AACI CRI
Clinical Research Innovation

ADAPTING CLINICAL TRIALS OFFICES FOR 2021 AND BEYOND

2021 ABSTRACTS AND POSTERS

Table of Contents

ABSTRACTS AND POSTERS

Clinical Trial Operations

Finance/CCSG/PRMS

Investigator-Initiated Trials

Table of Contents

Regulatory

Training, Quality Assurance, Remote Monitoring, and Auditing

Trial Recruitment & Community Outreach and Engagement

Trial Start-up and Activation

ABSTRACTS

Clinical Trial Operations

Table of Contents

Finance/CCSG/PRMS

Investigator-Initiated Trials

Regulatory

Training, Quality Assurance, Remote Monitoring, and Auditing

Table of Contents

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* *Honorable Mention* *Digital Presentation*

13th Annual AACI CRI Meeting: Adapting Clinical Trials Offices for 2021 and Beyond

The emergence of COVID-19 has been an unprecedented learning experience and a catalyst for change at AACI cancer centers, particularly in the technology realm. From working off-site and learning new software to embracing innovations like remote monitoring and eConsent, clinical trials offices (CTOs) have adapted in remarkable ways, and most are considering continuing workplace innovations that have proven beneficial for staff and patients.

To share how they have learned to overcome the pandemic's challenges and improve CTO operations, more than 1,000 cancer center clinical trial leaders and other colleagues registered for the 13th Annual AACI Clinical Research Innovation (CRI) Annual Meeting.

Meeting attendees considered what technology and cancer center operations might look like post-COVID in a panel discussion titled "All the Things We Never Want to Give Up Post-COVID." For example, presenter Andrea Kukla reported on training and educational opportunities offered at Mayo Clinic Cancer Center, including ways to enhance workforce development through virtual learning, and the pros and cons of virtual education.

The pandemic also brought changes to this year's annual meeting format. With a full year to plan a virtual event (compared to last year's last-minute shift from in-person), the program expanded from two to three days. That allowed AACI to facilitate deeper discussions by offering 10 breakout sessions on the second and third days of the meeting. Topics in the first set of breakouts ranged from trial-focused challenges such as activation, prioritization, and multisite investigator-initiated trials, to staff retention and training, community outreach and engagement, and implementing the shared investigator platform.

In a breakout session about using research patients' experiences to improve clinical trial participation, the annual meeting's keynote speaker, Mary "Dicey" Scroggins, who has participated in many clinical trials, described the ways that trials have been presented to her by cancer center staff. She emphasized that health care workers should not expect patients and family members to find trials on their own, and patients should not be expected to be knowledgeable about trials. She urged a uniform approach to presenting trials to all patients. Scroggins also said that trials should aim to suit a patient's lifestyle, for example, by making it possible for a patient to maintain a school or work schedule by receiving treatments, scans, or lab work at convenient times, such as weekends or evenings.

The meeting's final day began with role-based breakout sessions that covered an array of director, manager, and staff positions, along with discussions targeting CTO tasks such as protocol review and monitoring; quality assurance and compliance; training; regulatory oversight; and trial coordination, finance, and administration.

This year, the popular session on the National Cancer Institute's (NCI) Cancer Center Support Grant (CCSG) program was presented in two parts. Part One featured Dr. Gisele Sarosy, NCI's associate director for informatics and biomarkers, and Dr. Henry Ciolino, director of NCI's Office of Cancer Centers. They provided updates on the clinical trials reporting program and revisions to the funding opportunity announcement, including the functions and impact of disease working groups, that took effect in 2020. In a lively Q&A session, Dr. Ciolino answered a question about centers reporting their own accruals for multisite institutional studies, emphasizing the value of NCI's Clinical Trials Reporting Program (CTRP), noting that it made it possible for NCI to recently gather and share particularly timely data that reflected COVID-19's negative impact on cancer clinical trials.

13th Annual AACI CRI Meeting:
Adapting Clinical Trials Offices for 2021 and Beyond

In Part Two of the CCSG session, colleagues from the University of Virginia Cancer Center; The Ohio State University Comprehensive Cancer Center - James Cancer Hospital and Solove Research Institute; and Simmons Comprehensive Cancer Center, UT Southwestern Medical Center, discussed their recent virtual NCI site visits and ways to demonstrate the value of the clinical trials enterprise to the parent institution.

Another standing feature of the meeting, poster and abstract presentations, attracted 62 submissions this year from 27 cancer centers. The three winning abstracts, selected by the CRI Steering Committee and CRI Education Committee, were submitted by authors representing the University of Cincinnati Cancer Center, University of Florida Health Cancer Center, and Vanderbilt-Ingram Cancer Center.

Of course, the CRI annual meeting would not have been possible without corporate support. Exhibitors and other supporters engaged with attendees through virtual booths on the meeting website and through presentations that addressed the unique challenges of remote work and provided an overview of the services that vendors can offer to improve CTO operations.
In its second year as a virtual event, the CRI meeting once again highlighted the ingenuity of AACI cancer centers, which continue to find new and effective ways to collaborate.

AACI CRI 2021 Steering Committee

Chair - Theresa L. Werner, MD
Huntsman Cancer Institute, University of Utah

Tiffany Colvin, CCRC
University of Colorado Cancer Center

Thomas J. George, Jr., MD, FACP
University of Florida Health Cancer Center

Janie Hofacker, RN, BSN, MS
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Yale Cancer Center, Yale School of Medicine

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Mays Cancer Center at UT Health San Antonio MD Anderson

Bhanu Pappu, PhD, MHA
UPMC Hillman Cancer Center

Michael Sainz
Dartmouth-Hitchcock Norris Cotton Cancer Center

Anne Schnatterly, MBA, BSN, RN, CCRP
WVU Cancer Institute


CLINICAL TRIAL OPERATIONS

Cross-Modality Reconciliation for Management and Reporting of All Cancer-Related Clinical Research Data

C. Serway, E.D. Merchasin, R.C. Compton, U. Brown-Glaberman, C.Y. Muller
University of New Mexico Comprehensive Cancer Center

1. Background

The University of New Mexico Comprehensive Cancer Center Clinical Research Office has undertaken process improvements to optimize data capture, management, and reporting across all cancer related clinical research driven by the center sites. The expanded National Cancer Institute (NCI) reporting requirements and growth of our community engagement and participation in non-treatment intervention and non-intervention trials required creative solutions to ensure the highest level of data accuracy, and complete data capture. Here we describe the needed process changes and how our innovation and persistence led to significant improvements in data management of all cancer-related research.

2. Goals

To meet these challenges, we aimed to:

- Develop a process to identify and manage data from cancer related clinical research studies performed by Cancer Center Program members
- Perform comprehensive trial and accrual data reconciliations between all data sources—Clinical Trials Management System (CTMS), Clinical Trials Reporting Program (CTRP) and manual data feeds—quarterly
- Be prepared to meet upcoming CTRP non-interventional trial and accrual registration requirements
- Broaden operational reporting to include comprehensive demographics for participant accruals where appropriate

3. Solutions and Methods

For active trials not housed in our CTMS (Velos), we coordinated with Cancer Center Program leaders to manually collect trial and accrual data quarterly from each member. This was expanded beyond trial and accrual data to include composite demographic data per trial. We performed direct comparisons of CTRP/STRAP DT4 reports with hybrid DT4 report (CTMS and manual data) and did categorical comparisons to ID discrepancies across all DT4 fields. We facilitated reconciliation meetings with quality assurance and operations managers to review all discrepancies and ensure accuracy of proposed data corrections. Data discrepancies within the composite report (CTMS, CTRP, CTEP, and Sponsor), were resolved and new Population Sciences Interventional trials were registered in CTRP. Data was compiled in formats used for Cancer Center Support Grant (CCSG) progress reports and submissions (DT4, Clinical Protocol Data Management [CPDM]), with newly developed minority accrual monitoring templates.

4. Outcomes

Field by field comparisons identified the need for a great deal of data clean-up across systems, which now happens in real time as part of our reconciliation process. With our collaborative engagement of population sciences principal investigators and program leaders, we can now ensure accurate data reporting. We now track trials categorically across all cancer center members' departments in accordance with NCI guidelines. Newly developed comprehensive demographics tables are now used to monitor minority accruals spanning all cancer center member research.

5. Lessons Learned

Cross-system reconciliation is critical to ensure data accuracy locally and nationally. Engagement of clinical leadership was invaluable to ensure we remained aligned with CCSG reporting needs and clinical data accuracy always maintained. Leadership review of improved data capture is used to evaluate trail fit and impact within the catchment area. We plan to:

- Develop automated feeds of manual data into our CTMS as needed
- Automate all CCSG reporting using new visualization/analytics software
- Apply lessons learned to newly developing Population Sciences Clinical Working Group

Cross modality reconciliation for management and reporting of all cancer related clinical research data

Christine N. Serway, PhD [1]; Emily D. Merchasin, MS [1]; Richard C. Compton [1]; Ursa Brown-Glaberman, MD [1,2]; Carolyn Y. Muller, MD [1,3]

The University of New Mexico Comprehensive Cancer Center [1], Department of Internal Medicine, Division of Gynecology Oncology [2], Department of Internal Medicine Division of Hematology Oncology [3]

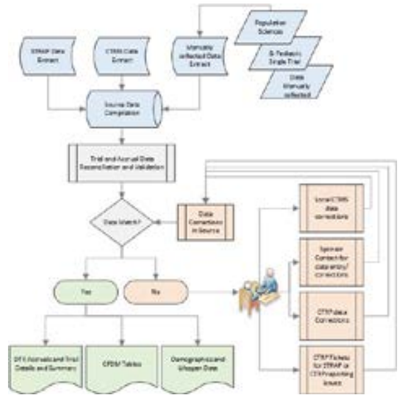
Background:

The University of New Mexico Comprehensive Cancer Center Clinical Research Office has undertaken process improvements to optimize data capture, management, and reporting across all cancer related clinical research driven by the Center sites. The expanded NCI reporting requirements and growth of our community engagement and participation in non-treatment intervention and non-intervention trials required creative solutions to ensure the highest level of data accuracy, and complete data capture. Here we describe the needed process changes and how our innovation and persistence led to significant improvements in data management of all cancer related research.

Goals:

To meet these challenges we aimed to:

- Develop a process to identify and manage data from cancer related clinical research studies performed by Cancer Center Program members.
- Perform comprehensive trial and accrual data reconciliations between all data sources (Clinical Trials Management System (CTMS), Clinical Trials Reporting Program (CTRP) and manual data feeds) quarterly.
- Be prepared to meet upcoming CTRP Non-Interventional trial and accrual registration requirements.
- Broaden operational reporting to include comprehensive demographics for participant accruals where appropriate.



Lessons Learned & Future directions:

- Cross system reconciliation is critical to ensure data accuracy locally and nationally.
- Engagement of clinical leadership was invaluable to ensure we remained aligned with CCSG reporting needs and clinical data accuracy always maintained.
- Leadership review of improved data capture is used to evaluate trail fit and impact within the catchment area.
- We plan to:
  - Develop automated feeds of manual data into our CTMS as needed
  - Automate all CCSG reporting using new visualization / analytics software.
  - Apply lessons learned to newly developing Population Sciences Clinical Working Group.

Solutions:

- For active trials not housed in our CTMS (Velos), we coordinated with Cancer Center Program leaders to manually collect trial and accrual data quarterly from each member. This was expanded beyond trial and accrual data to include composite demographic data per trial.
- We performed direct comparisons of CTRP/STRAP DT4 reports with hybrid DT4 report (CTMS and manual data) and did categorical comparisons to ID discrepancies across all DT4 fields.
- We facilitated reconciliation meetings with Quality Assurance and Operations Managers to review all discrepancies and ensure accuracy of proposed data corrections.
- Data discrepancies within the composite report (CTMS, CTRP, CTEP and Sponsor), were resolved and new Population Sciences Interventional trials were registered in CTRP.
- Data was compiled in formats used for CCSG progress reports and submissions (DT4, Clinical Protocol Data Management (CPDM)), with newly developed minority accrual monitoring templates.

Outcomes:

- Field by field comparisons identified the need for a great deal of data clean up across systems, which now happens in real time as part of our reconciliation process.
- With our collaborative engagement of Population Sciences PIs and Program Leaders, we can now ensure accurate data reporting.
- We now track trials categorically across all Cancer Center Member's departments in accordance with NCI guidelines.
- Newly developed comprehensive demographics tables are now used to monitor minority accruals spanning all Cancer Center member research.

Harness the Power of Automation for Clinical Research Management

D. Wilson, R. Kingsford, L. Hayes, J. Moehle, T. Werner
Huntsman Cancer Institute, University of Utah

1. Background

Managing a successful clinical trials office (CTO) requires leveraging data for various reasons including reporting to the National Cancer Institute, grants, tracking accrual, patient safety such as re-consent, and portfolio management. Data is spread across many systems and is entered by many users. Real-time and accessible data is essential for efficient and effective management of the clinical research enterprise. Quality control measures must be in place to ensure the accuracy of the data. The Huntsman Cancer Institute (HCI) CTO has 13 separate clinical trials research groups, 454 active interventional treatment trials, and 282 individual users actively entering data. Automating reports and safety checks ensures that the data entered is constantly being monitored and that reports are readily available with the most accurate and up-to-date information; and creates efficiency and availability from strained resources.

2. Goals

The HCI CTO's four primary goals of automating reports and quality checks are:

1. Provide our investigators and CTO leadership the ability to access presentable and up-to-date data for their trials and patients instantly
2. Increase the efficiency of the quality assurance and oversight processes
3. Provide coordination staff with automated emails to monitor patients/trials they are managing
4. Free up strained resources within our business systems team

3. Solutions and Methods

To accomplish these goals, several software platforms are used, including SQL Management Studio, SQL Developer, JasperSoft, SQL Server Reporting Services, and OnCore.

1. Analyze the desired output and data
2. Determine if automation is the right fit
3. Identify tools and level of automation required such as lists, graphs, system-generated emails, etc.
4. Develop code to be as fluid as possible to account for variable changes
5. Test and make enhancements as they are requested

4. Outcomes

The HCI CTO System Administrator automated 66 individual reports containing charts and graphs. Previous to automation, this required 11.6 hours of work. After automation, this can be completed in 16 minutes and is done weekly rather than ad hoc. These reports can also be run at any point using a web link. The leadership in each research group utilizes this to prepare for monthly meetings and provide metrics to investigators whenever requested. Key data points are monitored weekly for all patients and trials in our systems for quality assurance. An average of 1,411 new patients and 269 new protocols are entered yearly. Automated reports were created to ensure that all associated data points are accurate. Patient and protocol records are reviewed weekly and automatic emails are sent to the responsible users with a list of errors. This has led to improved data quality. Automating the creation of routine reports has greatly increased efficiency in business systems operations.

5. Lessons Learned

We have noted that it is not possible to automate some reports due to complexity of the data and desired format. Software has the possibility of adjusting the name/structure of the database, which can lead to required code adjustments. We plan to continue to expand our reports to further cover additional areas of interest and get rid of the need for any manual oversight.

View all abstracts and posters at **aaci-cancer.org/2021-abstracts**.

Harness the Power of Automation for Clinical Research Management

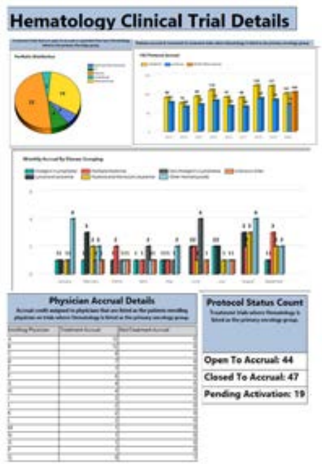
Dalton Wilson, BS; Rachel Kingsford, MS, CCRP; Laura Hayes, BS, CCRC; Jessica Moehle, BS, CCRP; Theresa L. Werner, MD

BACKGROUND

Managing a successful Clinical Trials Office requires leveraging data for various reasons including reporting to the National Cancer Institute, writing grants, tracking accrual, patient safety concerns such as re-consent, and portfolio management. Data is spread across many systems and is entered by many different users. Real-time and easily accessible data is essential for efficient and effective management of all areas of the clinical research enterprise. Robust quality control measures must be in place to ensure the accuracy of the data. The Huntsman Cancer Institute (HCI) Clinical Trials Office (CTO) has 13 separate clinical trials research groups, 454 active interventional treatment trials, and 282 individual users actively entering data. Resources for management and oversight in this area are consistently strained. Automating reports and safety checks ensures that the data entered is constantly being monitored, that reports are readily available with the most accurate and up-to-date information, and creates efficiency and availability from strained resources.

GOALS

- Provide our investigators and CTO leadership the ability to access presentable and up-to-date data for their trials and patients instantly;
- Increase the efficiency of the quality assurance and oversight processes;
- Provide coordination staff with automated emails to monitor patients/trials they are managing;
- Free up strained resources within our business systems team.



RESULTS

- 66 individual reports containing charts and graphs created.
- Key data points are monitored weekly for all patients and trials in our system.
- Automating reports and safety checks reduced the work load required by 98%.
- Data quality and efficiency in business systems operations have greatly increased.

CONCLUSIONS

We have noted that it is not possible to automate some reports due to complexity of the data and desired format. Software has the possibility of adjusting the name/structure of the database, which can lead to required code adjustments.

FUTURE PLANS

We plan to continue to expand our reports to further cover additional areas of interest and get rid of the need for any manual oversite.

A Quality Connection… An Enhanced Leadership Structure Through the Implementation of a Project Administrator

L. Lujan, S. Sharry, R. Kingsford, J. Moehle
Huntsman Cancer Institute, University of Utah

1. Background

Continued growth and increased trial complexity in clinical research portfolios require regular staffing assessments to ensure appropriate management and quality oversight of daily operations. At Huntsman Cancer Institute (HCI), we have disease-oriented clinical trial research groups (CTRGs) with six program managers (PMs) who are tasked to oversee each of these areas. In addition to increased enrollment and trials growing in complexity and volume, we have also experienced an influx of new faculty with clinical trial interests, all adding to the workload of the PM and leadership team. If left unchecked, this can present an increased threat of disconnect between day-to-day operations of our coordination teams and our clinical trials office (CTO) administrative leaders and investigators as well as the potential to negatively impact the quality and compliant manner in which clinical research should be conducted. Furthermore, without adequate oversight and support for our study teams, training and mentoring in disease-specific areas can suffer and workload can become more burdensome leading to threatened quality, decreased job satisfaction, and added turnover.

2. Goals

- Fully implement restructure of leadership team with addition of project administrators (PAs) to serve as a supportive link between CTO leadership, investigators, Huntsman Cancer Hospital/clinic staff, and the coordination teams
- Achieve positive audit/monitoring outcomes while fostering a proactive vs. reactive work environment
- Strengthen disease-specific training and mentoring to ensure appropriate level of staff competency and confidence in support of quality assurance program
- Provide resources for more seamless coverage and transition plans within the team to help balance workload
- Continue to provide added opportunities for professional growth and development, increased job satisfaction, and reduced turnover
- Improve overall quality of research conducted at HCI

3. Solutions and Methods

As full-time equivalents are approved, PAs will be strategically added to strengthen the leadership structure. To date, PAs have been added to support five of the six CTRGs, trial activation efforts, satellite site operations, CTO laboratory operations, and a liaison for our complex Phase I clinical trials.

4. Outcomes

Senior staff are most frequently promoted into the PA role. As such, this has created increased promotional opportunity and ability to retain more senior, experienced staff. To date, CTO leaders have noted improved communication; enhanced education through extended training and mentoring; improved audit and monitoring outcomes; and more seamless transition of trial assignments due to turnover or job reassignment. Trial activation has become more streamlined, consistent, and efficient, and improvements have been seen in satellite site operations laying the groundwork for increased accrual and trial activation. A more refined PA focus in our Phase I experimental therapeutics group has helped to increase communication and education with internal and external community providers, and patients and their families to navigate the increasing number of molecularly targeted therapies and cellular immunotherapy trials.

5. Lessons Learned

- Work to further define most appropriately balanced workload at the leadership level to support coordination efforts
- Implement process to ensure balance in portfolio and coordination workload is regularly assessed
- Continue to define and implement future measurements of increased staff competency and job satisfaction

A Quality Connection … An enhanced leadership structure through the implementation of a Project Administrator

Leanne Lujan, BS, CCRP; Susan Sharry, BS, CCRP; Rachel Kingsford, MS, CCRP; Jessica Moehle BS, CCRP

BACKGROUND

Continued growth and increasing enrollment along with added trial complexity in clinical research portfolios requires flexibility in organizational structure to ensure appropriate management and quality oversight of daily operations.

At Huntsman Cancer Institute (HCI), we have disease-oriented clinical trial research groups (CTRGs), each with an assigned program manager (PM) tasked to oversee each of these areas. In addition to the growth in enrollment, portfolios and complexity of trials, we have also experienced an influx of new faculty with clinical trial interests, all adding to the workload of the PM and leadership team.

If left unchecked, this can present an increased threat of disconnect between day-to-day operations of our coordination teams and our Clinical Trials Office (CTO) administrative leaders and investigators as well as the potential to negatively impact the quality and compliant manner in which clinical research should be conducted.

Furthermore, without adequate oversight and support for our study teams, training and mentoring in disease specific areas can suffer and workload can become more burdensome leading to threatened quality, decreased job satisfaction, and added turnover.

METHOD

- Fully implement restructure of leadership team with addition of project administrators (PAs) to serve as a supportive link between CTO leadership, coordination teams, investigators, Huntsman Cancer Hospital/clinic staff, and our sponsors and CROs.
- Continue to provide added opportunities for professional growth and development, increased job satisfaction, and reduced turnover

RESULTS

- Senior staff are most frequently promoted into the PA role. These added promotional opportunities have allowed us to retain our more senior, experienced staff for longer periods of time
- We have seen improved communication between our coordination teams and the ancillary groups working both internally at our cancer center as well as externally with our sponsors and CROs
- Strengthen disease-specific training and mentoring to ensure appropriate level of staff competency and confidence in support of quality assurance program
- Improved audit and monitoring outcomes.
- More seamless transition of trial assignments due to turnover or job reassignment

RESULTS(CON'T)

- Provide resources for more seamless coverage and transition plans within the team to help balance workload
- Improved efficiency in trial activation.
- A more refined PA focus in our Phase I experimental therapeutics group has helped to
- Improved communication and education with community providers, patients and their families to help navigate the increasing number of molecularly targeted therapies and cellular immunotherapy trials.

CONCLUSIONS

As FTEs are approved, PAs will be strategically be added to strengthen the leadership structure. To date, PAs have been added to support five of our six CTRGs, trial activation efforts, satellite site operations, CTO laboratory operations, and a liaison for our complex phase I clinical trials.

FUTURE PLANS

- Work to further define most appropriately balanced workload at the leadership level to support coordination efforts.
- Implement process to ensure balance in portfolio and coordination workload is regularly assessed.
- Continue to define and implement future measurements of increased staff competency and job satisfaction.
- Improve overall quality of research conducted at HCI

Smooth Sailing... Cellular Immunotherapy Trials Collaboration and Integration Process

S. Sharry, C. Cromar, K. Hicks, L. Lujan, J. Moehle, K. Pena
Huntsman Cancer Institute, University of Utah

1. Background

With the rapid increase in the number of cellular immunotherapy trials in the solid tumor and hematology areas at our institute, an apparent need was identified for a new operational process involving the clinical trials office, hospital/, and cell therapy groups. Cellular immunotherapy trials involve CAR T, TIL, BITE, and TCR cell therapies. These cellular immunotherapy trials involve new complex science concepts and procedures that presented logistical challenges and the increased need for communication and planning on each new trial. Responsibilities were not clearly defined; training, education, and effective communication between all areas were lacking formality, and focused improvements for these types of trials in particular were necessary. In comparison to the Huntsman Cancer Hospital (HCH) outpatient clinic staff, the HCH inpatient staff assignments rotate throughout the day/night and due to various health care providers, communication, education, and cross-training of key personnel was critical to ensure patient safety and trial compliance.

2. Goals

- Provide education on departmental operational processes to the clinical trials office, hospital/ clinic, and cell therapy groups
- Integrate current workflows between the clinical trials office and the hospital/clinic managers to enable seamless patient care while adhering to the complex protocol requirements

3. Solutions and Methods

- Monthly clinical trials office cellular immunotherapy-focused meetings are held with clinical trials office and hospital/clinic management to discuss updates on upcoming and active trials, issues, positive outcomes, and trends.
- Development of a trial-specific cellular immunotherapy tracking spreadsheet used by all committee members in Microsoft Teams was especially useful during the COVID pandemic for excellent communication between groups.
- Clinical logistics meetings were implemented to be held prior to a site initiation visit and attended by principal investigator, investigators, hospital, clinical research, and cell therapy groups.
- Trial-specific nursing instructions, fast fact sheets on the protocol, and contact information are provided pre-site initiation visit.
- Training of clinical trials office clinical research coordinators and clinic nurses on the new process was implemented.
- Inpatient management identified a skilled and focused nursing team to treat and care for clinical research immunotherapy trial patients with ongoing training provided.
- A proactive and constant theme was promoted across groups for clinical trial patients' safety.

4. Outcomes

- There is now a much better understanding of what challenges each group faces, while also seeing a more cohesive, collaborative, and unified environment between all areas that care for patients enrolled to these complex treatment trials.
- The process is seamless and meeting regularly alleviates potential issues from growing into a problem due to the regular and consistent communication between meeting members.
- Cross training of staff continues and having an operational system solidified helps new staff know their role and responsibilities.
- Hospital administration will create the new position of inpatient/clinical research nurse liaison to help facilitate the operational processes on both sides.

5. Lessons Learned

- Analyze deviation trends pre- and post-process implementation
- Develop a survey for contributors to measure process improvement and communication
- Evaluate EMR Report and Learn system trends since process implementation

Smooth Sailing... Cellular Immunotherapy Trials Collaboration and Integration Process

Susan Sharry, BS, CCRP, Catherine Cromar, BS, Leanne Lujan, BS, CCRP, Jessica Moehle, BS, CCRP, and Karen Pena, CCRP

BACKGROUND

With the rapid increase in the number of cellular immunotherapy trials in the solid tumor and hematology areas at our institute, an apparent need was identified for a new operational process involving the clinical trials office, hospital/clinic and cell therapy groups.

Cellular Immunotherapy Trials involve CAR-T, TIL, BITE and TCR cell therapies. These cellular immunotherapy trials involve new complex science concepts and procedures that presented logistical challenges and the increased need for communication and planning on each new trial. Responsibilities were not clearly defined and training, education and effective communication between all areas were lacking formality and focused improvements for these types of trials in particular were necessary.

In comparison to the Huntsman Cancer Hospital (HCH) outpatient clinic staff, the HCH inpatient staff assignments rotate throughout the day/night and due to various health care providers, communication, education, and cross-training of key personnel was critical to ensure patient safety and trial compliance.

METHOD

- Provide education on departmental operational processes to the clinical trials office, hospital/clinic and cell therapy groups.
- Integrate current workflows between the clinical trials office and the hospital/clinic managers to enable seamless patient care while adhering to the complex protocol requirements.

RESULTS

- Monthly Clinical Trials Office Cellular Immunotherapy focused meetings with clinical trials office and hospital/clinic management to discuss updates on upcoming and active trials, issues, positive outcomes and trends.
- Development of a trial specific cellular immunotherapy tracking spreadsheet used by all committee members in Microsoft Teams was especially useful during the COVID pandemic for excellent communication between groups.
- Clinical logistics meetings were implemented to be held prior to a Site Initiation Visit and attended by PI, investigators, hospital, clinical research and cell therapy groups.
- Trial specific nursing instructions, Fast Fact Sheets on the protocol and contact information are provided pre-Site Initiation Visit.
- Training of clinical trials office Clinical Research Coordinators and clinic nurses on the new process implemented.
- Inpatient management identified a skilled and focused nursing team to treat and care for the clinical research immunotherapy trial patients with ongoing training provided.
- Promote a proactive and constant theme across groups for our clinical trial patients' safety.

CONCLUSIONS

- There is now a much better understanding of what challenges each group faces, while also seeing a more cohesive, collaborative and unified environment between all areas that care for patients enrolled to these complex treatment trials.
- The process is seamless and meeting regularly alleviates potential issues from growing into a problem due to the regular and consistent communication between meeting members.
- Cross training of staff continues and having an operational system solidified helps new staff know their role and responsibilities.
- Hospital administration will create the new position of inpatient/clinical research nurse liaison to help facilitate the operational processes on both sides.

FUTURE PLANS

- Analyze deviation trends pre and post process implementation.
- Develop a survey for contributors to measure process improvement and communication.
- Evaluate Report and Learn* trends since process implementation.

Report and Learn is a system in our EMR (Epic) where research and clinical staff may report issues in real time for resolution, corrective action and site-wide improvements.

Facilitating Team Connection During COVID-19 Pandemic

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Huntsman Cancer Institute, University of Utah

1. Background

In the midst of the COVID-19 pandemic, in order to protect patients and staff, the clinical trials office (CTO) made the decision to work primarily remotely. This shift created a new team dynamic and an array of unique challenges for managers. There were employees feeling isolation from the team, but also at home in their personal lives. A number of staff members had recently been hired, some just weeks or days prior to the sudden remote work situation. Others hired during the past year had to learn the job and meet the team they are working with solely through a remote connection. Managers have had to deal with burnout, discouragement, and disconnection with the employees they are supervising. In order to combat these challenges, our program managers and project administrators implemented creative initiatives and activities to promote connection within their teams.

2. Goals

We hope the team connection efforts with leadership and employee engagement during this remote time period will lead to decreased turnover, increased job satisfaction, maintenance of a team element, productivity (accrual rate), more help between team members being offered, and less burnout with the efforts to maintain our team connection. Our plan is to create online surveys with both open-ended and Likert Scale questions that will be sent to the employees to gather qualitative and quantitative data on the impact of their management's team connection and employee engagement efforts.

3. Solutions and Methods

Approaches implemented to facilitate team connection include conducting weekly or bi-weekly team meetings with cameras on (if available) to help establish a personal connection. Meetings may include: discussions on CTO updates, standard operating procedures (SOP) reviews, team goals, team games (House Party, etc.), "getting-to-know-you" activities, trivia questions, team lunches, coordinating help between employees/teams, guest speakers, study spotlights, service projects, team building activities, and shout-outs to team members going above and beyond. Other activities include individual weekly, bi-weekly, or monthly manager check-ins with each team member; weekly assignments for team members to reach out to an assigned team member one-on-one; after-hours virtual team get-togethers, including employees' families and significant others; and department retreats where gift cards for food delivery are provided, which would allow for a departmental lunch.

4. Outcomes

From the limited data collected at this time, and written comments from team members, it appears that activities designed to facilitate team interaction do have a positive impact on the team and individual's work satisfaction. In the one team surveyed, the average of a self-reported "joy" indicator (scale of 1-10, with 10 being the highest) improved from 5.75 to 6.33 after the implementation of several team activities including an after-work virtual get-together, check-in questions during the team meetings, and weekly reach-out assignments for one-on-one team interaction. Additionally, on an anonymous survey, 73 percent of employees that had attended bi-monthly optional team-building activities said they were a worthwhile way to connect as a team, with the remaining 27 percent saying that they were somewhat worthwhile.

5. Lessons Learned

It does appear that continuing to hold activities that promote team connection and employee engagement is in the best interest of teams, individual employees, and the institution. From early observation, it does seem that when such activities are optional, the attendance is lower, which in turn lowers the number of people impacted. Our plan is to continue to work on creating team connection activities and implement department-wide surveys to measure the effectiveness of those activities. As local regulations allow, we will also be implementing periodic in-person events.

View all abstracts and posters at **aaci-cancer.org/2021-abstracts**.

Facilitating Team Connection During COVID-19 Pandemic

Janna Espinosa, BS, CCRP; Colleen Marshall, MPA, CCRP; Ashley Horstmeier, CCRC; Jessica Moehle, CCRP; Leanne Lujan, CCRP
Huntsman Cancer Institute at the University of Utah

BACKGROUND

In the midst of the COVID-19 pandemic, in order to protect patients and staff, the Clinical Trials Office (CTO) made the decision to work primarily remotely.

This shift created a new team dynamic and an array of unique challenges for managers. There were employees feeling isolation from their teams, but also at home in their personal lives. With remote work, burnout, discouragement, and disconnection had become more prevalent.

In order to combat these challenges, our program managers and project administrators implemented creative initiatives and activities to promote connection within their teams.

METHODS

Approaches implemented to facilitate team connection include:

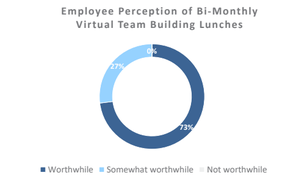
- Conducting Weekly or Bi-weekly Virtual Team Meetings with cameras on (if available) to help establish a personal connection.
  - Meetings include: CTO updates, Standard Operating Procedures (SOP) reviews, team goals, games (House Party, etc.), get to know you activities, trivia questions, team lunches, coordinating help, guest speakers, study spotlights, service projects, team building activities, shout outs to team members going above and beyond.
- Individual weekly, bi-weekly, or monthly manager check-in with each team member.
- Weekly assignments for team members to reach out to an assigned team member one-on-one.
- After hours virtual team get-togethers including employee's families and significant others.
- Department retreat including gift cards for food delivery being sent to each employee, allowing for a employer provided lunch.

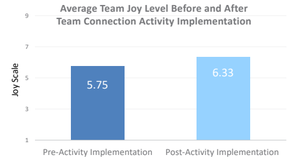
Examples of slides from a team "get to know you" activity

RESULTS

To assess the effectiveness of team connection efforts, surveys including quantitative and qualitative questions were conducted within one team of 18 individuals at various time points throughout the period of remote work:

- The team average of a self-reported "joy" indicator (scale of 1-10 with 10 being the highest) improved from 5.75 to 6.33 after the implementation of several team activities including after-work virtual get-togethers and weekly team reach out assignments.
- An anonymous Likert scale survey question indicated 73% of employees felt bi-monthly virtual team building lunches were a "worthwhile" way to connect as a team, the remaining 27% said they were "somewhat worthwhile" while the third option of "not worthwhile" was not selected by any of those surveyed.
- The anonymous survey also included an open-ended qualitative question asking for feedback on the virtual team building lunches. The comments were overwhelmingly positive.





CONCLUSIONS

The limited quantitative data collected at this time, and the qualitative feedback received from team members, suggest that activities designed to facilitate team interaction do have a positive impact on the team and individual's work satisfaction.

Anonymous feedback received on virtual team building lunches

Photograph from a "Bring Your Pet to the Virtual Office Team Building Lunch"

FUTURE PLANS

It does appear that continuing to hold activities that promote team connection and employee engagement is in the best interest of teams, individual employees, and the institution.

From early observation, it does seem that when such activities are optional, the attendance is lower, which in turn, lowers the number of people impacted.

Our plan is to continue to work on creating team connection activities and implement department wide surveys to measure the effectiveness of those activities.

As local regulations allow, we will also be implementing periodic in-person events.

Structured Collaboration With Clinical Partners to Enhance Research Participant Safety and Experience Along With Protocol Compliance and Expeditious Trial Activation

S. Willoughby, C. Davis
Robert H. Lurie Comprehensive Cancer Center of Northwestern University

1. Background

Excellence in professional collaboration between trials office and clinical staff is essential to patient safety and experience, protocol compliance, and rapid trial activation. With burgeoning cellular therapy trials in both hematological and solid tumor malignancies, along with increasing needs for inpatient care and monitoring for participants in complex Phase I trials, previous collaborative practices between the clinical trials office (CTO) and clinical areas became inadequate. In addition, our cancer center is embedded in a matrix of health system, hospital, medical group, and medical school/university. The cancer center CTO is situated within the medical school/university, and the clinical areas where trial participants receive treatment are distributed among the other entities. Key cross-entity leadership partnered to create tools and processes supporting evolving needs. These included improved communication, reciprocal process knowledge and transparency, a shared vocabulary for clinical and research staff, and clarification of ownership of discrete responsibilities.

2. Goals

The project goal was to enhance and expedite operational and patient care planning for clinical trials, as measured by decreased trial activation time. To maintain research and patient care quality, the project team also focused on protocol compliance and excellence in patient safety and experience.

3. Solutions and Methods

- Identified key stakeholders and defined their scope of responsibility from the time of trial activation through first patient treatment and team debrief
- Outlined the trial activation process to ensure transparency and appropriate sequencing of study start up tasks, creating a shared language to facilitate understanding between research and clinical staff
- Initiated a monthly meeting of key stakeholders to address gaps in current process, providing a forum to discuss feasibility, concerns, and process improvements; currently, the project team is engaged in exploring ways to improve the feasibility assessment process
- Developed support resources including a process map, job aids, reference documents, contact lists, communication templates, and upcoming trials lists

4. Outcomes

Solutions have been implemented and processes are being refined. Informal surveys indicate improved cross-entity relationships and awareness of upcoming clinical trials and their status. Improvement is expected in the following outcome metrics, which will be measured approximately 1-year post implementation:

- Trial activation time
- Clinical trials engagement survey

5. Lessons Learned

The following were vital to success of the project:

- Leadership engagement at the director level
- Early identification and involvement of key stakeholders to promote and support team engagement and change management
- Involvement of clinical staff, particularly education coordinators and charge nurses, in feasibility assessment and operational planning
- Definition of scope of responsibility across entities and development of a common language to communicate about clinical trials
- Supportive communication structures and resources, such as regular meetings, contacts and trials lists, job aids, and process maps
  - Initial project scope included cellular therapy trials managed by the cancer center CTO
  - Future plans include expanding to other complex clinical trials, within and outside the scope of the CTO

Structured Collaboration with Clinical Partners to Enhance Research Participant Safety and Experience, Protocol Compliance, and Expeditious Trial Activation

Project Leaders:
Cassandra Davis, MBA
Sherri C. Willoughby, RN, MSN

Team Members:
Clinical Trials Office Study Start Up, Feasibility, and Clinical Operations Managers
Clinical Operations and Patient Care, Cell Therapy Lab, and Apheresis Center Leadership

BACKGROUND

Problem Statement

Since 2016, when the first 2 CAR-T trials opened at NM, over 15 diverse cellular therapy trials have opened, with many more in the start-up process, and over 62 patients have been treated on CAR-T trials alone. Existent collaborative practices between the Cancer Center Clinical Trials Office (CTO) and clinical areas were strained to meet the evolving cellular therapy trial landscape due to:

- The sheer number of patients and trials, as well as novel therapeutics with unfamiliar and potentially life-threatening toxicities.
- Increasing needs for apheresis, cell lab, and inpatient care and monitoring for participants, along with the need for complex coordination between all of these areas and the CTO.
- Matrixed organizational structure, with the CTO situated within the medical school/university and the clinical areas where trial participants receive treatment distributed between the hospital, medical group, and other health system entities.

Project Goal

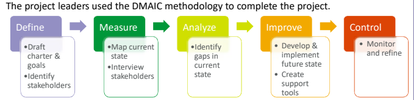
Enhance and expedite operational and patient care planning for clinical trials, while also maintaining research and patient care quality.

Outcome Metrics	• Trial activation time • Staff engagement
Supporting Tools and Resources	• Improved communication channels • Reciprocal process knowledge and transparency • Shared vocabulary for clinical and research staff • Clarification of ownership of discreet responsibilities
Key Deliverable	• Future state process map

METHODS

Methodology

The project leaders used the DMAIC methodology to complete the project.



Process Enhancement

Key deliverables involved enhancing the current process to:

- Clearly identify key stakeholders and their scope of responsibility, from time of trial start-up fee approval through activation, to first patient treatment and team debrief
- Ensure transparency and appropriate sequencing of study start-up tasks
- Outline communication steps and contacts, and create a shared language to facilitate understanding between research and clinical staff

Enhanced Process Map

Supporting Tools and Resources

To implement and sustain the new process, the team created tools and resources, such as:

- Monthly standing meeting to discuss upcoming trials, feasibility concerns, and process improvements
- Current and upcoming trials list
- Reference documents and checklists
- Communication templates


Open Immune Effector & Cellular Therapy Clinical Trials

Trial Name (Trial number to search NCT#)	Sponsor	Investigational Product	Indication/Dosage	Principal Investigator	Clinical Trials Office (CTO) Contact
AAAAA	99888	00001	PR+ or R/R AML	Dr. All	Research RN Name Contact Info

RESULTS

Solutions were implemented and are being refined. Informal surveys indicate improved cross-entity relationships and awareness of upcoming clinical trials and their status.

Outcome metrics will be measured 1 year post implementation

Trial activation time

CTO & Clinical Staff Engagement

Spotlight on Communication

While the main project deliverable was the process map, the most visible improvement is in the partnership between the CTO and clinical teams.

With better forums and structures for communication, clear ownership and discreet responsibilities, plus focused agendas, the team has developed trust and been more effective than ever before in communication.

CONCLUSIONS

Keys to Success

- Leadership engagement at the director level
- Early identification and involvement of key stakeholders to promote and support team engagement and change management
- Clinical staff, particularly education coordinators and charge nurses, involvement in feasibility assessment and operational planning
- Definition of scope of responsibility across entities and development of a common language to communicate about clinical trials
- Supportive communication structures and resources, such as regular meetings, contacts and trials lists, job aids, and process maps

Future Directions

- Outcome metrics will be measured 1 year post implementation
- Initial project scope included cellular therapy trials managed by the Cancer Center CTO. Future plans include expanding to other complex clinical trials, within and outside the scope of the CTO.

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D M A I C

Incorporating the Complexity of Screening Into Protocol Acuity: Updates to the SCCC Staff Scoring Model

E. Siglinsky, K. Crane, S. Grant, S. Meletath, A. Neal, H. Phan, S. Goksu, M.S. Beg, E. Williams
Simmons Comprehensive Cancer Center, UT Southwestern Medical Center

1. Background

The Simmons Comprehensive Cancer Center clinical research office (CRO) has been using a home-grown staffing model using protocol acuity to calculate coordinator and data effort on clinical trials for several years. Last year, analyses run based on our legacy staffing models and study budgets reflected that the complexity of trials over time had not changed substantially within the previous five years and did not appear to correlate with an increase in study budgets over the same period. Given the team's sense that complexity of trials had increased over the same time period, we hypothesized that the primary source of greater complexity was due to increased intensity of screening activities. Because our current staffing model used only a static score to evaluate screening activities of coordinators, the overall study acuities did not change to reflect this nuance. We recognized that further evaluation was needed to more accurately capture the impact of screening on the efforts of study personnel.

2. Goals

A working group of managers and coordinators formed in the fall of 2020 to review the current staffing model database and transition the static screening score to one that is study-specific.

3. Solutions and Methods

A list of typical screening procedures was compiled and the stages of pre-screening and screening through enrollment were outlined. As a group, scores for each procedure were determined in order to accurately measure screening activity. Through the process the group also revised the calculation for points per hour of work to apply to tasks that were time-based. While the focus was on screening procedures, some of the changes made impacted procedures outlined in the active study portion of the staffing model as well. After drafting the proposed changes, current studies were applied to the new system for validation.

4. Outcomes

After evaluating the entire screening process, we determined that there were four primary phases to the screening process:

1. Prescreening
2. Informed consent
3. Conduct of screening visits following informed consent
4. Evaluation of eligibility and enrollment

When six current studies were entered into the new staffing model, the screening score went from a static 10 points to an average 22.2 points per patient enrolled (range 17.4-26.7 points). When calculating this against the ideal number of points per coordinator in a given month period of time, the working group determined that the model more accurately reflected the maximum load for prescreening through enrollment for one individual. The proposed revisions to the staffing model database were presented to the CRO managers and are undergoing review.

5. Lessons Learned

Delving into and breaking down possible screening/pre-study procedures allows us to more accurately account for staff time and effort. Our next steps are to accept final feedback from CRO managers, apply changes to the existing database, and re-evaluate existing studies. We will then run similar analyses to our original project to determine whether our budgets are correlative with study complexity.

Incorporating the Complexity of Screening into Protocol Acuity: Updates to the SCCC Staff Scoring Model

Ellen Siglinsky, BS, CCRC, Kimberli Crane, MS, CCRP, Shanda Grant, RRT, MHA, CCRP, Silviya Meletath, MD, MBS, Amber Neal, BS, CCRP, Hannah Phan, MBA, MIS, Suleyman Goksu, MD, Muhammad Shaalan Beg, MD, MS, Erin Williams, MBA

The University of Texas Southwestern Harold C. Simmons Comprehensive Cancer Center, Dallas, TX

Background

The SCCC clinical research operations (CRO) has been using a home-grown staffing model using protocol acuity to calculate coordinator and data effort on clinical trials for several years. Last year, analyses run based on our legacy staffing models and study budgets reflected that the complexity of trials over time had not changed substantially within the previous five years and did not appear to correlate with an increase in study budgets over the same period. Given the team's sense that complexity of trials had increased over the same time period, we hypothesized that the primary source of greater complexity was due to increased intensity of screening activities. Because our current staffing model used only a static score to evaluate screening activities of coordinators, the overall study acuities did not change to reflect this nuance. We recognized that further evaluation was needed to more accurately capture the impact of screening on the efforts of study personnel.

Methods

A working group of managers and coordinators formed in the fall of 2020 to review the current staffing model database and transition the static screening score to one which is study-specific.

- A list of typical screening procedures was compiled and the stages of pre-screening and screening through enrollment were outlined.
- Scores for each procedure were determined in order to accurately measure screening activity.
- The calculation for points per hour of work were revised to apply to tasks that were time-based.
- Some of the changes made impacted procedures outlined in the active study portion of the staffing model as well.
- Current studies were applied to the new system for validation.

Results

- After evaluating the entire screening process, we determined that there were four primary phases:
  - Prescreening
  - Informed consent
  - Conduct of screening visits following informed consent
  - Evaluation of eligibility & enrollment
- When six current studies were entered into the new staffing model, the screening score went from a static 10 points to an average 22.2 points per patient enrolled (range 17.4 - 26.7 points).
- The working group determined that the model more accurately reflected the maximum load for pre-screening through enrollment for one individual.
- The proposed revisions to the staffing model database were presented to the CRO managers.

Discussion / Conclusion

Delving into and breaking down possible screening/pre-study procedures allows us to more accurately account for staff time and effort. We received final feedback from CRO managers in order to apply changes to the existing database and re-evaluate existing studies. We are in the process of entering current studies into a trial database. We will then run similar analyses as our original project to determine whether our budgets are correlative with study complexity.

UT Southwestern Harold C. Simmons Comprehensive Cancer Center

Does Mentorship Improve CRC Retention Rates and Employee Satisfaction?

E. Pon, E. Nurminen, M. Welsh, M. Narwal
UCSF Helen Diller Family Comprehensive Cancer Center

1. Background

The Helen Diller Family Comprehensive Cancer Center (HDFCCC) Clinical Research Support Office (CRSO) experiences high staff turnover of nearly 50 percent annually. The CRSO hires, trains, and manages all cancer clinical research staff. Of the CRSO's 130 employees, 100 are clinical research coordinators (CRCs). CRC turnover accounts for the majority of staff loss. High turnover results in loss of institutional knowledge, lower productivity, higher costs, and lower staff morale. Possible barriers to retention include low engagement and a lack of growth opportunities. Many CRCs are recent graduates from undergraduate or master's programs with little to no professional or clinical research experience. We seek out candidates who will remain in the role for a minimum of two years as most CRCs will need six months of training before they function at full capacity. While a majority of these staff work at HDFCCC for two years, some stay for less time. Some CRCs may leave the university because they lack growth — either in particular areas or titles. While leadership opportunities often open up across the 13 distinct disease programs that comprise the CRSO, staff may not view them as a favorable option. Since programs function independently, staff are siloed and develop a personal devotion to their disease program and its patients and clinicians. Additionally, programs vary in size and scope of work. The smallest program comprises one clinical research manager (CRM) and one CRC, whereas a larger program comprises one CRM, two clinical research supervisors (CRS), one protocol project manager (PPM), one senior CRC (Sr. CRC), and 15 CRCs. A CRC in a small program is unlikely to be as familiar with these other roles. Based on the HDFCCC programmatic structure and inherent professional growth limitations, we have developed a mentorship program to match CRCs and Sr. CRCs with more seasoned UCSF staff mentors. The intent of the program is to expose staff to roles outside of their disease group, break down silos that exist within programs, and foster a supportive environment to openly discuss professional goals and ways to develop skills to work towards achieving those goals.

2. Goals

The goals of the mentorship program include fostering community within the HDFCCC and providing professional development, leadership, and skill-building opportunities to both mentors and mentees. The mentorship program is considered successful if the participating mentees work at the HDFCCC longer than the median length of time that staff in their same type of role typically stay. The median length of time that CRCs and Sr. CRCs work at the HDFCCC is being calculated and will be included in the poster. We will also survey mentees and mentors before and after the completion of the program to evaluate employee satisfaction. This qualitative data will provide real-time feedback on how each participant viewed the program, and the effectiveness of various aspects: 1:1 mentor/mentee meetings, group events, and overall format of the program.

3. Solutions and Methods

We opened the call for applications to the mentorship program in November 2019. Of 100 eligible staff, 25 applied to be mentees. After reviewing applications and availability of mentors, we selected seven mentees and 10 senior staff to serve as potential mentors. As the relationship between mentor and mentee is a critical indicator to successful mentorship, we allowed mentees to determine which mentor would be a good fit for them. All participants attended a "matching event" in February where each mentee spoke with each potential mentor. After, participants ranked their top five mentor choices. After pairing the seven mentees with seven mentors, we hosted an orientation event to review expectations. Participating mentors and mentees are expected to commit to two to four hours per month for six months. There will be a one-to-two-hour monthly group event covering topics ranging from resume building and writing, to professional communication.

Mentors and mentees are expected to meet on their own at least once a month for 30 minutes. We developed a "Mentoring Agreement Form" to guide the discussion and expectation about the frequency and length of their check-ins.

4. Outcomes

Due to the pandemic, additional events beyond the February kick-off meeting were halted. As a result, we have not completed the first cohort and cannot present outcome data at this time. The following monthly events are planned once the program resumes, in addition to mentor/mentee meetings:

- Resume and career management document workshop
- Professional communication workshop
- Mock speed interviewing with feedback
- Mentor job presentations

5. Lessons Learned

Thus far, the 25-percent application rate demonstrates interest in mentorship among staff. CRMs and CRSs were eligible for the program but did not apply, which shows a greater interest by those in more entry-level roles. The program was interrupted by COVID-19 pandemic as UCSF went fully remote as of March 12, 2020. We resumed the program remotely in April 2021.

View all abstracts and posters at **aaci-cancer.org/2021-abstracts**.

UCSF Helen Diller Family Comprehensive Cancer Center

Does Mentorship Improve CRC Retention Rates and Employee Satisfaction?

By: Elizabeth Pon, Emily Nurminen, Madeleine Welsh, Manpreet Narwal

Background

The Helen Diller Family Comprehensive Cancer Center (HDFCCC) Clinical Research Support Office (CRSO) experiences high staff turnover of nearly 50% annually. The CRSO hires, trains, and manages all cancer clinical research staff. Of the CRSO's 130 employees, 100 are Clinical Research Coordinators (CRCs). CRC turnover accounts for the majority of staff loss. High turnover results in loss of institutional knowledge, lower productivity, higher costs, and lower staff morale. Possible barriers to retention include low engagement and a lack of growth opportunities.

Many CRCs are recent graduates from undergraduate or masters' programs with little to no professional or clinical research experience. We seek out candidates who will remain in the role for a minimum of two years as most CRCs will need six months of training before they function at full capacity. While a majority of these staff work at HDFCCC for two years, some stay for less time.

Some CRCs may leave the university because they lack growth—either in particular areas or titles. While leadership opportunities often open up across the 13 distinct disease programs that comprise the CRSO, staff may not view them as a favorable option. Since programs function independently, staff are siloed and develop a personal devotion to their disease program and its patients and clinicians. Additionally, programs vary in size and scope of work. The smallest program comprises one Clinical Research Manager (CRM) and one CRC, whereas a larger program comprises one CRM, two Clinical Research Supervisors (CRS), one Protocol Project Manager (PPM), one Senior CRC (Sr. CRC), and fifteen CRCs. A CRC in a small program is unlikely to be as familiar with these other roles.

Based on the HDFCCC programmatic structure and inherent professional growth limitations, we have developed a mentorship program to match CRCs and Sr. CRCs with more seasoned UCSF staff mentors. The intent of the program is to expose staff to roles outside of their disease group, break down silos that exist within programs, and foster a supportive environment to openly discuss professional goals and ways to develop skills to work towards achieving those goals.

Metrics/Goals to be Achieved

The goals of the mentorship program include fostering community within the HDFCCC and providing professional development, leadership, and skill-building opportunities to both mentors and mentees.

The mentorship program is considered successful if the participating mentees work at the HDFCCC longer than the median length of time that staff in their same type of role typically stay. The median length of time that CRCs and Sr. CRCs work at the HDFCCC is being calculated and will be included in the poster.

We will also survey mentees and mentors before and after the completion of the program to evaluate employee satisfaction. This qualitative data will provide real time feedback on how each participant viewed the program, and the effectiveness of various aspects: 1:1 mentor/mentee meetings, group events, and overall format of the program.

Methods

We opened the call for applications to the mentorship program in November 2019. Of 100 eligible staff, 25 applied to be mentees. We selected seven mentees and 10 senior staff to serve as potential mentors.

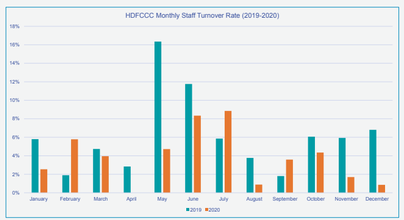
We set up a "Matching Event" in February 2020 where mentees spoke with each potential mentor. Mentees ranked their top five mentor choices and were paired.

We set up an orientation event, in which the following expectations were set.

- Participating mentors and mentees are expected to commit to two to four hours per month for six months.
- There will be a one-to-two-hour monthly group event covering topics ranging from resume building and writing, to professional communication.
- Mentors and mentees are expected to meet on their own at least once a month for 30 minutes.

HDFCCC Staff Turnover

Staff turnover data for 2019 and 2020 is presented below. This data represents turnover for all assistant CRCs, CRCs, Sr. CRCs, CRSs and CRMs.



Observations

- The highest staff turnover occur between May and July. This period aligns with staff who are leaving UCSF to attend professional and graduate school programs.
- Overall, staff turnover was higher in 2019 than 2020. Due to the COVID-19 pandemic, UCSF went fully remote on March 12, 2020. As a result, fewer staff left for other jobs or school during this time.

Current status of program

Due to the pandemic, additional events beyond the February kick-off meeting were halted. As a result, we have not completed the first cohort and cannot present outcome data at this time.

Given staffing changes and other commitments from the original mentees and mentors chosen, we re-opened the call for applications to the mentorship program in April 2021. Of 115 eligible staff, 21 applied to be mentees.

We are currently reaching out to potential mentors to determine how many we have available to pair with mentees.

Lessons learned and next steps

The two calls for applications yielded 25% and 18% application rates, respectively, which demonstrates interest in mentorship among staff. While no CRMs and CRSs applied during the first call for applications, 3 CRSs and 2 CRMs applied during the second call. Overall, this shows greater interest by those in more entry level roles; however, there is still interest for mentorship in a smaller subset of staff in manager roles.

Next steps

- Develop pre and post mentorship program surveys for mentees and mentors to complete
- Select final mentees based on number of mentors
- Finalize monthly group event schedule. Some topics being considered: resume and career management document workshop, professional communication workshop, mock speed interviewing with feedback, and mentor job presentations
- Facilitate matching event between mentees and potential mentors. Mentor bios will be provided to mentees, who will set up informational meetings with mentors they are interested in working with. Mentees will provide their mentor rankings, and program coordinators will choose final pairings.
- Mentorship program will begin in early July 2021 and end in December 2021

Doing More With Less: The Adoption of Slot Management Practices to Drive Resource Allocation in the Clinical Trials Office

C. Gregor
Vanderbilt-Ingram Cancer Center

1. Background

In 2019, the Vanderbilt-Ingram Cancer Center (VICC) identified the need for a more structured approach to portfolio management and resource allocation within the clinical trials office (CTO). New study submissions were increasing 12 to 15 percent each year while the number of CTO staff remained static. Further, CTO leadership noted 20 percent of studies submitted in 2018 were abandoned during start-up, resulting in wasted effort and lost revenue for the organization. All these factors combined, negatively impacted staff workloads, and contributed to an increase in staff turnover across the department. In response, CTO leadership implemented a new study allocation system with the goal of decreasing study start-up time, decreasing the number of studies abandoned during start-up, increasing accrual, and improving staff retention.

2. Goals

- Decrease start-up time to 120 days
- Increase accrual by 15 percent
- Decrease number of zero accrual studies by 15 percent
- Decrease abandoned studies by 15 percent
- Increase staff retention by 10 percent

3. Solutions and Methods

CTO leadership compared the number of new study submissions against the number of studies opened each year for the preceding five years (Fig. 1). Based on this data they set 120 new studies as the annual capacity cap for the CTO. They proposed allocating 100 studies across all disease teams (DTs) while retaining the additional 20 study slots to for performance-based incentives around key cancer center goals. These goals were measured every three months and additional slots were allocated based on:

- Highest NCTN accrual
- Highest overall accrual
- Highest average accrual per protocol
- Key project for new faculty recruitment
- Project relevance to cancer center mission (grants, SPOREs, etc.)

DTs received their initial allocation of study slots based on historical performance data around the average number of studies submitted, studies opened, studies abandoned, overall accrual, and accrual per protocol. DTs were ranked based on these performance indicators and then assigned slots based on their order. Every DT received two studies as a base allotment and then additional slots were handed out based on ranking.

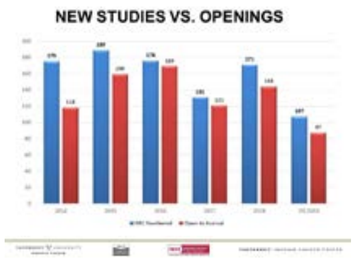
4. Outcomes

At the end of 2020, study start-up timelines decreased by 20 percent and staff retention improved by 41 percent. The number of abandoned studies decreased by 75 percent from 2018 and 53 percent of the DTs saw an improvement in accrual per protocol. The cancer center did not see an improvement in overall accrual in 2020, however much of that can be credited to the impact of COVID-19.

5. Lessons Learned

To date, most DTs have accepted the slot allocation program as a positive improvement and agree that the allocation has promoted more thoughtful and robust discussions around their portfolios. CTO leadership agreed to continue the slot allocation program in 2021, however a higher emphasis has been placed on accrual per protocol as a measure of DT performance rather than overall accrual numbers. This decision was made after CTO leadership noted that rewarding straight accrual numbers benefited larger teams at the expense of smaller ones and unfairly skewed the performance data for the following year. As such, that metric was eliminated for performance incentives. Additionally, performance review was moved to every six months to allow DTs more time to demonstrate improvement.

Figure:



DOING MORE WITH LESS: THE ADOPTION OF SLOT MANAGEMENT PRACTICES TO DRIVE RESOURCE ALLOCATION IN THE CLINICAL TRIALS OFFICE

CATHERINE GREGOR, MBA, CCRP, CCRC - DIRECTOR, CLINICAL RESEARCH ADMINISTRATION - CATHERINE.D.GREGOR@VUMC.ORG

VANDERBILT UNIVERSITY MEDICAL CENTER

BACKGROUND

In 2019, the Vanderbilt-Ingram Cancer Center (VICC) identified the need for a more structured approach to portfolio management and resource allocation within the Clinical Trials Office (CTO). New study submissions were increasing 12-15% each year while the number of CTO staff remained static. Further, CTO leadership noted 20% of studies submitted in 2018 were abandoned during start-up, resulting in wasted effort and lost revenue for the organization. All these factors combined, negatively impacted staff workloads, and contributed to an increase in staff turnover across the department. In response, CTO leadership implemented a new study allocation system with the goal of decreasing study start-up time, decreasing the number of studies abandoned during start-up, increasing accrual, and improving staff retention.

GOALS

- Decrease Start-Up Time to 120 Days
- Increase Accrual 15%
- Decrease Number of Zero Accrual Studies by 15%
- Decrease Abandoned Studies by 15%
- Increase Staff Retention by 10%

CTO leadership compared the number of new study submissions against the number of studies opened each year for the preceding five years **(Fig. 1).** Based on this data they set 120 new studies as the annual capacity cap for the CTO. They proposed allocating 100 studies across all Disease Teams (DTs) while retaining the additional 20 study slots to for performance-based incentives around key Cancer Center goals

Figure 1

METHODS CONT.

These goals were measured every three months and additional slots were allocated based on:

- Highest NCTN accrual
- Highest overall accrual
- Highest average accrual per protocol
- Key project for new faculty recruitment
- Project relevance to Cancer Center mission (Grants, SPOREs, etc.)

DTs received their initial allocation of study slots based on historical performance data around the average number of studies submitted, studies opened, studies abandoned, overall accrual, and accrual per protocol. DTs were ranked based on these performance indicators and then assigned slots based on their order. Every DT received two studies as a base allotment and then additional slots were handed out based on ranking.

At the end of 2020, study start-up timelines decreased by 20%. The number of abandoned studies decreased by 75% from 2018 and 53% of the DTs saw an improvement in accrual per protocol. The Cancer Center did not see an improvement in overall accrual in 2020, however much of that can be credited to the impact of COVID-19.

FUTURE DIRECTIONS

To date, most DTs have accepted the slot allocation program as a positive improvement and agree that the allocation has promoted more thoughtful and robust discussions around their portfolios. CTO leadership agreed to continue the slot allocation program in 2021, however a higher emphasis has been placed on accrual per protocol as a measure of DT performance rather than overall accrual numbers. This decision was made after CTO leadership noted that rewarding straight accrual numbers benefited larger teams at the expense of smaller ones and unfairly skewed the performance data for the following year. As such, that metric was eliminated for performance incentives. Additionally, performance review was moved to every six months to allow DTs more time to demonstrate improvement.

VANDERBILT UNIVERSITY MEDICAL CENTER NCI NCI National Cancer Institute VANDERBILT-INGRAM CANCER CENTER

FINANCE/CCSG/PRMS

Staff Effort Estimate Calculator: A Successful Multisite Program Budget and Staffing Tool

A. Hinman, A. Baim, A. Carabajal, R. Selle, B. Oleson, J. Thomas
Medical College of Wisconsin Cancer Center

1. Background

A successful multisite program requires an accurate estimate of staff effort in order to sufficiently support funding proposals. The program must define how its operations integrate and differentiate from existing clinical trial office operations. We developed a budget estimate tool to provide funding proposal justification and assist in projecting multisite program staffing needs. Here, we detail how our multisite operational plan and staff effort estimate calculator have become invaluable tools for the MCW Cancer Center Clinical Trials Office Multisite Program.

2. Goals

- Completed multisite program operations plan and staff effort estimate calculator
- Received funder feedback about multisite budget
- Obtained approved multisite budget proposal(s)
- Gained approval for staff hiring requests from human resources

3. Solutions and Methods

- Define multisite program structure and staff roles in an operational plan
- Develop Excel-based multisite budget estimator
- Utilize estimator for multisite funding proposals and staff hiring decisions

4. Outcomes

The MCW Multisite Program operations plan and staff effort estimate calculator (Excel-based) were created in 2017. After implementation, all eight multisite funding proposals with an approved letter of intent and completed funder fair market value analysis obtained multisite budget approval, totaling over $9.7 million ($1.4 million dedicated to multisite), although a few are still pending review. Funder feedback required only minor clarifications. These were addressed by sharing details from the estimator. The MCW Department of Human Resources approved two program staff positions using data generated from the estimate calculator. In addition, the tool served as an important source in the administrative decision to pause acceptance of new multisite studies during the height of the COVID-19 pandemic.

5. Lessons Learned

The staff effort estimate calculator was successfully utilized to obtain funding for multisite program studies and to justify the need for new staff positions. The calculator allows for constant refinement based on team feedback (e.g., perceived effort), the impact of process changes, and experience (e.g., external site declining participation or slower than anticipated accrual rates). It is crucial that study-related data input into the estimator (e.g., accrual goals from statisticians, estimated time to enrollment completion, duration of patient treatment and follow-up) is accurate. These elements have greater impact on the budget than the specific estimated effort assigned to various tasks. After initial implementation of the estimator, we discovered that scrutiny of this sensitive study-related data input was possible through directed questions to the study principal investigator and statistician, in addition to applying more liberal time windows (e.g., average treatment or follow-up duration). By calculating the full time equivalent numbers of active and pending multisite studies, along with the categories of tasks assigned to various positions, we have been able to assess current and future staffing needs. One current limitation is validation of estimated effort to actual effort. This is a future goal, which may be accomplished through the use of our actual effort-tracking billing system, whereby staff enter their daily effort according to the tasks on which they worked. We can then correlate that effort with the various categories of the estimator.

Staff Effort Estimate Calculator: A Successful Multisite Program Budget and Staffing Tool

Alexander Hinman, BA, CCRP; Arielle Baim, BA, CCRP; Tony Carabajal, BA; Rebecca Selle, BA, CCRP; Betty Oleson, BSN, RN, CCRP; James Thomas, MD, PhD

Background

A successful multisite program requires an accurate estimate of staff effort in order to sufficiently support funding proposals. The program must define how its operations integrate and differentiate from existing clinical trial office operations. We developed a budget estimate tool to provide funding proposal justification and assist in projecting multisite program staffing needs. Here, we detail how our multisite operational plan and staff effort estimate calculator have become invaluable tools for the MCW Cancer Center Clinical Trials Office Multisite Program.

Goals

- Completed multisite program operations plan and staff effort estimate calculator
- Received funder feedback about multisite budget
- Obtained approved multisite budget proposal(s)
- Gained approval for staff hiring requests from human resources

Methods

- Define multisite program structure and staff roles in an operational plan
- Develop Excel-based multisite budget estimator
- Utilize estimator for multisite funding proposals and staff hiring decisions

Contact

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Download calculator (Excel)

www.mcw.box.com/v/MCWcalculator

Acknowledgements

Special thanks to Ms. Carrie O'Connor for technical writing assistance.

Results

The MCW Multisite Program operations plan and staff effort estimate calculator (Excel-based) were created in 2017. After implementation, all eight multisite funding proposals with an approved letter of intent (LOI) and completed funder fair market value (FMV) analysis obtained multisite budget approval, totaling over $9.7 million ($1.4 million dedicated to multisite), although a few are still pending review. Funder feedback required only minor clarifications. These were addressed by sharing details from the estimator. The MCW Department of Human Resources approved two program staff positions using data generated from the estimate calculator. In addition, the tool served as an important source in the administrative decision to pause acceptance of new multisite studies during the height of the COVID-19 pandemic.

Conclusions

The staff effort estimate calculator was successfully utilized to obtain funding for multisite program studies and to justify the need for new staff positions.

The calculator allows for constant refinement based on team feedback (e.g., perceived effort), the impact of process changes, and experience (e.g., external site declining participation or slower than anticipated accrual rates). It is crucial that study-related data input into the estimator (e.g., accrual goals from statisticians, estimated time to enrollment completion, duration of patient treatment and follow-up) is accurate. These elements have greater impact on the budget than the specific estimated effort assigned to various tasks. After initial implementation of the estimator, we discovered that scrutiny of this sensitive study-related data input was possible through directed questions to the study PI and statistician, in addition to applying more liberal time windows (e.g., average treatment or follow-up duration).

By calculating the full-time equivalent (FTE) numbers of active and pending multisite studies, along with the categories of tasks assigned to various positions, we have been able to assess current and future staffing needs. One current limitation is validation of estimated effort to actual effort. This is a future goal, which may be accomplished through the use of our actual effort-tracking billing system, whereby staff enter their daily effort according to the tasks on which they worked. We can then correlate that effort with the various categories of the estimator.

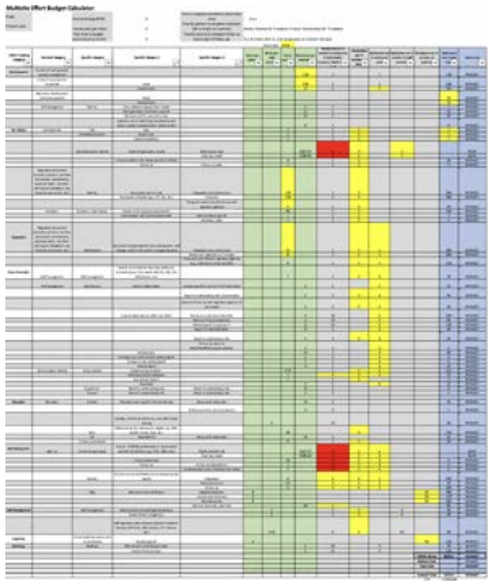


Figure 1: Multisite Effort Budget Calculator (example only, actual hours/FTE differs from this screenshot)

Statistically Significant Impacts of a PRMC Charter Alignment With NCI Practices

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

1. Background

In 2018, University of Cincinnati Cancer Center (UCCC) Protocol Review and Monitoring Committee (PRMC), along with the clinical trials office staff, revised the PRMC charter to optimize the review process to align with best practices of existing NCI-Designated Cancer Centers.

2. Goals

The goal of the present study was to streamline the PRMC review process to achieve efficiencies and maximize resources.

3. Solutions and Methods

One of several updates to the UCCC PRMC charter was the expedition of the administrative review process. Historical data of reviewed studies were analyzed by charter that was in effect. Data elements included type of review (administrative, fast track, full, chair, response to contingencies), and turnaround time in days from time of submission to approval. Out of 510 possible studies, 407 were eligible for analysis. To be eligible, a study must have had complete data to enable total turnaround time determination. If the study did not have a time-stamped submission date, we estimated the submission date by utilizing the deadline for PRMC submission (two weeks prior to meeting). Turnaround time was defined as total number of days that lapsed between submission and final approval. Standard statistical analyses were utilized to assess for significance pre and post charter revision.

4. Outcomes

Using an independent t-test, the new charter resulted in improved turnaround times when compared to the previous charter (3.4 days shorter; p = 0.002, Cohen's d = 0.31). To assess workload under each charter, the number of studies was reviewed by charter and review type. There was an overall 14 percent decrease in full-committee meeting workload between the previous and new charters. Administrative review (45 percent) and fast track reviews (21 percent) increased under rules of the new charter, which allowed the remaining review types to have a decrease in workload (38 percent to 90 percent).

5. Lessons Learned

Developing a new PRMC charter resulted in improved efficiencies for the committees. Furthermore, it facilitated optimal utilization of committee member time, talent, and resources as more trials are appropriately excused from full-committee UCCC PRMC review. This dynamic substantially reduced the full-committee workload, thereby facilitating increased attention to investigator-initiated and industry sponsored trials at full-committee PRMC meetings.

Figure:

Figure 1. Turnaround Time Based on Charter Type (means)

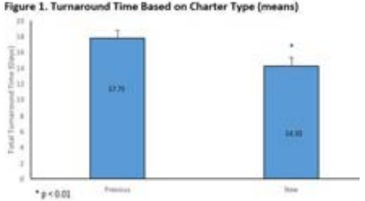


Figure 2. Turnaround Time Based on Charter Type (medians)

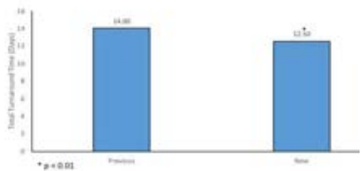
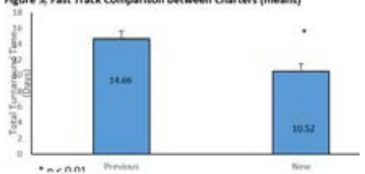


Figure 3. Fast Track Comparison between Charters (means)



Revising an Institutional PRMC Charter to Achieve NCI Standards: Impacts, Efficiencies, and Potential for Further Improvement

C. Vollmer, MBA; C. L. Allen, MS; N. Kurtzweil, JD; B. Hughes, E. Kantemneni; T. J. Herzog, MD
University of Cincinnati Cancer Center, University of Cincinnati, Cincinnati, OH

Introduction

As an aspiring center seeking NCI designation, the University of Cincinnati Cancer Center (UCCC) analyzed its clinical trial regulatory processes to ensure continued improvement in efficiency and resource allocation. In 2018, UCCC's Protocol Review and Monitoring Committee (PRMC) in conjunction with the Clinical Trials Office staff reviewed and extensively revised the PRMC Charter to optimize the review process of the UCCC PRMC to align with best practices from existing NCI Designated Cancer Centers.

Methods

The following specific updates were made to the UCCC PRMC Charter:

1. Created an expedited administrative review process
2. Permitted deferral to a single Protocol Review and Monitoring System (PRMS) of a multi-center trial
3. Ensured accrual reviews uniformly define and account for rare cancers
4. Added Data Table 4 study type definitions
5. Identified member roles and responsibilities clearly and
6. Clarified the PRMC's authority to open and terminate protocols.

Strategies for Data Analysis

Out of a possible 510 studies, 407 were eligible for analysis (Figure 1).To be eligible, a study must have replete data enabling calculation of total turnaround time, which requires submission and approval dates. If the study did not have a time stamped submission date, we estimated the submission date by utilizing the deadline for PRMC submission (two weeks prior to meeting). Turnaround time was calculated by subtracting the submission date from the approval date. This provided the number of days that lapsed between the two time points, and statistical analysis was then performed to compare mean and median turnaround times between the new charter versus the previous charter.

Figure 1. Consort Diagram

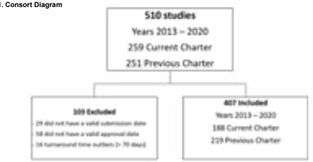


Table 1. Results of Independent t-test

	N	Mean	SD	t-test	Cohen's d
Previous	219	17.75	10.32	0.002	0.31**
Current	188	14.33	11.71		

* statistically significant < 0.05 ** small-medium effect size

Figure 2. Turnaround Time by Charter

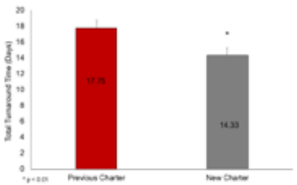
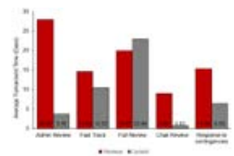


Figure 3. Turnaround Time By Charter and Review Type



Results

Using an independent t-test, the new charter has a shorter turnaround time when compared to the previous charter of almost 3.4 day (p = 0.002, Cohen's d = 0.31) (Table 1 and Figure 2).

To assess workload under each charter, the number of studies was reviewed by charter and review type. There was an overall 14% decrease in workload between the previous and new charters. Administrative review (45%) and fast track reviews (21%) had an increase in workload, which allowed the remaining review types to have a decrease in workload (38% - 90%). The average turnaround time by charter and review type can be seen in figure 3.

Discussion

Developing and approving a new PRMC Charter statistically significantly resulted in improved efficiencies for the committees. Furthermore, it facilitated the optimal utilization of committee member time, talent, and resources as the increase in fast-tracked and NCI cooperative group trials excused from full UCC PRMC committee review substantially reduced full committee work-load post-amendment. This dynamic facilitated increased attention to investigator-initiated trials and industry sponsored trials at PRMC meetings.

University of CINCINNATI

* MSK's NCI Network Program

J. Mohr, L. Gaffney, C. Houston, M. Warren, C. Aghajanian, P. Sabbatini, E. Cottington, S. Ramaswami, B. Zakrzewski, J. Klinger, S. Dominguez, S. Terzulli, J. Nunner, A. Rodavitch, K.R. Simpson, S. Hanley
Memorial Sloan Kettering Cancer Center

1. Background

As an NCI-Designated Comprehensive Cancer Center, Memorial Sloan Kettering (MSK) receives funding via the Cancer Center Support Grant (CCSG) which requires collaboration in National Cancer Institute (NCI) research efforts. MSK does this largely though participation in and enrollment to NCI-sponsored group studies. As part of the CCSG renewal process, MSK examined our NCI-sponsored group portfolio and noted siloed physician leadership, quality concerns, and limited financial support.

2. Goals

MSK formed a central team of NCI experts to manage regulatory compliance, create a nimble protocol activation process, improve audit results, and initiate institutional cost sharing to ensure sufficient funding of clinical trials and to determine the true cost of these trials.

3. Solutions and Methods

The NCI Network Committee was established and consists of grant and NCI group principal investigators (PIs) in addition to disease specific champions. Members meet monthly to review protocols in the activation process, accrual metrics, non-performing studies and grant and data metrics. NCI subject matter experts were centralized and make up the NCI Network Team. They have three areas of focus: protocol activation, operations/regulatory management, and quality assurance. They provide oversight and support to all MSK PIs and study teams participating in NCI Group protocols. To streamline activation, the NCI Network team developed a workflow to solicit timely decisions by MSK PIs on which trials to activate. Decisions and timing metrics are kept in a REDCap database. Select operations and regulatory tasks were centralized, allowing more time for data entry and patient management by the study teams. Quality assurance measures were implemented including risk-based monitoring (RBM) on a subset of trials, an escalation plan for trials with data timeliness concerns, and 100 percent retrospective source verification for eligibility and informed consent.
In addition, we track activation, data entry, and regulatory metrics to evaluate the progress of our program. To address the limited funding for these clinical trials, it was determined by MSK that they would cost-share the clinical trial expenses related to these trials as opposed to requiring the MSK PI to identify supplemental funding. The centralized team is supported by grant funding and each clinical trial is supported by the pre-determined annual amount per grant. Once the annual amount identified per grant is exhausted, the clinical trial expenses transition to the applicable cost share fund.

4. Outcomes

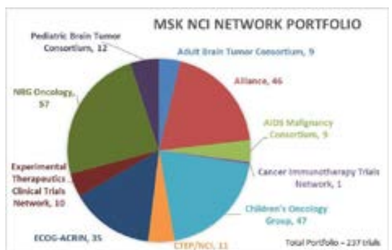
Compared to pre-centralization data, we've improved data reporting timeliness while increasing our portfolio (Figure 1). We have also reduced the time from NCI approval to MSK confirming they want to open the trial to activation at MSK and in 2021 we are going to see further improvement with new workflows that further streamline the activation process.

5. Lessons Learned

This program is necessary for ensuring the focus, direction and efficient use of institutional resources. In a survey of site PIs, 70 percent indicated they were extremely satisfied with the program. Future plans:

- Utilize REDCap database to monitor new activation process and aid grant reporting
- Expand RBM to occur after initial subject enrollment to identify and correct issues early on
- Build on current program to increase PI satisfaction

Figure:



* *Honorable Mention*

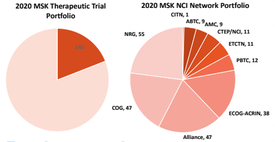
Memorial Sloan Kettering Cancer Center

MSK's NCI Network Program

Jacquelin Mohr, MS, Leigh Gaffney, MPH, Collette Houston, Carol Aghajanian, MD, Paul Sabbatini, MD, Eric Cottington, PhD, Sudha Ramaswami, MS, CPA, Barry Zakrzewski, MS, Joseph Klinger, MBA, Steven Dominguez, Stephanie Terzulli, PhD, Jaclyn Nunner, Ann Rodavitch, MA, Katherine Rolla Simpson, Sara Hanley, MSW, Mary Warren, MSW
Memorial Sloan Kettering Cancer Center (MSK)

Introduction

As an NCI-Designated Comprehensive Cancer Center, MSK receives funding via the Cancer Center Support Grant (CCSG) which requires collaboration in NCI research efforts. MSK does this though participation in and enrollment to NCI sponsored group studies. As part of the CCSG renewal process, MSK examined our NCI sponsored group portfolio and noted siloed physician leadership, quality concerns and limited financial support. At the direction of Leadership, MSK's NCI Network Program was created.



Background

NCI Network Committee (NNC)

NCI group PIs in addition to disease specific champions formed to oversee MSK's NCI sponsored trials. Members meet monthly to review protocols in the activation, accrual metrics, non-performing studies and grant and data metrics.

NCI Network Team (NNT)

NCI subject matter experts were assembled to create the NNT. The team focuses on Protocol Activation, Operations, Regulatory and QA. The team works alongside Clinical Research Operations to support all study teams participating in NCI Group protocols.

Methods

Activation

The NNT developed a strategy to solicit decisions by MSK PIs on trials to activate. We partnered with the Protocol Review and Activation Cores (PRC and PAC) to streamline activation requirements in order to open studies within 15 days. We also developed a 'Just-in-Time' or rapid activation approach for participants waiting. Decisions and timelines are recorded in a database.

Data Oversight & QA

The NNT implemented an oversight approach that assesses data status monthly and works with PIs and study teams when there are data concerns. We worked with Operations to create an escalation plan for concerns. In addition, the NNT instituted a retrospective review of eligibility (ECL) and informed consent (ICF) for 100% of all participants. Lastly, the NNT employed Risk Based Monitoring (RBM) to review high-risk trials (n=11).

Cost Sharing

Leadership confirmed their commitment to these studies and committed to share costs. The grants/subawards are used to support the NNT and provide a pre-determined annual amount for studies. Once the annual amount identified is exhausted the expenses are transitioned to a cost share fund.

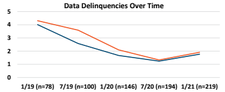
Results

Activation Highlights

- The first two trials using the streamlined approach were activated within 15 days, compared to 101 days (2020 median).
- Used JIT approach to open a trial for pediatric patient in 4 days.

Data & QA Metrics

- Source verified 215 patients for ECL/ICF of which 139 had documentation issues highlighted for correction thus avoiding potential audit findings.
- Improved data reporting timeliness which has led to improved performance monitoring reports from Alliance and NRG.



n = number of trials

Cost Sharing Metrics

- 2020 expense and reimbursement were tallied to determine the Program cost.
- 83% of the 2020 cost was supported by NCI. The remaining 17% was covered by MSK; 13% on Sr. Mgmt and positions deemed institutional responsibility and 4% from the cost share for Clinical & non-Clinical staff.

Conclusions

Program accruals returned to pre-COVID numbers in Q1 2021; we anticipate exhausting NCI support sooner and require an increase in institutional cost sharing. This Program is necessary for ensuring the focus, direction and efficient use of NCI and institutional resources. This investment in infrastructure allows us to support our contribution to NCI Sponsored research.

Future Plans

- Compare 2020 & 2021 activation timelines and Program cost
- Evaluate compliance of studies with streamlined activation
- Implement 'time outs' to identify potential issues in real time
- Increase NNT Monitoring staff to expand the number of studies and volume of RBM
- Continue to evaluate PI satisfaction

NCI Network Committee	
Carol Aghajanian, MD	NCTN Grant Holder, NNC Chair
Chris Barker, MD	Radiation Oncology
Christopher Comstock, MD	ECOG-ACRIN Site PI
Ira Dunkel, MD	PBTC National/Site PI
Christopher Forlenza, MD	COG Site PI
Daphna Gelblum, MD	Radiation Oncology
Julia Glade Bender, MD	COG
Nancy Lee, MD	NRG Site PI
Michael Morris, MD	Alliance Site PI
Alison Moskowitz, MD	CITN Site PI
Ariela Noy, MD	AMC Site PI
Valerie Rusch, MD	Vice Chair, Research; Surgery
Martin Tallman, MD	ECOG-ACRIN Disease Chair
William Tap, MD	ETCTN Site PI
Oliver Zivanovic, MD	NRG Site PI

Acknowledgements

Thank you to the NNC and NNT for all your hard work and dedication on these important trials.

INVESTIGATOR-INITIATED TRIALS

* Use of R-Scripts Can Help to Decrease Time and Improve Accuracy on Summary Tables for IND and Semi-Annual Reports

B. Palmer, A. Brikha, F. Lin, J. Woodman
Robert H. Lurie Comprehensive Cancer Center of Northwestern University

1. Background

Robert H. Lurie Comprehensive Cancer Center (RHLCCC) is responsible for submitting roughly 50 annual investigational new drug (IND) reports to the FDA and 180 semi-annual reports (SARs) to the IRB. Creating these reports involves generating summary tables for All Adverse Events (AEs), Related AEs, and demographics. On average, these three tables take 142.4 minutes to complete for one IND report. SARs require only the demographics table averaging 11.6 minutes per report. There is variation in time required to complete each table due to differing Excel abilities within the team. Further, the process is error-prone because of the amount of manual work required. The RHLCCC spends roughly 153 hours a year on table creation for SARs and IND reports.

2. Goals

First aim: Reduce time to complete summary tables required for IND and SARs submissions Second aim: Remove user error on summary tables for IND and SARs to improve accuracy

3. Solutions and Methods

Custom programmatic R-scripts were written to automatically calculate and complete each of the tables. R-scripts remove the manual work required, thus removing human error and reducing the time spent on the task. The R-scripts were integrated into our homegrown clinical trial management system utilizing a sandboxed environment on a remote server. This method was chosen to ensure the security and protection of patient data. Four Quality Assurance Monitors (QAMs) (n=4) responsible for SAR and IND reporting were timed on a standardized version of creating each table before and after R-script implementation. Their work was collected and compared with an answer key to check for accuracy.

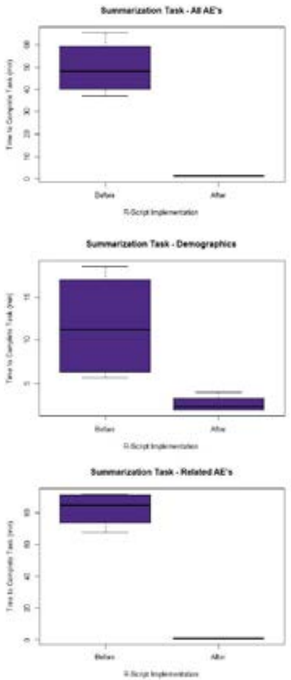
4. Outcomes

There was a 91.3 percent reduction in incorrect calculations and typos after R-script implementation. A paired-samples t-test was conducted on the three tables to compare time to complete before and after R-script implementation. There was a significant difference in the time to complete the table for all AEs before (M=49.7 minutes, SD=12.4) and after R-script implementation (M=1.3, SD=0.2); t(3)=7.8, p = 0.998. There was also a significant difference in the time to complete the table for related AEs before (M=81.1, SD=11.1) and after R-script implementation (M=1.2, SD=0.1); t(3)=14.7, p = 0.999. Finally, there was also a significant difference in the time to complete the table for demographics before (M=11.6, SD=6.3) and after R-script implementation (M=2.6, SD=1.0); t(3)=2.9, p = 0.970. There was a 92.2 percent reduction in time spent on tables for IND and SARs reports.

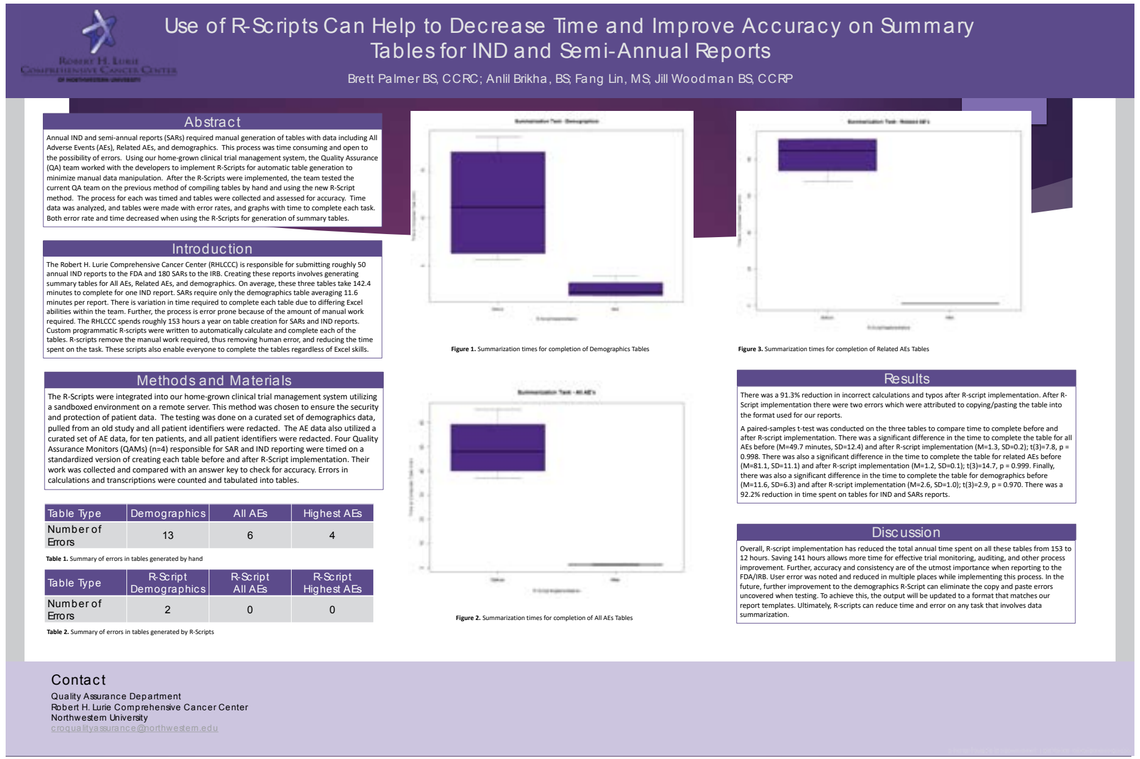
5. Lessons Learned

Overall, R-script implementation has reduced the total annual time spent on all these tables from 153 to 12 hours. Saving 141 hours allows more time for effective trial monitoring, auditing, and other process improvement. Further, accuracy and consistency are of the utmost importance when reporting to the FDA/IRB. User error was noted and reduced in multiple places while implementing this process. In the future, further improvement to the demographics R-script can eliminate copy and paste errors. To achieve this, the output will be updated to a format that matches our report templates. Ultimately, R-scripts can reduce time and error on any task that involves data summarization.

Figure:



* *Honorable Mention*



REGULATORY

* Developing a Tool to Assess Regulatory Acuity and Workload

M. Kannon, S. Scott
UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

1. Background

Accurately assessing the personnel resources needed to support the regulatory component of clinical trial operations is crucial to the effective conduct and management of clinical research portfolios. The absence of a validated assessment tool for regulatory resourcing assessment, such as OPAL for clinical resourcing, makes the assessment of necessary regulatory personnel resources and appropriate staffing more challenging within a clinical trial organization (CTO). Without a formal mechanism to assess current regulatory staffing resource needs and anticipate future regulatory staffing resource needs, CTOs are left to react to staffing shortages instead of proactively planning for and anticipating the needs of the team. This leaves staff feeling overworked and may impact morale and staff turnover adversely.

2. Goals

The goal of this project is to develop and pilot a new regulatory acuity and workload tool that will assess workload and capacity of regulatory staff through the utilization of metrics. The reporting of these metrics will inform regulatory and CTO leadership of the needed staffing resources to support existing disease team workloads and allow for projection of resource changes over time as the cancer center trial portfolio expands and contracts.

3. Solutions and Methods

Our regulatory acuity and workload tool assigns an overall score to the trial portfolio for each disease group. The score is calculated based on the following variables for each study in the portfolio: study status (new, protocol review committee-approved, open to accrual, closed to accrual with patients in follow-up, closed to accrual without patients in follow-up, suspended), sponsor type (institutional [UNC or non-UNC], national, industry-sponsored), phase of study (Phase I, I/II, II, III, pilot), type of institutional review board (IRB) of record (local, commercial, NCI Central IRB), and investigational new drug (IND) score (UNC held, single patient IND, non-UNC held). Each criterion is scored from 1 to 3, with 1 indicating an assessment of fewer resources needed to manage the regulatory workload and 3 indicating an assessment of greater resources needed. The total score for each study and for the disease group in total is tabulated and compared against the institutional standard set for each regulatory role — regulatory associate and regulatory assistant. Utilizing this tool, we are then able to determine if the personnel resources for the disease team portfolio are sufficient based on the overall portfolio score and a comparison of historical metrics. These metrics have been shared with disease team leaders at bi-annual disease team meetings since 2018.

4. Outcomes

Our regulatory acuity and workload tool has allowed us to more accurately track current staffing needs based on the current study portfolios for our disease teams and anticipate needed staffing adjustments based on anticipated portfolio growth. In addition, as new disease teams and stakeholders have joined our CTO, our regulatory acuity tool has allowed us to more accurately evaluate the personnel needed to support the additional work of our growing CTO trial portfolio. The presentation of this data to disease group leaders has been very well received, providing transparency in resource allocation decision making. It has also allowed CTO leadership to incorporate anticipated growth in the regulatory workforce into annual budgeting exercises.

5. Lessons Learned

From the development of this tool, we learned that historically our office had been understaffed with regards to regulatory support for our disease teams' portfolios. With the development of this tool, we have been able to more accurately assess the personnel resources needed to support the regulatory workload for our disease teams' growing trial portfolios. In order to enhance our tool's ability to more fully assess the resources needed for regulatory support, we are working to explore ways to leverage additional trial data currently stored in our clinical trial management system, OnCore.

* *Honorable Mention*

Developing a Tool To Assess Regulatory Acuity and Workload

M. Alison Kannon, MS, Shaw W. Scott, JD

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

Background

Accurately assessing the personnel resources needed to support the regulatory component of clinical trial operations is crucial to the effective conduct and management of clinical research portfolios. The absence of a validated assessment tool for regulatory resourcing assessment, such as OPAL for clinical resourcing, makes the assessment of necessary regulatory personnel resources and appropriate staffing more challenging within a clinical trial organization (CTO). Without a formal mechanism to assess current regulatory staffing resource needs and anticipate future regulatory staffing resource needs, CTO's are left to react to staffing shortages instead of proactively planning for and anticipating the needs of the team. This leaves staff feeling overworked and may impact morale and staff turnover adversely.

Purpose

The goal of this project is to develop and pilot a new regulatory acuity and workload tool that will assess workload and capacity of regulatory staff through the utilization of metrics. The reporting of these metrics will inform regulatory and CTO leadership of the needed staffing resources to support existing disease team workloads and allow for projection of resource changes over time as the cancer center trial portfolio expands and contracts.

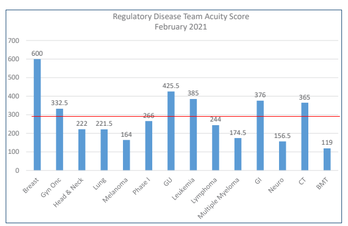


Figure 1: Regulatory acuity score for each disease group in the CTO compared against the institutional standard of 300

Workload Tool

Our regulatory acuity and workload tool assigns an overall score to the trial portfolio for each disease group.

The score is calculated based on study variables and criteria, which are each scored from 1 to 3, with 1 indicating an assessment of fewer resources needed to manage the regulatory workload and 3 indicating an assessment of greater resources needed. The total score for each study and for the disease group in total is tabulated and compared against the institutional standard set for each regulatory role - Regulatory Associate and Regulatory Assistant.

Utilizing this tool, we are able to determine if the personnel resources for the disease team portfolio are sufficient based on the overall portfolio score and a comparison of historical metrics. These metrics have been shared with disease team leaders at bi-annual disease team meetings since 2018.

Study Variables

Study Status
- **In Activation** (Score of 3)
- **Open to Accrual/Suspended** (Score of 2)
- **Closed to Accrual with Patients in Follow up** (Score of 1.5)
- **Closed to Accrual without Patients in Follow up** (Score of 1)

Sponsor Type
- **Institutional (UNC)** (Score of 3)
- **Institutional (Non-UNC)** (Score of 2)
- **National** (Score of 1.5)
- **Industry Sponsored** (Score of 1)

Study Phase
- **Pilot or N/A** (Score of 3)
- **Phase I or Phase I/II** (Score of 3)
- **Phase II or Phase II/III** (Score of 2)
- **Phase III** (Score of 1)

IRB of Record
- **Local** (Score of 3)
- **Commercial** (Score of 2)
- **NCI Central IRB** (Score of 1)

IND
- **UNC held IND** (Score of 3)
- **UNC held Single Patient IND** (Score of 2)
- **Non-UNC held IND** (Score of 1)

Outcomes

From the development of this tool, we learned that historically our office had been understaffed with regards to regulatory support for our disease teams' portfolios. Our regulatory acuity and workload tool has allowed us to more accurately track current staffing needs based on the current study portfolios for our disease teams and anticipate needed staffing adjustments based on anticipated portfolio growth. In addition, as new disease teams and stakeholders have joined our CTO, our regulatory acuity tool has allowed us to more accurately evaluate the personnel needed to support the additional work of our growing CTO trial portfolio. The presentation of this data to disease group leaders has been very well received, providing transparency in resource allocation decision-making. It has also allowed CTO leadership to incorporate anticipated growth in the regulatory workforce into annual budgeting exercises.

Future Directions

To enhance our tool's ability to more fully assess the resources needed for regulatory support, we are exploring ways to leverage additional trial data currently stored in our Clinical Trial Management System (CTMS), OnCore, including but not limited to:

- Incorporation of monitor visit metrics
- Incorporation of IRB action metrics
- Incorporation of expedited reporting metrics

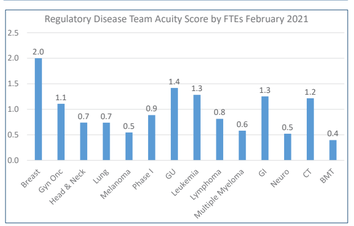


Figure 2: Full time equivalents (FTEs) needed for each disease group as calculated by dividing the acuity score for each disease group by the institutional standard of 300.

TRAINING, QUALITY ASSURANCE, REMOTE MONITORING, AND AUDITING

Saved by Automation! How Technology and Innovative Thinking Significantly Increased Productivity of the MSK CR Audit Program

S. Puleio, J. Simpronio
Memorial Sloan Kettering Cancer Center

1. Background

In 2017, the clinical research (CR) audit program at Memorial Sloan Kettering Cancer Center (MSK) was charged with increasing the scope of internal audits conducted across the clinical research portfolio. Prior to 2017, CR quality assurance conducted 22 audits of MSK clinical trials. This is in contrast to 2019 and 2020, where 99 (350 percent increase) and 125 (468 percent increase) risk-based audits, respectively, were conducted. Naturally, this resulted in a workload increase surrounding auditing activities, such as creating/finalizing audit reports, exposing the limitations of manual audit reporting.

2. Goals

As a result of the above, focus was turned to utilizing electronic systems, particularly the MSK Protocol Information Management System (PIMS) to increase productivity of audit report creation. PIMS is an in-house developed application that manages all steps involved with the protocol life cycle, including protocol auditing.

3. Solutions and Methods

The CR Audit Program conducts ~10 audits a month, each requiring a custom audit report to be completed, previously generated using Microsoft Word. In 2020, the CR Audit Program began working with PIMS IT developers to build a PIMS audit submissions module to automate the audit report process, which was successfully launched in June 2020. The PIMS audit submissions module allows the audit report to be built directly into PIMS and includes key features, such as automation and validation functionality, audit deficiency drop-down options and default deficiency ratings, a user-friendly interface and navigation, and a "My Queue" feature to track all pending audit assignments. Each member of the CR Audit Program was asked to estimate their time to completion (in minutes) for 10 audit reports (e.g., 5 reports pre-PIMS audit submissions and 5 reports post-PIMS audit submissions). The CR Audit Program managers, involved with reviewing audit reports, were also asked to average their time saved with their review process.

4. Outcomes

CR auditors are saving, on average, about 280 minutes (4 hours and 40 minutes) per audit. This is a 43 percent average increase in productivity. The CR Audit Program managers are saving, on average, about 240 minutes (4 hours) per audit, which is a 67 percent average increase in productivity. This process also eliminates manual entry of the audit deficiencies into the PIMS audit database.

5. Lessons Learned

The PIMS audit submissions module automation features have the greatest impact on the CR Audit Program's productivity. Most human errors are eliminated, and efforts are spent primarily on the quality of the deficiency content in the audit report.

Memorial Sloan Kettering Cancer Center

Saved by Automation! How Technology and Innovative Thinking Significantly Increased Productivity of the Clinical Research (CR) Audit Program

Jacqueline Simpronio & Susan Puleio, ACRP-CP, CCRP

BACKGROUND

In 2017, the CR Audit Program at Memorial Sloan Kettering Cancer Center (MSK) was charged with increasing the scope of internal audits conducted across the clinical research portfolio. Previously, in 2016, CR Quality Assurance conducted 22 audits of MSK clinical trials. This is in contrast to 2019 and 2020, where 99 (350% increase) and 125 (468% increase) risk-based audits, respectively, were conducted. Naturally, this resulted in a workload increase surrounding auditing activities [e.g., creating/finalizing audit reports], thus exposing the limitations of manual audit reporting.

The CR Audit Program conducts ~10 audits a month, each requiring a custom audit report to be completed, previously generated using Microsoft Word.

Focus was turned to utilizing electronic systems, particularly the MSK Protocol Information Management System (PIMS), in order to increase productivity of audit report creation. PIMS is an in-house developed application that manages all steps involved with the protocol life cycle, including protocol auditing.

In 2020, the CR Audit Program began working with PIMS IT Developers to build a PIMS Audit Submissions Module to automate the audit report process.

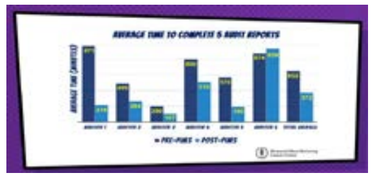
METHODS

The PIMS Audit Submissions Module was successfully launched in June 2020.

This Module allows the audit report to be built directly into PIMS and includes some of the following key features:

- Automation and validation functionality
- Direct filing of audit reports into an audit database
- Audit deficiency drop-down options and default deficiency ratings
- User friendly interface and navigation
- "My Queue" feature to track all pending audit assignments

RESULTS



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

To fully understand time-saved and improved efficiency, data collected was calculated on each level of the Audit Reporting Process, pre- and post-PIMS Audit Submissions Module implementation.

Audit Reporting Process Includes (measured in time)

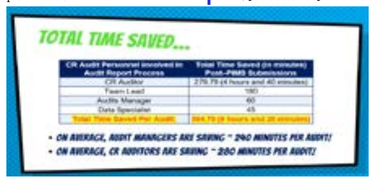
1. Data Entry into Word Document vs PIMS Audit Submissions Module
2. First Level Manager Review of Report, Pre-PIMS vs. Post-PIMS
3. Second Level Manager Review of Report, Pre-PIMS vs. Post-PIMS
4. Final Auditor Corrections of Report, Pre-PIMS vs. Post-PIMS
5. Manual Copying of Data from Word Document into Audit Database Prior to PIMS Audit Submissions Module Implementation

Six Auditors estimated time to complete 5 initial audit report, pre-PIMS vs. Post-PIMS.

Estimates were calculated using the following criteria:

1. Estimated time to enter audit deficiencies
2. Estimated time to tally deficiencies and extrapolate summary sections
3. Estimated time to review completed audit report prior to first level manager review
4. Estimated time to make updates after receiving comments/corrections (in total)

Additionally, two Audit Team Leads and CR Audits Manager averaged their review time, pre-PIMS vs. post-PIMS.



CONCLUSION

1. PIMS Audit Submissions Module has demonstrably helped the CR Audit Program function more efficiently.
2. Most "human" errors have been eliminated as a direct result of PIMS automation.
3. CR Audit Program now handles significant workload increase while reducing errors and omissions and improving quality.
4. CR Audit Specialist, previously responsible for manually entering audits into audit database, spends more time working on metrics and special projects and less time on data entry.

ACKNOWLEDGMENTS

MSK CR Informatics and Technology (CRIT) Unit

PIMS IT Developers
- Michael Ayerov
- Haritha Daggumati

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- Nara Chhua
- Debbie Marcellus-Duval
- Danae De Blasi
- Reena Dholakia
- Charina Duarte
- James Lozada
- Michael McGinn
- Ashley Soh
- Jennifer Tom
- Vimal Singh
- Jane Myers
- Jean Kelly

Strengthening Monitoring/Auditing Collaboration With Sponsors

A. Granobles, F. Puma, K. Yataghene, K. Mantha-Thaler, N. Cimaglia
Memorial Sloan Kettering Cancer Center

1. Background

The Monitoring and Auditing Tracking System (MATS) is a clinical research platform developed to track external monitor/auditor visitations. A primary function of MATS is to facilitate monitoring visits for Memorial Sloan Kettering's (MSK) industrial-sponsored portfolio with scheduling, requesting access to systems, collecting and sharing feedback, and storing relevant data. MATS enables real-time identification and communication of significant issues/trends immediately after an external monitoring/audit visit with the completion of its digital feedback form – the cornerstone of the MATS quality initiative.

The objectives of the feedback form are:

- Real-time communication of significant issues identified by external monitors/auditors to the principal investigator and research staff for immediate action
- Escalation pathway to clinical research leadership for awareness
- Evaluation of trends by the clinical research quality assurance unit across all departments/services as early risk indicators of patient safety, regulatory and/or protocol compliance data in 2019 indicated a decrease in feedback form completion

Due to the high value of the missing data, it was key to act swiftly to identify the reason for this non-compliance and implement process improvements to maintain and strengthen MSK relationships with its sponsors.

2. Goals

- Increase the completion rate by identifying the root cause(s) for non-compliance
- Improve the granularity of data received by revising feedback questions to improve utility when shared with stakeholders
- Maintain and strengthen relationships among MSK and sponsors

3. Solutions and Methods

- A cross-collaborative working group was formed within the clinical research administration (CRA) unit to dissect the process and content of the feedback form
  - o Root causes identified:
    1. Awareness: increase messaging regarding compliance
    2. Education/instruction: simply feedback form so that completion is more user friendly and intuitive
    3. Technical: monitors/auditors encounter technical issues while completing or submitting the feedback form
- Hands-on approach with its larger industrial partners (sponsors and CROs) to do the following:
  - o Serve as consultants for the revamp of the feedback form content Monitoring, and Auditing
  - o Re-educate their staff on the importance of compliance
  - o Attend recurrent information session meetings with MSK to reinforce expectations for compliance
- Enhancements were made to the feedback form content, including improvement of significant data collected, and to streamlining the interface of the feedback form
- New document resources were developed to support all users

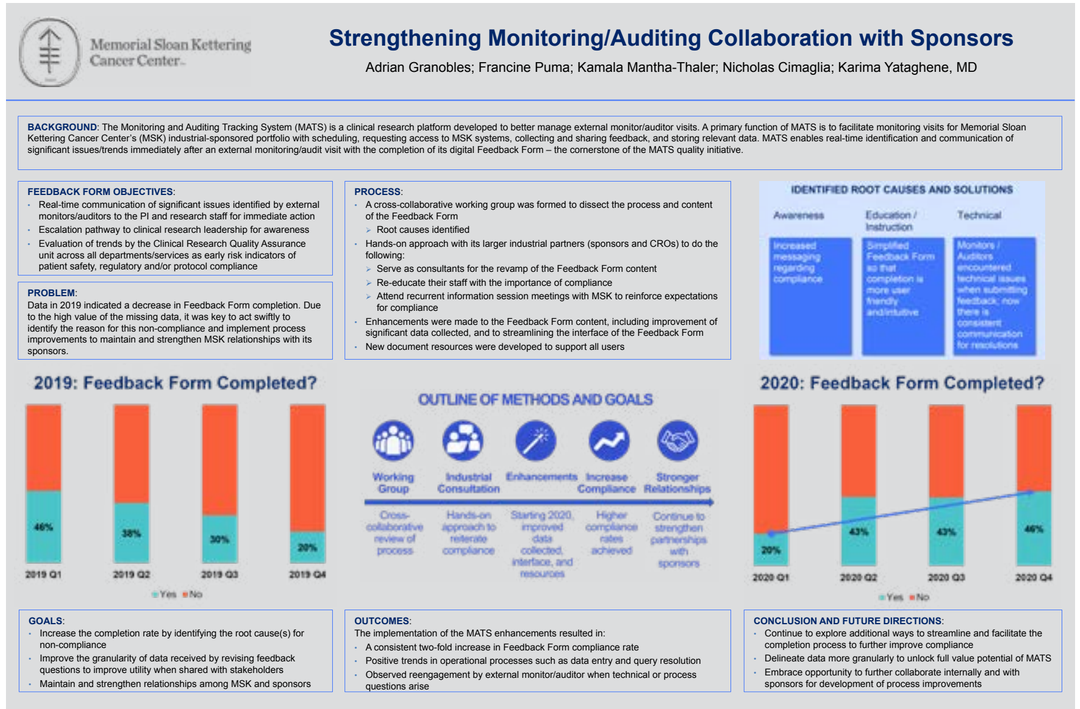
4. Outcomes

The implementation of the MATS enhancements resulted in:

- A consistent two-fold increase in feedback form compliance rate
- Positive trends in operational processes such as data entry and query resolution
- Observed reengagement by external monitor/auditor when technical or process questions arise

5. Lessons Learned

- Continue to explore additional ways to streamline and facilitate the completion process to further improve compliance
- Delineate data with more detail to unlock the full value potential of MATS
- Embrace opportunity to collaborate further both internally, across CRA, and externally, with sponsors, for information sharing and development of process improvements



1 Electronic Source Documentation in Epic Reduces Key Audit Findings and Aids in Remote Coordinating and Auditing

N. Kurtzweil, M. Marcum, T. Wise-Draper
University of Cincinnati Cancer Center

1. Background

In 2018 space for paper charts became increasingly limited. Auditing revealed source wasn't being created or reviewed in a timely manner. Additionally, the clinical trials office (CTO) and cancer clinics are in separate buildings making obtaining principal investigator (PI) signatures difficult. Moreover, research logs weren't standardized and current protocols were hard to access through a virtual private network (VPN) in clinic. A solution for these documentation shortcomings beyond increased staffing and space was needed.

2. Goals

The use of standardized electronic logs and SmartPhrases in our electronic medical record system, Epic, was intended to increase timely creation of source documentation, reduce delays in maintaining source and PI reviews, and reduce the number of internal audit findings attributable to paper source usage. This was also intended to allow for remote auditing and monitoring.

3. Solutions and Methods

In 2019 the CTO implemented the use of electronic source documentation in Epic. The CTO developed Epic SmartPhrases to standardize source documentation and visit notes. Electronic logs were developed within Epic for lab/EKG clinical significance (CS), adverse events (AE), medical history, con-meds and RECIST to enable PI review and sign-off. In 2019 protocols were transitioned to an online eRegulatory system (Complion).

4. Outcomes

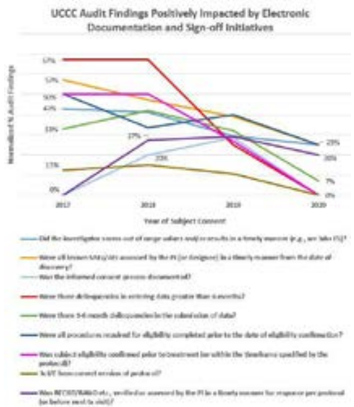
Comparing normalized internal audit data from subjects consented in 2017-2020, our standardized metrics have quantified the benefits of documenting primarily within electronic systems. The accompanying graph details the most significant percentage changes in key audit findings during this time period. Below the change in frequency of each is summarized, and a brief description of which electronic documentation tool or abandoned paper source-based practice impacted each.

- One hundred percent decrease in:
  - o Not documenting the consent process (SmartPhrase for consent discussion)
  - o 6+ month delinquencies in data entry (no printing and wet-ink signature delays)
  - o Eligibility documentation occurring after treatment (education, visit SmartPhrases, and allowing confirmations via email)
  - o Eligibility criteria from incorrect protocol version (use of eRegulatory)
- Thirty-two percent decrease in AEs not being assessed by PIs/Sub-Is in a timely manner (electronic AE logs)
- Twenty-six percent decrease in three to six months data entry delinquencies (no printing and wet-ink signature delays)
- Twenty-five percent decrease in documentation of eligibility procedures after eligibility was confirmed (electronic CS, medical history, and RECIST logs; and visit SmartPhrases)
- Eighteen percent decrease in PIs not documenting CS in a timely manner (electronic CS logs and visit SmartPhrases)
- Seven percent decrease in RECIST not being assessed in a timely manner (electronic RECIST logs)

5. Lessons Learned

While a change from paper to electronic source improved key audit findings, other contributing factors were: increased staffing, detailed workflows, and an educator position. Each electronic tool was developed gradually allowing early adopters to test and champion use with peers. Having electronic documentation by 2020, the CTO easily continued auditing, monitoring, and data entry activities remotely during the COVID-19 restrictions. In the future we hope to implement electronic consenting within a Part 11-compliant system, and to find solutions to allow our EPIC records to interface directly with data capture systems to reduce transcription errors and free up additional staff time to focus on clinical duties.

Figure:



Electronic Source Documentation in EPIC Reduces Key Audit Findings and Aids in Remote Coordinating and Auditing

N. Kurtzweil, JD,CCRP; T. Wise-Draper, MD, PH.D.; M. Marcum, MS, CCRP
University of Cincinnati Cancer Center, University of Cincinnati, Cincinnati, OH

Introduction

In 2018, space for paper charts became increasingly limited. Auditing revealed source was not being created or reviewed in a timely manner. Additionally, the clinical trials office (CTO) and cancer clinics are in separate buildings making obtaining PI signatures difficult. Moreover, research logs were not standardized, and current protocols were hard to access through VPN in clinic. A solution for these documentation shortcomings beyond increased staffing and space was needed.

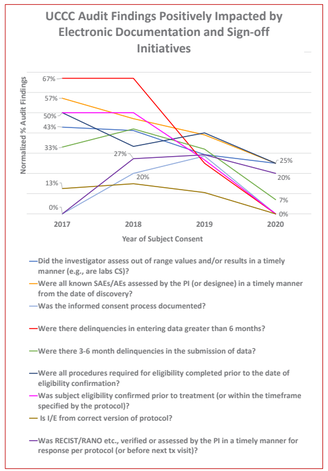
The use of standardized electronic logs and smart phrases in our electronic medical record system EPIC was intended to: increase timely creation of source documentation, reduce delays in maintaining source and PI reviews, and reduce the number of internal audit findings attributable to paper source usage. This was also intended to allow for remote auditing and monitoring.

Methods

In 2019, the CTO implemented the use of electronic source documentation in EPIC. The CTO developed EPIC smart phrases to standardize source documentation & visit notes. Electronic logs were developed within EPIC for lab/EKG clinical significance (CS), AEs, medical history, con-meds and RECIST to enable PI review and sign-off. In 2019, protocols were transitioned to an online eRegulatory system (Complion).

Results

Comparing normalized internal audit data from subjects consented in 2017-2020, our standardized metrics have quantified the benefits of documenting primarily within electronic systems. The accompanying graph details the most significant percentage changes in key audit findings during this time-period. Below the change in frequency of each is summarized, and a brief description of which electronic documentation tool or abandoned paper source-based practice impacted each.



Contact: Nicky Kurtzweil, JD, CCRP
QA & Data Clinical Research Manager – UCCC CTO
kurtzwny@ucmail.uc.edu

Results (cont.)

- **100%** decrease in:
  - Not documenting the consent process (smartphrase for consent discussion)
  - 6+ month delinquencies in data entry (no printing and wet-ink signature delays)
  - Eligibility documentation occurring after treatment (education, visit smartphrases, and allowing confirmations via email)
  - Eligibility criteria from incorrect protocol version (use of eRegulatory)
- **32%** decrease in AEs not being assessed by PIs/Sub-Is in a timely manner (electronic AE logs)
- **26%** decrease in 3–6-month data entry delinquencies (no printing and wet-ink signature delays)
- **25%** decrease in documentation of eligibility procedures after eligibility was confirmed (electronic CS, medical history, and RECIST logs; and visit smartphrases)
- **18%** decrease in PIs not documenting CS in a timely manner (electronic CS logs and visit smartphrases)
- **7%** decrease in RECIST not being assessed in a timely manner (electronic RECIST logs)

Discussion

While a change from paper to electronic source improved key audit findings other contributing factors were increased staffing, detailed workflows and an educator position. Each electronic tool was developed gradually allowing early adopters to test and champion use with peers. Having electronic documentation by 2020, the CTO easily continued auditing, monitoring and data entry activities remotely during the COVID-19 restrictions.

In the future we hope to implement electronic consenting and to find solutions to allow our EPIC records to interface directly with electronic data capture systems to reduce transcription errors and free up additional staff time to focus on clinical duties.

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

* Equity and Diversity Initiatives Within a Cancer Center's Clinical Trials Office

M. Dworak, M. Loza, D. Berkow-Schwartz
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1. Background

The events surrounding George Floyd's death permanently impacted the Minneapolis and St. Paul communities the Masonic Cancer Center serves. In an effort to combat institutional racism, implicit biases, and discrimination, an Equity, Diversity and Inclusion (EDI) Committee was launched at the University of Minnesota Clinical Trials Office (CTO) to increase equity work within the clinical trials workspace. The EDI committee aims to increase equitable practices in three domains: patient engagement and recruitment, office environment, and clinical trial structure.

2. Goals

The Continuum on Becoming an Anti-Racist Multicultural Organization, adapted by Melia LaCour, is a tool designed to gauge an institution's level of organizational antiracism. The continuum is a scale from one to six; one is defined as an exclusionary institution that intentionally and publicly excludes or segregates people of disability, color, or other marginalized groups. The high end of the spectrum, six, is defined as being a fully inclusive, antiracist, multicultural organization in which members across all identity groups participate in decision making that shapes the institution. Employees utilized the continuum to assess where the CTO and university fit, providing a baseline assessment. A 66 percent response rate (n=52) ranked the CTO an average of 3.67, compared to the University of Minnesota at 4.12.

3. Solutions and Methods

The EDI Committee, established in June 2020, meets weekly to collaborate on EDI-related projects. Brainstorming sessions with staff and leadership led the committee to implement solutions promoting change through education, shared resources, and outreach. To date, 10 discussion sessions were offered to employees. A centralized Google Drive containing EDI resources and projects was developed. Of note, the revision to the CTO's mission now includes an equity, diversity, and inclusion statement. Signage promoting inclusivity and delineating gender norms was placed throughout the office. The work policy for email signatures was modified to include personal pronouns, in aims to eliminate gender assumptions. Committee members are invited to attend protocol-writing meetings to address equity within this process. These projects exemplify CTO's move towards equitable practices at an institutional level.

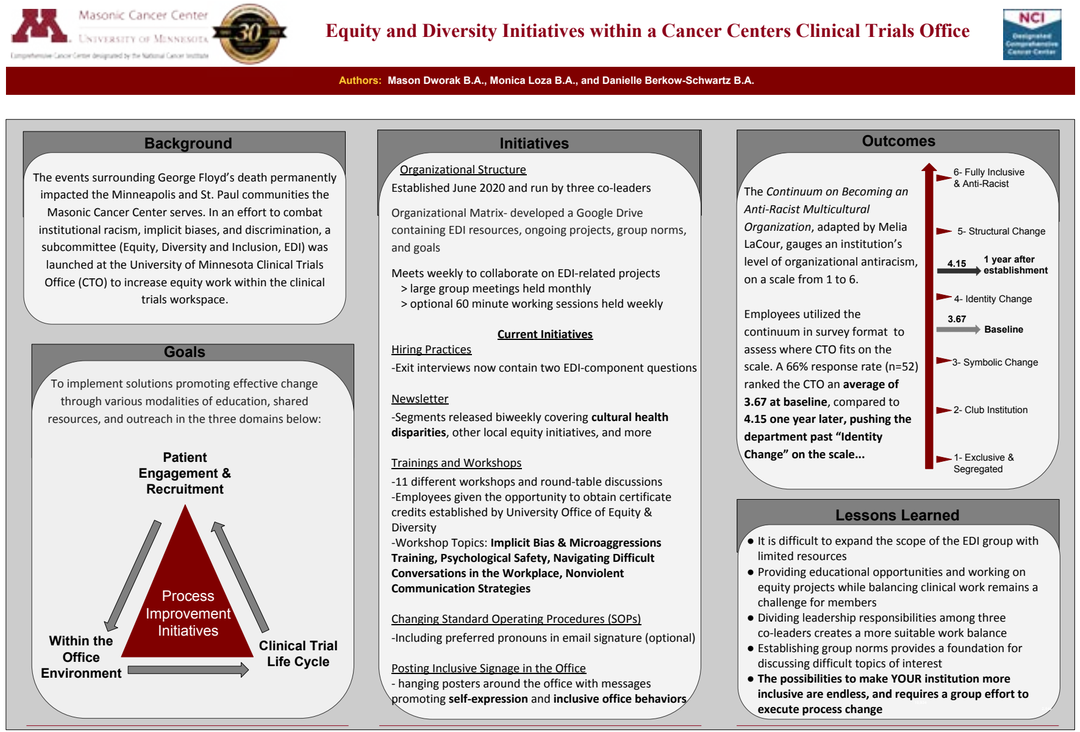
4. Outcomes

Employees completed a secondary survey (n=83) in March 2021 regarding EDI initiatives. With a 53 percent response thus far (n=44), 47.7 percent of respondents noted a drastic increase in EDI resources and educational opportunities. Over 75 percent of respondents stated they have participated in at least one EDI event. All respondents indicated that the EDI committee's mission positively impacts the CTO and its office environment; contrarily, 83.8 percent of respondents indicated the committee needs to do more to be truly effective. The Continuum on Becoming an Anti-Racist Multicultural Organization survey will be readministered at the end of March 2021 to measure change from baseline.

5. Lessons Learned

The EDI initiatives are ever-changing based on time capacity, staff engagement, and levels of effectiveness. Limitations include balancing workload between committee members, as well as measuring change with subjective surveys. Establishing group norms, keeping members accountable, and pushing leadership to participate drive the committee forward in its efforts to see equitable change in patient engagement and recruitment, within the office environment, and clinical trial structure.

* *Honorable Mention*



Onboarding and Training New Staff While Working Remotely During a Global Pandemic

E. Laskowski, J. DeJong, H. Apell
The University of Kansas Cancer Center

1. Background

The University of Kansas Cancer Center (KUCC) has a robust onboarding and training program for new employees; however, prior to the global pandemic, the majority of onboarding and training was provided in person with no virtual training options. We were not equipped to conduct training and onboarding in the remote setting. The development of additional training methods utilizing online training platforms, virtual training meetings, and recorded training sessions were required in order for new staff to feel supported while most clinical trials office (CTO) staff were working remotely.

2. Goals

- Transfer our standard operating procedures (SOPs) and guidance documents to the smart learning management solution, SABA
- Record virtual training sessions for new employees and investigators, in order to generate a recorded training library for new and seasoned employees
- Upload additional guidance and training to the CTO intranet site to provide a centralized location for staff to access information while working remotely
- Collect user feedback via REDCap survey, six to eight weeks following employee start date, to continue to improve virtual onboarding and new employee satisfaction

3. Solutions and Methods

The initial step was to gain access to virtual training platforms such as Skype, Zoom, and Microsoft Teams, which would allow us to screen share and present training materials, while utilizing the video option to engage new employees. We transferred all of our SOPs and guidance documents into SABA, where staff are required to complete a five-question knowledge check to assess their understanding of the content. CTO new employee orientation was hosted via Zoom and recorded for future staff that were hired during the pandemic. To support our investigators, we created a dedicated investigator page on our CTO intranet site that included recorded PowerPoint trainings, resources, and a handbook that can be accessed electronically. We also offered virtual training sessions quarterly, to keep staff engaged and continue to provide support while working remotely. These training sessions were saved in an electronic training folder for staff and new hires to access.

4. Outcomes

In 2020, 35 new employees were hired and onboarded to the CTO at KUCC during the global pandemic. Feedback was collected via a REDCap survey on the remote onboarding experience in hopes to improve our methods. Overall, the response was positive; our poster details these results.

5. Lessons Learned

We have learned that we need to find additional training options for staff who do not enjoy learning virtually and incorporate methods to effectively train based on all learning styles. This will allow for a more well-rounded onboarding and training program that includes virtual and in-person training utilizing audio, visual, and kinesthetic methods. The following feedback will be used to improve our processes:

- Colleagues not using their video during a training session
- Internet connection issues
- Lack of in-person shadowing in clinic
- Too much time between training and application of the task

We are working toward transferring our core competencies to a virtual training platform utilizing SABA. We also plan to collaborate with the University of Kansas Medical Center (KUMC) to standardize computer-generated training across the university campuses.

Onboarding and Training New Staff While Working Remote During a Global Pandemic

Jilliann De Jong, CCRP; Emily Laskowski, CCRP; Hobs Apell, BS

BACKGROUND

The University of Kansas Cancer Center (KUCC) Clinical Trial Office (CTO) has a robust onboarding and training program for new employees; however, prior to the global pandemic the majority of training was provided in person, with no virtual training options. KUCC was not equipped to conduct training and onboarding in a remote setting. The development of additional training methods utilizing online training platforms, virtual training meetings, and recorded training sessions were required in order for new staff to feel supported while most CTO staff were working remote.

GOALS

- Transfer our Standard Operating Procedures (SOPs) and Guidance Documents to the smart learning management solution, SABA.
- Record virtual training sessions for new employees and Investigators, in order to generate a recorded training library for new and seasoned employees.
- Upload additional guidance and training to the CTO intranet site to provide a centralized location for staff to access information while working remote.
- Collect user feedback via REDCap survey, 6-8 weeks following employee start date, to continue to improve virtual onboarding and new employee satisfaction.

METHOD

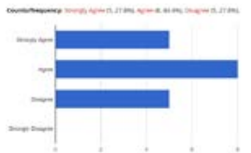
- Accessed virtual training platforms such as Skype, Zoom, and Microsoft Teams; which allowed us to screen share and present training materials, while utilizing the video option to engage new employees.
- Transferred all SOPs into SABA, where staff are required to complete a five-question knowledge check to assess their understanding of the content.
- Hosted CTO new employee orientation via zoom and recorded for future staff hired during the pandemic.
- Supported our Investigators by creating a dedicated page on the CTO intranet site that includes recorded PowerPoint trainings, resources, and a handbook that can be accessed electronically.
- Offered virtual training sessions quarterly, to keep staff engaged and provide support while working remote. Training sessions were saved in an electronic training folder for staff and new hires to access.

RESULTS & CONCLUSION

In 2020, 35 new employees were hired and onboarded to the KUCC CTO during the global pandemic. Feedback was collected via a REDCap survey on the remote onboarding experience in hopes to improve our methods.

- ***94.4% strongly agreed or agreed*** *they felt supported during onboarding, while staff were remote.*
- ***72.2% strongly agreed or agreed*** *that reviewing our SOPs and Guidance Documents within SABA and taking a quiz after, helped them retain the content longer.*
- ***50%*** *accessed the recorded training sessions often or somewhat often and* ***94.2%*** *found them* ***very helpful or somewhat helpful.***
- ***100%*** *found the CTO intranet site* ***very helpful or somewhat helpful*** *during their onboarding.*
- ***94.4% strongly agreed or agreed*** *the training sessions via zoom were beneficial.*

Found SOP Training within SABA Helpful



Found Training Sessions Via Zoom Helpful

LESSONS LEARNED & FUTURE PLANS

- Generate additional training options for staff that do not enjoy learning virtually and incorporate methods to effectively train based on all learning styles, including virtual and in-person training utilizing audio, visual, and kinesthetic methods.
- Transferred our core competencies to a virtual training platform utilizing SABA.
- Collaborate with the University of Kansas Medical Center (KUMC) to standardize computer-generated training across the University campuses.
- The following feedback will be used to improve our processes:
  - Frustration with colleagues not using their video during a training sessions
  - Internet connection issues
  - Lack of in person shadowing in clinic

TRIAL RECRUITMENT & COMMUNITY OUTREACH AND ENGAGEMENT

Strengthening Connections: Integrating Clinical Trials Into Patient and Public Education

G. Nachaegari, S. Fraser, D. Branson, J. Moehle, T. Werner
Huntsman Cancer Institute, University of Utah

1. Background

Providing patient education and facilitating access to clinical research are two vital ways that cancer centers serve communities; however, many education and research programs are developed independently with minimal coordination between departments. Huntsman Cancer Institute (HCI) is strengthening connections between our patient and public education program and the clinical trials office to ensure that all of our patients receive timely, accurate information about clinical trials and appropriate referrals to care.

2. Goals

- Strengthen connections between clinical trials office outreach and other cancer center resources like the patient and public education department
- Increase clinical trial accruals among women, minorities, and individuals from rural/underserved areas
- Develop metrics to capture clinical trial enrollments facilitated by this interdepartmental collaboration (see figure)

3. Solutions and Methods

HCI's patient and public education department and clinical trials office are already collaborating in several areas, including:

- Clinical trial inquiries
  - Health educators at the G. Mitchell Morris Cancer Learning Center educate patients and families about clinical trials before referring them to the clinical trials office for follow-up by appropriate research teams
- Health equity and inclusion
  - The clinical trials office hosted a meeting with HCI's Spanish-speaking, American Indian, and adolescent/young adult patient navigators to discuss common misconceptions and cultural barriers to clinical trials participation
- Satellite and affiliate sites
  - The clinical trials office established a satellite site project administrator position to help oversee clinical trials at nearby HCI facilities and created an affiliate site committee to support National Cancer Institute (NCI) trial activation at more distant affiliate sites

Clinical trials office staff and investigators also support HCI's community outreach goals through:

- Joint treatment planning conferences
  - Physicians from other area hospitals routinely join HCI investigators for treatment planning conferences where clinical trials are discussed
- Clinical trial referrals
  - Clinical trials staff created a secure online referral form for external providers to request information about available clinical trials for specific patients and established a clinical trials navigator position to serve as a single point of contact for trials that span more than one disease group

4. Outcomes

Although these strategies are continually being refined, we expect the following benefits as a result of our ongoing collaboration:

- Streamlined process for patients and families seeking clinical trial information
- Shorter timelines for providers referring patients to clinical trials
- Increased clinical trial accruals among women, minorities, and individuals from rural/underserved areas

5. Lessons Learned

As we continue to strengthen the relationship between HCI's education and research programs, we are in the process of incorporating the following additional strategies:

- Promoting clinical trials in rural/underserved areas via patient and public education
- Developing metrics to identify clinical trial enrollments facilitated by this partnership between groups
- Improving access and eliminating barriers to care through quarterly health equity subcommittee meetings
- Offering virtual clinical trials education as part of the NCI Community Health Educator grant
- Continuing clinical trials training for patient navigators as new staff are hired
- Providing clinical trials training for financial advocates to help reduce financial barriers to accrual
- Updating the clinical trials search functionality on the HCI website

View all abstracts and posters at **aaci-cancer.org/2021-abstracts**.

Strengthening Connections: Integrating Clinical Trials into Patient and Public Education

Gayatri Nachaegari, M.Pharm, CCRP; Susanna Fraser, MPH, CCRC; Donna Branson, BA; Jessica Moehle, BS, CCRP; Theresa L Werner, MD

BACKGROUND

Providing patient education and facilitating access to clinical research are two vital ways that cancer centers serve our communities; however, many education and research programs develop independently with minimal coordination between departments.

Huntsman Cancer Institute (HCI) is strengthening connections between our patient and public education program and the clinical trials office to ensure that all patients receive timely, accurate information about clinical trials and appropriate referrals to care.

GOALS

1. Strengthen connections between clinical trials office outreach and other cancer center resources like the patient and public education department
2. Increase clinical trial accruals among women, minorities, and individuals from rural/underserved areas
3. Develop metrics to capture clinical trial enrollments facilitated by this interdepartmental collaboration

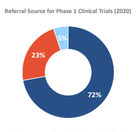
CURRENT STRATEGIES

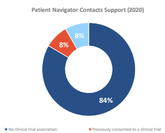
HCI's patient and public education department and clinical trials office are already collaborating in several areas, shown in Figure 1 below.

Both teams are working to streamline our information sharing to better capture the impact of different outreach programs on clinical trial enrollments, particularly among underserved populations.

Figure 1

Though limited, our existing data provides valuable direction for improving community outreach and collaborative efforts.





OUTCOMES

Although these strategies are continually being refined, we expect the following benefits:

- Streamlined process for patients and families seeking clinical trial information
- Shorter timelines for providers referring patients to clinical trials
- Increased clinical trial accruals among women, minorities, and individuals from rural/underserved areas

FUTURE STRATEGIES

We continue to strengthen the relationship between HCI's education and research programs by incorporating the following strategies:

- Promoting clinical trials in rural/underserved areas via patient and public education
- Developing metrics to identify clinical trial enrollments facilitated by this partnership between groups
- Improving access and eliminating barriers to care through quarterly Health Equity subcommittee meetings
- Offering virtual clinical trials education as part of the NCI Community Health Educator grant
- Continuing clinical trials training for patient navigators as new staff are hired
- Providing clinical trials training for financial advocates to help reduce financial barriers to accrual
- Updating the clinical trials search on the HCI web site

TRIAL START-UP AND ACTIVATION

One Committee to Review Them All: A Single, Multidisciplinary COVID-19 Research Committee

J. Migliacci, S. Hanley, A. Rodavitch
Memorial Sloan Kettering Cancer Center

1. Background

On January 20, 2020, when the first case of a novel coronavirus (COVID-19) was confirmed in Washington, its major impact was unknown. Memorial Sloan Kettering's (MSK) Hospital Incident Command System (HICS) was activated on February 5, with our first COVID-19 case identified in early March. By March 17, our Protocol Activation and Human Research Protection Program was fully remote and on March 23, MSK leadership requested the creation of the COVID-19 Research Committee.

2. Goals

Given the race to identify safe and effective treatments for COVID-19, modifications to MSK's workflows and review processes were needed. The goal was to create a COVID-19 Committee as a "one-stop" committee, providing comprehensive review of clinical research related to COVID-19, including scientific review mandated by the Cancer Center Support Grant (CCSG) guidelines, prior to review by the institutional review board. This committee would be charged includes prioritizing the research portfolio to prevent overlap of efforts.

3. Solutions and Methods

Figure 1 illustrates the quick timeline of events leading up to and after the creation of the COVID-19 committee. Our Protocol Information Management System (PIMS) was leveraged to efficiently manage and track COVID-19 research. The COVID-19 committee was created within seven days, as opposed to the several months it typically takes for such enhancements. The charge of the new committee was to prioritize and expedite all clinical research related to COVID-19 in support of the institutional effort to rapidly activate therapeutic and other COVID-19 related research. These changes were implemented by the Protocol Review Core (PRC). Members included faculty from multiple disciplines, disease management groups and departments. From March to June, the committee held 18 meetings, sometimes twice a week, and continued to review protocols through September outside of meetings: in total, reviewing 22 prospective, 42 retrospective, and 4 biospecimen protocols.

4. Outcomes

Of the 22 prospective protocols, 8 were removed from the activation pipeline for various reasons. The remaining 14 protocols (100 percent) opened to accrual (OTA) at the time of this data lock, in a median of 44 days. In comparison, the medicine committees reviewed 58 protocols in a similar timeframe, only 43 percent of which were OTA. This unique single committee structure enabled protocols to open in an unprecedented timeframe. Notably, 5 of the 7 therapeutic protocols have enrolled 136 participants (in total), with first patients enrolled in ≤ 1 day.

5. Lessons Learned

Observing how this new "one-stop" committee has enabled such quick activation; our unit is now exploring how to utilize multidisciplinary committees to reduce the time to activation for all research protocols. Some considerations have been sustainability of review timelines. The time commitment and quick turn-around demand from a single committee to review all 300+ protocols in our activation pipeline each year needs to be considered. An idea we hope to explore further is to group protocols by disease and create a group of committees by disease management team. Figure:

Memorial Sloan Kettering Cancer Center

One Committee to Review Them All: A Single, Multi-Disciplinary COVID-19 Research Committee

Jocelyn Migliacci, MA, Sara Hanley, MSW, and Ann Rodavitch, MA
Memorial Sloan Kettering Cancer Center

Background

On 1/20/2020 when the first case of a novel coronavirus (COVID-19) was confirmed in Washington, its major impact was unknown. MSK's Hospital Incident Command System (HICS) was activated on 2/5, with our first COVID-19 case identified in early March. By 3/17, our Protocol Activation and Human Research Protection Program was fully remote and on 3/23, , MSK leadership requested the creation of the COVID-19 Research Committee.

Goal

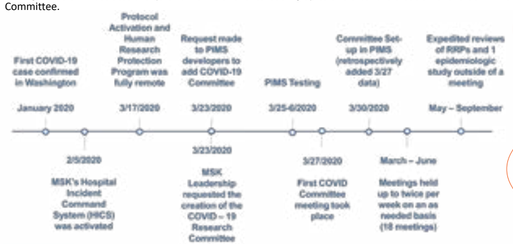
The goal was to create a COVID-19 Committee as a **"one-stop" committee**, providing comprehensive review of clinical research related to COVID-19, including scientific review mandated by the Cancer Center Support Grant (CCSG) guidelines, prior to IRB review.

Role of the Committee

- To prioritize and expedite all clinical research related to COVID-19 in support of the institutional effort to rapidly activate therapeutic and other COVID-19 related research.
- To monitor the COVID-19 research portfolio to prevent overlap of efforts.
- To list all studies on the Clinical Research Portal for transparency.
- To bring together faculty from multiple disciplines, disease management groups and departments, including Physicians, Statisticians, Nurses, Pharmacists, Legal, IRB Leadership, etc.

Creation of the COVID-19 Committee

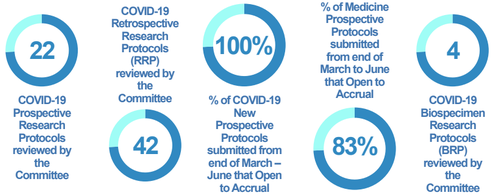
The figure below illustrates the quick timeline of events leading up to and after the creation of the COVID-19 Committee.



MSK's Protocol Information Management System (PIMS) was leveraged to efficiently manage, and track COVID-19 research. The COVID-19 Committee was created within **7 days**. Typically, it would take several months to roll out this type of large enhancement.

- Of the 8 therapeutic protocols that opened to accrual, 5 protocols have enrolled **146 participants** (in total)
- The first patient on each of the 5 studies was enrolled within ≤ **1 day** of each study opening to accrual.

Metrics (updated as of June 2021)



Impressive decrease in Time to Activation (TTA) and Time to IRB Approval (TTIA) for the protocols reviewed by the COVID – 19 Committee

COMMITTEE	Median TTA	Median TTIA
COVID-19 COMMITTEE	44 days	27 days
MEDICIINE COMMITTEE	194 days	119 days

Next Steps

- **Our unit is exploring how to utilize multidisciplinary committees to reduce the time to activation for all research protocols.**
- **One option we are exploring is to group protocols by disease and create a group of committees by Disease Management Team.**

Study Start-up Activation Dashboard - Improving Transparency

L. Wall, A. Spratt, N. Connellan
The University of Chicago Medicine Comprehensive Cancer Center

1. Background

The University of Chicago has an institution-wide initiative to reduce our study start-up timelines so that we can offer our patients novel cutting-edge treatment options. Study activation is a resource intensive process which involves time and effort from multiple stakeholders responsible for the discrete steps of the overall process. These include the principal investigator (PI), operations team, regulatory, budget managers, contracts/legal team, coverage analysts, and investigational drug pharmacy, in addition to the various institutional review committees. We sought to identify opportunities for efficiency and standardization to reduce start-up timelines. However, the biggest challenge was trying to understand "whose desk is it on." With multiple stakeholders and workflows involved it was challenging to know where trials would bottleneck as we lacked any common tracker that detailed the activation timeline for each trial in the activation pipeline. Effective communication and good collaboration across the various offices involved is critical to opening trials timely.

2. Goals

Identify and create an internal dashboard to provide transparency on where trials are in the start-up process. This dashboard had to be available to be edited by multiple users simultaneously as well as accessible from both on- and off-campus locations. This transparency will allow us to better analyze study start-up progress, identify areas where trials are bottlenecked, and develop metrics to track progress to ensure we are meeting our target timelines.

3. Solutions and Methods

We created a dashboard utilizing web-based team workspace that was freely available to us under a university-held license (Confluence). This platform allows for editing by multiple users and includes alert functions for when changes are made. The primary purpose of the dashboard is to provide the relevant stakeholders with status updates for each step in the activation process. This encompasses sponsor site selection/feasibility, first-tier scientific review, scientific and other internal review committees, coverage analysis, treatment plan build, contract/budget negotiations, site initiation visits, and research staff assignments. The dashboard is updated before each disease team's weekly research meeting.

4. Outcomes

The dashboard (see figure) has proven to be invaluable in identifying where the protocol is in the start-up process and has also helped hold the different parties accountable. Use of this dashboard has highlighted the commitment from all involved in shortening protocol activation timelines. In addition to increased transparency, it has spotlighted the volume of work across not only the individual disease programs, but the entire cancer center enterprise. This has helped with discussions regarding prioritization and clinical research staffing needs. It has also allowed us to identify, pause, or terminate studies earlier in the process, by calling attention to those that have hit significant roadblocks, thus ensuring that the research staff are focusing efforts on the projects that are the most value-add. It has facilitated conversations with the PIs and sponsors regarding their role in the activation process, thus holding them accountable as well. Lastly, it has decreased the need for individual emails or calls amongst the stakeholders asking for frequent updates. In conclusion, the start-up dashboard has accomplished our goal of increased transparency and will help us build out metrics in the future. It will allow us to put in place effective and proactive measures to ensure that we are using start-up resources effectively. It's important that key stakeholders work together and partner to proactively identify study start-up related issues and execute action plans to mitigate risks to timely activation.

5. Lessons Learned

Transparency around this process helps hold stakeholders accountable for their role in the activation process. Study activation is a complex and time-consuming process. The dashboard has identified a need for continued and strategic prioritization of new trials across the disease teams so that resources are being spent on the right trials.

AT THE FOREFRONT
UChicagoMedicine
Comprehensive Cancer Center

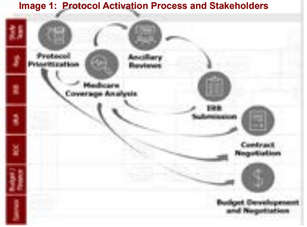
Study Start-up Activation Dashboard – Improving Transparency

Lauren Wall, MS; Amanda Spratt, CCRP; Niall Connellan, BS
University of Chicago Comprehensive Cancer Center

Background

The University of Chicago has an institution-wide initiative to reduce our clinical trial start-up timelines. Study activation is a resource intensive process which involves time and effort from multiple stakeholders responsible for the discrete steps of the overall process

Image 1: Protocol Activation Process and Stakeholders



The biggest challenge in trying to identify opportunities for efficiency and standardization to reduce start-up timelines was trying to understand "whose desk is it on." With multiple stakeholders and workflows involved it was challenging to know where trials would bottleneck as we lacked any common tracker that detailed the timeline for each trial in the activation pipeline.

Goals

- Create an internal dashboard to provide key metrics and updates for clinical trials in study start-up phase
- Identify best platform for dashboard that allowed simultaneous editing by multiple users and which as accessible from locations both on- and off-campus.
- Create resource to allow Cancer Center and University administrators and leadership to identify areas where clinical trials bottlenecked in the activation process
- Develop metrics to track progress to ensure we are meeting target activation timelines.

METHODS

We created a dashboard utilizing a web-based team workspace that was freely available to use under a University-held license (Confluence). This platform allows for editing by multiple users and includes alert functions to notify relevant stakeholders when updates and changes are made.

The dashboard is central location to report and monitor status updates across the protocol activation process including:

- Sponsor site selection and feasibility
- First-tier scientific review at programmatic level
- Scientific Review Committee (SRC) submission, review, and outcome details and dates
- Institutional Review Board (IRB) submission, review, and outcome details and key dates
- Medicare Coverage Analysis (MCA)
- Treatment plan build
- Contract and budget key dates and milestones
- Site Initiation Visit
- Research staff assignments

The dashboard is updated on a weekly basis prior to each disease team's research meeting which is attended by principal investigators, research nurses, regulatory staff, coordinators, data managers, clinical pharmacists, and other individuals involved in clinical trials conduct at our site.

Clinical Trial Start-up Activation Dashboard

RESULTS

The dashboard has met the intended goal of increased transparency across the protocol activation process. It has proven to be invaluable in identify where the protocol is in the start-up process and has been successful in holding the different parties and groups accountable for their role in timely trial activation.

Key outcomes:

- Spotlight the volume of work across the individual disease portfolios as well as the entire Cancer Center enterprise. This has helped guide and facilitate discussions regarding prioritization and clinical research staffing needs.
- Identify and pause or terminate start-up activities earlier in the process for trials that have hit signification roadblocks to activation
- Ensuring that research staff across the protocol activation process are focusing efforts on the projects that have the most value-add for the Cancer Center.
- Facilitate discussions with principal investigators and trial sponsors regarding their roles in the activation process thus holding them accountable as well
- Decreased the need for individual emails or calls between the various stakeholders asking for frequent updates.

The dashboard tool has proven success largely due to the support and buy-in of all relevant stakeholders including leadership from our regulatory, financial, nursing informatics, pharmacy, and clinical operations teams highlighting the collaborative nature of clinical research and commitment across the University to shortening protocol activation timelines.

Transparency around this process helps hold stakeholders accountable for their role in activation process. Study activation is a complex and time-consuming process. The dashboard has identified a need for continued and strategic prioritization of new trials across the disease teams so that resources are being spent on the right trials.

The start-up dashboard has accomplished our goal of increased transparency and will help us build out metrics in the future. It will allow us to put in place effective and proactive measures to ensure that we are using start-up resources effectively. It has highlighted commitment and value of ensuring that key stakeholders work together and partner to proactively identify study start-up related issues and execute action plans to mitigate risks to timely activation.


ABSTRACTS

CLINICAL TRIAL OPERATIONS

Operationalizing a New Therapy Across Research Groups: A Team-Based Approach to Managing CAR T Clinical Trials

L. Waitkus
Cleveland Clinic Cancer Center

1. Background
The expansion of CAR T-cell therapy in oncology research has been experienced by the Research Program at the Cleveland Clinic. As more cell therapy trials opened and patients enrolled, functional challenges of these complex trials were identified, and action plans were developed to address issues as they arose. At the beginning of 2020, momentum increased for CAR T therapy and a need to develop a formal team-based operations plan of starting up and managing these trials was identified.

2. Goals
The goal was to develop a Cellular therapy Assist Team (CAT), a core group of researchers with specialized CAR T clinical trial knowledge, as a means to assist research groups in running CAR T-cell therapy trials, increase collaboration across groups, provide education on cellular therapy, and ensure the research department has adequate resources and personnel in order to successfully run cellular therapy trials. A secondary goal was to increase the number of CAR T trials and increase the number of patients enrolled on these trials compared to previous years.

3. Solutions and Methods
The CAT is housed in the Blood and Marrow Transplant (BMT) research group and includes a lead physician, lead research nurse, and BMT data/regulatory supervisor. Department physicians alert the core team when there is interest in a new cell therapy trial. The CAT's involvement includes reviewing the protocol, assisting in completion of sponsor site feasibility questionnaires, participating in an internal feasibility review, involvement in cell therapy-specific budget creation, assisting with site Institutional Biosafety Committee application and approval, facilitating communication between research groups and the apheresis department and cell processing lab, coordinating location of infusions between inpatient and outpatient units, and training outpatient personnel on cell therapy infusion protocols and safety. The core group communicates frequently via email and meets every two weeks. A larger CAT group comprised of the core group along with physicians from the leukemia, myeloma, lymphoma, melanoma, Phase I, and thoracic oncology research groups meet every other month to review the cell therapy portfolio, assess any challenges/feedback, brainstorm new ideas and processes, and provide education opportunities.

4. Outcomes
From 2015-2019, six CAR T-cell clinical trials were opened to accrual within the Lymphoma and BMT Research Programs and 16 patients received treatment on these studies. In 2020 alone, there were eight clinical trials opened, a 400 percent increase compared to the two trials in 2019, and 18 patients enrolled, a 300 percent increase compared to the six patients enrolled in 2019. Additionally, there was expansion in the number of research groups that opened cell therapy trials. Groups that opened trials include BMT, lymphoma, myeloma, melanoma, and lung research groups.

5. Lessons Learned
As research in cellular therapy continues to grow, sites must continue to grow their resources and knowledge in order to operationalize these complex trials. The increase in both the number of clinical trials and patients enrolled to CAR T-cell clinical trials after formation of the CAT demonstrates the need for continuation and expansion of this team-based approach. Future efforts include incorporating CAR T budget specialists into the CAT and expanding cellular therapy infusions in the outpatient setting.
Figure:

COVID Response: Providing Ongoing Oncology Clinical Research Support During a Pandemic

B. Oleson, J. Thomas, J. Bollmer, K. Schroeder, D. Pastorek, P. Jacobs, M. Pigsley, S. Zindars, G. Coly
Medical College of Wisconsin Cancer Center

1. Background
The first case of COVID-19 was discovered in the United States January 21, 2020. Less than two months later, the Medical College of Wisconsin (MCW) and adult Cancer Center Clinical Trials Office (CCCTO) transitioned to a mandatory work-from-home status for all non-essential staff. We had 261 patients receiving protocol interventional therapy at that moment. In the next month, 20 percent of our research team was furloughed. The most pressing issue was whether to suspend our research enterprise to new enrollment and focus only on current patients already under therapy or to allow select trials to remain open and additionally continue the new trial activation process.

2. Goals
Our goal was to develop criteria as to which trials should remain open for continuing enrollment and action on those in the activation process. At the same time, we needed to keep our patients and team safe while maintaining protocol compliance.

3. Solutions and Methods
The CCCTO leadership initiated the institutional discussions about clinical research management during the pandemic. Team managers completed a business continuity plan as requested by the MCW Office of Research, with our CTO medical director driving institutional decision making. The managers developed remote work responsibilities, communication plans, and workflows for their teams. Most trials were suspended, but MCW allowed a subset of cancer studies to remain open: trials where patients had no effective standard of care option (including some Phase I trials) or trials where the treatment intervention (e.g., hyperfractionated radiation therapy) required fewer on-site visits. The disease-oriented teams reviewed their portfolios using these criteria and identified studies to remain open, and the CTO medical director and administrative director then reviewed and approved the trial lists. Our institution developed a three-staged plan for trial reactivation, with the first phase beginning in May. We completed a document listing each trial's impact on services provided by hospital partners, e.g., likelihood of a subject needing ICU support or extended inpatient stay. We then submitted the CTO's reactivation proposal for institutional approval. The timing of each stage of reactivation was based on COVID related census and the capacity of our partner hospital to support the clinical research enrollment impact.

4. Outcomes
From 140 treatment trials available for enrollment on March 15, 2020, we dropped to a low of 42 by June 1. Through thoughtful reactivation and new trial activation, we reached pre-COVID levels of trial availability of 145 on November 16. Despite allowing only minimal staff presence on site and fewer on-site patient visits, we were able to offer treatment trial enrollment at a stable number (1.0 percent accrual increase compared to 2019).

5. Lessons Learned
Our approach to ongoing enrollment during the pandemic was a relative success. The measured approach to trial reactivation and increasing on-site staff support proved sufficient to maintain trial accrual. Continued robust accrual coupled with staff furloughs and offsite CTO staff did stress the available staff and led to delays in pending projects.

Automating Protocol Training Documentation: Regulatory Compliance in a Click

R. Lehrman, P. Lim, C. Abate, J. Buthorn, A. Foster, E. Hamilton, H. Kiesler, K. Yataghene
Memorial Sloan Kettering Cancer Center

1. Background

A protocol's regulatory binder comprises essential documents and demonstrates the compliance of the investigator, sponsor, and monitor with the standards of good clinical practice and with all applicable regulatory requirements. At MSK these are housed in the Protocol Information Management System (PIMS). Although regulatory binders are electronic, maintenance can be a manual process. Non-compliance with regulatory requirements can have serious consequences for the investigators, the institution, and can impact an application for drug approval. We describe ongoing efforts to optimize the automation of one aspect of the PIMS binder, protocol training documentation. Documentation of protocol training is required before the start of any research related activity and throughout the life of the study. Notable timepoints include at the site initiation visit, when significant amendments are approved by the institutional review board, and ad-hoc to ensure continuous compliance. Historically, this has been a manual process which involves the study team preparing paper logs and collecting signatures or requesting emails from investigators to confirm the training material has been reviewed. Once completed, training documentation was scanned and uploaded into PIMS and the documents were certified.

2. Goals

Success will be analyzed using metrics including time and effort savings as well as a notable improvement in audit findings from the established baseline.

3. Solutions and Methods

A PIMS enhancement was released on September 28, 2020 to automate this process. Training emails, inclusive of training material, can now be electronically initiated by the study team in PIMS. Investigators review and acknowledge their understanding of the training through clicking a URL within the email, automatically generating training documentation that is immediately visible in the regulatory binder.

4. Outcomes

Positive: Protocol training documentation is automatically filed in an organized manner, making it easier to review, track, and maintain. This allows for a consistent standard across the institution. This new process eliminates a potential source of error in regulatory documentation. Preliminary data shows marked improvement in study team time and effort. Thus far, the new process has been well received.

5. Lessons Learned

Future goals include a mechanism to monitor investigator completion and generate notifications.

Clinical Trial Finder - A Comprehensive Mobile Application

D. Mudaranthakam, V. Murakonda, A. Tribitt, J. Scott, B. Broome, J. Thompson, M. Mayo, B. Gajewski, T. Lin
The University of Kansas Cancer Center

1. Background

Engagement is a critical aspect of the successful completion of a clinical trial. Without enough engagement and recruitment, clinical trials are frequently terminated or unable to achieve statistically significant results. Significant factors associated with poor recruitment in failed trials include low physician referral rates, lack of awareness of clinical trials in patients, and a lack of available information regarding clinical trials. Nearly one in four publicly sponsored cancer clinical trials failed to achieve adequate recruitment to demonstrate statistical significance in their findings.

2. Goals

To overcome the recruitment obstacle, it is vital to foster engagement from the three primary stakeholders of a clinical trial: patients, physicians, and study teams.

3. Solutions and Methods

Our efforts to increase engagement among all three major stakeholders led us to develop solutions tailored to their needs. With this in mind, a software tool was designed for each stakeholder: a mobile referral app for physicians (named as KUCC Clinical Trial Finder); a cancer clinical trial search system for patients on the KU Cancer Center website (Find a Clinical Trial); and an accrual prediction application for the study teams (KUCC Accrual App.).

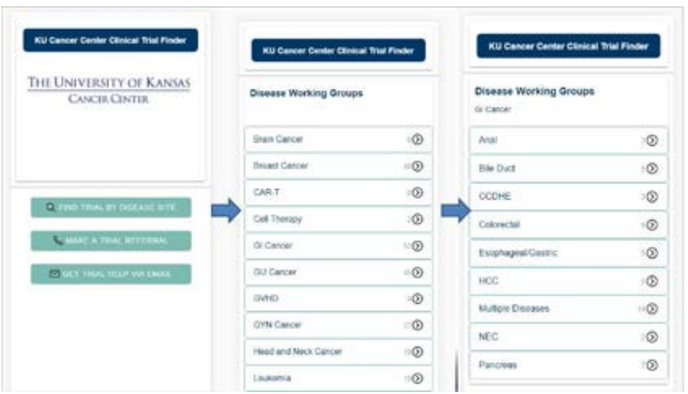
4. Outcomes

The mobile application was launched in late 2020 for both Apple and Android users. So far, more than 300 users have downloaded the application. We have received overwhelming appreciation regarding the ease of use and a comprehensive list available at the fingertips. Patients and their families are also able to utilize the application to identify the various open trials that are available.

5. Lessons Learned

Our non-cancer disease teams have approached our team to build a similar application to streamline their studies. We anticipate extending the application to other major non-cancer diseases such as cardiology, internal medicine, and neurology.

Figure:



OPTIK - Organize Prioritize Trends to Inform KU Cancer Center Members

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The University of Kansas Cancer Center

1. Background
An increasingly diversified demographic landscape in rural and urban America warrants the attention of The University of Kansas Cancer Center (KU Cancer Center) researchers, clinicians, outreach staff, and administrators as the institution assesses ways to reach its expansive, bi-state catchment area. Within the counties of the KU Cancer Center catchment area, patient level and public health data are available and categorized by varying geographic regional boundaries. Multiple data sources and different data collection processes complicate summarizing catchment area data.

2. Goals
A tool that can consistently blend data from multiple sources to provide KU investigators data and visualization can be used to draw inferences.

3. Solutions and Methods
A curated data warehouse that retrieves and structures the data, with a common denominator, can support meaningful use of the data in a standard and consistent format. The KU Cancer Center built a data warehouse, Organize and Prioritize Trends to Inform KU Cancer Center (OPTIK), which functions to streamline the process of synthesizing data regarding Kansas and Missouri demographics, cancer risk factors, and incidence and mortality rates.

4. Outcomes
OPTIK standardizes these diverse data sources to enable analyses of the cancer burden at local, regional, and national levels while upholding a strict standard of patient privacy. The OPTIK database enables researchers to use available data and create heat maps and other visualizations to aid in funding proposals, presentations, and research activities.

5. Lessons Learned
Furthermore, using knowledge provided by OPTIK, the KU Cancer Center is able to prioritize action items for research and outreach, and more effectively communicate the impact of those efforts.

Citation: https://academic.oup.com/database/article/doi/10.1093/database/baaa054/5876850 https://optik.shinyapps.io/OPTIK/.

We Have 99 Problems But a Participant Withdraw is No Longer One

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Barbara Ann Karmanos Cancer Institute, Wayne State University

1. Background
One of the essential components of clinical research is accurate and timely reporting of a participant's status, which includes the research participant's decision to discontinue treatment or withdraw themselves completely from a clinical trial. Through the evolution of the clinical research program at the Karmanos Cancer Institute (KCI), the terminology used by investigators and clinical trials staff to document a participant's decision to discontinue treatment has evolved into categorizing them as a "withdraw." Source documentation reflecting a participant withdrawal subsequently requires a different pathway for reporting versus a participant's decision to discontinue from the primary intervention. The Clinical Trials Office (CTO) identified this as an area of opportunity for us to: 1) Understand and educate the clinical research team on the accurate terminology to define a participant's decision to discontinue treatment or withdraw from study; 2) Increase accurate documentation, standardization, and reporting consistency for participant-initiated discontinuations/withdrawals; 3) Increase participant comprehension of the outcome of their decision.

2. Goals
Resources from OHRP, FDA, GCP, and collaborating institutional review boards were reviewed to guide the documentation process and establish definitions for use throughout this initiative. Collectively understanding the definitions of the applicable terminology was essential. A subsequent goal was to generate a template for real-time use by the clinical research nurses (CRN), which can be recorded in the medical record, to accurately document the participant's decision. Creation of a CTO Policy and Workflow was also required.

3. Solutions and Methods
Participants enrolled on a clinical trial may discontinue and/or withdraw participation at any time. It is the responsibility of the investigator and research team to confirm the details of the participant's request. The CTO implemented a policy and workflow to guide the clinical research team to accurately document the participant's decision, in real time. The utilized template includes pre-defined questions that allow the CRN and participant to determine the subsequent course of action. The completed template is recorded as a clinical document in real time in our cancer center's electronic health record (EHR) and is accessible to the applicable clinical research team and sponsor/CRO representatives for monitoring purposes. Furthermore, this policy provides definitions of a participant withdrawal and discontinuation, which can now be provided as a source for education of various members of the research team.

4. Outcomes
A positive change that has occurred is the increase of source documentation in the participant's EHR, which outlines a clear decision by the research participant. This initiative has eliminated subsequent follow-up between the CRN and CTO study coordinators to determine and report the participant's decision. Additionally, the standardized definitions within the policy promotes consistent documentation in our cancer center's Clinical Trials Management System. This policy was implemented in October 2020, and over the last six months, 13 participants discontinued treatment or withdrew from study. We were able to capture 85 percent compliance utilizing this standardized process and template.

5. Lessons Learned
Instances of participant-initiated discontinuation or withdrawal continue to be evaluated for compliance. Education to the treating physicians, non-physician providers, and clinical research team regarding proper documentation and terminology for discontinuations and withdrawals is ongoing.

Executing a Healthy Volunteer Study During COVID-19 Pandemic

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City of Hope Comprehensive Cancer Center

1. Background

During the COVID-19 pandemic, City of Hope (COH), like other institutions, implemented and enforced visitor restrictions, including employees, both at main campus and community sites. Additionally, many patient visits were conducted via telemedicine. These restrictions dramatically decreased the number of healthy individuals accessing COH, learning about and potentially participating in healthy volunteer studies. This significantly impacted our Phase I COVID vaccine healthy volunteer study. Study participants were managed separately in a section of our clinical research unit (CRU) on evenings and weekends. Unfortunately, physician availability on evenings and weekends visits was limited. While consenting was completed remotely, all other study visits (12) required in-person assessments. The limited availability of space and physicians caused accrual delays. To meet the enrollment goal and move into Phase II, the study team needed to increase visibility, study access, and safely manage study participants and COH patients.

2. Goals

To achieve accrual goals, the study needed to be conducted outside COH main campus and was not originally operationalized for the community setting. The study requires nurses to complete multiple procedures and exams at each visit. We needed an innovative solution to execute the trial in the COH community with trained staff while also limiting the people accessing the clinic.

3. Solutions and Methods

We decided to use the COH bloodmobile unit, park it at select COH community sites, and complete study procedures in the unit, limiting the participants entering the community clinic. We hired an experienced per diem research nurse practitioner to provide study support. We selected a site with research-trained physicians for injection visits requiring MD observation post-administration. We worked closely with pharmacy and developed a clinic schedule for all injection visits to occur on Saturdays allowing use of clinic space during their closed hours. All other study visits were scheduled and conducted in the mobile unit on weekdays.

4. Outcomes

To enroll the maximum daily number of patients, based upon research lab draw requirements, we scheduled two rounds of participant enrollment visits. We did not move forward with the fist start date schedule due to limited number of participants wanting the specific community location. The second community site enrollment was scheduled for April/May.

5. Lessons Learned

After identifying the community site, we engaged marketing, updated study flyers, and established a number for participants to call with staff answering that could outline the community site schedule and Category: Clinical Trial Operations – Work in Progress track participants interested in the community site. Additionally, we simplified complex and slow patient enrollment processes. Updating flyers and institutional review board approval took time, giving us under two weeks of community advertising. Unfortunately, the timing limited our ability to consent enough participants for our first community site scheduled start day. The FDA emergency use-approved vaccines also reduced interest. It is unclear if a second scheduled community start date will be necessary as we are able to enroll participants more quickly, and the expanded marketing increased interested participants. However, we now have a plan to implement healthy participant studies at community sites, even with limited space access, including the Phase II portion of this study.

Clinical Trial Operations – Work in Progress

Increasing the Utilization and Efficiency of a Phase I Program to Support Pan-Tumor Clinical Trials

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Cleveland Clinic Cancer Center

1. Background

The Phase I program research group at Taussig Cancer Center is comprised of our lead investigator Dale Shepard, MD, PhD, and is focused on bringing in novel Phase I trials that span across disease groups to best serve our diverse patient population of solid tumors and genomic studies. Having a dedicated Phase I program has allowed Cleveland Clinic to grow in the amount of novel and early phase clinical trials, but its growth depends on the primary disease program's clinical team to refer patients to these trials to make it successful since ultimately, they are the personnel that evaluate these patients on a daily basis. Our main goal was to increase the awareness of the individual disease programs and their staff on the trials that we have open for their specializations and overall increase the efficiency of opening these trials to help provide options for patients.

2. Goals

- Increase awareness of Phase I studies across the other disease programs including brain; breast; gastrointestinal; genitourinary; gynecologic oncology; head and neck; lung; and melanoma
- Boost accrual of Phase I studies
- Streamline processes for study start-up

3. Solutions and Methods

In order to best serve our physician groups across several disciplines we implemented a real-time updated spreadsheet of all currently accruing Phase I trials broken down by disease type to provide a snapshot discussion that can be shared at bi-weekly team updates with providers. The search terms include institutional review board number and study title, targeted disease group, therapeutic category, prior number of therapies, ECOG performance, prior brain met criteria, and slot availability. Due to the nature of Phase I studies slot allocation change occurs rapidly and this list is kept up-to-date in real time to ensure providers have the most accurate information when viewing potential Phase I trials for their patients. The research coordinators maintain this list and review it in conjunction with our Phase I matrix that is a visual representation of what studies we have broken down by disease type and hyperlinked to the current protocol and informed consent document as well as the complete list of inclusion and exclusion criteria and study personnel. A single group email was set up so any provider can reach out directly to the Phase I clinical team personnel to pre-screen a patient and is monitored by several team member to improve response time. Furthermore, these patients can be monitored for future study enrollment. Having a single email allows for the clinical to only have to recall one general email that the whole Phase I clinical team has access to rather than recalling which personnel leads which study. This makes it quick and simple to send potential patients to the clinical team to get pre-screened. There has been a focus on our time to open for study start-up and increasing efforts to reduce study activation time to provide new treatment options to patients who may not have any other options. This includes simultaneous efforts across departments to complete feasibility; create budgets; draft informed consents; comply with data and regulatory requirements; submit to our protocol review monitoring committee, institutional review board, and other ancillary services; review calendars; and complete budget and contract negotiations.
We track progress of these efforts through weekly updates. We have worked with our quality program improvement department to identify process improvement opportunities and outline guidelines for escalation procedures. This started with identifying issues that we could impact for Phase I start-up projects that focused on standardized communication with sponsors and spurred into other projects around informed consent improvement projects and updating sponsor questionnaires, which are sent from the research coordinator to the sponsor shortly after site selection. These exercises helped streamline what continual improvement projects to work towards and develop to improve our start-up process across Phase I studies.

4. Outcomes

In 2020 the overall accrual of therapeutic and no-therapeutic trials across Phase I studies run out of the group was 38 patients compared to 11 patients in 2019, which represented almost a 250 percent growth. Initial data demonstrated a five-fold increase in patients being pre-screened than prior to the implementation of the real-time Excel sheet and "one-stop-shop" email address. Measure time to open from site selection, principal investigator approval, and protocol distribution to site activation, our median days to open a trial at the end of 2020 was 128 days.

5. Lessons Learned

Internal spreadsheets updated in real time are providing physicians with real-time data on what studies have available slots and weekly meetings about start-up timelines are helping improve upon processes by identifying gaps and problem-solving across departments to continue to decrease our time to study activation. Establishing closer relationships with the physician leaders of each tumor type to help better assess the feasibility of trials and their accrual estimates also helps increase awareness of competing trials they may have running in their own groups. Involving finance from the start prior to internal budget creation helps establish a relationship with sponsor budget/contract staff early on and establish priorities and timelines for opening. More user-friendly searchable terms for intranet (internal site that houses all of our clinical trials) use are being reviewed through other mechanisms to allow providers and potential patients access to trials that we have open directly through our website.

* There and Back Again: A Satellite Site Operations Tale

B. Glenn, K. Stephens, A. Horstmeier, E. D'Astous, J. Moehle, T. Werner
Huntsman Cancer Institute, University of Utah

1. Background

Of all National Cancer Institute (NCI)-Designated Comprehensive Cancer Centers in the United States, Huntsman Cancer Institute (HCI) serves the largest geographic region. Three HCI satellite locations were established at community clinics to better reach and care for patients. The availability of clinical trials at our satellite locations helps expand treatment opportunities for our patients. Although it may be more convenient for patients, having multiple locations poses unique challenges to managing clinical trials. At HCI, the clinical trials office has coordination teams that focus on particular disease groups. However, the satellite team works with multiple disease groups and a variety of providers. Challenges to this model include miscommunication and maintaining continuity in trials across different teams.

2. Goals

There are currently 230 trials open to accrual at HCI, with 45 open at our satellite locations. We want to expand the portfolio of trials available at the satellite locations and see continued growth in patient visits and accruals.

3. Solutions and Methods

It is critical that coordinators communicate and work together across sites when enrolling, transferring, or screening patients. We have established ongoing training and created processes to better facilitate communication when coordinating trials across locations. Patient transfers from the main HCI to a satellite location require special attention. There is a level of continuity of care insomuch as our providers are consistent between sites. We have established a patient transfer process outlining timelines and dictating responsibilities for when patients change study locations permanently or for one visit. This process ensures the patient is cared for, scheduled appropriately, and that study procedures are completed consistently across sites and study teams. Additionally, the satellite site team has a dedicated project administrator. This position provides oversight for all aspects of satellite site operations, acts as a liaison between teams and locations, and coordinates process improvement activities. New hires attend a satellite operations training course with the project administrator. This course dictates the collaboration needed between the teams. Ongoing training through MasterControl requires all study teams to review the calendar template and work practice document outlining the patient transfer process.

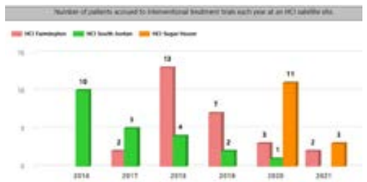
4. Outcomes

The graph below reflects the lack of consistent growth in patient accruals to clinical trials at HCI satellite locations over time. Although some of these variations can be attributed to changes in provider and trial availability, we anticipate a steady increase in accruals in upcoming years. This growth is projected since implementing the transfer process, hiring a dedicated project administrator to manage satellite operations in 2019, and opening the new Sugar House location in 2020.

5. Lessons Learned

We would like to see growth in the number of patients accrued at the satellite locations while maintaining quality and consistency across all of the HCI locations. Additionally, the COVID-19 pandemic has led to widespread use of instant messaging and conference calls, which has the positive impact of increasing collaboration between the satellite and disease group teams. We have learned the critical nature of maintaining communication and integrating teams across locations. This integration continues to occur through training, communication, process development, and quality improvement.

Figure:



* *Honorable Mention*

Establishing an Employee Engagement, Equity, and Education Committee During Remote Operations

J. Feola, M. Kimber, A. Hoeschen, M. Dworak, M. Loza
Masonic Cancer Center, University of Minnesota

1. Background

The retention of talented clinical research professionals is a top priority for all clinical research enterprises. Initiatives fostering positive interactions with colleagues, creating learning opportunities, and seeking to create a more equitable workplace can significantly enhance morale, job satisfaction, and retention. The abrupt shift to a remote working environment in the clinical research field has further underscored the need for robust employee engagement programs, many of which have required reimagination to accommodate the virtual workplace. An employee engagement working group was established for the first time in the Masonic Cancer Center Clinical Trials Office (CTO) in 2017. Although working groups were designed as short-term projects with employee participation lasting a year, the need to maintain employee engagement initiatives was emergent. However, full rotation of group membership at the end of each year inhibited progress on long-term projects. Furthermore, as a working group, the employee engagement team operated separately from other departmental teams with similar goals, missing opportunities for collaboration. With this in mind, a proposal to redesign the employee engagement group was developed in June 2020.

2. Goals

1. Establish permanent committees, rather than temporary working groups, that foster and promote employee engagement, equity and diversity, and education

2. Provide remote engagement opportunities that allow colleagues to make connections with one another

3. Solutions and Methods

A wide array of CTO staff engaged in collaborative discussions to develop the structure of the committee and ultimately broaden its scope to incorporate relevant focus areas. Thus, the Employee Engagement, Equity, and Education "Quad E" Committee was established, along with four subcommittees: Equity, Diversity, and Inclusion; Early Education and Onboarding; Mentoring and Ongoing Education; and Engagement in Learning. The new committee structure was introduced via presentations at team meetings, and regular Quad E committee meetings began in September 2020. Meetings include dedicated time for subcommittee leaders to share updates and identify areas of cross-committee collaboration.

4. Outcomes

Five employees joined the Quad E Committee, with regular participation from an additional seven employees who serve as subcommittee co-leaders. In total, 38 percent of CTO staff participate in at least one committee. As of March 2021, the Quad E Committee has facilitated 11 unique virtual engagement opportunities, such as themed coffee chats and yoga sessions, with three additional activities in development. In a department-wide survey conducted in October 2020, Quad E initiatives were viewed favorably, with an average score of 4.46 on a scale of 1-5, with 1 being least favorable and 5 being most favorable.

5. Lessons Learned

Preliminary observations of our remote programs indicate that engagement in recurring events declines over time, which suggests that a wide offering of opportunities may enhance participation. We also identified a need to promote future participation on the committees by presenting them to new staff and developing annual recruitment strategies. Department-wide satisfaction in Quad E initiatives will be reassessed after a full year of operation under the new committee structure while remote operations continue, and as increased on-site operations resume. Regular evaluation of the Quad E Committee's initiatives will be key to understanding staff needs.

Transformative Lessons for Clinical Trials From the COVID-19 Pandemic: Remote Monitoring, Virtual Research Visits, and Added Flexibility for Patients

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Mayo Clinic Cancer Center

1. Background

The onset of the COVID-19 global pandemic required creative strategy in clinical trial operations while keeping staff and patients safe. Virtual clinical trials operations were adjusted based on trial characteristics: visit frequency, inpatient vs. outpatient therapies, infusions vs. oral medications, etc. The FDA Guidance published in March 2020 served as an excellent resource. From the beginning, it was clear that flexibility would be essential. Lessons learned from the pandemic will change the way we conduct clinical trials for years to come.

2. Goals

1. Explore opportunities to transition research appointments to fully virtual visits

2. Virtual visits for site qualification (SQVs), study initiation (SIVs), audit/monitoring, and closeouts

3. Pharmacy virtual visits for SQVs, SIVs, monitoring/auditing, and closeouts

4. Staffing plans to minimize COVID-19 exposure risk

3. Solutions and Methods

1. Patients
   a. Phone/virtual visits: received approval from sponsors for virtual visits and use of external laboratory results. Study teams regularly discussed which patients could transition to virtual visits.
   b. Communication: implemented secure messaging through Epic and the Doximity app for virtual calls.

2. Sponsor/Study Teams
   a. Remote monitoring: implemented an institutional mandate for permanent remote monitoring visits through EpicCare Link/SimpleShare.
   b. Deviation management: developed a COVID-19 specific EPIC SmartForm for deviation documentation, necessary for identification and reporting. The IRB allowed for cumulative submission of COVID-19 related deviations during annual continuing review.

3. Pharmacy
   a. Drug shipment: assessed options for drug shipment and commercially available agents that could be dispensed locally. Developed a standardized SmartPhrase within EPIC for communications with pharmacy.
   b. Pharmacy audits/monitoring visits: implemented virtual tours of the pharmacy using iPads with a secured Zoom account. Electronic temperature logs were made available for monitor review and a video of our facility was created for SQVs and SIVs.

4. Staff
   a. Teleworking: early in the pandemic, all data clinical research coordinators (CRCs) were moved to full telework and 75 percent of clinical CRCs worked remotely. Currently, 25 percent of clinical CRCs rotate working remotely.
   b. Adverse event (AE) capture and paper source: implemented an electronic AE documentation process through EPIC. Paper documents were mailed to patients or sent electronically.
   c. New staff: initially remained on site. Implemented a hybrid (remote/onsite) 8-week training program.

4. Outcomes

1. Patients: increase in the use of virtual visits observed.

2. Sponsor/study team: from September to December 2020, we released 12,392 individual patient charts for 858 remote monitoring visits. These charts spanned 107 unique CRCs and 469 studies across the cancer center inclusive of all Mayo Clinic sites.

3. Pharmacy: during 2020, we conducted 360 virtual pharmacy monitoring visits, seven virtual audits, and mailed out 499 research prescriptions.

4. Staff: we transitioned from 100 percent onsite work to 53.5 percent onsite and 46.5 percent offsite. As of November 2020, on quarter of clinical CRCs continue to work remotely using a patient load dependent weekly rotation. Additionally, we trained 34 new CRC hires using the new training program.

5. Lessons Learned

- Provided flexibility for research participants via virtual visits
- Significantly increased efficiency through remote monitoring/audits
- Completed transition to long-term remote monitoring
- Implemented long-term teleworking strategy for all CRC staff
- Developed hybrid remote/onsite new hire training and onboarding program
- Continue exploring transition options from paper to electronic source, including e-consenting for cancer center research participants

Transitioning to Remote Monitoring Visits at the Helen Diller Family Comprehensive Cancer Center

M. Kock
UCSF Helen Diller Family Comprehensive Cancer Center

1. Background

As of March 16, 2020, the city and county of San Francisco implemented a shelter-in-place order that required our study teams to quickly begin working remotely. As a result, many of our monitoring visits were cancelled or postponed. Due to the need of ongoing monitoring, many study teams were overwhelmed with requests to manually scan in source documents to share with study monitors and/or unable to share electronic source documents with sponsors in a secure fashion.

2. Goals

Our primary goal was to develop a workflow that allowed study monitors secure access to our electronic source documents so that we could continue to safely treat and enroll patients onto our clinical trials. Due to limited staffing on site, we also needed to identify a solution that effectively utilized our clinical research coordinators' (CRCs) time on campus preparing for monitoring visits.

3. Solutions and Methods

We worked with our IT and legal team to establish a workflow and participation agreement that allowed monitors access to our study patients' electronic medical record using MD Links. While establishing our workflow and sponsor level agreements, we reached out to multiple cancer centers to understand their workflows, lessons learned, and best practices. We then piloted our workflow with two of our main study sponsors. After successful visits, we then expanded to the entire cancer center. As of December 2020, this workflow was implemented across all research at UCSF.

4. Outcomes

During 2020, we conducted over 592 monitor visits remotely. This represents over 60 percent of our yearly monitoring visits and over 30 of our clinical trials sponsors.

5. Lessons Learned

We are focusing on standardizing our workflows and working with our IT team to fully use our EMR to its capacity for research purposes.

From Take-Off to Landing: The Creation and Implementation of a CCPS Navigator Resource

A. Trainor, A. Ivey, T. George, L. Pettiford, A. Anderson
University of Florida Health Cancer Center

1. Background

The UF Health Cancer Center (UFHCC) Clinical Research Office (CRO) is responsible for tracking and reporting all cancer-relevant research activity and also provides infrastructure for the Protocol Review and Monitoring System (PRMS) process. The CRO quickly identified that Cancer Control and Population Sciences (CCPS) study teams needed additional support to navigate the UFHCC review process and centrally report protocol status updates and subject accrual information. The CRO historically has relied upon CCPS investigators/staff for these functions with resulting inconsistencies when capturing CCPS study activity. In December 2018, the CRO responded by creating a full-time CCPS navigator position to provide assistance and guidance in an effort to address the inconsistencies noted and improve research efficiencies throughout the protocol lifecycle.

2. Goals

- Enhance CCPS investigators' understanding of ancillary review processes
- Improve protocol review efficiency during the two-stage PRMS process
- Improve capture of subject accrual entry and data maintenance
- Streamline distribution of information

3. Solutions and Methods

- Creation and integration of "navigator" position
  - Direct contact for study activation, including triage through PRMS review process
  - Liaison between CRO; CCPS research program; and Community Outreach, Engagement, and Equity program (COEE)
  - Support for integrating CCPS interventions into clinical settings (workflow, logistics)
- CCPS protocol template development and deployment
  - Resource for more efficient PRMS review of CCPS protocols
  - Template captures key areas of review required by PRMS and IRB
- CCPS data management plan
  - Clearly defined CRO expectations for data capture and accrual entry
- CCPS navigator webpage
  - Central distribution of resources and relevant clinical research information

4. Outcomes

- Enhanced connections between CCPS investigators, COEE program, CRO, and the clinicians –Use of navigator service to connect lead investigators to disease-site clinicians relevant to study design and patient population needed for recruitment
- Decrease review timeline with SRMC –Creation and distribution of a protocol template to reduce SRMC queries and requested revisions
- Improved efficiency of data collection, capture, and protocol activation

The CCPS navigator facilitates CCPS study activation, regulatory maintenance, and timely data collection and entry. With deployment of this resource, CCPS investigators now demonstrate an improved understanding of the PRMS review process; increased logistical support for deployment of interventional studies in clinical areas; and improved, routine (monthly) capture of accrual activity and protocol status allowing for accurate, real-time analysis of the CCPS research portfolio.

5. Lessons Learned

- Integration of a new resource must be organic and develop from invested stakeholder needs
  - CCPS leadership advocacy for navigator use is key, as are investigator testimonials regarding efficiencies gained and overall value of the resource
  - New CCPS needs assessment planned for late 2021
- Creation of educational modules specific to CCPS faculty and staff needs
  - General information about the cancer diagnosis and treatment lifecycle
- Extension of CCPS support into other, already established areas of the CRO
  - Extend enhanced assistance with protocol authoring and study development/activation through the Project Management Office

Figure:

Implementation of Electronic Informed Consent for Cancer-Relevant Clinical Trials at the UFHCC

A. Riggs, T. Toon, A. Anderson, A. Ivey, T. George
University of Florida Health Cancer Center

1. Background

The University of Florida Health Cancer Center (UFHCC) Clinical Research Office (CRO) has a diverse portfolio of cancer-relevant studies. Historically, the CRO has documented informed consent during in-person visits utilizing paper forms. We had long recognized the need for increased flexibility in the consent process, but COVID-19 became the catalyst for needed change. The paper informed consent form (ICF) creates increased administrative burden and opportunity for errors. After a paper ICF is signed, research staff digitize the document for upload to the clinical trial management system and electronic health record. Original paper ICFs can be inadvertently misplaced and pages easily separated. Additionally, expired or outdated versions can be retrieved leading to deviations and potentially compromising informed decision making. Furthermore, our catchment area is largely rural with many of our patients facing transportation challenges. Visits to the site for the sole purpose of consent to initiate screening are a barrier to participation. The deployment of electronic informed consent (eIC) also addresses this critical issue.

2. Goals

- Minimize travel burden for participants
- Minimize the administrative burden for research staff
- Improve trial accrual and regulatory compliance

3. Solutions and Methods

The University of Florida supported our needs and provided the infrastructure to broadly implement eIC. The REDCap platform was chosen as it is easy to navigate, intuitive for end users, and adheres to OHRP and FDA requirements. At the time of eIC implementation in Spring 2020, REDCap already allowed for the collection and storage of protected health information. To assist users, instruction manuals and guidance documents were created to highlight key features utilized as part of the consenting process. Expansion of eIC is following a tiered approach. Each tier includes four categories of implementation (see Figure 1) to prioritize specific studies and patient populations. This allowed us to focus initial efforts in areas where eIC would have the greatest impact. We also incorporated collection of demographic data and documentation of local HIPAA authorization into our eIC process.

4. Outcomes

To date, 16 participants have documented consent electronically, potentially reducing travel burden and decreasing COVID-19 exposure risk during a vulnerable time in their health. Using eIC has given the research staff more flexibility in scheduling and managing the flow of procedures during the screening process. The screening process has become more agile while simultaneously reducing administrative burden. Allowing electronic documentation rather than paper storage enables an emailed copy of the signed ICF to be sent directly to the participant. Electronically signed documents automatically saved in PDF format within REDCap easily upload to other systems. This has decreased potential for errors that can arise from copying, scanning, and filing paper versions of the forms.

5. Lessons Learned

Since early adaption of the eIC, adjustments have been made within REDCap to allow for different consenting scenarios. Examples include options for multiple consent forms for a protocol and/or participant, use of a legally authorized representative, and obtaining assent. Each adjustment provides staff with increased knowledge in the broad application of REDCap. We are currently in Tier 3 of our implementation process. Future efforts include implementing eIC across all studies.

Figure:

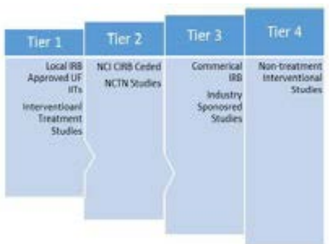

Figure 1. Tiered adoption of eIC

Adapting Adverse Event Log Creation During COVID-19: Development of the Winship eAE Log Application

D. Smith, M. Ellingson, V. Parker, M. Martin, T. Adewuya, P. Bourbo, S. Brown, L. Cox, M. Williams, L. Floyd, B. Gamble, M. Hananel, T. Kurilo, A. Lesinski, K. Nguyen, C. Shah, C. Sharp, A. Trumbull, A. Overby, M. Behera
Winship Cancer Institute of Emory University

1. Background
Oncology clinical trial protocols are highly regimented and complex, outcomes are centered on timing, and patient safety is paramount. One of the challenging aspects is the tracking and assessment of an adverse event (AE) that occurs during a clinical trial. While AE tracking is typically performed in near real time with paper logs, site workflows have historically been inefficient, time consuming, and labor intensive, requiring multiple in-person interactions. With the onset of the COVID-19 pandemic, every aspect of cancer care and clinical operations was strained, and inefficiencies in analog AE recording processes were extrinsically magnified, as the transfer of paper documents involving in-person interactions was deemed unsafe. To address these challenges, a new electronic AE tracking tool, the eAE Log application, was created.

2. Goals
The highest priorities in design of the eAE Log were ICH GCP requirements, maintaining regulatory compliance regarding access and storage of patient data aligning with FDA Title 21 CFR part 11 guidelines, and usability with automated workflows and escalation rules. Comprehensive audit trails were thus a requirement in providing an ongoing log of activity and changes to AE assessments.

3. Solutions and Methods
We relied upon our clinical trial management system (CTMS) as the single source of truth regarding clinical trial management and subject enrollment to circumvent entry of duplicate data. The eAE Log supplements data pulled in real time from the CTMS with the typical assessments required for adverse events (e.g., attribution to drug/device/procedure, seriousness of AE), and allows staff to remotely monitor AEs across all studies to which they are assigned in a single easy to use interface.

4. Outcomes
Data from this initiative shows steadily increasing staff adoption since implementation with promising timelines demonstrating faster turnaround from AE creation to assessment and signature. We will report the challenges that were encountered in the implementation of this technology, as well as lessons learned from the process.

5. Lessons Learned
The eAE log has provided an easy to use and dependable electronic method of AE reporting at a time when study staff and investigators were restricted from in-person interactions during the COVID-19 pandemic. The tool also supports remote monitoring and auditing. To further promote utility to users, future refinements for the software include incorporation of serious adverse event and deviation reporting, as well as possible implementation of new logs, including medical history and concomitant medications and procedures.

Enhancing the DSG Review at the UFHCC

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University of Florida Health Cancer Center

1. Background

The University of Florida Health Cancer Center (UFHCC) protocol review and monitoring system (PRMS), comprised of the Disease Site Groups (DSGs) and the Scientific Review and Monitoring Committee (SRMC), is charged with performing rigorous evaluations of feasibility and scientific merit of all cancer-relevant research studies. To enhance quality and review timeliness, UFHCC leadership crafted well-defined roles and responsibilities for DSG leadership. These specifications were needed to provide clear and consistent expectations for first-stage PRMS review. Initial problems identified while fulfilling this responsibility were: inconsistent communication between investigators within DSGs, lengthy DSG review times, variable DSG review documentation for rigor or merit, and communication delays between DSGs and SRMC. These problems arose at SRMC when studies were tabled or approvals delayed due to varied scientific or statistical concerns, which required additional revisions to address SRMC queries.

2. Goals

- Establish clear expectations for DSG reviews
- Improve communication from DSG to SRMC
- Consistently confirm review of scientific merit and support

3. Solutions and Methods

UFHCC leadership identified problems stemming from decentralized and inconsistent application of guidelines by the 13 DSGs. To streamline and overcome inconsistencies during initial review of newly proposed interventional trials, the UFHCC deployed DSG reviewer assessments within Qualtrics, an online survey tool. Each survey includes standard and customizable fields whereby DSG members endorse or decline a trial and answer feasibility questions relevant to the DSG-specific study population. Voting is done completely online, or trial discussion occurs at a scheduled DSG meeting where a survey is sent out after the meeting to record votes and discussion of feasibility and merit. The initial phase of this process was initiated in 2020 within 12 of the 13 DSGs. All votes are recorded and forwarded to the relevant DSG leader(s) for review and final approval.

4. Outcomes

There were no barriers to adoption of Qualtrics, and high engagement was seen. The average response rate across all DSGs in 2020 was 73 percent (range, 54-100 percent). Reviews done through Qualtrics documented improved investigator feedback with key questions of feasibility and merit more thoroughly addressed. In addition, this DSG process appeared to accelerate the SRMC review timeframe. In 2020, time to decision decreased from 39 to 16 days overall for SRMC initial reviews (Figure 1). In addition, a slight increase in the number of trials declined by the DSGs was seen from 2019 (65 percent) to 2020 (68 percent), suggesting Qualtrics helped DSGs become more critical during reviews (Figure 2).

5. Lessons Learned

Providing Qualtrics during initial DSG reviews allowed each DSG to be accountable for their portfolio and promoted "buy-in" from DSG voting members, increasing documentation of their scientific review rigor. The ability to record all votes through Qualtrics has allowed for more consistent communication between the DSGs and SRMC. Qualtrics provided DSGs opportunities to provide feedback that may not be shared during a convened meeting where conflicts or time restrictions may arise. Future efforts look to further refine DSG activity to better address protocol feasibility and relevance to UFHCC's unique catchment area. Additionally, we look to advance the DSG review process within our remaining DSG, the Cancer Control and Population Sciences Group.

Figure:

Figure 1: Time to SRMC decision for interventional trials from 2019 to 2020.

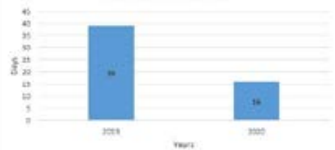
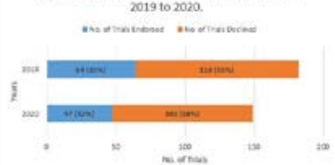


Figure 2: Trials endorsed & declined by DSGs from 2019 to 2020.



Managing Investigator-Initiated Clinical Trials Registration to Reduce Overall Reporting Errors at a Consortium Cancer Center

K. Hoy, A. Savadelis, A. Firstencel, H.J. Pounardjian
Case Comprehensive Cancer Center

1. Background

Registration of all clinical research studies in Clinicaltrials.gov (CTgov) has been required by law since 2007 (FDA U.S. Public Law 110-85), and further in 2017 (42 CFR 11.22). However, compliance with these regulations has been poor, with up to 50 percent of all studies failing to report or reporting late. The FDA intends to publicly announce all non-compliance and enforce civil penalties up to $10,000 (adjusted for inflation) a day for non-compliance. As of the date of this publication, there have been no fines levied. Recently, there have been several publications calling for greater compliance and reporting of clinical trials. Furthermore, there has been a focus on the lack of punitive civil action from the FDA. It is in the best interest of all NCI-Designated Cancer Centers to comply with these regulations to avoid receiving the initial financial penalty. To address this important issue, the clinical research office (CRO) offers centralized registration and results reporting support, but information must be provided and verified by the principal investigator (PI). Our office is able to pull some preliminary information from the clinical trials management system, OnCore™, such as participant flow, baseline characteristics, and some adverse event data. However, outcome measure data and remaining adverse event information must be provided to the CRO office by the PI in a timely manner. The CRO has worked to reduce these errors over time by implementing a two-part strategy:

1. Centralized registration of all studies prior to initiation
2. Reviewing quarterly reports from the Data Safety and Toxicity Committee (DSTC)

2. Goals

- Reduce reporting errors to fewer than 10 total
- Increase compliance with results reporting by following studies on a quarterly basis and at initial registration

3. Solutions and Methods

Registration:

- Scope: All Interventional trials that study cancer
- Deadlines: Must be registered in CTgov before any participants are enrolled
- Process: After PRMC approval, CRO will reach out to study team with record draft and clarifying questions > PI approval needed to release study for review > approved by CTgov or returned with QA comments > (repeat as necessary) > study approved and assigned NCT number

Results Reporting:

- Updated DSMP plan to include results reporting
- DSTC provides reports quarterly to the CRO to stay up to date with results

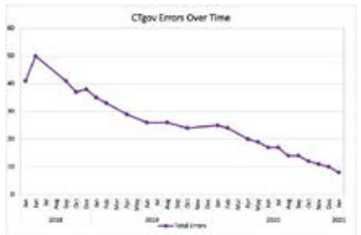
4. Outcomes

Total errors reduced from January 2018 (40+) to January 2021 (less than 10)

5. Lessons Learned

- Development of standard registration process reduces errors over time
- Tracking errors through coordination with the DSTC allows for more efficient results reporting

Figure:



Investigator-Initiated Trials - Work in Progress

Development, Management, and Oversight of Investigator-Initiated Multicenter Trials

J. Walkley, M. Warren, K. Muenkel, S. Hughes, C. Friedman, C. Houston
Memorial Sloan Kettering Cancer Center

1. Background

Investigator-initiated trials (IIT) often come with minimal funding. When proposed as multicenter, there is a need to address management and oversight internally rather than hiring a clinical research organization (CRO). In 2009, Memorial Sloan Kettering (MSK) created the Multicenter (MCT) Office, which was dedicated to multicenter trials where MSK is the sponsor and/or data coordinating center. The portfolio has grown from 75 to 260 trials, with increasing complexity. In 2020, MCT defined the trials which require their oversight, including therapeutic, high risk, or moderate risk, that have a primary or secondary endpoint of safety and/or efficacy. In alignment with portfolio growth and increased complexity, MCT expanded to three teams: Multicenter Activation, Multicenter Compliance, and Multicenter Protocol Operations. Each team serves a function to provide oversight and quality assurance regardless of trial type.

2. Goals

The goals of MCT are as follows:

Multicenter Activation

- Ensure feasibility of protocol(s) as multicenter IIT(s)
- Activate participating site(s), inclusive of negotiating budgets and contracts and collecting applicable regulatory documents and institutional review board (IRB) approval(s)

Multicenter Compliance

- Develop resources and policies for activating and overseeing participating site(s)
- Oversee regulatory compliance and serve as a central resource for all multicenter IITs

Multicenter Protocol Operations

- Oversee day-to-day management of multicenter IITs at participating site(s)
- Ensure quality assurance and oversight of participating site(s) and MSK
  - Real-time eligibility review of all external enrollments prior to registration
  - Retrospective eligibility review of randomly selected MSK enrollments
  - Risk-based monitoring of MSK and participating site(s)
- Standardize routine tasks, i.e. outside safety report and amendment distributions

3. Solutions and Methods

Multicenter Activation reviews each multicenter IIT prior to IRB submission and completes a feasibility assessment. The review confirms the study has funding to cover the multicenter costs, contract includes language to run as a multicenter trial, and the protocol and appendices include the appropriate multicenter language. The team has standardized the participating site activation process, e.g., emails, meeting templates, ICF review checklist. Multicenter Compliance provides central services to the institution, including pre-review of all multicenter IIT amendments prior to IRB submission, tracking auditing of participating sites, and tracking regulatory document collection at participating sites, e.g., amendment approvals and annual reviews. Multicenter Protocol Operations has a two-pronged approach to eligibility review and verification. Real-time reviews of all participating site enrollments are completed prior to registration. Random retrospective reviews are completed of MSK enrollments. An MCT staff member performs risk-based monitoring of MSK and each participating site.

4. Outcomes

There are 137 therapeutic trials; 51 are managed by Multicenter Protocol Operations. The Multicenter Activation team is overseeing the activation of 28 studies across 75 sites.

5. Lessons Learned

- MCT is working with the MSK Office of General Counsel to develop resources and trainings focused on the General Data Protection Regulation (GDPR). There are plans of hiring a CRO to assist with compliance with this new regulation.
- Participating site Time To Activation (TTA) remains a challenge; a goal is to reduce TTA. To avoid conflicting interests with activating studies at MSK, we are exploring expanding resources including dedicated staff for budget and legal review.

2 A Catalyst for Success: How the I2T3 is Transforming IIT Development at UFHCC

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

1. Background

In an effort to increase investigator-initiated trial (IIT) development and support, as well as facilitate engagement and mentorship between junior and senior investigators across DSGs, the associate director for clinical research started a collaboration with the University of Florida Health Cancer Center (UFHCC) Project Management Office (PMO) to develop a series of monthly "IIT Think Tank" ("I2T3") meetings, which kicked off in February 2020. Led by the PMO manager, these meetings include discussions about concept ideas, protocol development as well as industry and grant support.

2. Goals

The goals of the I2T3 meetings include increasing the number of IIT concepts that develop into protocols and accelerate the time between conception and implementation of innovative research trials. Through discussion, we also hope to support the operational success and sponsorship of IITs.

3. Solutions and Methods

The I2T3 standing agenda includes presentations of new and ongoing concept ideas and a brief educational topic. With every concept presented, senior and multidisciplinary peer investigators provide feedback and guidance to maximize the trial's success, scientific rigor, and efficiency. The composition of the group is designed to include junior and senior investigators to facilitate mentorship, our lead biostatistician to guide endpoint creation and sample size discussions, and representatives of our Community Outreach, Engagement & Equity (COEE) group to include the perspectives from our unique catchment area. Investigators representing various UFHCC oncology disciplines also attend to encourage collaborations and networking across research programs. Project managers and study start-up specialists also attend to advise on recruitment and feasibility concerns, investigational new drug (IND)/investigational device exemption (IDE) and regulatory considerations and facilitate funding opportunities. UFHCC leadership is present at these meetings to guide concepts toward translating homegrown UF science and provide guidance on potential for internal resources.

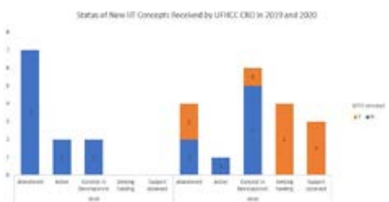
4. Outcomes

During the first year of operation, 10 concepts were discussed in this group, with five proposals submitted to industry for support; three were successfully supported and are in final protocol drafts, and four are actively seeking funding. Compared to 2019, the clinical research office (CRO) at UFHCC saw increased concept intake by nearly 64 percent in 2020 (11 concepts received in 2019 and 18 in 2020). Of the 18 concepts received in 2020, 10 of them (56 percent) originated from I2T3 group discussions.

5. Lessons Learned

Providing a structured and dedicated time to incubate concepts for IIT development is beneficial, not just to administratively "keep the ball rolling," but also supports investigator and PMO collaboration, mentorship, communication, and industry partnerships. Investigators (particularly junior) learn through development of their own concepts and contributions to peer concepts and projects. Educational sessions have included topics such as FDA IND process, novel statistical methods, decentralized trial design, and translational correlative standardization. In the future, we expect to collect data on time to IIT study activation to support our impression that these meetings have contributed to a more efficient path to activation, compared to IITs that are managed outside this group (either by UFHCC PMO or by the investigator). Data on protocol success/deviation rates will also be useful to assess whether early concept discussions were successful to head-off some of the typically unforeseen complications of actual study implementation in clinic.

Figure:



REGULATORY

Implementation of a Fully Electronic Regulatory Binder for Clinical Trials During COVID Pandemic

C. Kennedy, B. Sharp, K. Penas
Fred and Pamela Buffett Cancer Center

1. Background
At the start of the COVID pandemic, most staff were transitioned to work remotely. To adequately address the challenges, the University of Nebraska Medical Center implemented eReg Lite—an eRegulatory management system designed to help sites quickly pivot to remote workflows—to achieve a fully electronic binder. After February 2021, our organizations transitioned to eReg and continue to show improvements.

2. Goals
Goals achieved through the implementation of eReg Lite included: collecting electronic signatures, standardized tracking of outstanding regulatory requirements, and remote monitoring sessions for sponsors.

3. Solutions and Methods
eReg Lite and eReg help create a standardized electronic regulatory binder using an NIH template. eReg Lite and eReg allow for email notification for principal investigators, clinical staff, and other team members.

4. Outcomes
After implementing eReg lite and eReg, our organization saw an increase in our regulatory coordinators' efficiency. The regulatory coordinators met and exceeded previous metrics despite the COVID pandemic and remote working challenges. The regulatory coordinators improved the tracking of outstanding requirements and received electronic signatures (21 CFR part 11). Using the standard reports in eReg Lite and eReg, the regulatory coordinators could easily view what requirements were still outstanding for clinical staff on an individual and protocol level.

5. Lessons Learned
The COVID-19 pandemic required an innovative solution to continue providing clinical trials. By implementing eReg Lite and eReg, our organization provided continued regulatory compliance efficiently and cost-effectively to the Fred and Pamela Buffett Cancer Center. Our cancer center continued to provide ongoing and new clinical trials to our population regardless of the COVID pandemic and remote working obstacles with eReg Lite and eReg.

Fast Financials: An Automated Approach to Financial Disclosures

A. Foster, J. Buthorn, A.M. Gonzalez-Dadiz, K. Yataghene
Memorial Sloan Kettering Cancer Center

1. Background
A financial disclosure form (FDF) is an essential document used to determine if an investigator on a clinical trial (protocol) has financial disclosures that may represent a conflict of interest. This form is collected prior to study initiation, throughout the study as required, and at study completion to ensure any potential bias is appropriately mitigated. As of 2015, all FDFs at Memorial Sloan Kettering Cancer Center (MSK) are stored electronically within the Protocol Information Management System (PIMS) which is an in-house developed application that supports protocol submission and management including regulatory binder storage. Historically, FDFs were obtained using templates provided by the trial sponsor. This required the study team to pre-fill the applicable form with study identifiers and distribute to all investigators for wet-ink or electronic completion and signature. Once signed, all forms were to be collected and uploaded to the regulatory binder. This manual process was redundant, inefficient, labor-intensive, and time consuming.

2. Goals
Our goal with this PIMS enhancement is to decrease time of completion, streamline reconciliation efforts, and maximize regulatory compliance. Collected metrics will compare how long FDF completion took before and after this enhancement. Future metrics will aim to quantify overall compliance benefit.

3. Solutions and Methods
Effective August 24, 2020, PIMS was enhanced so that FDFs can be completed, e-signed, and automatically filed in the electronic regulatory binder for each clinical trial. To support this automated capture, a standardized electronic template was developed for use across all industry-sponsored trials. This form is automatically filled with select fields from PIMS (protocol title, principal investigator, MSK IRB number, and sponsor protocol number). With a few clicks, the study team can distribute this form to all applicable study investigators by adding to their PIMS UserWork (task list) and notifying them by email. Once completed, the FDF is automatically filed in the appropriate folder within the regulatory binder. This decreases potential room for error while ensuring timely completion and reduced administrative efforts. Additionally, the PIMS system is 21 CFR Part 11 compliant as required by the FDA.

4. Outcomes
Using the new automated workflow, the time needed to reconcile one FDF was decreased 90 percent (from 20 minutes to two minutes), contributing to a savings of $10.26 per FDF. In 2019, 12,694 FDFs were completed using the historical process, not accounting for ad hoc requests. Had the new workflow been utilized, the study teams would have saved $130,240.40, not accounting for additional investigator efforts. We are still collecting metrics to demonstrate an increased regulatory compliance with this new workflow.

5. Lessons Learned
Category: Regulatory – Completed Project
Sponsor engagement has been challenging; however, most have been agreeable to the use of our new form with a handful requiring minor modifications. Future expansion would include usage of this platform for non-industry trials. Additionally, this automated platform will support the development of dashboards to support ongoing enhanced regulatory oversight.

Regulatory Team Increasing Efficiency and Reducing Footprint in the Office

C. Vollmer
University of Cincinnati Cancer Center

1. Background

The COVID-19 pandemic affected almost every aspect of personal and professional life, changing how our whole office functioned. Like most institutions, the early pandemic forced remote work for many of our staff. This shift resulted in major changes to our internal workflows — many involving how we shared and documented information. We had already made a huge push toward electronic regulatory binders in 2019, but before 2020 were still maintaining physical binders for each study with many paper and wet-ink documents. This practice was causing paper waste, as many documents were unnecessarily printed and filed in a physical binder (in duplicate with the electronic binder). This was resulting in space inefficiencies, as our office was struggling to find space to house large investigative site files. And finally, at a large and sprawling institution like University of Cincinnati (UC), this was causing inefficiency in trying to locate investigators and obtain wet-ink signatures from across the campus.

2. Goals

With pandemic-driven remote work, it quickly became necessary to achieve 100 percent electronic regulatory binders, with all documents and signatures filed electronically, and completely eliminate the need for paper documents, physical binders, and wet-ink signatures.

3. Solutions and Methods

Working in collaboration with our electronic regulatory service, Complion, we adapted many standard operating procedures (SOP) and workflows to revolve around our electronic binder. This shift included electronic conflict of interest forms, electronic monitoring logs, and fully electronic delegation logs. Additionally, we shifted our practice such that we use electronic signatures on all documents, and electronic attestation of training; fully eliminating the need for paper and wet-ink signatures.

4. Outcomes

From 2019 to 2020 we saw a 55 percent increase in the number of documents filed electronically (Figure 1 – 2019: 4,716 vs. 2020: 10,417) From 2019 to 2020 we saw a 50 percent increase in the number of electronic signatures obtained through Complion (Figure 2 – 2019: 3,866 vs. 2020: 7,743) We have also been able to see a significant decrease in the average number of boxes of paper ordered by our office per month, decreasing 40 percent from 2019 to 2020 (Figure 3 – 2019: 4 vs. 2020: 2.4).

5. Lessons Learned

We continue to educate our collaborating sponsors and clinical research organizations on our electronic system, the electronic signatures and training documentation, how they can use Complion to document visits, and eliminating the need for a physical trial master file. We hope in the future to eliminate other areas where paper and physical documentation can be eliminated across the office. A paperless future will require creative implementation of our electronic systems and modified workflows and SOPs. While the pandemic has brought devastation in many areas of life, there have also been creative and innovative achievements that have occurred, especially in the workplace. We see our achievements as an increase in productivity and efficiency, as well as an important step toward sustainability and a small step to reducing the footprint we leave.

Figure 1

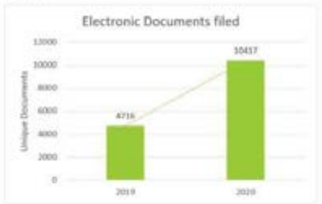


Figure 2

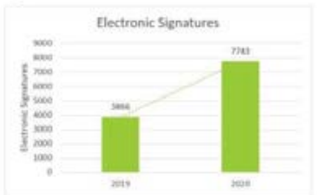
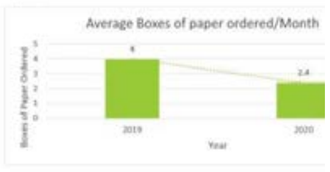


Figure 3



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Partnering With Foreign Collaborators and the Institutional Review Board to Document Human Subjects Protection Requirements for Sites Outside of the United States

V. Santana, L. Faughnan, E. Fernandes, K. Prive, P. Naidu
Comprehensive Cancer Center, St. Jude Children's Research Hospital

1. Background

Changes in the Common Rule for human subjects research require that sponsor institutions provide a mechanism to document assurances of equivalent protections for non-federally funded projects without a federal-wide assurance at foreign sites. To conform to the same or equivalent ethical and regulatory standards in which research conducted in the United States is held and to applicable local laws, we developed a partnership process with our Institutional Human Research Protection Program office to ensure that adequate provisions are in place for research sponsored by St. Jude Children's Research Hospital (St. Jude) that is conducted outside of the U.S. This process ensures we have sufficient information about the local research context and laws by reviewing written materials or discussing the planned research with local institutional review board (IRB) officials. Our process also ensures that the required information and documents are available for adequate review by the St. Jude IRB.

2. Goals

Our goal was to establish a centralized and standardized way to collect, document, and appraise equivalent human subjects protection (HSP) requirements for non-U.S. sites.

3. Solutions and Methods

We established a two-step centralized mechanism to document assurances of equivalent protections. First, in the Department of Global Pediatric Medicine (GPM), which collaborates on studies conducted in low- to middle-income countries (LMICs), we designed a guidance document and worksheet with specific elements that address the scope of standards at collaborating foreign institutions. The worksheet includes questions that address local institutional responsibilities and regulations, as well as research ethics committee responsibilities, such as the appropriate scope and quality of review and processes for informed and voluntary participation. Once collaborating institutions provide this information, it is then included in their regulatory files and is available upon request to our IRB. The forms are available in English and in Spanish. Second, St. Jude investigators who sponsor research activities at non-U.S. sites submit the "Transnational Non-U.S. Research Site Assessment" form to the St. Jude IRB for review and approval. This form includes information derived from Step 1 and comprises four sections. It is submitted along with new study applications and can be accompanied by supplementary information obtained in Step 1.

4. Outcomes

Presently, we have established documentation from four countries including Peru, Ecuador, Bolivia, and Paraguay and at eight sites. During in-country regional scientific workshops sponsored by GPM, we conduct training and education sessions on the equivalency process and engage in additional discussions to further our appreciation of local contexts.

5. Lessons Learned

The variable knowledge level of foreign site personnel regarding HSP procedures is challenging, particularly with colleagues in LMICs. However, the opportunity presented by this variability led us to propose recording video educational sessions on HSP procedures to broadly disseminate these materials and ultimately further compliance with HSP requirements.

Regulatory Completion Timelines: A Prospective and Retrospective Analysis of the Effect of an eRegulatory System

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1. Background

The accurate and timely completion of essential regulatory documents is a vital part of the conduct of and management of clinical research portfolios. At Lineberger Comprehensive Cancer Center, we had historically maintained our regulatory files in a paper or a mixed paper and electronic format (hybrid) binder system. As these systems were not 21 CFR Part 11 (Part 11) compliant, we found that an increasing amount of physical and personnel resources were needed to maintain the wet-ink signatures required for compliant essential regulatory documents, as evaluated by the physical space needed for filing cabinets and our regulatory acuity tool. In order to reduce the need for physical resources and free personnel resources so they could be redirected towards other regulatory priorities, we began the journey of implementing an eRegulatory system.

2. Goals

The goal of implementing an eRegulatory system (Florence eBinders) was to reduce the amount of time needed to complete essential regulatory documents. This has been evaluated based on the time needed to complete initial regulatory documents for study activation as data for those metrics was already tracked in our clinical trial management system, OnCore. The primary objective of this project was to determine if the independent variable, the implementation of Florence eBinders, reduced the dependent variable, the duration (calendar days) from "Start of Work" email to date of the completion of the initial essential regulatory documents, such as the FDA 1572 Statement of Investigator, Financial Disclosure Forms, collection of curriculum vitae, collection of licensure, and collection of applicable documents for institutional review boards and clinical laboratory facilities noted in box six and box four of the FDA 1572 respectively (Document Completion). Completion of these documents was defined as completion and final acceptance of the documents by the study sponsor.

3. Solutions and Methods

The intervention, implementation of Florence eBinders, a Part 11 compliant eRegulatory system, took place at LCCC's Clinical Protocol Office on August 24, 2020. Florence is an electronic trial master file (eTMF) system produced and marketed by the company Florence Health Care, which shares the same name as its eTMF product. It allows for the creation of a customized binder structure for the electronic storage of study regulatory and essential trial documents. In addition, Florence allows for the completion of Part 11-compliant electronic signatures. It is recognized that during the past six-month period, the roll-out of Florence has been staggered, with 73 percent of faculty and non-regulatory staff presently active in the system.

4. Outcomes

While the current analyses continue, the implementation of the Florence Part 11 compliant eTMF systems positively impacted the completion timelines. As the roll-out of Florence has been staggered,November 1, 2020 was selected as the "Date of Implementation" for the purposes of this project. Data from an interim analysis conducted on a retrospective population of 15 studies opened to accrual from September 1 to October 31, 2020 and a prospective population of 14 studies opened to accrual from November 1, 2020 to February 18, 2021 noted the following results: Baseline values (measured by the retrospective population of studies opened to accrual from September 1 to October 31, 2020) of mean number of calendar days required for initial document completion was 198.67 days. A measurement of approximately three and a half months of interim analysis data post-implementation of the Florence intervention (measured by the prospective population of studies opened to accrual from November 1, 2020 to February 18, 2021) shows a reduction of 50.58 calendar days, with the mean number of calendar days required for document completion being 148.09 days.

5. Lessons Learned

Data will continue to be collected and reviewed at six-month intervals to determine if the trend is statistically significant and sustained over time. It is anticipated that as the office gets to 100 percent adoption of the system, the mean activation time will continue to decrease. The current data trend suggests that the implementation of a Part 11 compliant eRegulatory system can reduce the time needed by regulatory staff to complete regulatory documents. This may also reduce the effort expended by regulatory team members to complete this task.

Regulatory – Work in Progress

Implementing the Shared Investigator Platform at the UFHCC

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1. Background

The University of Florida Health Cancer Center (UFHCC) Clinical Research Office (CRO) began implementing the Shared Investigator Platform (SIP) in late 2019. One of the first challenges identified was that the system did not align with internal workflows. Being a large academic institution, we have six Health Science Center Colleges, which each have dedicated research staff and specialties. The SIP system allows only one facility profile manager for the entire institution. After working with Cognizant to clear this initial structural hurdle, we began registering research personnel within SIP. Including investigators, pharmacists, and staff, we identified more than 100 research professionals needing registration. Obtaining support from busy investigators is one of the largest obstacles to overcome for successful implementation of SIP at our site. Initial SIP registration requires multiple logins to set up, secure, and activate each user account. These logins occur prior to users reaching a location within SIP where a delegate can be chosen. The SIP Registration Quick Guide provided by industry partners overlooks a number of key steps during initial registration that we need our users to perform locally.

Another significant challenge with implementing SIP is communication with industry partners. During the early phase of SIP implementation, sponsors persisted in contacting our investigators directly while we were finalizing our internal process. This hindered efforts by causing site-specific needs to be overlooked. This ultimately increased the burden on investigators/users.

2. Goals

- Reduce burden on investigators
- Improve communication with industry sponsors
- Improve availability of site materials

3. Solutions and Methods

The UFHCC protocol activation coordinators (PAC) are dedicated to shepherding new studies throughout study start-up. Working closely with the PAC team has been an integral part of decreasing the burden on investigators; PAC identifies studies that will use SIP. PAC become liaisons for communication with sponsors by addressing SIP use expectations during the start-up process to reduce future delays at site initiation visits and site activation. Registration of new faculty/staff within SIP is now done during onboarding.

4. Outcomes

Collaboration and enhanced communication with industry sponsors has reduced incidences of duplicate SIP invitations, thus allowing UFHCC specific instructions be sent to our staff/investigators. This allows completion of initial account creation, registration, association, and delegation during one sitting, which reduces effort spent on SIP registration. At the time this abstract was written, over half (57 percent) of UFHCC research staff/investigators have registered in SIP. This evolving initiative requires additional effort to reach full registration compliance. However, we have yet to see efficiencies in protocol start-up or communication with industry partners through the SIP program at this juncture. We have noticed that feasibility questionnaires are more appropriately routed to the correct staff for completion. We are confident that increased collaborations with industry sponsors will continue to help pave the way to a less burdensome experience with SIP.

5. Lessons Learned

Collaboration is key. The successful implementation of SIP at UFHCC relies on understanding how sites and sponsors will utilize the platform. Clarifying expectations early in the process is important to lessen the burden on site users and smooth integration of SIP into our site's workflow.

Figure:

Maintaining Specimen Compliance for a High Volume of Complex Clinical Trials

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1. Background

One of the biggest challenges in managing clinical trials' central laboratory specimens is the increasing complexity of the specimen requirements on individual trials. The higher complexity requires additional effort and oversight to determine and execute specimen needs at each patient appointment. In addition, the reference materials for the specimen management components frequently contain contradictory or unclear information, which requires additional time and specific knowledge to obtain clarification. Lastly, the format of the information provided by sponsor and central labs is not standardized, so it requires additional time to become familiar with the provided information.

2. Goals

- Develop a system that compiles and centralizes the specimen information coming from the protocol, lab manuals, clarification letters, and other reference materials into one uniform source
- Reduce time and effort required to prepare, process, and ship central lab specimens
- Reduce the number of specimen deviations
- Utilize staff skills and knowledge by defining specific roles and responsibilities

3. Solutions and Methods

- Created specimen guides and processing instruction to house the required information to schedule, collect, process, and ship central lab specimens
- Defined roles within the specimen team: junior level staff who complete the day-to-day laboratory operations such as preparing, collecting, processing, and shipping specimens, and senior staff who focus on trial specific information and interpreting protocols and lab manuals

4. Outcomes

We have implemented a system where senior laboratory staff create the documents (specimen guides, processing instructions, and tissue guides) that house the information from all the reference materials and sponsor clarifications in one location and in a single format. These documents are created during trial start-up and updated with each trial amendment. Once these documents obtain dual review and sign-off, they are a single source for the lab operations staff to use during preparing, collecting, processing, and shipping specimens.

5. Lessons Learned

- The process of creating the documents with centralized information is time consuming but the time is recuperated in day-to-day operational steps Monitoring, and Auditing –
- Having clear instructions for staff to follow has significantly reduced the number of protocol deviations
- The lab staff now have opportunities for advancement due to the different roles within the team; moving forward, we are shifting the information from Word and Excel documents into a lab information system which links to our clinical trials office patient management database

Risk-Based Monitoring Model: Safeguarding Single-Center, Investigational New Drug, Investigator-Initiated Trials at Memorial Sloan Kettering Cancer Center

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Memorial Sloan Kettering Cancer Center

1. Background

Annual increases of investigator-initiated trials (IITs) and limited resources necessitated the adoption of a risk-based model (RBM) in 2017 by the clinical research quality assurance (CRQA) unit to ensure adequate sponsor oversight. In 2020, CRQA launched an innovative redesign of the RBM program focused on single-center, Memorial Sloan Kettering (MSK)-held investigative new drug (IND), IITs. The essence of the versatile RBM approach is defining and monitoring critical data points related to a protocol's primary and secondary objectives to mitigate risk and safeguard the safety, quality, and overall integrity of the clinical trial.

2. Goals

- Increase scope of monitoring oversight
- Standardize monitoring practices with creation of RBM tools and resources to ensure consistency of performance and improved oversight of staff
- Reduce source document verification
- Define key risk indicators based on protocol objectives

3. Solutions and Methods

RBM workflow process:

- Protocol selection
  - o Utilize an institutional protocol risk assessment tool
  - o Identify specific critical data points
  - o Create an RBM plan with principal investigator approval
- Monitoring tools
  - o Template presentation for monitoring initiation visit
  - o Tracking and data collection toolkit for standardization of monitoring approach
  - o Templates for monitoring visit reporting
  - o Checklist for pharmacy visit and drug accountability
  - o Robust and standardized index of deficiency categories
- Monitoring initiation
  - o Present RBM plan
  - o Review expectations of monitor and study staff during visits
  - o Modify the RBM plan prior to finalization, if necessary
- Conduct routine monitoring visits
  - o Verify participant data in source documents
  - o Regulatory review
  - o Pharmacy review, including drug accountability
  - o Report generation

Summarize deficiencies and actions to correct and prevent their recurrence

Apply visit rating of "Acceptable," Acceptable - requires follow-up," or "Unacceptable," based on number of deficiencies identified

4. Outcomes

- Increased scope of monitoring
  - o Increased by 100 percent the number of protocols reviewed in 2020 compared to 2019
  - o Increased by 56 percent the number of monitoring visits conducted in 2020 compared to 2019
  - o Increased by 21 percent the total number of participants monitored in 2020 compared to 2019
- Improvement in acceptable rating from 72 percent in 2019 to 86 percent in 2020

5. Lessons Learned

- Improved efficiency demonstrated by increased scope and productivity with fewer resources, less time and effort, and increased oversight
- Prevented non-compliance by identifying areas of risk and developing corrective actions with study teams
- Versatility of RBM approach allowed for the successfully adoption by multisite unit within MSK under the guidance of CRQA
- Future directions:
  - o Continue improvement in efficiency through automation
  - o Further redesign of the RBM program with application of lessons learned
  - o Establishment of a monitoring council to ensure ongoing review of the monitoring portfolio to determine proper actions

Training, Quality Assurance, Remote Monitoring, and Auditing – Completed Project

Demonstrating Safety and Necessity of Clinical Trials Deviations for Improving Flexibility and Inclusivity of Clinical Trials Enrollment Utilizing a Centralized Deviation Database

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Simmons Comprehensive Cancer Center, UT Southwestern Medical Center

1. Background

The COVID-19 pandemic forced an urgent need to allow for more flexibility so that patients could continue to be enrolled and treated on clinical trials. This offered a unique opportunity to study the effect of changes in study procedures on patient safety. In March 2020, the FDA released guidance on the conduct of clinical trials during the COVID-19 public health emergency. Sponsors and sites revised policies to implement newly permissible processes in order to continue to conduct clinical research safely such as telehealth, electronic consent documentation, shipping oral investigational product to patients, and remote monitoring. With this came a need to closely track protocol deviation data, especially deviations that were a direct result of these newly implemented processes.

2. Goals

This study was approved by the UT Southwestern institutional review board (IRB #STU-2020-0365). We established a protocol deviation database to monitor quality of clinical trials by tracking trends in protocol deviations and identification of patterns in order to prevent serious noncompliance. By developing the database to capture specific datapoints related to patient safety, including individual study assessments such as labs, ECGs, and imaging, related adverse events, and relationship to COVID-19 study modifications, it also allows us to demonstrate the impact of protocol deviations on patient safety.

3. Solutions and Methods

A working group was formed to evaluate existing deviation tracking and develop a centralized process. Existing Excel trackers and study databases were reviewed to create a REDCap database survey form to capture deviation data and allow for regulatory documentation in the study files. User testing was conducted for additional feedback to finalize the survey and all cancer center study teams were trained on the final database and process. The database survey included information on type, timing, and severity of deviations, COVID-related decisions, and detailed description of event and corrective and preventative action.

4. Outcomes

From September 1, 2020 through February 28, 2021, 341 deviations were recorded in the database for 77 oncology clinical trials and 82 unique patients across 8 cancer subtypes. Of these, 114 (33 percent) were designated COVID-related. None resulted in an adverse event.

5. Lessons Learned

This database demonstrates the utility of a centralized database for protocol deviations at clinical trials sites to track safety metrics, facilitate data-driven insights to improve quality assurance, and enable regulatory documentation. Findings also support the overall safety of allowing protocol deviations for patients being treated on clinical trials. Continued research is needed into the safety and importance of clinical trials continuing to improve flexibility and inclusivity and determine the level to which increased flexibility will not impact safety while improving overall inclusiveness of clinical trials.

References: Gerber DE, Sheffield TY, Beg MS, Williams EL, Clark VL, Xie Y, Holbein MEB, Skinner CS, Lee SJC. Experience, Perceptions, and Recommendations Concerning COVID-19-Related Clinical Research Adjustments. J Natl Compr Canc Netw. 2020 Oct 7:1-8. doi: 10.6004/jnccn.2020.7643. Epub ahead of print. PMID: 33027755.

Creation of a Sponsor Quality Management Plan Under GCP Revision 2: Checks and Balances, Quality Systems, and Cross-Functional Communication

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1. Background

Conduct and oversight of clinical trials as a sponsor is increasingly complex for academic cancer centers, particularly when the center is responsible for on-site manufacture of investigational product, such as CAR T cells. In March 2018, the FDA adopted E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1). A key requirement of this guidance for clinical trial sponsors is the implementation of a quality management system. In response, Lineberger Comprehensive Cancer Center (LCCC) started an initiative to design a comprehensive quality management plan (QMP), beyond the scope of our NCI-required data and safety monitoring plan (DSMP), focused on LCCC as the sponsor to ensure human subject protection and the reliability of trial results.

2. Goals

The goal of this initiative was to develop a sponsor QMP with all systems described in FDA's guidance: clinical process and critical data identification, risk identification, risk evaluation, risk control, risk communication, risk review, and risk reporting.

3. Solutions and Methods

A cross-functional working group was formed to develop the QMP with the majority of the participants being staff within the clinical trials office (CTO) recognized as subject matter experts, including multicenter project managers; monitors; coordinators for the DSMC, PRC, and audits; and data managers. This group was further supported by members of CTO leadership. The group met monthly with action items between meetings. Gap analysis was performed to determine processes existing, lacking, or requiring formalization. All processes were evaluated for redundancies and cross-functional links. For complicated process development, smaller working groups were established (e.g., updating the LCCC DSMP, overhauling a data management plan, and designing a multicenter site escalation plan).

4. Outcomes

A comprehensive QMP was established supported by numerous SOPs, policies, job aids, and procedures. The success of the QMP is illustrated in:

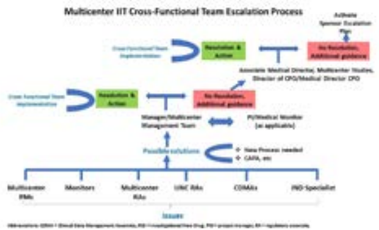
- Clear methods to ensure quality management
- Overarching schema to aid in staff training
- Improved delineation of roles and responsibilities

One specific example highlighting the success was the creation of a standardized cross-functional sponsor escalation plan to address queries from multicenter clinical trial sites and other issues with enrollment, data, regulatory, compliance, and communication (see figure). This plan resulted in the reduction of response time from days or weeks to days or hours (depending on issue complexity). The QMP was approved by LCCC leadership, is 18 pages long, is available in our learning management system, and is required reading for all CTO staff involved in the management of investigator-initiated trials.

5. Lessons Learned

The most resounding lesson learned was that in a specialized clinical trial infrastructure most CTO staff and leaders lack the overarching understanding of how the functional groups can interact to create cross-functional systems of communication and quality. Many groups did not appreciate how collaboration could reduce overall burden on any one functional group and create better systems of checks and balances. Development of this plan will improve staff training/onboarding, serving as required reading material to highlight the overarching cancer center sponsor infrastructure. The QMP will also serve as the framework for development of trainings focused on our sponsor infrastructure.

Figure:



Remote Onboarding and Training in the Clinical Trials Office

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1. Background

The COVID-19 pandemic has led to our clinical operations staff to have to work remotely with a rotating in-office schedule. This created a challenge to onboarding and training new coordinators as social distancing posed a barrier to one-on-one training. Our rotating schedules, and the cessation of in-person meetings, made it difficult to assess how a new hire was progressing through the tasks they would need to execute on their own. We also needed to track the transfer of study subjects from one coordinator to the next. It was apparent that we needed a way to collaboratively share and document information between trainers and trainees regarding job expectations.

2. Goals

A primary goal was to be able to remotely monitor the progress of trainees towards full job competency. We desired to place the trainee in control of deciding when they felt a task had been completed and they were confident to move forward on their own. We also wanted a task tracker that would allow the trainer to assign a due date or priority score to each task requiring mastery. Finally, we wanted a document that could provide resources to the new employee as they moved on to solo work by incorporating links to important task related information they could access in the future.

3. Solutions and Methods

We decided to implement cloud-based lists of job-related tasks and resources, tailored to different job roles, using Google Sheets. This shared document was beneficial in that it was available to multiple users at a time and could be accessed from anywhere as long as the user had internet service. This process was first developed for the data coordinators and included tasks with links or instructions for new employees to register for trainings, create accounts, and included the different types of interoffice meetings required by the role. (See figure.)

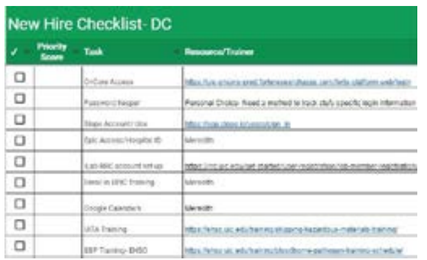
4. Outcomes

The implementation of the training checklist has streamlined the onboarding process and provided an organizational tool for our supervisors. We have created five variations of the checklist to accommodate our different clinical operations positions and have received positive reactions from the employees that have used this system. They have provided feedback that the checklist helped achieve an effective and efficient transition and it was clear what was expected of them, how urgently it should be accomplished, and the resources necessary. Our supervisors have appreciated having checklists that are specific to the job each new coordinator will take on and provide reassurance that nothing is being forgotten.

5. Lessons Learned

The clinical operations team in our office has successfully implemented a remote training platform using Google Sheets to communicate and monitor training tasks. We continue to improve the system and make individualized updates with every hire. Next steps for are to expand this program to other units in the clinical trials office in hopes that it can be adapted to improve training on standard operating procedures, and to include roles in regulatory and finance.

Figure:



Reducing Turnover During a Pandemic: Growing Leaders at an NCI-Designated Cancer Center

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1. Background
Is it true that people don't leave jobs, they leave managers? Following the 2019 work culture survey, Duke Cancer Institute (DCI) recognized a novel approach was needed to improve staff retention. While work culture required improvement, more concerning was the 2020 turnover rate at 20 percent. Further, DCI experienced rapid change and growth as research, research support, and community outreach and education (COE) staff adapted to new leadership roles. Though new managers attended HR-focused manager training, this did not address the unique leadership challenges at an NCI-Designated Cancer Center. To meet the increased need to develop engaged leaders, DCI implemented the leadership development program.

2. Goals
The goal was to reduce turnover and improve staff morale by enhancing leaders' ability to grow diverse, resilient teams and improve staff retention at all levels.

3. Solutions and Methods
The DCI designed a leadership series with 11 required courses for all research, research support, and COE managers. Nine cohorts of 8-10 newly appointed and seasoned managers comprised the series. Based on adult learning methodology, courses were designed using an efficient "chunked" approach and incorporated repetition to optimize learning. Cohorts met biweekly and completed one to two hours of pre- and post-coursework per class. Content focused on resilience; change management; teambuilding; communication; and diversity and inclusion. While primarily aiming to improve leadership, management, and communication, participants also improved technology skills through immersion. Participants developed presentation skills by delivering course summaries to the cohorts. Pre-, mid-, and post-program evaluations were implemented to measure growth. Participants identified their specific challenges including navigating difficult conversations; managing and motivating a remote workforce during a stressful pandemic; and retaining employees. Participants addressed individual needs by creating action plans that included reflection, goals, and tracking additional optional training.

4. Outcomes
Because this initiative is tied to staff retention and work culture, this is a long-term investment in DCI leaders. Actual program impact cannot be measured until the next work culture survey in 2022. Mid-program evaluation data indicated coursework and content meets or exceeds 87.5 percent of the participants' expectations; 50 percent of participants want ongoing touchpoints with their cohort and 50 percent want touchpoints with additional cohorts. One hundred percent of participants self-reported incorporating course content into their daily management style.

5. Lessons Learned
Based on mid-program feedback, the leadership team is becoming more engaged, self-aware, and emotionally intelligent. Although early in program implementation, participants have reported increased awareness of their leadership and communication styles. While managers were intentionally assigned to specific cohorts, encouraging collaboration and breaking silos, the most senior managers should have comprised the first cohort to reinforce the content middle managers would later receive. Looking forward, cohorts will be created for staff with leadership potential, filling a need for succession planning and career development. DCI will determine program impact and future training opportunities based on data from the 2022 work culture survey. Until then, plans include ongoing learning in the form of an on-demand monthly quick tip that reinforces concepts from the series and reconvening cohorts quarterly to share successes and address new challenges.

Training, Quality Assurance, Remote Monitoring, and Auditing – Work in Progress

Transitioning to Remote Monitoring: Challenges and Successes

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1. Background
As a result of the COVID-19 pandemic, clinical research oversight at Huntsman Cancer Institute immediately transitioned to a remote environment. Prior to the pandemic, our clinical site monitors had primarily reviewed paper documentation in the form of physical subject study charts. In addition, our usual practice of meeting with study teams and principal investigators (PI) transitioned from in-person meetings to virtual meetings. By shifting to a remote environment, it was necessary to adjust many of our current practices to accommodate potential delays in our oversight timelines as the pandemic unfolded.

2. Goals
According to our data and safety monitoring plan (DSMP), investigator-initiated trials (IITs) are reviewed after the first patient enrollment. Subsequent monitoring should occur every three months for high-risk trials, every six months for moderate-risk trials, and annually for low-risk trials. Our goal is to complete a single monitoring visit within one month in order to maintain compliance with our DSMP. Our goal was to maintain this timeline despite the unprecedented circumstances. Our department also provides quality assurance (QA) reviews for National Clinical Trials Network and industry studies. Our goal for QA review timelines is similar to our IIT oversight.

3. Solutions and Methods
Monitoring transitioned to direct review of our electronic medical record, Epic, instead of the paper study chart. Study teams uploaded paper source documentation electronically to a secure shared file. We worked with our clinical trials office to develop a Part 11-compliant signature system. We created an electronic case report form in OnCore, our clinical trials management system, to track queries. Our team emphasized the importance of upholding our data and safety oversight while accommodating an exceedingly fluid environment.

4. Outcomes
We saw a decrease in time spent on IIT monitoring in 2020 compared to 2019 and an overall increase in the time spent on QA reviews in 2020 compared to 2019. (See figure.)

5. Lessons Learned
During the pandemic, our department prioritized IITs to ensure compliance with our DSMP. We performed eight additional QA reviews in 2020, in comparison to 2019, with the same staffing. This demonstrates that overall productivity was not affected by remote work. Fluctuations in review timelines may have been impacted by a variety of factors, such as the following: accessibility of electronic records, increase in PI involvement during monitoring visits, virtual availability, and efficiency in working remotely as opposed to an office setting. Going forward, we plan to continue with a remote work environment for our monitoring staff and further utilize electronic source documentation. We aim to create electronic records from the beginning instead of uploading paper documentation retrospectively, and as necessary, only complete a limited or risk-based review. If documentation needs to be uploaded, we will outline the required items at the time of monitoring notification to ensure study staff has sufficient time to provide this information.

Figure:

Year	# of IIT monitoring visits	Average # of QA reviews	Average # of days to complete IIT Monitoring	Average # of days to complete QA review
2019	49	38	37	31
2020	49	46	32	53

Rolling With the Changes: Onboarding Staff Remotely During the COVID-19 Pandemic

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1. Background

The first case of COVID-19 was discovered in the United States January 21, 2020. Less than two months later, the Medical College of Wisconsin (MCW) Cancer Center Clinical Trials Office (CCCTO) transitioned to a mandatory work-from-home status. The cancer center, however, already committed to several new hires prior to this and was forced to find a solution for remote onboarding. Prior to the pandemic, training was almost 100 percent in person, which allowed for dynamic exchanges between the trainer and the trainee. However, with these new remote requirements, we needed to establish an alternative.

2. Goals

We focused on two goals: keeping onboarding both safe and effective. The continually increasing subject accrual during the pandemic made it imperative that new staff members have the training necessary to make an impact soon after their date of hire.

3. Solutions and Methods

The CCCTO employs two staff educators (total FTE of 1.8), who were tasked with modifying the onboarding program to meet the new remote working requirements. All real-time trainings were moved to a WebEx platform, utilizing predeveloped PowerPoint presentations. To increase staff engagement, we asked that webcams be utilized. We used the "teach-back" method during training to create more interaction and dialogue. Handouts were provided in a shared Box.com folder that new staff could easily access, save, and annotate. The new staff members received "homework items" to address independently during their downtime. These included online instruction, materials focused on disease, and educational videos. Educators also incorporated training on resources and workflows specific to the new remote work environment (e.g., utilization of Citrix, etc.).

4. Outcomes

Although the CCCTO educators were able to train new staff remotely, it was not an ideal learning environment. They believe that new staff members did not thrive in their positions until they were able to attend work in person regularly. Many staff members working at home did not have two monitors or a printer to allow efficient notetaking during presentations. This proved to be an added challenge. Since restrictions have eased slightly and vaccinations have steadily increased on campus, the CCCTO educators are using more in-person training again. Large conference rooms are now used for these trainings, allowing staff to spread out to attend in-person instruction safely.

5. Lessons Learned

The CC CTO is fully prepared to onboard staff in a remote setting after utilizing this method for nearly a year. However, since this method was not preferred for onboarding, new staff now start their first several weeks of employment almost exclusively on campus. This allows them to integrate with their respective disease teams and to form relationships with coworkers. The CCCTO has personal protective equipment and workspace protocols in place that allow for a safe-on-campus presence during this critical time.

Training, Quality Assurance, Remote Monitoring, and Auditing – Work in Progress

Ensuring the Next Generation of Clinical Researchers

A. Anderson, L. Pettiford, A. Ivey, T. George
University of Florida Health Cancer Center

1. Background

The UF Health Cancer Center (UFHCC) Clinical Research Office (CRO) internship was developed to expose recent college graduates, planning future careers in health care, to clinical research. We noted that many health care providers have limited exposure to clinical research during formal education and struggle with integrating research processes into routine care[1]. Simultaneously, we recognized this program could help address the high staff turnover commonly experienced within research organizations. Previously, the CRO hired staff with no experience into clinical research coordinator (CRC) roles. Turnover rates were as high as 30 percent within two years of employment with many staff ultimately determining their long-term career goals were misaligned with research. We recognized that the program could identify interns with an affinity for cancer research and provide opportunities for promotion into permanent CRC positions.

[1]Michaels, M., D'Agostino, T.A., Blakeney, N. et al. J Canc Educ (2015) 30: 152. https://doi.org/10.1007/s13187-014-0662-6

2. Goals

One program goal is to expose future health care providers to clinical research, so they gain an understanding of how research integrates with and impacts cancer care. For others, the program serves as an entryway into a clinical research career.

3. Solutions and Methods

This internship program launched in January 2019. Two interns are selected each fall and spring semester for this year-long salaried commitment. Interns work as clinical research assistants (CRAs), supporting study teams with the research process. Each intern undergoes a six-week orientation and is assigned a mentor to prepare them to participate in data capture and entry, laboratory procedures, and regulatory affairs. In addition, interns participate in a quality improvement (QI) project and data analysis. Below is a list of areas covered during the internship:

- Good clinical practice and research ethics
- Biology and treatment of cancer
- Informed consent
- Study management and operations
- Principles of data management

4. Outcomes

This program remains ongoing; the fourth intern cohort is planned for June 2021. To date, intern QI projects have resulted in CRO process improvements. For example, one intern implemented an office-wide messaging process to alert staff of clinical subject arrivals, thereby streamlining clinic and research staff communication which, in turn, improved the efficiency of study-related clinic visits. This intern was Category: Training, Quality Assurance, Remote Monitoring, and Auditing – Work in Progress accepted to a prestigious pharmacy program and upon graduation, hopes to continue working in the field. The program exposed him to opportunities within investigational drug services as well as the role pharmacists play in the development and implementation of study protocols. So far six interns have completed the program with four moving into full-time permanent positions within the CRO. Five of six interns have now been accepted into graduate programs in medicine, pharmacy, nursing, and public health. All cited their CRO experience as a significant factor in securing acceptance to these programs.

5. Lessons Learned

Hiring these bright and motivated interns has been invaluable to our program. They are engaged, eager to learn, and willing to tackle research challenges. Future directions include expanding opportunities within the CRO's investigator-initiated trials project management office and pediatrics division, and assessing permanent recruitment for interns who wish to continue careers in oncology clinical research. We also plan to offer undergraduate summer opportunities to further promote research as a career.

Implementation of a Research-Specific, Electronic Orientation for Clinical Research Professionals

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

1. Background

The UF Health Cancer Center (UFHCC) Clinical Research Office (CRO) is the clinical trials arm of the cancer center, responsible for the development, regulatory maintenance, clinical conduct, and oversight of clinical research. Historically, onboarding of new clinical research staff consisted of standard requirements established by the academic institution, while research and position-specific training was provided by CRO division managers and senior staff members. Consequently, the quality and comprehensiveness of initial training was highly variable, contributing to inconsistent performance of essential research tasks, decreased job confidence, and high levels of attrition within the first two years of hire. As a result, a centralized, electronic-based onboarding process was developed and implemented to provide a comprehensive and consistent research-focused orientation.

2. Goals

- Develop a clinical research specific onboarding curriculum for a diverse population of clinical research professionals
- Enhance delivery and accessibility through the use of an electronic learning platform

3. Solutions and Methods

In late 2018 a position dedicated to the centralized management of initial and ongoing training of clinical research staff was created. This hire, with the assistance of leadership, division managers, and content area experts, identified six general categories essential to the conduct of research at the UFHCC. Content-based training was developed and combined with institutional training requirements to create a six-week, comprehensive onboarding program. Onboarding was built into an electronic learning management system (eLMS) to facilitate remote delivery, as well as to enable real-time monitoring by the training and education coordinator. Pre- and post-onboarding assessments were included to assess the efficacy of the content-based curriculum.

4. Outcomes

From January 2020 through March 2021, seven new staff members with diverse professional and educational backgrounds were onboarded using the new eLMS-based curriculum. Currently, four individuals have successfully completed orientation within the required two months of hire and three are still in process and on-track to complete on time. Time to completion of essential training activities has greatly improved with centralized monitoring. Of the four individuals who completed the orientation processes, improved general research knowledge is evidenced by an average 18 percentage point increase from pre-orientation testing to post-orientation testing. Subjectively, individuals oriented in the new system exhibit greater confidence in performing job responsibilities and demonstrate improved awareness of internal policies and resources than their predecessors. Assessments are administered with a pass-fail threshold in order to ensure not only completion of requirements, but retention and comprehension of information provided Implementation of these assessments allowed for identification of areas where learning materials and/or delivery could be improved.

5. Lessons Learned

Future goals include modification of the onboarding program for institutional clinical research staff who engage in cancer-relevant research inconsistently as well as delivery of more advanced content in a classroom-based format that allows for real-time discussion and questions, ultimately improving comprehension and applicability of the information gained.

Figure:

Implementation of Professional Competency Development Program for Clinical Research Professionals

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1. Background

The role of the clinical research professional (CRP) has evolved notably over the last decade in order to meet the needs of an increasingly complex research, compliance, and regulatory environment. The role and responsibilities of the CRP vary significantly both within and across institutions, adding additional layers of difficulty in providing meaningful professional development opportunities. Professional organizations such as the Association of Clinical Research Professionals (ACRP) and the Joint Task Force (JTF) for Clinical Trial Competency have worked to develop universally applicable competency frameworks to assist in aligning competency-based efforts across institutions, however no standardized system exists for the application of these frameworks into ongoing training and development for CRPs. In order to address this need, University of Florida Health Cancer Center implemented a clinical research office (CRO)-wide educational initiative based on the eight competency domains and associated leveled core competencies for CRPs developed by the JTF.

2. Goals

- Assess the professional development needs of a diverse and complex clinical research workforce
- Provide ongoing, research-specific training to elevate the performance of our clinical research team

3. Solutions and Methods

A multi-tiered research competency development program was implemented to assess learner needs, deliver education through a spiral curriculum model, re-assess to determine progress and identify future educational directions. Prior to educational intervention, staff completed a self-assessment ranking their understanding of the JTF core competencies, and managers were asked to evaluate staff members using the same assessment. Monthly educational lectures (in person and via Zoom) were scheduled during a standard monthly staff meeting and content area experts were recruited to broadly address each of the JTF research specific domains at a fundamental level. These lectures were followed by small group discussions led by division managers to reinforce concepts and facilitate the application of general concepts to role-specific job responsibilities and performance. Once the full series of lecture and small group discussions were complete, the self and manager assessments were repeated to determine the impact of the educational interventions and guide future educational programming.

4. Outcomes

Monthly domain lectures and subsequent small group discussions were implemented in totality via Zoom starting July 2020, with the final lecture delivered in March 2021. Research contact hours for ACRP and the Society of Clinical Research Associates (SOCRA) were offered whenever possible to encourage attendance, and in-lecture polling applications incorporated to encourage and improve audience engagement. Overall staff response has been positive with attendance rates > 90 percent, and high levels of engagement during lectures and small group discussions.

5. Lessons Learned

Future directions include post-intervention assessment analysis, and development of scenario-based assessments that test the ability to apply concepts to real-world situations and more accurately evaluate understanding and determine future educational opportunities and curriculum development. If successful, development of modified online-only curriculum may be explored, inclusive of SOCRA contact hours, as a resource for research professionals at other cancer centers.

Figure:

MCRCT Center Clinical Trial Competency Project (https://mcrtcenter.org/clinical-trial-competency/)

TRIAL RECRUITMENT & COMMUNITY OUTREACH AND ENGAGEMENT

* Exploring the Perceptions and Satisfaction of Princess Margaret Clinical Trial Participants

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1. Background

While assessment of patient satisfaction with clinical care has become standardized at most large health care institutions, there is limited comparable systemic evaluation of patients' experiences in a clinical research context. The incorporation of participant feedback and perspectives into clinical research programs has been shown to improve quality, outcomes, and patient protection. Aligning research goals with patient needs can help increase recruitment and retention, decrease implementation issues, and create programs that are more responsive to patient needs.

2. Goals

An exploratory project was initiated to evaluate the feasibility of obtaining feedback from clinical trial participants at Princess Margaret Cancer Centre about their satisfaction with, and perceptions of, their clinical trial experience. The objectives of this initiative were to elucidate the relative importance of various factors affecting clinical trial accrual, retention, and withdrawal among clinical trial participants, and to provide information on the experiences of participants about their clinical trial involvement.

3. Solutions and Methods

A validated patient satisfaction survey was mailed to 308 surviving patients who enrolled in a clinical trial between November 1, 2019 and March 1, 2020. The survey was designed to evaluate research participants' experiences, and to assess a range of topics, including motivation to participate in, or withdraw from, research; the informed consent process; and interactions with the research team. A descriptive analysis of the aggregate results was performed. Frequencies were calculated for categorical variables, while mean and median values were determined for continuous variables.

4. Outcomes

Twenty-eight percent of participants completed the survey. Participants assigned high ratings to their overall research experience, with a median score of 9 out of 10. Ninety-four percent indicated they would "definitely" or "probably" recommend research to their friends and family. Ninety-three percent of participants indicated they did not experience any pressure to participate in a trial and 92 percent reported they were treated with courtesy and respect at all times. The most influential motivators for clinical trial participation were access to new treatment, research center reputation, and a desire to help others. In rating factors influencing participant retention, the highest ratings were assigned to accessing new treatment and quality of life improvement. The decision to withdraw from clinical trials was most heavily influenced by side effects and pain, followed by interactions with the study team, and not receiving test results. Obtaining a summary of research results was the most likely variable to influence future study participation.

5. Lessons Learned

Evaluating the experiences and satisfaction of the Princess Margaret Cancer Centre clinical trial patient population is feasible. The exploratory findings show that the majority of participants were very satisfied with their experiences and highlighted actionable items to consider in order to improve participant recruitment, retention, and satisfaction. The perception of Princess Margaret's institutional reputation was a highly rated factor influencing the decision to participate in clinical trials. The feedback derived from participants provides an opportunity to assess existing local practices, identify gaps, and implement quality improvement modifications. The results of this pilot study will serve as a baseline and reference point for ongoing program evaluation.

* *Honorable Mention*

Use of a Site Profile to Streamline Site Selection and Feasibility

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1. Background

Feasibility questionnaires (FQs) and site selection visits (SSVs) require the same content repeatedly over time. This results in redundant, lengthy meetings; forms completion; and correspondence for different trials offered through the same sponsor or contract research organization (CRO), and across sponsors/CROs.

2. Goals

Our goal was to decrease time spent communicating redundant site details with sponsors/CROs for feasibility and site selection.

3. Solutions and Methods

Our solution was to package site-specific statistics, resources, capabilities, SOPs, processes, and timelines for sponsors in the form of a site profile. To create the site profile, we first polled our research managers about what content to include, focusing on sponsors' frequently asked questions. A designated point person created an outline of the desired content and began inserting information. The document covers the following areas: general overview of the cancer center (catchment area demographics, staffing, disease specialties, contact information), summary of study start-up process, descriptions of clinical facilities (inpatient floors, outpatient clinics, imaging/radiation therapy capabilities), research lab, investigational pharmacy, data management, and sponsor monitoring visit policy. For specific content, the coordinator reached out to clinical trials office staff (regulatory manager, budget manager, disease managers, lab staff, quality assurance manager), as well as hospital partners in pharmacy, service line management, radiation oncology, interventional radiology, and the hospital's compliance office. The coordinator organized all the responses into the site profile document and circulated for feedback. Once the site profile was ready, we began sharing it with sponsors. We try to refer sponsors to the document in lieu of completing their feasibility forms. When sponsors still require their FQ be filled out, we use the site profile as a reference and copy information into the FQ or write "see site profile." In preparation for SSVs, the site profile is emailed to sponsors along with a reverse FQ, and other commonly requested documentation to supplement the site profile. To see our site profile, please visit: https://www.mcw.edu/departments/cancer-center/clinical-trials/sops-for-research-staff

4. Outcomes

Sponsors/CROs were hesitant to rely on our site profile initially but have warmed up to the point of complimenting and remarking that few items remain for discussion. We have noted a marked decrease in the duration of SSVs, as well as necessary action items and correspondence with sponsor/CRO following the SSV. We expect there is increased consistency and efficiency of information sharing across teams.

5. Lessons Learned

Based on the outcomes described above, we feel that the site profile has been beneficial overall. Managers are responsible for FQs and SSVs, but we are considering administrative support for content packaged in our site profile to decrease expense and increase manager bandwidth. One downside is that the document requires ongoing maintenance. We update as needed when major changes occur and review annually to ensure it accurately reflects our site's current capabilities. We are planning to expand clinical trials at our network hospitals, so for next steps, we are considering creating a site profile for each community site. We are also planning to create a virtual (video) tour of our facilities with the hope of further streamlining pre-activation interactions with sponsors.

* Strategies for Improving Time-to-Activation of Clinical Trials

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1. Background

Delays in clinical trial activation can impede availability of novel therapies, combination regimens, or innovative patient care. Various steps in trial establishment processes obstruct timely activation, including time required for contract and budget negotiation, institutional review board acceptance, number of committees requiring approval prior to study initiation, and scheduling site initiation visits. To address these challenges, strategies need to address both sponsor-institution interactions and intra-institutional procedural obstacles. We sought to reduce our time to activation by identifying, understanding, and resolving redundant and inefficient procedural activities.

2. Goals

Our short-term target for trial activation time was 120 days with a 90-day final goal. A task force of senior institutional leadership was established in 2017 to achieve this goal. We reviewed and documented all steps in the current process, which were comprehensively analyzed to eliminate redundancy, revise workflows, start simultaneous processing of multiple regulatory and internal processes (including IRB and coverage analysis), and review pending studies monthly by disease center teams. We implemented automated reminders in the clinical trial management system (CTMS) to alert involved staff when a step approaches the allocated processing time. Management also receives monthly reports to monitor progress and intervene as necessary.

3. Solutions and Methods

The task force meets quarterly to review the trial activation process. Monthly reviews of pending trials for intellectual property (IP) and risk issues were instituted. Our clinical trials management application (CTMA) for metrics-based tracking of trial procedures tracks time spent on each component of the activation process, with email alerts sent to personnel at designated threshold periods. Furthermore, eReg software and eSignature tool were implemented to accelerate activation processing. The Clinical Protocol and Data Management (CPDM) assisted study cost out and preparation of source documents and orders commences immediately after protocols are submitted to the protocol review committee (PRC).

4. Outcomes

Our CTMS program enabled us to identify trials and sponsors that challenge trial activation the most, and the task force developed individually tailored mitigation strategies. CTMS enhancement allows calculation of the complexity of new protocols and required CRS staff workload for efficient trial performance, which is expected to reduce planning time for every new trial. The implemented continuous improvement approach reduced activation times by 19 percent and 62 percent for all adult and national protocols, respectively and the overall reduction from 2018 to 2020 was approximately 21 percent.

5. Lessons Learned

Steps implemented by the task force that substantially reduced trial activation delays include conducting regulatory, legal, and contract reviews simultaneously following protocol approval by the PRMC/PRC and streamlining reviews by the radiation safety committee whenever appropriate. The simultaneous submission of protocols to the IRB and IND applications to the FDA also reduced activation times. This division of processes reduced median activation times for industry, national, and external-peer reviewed trials by 29 percent, 62 percent, and 43 percent, respectively. Implementing this strategy from July 2017 to December 2020 overhauled, redesigned, and vastly improved our trial activation process, thereby providing a platform to ensure the gains and advances accomplished are maintained and built upon.

* *Honorable Mention*

Process Improvements to Shorten Clinical Trial Activation Times Within a National Cancer Institute-Designated Comprehensive Cancer Center

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1. Background

Lengthy clinical trial activation times limit patients' access to novel treatments, delay trial completion, and frustrate sponsors, investigators, and administrators, yet delays remain ubiquitous. When the Association of American Cancer Institutes (AACI) Clinical Research Innovation (CRI) surveyed its members, average activation time was approximately 180 days, well beyond the desired 90-day activation time expected by reviewers evaluating National Cancer Institute (NCI)-Designated Cancer Centers. After repeated attempts to improve existing processes, the Clinical Protocol and Data Management service (CPDM) at Wake Forest Baptist Comprehensive Cancer Center (WFBCCC), an NCI-Designated Comprehensive Cancer Center, undertook a ground-up evaluation and revision of its activation processes to improve trial activation.

2. Goals

In collaboration with WFBCCC leadership and relevant stakeholders, including faculty, the institutional office of sponsored projects (OSP), and institutional clinical trials office (CTO), and with the cooperation of the institutional review board (IRB), CPDM initiated a 90 Day Challenge with the goals of reducing the median time to activation, measured from the time of submission to the Protocol Review Committee (PRC) to trial activation to under 90 days.

3. Solutions and Methods

After a review of trials activated in the preceding 12 months, sources of delay were identified, and workflow was revised to address these delays. Specific problems included incomplete PRC submissions, a failure of investigators to adequately address operational deficiencies prior to PRC submission and excessively long delays in the performance of various stakeholders' tasks. Changes to address these problems included the creation and empowerment of a CPDM Feasibility Group (CPDM-FG) comprising CPDM clinical, data and regulatory staff, representatives from nursing, pharmacy, pathology, medical oncology, minority health care equity and others, to ensure that all operational issues and impediments are addressed, and all required documentation is in order prior to PRC submission. Workflow changes include running activation steps in parallel and earlier in the activation process, initiating them immediately after PRC approval. Further, strict mandatory timelines were implemented and enforced for all internal stakeholders throughout the activation process with a particular emphasis on contract and budget negotiations. Currently, the entire activation process is tracked, including details about document exchanges and hand-offs between various stakeholders, both internal and external. Weekly meetings within CPDM and with OSP and CTO occur to identify and address delays exceeding the prescribed times.

4. Outcomes

To date median times from PRC submission to PRC approval, PRC submission to IRB approval and PRC submission to trial activation have markedly improved and now meet and exceed NCI metrics for trial activation times with a median time of activation of 72 days. Investigator and staff satisfaction is improved, and resources are being used more efficiently.

5. Lessons Learned

Dramatic improvement in trial activation times is possible. Although the process can be resource intensive and necessarily require the cooperation and collaboration of all stakeholders for maximum benefit. We continue to revise our processes based on ongoing evaluation and are looking to greater engagement with external partners to ensure continued improvement in trial activation times.

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