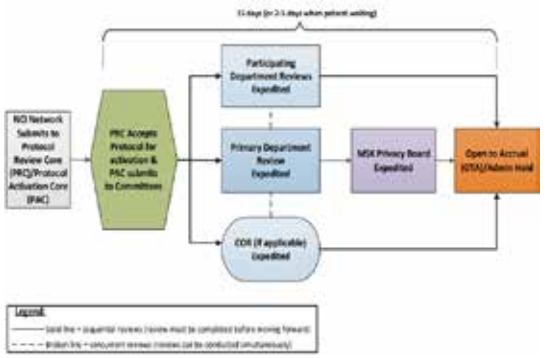
- Identify NCI trial for prioritization
- Determine key operational items required for opening
- Standardize language, decrease # of signatures
- Enable expedited, concurrent reviews

Key Start-up Requirements

We identified five start-up requirements (eligibility checklist, regulatory documents, sponsor activation, initial protocol training, and study-specific contract, if applicable) needed to OTA. The remaining start-up requirements needed to be initiated during the review process and completed within 45 days following OTA (or before the third enrollment).

Expedited, Concurrent Reviews

A streamlined review process allowed for expedited, concurrent reviews. Review time was also cut significantly by using simplified standard language in the Research Proposal Submission Form, eliminating Service Chief sign-off, and ensuring all collaborators adopted the new timeframes.



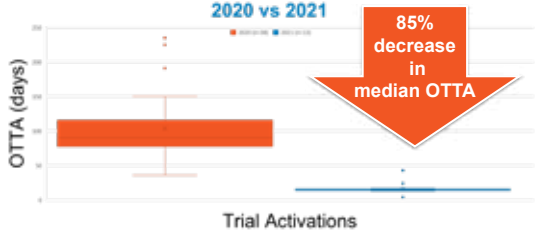
Goals

- Decrease OTTA to 15 days for NCI-sponsored trials
- Pilot Just-in-Time (JIT) model to open trial in 2-5 days

Results

Post roll-out in 2021, we activated 13 trials with a median OTTA of 14 days and a minimum of 4 days for a pediatric trial opened via JIT for an eligible patient. The lesser number of activations was the intended result of a more discerning approach to trial selection. This initiative benefits MSK's patients, giving them access to important research studies, and supports our institutional commitment to NCI-sponsored research.

Overall Time to Activation 2020 vs 2021



Future Plans

- Collect and evaluate 2022 OTTA/ JIT metrics
- Develop workflow to fast-track contract execution
- Expedite Institutional Biosafety Committee reviews

Acknowledgements

Thank you to the following collaborators for their hard work and dedication to making this initiative a success: NCI Network Program, Protocol Activation Core, Protocol Review Core, Local NCI Group Principal Investigators, Human Research Protection Program, Clinical Research Finance, Protocol Operations

Strategies to Expedite Activation of Expanded Access Protocols at Memorial Sloan Kettering Cancer Center

X. Lekperic, E. Valentino, S. Hanley, A. Rodavitch
Memorial Sloan Kettering Cancer Center

1. Background

An NCI-Designated Comprehensive Cancer Center, Memorial Sloan Kettering (MSK) has over 1,000 clinical trials and expanded access protocols (EAP). EAPs provide access to pre-approval, investigational drugs outside of a clinical trial and patients who rely on them often have no other similar or acceptable therapeutic options available. It is essential to review and activate EAPs efficiently so patients can have access to treatment as soon as possible. MSK's Protocol Review Core (PRC) and Protocol Activation Core (PAC) identified roadblocks in reviewing and activating EAPs and established a working group to improve our processes.

2. Goals

- Create an institutional EAP review and activation workflow
- Decrease EAP Time to IRB Approval (TTIA) [time from primary department submission to IRB approval] and Time to Activation (TTA) [time from primary department submission to activation]

3. Solutions and Methods

The working group first streamlined the institutional definition of an EAP to include any protocol with a primary objective of providing access to a treatment or device with no scientific endpoints. We then conducted a pilot, met with various groups (finance, legal, pharmacy, etc.), and finally implemented a new review and activation workflow comprised of:

- Lean administrative pre-review process
- Expedited, concurrent pre-IRB reviews to eliminate bottlenecks
- Streamlined and focused committee reviews
- Administrative protocol review and monitoring system (PRMS) reviews focused on resources and prioritization
- Enhanced internal communication between PAC and PRC and use of shared tools such as:
  - Trello boards
  - Internal protocol information management system (PIMS)
  - Protocol tracker
- Condensed activation process
  - ICF drafted early (within 3 days of primary department submission)
  - CTMS calendar request, budget, contract flagged as high priority to expedite calendar build and external negotiation timelines (if applicable)
  - Flexibility with the internal start-up tools required to open to accrual (e.g., protocol order sets and CTMS calendar completion)

4. Outcomes

The new EAP review and activation workflows have improved communication and transparency between PAC/PRC and the greater MSK research community, sponsors, and CROs.

When comparing 7 EAPs pre-EAP pilot versus 7 EAPs in the pilot, there were significant improvements in our various review and activation metrics such as:

- 58 percent decrease in time from primary department submission to PRMS approval (12 to 5 median days)
- 35 percent decrease in time from primary department submission to IRB approval (26 to 17 median days)
- 18 percent decrease in TTIA (51 to 42 median days)
- 24 percent decrease in TTA (81 to 62 days)
- 33 percent decrease in difference between TTA and TTIA (30 to 20 median days)

5. Lessons Learned and Future Directions

Lessons Learned:

- Protocol review and activation efficiency is only as good as the communication between teams
- Defining scope of reviews ensures efficiency of protocol review committees
- Activation workflows must consider and involve external teams (e.g., budgets, contracts, etc.)
- Investigator Initiated Trials take longer and must be considered separately from externally sponsored protocols

Future Directions:

- Further decrease time from primary department submission to IRB submission
- Further decrease TTIA, TTA, and the difference between them so that patients can access treatment quickly post-IRB approval
- Use EAP workflow experience to identify and eliminate bottlenecks in other types of protocol reviews

Strategies to Expedite Activation of Expanded Access Protocols at Memorial Sloan Kettering Cancer Center

Xhenete Lekperic, Sara Hanley, MSW, Emily Valentino, MPH, Ann Rodavitch, MA

Memorial Sloan Kettering Cancer Center

Background

- An NCI-Designated Comprehensive Cancer Center, Memorial Sloan Kettering (MSK) has over 2,000 active clinical trials and expanded access protocols (EAP).
- EAPs provide access to pre-approval, investigational drugs outside of a clinical trial and patients who rely on them often have no other similar or acceptable therapeutic options available.
- It is essential to review and activate EAPs efficiently so patients can have access to treatment as soon as possible.
- MSK's Protocol Review Core (PRC) and Protocol Activation Core (PAC) identified roadblocks in reviewing and activating EAPs and established a working group to improve our processes.

Goals

- Create an institutional EAP review and activation workflow
- Decrease EAP Time to IRB Approval (TTIA) [time from primary department submission to IRB approval] and Time to Activation (TTA) [time from primary department submission to activation]

Methods & Solutions

Working group was created, and first task was to streamline institutional definition of EAP: *any protocol with a primary objective of providing access to a treatment or device with no scientific endpoints.*

Conducted 16-week pilot of 7 protocols. Pilot included PRC and PAC meetings with research operations, legal, finance, information technology, and pharmacy teams to streamline workflow details.

Presented workflow proposal and pilot data to all stakeholders then Center leadership. Then, implemented new review and activation workflow and trained PRC and PAC staff.

New review & activation workflow includes:

- Lean, administrative pre-review process so protocols can expeditiously begin review & activation process
- New EAP Review Flow (Figure 1) with expedited, concurrent, streamlined, and focused pre-IRB reviews to eliminate bottlenecks
- Administrative Research Council (RC) reviews focused on resources and prioritization. RC is MSK's Protocol Review and Monitoring System (PRMS).
- Enhanced internal communication between PAC and PRC including shared tools such as EAP identification workflow (Figure 2), Trello Board for tracking activation tracks, Internal Protocol Information Management System (PIMS), and protocol trackers.
- Condensed activation process including early informed consent form creation (within 3 days of starting review process), expedited CTMS calendar build, budget finalization, and contract execution (all flagged as high priority by PAC). There is also flexibility with internal start-up tools required to Open to Accrual such as protocol order sets and CTMS calendar completion.

Figure 1:
Externally Sponsored Expanded Access Protocol Review Flow

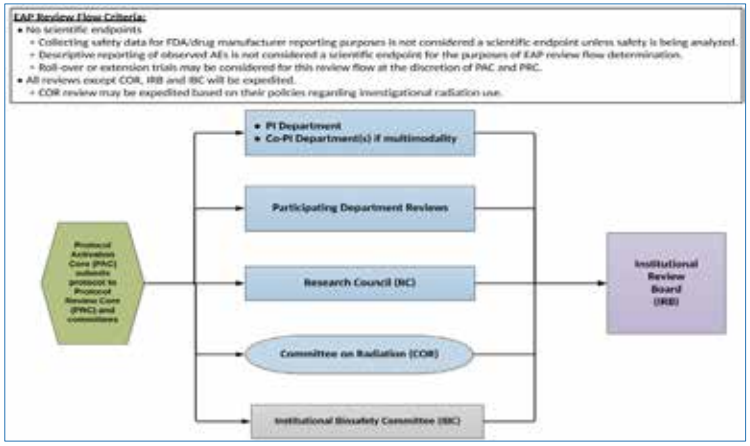
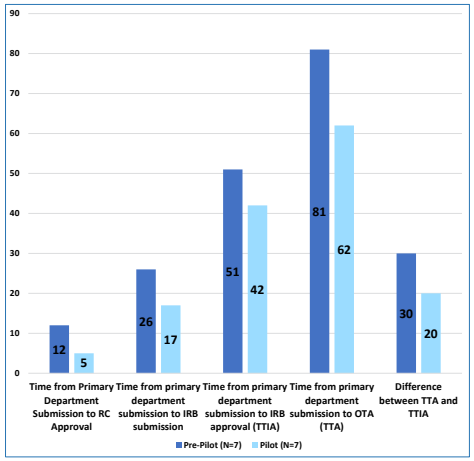


Figure 2:
Expanded Access Protocol Identification Workflow

Figure 3:
Expanded Access Workflow Review & Activation Metrics Impact



Outcomes

Improved communication and transparency:

- Enhanced communication between PRC/PAC
- Transparency and enhanced collaboration with study teams, sponsors, and CROs

Improved submission & review metrics:

- 58% decrease in Time from primary department submission to RC approval (12 to 5 median days)
- 35% decrease in Time from primary department submission to IRB approval (26 to 17 median days)

Improved activation metrics:

- 18% decrease in TTIA (51 to 42 median days)
- 24% decrease in TTA (81 to 62 days)
- 33% decrease in difference between TTA and TTIA (30 to 20 median days

Lessons Learned

- Protocol review and activation efficiency is only as good as the communication between teams
- Defining scope of reviews ensures efficiency of protocol review committees
- Activation workflows must consider and involve external teams (e.g., budgets, contracts, etc.)
- Investigator Initiated Trials take longer and must be considered separately from externally sponsored protocols

Future Directions

- Further decrease time from primary department submission to IRB submission
- Further decrease TTIA, TTA, and the difference between them so that patients can access treatment quickly post-IRB approval
- Use EAP workflow experience to identify and eliminate bottlenecks in other types of protocol reviews

Enhancing 1st Stage Protocol Review – A Quantitative Approach

L. Wall, A. Spratt, R. Szmulewitz
The University of Chicago Medicine Comprehensive Cancer Center

1. Background

Clinical trial success is contingent upon a thoughtful and robust feasibility assessment. Protocols that do not fit our catchment area's needs and patient population are unlikely to accrue and waste time, money, and resources. Like most centers, we experienced significant staffing challenges across the entire enterprise post-pandemic. This coupled with trial complexity and increasing pressures to decrease start-up timelines have challenged us to evolve new approaches to trial review.

Our first stage review is conducted at the disease program level. However, we lacked set review standards, so it was unclear how effective these meetings were, what percentage of trials were declined, and why. Since first stage review happens early in the protocol activation lifecycle, we recognized the opportunity to make this process more robust to ensure we use our resources efficiently. We set out to better understand the effectiveness and outcomes of the process and identify areas of improvement.

2. Goals

We worked with our 14 disease-specific programs to enhance, organize, and document our first stage review to ensure our cancer center thoroughly vets trials, and:

- Provide a standardized system to track and streamline our first stage review documentation
- Create a quantitative metric to guide the first stage review discussion to focus our efforts and resources on the most value-added trials

3. Solutions and Methods

We developed a web-based first-stage dashboard to track clinical studies our disease programs considered for participation. Teams logged all trials presented and documented the outcome (i.e., approve, decline), outcome reason (i.e., competing trials, patient population), and a prioritization ranking to focus study start-up efforts.

We created a feasibility sorecard to provide a quantitative metric for programs to use when deciding whether to pursue a trial. The scorecard considers the following elements:

- Trial source and phase
- Competing trials
- PI authorship
- scientific merit
- patient population/accrual goals /duration
- network participation
- financial impact
- Sponsor relationship (new sponsor, established sponsor, master CTA, rate cards)
- cancer center and institutional resources (staffing, facilities, etc.)

Within each category, individual responses were scored. Overall score ties to color-code of green, yellow, red. Certain elements such as institutional trials, patient population, and competing trials are weighted higher and thus have a greater impact on overall score.

Green = Recommend
Yellow = Use caution
Red = Strongly recommend declining

4. Outcomes

The feasibility dashboard has increased overall visibility surrounding the volume of studies presented to our disease groups and their outcomes. Data shows a balanced process with comparable rates of approving and declining of studies.

Physicians and study staff have been overwhelmingly receptive to implementing the scorecard. Program leaders are challenged with maintaining a balanced portfolio and the scorecard provides them with a quantitative tool to guide their colleagues and recommend declining at risk studies. The scorecard also guides discussion around topics that have never been openly considered when deciding to move forward with a study. These upfront conversations about current staffing and workload resulted in positive staff feedback. We hope that by acknowledging their workload as part of the process will improve staff satisfaction and retention rates. Lastly, the process includes upfront input from our network physicians which is crucial to ensuring we meet the needs of our community sites.

5. Lessons Learned and Future Directions

Initially, our first stage review process felt like another layer added to an already lengthy start-up process. However, we recognized that having a robust, standardized process empowered disease programs to focus on multidisciplinary needs instead of individual investigator interests. Moving forward, we will continue to monitor this data and enhance our standard definitions of review outcomes. By doing this we can proactively assess programs and resource needs. For example, if studies that would have filled an unmet need are continually declined due to lack of staffing or other resources, we can adjust by increasing staffing levels in those programs. We also want to allow disease programs to tweak the scorecard to make it more disease-specific to increase the effectiveness of the tool. We will begin to track the scorecard metrics and compare them to outcome decisions (e.g., does a trial with red score correlate with program decision to approve or not).

Lastly, we will closely track if our enhanced review process improves our study start-up timelines, increases participation and enrollment at our network sites, increases number of trials that meet accrual targets, and improves our overall workload.

Enhancing 1st Stage Protocol Review - A Quantitative Approach

Lauren Wall, MS; Amanda Spratt, CCRP; Russell Szmulewitz, MD
University of Chicago Comprehensive Cancer Center

BACKGROUND

Clinical trial success is contingent upon a thoughtful and robust feasibility assessment. Protocols that do not fit our catchment area's needs and patient population are unlikely to accrue and waste time, money, and resources. Like most centers, we experienced significant staffing challenges across the entire enterprise post-pandemic. This coupled with trial complexity and increasing pressures to decrease start-up timelines have challenged us to evolve new approaches to trial review.

At our center, we rely on the disease programs to conduct the 1st Stage Review. However, we lacked set review standards, so it was unclear how effective these meetings were, what percentage of trials were declined, and why. We recognized the opportunity to enhance our 1st Stage Review process to make this process more robust. We set out to better understand the effectiveness and outcomes of the process and identify areas of improvement.

To this end, we worked with our 14 disease programs to enhance, organize, and document their 1st Stage Review to ensure our cancer center thoroughly vets trials, and:

- Provide a standardized system to track and streamline our 1st Stage Review documentation.
- Create a quantitative metric to guide the 1st Stage Review discussion to focus our efforts and resources on the most value-added trials.

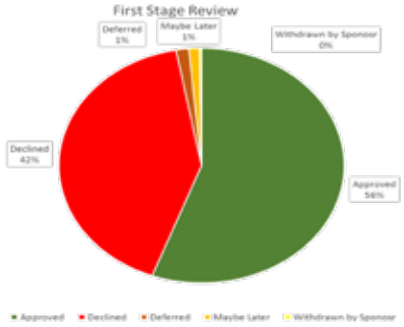
MATERIALS AND METHODS

We first developed a web-based 1st Stage dashboard to track clinical studies our disease programs considered for participation. Teams logged all trials presented and documented the outcome (i.e., approve, decline), outcome reason (i.e., competing trials, patient population), and a prioritization ranking to focus study start-up efforts.

We then created a Feasibility Scorecard to provide a quantitative metric for programs to use when deciding whether to pursue a trial. Within each category, individual responses were scored. Overall score ties to color-code of Green, Yellow, Red. Certain elements such as institutional trials, patient population and competing trials are weighted higher and thus have a greater impact on overall score.

RESULTS

The Feasibility Dashboard has increased overall visibility surrounding the volume of studies presented to our disease groups and their outcomes. It also increased conversation regarding clinical trial portfolios, resources, and needs of our program. Data shows a balanced process with comparable rates of approving and declining of studies.



Physicians and study staff have been overwhelmingly receptive to implementing the scorecard. Program leaders are challenged with maintaining a balanced study portfolio and the scorecard provides them with a quantitative tool to guide their colleagues and recommend declining potentially risky studies. The scorecard also guides discussion around topics that have never been openly considered when deciding to move forward with a study. These upfront conversations about current staffing and workload resulted in positive staff feedback. We hope that by acknowledging their workload as part of the process will improve staff satisfaction and retention rates. Lastly, the process includes upfront input from our network physicians which is crucial to ensuring we meet the needs of our community sites.

Green = Recommended

Yellow = Use Caution

Red= Strongly Recommend Declining

FUTURE DIRECTIONS

Initially, our 1st Stage Review process felt like another layer added to an already lengthy start-up process. However, we recognized that having a robust, standardized process empowered disease programs to focus on multi-disciplinary needs instead of individual investigator interests. Moving forward, we will continue to monitor this data and enhance our standard definitions of review outcomes. By doing this we can proactively assess programs and resource needs. For example, if studies that would have filled an unmet need are continually declined due to lack of staffing or other resources, we can adjust by increasing staffing levels in those programs. We also want to allow disease programs to modify the scorecard to make it more disease-specific to increase the effectiveness of the tool. We will begin to track the scorecard metrics and compare them to outcome decisions and study performance (e.g. does a trial with red score correlate with program decision to approve or not; does the initial score reflect actual study enrollment, ease of activation).

Lastly, we will closely track if our enhanced review process improves our study start-up timelines, increases participation and enrollment at our network sites, increases number of trials that meet accrual targets, and improves our overall workload.

Clinical Trial Research Group (CTRG) Guidelines for Trial Portfolio Management

J. Moehle, L. Lujan, S. Sharry, N. Agarwal, H. Colman, D. Gaffney, T. Werner
Huntsman Cancer Institute, University of Utah

1. Background

Clinical investigators are interested in activating the majority of new trial opportunities presented to them and can have hard time saying no. Huntsman Cancer Institute (HCI) has had a high number of new clinical faculty recruited and trained to be principal investigators (PI) in the past several years coupled with a record number of trials that were activated in 2020. The portfolios were becoming saturated, and CTO resources stretched thin. A guideline was needed to help investigators understand how to select and prioritize new trials as well as manage active trials in their portfolio.

2. Goals

The goal was to provide a guideline of best practices, that was not a policy, mandate, or rule, while allowing disease specific flexibility and autonomy by physician leaders.

3. Solutions and Methods

A guideline grounded in the HCI cancer center priority for trials, as well as those that brought investigator authorship or institutional accolade, was implemented April 2021. It included the criteria by which the protocol review and monitoring committee (PRMC) evaluates accrual and/or issues warning letters for poor performing trials (criteria that was not always commonly known by investigators). A clinical trial research group ratio was also developed to show each disease team their unique ratio of new patient accrual performance as compared to the number of open trials they had in a given year. Based off National Cancer Institute (NCI) data of disease incidence, each disease team was placed in an appropriate tiered ratio. The ratio is just one tool to consider in the guideline.

CTRG Guidelines for Trial Portfolio Management: Robust oversight in making trial decisions should also account for CTO support/resource limitations, underperforming trials, or trials that at no longer as scientifically relevant or serve the patient population. Additional considerations outlined in this guideline may also be considered for careful selection of new trial activation or closure of an existing trial.

CTRG Ratio (thresholds based off catchment area and NCI disease incidence):

1. Trial can accrue
   - o At least 1+ patients per year, or
   - o 1 patient per year (formally classified rare disease trials)
2. Consider a points-based system to open a trial or close an existing trial
   - o One (1) point for "Yes" to:
     - a) IIT studies and/or academic leadership on the steering committee or study chair-ship*
     - b) Trial based on institution's science*
     - c) Fiscally appropriate (specifically, IITs and industry trials are not in deficit)
     - d) Catchment area cancers based on Utah incidence* (including breast, prostate, melanoma, colorectal, lung, leukemia
     - e) Trial will change practice if positive (high impact; a rare disease trial can be practice changing)
   - f) PI screening and accrual performance across trials in CTRG
   - g) Junior investigator (first three years as faculty) leading the trial

*Important for CCSG

The guideline also included the criteria by which the PRMC evaluates accrual and/or issues warning letters for poor performing trials. The criteria by which the PRMC evaluated trial performance was not commonly known by investigators.

4. Outcomes

The guide is helpful and consulted regularly at each of disease team meetings as new trials are considered and ongoing trials are reviewed.

5. Lessons Learned and Future Directions

It was recommended that rather than use the disease incidence rate nationally, this be revised to be the state level disease incidence for more applicability to our cancer center catchment area.

Clinical Trial Research Group (CTRG) Guidelines for Trial Portfolio Management

Jessica Moehle, CCRP; Leanne Lujan, BS, CCRP; Susan Sharry, CCRP; Neeraj Agarwal, MD; Howard Colman, MD; David Gaffney, MD, PhD; Theresa L. Werner, MD
Huntsman Cancer Institute at the University of Utah

BACKGROUND

- Clinical investigators are interested in activating the majority of new trial opportunities presented to them and can have a hard time saying no.
- A guideline was needed to help investigators understand how to select and prioritize new trials as well as manage active trials in their portfolios.
- Robust oversight in making trial decisions must account for CTO support/resource limitations, underperforming trials or trials that are no longer as scientifically relevant or serve the patient population. This guideline may also be considered for selection of new trials for activation or closure of existing trials.

METRICS/GOALS

- The goal was to provide a guideline of best practices to each disease area. Some lead by seasoned clinical trialists, some are new leaders.
- Important: Not a policy, mandate, or rule.
- Need flexibility for physician leaders.

METHODS

- Guideline grounded in HCI priority for trials but also support for junior faculty : IITs, CTN, Industry (Phase 1/FIH, Phases 2 and 3), and institutional authorship/accolade.
- Trial accrual to open ratios consider NCI disease prevalence (Figure 1).
- Reviewed and approved by Clinical Research Executive Committee.
- Distributed to CTO Physician Leaders and all CTRG disease groups.

Figure 1

CTRG Ratio – Thresholds based off catchment area and NCI disease incidence.

1. Trial can accrue
   a) At LEAST one+ patients per year or
   b) One patient per year (formally classified rare disease trials)
2. Consider a points-based system to open a trial or close an existing trial.
   a) One (1) point for "Yes" to:
      - IIT studies and/or academic leadership on the steering committee or study chair-ship (important for the CCSG).
      - Trial based on institution's science (important for the CCSG).
      - Fiscally appropriate (specifically IITs and Industry trials are not in deficit).
      - Catchment area cancers (important for the CCSG).
3. Trial will change practice if positive (high impact; a rare disease trial can be practice changing).
4. PI screening and accrual performance across trials in CTRG.
5. Junior investigator (first three years as faculty) leading the trial.

OUTCOMES

- The guide is helpful and consulted regularly at each of disease team meetings as new trials are considered and ongoing trials are reviewed.
- CTRG leaders expressed appreciation for this supportive guideline for their decision-making processes.

Figure 2

CTRG Accrual Ratio, 2021

CTRG Ratio Threshold:	Rate of New Cases/100,000	2021 Ratio*
3	50+/ 100,000	
	Breast	2.80
	Lung	3.00
2.5	20-50/100,000	
	GU	3.13
	Melanoma	2.53
2	10-20/100,000	
	GYN	2.50
	GI	1.10
	H&N	1.47
1.5	0-10/100,000	
	Lymphoma	2.70
	Myeloid/MPN	2.37
	Brain	2.97
	Myeloma	2.60
	Sarcoma	.53

*Ratio is an average of:
1. All Accrual to Open Trials / No. of Open Trials
2. Accruals to Open Trials/ No. of Open Trials (excluding Phase I)
3. Accruals to Open Trials/ No. of Open Trials (excluding Rare Disease)

FUTURE PLANS

- Recommended to use the disease incidence at the states level disease incidence for more applicability to our cancer center catchment area.

Acknowledgements: We appreciate the other cancer centers who contribute to the AACI Listserv.

Technology and Centralization in Early Study Start-up Activities

E. Lebleu, L. Lujan, J. Moehle, T. Werner
Huntsman Cancer Institute, University of Utah

1. Background

Creating a successful and balanced clinical trial portfolio is a multifaceted process that begins with managing incoming new study opportunities. At Huntsman Cancer Institute (HCI) our clinical trials office (CTO) received > 400 new study invitations in 2021. In order to maintain and improve the quality of the invitations—as well as our relationships with sponsor partners—tracking early in the study lifecycle, maintaining streamlined processes, and communicating with sponsors is essential. Managing new study invitations and the process afterwards had been additional work for our trial disease group program managers (PM). In order to better prioritize this important aspect of a trial, we created the new position of trial activation administrator (AA).

2. Goals

The goals of the position: centralize sponsor communications, homogenize early study start-up portion of our study lifecycle, reduce burden of new-study work on the PMs, and solidify ownership of the early study start-up process.

3. Solutions and Methods

In July 2020, we hired this new position. The AA assumed the early start-up work of one disease group at a time, progressively incorporating all groups. An Access database with specific database views for our disease teams was designed and built by the AA for tracking trials, who also helped create tools and templates for early study start-up. After all disease groups were incorporated into the workflow, the AA assumed responsibility over new CDA requests.

4. Outcomes

- AA manages and routes all new study inquires allowing for consistency in review process across groups; this has created a high level of efficiency for start-up activities and reduced resources expended across PMs
- AA interfaces with all incoming trial sponsors which removes the need for PMs to answer sponsor questions and status inquiries
- Automated front-end reports for each team allow our PMs to stay informed in real time about studies' statuses without being actively involved in all steps
- Semi-automated charts/reports run from database information allow our leadership to keep informed about the distribution and number trials in start-up
- Visual aids related to start-up milestones increase sponsors' understanding of our start-up process
- Templates were created (EMR/source data, contact information) reducing the number of sponsor forms that need to be completed during start-up
- Virtual tour website created, allowing our PSVs to remain remote, reducing the burden of holding PSVs
- Observed 25 percent increase in trials activated in 2021 (v. 2020)

5. Lessons Learned and Future Directions

The volume of incoming trials would make this position nearly impossible without effective use of technology. Additionally, having the AA assume all tasks related to early study start-up was not entirely feasible due to the number of meetings that the AA needed to attend. As PMs already were attending these meetings, we divided the work and minimized overlap between the PMs and AA. Also, our increased new trial volume has highlighted a need for better trial vetting strategies at an early stage. Going forward, we hope to create more user tools for communicating information to teams and sponsors. In addition, we hope to use technology and tools/templates to automate or improve the workflow of additional parts of this process.

Technology and Centralization in Early Study Startup Activities

Emerson Lebleu, MS; Leanne Lujan, BS, CCRP; Jessica Moehle, BS, CCRP; Theresa L. Werner, MD
Huntsman Cancer Institute at the University of Utah

BACKGROUND

Creating a successful and balanced clinical trial portfolio is a multifaceted process that begins with managing incoming new study opportunities. At Huntsman Cancer Institute (HCI) our Clinical Trials Office (CTO) received > 400 new study invitations in 2021. In order to maintain and improve the quality of the invitations, as well as our relationships with sponsor partners, tracking early in the study lifecycle, maintaining streamlined processes, and communicating with sponsors is essential. Managing new study invitations and the process afterwards had been additional work for our trial disease group program managers (PM). In order to better prioritize this important aspect of a trial, we created the new position of Trial Activation Administrator (AA).

METRICS/GOALS

- Centralize sponsor communications.
- Homogenize early study startup portion of our study lifecycle.
- Reduce burden of new-study work on PMs.
- Solidify ownership of the early study startup process.

METHODS

- July 2020, we hired this new position.
- AA assumed the early startup work of one disease group at a time, progressively incorporating all groups.
- An access database with specific database views for our disease teams was designed and built for tracking trials.
- Tools and templates for early study startup were created.
- After all disease groups were incorporated into the workflow, the AA assumed responsibility over new CDA requests.

OUTCOMES

- AA manages and routes all new study inquires allowing for consistency in early review process across groups (Figure 2, process outline).
- AA interfaces with all incoming trial sponsors, which removes the need for PMs to answer sponsor questions and status inquiries.
- Automated front-end reports for each team allow our PMs to stay informed in real time about studies' statuses without being actively involved in all steps.
- Semi-automated charts/reports run from database information allow our leadership to keep informed about the distribution and number trials in startup.
- Visual aids related to startup milestones increase sponsors' understanding of our startup process.
- Templates were created (EMR/Source Data, Contact Information) reducing the number of sponsor forms that need to be completed during startup.
- Virtual tour website created, allowing our PSVs to remain remote, reducing the burden of holding PSVs.
- 25% increase in trials activated in 2021 (v. 2020) (Figure 1).

Figure 1

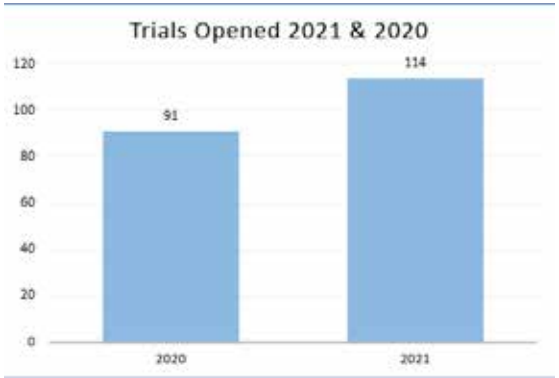
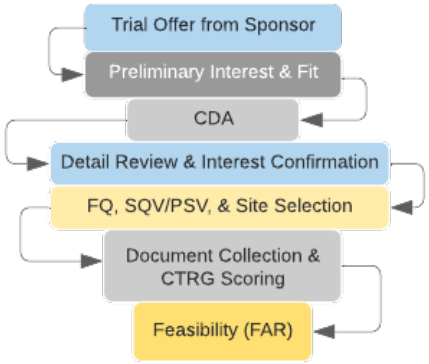


Figure 2



LESSONS & FUTURE PLANS

The volume of incoming trials would make this position nearly impossible without the effective use of technology. Additionally, having the AA assume all tasks related to early study startup was not entirely feasible due to the number of meetings that the AA needed to attend. As PMs already were attending these meetings, we divided the work and minimized overlap between the PMs and AA. Also, our increased new trial volume has highlighted a need for better trial vetting strategies at an early stage. Going forward, we hope to create more user tools for communicating information to teams and sponsors. In addition, we hope to use technology and tools/templates to automate or improve the workflow of additional parts of this process.

Improving Trial Activation Timelines: A Comprehensive Process Improvement Project

P. Arlen, L. Thyssen, K. Williams
Sylvester Comprehensive Cancer Center, University of Miami Health System

1. Background

Clinical trial activation at a matrix cancer center requires complex processes involving multiple stakeholders, including the university, the hospital, sponsors, and departments. The median trial activation time in 2021 at Sylvester was 226 calendar days, which exceeds our target of 90 calendar days. To reverse the trajectory and examine the trial activation process, Sylvester initiated a Lean Six Sigma process improvement project. Lean Six Sigma methodology focuses on improving performance by systematically minimizing waste and improving flow across processes.

2. Goals

The overall goal is to reduce Sylvester's trial activation time to a median of fewer than 90 calendar days, which represents a 48 percent reduction from our 2021 median.

3. Solutions and Methods

The project is being completed in five phases:

1. Define: Current state
2. Measure: Baseline and timeline
3. Analyze: Pain points and root cause analyses
4. Improve: Action plans and project portfolio, followed by implementation
5. Control: Progress reports

The deliverable of the first two phases was a value stream map (VSM), which provides a holistic view of our current state process by visualizing the movement of a trial from start to finish. Based on the analysis of the current state performance metrics, we identified multiple focus areas for the root cause analysis (RCA) phase.

We met with subject matter experts (SMEs) from numerous departments to conduct the RCA and identify pain points. We used process improvement tools such as brainstorming, multi-voting, and the Five Whys to guide the SMEs through the analysis.

The root causes identified were used as a vehicle to collect improvement ideas, which were then analyzed and scored on impact and effort. The results of the impact-effort analysis were displayed in a matrix that differentiates potential solutions that have high impact and require low effort ("quick wins"), those with high impact but high effort ("major projects"), and those with low impact and high effort ("not worth doing").

4. Outcomes

The VSM visualized our current state, which involves 44 main processes that are divided into 13 process blocks across the trial activation process. The improvement ideas collected showed distinctive patterns in the suggestions submitted to the project team. Improvements in communication, training, and standard operating procedures (SOPs)/workflow made up more than 50 percent of all suggestions across the focus areas.

The impact-effort analysis of potential solutions for the activation checklist revealed eight "major projects" and three "quick wins" that will have a high impact on the time required to complete the activation checklist. The potential solutions categorized as "quick wins" were:

1. Creation of task lists per team for checklist processes
2. Weekly meetings with all teams involved in the checklist to discuss handoffs
3. Monthly meetings to increase awareness of responsibilities of each team member in the process

5. Lessons Learned and Future Directions

Sylvester plans to continue its process improvement efforts with the implementation of projects that are categorized as quick wins in the Impact-Effort Matrix. This implementation will use the Plan-Do-Check-Act approach to stimulate continuous improvement of trial activation processes with the goal of reducing trial activation time to a median of 90 calendar days.

View all abstracts and posters at **aaci-cancer.org/2022-abstracts**.

Improving trial activation timelines: A comprehensive process improvement project

Laura Thyssen, MBA, MS; Kelly Williams, BA, PMP; Philip A. Arlen, PhD
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

Problem Statement

Clinical trial activation at a matrix cancer center requires complex processes with multiple stakeholders. The median trial activation time in 2021 at Sylvester was 226 calendar days, which exceeds our target of 90 days. To achieve this goal, we examined the trial activation process using a Lean Six Sigma process improvement project.

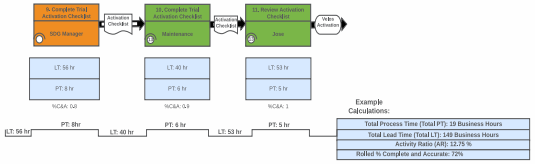
Goals

The overall goal is to reduce Sylvester's trial activation time to a median of fewer than 90 calendar days, which represents a 48% reduction from our 2021 median.

DEFINE: Current state

The deliverable was a value stream map (VSM), which provides a holistic view of our current state process by visualizing the movement of a trial from start to finish. The VSM depicted our current state, which involves 13 process blocks across the trial activation process.

Example: VSM Portion of Activation Checklist



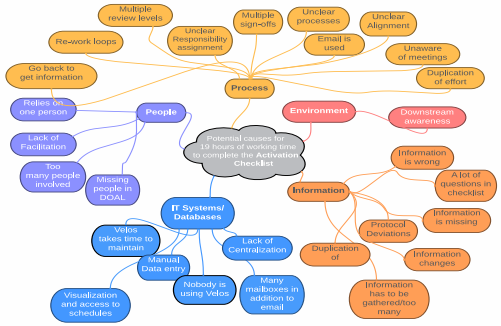
MEASURE: Baseline with timeline

Through an analysis of our current state performance metrics, we identified multiple focus areas for the root cause analysis (RCA) phase:

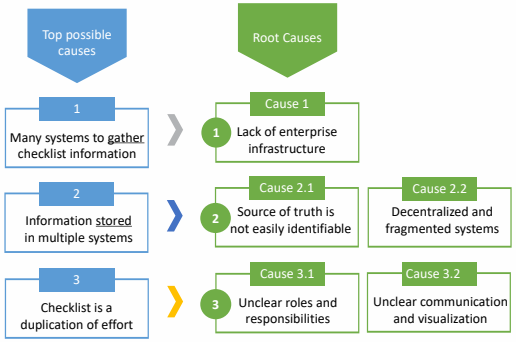
ANALYZE: Root cause analyses (RCA)

We met with subject matter experts (SMEs) to conduct the RCA and identify pain points. We used process improvement tools such as brainstorming, multi-voting, and the Five Whys to guide the SMEs through the analysis.

Example: Brainstorming – Activation Checklist



Example: Five Whys Root Causes – Activation Checklist



IMPROVE: Action plans

We collected 25 pages of improvement ideas from SMEs which equaled 179 individual ideas. These ideas showed distinctive patterns in the suggestions submitted to the project team. Improvements in communication, training, and standard operating procedures (SOPs) and workflows comprised more than 50% of all suggestions across the focus areas.

The root causes identified were used as a vehicle to collect improvement ideas, which were then analyzed and scored on impact and effort. The results of the impact-effort analysis were displayed in a matrix that differentiates potential solutions that have high impact and require low effort ("quick wins"), those with high impact but high effort ("major projects"), and those with low impact.

Example: Impact-Effort Matrix – Activation Checklist

PROPOSED PROJECTS

Category	Number in Matrix	Suggested Output	Score Impact - Effort
Quick Wins	9	Task list per team	9-4
Quick Wins	12	Weekly meeting with teams to discuss handoffs and progress	8-5
Quick Wins	8	Monthly meeting with teams to increase awareness of responsibilities and updates	7-5
Major projects	4	Velos as centralized system	9-10
Major projects	1	Centralized checklist that is divided by department	8-7
Major projects	3	Creating checklist in Velos status page	8-8
Major projects	13	Update workflow to include responsibility for status updates Input statuses and show workflow in OPERA	8-8
Major projects	14	Determine segment owners and keep accountable for information	8-7
Major projects	11	Verification of data in Velos	7-6
Major projects	10	Weekly training meetings on processes	7-7
Major projects	2	Checklist divided by timepoints in OPERA	6-7

CONTROL: Future Directions (PDCA)

Sylvester plans to continue its process improvement efforts with the implementation of projects that are categorized as quick wins in the Impact-Effort Matrix. This implementation will use the Plan-Do-Check-Act approach to stimulate continuous improvement and to reduce activation times to a median of 90 calendar days.

Implementation of a Feasibility Committee – University of Cincinnati Cancer Center (UCCC) Study Operations & Administrative Review (SOAR)

A. Kastl, M. Marcum
University of Cincinnati Cancer Center

1. Background

The University of Cincinnati Cancer Center (UCCC) clinical trials office (CTO) looked critically at the study start-up process, identifying several inefficiencies:

1) initiating the start-up process with an incomplete packet of information from the sponsor created re-work as new details arose
2) delays in the hospital ancillary services (investigational drug service pharmacy, radiology, lab/pathology) approval of protocols during the required hospital approval process
3) an assumption of site feasibility when site selection occurred

There was no committee critically looking at the operational requirements of each protocol early in the process. Late feasibility issues caused wasted time, effort, and resources.

2. Goals

Institute operational review of all new protocols that will be managed by the UCCC CTO without increasing time-to-activation. Evaluate the committee impact by measuring the time from site selection to receipt of full protocol packet inclusive of disease group review; decreasing the time required for ancillary hospital reviews during study activation process; and earlier determination of a protocol that should not move forward in start-up.

3. Solutions and Methods

SOAR Committee reviews all protocols utilizing UCCC CTO resources prior to scientific committee review. The committee meets weekly and is comprised of CTO staff, laboratory manager, infusion suite manager, pharmacy, radiology, pathology, inpatient manager, and others based upon the protocol. A complete protocol packet inclusive of the disease group review is required for a trial to be placed on the SOAR agenda. Reviews are recorded in a REDCap form designed to facilitate documentation of key information by committee members in advance, during, and for resolution after the meeting of any action items. Each study is reviewed for accrual period, adequate funding, operations support, laboratory needs, staffing, imaging/radiation safety review requirements, clinical/hospital integration and locations, and pharmacy requirements at a minimum. The REDCap form is provided to the scientific review committee, regulatory staff, coordinator staff, and budget staff to facilitate start-up operations.

4. Outcomes

After review of 128 new studies median time from site selection to receipt of a full packet for SOAR review is 12 days, inclusive of UCCC disease group review and approval.

There is no data to support a decrease in time required for ancillary hospital reviews, as the hospital approval process also requires IRB approval and fully executed clinical trial agreement.

A total of 14 studies were identified as not feasible to move forward early in the start-up process as a result of SOAR demonstrating valuable impact to institutional resources.

5. Lessons Learned and Future Directions

Although unable to show a decrease in hospital approval turnaround time as the result of improved efficiencies in the ancillary review, hospital ancillary services have embraced the improved workflow after the implementation of SOAR such that there are discussions to change the hospital approval process at the institutional level by integrating it into SOAR.

Large institutional changes in the trial activation process involving budgeting and contracting were instituted mid-year have impacted the ability to assess the true impact of SOAR on time to activation, so this goal metric will be evaluated in the future.

Implementation of a Feasibility Committee-
University of Cincinnati Cancer Center (UCCC) Study Operations & Administrative Review (SOAR)

Alison Kastl, BS, CCRC; Michelle Marcum, MS, CCRP University of Cincinnati Cancer Center (UCCC), Cincinnati, OH

Background of the problem:

UCCC CTO identified several inefficiencies in the study start up process:

1. Initiating the startup process with an incomplete packet of information from the sponsor created re-work as new details arose,
2. Delays in the hospital ancillary services (investigational drug service pharmacy, radiology, lab/pathology) approval of protocols during the required hospital approval process, and
3. An assumption of site feasibility when site selection occurred. There was no committee critically looking at the operational requirements of each protocol early in the process. Late feasibility issues caused wasted time, effort, and resources.

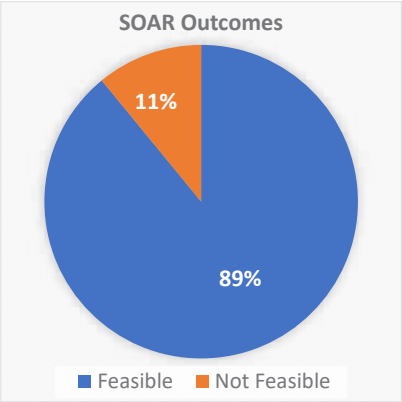
Metrics or goals to be achieved:

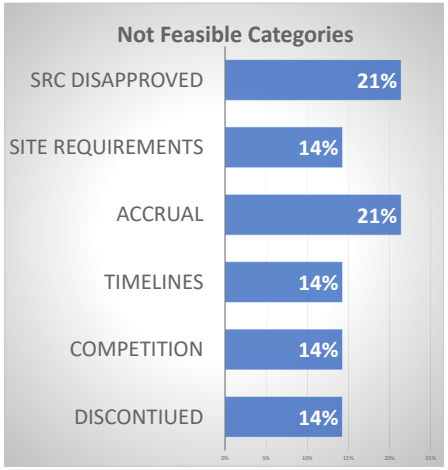
Institute operational review of all new protocols that will be managed by the UCCC CTO without increasing time-to-activation. Impact was measured by:

1. Measuring the time from site selection to receipt of full protocol packet inclusive of disease group review,
2. Decreasing the time required for ancillary hospital reviews during study activation process, and
3. Earlier determination of a protocol that should not move forward in start-up.

Solutions of methods implemented:

- SOAR Committee meets weekly to review all protocols utilizing UCCC CTO resources prior to scientific review
  - Comprised of several stake holders (e.g., CTO staff) based on protocol
- Complete protocol packet is required for a trial to be placed on the SOAR agenda





Solutions of methods implemented (cont'd):

- Reviews are recorded in a REDCap form designed to facilitate documentation of key information by committee members in advance, during, and for resolution after the meeting of any action items.
- Each study is reviewed for accrual period, adequate funding, operations support, laboratory needs, staffing, imaging/radiation safety review requirements, clinical/hospital integration and locations, and pharmacy requirements at a minimum.

Outcome:

- After review of 128 new studies median time from site selection to receipt of a full packet for SOAR review is 12 days, inclusive of disease group review and approval.
- There is no data to support a decrease in time required for ancillary hospital reviews, as the hospital approval process also requires IRB approval and fully executed clinical trial agreement.
- A total of 14 studies were identified as not feasible to move forward early in the start-up process as a result of SOAR demonstrating valuable impact to institutional resources.

Lessons Learned & Future Directions

- Ongoing discussions to change the hospital approval process at the institutional level to integrate it into SOAR.
- Large institutional changes in the trial activation process involving budgeting and contracting were instituted mid-year have impacted the ability to assess the true impact of SOAR on time to activation, so this goal metric will be evaluated in the future.

University of CINCINNATI CANCER CENTER

Value Stream Mapping: Maximizing Value, Minimizing Waste, and Improving Flow Across the Clinical Trial Activation Process

P. Arlen, L. Thyssen, K. Williams
Sylvester Comprehensive Cancer Center, University of Miami Health System

1. Background

Trial activation is an inherently complex process. At a matrix cancer center, this process is further complicated by the requisite participation of various institutional, administrative, and departmental representatives across the university, resulting in numerous inefficiencies and delays. In 2021, the median activation time at Sylvester was significantly more than our target of 90 calendar days. To address the discrepancy, we utilized Value Stream Maps (VSM), a Lean Six Sigma tool, that provides a holistic perspective of the workflow. VSMs enable strategic improvements, as opposed to tactical solutions, by depicting both macro and micro perspectives of process steps and information flow. We also expect to realize future process improvements to maximize value, minimize waste, and improve flow across the process.

2. Goals

We aim to reduce the median trial activation time to our target of 90 calendar days. To be successful, we needed to understand the current state by establishing a baseline with associated timeline. The VSM follows one industry-sponsored interventional treatment trial from the time the study is assigned to a PRMC meeting until it is open to accrual. Additionally, we used the VSM to identify current state metrics for each process step.

3. Solutions and Methods

A VSM provides a visualization of how work, products, and information flow through a system. The key components of our VSM are to focus on the principal investigators as our customer, link processes with information flow, document process performance, establish a common language, provide a blueprint for improvement, and engage stakeholders.

Through this process, we identified waste and bottlenecks, and analyzed data attributes specific to the VSM, including process time (time it takes to complete process tasks uninterrupted), lead time (time it takes to complete work including process time and delays), activity ratio (how quickly work flows through the process), percent complete and accurate (probability of a trial making it through the entire process without rework). Detailed metrics were collected for each process step to measure performance from an enterprise perspective. The map also depicts the software applications each process block interfaces with; whether they are being used to store data, input data, or produce outputs; and whether they communicate with each other.

4. Outcomes

We performed a bottleneck analysis of the current state VSM to identify waste in the process.

The macro perspective of our current state indicates that only 7.3 percent of our overall process is value-added activity. The map identified 13 applications required to complete the activation process.

Most processes involve manual information flow with a disproportionate use of email and Box communication.

The micro perspective revealed the following three focus areas that significantly impact the overall activation timeline:

1. Trial activation checklist: Most dedicated effort (19 business hours), with only one FTE dedicated to the step
2. Delegation log: Longest lead time of 321 business hours due to the number of signatures required
3. IRB submission: 100 percent of submissions must be reworked

5. Lessons Learned and Future Directions

Sylvester plans to continue its process improvement efforts for the focus areas by implementing projects to reduce waste and improve process flow.

Value Stream Mapping: Maximizing Value, Minimizing Waste, and Improving Flow Across the Clinical Trial Activation Process

Laura Thyssen, MBA, MS; Kelly Williams, BA, PMP; Philip A. Arlen, PhD
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

Problem Statement

Trial activation is an inherently complex process. At a matrix cancer center, this process is further complicated by the requisite participation of institutional, administrative, and departmental representatives across the University, resulting in numerous inefficiencies and delays. In 2021, the median activation time at Sylvester was significantly more than our target of 90 calendar days.

Goals

We aim to reduce the median trial activation time to our target of 90 calendar days. To be successful, we needed to understand the current state by establishing a baseline with associated timeline.

Methods

Value Stream Maps (VSM) enable strategic improvements, as opposed to tactical solutions, by depicting both **macro** and **micro** perspectives of process steps and information flow. The VSM follows one industry-sponsored interventional treatment trial from Protocol Review and Monitoring Committee (PRMC) Submission until activation.

The key components of our VSM are to focus on the Principal Investigator as our customer, link processes with information flow, document process performance, establish a common language, provide a blueprint for improvement, and engage stakeholders.

Detailed metrics were collected for each process step to measure performance from an enterprise perspective. The map also depicts the software applications each process block interfaces with; whether they are being used to store data, input data, or produce outputs; and whether they communicate with each other.

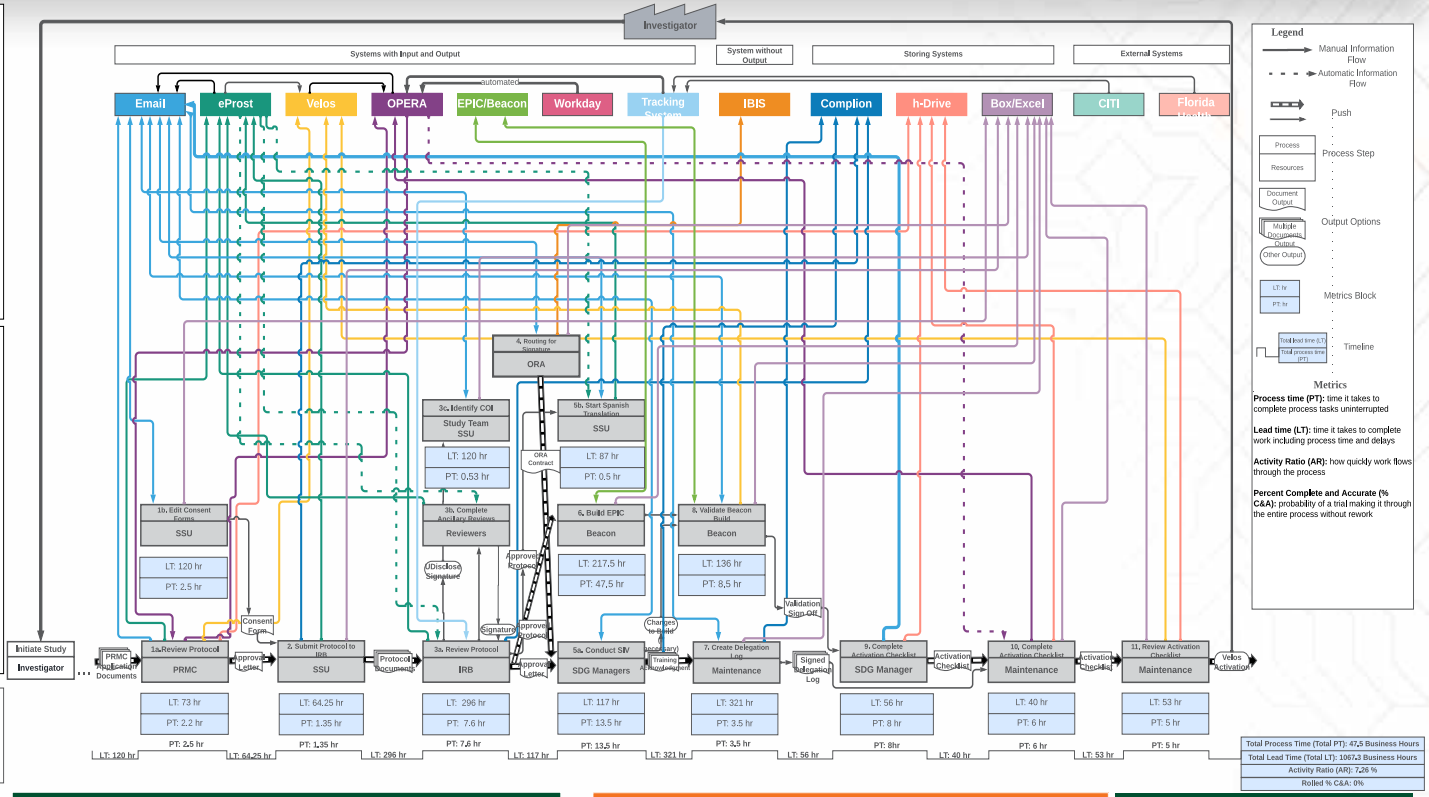
Analysis of Current State

Through the VSM, we identified waste and bottlenecks, and collected detailed metrics for each process step to measure performance from an enterprise perspective.

Information Flow

Product Flow

Timeline



Macro perspective

- Only **7.3%** of our overall process is value-added activity
- 0% Rolled % Complete and Accurate indicates that a trial must be reworked at one or more points in the workflow
- 13 different systems applications are required to complete the activation process
- Most processes involve manual information flow with a disproportionate use of email and Box communication

Micro perspective

- The focus areas with significant impact to the overall activation timeline were identified:
  1. **Activation checklist**: Most dedicated effort (19 business hours), with only one FTE dedicated to the step.
  2. **Delegation Log**: Longest lead time of 321 business hours due to the number of signatures required.
  3. **IRB submission:** 100% of submissions must be reworked.

Future Directions

Sylvester plans to continue its process improvement efforts for the focus areas by implementing projects to reduce waste and improve process flow.

Enhancing Transparency and Interoperability: Developing an Enterprise-Level Portal to Streamline Trial Activation Processes

P. Arlen, M. Santiago, K. Williams, L. Thyssen, G. Degennaro, A. Ward, N. Reyes, C. Valdivia
Sylvester Comprehensive Cancer Center, University of Miami Health System

1. Background

The protocol activation timeline is one of the most critical areas for process improvement at Sylvester Comprehensive Cancer Center (Sylvester). To accurately track metrics and identify roadblocks, we recognized the need for collaborating departments to communicate effectively and access data easily and efficiently. The many applications and various methods for collecting information (i.e., paper, digital, etc.) resulted in competing data sets and data islands; therefore, we sought a way to consolidate key dates and data in one easy-to-use portal. This study describes the process for developing and implementing this portal, the Operational Portal Enhancing Research Activities (OPERA), with the goal of capturing all steps within the clinical trial life cycle to provide transparency to research staff and faculty.

2. Goals

The implementation of OPERA was intended to integrate and automate the work packages comprising the protocol life cycle, creates a single "source of truth" that aggregates data from multiple systems, minimizes the number of physical/paper processes, helps visualize workflows and captures relevant data for understanding and managing workload and performance.

3. Solutions and Methods

OPERA was built to gather data from several independent data sources, both external and internal, as well as to capture supplemental data that align with Sylvester's operational requirements. Due to the scale and complexity of OPERA, and the current constraints on internal resources, the project work was implemented one milestone (module) at a time; prioritized by the sponsor; and delivered, through a hybrid-agile project management method. Each module was estimated to take about 48 business days to complete. Each module was treated as an individual project and adhered to the project life cycle/ resources available to support the project work.

4. Outcomes

- 100 percent of new studies have benchmark data to monitor progress toward achieving goals for trial activation
- More than 1,000 protocols have been captured in OPERA to date
- 323 accrual reviews and 519 amendments have been captured in OPERA in its first year of use
- Having the data electronically accessible in a single place has allowed for an easy transition to a remote work environment due to COVID-19

5. Lessons Learned and Future Directions

Iteratively adapting each module allowed for testing and drawing feedback before and after launch. With each newly implemented module, we made tweaks to help improve the process for the next iteration. As a result of the data collected, we have begun incorporating the data into dashboards and reports, enabling further improvements in protocol activation time and transparency. For the future of OPERA, to further enhance transparency and interoperability, the implementation of trial maintenance and closure components will be implemented.

Enhancing Transparency and Interoperability

Developing an Enterprise-Level Portal to Streamline Trial Activation Processes

Matthew Santiago, BS; Kelly Williams, PMP; Laura Thyssen, MBA, MS; Geoffrey Degennaro, MS; Alyssa Ward, BHSA; Niurbis Reyes, MS; Courtney Valdivia, BA; Philip A. Arlen, PhD
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 AND PURPOSE

The trial activation timeline is one of the most critical areas of process improvement at the University of Miami Sylvester Comprehensive Cancer. To accurately track metrics and identify roadblocks, we recognized the need for collaborating departments to communicate effectively and access data easily and efficiently. The use of many different applications (currently 25) and methods of data collection (e.g., paper, digital, etc.) creates competing dataset, inefficiency, and confusion. Therefore, we sought a way to consolidate key information points. We describe here the development and implementation of the Operational Portal Enhancing Research Activities (OPERA), with the goal of capturing all steps within the clinical trial life cycle to streamline efficiency and to enhance transparency to research staff and faculty.

METHODS

OPERA was developed to gather data from several independent data sources, both external and internal, as well as to capture supplemental data that align with Sylvester's operational requirements.

Due to the scale and complexity of OPERA, and current constraints on internal resources, the project work was implemented one milestone (module) at a time; prioritized by the sponsor; and delivered through a hybrid-agile project management method. Each module was estimated to take about 48 business days to complete and was treated as an individual project that adhered to the project life cycle/resources available to support the project work.

FUTURE DIRECTIONS

Enhance Inter*operab*ility: As OPERA development progresses to become a full-scale innovative solution to manage clinical trial activities, specific modules are being developed to integrate siloed data sources and workflows.

Improving *Operations*: Additional modules for credentials management, feasibility review, and Site Disease Group review will be completed by Q4 2022. Trial maintenance and closure components are also identified in our future state project plans.

Collaborative Tools. Operationalize data through visualization tools, such as dashboards and other business intelligence solutions, to ensure transparency and integrity of data across and within all stakeholders.

OUTCOME

100%
Of new studies have benchmark data to monitor progress toward time to activation goals

1,000
Protocols captured in OPERA to date

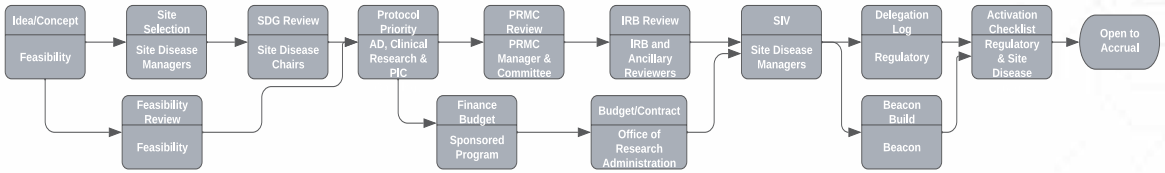
323
Accrual reviews captured in first year of use

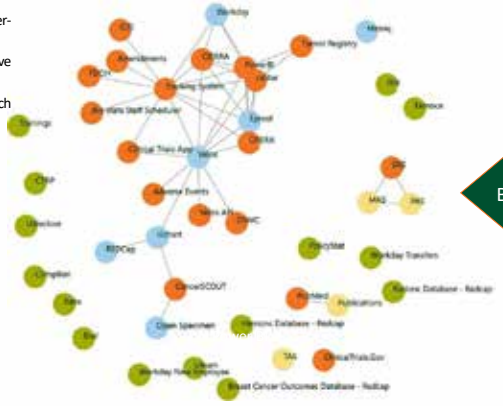
519
Protocol amendment reviews captured in first year of use

GOALS

- Standardize, centralize, and simplify data needs by improving data literacy
- Improve transparency by eliminating data silos
- Refine and improve Site Disease Group and feasibility reviews
- Incorporate initial study intake, credentials, and metrics tracking
- Provide access to tools to identify and aid low accruing clinical research protocols
- Streamline communication among inter-disciplinary departments
- Feature engineering to help predict and improve trial enrollment
- Provide access to potential clinical research protocols to our patients during intake
- Automate the protocol prioritization process

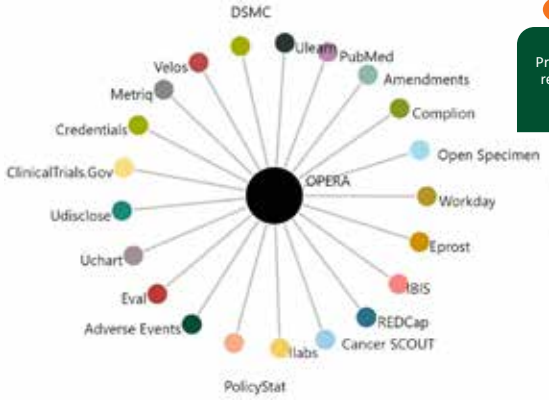
Clinical Trial Life Cycle





Before

After



PARTNERING IN PROGRESS

2022 ABSTRACTS

PARTNERING IN PROGRESS

CLINICAL TRIAL OPERATIONS

Solutions for Clinical Research Continuity During the COVID-19 Pandemic

N. Nahmias, J. Sanchez, A. Olier-Pino, A. Allred, K. Aviles, L. Corrales
Sylvester Comprehensive Cancer Center, University of Miami Health System

1. Background

At the beginning of the COVID-19 pandemic, clinical trial sites were forced to create new and innovative strategies to ensure continued compliance with study milestones. On March 17, 2020, all research staff at Sylvester Comprehensive Cancer Center (SCCC) clinical research services (CRS) began working remotely. The CRS quickly transitioned with the addition of twice weekly virtual meetings for each site disease group (SDG) to ensure the continuity of communication flow and patient care. SCCC and the University of Miami system adapted quickly with innovations to counter challenges posed by the pandemic, including shipment of oral medications, monitoring of staff safety and well-being, development of remote informed consent procedures, travel limitations, interruption of treatment, and transition to telehealth.

2. Goals

The goal of our team was continuity of care within clinical research. We had many subjects in the middle of treatment, and many that come from the local area as well as Latin America to obtain care.

3. Solutions and Methods

Disruption caused by the pandemic highlighted the importance of adaptation and flexibility in designing patient- and sponsor-friendly approaches in establishing sustainable trials, including COVID mitigation plans that were approved by the institutional review board (IRB). At the start of the pandemic, SCCC had approximately 275 active patients in clinical trials, with approximately 89 percent transitioned to telehealth visits to ensure continuity of care. Required lab monitoring was conducted through laboratories near patient homes to reduce exposure risk. Radiologic testing continued as required per protocol. Patients on oral drug regimens (112 subjects over 47 trials) received medication shipped to their homes per FDA, NCI, and sponsor-specific guidelines, reaching multiple countries including the United States, Russia, Brazil, and Argentina. A standard operating procedure (SOP) was implemented for conducting remote informed consent via videocall to limit subject onsite visits and quality of life (QoL) surveys were also performed remotely via standard mail.
With the support of our clinical research leadership, SCCC never fully closed enrollment during the pandemic and was able to continue enrolling and treating our subjects on clinical trials.

4. Outcomes

Promising advances that emerged include:

- Creating sponsor newsletter to address blanket study mitigations
- Establishing and communicating new in-home patient visit procedures
- Transitioning clinical trial activity to homecare models
- Creating managed access programs for medication pre-approval
- Accelerating cost effective therapies through the sharing and analysis of real time data

5. Lessons Learned and Future Directions

The pandemic has illustrated the need to have a complete remote environment with regards to clinical trial data. This has allowed us to continue our implementation of having research source documents uploaded to a separate section of the electronic medical record so that all data is housed for access remotely. We are also working with our research data group to ensure that we continue to develop our clinical trials management system to meet the needs for remote access.

Data Automation to CIBMTR

C. Thomas, R. Panchal, J. Konecny, T. Casali
Memorial Sloan Kettering Cancer Center

1. Background

Memorial Sloan Kettering (MSK) submits transplant-related outcomes data to the Center for International Blood and Marrow Transplant Research (CIBMTR). CIBMTR collects this outcome data for all allogeneic transplantation performed in the U.S. for the Stem Cell Therapeutic Outcomes Database (SCTOD), as required by U.S. law. U.S. transplant centers also voluntarily submit autologous transplantation data, and transplant centers worldwide voluntarily submit both autologous and allogeneic transplantation data. Typically, this data is collected using an online data capture system called FormsNet and is populated by manual entry by a site data manager. The completion of CIBMTR forms is a labor intense process and the MSK Adult Medicine and Pediatric BMT clinical research coordinators spend several hours extracting data from various EMR (Electronic Medical Record) forms and enter that data manually in CIBMTR. This process is inefficient, error prone, time consuming and is driven by a document-centric process. Additionally, several hours are dedicated to QA this manually entered data.

2. Goals

The goals of this project are to reduce site staff time for manual data entry and improve data quality. With the initial phase 1 release in December 2020, we automated the demographics submission that registers a patient with CIBMTR. In phase 2, which is currently in progress, we will be automating the submission of complete blood count with differential labs data (at transplant). Phase 3 will be automation of complete blood count with differential labs post-transplant and chemistry variables; in phase 4 we will add additional data elements to this automation.

3. Solutions and Methods

The data transformation initiative (DTI) aims at collecting data using a source-to-target approach: meet the data where it is as per the source environment. As part of the initial exploration, we determined where the source data was residing and how to identify the subset of data needed from that. Once the business rules and logic were determined to pull that data, we built an in-house application called BMTverse that serves as the user interface for the data transfer between MSK and CIBMTR. Data collected from various internal source systems are displayed in BMTverse and site data managers determine which patient demographics and/or labs should be submitted to CIBMTR.

4. Outcomes

Compared to pre-automation, the DTI process saves approximately 5 minutes per patient on demographics data submission. Twenty-two lab panel components are added to automation and these labs will be used to answer 273 questions across 28 forms in FormsNet, currently 190 of 273 form questions are ready for automation and we are in the process of sending pre-transplant data as part of the phase 1 initiative. The data automation has reduced the time they have to spent on data extraction and manual data entry.

5. Lessons Learned and Future Directions

Time required to complete CIBMTR forms included chart review, data extraction, data entry and clinical research coordinator data entry experience. The data automation initiative has already saved time and will continue to reduce this administrative data reporting burden tremendously as we acquire and automate more data submissions to CIBMTR.

Figure: *From 12/19/21-2/26/22 on patient demographics:*

Patient Type	Patients Sent	Data points Sent	CRC Time saved (Mins)
Adults	62	434	310
Peds	9	63	45

Memorial Sloan Kettering Cancer Alliance's Cancer Control and Population Science Subcommittee

S. Yoon
Memorial Sloan Kettering Cancer Center

1. Background

The Memorial Sloan Kettering (MSK) Cancer Alliance Cancer Control and Population Science (CCaPS) Subcommittee began as the Minimal Risk Task Force in early 2018 before being elevated to a formal subcommittee on January 1, 2020. The subcommittee was formed by MSK and the MSK Cancer Alliance partners Hartford Healthcare, Lehigh Valley Cancer Institute, and Miami Cancer Institute as an initiative to expand research activities beyond oncologic therapeutic clinical trials and to include population science research.

2. Goals

The subcommittee's goals and initiatives are to focus on the initiative to expand research activities beyond oncologic therapeutic clinical trials and to include population science research. The increase in study activity on population sciences and the number of shared publications is the metrics we would like to provide.

3. Solutions and Methods

The subcommittee is led by Allison Lipitz-Synderman, PhD, from MSK, and Andrew Salner, MD, from Hartford Healthcare, and is made up of representatives from each site and MSK research and administration staff. The subcommittee is tasked with facilitating collaborators across the MSK Cancer Alliances, supporting the development of new research ideas, facilitating the grant application process, streamlining the research protocol process, and tracking research collaborations.

4. Outcomes

In November 2020, the subcommittee issued its first ever request for applications designed to stimulate collaborative research involving diverse populations across academic and community oncology settings. During the first stage of submissions, 13 investigators submitted letters of intent. Out of the 13 letters of intent submitted, the grant award committee selected seven to proceed to full applications. Then, after a lengthy and rigorous review process, the committee announced that four proposals were selected for funding.

Furthermore, in 2021 the subcommittee had a total of 60 unique research collaborators covering all institutions, 20 grants submitted, and six projects opened, and is awaiting response on three peer-reviewed publications under review.

5. Lessons Learned and Future Directions

The subcommittee's future goals and initiatives are to focus on the execution of ongoing projects, involve patients from each site so they can provide feedback on ongoing work, participate in new diversity and equity research, and engage trainees and junior staff from each institution to facilitate ongoing studies and introduce them to population science research.

Microsoft Power Platform: Improving Efficiency, Communication, and Documentation in the Clinical Research Setting

M. Fritz, J. Plassmeyer, M. Horak, T. Cronauer (Horne), S. Perry, J. Griffo, D. Cleary
UPMC Hillman Cancer Center

1. Background

At UPMC Hillman Cancer Center (HCC) we've encountered barriers providing quality, complete, and accurate paper documentation. A significant portion of our documented source is paper based. A paper-based approach to documentation is associated with many drawbacks and unique challenges, which are usually observed during implementation and integration of new cancer research processes. The COVID-19 pandemic added an additional layer of complexity and fueled a call to action. This resulted in the facilitation of department wide process improvements. Throughout the pandemic, cancer centers nationwide have faced obstacles transitioning from office to remote work. This led to a decline in compliant source documentation effecting quality, maintenance, and completion of records. Paper documentation has numerous inefficiencies that include maintaining current versions of documents, duplication of staff effort, errors, storage, and the ability to obtain real time signatures.

2. Goals

In compliance with the U.S. Food and Drug Administration's (FDA) 21 CFR Part 11 regulations, our goal has been to transition into a fully electronic system. Surveys built through the Microsoft Power platform conveyed that moving into the electronic era was supported by many roles at HCC including coordinators, data managers, management, and investigators. As we continue to eliminate paper documentation and template correspondence, we hope to use this platform for the storage of a digital chart, eliminate the use of stored email templates, and improve compliance to research documentation.

3. Solutions and Methods

UPMC HCC utilizes low-cost software which vastly improved efficiency in our source documentation used for electronic adverse event (eAE) logs and subject scheduling processes. New eAE logs, implemented 03/2021, drastically reduced turnaround times related to investigator review and approval, and good clinical practice (GCP) related errors in documenting per our recent internal quality control actions. Development of a fully electronic scheduling application has shown improvement in compliance, while simultaneously decreasing staff associated time on task when compared to previous processes. These changes highlighted the importance of resource utilization in a time when staff satisfaction and retention were critical for maintaining operations. Furthermore, these improvements substantially reduce costs associated with paper use, while mutually benefiting our environment.

4. Outcomes

The implemented processes have shown to be effective, via staff feedback, at driving positive change in satisfaction, compliance, and ease of use. Process changes have created fewer errors in data entry, allowing staff to focus on other responsibilities or trial related tasks.

5. Lessons Learned and Future Directions

Electronic source is a big step in the right direction but has its fair share of challenges. Ensuring full compliance with FDA regulations and GCP documentation is a critical piece in the development process. In addition, learning new and complex software has opened many opportunities that can be utilized to improve clinical trial start-up, conduct, and closure moving forward. HCC has and will continue to investigate all available resources to drive advancement in this field. We plan to utilize the UPMC Center of Excellence, which ensures any department within the institution can learn and develop in the Power Platform. These are the first of many changes to come at UPMC HCC as we constantly strive for continuous process improvement to clinical trial operations.

Surveying Staff Satisfaction to Work Toward Improved Employee Retention

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UPMC Hillman Cancer Center

1. Background

The UPMC Hillman Cancer Center clinical research services (CRS) department supports oncologic clinical trials across 34 central and community network sites. Over 200 full time staff, working in clinical, fiscal, regulatory, operational, quality assurance, and managerial positions, make up the department. Central site staff are grouped by disease modality center (DMC), whereas community network staff work across all DMCs.

Not unlike other areas of health care, staff turnover within CRS has been exacerbated during the pandemic. Overall turnover in the department in 2021 was approximately 30 percent. A staff satisfaction survey was launched in spring 2022 to elucidate sources of staff enjoyment and stress within the department.

2. Goals

- Broad staff participation in survey completion with representation across community network sites and at least 60 percent staff completion rate
- Identify areas for improvement within the department, as well as understand what staff enjoy about their work to make positive changes in the department and ultimately stabilize retention

3. Solutions and Methods

- An anonymous staff survey with 13 Likert-scale, 2 open-ended, and 2 multiple-response questions was deployed to identify areas of employee satisfaction and dissatisfaction within CRS
- One question on staff locality (e.g., central site, Magee Womens Hospital, community network site) and one on duration of employment in CRS will allow for data interpretation from these two lenses
- Likert-scale questions (5-point scale, ranging from "disagree" to "agree") were centered around employee feelings of support and satisfaction in their role and in their disease center or community site; multiple-response questions varied based on how the employee responded to the duration of employment question, but covered themes such as training, enjoyable versus challenging aspects of CRS, and reasons for retention
- The survey was self-administered in SharePoint and will be opened bi-annually to identify trends between employment duration and satisfaction or dissatisfaction; survey redeployment will also allow leadership to track effectiveness of changes implemented towards making improvements in the department

4. Outcomes

Staff were provided a two-week window in which to complete the survey. Staff were very receptive to providing feedback and 80 percent of staff completed the survey. Preliminary results show staff enjoy being part of cutting-edge cancer research and having a flexible work schedule. Staff see opportunities for career growth and recognition for good performance as areas for improvement. Preliminary results show workload is a concern and 51 percent of staff feel overwhelmed in their roles.

5. Lessons Learned and Future Directions

This method of surveying staff was an effective way to get feedback and insight on employee satisfaction and workload. After results are analyzed, department leadership will present the findings, and staff-led working groups will be formed to generate ideas to enhance recognition and address other areas of improvement identified in the survey.

PARTNERING IN PROGRESS

QUALITY ASSURANCE, REMOTE MONITORING, AND AUDITING

Standardized Quality Metrics in Cancer Clinical Trials: A Qualitative Study

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1. Background

Cancer trials are lacking any universal metrics that are outside of study timelines and start-ups. It is difficult for a clinical trials office (CTO) to measure the safety and efficacy within the department. Finding how quickly a study was started or number of patient accruals is easy, however there is no universal data to show the safety of the study and the safety of the procedures behind the scenes in the CTO that support patient safety.

The general problem to be addressed is the lack of universalized quality and safety metrics for clinical trials cancer research (outside of study timelines) resulting in the inability for health care organizations to measure safety, performance, and improve expenditures.

2. Goals

Answer these questions:

1. Why is there a lack of measurable research metrics within cancer clinical trials outside of study timelines?
   a. What contributes to the lack of measurable research metrics?
   b. What actions could cancer clinical trials participate in to encourage measurable metrics outside of study timelines?
2. Why aren't there ways to measure a cancer clinical trials organization's achievement?
   a. What metrics can be measured to assess fiscal impacts on a CTO?
   b. What metrics can be measured to assess safety of a trial?
   c. What are the drivers for achievements within cancer research performance metrics?
3. What cultural elements are present in cancer research clinical trials that prevent collaboration and universalized standards?

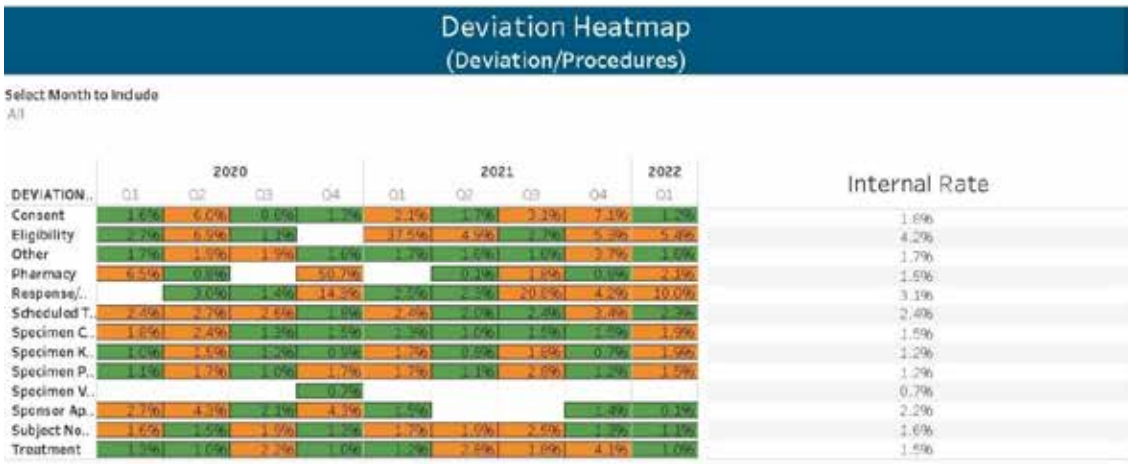
3. Solutions and Methods

We believe the qualitative design with a flexible rationale is the most appropriate method because the problem statement will be focused on qualitative research, (i.e., finding out why there aren't measurable research metrics in cancer clinical trials). When researching the "why" it will also be important to show what is available now. This will be a grounded theory, historical study, and action research study. With thorough data analysis and the theory of successful universal metrics in cancer research, followed by review of historical studies and the action of potential improvements.

4. Outcomes

We will use a heatmap that consists of a standard deviation between common categories in clinical trials to measure outcomes. This is a work in progress and more outcomes, benchmarks, key drivers, and categories will be added to encompass all the data we seek to gather. (See Figure.)

Figure



5. Lessons Learned and Future Directions

To understand why we don't have metrics already in place we need to know the history behind clinical trials (Jones et al., 2020; Walter et al., 2021).

To form the opinion of the importance of measurable metrics outside of clinical trial study timelines this question is important to build a foundation on the importance of measuring these (Smith et al., 2018). Being able to answer what metrics would measure safety and fiscal impacts and learning what drives these outcomes can help find where the implementation needs to begin (Walker et al., 2018).

Finally, it will be important to address the culture that is found within clinical trials.

PARTNERING IN PROGRESS

REGULATORY

Digitalizing and Automating Clinical Research Protocol Regulatory Binders for Greater Efficiencies

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1. Background

Management of onsite clinical research (CR) protocol regulatory binders and external stakeholder review is resource intense and inefficient. We describe the best practices in place at Memorial Sloan Kettering (MSK) since 2015 for electronic regulatory binder digitalization and subsequent 2019 automation of five key regulatory document types.

2. Goals

Our primary objective was to show the efficiency gains for automating five electronic regulatory (eReg) time and effort (TE) intense document types versus traditional paper-based manual methods

3. Solutions and Methods

Staff TE was assessed before and after automation. Two questionnaires were used to assess satisfaction with virtual eReg system performance for active external monitors, and with MSK research regulatory associates (RRA) who have responsibility for maintaining these digital files.

4. Outcomes

Annual RRA TE saved with automation was 609 hours per year (20 percent average decrease), and a reduction of manual processing across these five document types by 70 percent (mean 70 percent, standard deviation 39.7 percent, range 5-100 percent). Seventy percent of monitor survey respondents were satisfied with virtual access to the eReg binder application overall, with only 14 percent not satisfied, and 16 percent being neutral. RRA survey respondents noted their overall satisfaction with automation (84 percent) and would recommend that other sites set up their eReg binder in the same way (93 percent). Most users (77 percent) noted automation improved their ability to perform higher level regulatory tasks.

5. Lessons Learned and Future Directions

eReg automation allows for the more efficient use of RRA staff and monitor TE. Automation of regulatory binder paper-based processes saved staff significant TE that can be reallocated for higher level regulatory tasks.

Optimization of a Regulatory eBinder Platform

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1. Background

The Fred Hutchinson/University of Washington Cancer Consortium did not have an electronic solution to manage clinical trial regulatory files that met FDA Title 21 CFR Part 11 compliance. To increase standardization and efficiencies, and to support the compliant management of electronic clinical trial documents and workflows, the cancer consortium implemented a commercial electronic regulatory binder system, Florence eBinders. Initial rollout of eBinders was completed as a pilot with our Phase I program and was deployed across all disease groups in April of 2020.

Since implementation, we have created a dedicated support team and user group to optimize and expand system utilization, not only for regulatory, but for other functions such as subject management. These efforts have enabled us to realize the same efficiencies we've experienced in regulatory in other areas of clinical trial operations.

2. Goals

Goals achieved through dedicated resources and focused efforts to optimize the efficiencies, scope, and utilization of the eBinder system include the design and implementation of electronic subject data collection and study team documents, training, and communications management.

3. Solutions and Methods

A dedicated eBinder support team was created to build more system expertise, to provide more tailored training, and to increase study team engagement. A user group with diverse disease group representation was formed to provide input on process design, prioritization of new functionality, and feedback on newly implemented workflows. Collectively, the group has successfully designed, tested, implemented, and refined new eBinder functionality.

4. Outcomes

By developing a more robust eBinder support team and user group, we were able to pilot new uses of the system and provide teams with more defined "out-of-the-box" solutions. In addition, we were able to connect with individual disease teams to observe best practices of system use, refine, and roll out to the broader consortium.

By utilizing the electronic capabilities for data completion and signature collection, we were able to create a comprehensive, electronic subject data collection workflow within the system. Teams collect clinical data and signatures within the eBinder which are made available for efficient data abstraction and monitor review without additional scanning or certification steps. We have also leveraged the eBinder as a digital repository for study team documents such as team minutes, training, and safety reports, providing transparency and accessibility for all study team members regardless of time or location. Our site is in the process of developing eConsent workflows supported by the Florence system.

5. Lessons Learned and Future Directions

Having a dedicated team of subject matter experts who have space to collaborate with teams, design workflows and process documents, and act as guides for new ways to use the system, is critical to realize the value of an eBinder system beyond regulatory processes. We've continued to expand the scope of our goals for utilizing the system as a solution for compliant, standardized, and efficient processes that will continue to move us away from paper-based models.

Supporting Virtual Clinical Trials: How the Generation of DOAs in PIMS has Enabled Clinical Trial Compliance in a Remote World

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1. Background

There are various regulatory documents needed to be collected, approved, signed, and stored to open and continue research studies at Memorial Sloan Kettering (MSK). If regulatory standards are not upheld, this can cause delays, remediations with patients, and adverse consequences for sponsors and the institution. Some of these documents have been digitized and automatically maintained in an internal MSK platform called the protocol information management system (PIMS), but others require upkeep through paper and manual processes. We describe a continuation of this type of work done to one of these critical, paper documents, the study-specific delegation of authority (DOA) log.

All therapeutic and some non-therapeutic studies require a DOA. It details applicable staff, the specialized tasks each are given authority to do, and the timeframe in which each have these capabilities for a study. This log must be approved and signed by the principal investigator (PI) of a study before any research can be done and continually maintained during its lifecycle.

Previously, this was a manual process requiring staff to create the document offline, have PIs sign through a wet signature in person or through fax and email, and then upload into the PIMS eReg binder. This required ample attention, time, and effort to maintain compliance as staff reorganization is a frequent occurrence. This was further exacerbated due to the pandemic, solidifying the need to provide virtual means for log management.

2. Goals

1. Compliance
2. Time saved
3. Efficiencies

However, the ultimate goal is to allow resources to shift effort away from unnecessary procedures and towards patient care, while also increasing the overall ability for continued compliance.

3. Solutions and Methods

Created a workflow within PIMS that allows staff to initiate, manage, and store study specific DOAs, providing the ability to process everything electronically. The method follows the below:

1. Initiate DOA, pulling in staff based on the face sheet and those tied to the specific service
2. Update DOA details directly in tool, while system provides suggested inputs throughout
3. Send notice to PI to sign off on changes
4. After PI approval, eSignature automatically added, DOA document created, and stored in eReg binder

4. Outcomes

1. Standardized the DOA process across MSK for new studies
2. Removed the constraint on wet signatures, fax, email, and offline creation of documents by providing one coherent workflow within one tool.
3. Decreased time spent on DOA maintenance and increased overall efficiency

5. Lessons Learned and Future Directions

There are many pieces to ensuring that a study is compliant and maintained well. However, in an ever-changing world that is rapidly going virtual, there need to be better efficiencies to meet the demands of cancer research, offering in return more space for innovation and growth.

There are hopes to extend the functionality to retrospectively update all study specific DOAs for existing studies as well. As this is limited to only MSK studies, future enhancements are planned to allow externally generated studies and external users to also be maintained through this process. The overall roadmap would be to continue optimizing workflows and documents that follow inefficient, manual, and paper processes.

PARTNERING IN PROGRESS

TRIAL RECRUITMENT & COMMUNITY OUTREACH AND ENGAGEMENT

Improving Gender Diversity and Representation in Clinical Trials

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OHSU Knight Cancer Institute

1. Background

The language we use when we talk with people about their bodies and lifestyles can contribute to inequalities and harm for transgender, non-binary, and gender-diverse individuals and people on the sexual orientation spectrum. Using inclusive language reduces biases in clinical and research practices; without inclusive language and practices, we risk systemic inequality.

In 2021, an investigator submitted reportable new information (RNI) to the OHSU IRB: two subjects withdrew from a study because the study team used language "too heteronormative" that made the subjects uncomfortable. The study team initiated corrective and preventive actions. Data Safety and Monitoring Committee (DSMC) and Protocol Review and Monitoring System (PRMS) administrators in the Knight Cancer Institute (KCI) clinical trials office (CTO) investigated KCI-wide language use.

KCI pursues research that affects all individuals and communities. We want all individuals and communities in clinical research so that studies are ethical and equitable, and the data we generate are generalizable. DSMC and PRMS administrators unfortunately discovered that most KCI templates relied on binary sex classifications and non-inclusive language that failed our LGBTQIA+ population.

2. Goals

Our primary goal was to uncouple gender from sex and replace non-inclusive language with inclusive language in materials, templates, and interactions.

Specific goals:

- Eliminate sex-based, gendered, heteronormative, non-inclusive terms; replace with inclusive terms that respect sexual orientation and gender identity
- Detect and reduce biases in KCI research operations and interactions
- Champion inclusive language at KCI, in the medical system, and with governing agencies

A rapid assessment of site medical records shows that as of March 2022, of about 4,000,000 patients, about 3,800 identify as male, female, or unknown; of those, 2,591 identify gender as other than male/female.

3. Solutions and Methods

CTO programs implemented changes to avoid conflation of sex and gender and normalize inclusive language.

- PRMS:
  - Revised KCI consent form template to use inclusive terms (e.g., changed "women of child-bearing potential" to "person who can become pregnant")
  - At initial and subsequent reviews of study materials, identifying non-inclusive language and suggesting alternatives
- DSMC:
  - Including coaching on inclusive language in audits
  - Identifying non-inclusive language in study materials and suggesting alternatives
- Education & Onboarding:
  - Including principles of inclusive language in trainings
- Scientific Writing:
  - Updating all KCI protocol templates to use inclusive terms
- Informatics:
  - Evaluating data conventions
- Administration:
  - In public-facing materials, eliminating non-inclusive language (e.g., changing "Males and females" to "Individuals")
  - Normalizing use of pronouns in interactions

4. Outcomes

Outcomes have been positive with no reported resistance. Inclusive language enhances clinical research communications and operations.

5. Lessons Learned and Future Directions

Inclusive language is achievable. The KCI CTO implemented changes quickly and inexpensively. KCI will continue to prioritize diversity, equity, and inclusion (DEI) because it demonstrates integrity, compassion, and leadership. KCI's DEI work promotes a diverse and culturally competent workforce, embraces our responsibility to reduce health care disparities in our catchment area, and ensures that all are welcome in clinical research.

PARTNERING IN PROGRESS

TRIAL START-UP AND ACTIVATION

Collaboration to Develop Recommendations to Improve Trial Activation Timelines

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Huntsman Cancer Institute, University of Utah; The University of Kansas Cancer Center; Memorial Sloan Kettering Cancer Center; Mays Cancer Center at UT Health San Antonio MD Anderson; Robert H. Lurie Comprehensive Cancer Center of Northwestern University; AbbVie; Genentech; Janssen Oncology; Merck

1. Background

In July 2020, during the first months of the COVID-19 pandemic, the CRI steering committee met with the AACI Corporate Roundtable industry leaders to discuss mutual clinical research challenges. One topic of interest was trial activation timelines. In a 2018 survey developed by AACI for its members to use for benchmarking purposes, 61 AACI cancer centers reported the median trial activation time was 167 days, above the National Cancer Institute (NCI) benchmark of 90 days. Many delays result from stalled negotiations and a lack of communication responsiveness from both sides. The starting point for trial activation varies between sponsors and trial sites, and resources dedicated to industry-sponsored trials may vary based on cancer center priorities. However, both sites and sponsors agree that transparency in communication is key to trial activation; for example, when protocol amendments are available, the site should be aware of these to avoid delays in trial activation. AACI created the Trial Activation Task Force from this meeting's discussion.

2. Goals

During the pandemic, collaborations between industry and trial sites became a priority for sponsors and cancer centers to activate trials faster and minimize costly delays. Both agreed contract and budget negotiations were areas to target and develop expectations for both sides to avoid delays and improve communications to resolve any issues.

3. Solutions and Methods

In November 2020, the task force had its first meeting. The task force identified key areas in the activation process for improvement. After the initial meeting, we divided the task force into small groups to discuss:

a) Developing communications pathways and workflow maps
b) Determining the benefits of implementing a National Coverage Analysis (NCA) for industry-sponsored trials
c) Utilizing master trial agreements (MTA) to shorten contract negotiations
d) Educating industry on the requirements for academic cancer centers who have or are seeking NCI designation and the cancer center's protocol review and monitoring systems (PRMS) used to develop a trial prioritization

To develop recommendations, the task force was subdivided into three working groups (WG):

1) Streamline Contract Negotiations
2) Streamline Trial Site Activation Committee Reviews and Communications – "The Clock"
3) National Coverage Analysis

4. Outcomes

Each WG developed a charter to guide them in developing recommendations. Discussions, surveys, and polls were used to create the following suggestions:

1) Develop a process map outlining start-up workflows and staff contact information
2) Utilize study "kick-off" meetings to create expectations for trial activation
3) Encourage transparent communications and have an escalation process when negotiations are stalled
4) Make available all study information to truncate review timelines
5) Encourage MTAs to speed up negotiations and use the last budget negotiated as a starting point; provide CPT codes to assist in developing an accurate MCA
6) Develop master CDAs to eliminate unnecessary negotiation of a CDA for unwanted trials

5. Lessons Learned and Future Directions

Sites and industry share the frustrations with working together to activate trials, and transparency in communication and expectations builds relationships and collaboration.

Evaluation of a Prioritization Matrix for Electronic Order Build in an Investigational Drug Service

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1. Background

Investigational drug services (IDS) play an important role in safely and efficiently managing agents in clinical studies. However, in institutions with large research portfolios, it can be challenging to prioritize which studies to initiate and how to focus effort given finite resources. The implementation of drug orders in the electronic health record system was identified as a time-intensive process that could benefit from a prioritization schema. Currently, a comprehensive build involving physician and nursing communications, hold parameters, supportive care orders, and investigational drug orders is prepared before enrollment begins for all studies requiring on-site administration.

2. Goals

We sought to create standardized criteria for prioritizing studies that had the potential to justify abbreviated order builds. As a test of concept, the matrix was applied to a sample of recently initiated studies by the Michigan Medicine Research Pharmacy.

3. Solutions and Methods

A 2x2 matrix with study complexity on one axis and safety risk level on another was developed by the authors. The matrix sorted studies into three priority groups based on study characteristics. Each priority corresponded to the degree of order build that would be required prior to enrollment of the first subject. Priority 1 (high complexity, high safety risks) would require a comprehensive build; Priority 2 (mixed degrees of complexity and safety) would involve only a drug orderable; and Priority 3 (low complexity, low safety risks) would use a generic editable drug order template.

4. Outcomes

Twenty studies were included in the analysis (10 hematology/oncology and 10 non-hematology/oncology studies). Six studies were deemed to be Priority 1 and would have required a comprehensive build; of these, 4 were non-hematology/oncology protocols. Thirteen studies were categorized as Priority 2; of these, 8 were hematology/oncology studies and involved ISMP High-Alert Medications. Indeed, among the Priority 2 studies, high safety risks were more commonly the reason for an elevated priority than high study complexity. There was 1 study (a non-hematology/oncology protocol) that was scored as Priority 3.

5. Lessons Learned and Future Directions

Nearly all studies would require a degree of order build prior to first patient enrollment. Relying on just-in-time orders to reduce workload does not appear tenable given the low number of Priority 3 studies. Further, the downstream implications of creating an abbreviated build versus a comprehensive build must be considered (e.g., impact on nursing staff).

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