



AACI CRI

Clinical Research Innovation

**CANCER CLINICAL RESEARCH
FOCUS ON THE FUTURE**

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12th Annual AACI CRI Meeting: Cancer Clinical Research Focus on the Future

When AACI's Clinical Research Innovation (CRI) Steering Committee convened last fall to plan the 12th Annual AACI CRI Meeting, the group mapped out a robust, three-day meeting centered on the future of clinical research. Just four months later, the novel coronavirus (COVID-19) was officially declared a pandemic and everything changed in an instant.

Recognizing the enormous impact of COVID-19, the steering committee designed an updated agenda for a two-day, virtual meeting that focused on the challenges posed by the pandemic — and the creative, innovative solutions implemented by AACI cancer centers.

The meeting shattered previous attendance records, with over 1,000 registrants representing 87 cancer centers, and more than 500 attendees participating in real time. Session topics spanned technology to facilitate remote work, organizational change, and working effectively across multiple generations.

In a panel discussion on harnessing technology to improve cancer clinical trials, Dr. Muhammad Beg, Simmons Comprehensive Cancer Center, UT Southwestern Medical Center, reported

on the role of wearable devices and sensors in monitoring cancer patients. The panel also featured presentations by Theresa Cummings, University of Maryland Greenebaum Comprehensive Cancer Center; and Leslie Pettiford, University of Florida Health Cancer Center, and was moderated by Collette Houston, Memorial Sloan Kettering Cancer Center. What AACI cancer centers have learned from remote work and the use of novel technologies during the pandemic will continue to improve the efficiency of clinical trials offices well into the future.

AACI cancer centers have nimbly adapted to change, creating flexible work environments, improving employee satisfaction, and reducing turnover in their clinical trials offices (CTOs). As we learned from Kimberly Jenkins, Cleveland Clinic Cancer Center, trust is key to achieving these goals — and a must throughout the evolving COVID-19 crisis.

Jenkins highlighted the importance of trust for everything from training, communication, and management, to determining pay and goals. Michael Sainz, Dartmouth-Hitchcock Norris Cotton Cancer Center, moderated the panel discussion, with presentations from Andrea Skafel, UCSF Helen Diller Family Comprehensive

Cancer Center; and Stefanie Belanger, UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill.

Generational humorist Meagan Johnson embraced the virtual format, conducting video interviews with members of several AACI cancer centers to add a personal touch to her keynote, which addressed the “signposts” that define each generation and impact their work style. Johnson's keynote provided an informative and entertaining overview of the generations in the workplace and how their interactions will shape the way future generations work.

Dr. Henry Ciolino, director of the National Cancer Institute's (NCI) Office of Cancer Centers, presented updates to the NCI Cancer Center Support Grant (CCSG) program, focusing on the P30 Funding Announcement. Dr. Gisele Sarosy, NCI's associate director for informatics and biomarkers, joined Dr. Ciolino to answer questions about community outreach and engagement, including accruing underserved populations to trials.

With many site visits moving to virtual platforms, it was especially important this year for AACI cancer centers to learn about the latest updates to the CCSG application and hear firsthand from centers who have just completed their visits.

12th Annual AACI CRI Meeting: Cancer Clinical Research Focus on the Future

In a session moderated by Alex Zafirovski, Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Dr. Carrie Lee shared lessons learned from the first virtual site visit conducted at her institution, UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill. Dr. Lee described the importance of giving your CTO ample time to plan the virtual site visit, including scripting, rehearsing, and recording presentations; gaining familiarity with technology platforms; and coordinating internal communication during the virtual visit.

Authors from 31 cancer centers submitted 77 abstracts for the annual meeting. The second day of the meeting began with remarks from CRI Steering Committee Chair Dr. Theresa L. Werner, Huntsman Cancer Institute, University of Utah, followed by information-rich presentations by three abstract winners, selected by the CRI Steering Committee and CRI Education Committee. The abstract presenters were Kimberly Jenkins, Cleveland Clinic Cancer Center; Shirley Cheng, University of Hawai'i Cancer Center, University of Hawai'i at Mānoa; and Britni Secor, Mays Cancer Center, UT Health San Antonio.

Seven honorable mention posters, one from each abstract category, were also presented by Ryan Chiechi, City of Hope Comprehensive Cancer Center; Tiffany Cull, University of Colorado Cancer Center; Rachel Kingsford, Huntsman Cancer Institute, University of Utah; Maureen Kelley, Barbara Ann Karmanos Cancer Institute, Wayne State University; Dr. Victor Santana, Comprehensive Cancer Center, St. Jude Children's Research Hospital; Jaime Wurth, Masonic Cancer Center, University of Minnesota; and Caitlin Sanford, Memorial Sloan Kettering Cancer Center.

Of course, the meeting would not have been possible without corporate support. AACI extends its appreciation to the following exhibitors and supporters, who engaged attendees through the meeting app and presentations that addressed common CTO challenges: Advarra, home of Forte Technology Solutions; ASCO; Complion; Essex Management; Florence, Huron; Merck; Novartis; and Veeva Systems.

AACI CRI 2020 Steering Committee

Chair - Theresa L. Werner, MD

Huntsman Cancer Institute, University of Utah

Tricia Adrales Bentz, MHA, CCRP

*Hollings Cancer Center
Medical University of South Carolina*

Stefan C. Grant, MD, JD, MBA

Wake Forest Baptist Comprehensive Cancer Center

Janie Hofacker, RN, BSN, MS

Association of American Cancer Institutes

Collette M. Houston

Memorial Sloan Kettering Cancer Center

Tara L. Lin, MD

The University of Kansas Cancer Center

Melissa Anne Nashawati, MPA

Mays Cancer Center, UT Health San Antonio

Bhanu Pappu, PhD, MHA

UPMC Hillman Cancer Center

Helen Peck, RN, MA, OCN, CCRP

Wilmot Cancer Institute, UR Medicine

Jessica Rhee, MD, MS

*University of Hawai'i Cancer Center
University of Hawai'i at Mānoa*

Michael Sainz


Dartmouth-Hitchcock Norris Cotton Cancer Center

Alex Zafirovski, MBA

*Robert H. Lurie Comprehensive Cancer Center of
Northwestern University*



2020 ABSTRACTS AND POSTERS



CLINICAL RESEARCH OPERATIONS

* Centralized Research Patient Scheduling & Authorizations

R. Chiechi, P. Herena, M. Kenney, B. Williams, M. Licata

City of Hope Comprehensive Cancer Center

1. Background

Patient scheduling is a known challenge in any medical setting. There is an inherent challenge in coordinating patient care, ensuring alignment with appropriate providers at optimal times. Care coordination is further tested with the addition of the requirements and complexities of a clinical trial. This becomes even harder with strained human resources and limited scheduling capacity. The Briskin Center for Clinical Research (BCCR) is an outpatient treatment center focused on providing care for clinical trial patients, including research infusions, evaluation and management visits, and other research related procedures that reports up to clinical research operations.

Over the last three years, the BCCR experienced consistent patient visit growth of 18%; however, with limited human resources and clinical trial scheduling complexities, this increase in patient visits caused the BCCR to experience peaks and troughs throughout the day resulting in patient wait delays for infusions, unanticipated gaps between appointments, and uneven nursing/patient ratios. To allow for more patient capacity, maximize research patient scheduling, ensure appropriate staffing ratios, limit delays and manage increased capacity for patient treatment, under the clinical research operations leadership, the BCCR with the COH Clinical Trials Office (CTO) initiated a multi-prong pilot program.

2. Goals

1. Effective use of the schedule to maximize infusion capacity and limit daily peaks and troughs, resulting in:
 - Reduced patient wait times
 - Improved nursing ratios and staffing
 - Generation of scheduling capacity without increasing resources
2. Identify and train research specific scheduling team members providing them tools to successfully schedule clinical trials patients to:
 - Reduce multiple exchanges with care team
 - Reduce scheduling-related deviations

3. Solutions and Methods

- Overhauled the Epic infusion schedule template maximizing patient slots throughout the day
- Established a central research scheduling (n=6) and authorizations (n=2) team with direct reporting lines to Clinical Research Operations department
- Educated the scheduling team on the importance of spread out booking and utilizing study windows

4. Outcomes

- Reduced the peak to better level load each day by controlling the schedule availability
- Decreased average wait time by 58%
- Increased volume without increasing capacity
- Reduced the number of back and forth emails pertaining to scheduling

5. Lessons Learned

- A recurring process to review schedule availability is essential for safely providing maximal patient schedule slots
- Improved use of the schedule increased overall patient volume and reduced wait times for patients
- Direct and centralized oversight of the scheduling and authorization team for research patients better aligns the goals between the CTO and the BCCR with improved overall coordination of care for patients on trial

Moving forward, the CTO and BCCR intends to expand the role of scheduling and authorizations within and improve the tools to give more scheduling autonomy to the schedulers to best manage patients on trial.



Centralized Research Patient Scheduling & Authorizations Clinical Trials Operations

By: Ryan Chiechi, MBA, MHA · Pamela Herena, MSN, RN, OCN · Meghan Brenan Licata, PhD, RN, ONP
Michael Kenney · Brenda Williams, BSN, RN · Ashley Baker Lee, MBA

BACKGROUND

Patient scheduling is difficult in any medical setting. There is an inherent challenge in coordinating patient care, ensuring alignment with appropriate providers at optimal times. Care coordination is further tested with the addition of the requirements and complexities of a clinical trial. This becomes even harder with strained human resources and limited scheduling capacity. City of Hope's (COH) Briskin Center for Clinical Research (BCCR), which reports to Clinical Research Operations, is an outpatient treatment center focused on providing care for clinical trials patients, that includes research infusion, injections, drug administration, labs, EKGs, evaluation and management visits, and other research related procedures. Over the last 3 years, the BCCR experienced consistent patient visit growth of 18%; however, with limited human resources and clinical trial scheduling complexities, this increase in patient visits caused the BCCR to experience peaks and troughs throughout the day resulting in patient wait delays for infusions, unanticipated gaps between appointments and uneven nursing/patient ratios. To allow for more research patient capacity, maximize scheduling, ensure appropriate staffing ratios, limit delays and manage increased treatment capacity, under the clinical research operations leadership, the BCCR, with the COH Clinical Trials Office (CTO), initiated a multi-prong scheduling pilot program.

GOALS

- Effective use of the schedule to maximize infusion capacity and limit daily peaks and troughs resulting in:
 - Reduction in patient wait-times;
 - Improvement in nursing ratios and staffing; and
 - No additional staffing resources.
- Identify and train research dedicated scheduling team members, providing them tools to successfully schedule clinical trials patients that:
 - Limited multiple exchanges with care team; and
 - Reduced scheduling related deviations.

METHODS

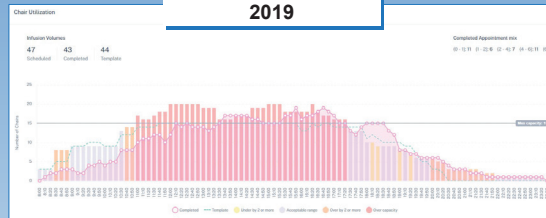
- Revised Epic infusion schedule template maximizing patient slots throughout the day with a balanced spread.
- Established a central research scheduling (n=6) and authorizations (n=2) team with direct reporting lines to Clinical Research Operations department.
- Educated the scheduling team on the importance of booking distributions and study windows to best use the available slots.

OUTCOMES

- Reduced the peak to better level load each day by controlling the scheduling availability.
- Decreased average wait time by 27% last year.
- Increased volume without increasing staffing capacity.
- Reduced the number of back and forth exchanges pertaining to scheduling.

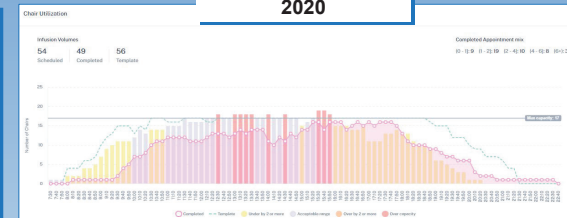
Key Metric	AUG - NOV 2017	AUG - NOV 2018	AUG - NOV 2019
Scheduled Patients	32 pts (78 hr)	32 pts (88 hr) +0% (+14%)	38 pts (104 hr) +18% (+32%)
Treated Patients	30 pts (81 hr)	30 pts (83 hr) +0% (+9%)	34 pts (111 hr) +14% (+27%)
Chair Wait Time	57 min (64 min at peak)	33 min (33 min at peak) -42% (-49%)	24 min (25 min at peak) -58% (-61%)

Tuesday, May 28, 2019



Same Day in 2019 vs 2020 Day after Memorial Day

Tuesday, May 26, 2020



2019

- 47 Scheduled Treatments
- Last Patient scheduled/left: 11:20pm
- Most patients scheduled in unit at one time: 20 (cap 17)
- Times actual was over chair capacity: 2
- Average period wait time: 40min

2020

- 54 Scheduled Treatments (up 14%)
- Last Patient scheduled out 8:20pm (left 11:20pm)
- Most patients scheduled in unit at one time: 18 (cap 17)
- Times actual was over chair capacity: 0
- Average period wait time: 25min (down 15 min/~40%)

LESSONS & FUTURE PLANS

Lessons:

- A recurring process to review schedule availability is essential for safely providing maximal patient schedule slots.
- Improved use of the schedule increased overall patient volume and reduced wait times for patients.
- Direct and centralized oversight of the research scheduling and authorization team better aligns the goals between the CTO and the BCCR with improved overall coordination of care for patients on trial.

Future Directions:

Moving forward, the CTO and BCCR intends to expand the role of scheduling and authorizations within and improve the tools to give more scheduling autonomy to the schedulers to best manage patients on trial.

Research Operations Innovation Program

R. Chiechi, S. Rosen, A. Lee, M. Licata, M. Kenney, A. Hammond, M. Bush, J. Light
City of Hope Comprehensive Cancer Center

1. Background

City of Hope (COH) Research Operations (RO) team is committed to providing COH basic, translational, and clinical programs excellent operational and regulatory support. The RO staff assist investigators, remove administrative barriers and help rapidly and safely move science forward. There are five large teams supporting RO. These include Research Applications and Data Management, Clinical Research Services, Research Administration, Research Protections, and Clinical Research Operations. All five teams, under a single leader, work together to further COH scientific discovery, and support and provide infrastructure for the research portfolios and programs. There remain opportunities for more collaborative, efficient, standardized processes, and potential for staff development and engagement.

2. Goals

The selected proposals supported the following initiatives:

- Enhance community research
- Enterprise-wide implementation of precision medicine
- Promote efficient use of resources and financial accountability
- Continue to advance CAR T and/or IEC programs
- Increase employee engagement scores

3. Solutions and Methods

In 2019, COH RO created a Research Innovations Program to boost collaboration and generate innovative ideas among the five RO teams, resulting in enhanced operational excellence, efficiency, and engagement. Projects must be led by RO staff with planned completion by the end of 2020 Fiscal Year (FY 20). Each project needed a sponsor from the team as the project contact to serve as the project leader. Senior leaders could participate as project team members, but could not sponsor any proposal.

Leadership issued the request for proposals (RFP) for collaborative programs, workflows or potential new systems addressing operational matters on September 15, 2019. Proposals were reviewed by a leadership committee, with the intent to select five for funding in FY 20. In total, 12 proposals were submitted, spanning basic science, clinical trials, and employee development.

4. Outcomes

The committee selected six well-conceived and developed proposals, one more than anticipated. All the selected projects offered to close a gap and foster a highly engaged work environment, they included:

- Research Operations Collaborator Content Management System for Subsites & Sponsors
- Research Operations Orientation Program
- Research Operations Campus Recruiting Project
- Developing a Research Operations Conference Travel Policy
- Use of Mobile Performance Board Template to Identify Challenges & Drive Change
- Expanded Lunch & Learn Program

Subsequently, the six program sponsors provided the RO staff a project overview, implementation plan, and addressed questions. During FY 20, project sponsors will provide the RO team project updates and progress with plans for sustainability beyond FY 20.

5. Lessons Learned

Although the projects only recently launched, there is a clear display of connectedness and the planned outcomes well-received by RO staff. Beyond the collaborative nature, the RO project provided leadership a window to better understand staff needs and challenges on a departmental level. The RO leadership team received valuable feedback regarding issues surrounding employee engagement, barriers and administrative burden specific to the RO team. This allows not only these projects to move forward but for leadership and teams to consider the challenges of the employees when considering solutions and new initiatives.



Research Operations Innovation Program

Clinical Trials Operations

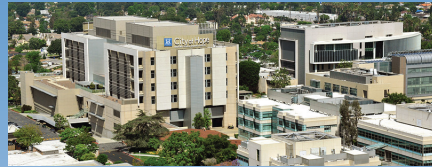
By: Ryan Chiechi, MBA, MHA · Mathew Bush · Amanda Hammond, JD · Meghan Brenan Licata, PhD, RN, ONP
Jason Light, MPH, MS · Michael Kenney · Brenda Williams, BSN, RN · Adrine Chung · Ashley Baker Lee, MBA

BACKGROUND

City of Hope (COH) Research Operations (RO) team is committed to providing COH basic, translational, and clinical research programs excellent operational and regulatory support. The RO staff assist investigators, remove administrative barriers and help rapidly and safely move science forward. There are five teams that comprise RO: Research Applications and Data Management, Clinical Research Services, Research Administration, Research Protections, and Clinical Research Operations. All five teams, under a single leader, work together to further COH scientific discovery through provision of top-caliber operational support to research portfolios and programs. There remain opportunities for more collaborative, efficient, standardized processes, and potential for staff development and engagement.

METHODS

In 2019, COH RO launched a competitive, project-based Research Innovations Program amongst the five RO teams aimed to boost collaboration and generate innovative operational improvement ideas in alignment with enterprise strategic priority. *De novo* project concepts were required to be conceived of and led by ground-level RO staff with a short completion timeline. Each project required a project leader to guide and direct project completion, however senior leaders within RO could not serve in this role in order to facilitate bottom-up ideas and broader team participation. A formal request for project proposals was issued and twelve proposals were received, addressing a variety of topics including improved support for basic science, improvements to clinical trial processes and enhanced employee professional development opportunities. Five projects were planned to be selected for execution.



OUTCOMES

The committee, comprised of executive and scientific leaders, selected six well-conceived and developed projects, one more than anticipated. All the selected projects offered to close an identified gap and foster a highly engaged work environment, they included:

- Research Operations Collaborator Content Management System for Subsites & Sponsors;
- Research Operations Orientation Program;
- Research Operations Campus Recruiting Project;
- Developing a Research Operations Conference Travel Policy;
- Use of Mobile Performance Board Template to Identify Challenges & Drive Change;
- Expanded Lunch & Learn Program.

Subsequent to selection, the six project leads developed a detailed project charter and implementation plan, addressing review questions. In FY20, during execution, project leads will provide the RO team project updates and progress with plans for sustainability beyond FY20.

METRICS AND GOALS

The selected proposals supported the following enterprise-wide strategic initiatives:

- Enhance community research;
- Enterprise-wide implementation of Precision Medicine;
- Promote efficient use of resources and financial accountability;
- Continue to advance CAR T and/or IEC programs;
- Increase employee engagement scores;

FUTURE PLANS

Although the projects only recently launched, there is a clear display of connectedness and the planned outcomes well-received by RO staff. Beyond the collaborative nature, the RO Innovation Program provided leadership a window to better understand staff challenges and priorities on a ground level. The RO Leadership team received valuable feedback regarding issues surrounding employee engagement, barriers and administrative burden specific to the RO team. This allows not only these projects to move forward but for leadership and teams to consider the challenges of the employees when considering solutions and new initiatives.

Operationalizing Protocols Through Treatment Plan Guidelines

M. Licata, C. Krygsman, P. Mack, A. Chung, A. Yi, A. Lee, R. Chiechi, P. Herena, B. Williams

City of Hope Comprehensive Cancer Center

1. Background

In December of 2017 City of Hope (COH) implemented the electronic medical record (EMR), Epic with Beacon treatment plans for drug protocols. At COH, research operations use Beacon treatment plans to build standard of care and investigational product (IP) administration treatment plans for all patients on treatment trials. To support this endeavor, COH established positions, Protocol Content Administrators (PCA), to be filled with personnel with clinical background. The PCAs create each Beacon treatment plan according to the trial protocol, get study team (PI, nurses, coordinator and pharmacist) validation, and send to the Beacon team for Epic build. The research treatment nurses, due to time and resource constraints cannot always participate in validation meetings. To ensure uniformity and treatment nurse input, COH assigned lead infusion nurses from the Briskin Center for Cancer Research (BCCR) to review treatment plans after validation.

Upon review, differences between treatment plan structure and consistent plans were identified. Additionally, gaps existed regarding standard oncology nursing processes, such as dual nurse dosage verification, as drug dose calculations were not included in treatment plans. Resolution of these issues required repetitive communication between treatment nurses, research nurses, and PCAs, resulting in staff frustration and IP administration delays. Additionally, the creation and validation of treatment plans required numerous team members; however, this costly process did not yield the highest quality product. COH needed an improved process and product to reduce staff concerns and resources while ensuring research patient safety.

2. Goals

We needed an improved process that resulted in:

- A treatment plan with instructions for standard, quality, and safe patient care
- Consistent and understandable treatment plans
- Less utilization of staff time and resources
- A rapid study activation timeline

3. Solutions and Methods

The lead BCCR treatment nurses, with the clinical research team, developed treatment plan guidelines. The development of guidelines also included clinical investigational drug pharmacists. The guidelines contained standard language for procedures and instructions to meet nursing needs, as well as protocol requirements. For example, under “research labs” the guidelines required the use of minutes for all collection windows (instead of hours or percentages) and inclusion of restrictions, such as peripheral draw only.

4. Outcomes

The four-page guidelines offer consistent instructions for inclusion of study tasks and a training tool for new PCAs, research team members, and BCCR treatment nurses. The tool will be implemented April 1 evaluating the above metrics.

5. Lessons Learned

Many institutions implemented Beacon treatment plans for research in different ways. With the best of intentions, COH focused on implementing treatment plans for all trials prior to activation, regardless of phase or disease type. While concentrating on ensuring consistency with the protocol, clinical information was omitted, causing delays and potential patient safety concerns. The proposed guidelines, collaboratively developed, provide focused research and clinical standards, allowing for reliable, standardized and consistent research treatment plans.



Operationalizing Protocols Through Treatment Plan Guidelines

Pam Herena, MSN, RN, OCN; Chris Krygsman, BSN, RN; Patrah Mack, MSN, RN, OCN;
Meghan Licata, PhD, RN, ONP; Brenda Williams, BSN, RN; Ashley Baker Lee

BACKGROUND

In 2017, City of Hope (COH) implemented EPIC as their electronic medical record (EMR). Beacon is EPIC's oncology module that COH uses to build therapeutic treatment plans. These treatment plans are utilized for both standard of care and investigational product (IP) for patients on treatment trials. Due to the complexity of treatment trials, individuals responsible for building these plans from the protocol, pharmacy and lab manuals, needed to have clinical and research related knowledge. COH created a new role, Protocol Content Administrators (PCA), to support the treatment plan builds for research. COH hired personnel with clinical background to work with our disease teams to build and validate the treatment plans. A COH goal was to have the Briskin Center for Cancer Research (BCCR) nurses, our outpatient research treatment facility, participate in this process. The BCCR nurses provide direct care to research patients and utilize the treatment plans; however, they are often not able to attend the validation meetings. In order to ensure treatment nurses were represented during Beacon validation meetings, leadership assigned a lead BCCR infusion nurse to review treatment plans for clarity after the validation meetings, but prior to the actual build.

CHALLENGES

During the validation process the BCCR Lead identified some challenges:

- Differences between treatment plan structures and consistent plans;
- Knowledge caps of standard oncology nursing processes and policies;
- Inconsistencies between different PCAs work product;
- Terminology copied from the protocol was ambiguous and required clarification;
- Patient delays for treatment plan clarifications;
- Limited understanding between PCAs and treatment nurses of work processes and requirements; and
- Repetitive communication between numerous staff resulting in frustration for both teams.

SOLUTIONS

In collaboration with the other BCCR nurses and the clinical research team, the lead BCCR treatment nurses, developed treatment plan guidelines for the PCAs. The guidelines:

- Adhered to nursing policy and scope of practice;
- Contained standard language for procedures and instructions to meet nursing needs and protocol requirements

For example, under "research labs" the guidelines required the use of minutes for all collections windows (instead of hours or percentages) and inclusion of restrictions, such as "peripheral draw only".

Scheduled regular meetings with lead treating nurses and PCAs to review guidelines and issues with treatment plans and processes weekly.



GOALS

1. Creating a final product for standard, quality and safe patient care.
2. Consistent and understandable treatment plans.
3. Reduction in staff time and resources
4. A rapid activation time line

OUTCOMES

We continue with collaboration meetings; however, we have run into additional challenges. At this time we are still working on implementing the guidelines created by the treatment nurses and still support this work.

Moving Cellular Therapy Clinical Trials in the Outpatient Setting: Aligning With Institutional Standards and FACT

P. Herena, M. Licata, B. Williams, C. Krygsman, R. Chiechi, A. Lee, M. Shields, A. Chung
City of Hope Comprehensive Cancer Center

1. Background

Until recently, cellular therapies (CT) were mostly administered inpatient with around-the-clock care, by staff familiar with Foundation for the Accreditation of Cellular Therapy (FACT) standards and trained in FDA required Risk Evaluation and Mitigation Strategy (REMS). Providing safe patient care can be challenging with complicated CT trials and requires detailed patient education and monitoring. Converting investigational CT to the outpatient setting and aligning with FACT standards creates many obstacles. With a plan to grow CT research, City of Hope (COH) recently transitioned multiple CT trials to the Briskin Center for Clinical Research (BCCR), an outpatient oncology research unit providing therapeutic first-in-human (FIH) through Phase 3 trials.

Challenges included: process development to align with standard of care (SOC), FACT knowledge gaps of BCCR treatment staff, numerous investigational CT treatments, and advanced planning for CT study requirements.

2. Goals

To meet these challenges, BCCR aimed to:

1. Innovatively adjust BCCR schedule for growing needs of CT studies
2. Align SOC and research CT policies, ensuring safety and FACT requirements
3. Manage resources associated of new outpatient CT studies
4. Collaborate with the Clinical Trials Office (CTO) to streamline CT study initiation

3. Solutions and Methods

1. BCCR leadership limited CT patient assignments to experienced registered nurses (RN) and developed a licensed vocational nurse (LVN) position to assist with the CT studies. To accommodate schedules for CT study patients, the service line director updated scheduling procedures with CT trial scheduling guidelines.
2. Most FACT policies are not always appropriate for outpatient or research settings as they may not conform with study requirements, including post-treatment assessments or discharge. To ensure consistency with SOC, the BCCR and clinical research nurses (CRNs), reviewed all CT research protocols, determined necessary processes, and added protocol specific requirements to SOC policies. The CTO created a research-specific FACT wallet card and revised the after-visit summary to conform with the SOC.
3. The physician or advanced practice providers (APP) usually administers the CT for investigator-initiated CT studies after the BCCR RN premedicates the patients. To reduce RN expense, the CT dedicated LVN will manage and premedicate patients prior to CT product arrival. Upon arrival, the RN will perform product check and evaluation. This eliminates the cost of an RN on stand-by for several hours until product arrival. Additionally, trial supplies, including personal protective equipment (PPE), were updated for cost reduction.
4. To streamline activation, the BCCR assigned a lead RN to CT studies. This allows the lead RN early access to the protocol and lab delivering the CT product to assist CRNs align protocol required procedures with SOC and ensure treatment plans are accurately updated.

4. Outcomes

The process was recently fully integrated. We will evaluate the ability to schedule more research patients, reduce nursing time and supply costs, and ensure alignment with SOC.

5. Lessons Learned

The disconnect between SOC and research CT policies and processes offered an opportunity to collaborate and educate our SOC partners. Plans include training all BCCR nurses to care for patients on CT studies. Teams will partner on detailed CT study in-services, monitoring volume for staffing and space needs and cost-saving opportunities.



Moving Cellular Therapy Clinical Trials in the Outpatient Setting: Aligning with Institutional Standards and FACT

Pam Herena, MSN, RN, OCN; Chris Krygsman, BSN, RN; Mary Shields, MSN, RN, OCN;

Meghan Licata, PhD, RN, ONP; Brenda Williams, BSN, RN; Adrine Chung; Ryan Chiechi, MBA, MHA

BACKGROUND

The Briskin Center for Clinical Research (BCCR) at City of Hope (COH) is a outpatient oncology research unit which provides therapeutic first-in-human (FIH) through Phase 3 clinical trial treatments. Recently, we were given the opportunity to integrate multiple cellular therapy (CT) trials into our unit.

There are over **300** treatment studies that utilize BCCR for outpatient treatments. The processes, training and orientation have been standardized to allow for easy adaptation for any oncology therapeutic study; however, CT trials brings new opportunities.

The recent trend of providing CT in the outpatient setting includes many challenges:

- Institutional Standards aligned with inpatient processes
- Foundation for the Accreditation of Cellular Therapy (FACT) standards
- Complex CT trials
- Knowledge gaps
- Training
- Patient safety

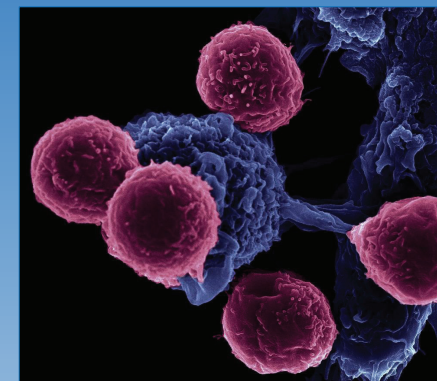


Briskin Center for Clinical Research at City of Hope

GOALS

To meet the challenges, the BCCR team aimed to:

- Innovatively adjust BCCR schedule for growing needs of CT studies;
- Align standard of care and research CT policies, ensuring safety and FACT requirements;
- Responsibly manage resources associated with new outpatient CT studies; and
- Collaborate with the Clinical Trials Office (CTO) to streamline CT study initiations.



METHODS

In order to achieve success implementing CT in the outpatient setting, BCCR leadership:

1. Chose a select number of BCCR nurses to train and orient to CT infusion and patient care;
2. Implemented a Licensed Vocational Nurse (LVN) role to elevate some of the prep work (e.g. labs, oral medication);
3. Worked with the service line director to create scheduling guidelines for CT trials;
4. Added specific research CT trial information into our CT policies to ensure alignment and standardized processes; and
5. Streamlined study activation, by assigning a lead nurse to work with CTO in operationalizing CT trials and train and validate all newly trained BCCR nurses that join the CT treatment team.

FUTURE DIRECTIONS

We successfully implemented CT trials into the BCCR outpatient unit. There is a lot of collaboration required among different departments due to the complexity and varied CT trials protocols. This can slow down the processes and create department challenges.

We will continue to evaluate our space utilization to ensure we can support the continued growth in the CT trial space. Creating streamlined collaboration will help ensure we continue with our rapid activations. We also plan to role out the education, training and orientation to all the nursing staff in Briskin.

One Small Step: Eliminating Investigator Sign-offs on Individual Epic Lab Reports

R. Selle, J. Thomas, B. Oleson

Medical College of Wisconsin Cancer Center

1. Background

Investigators have long been tasked with physically signing and dating study subject lab reports originating from the electronic medical record, along with indicating clinical significance for any out-of-range value. This has put an undue burden on study staff, as this is often duplicative effort. It is standard practice for the investigators to review patient labs in Epic prior to treatment. Often, it is not feasible for study staff to obtain a physical signature on printed labs prior to treatment, so signatures are often obtained days or weeks after treatment, providing little value to this process.

2. Goals

While experiencing rapid growth and limited budgets, like many U.S. cancer centers, the MCW Cancer Center Clinical Trials Office (CTO) has had to do more with less in many areas. The Cancer Center CTO needed to find a way to reduce the burden of these lab sign-offs, which had proved problematic for research nurses, coordinators, assistants, as well as investigators. The MCW Cancer Center CTO had to find a way to maximize productivity while still maintaining patient safety and proper study oversight. Signing off on laboratory reports that were days or weeks in the past was a hindrance to study staff and was taking time away from performing other meaningful safety-related tasks.

3. Solutions and Methods

In 2017, the MCW Cancer Center CTO implemented a Standard Operating Procedure that eliminated sign-offs on individual study subject laboratory reports, citing duplicative effort. As a standard practice, the study coordinator and the subject's clinical team review patient laboratory results prior to treatment. These values are examined alongside the protocol to check for any necessary dose modifications, sponsor reporting, or other necessary actions. The investigator then approves the subject for treatment by signing the treatment orders. The study coordinator or research nurse determines clinical significance by reviewing the clinic documentation and establishing if any action resulted from the lab value (treatment held, supplementation given, repeat lab draws, etc.). Only if a lab result is considered clinically significant, is it then reported as an adverse event.

4. Outcomes

The MCW Cancer Center CTO has not collected and analyzed formal time saving data around this issue. However, MCW Cancer Center CTO study staff anecdotally report considerable time savings by no longer having to obtain physician signatures on labs. This has been widely accepted by sponsors and auditors since the SOP's official approval in 2017.

5. Lessons Learned

Currently, staff are still obtaining physician signatures on lab reports that come from central labs, since they are not in the medical record. MCW Cancer Center CTO is exploring the need for these signatures, since they are often received by sites in the days after treatment, and therefore, not being used for treatment-related decisions.

One Small Step: Eliminating Investigator Sign-offs on Individual Epic Lab Reports

Rebecca Selle, BS, CCRP; Betty Oleson, BSN, RN, CCRP; James Thomas, MD, PhD - Medical College of Wisconsin

Abstract

Clinical Investigators have long been tasked with physically signing and dating study subject lab reports originating from the electronic medical record (Epic), along with indicating clinical significance for any out-of-range value. This has put an undue burden on study staff, as this is often duplicative effort, providing little value. While experiencing rapid growth and limited budgets, the MCW Cancer Center Clinical Trials Office (CTO) has had to do more with less in many areas. The MCW Cancer Center CTO needed to find a way to maintain patient safety, but reduce the burden of these lab sign-offs, which had proved problematic for research nurses, coordinators, assistants, as well as investigators. In 2017, the MCW Cancer Center CTO implemented a Standard Operating Procedure that eliminated sign-offs on individual study subject laboratory reports, citing duplicative effort. The MCW Cancer Center CTO study staff anecdotally report considerable time savings by no longer having to obtain physician signatures on labs. This SOP has been widely accepted by sponsors and auditors since the SOP's official approval in 2017. Currently, staff are still obtaining physician signatures on lab reports that come from central labs, since they are not in the medical record, but this process is being examined further.

Introduction

In an effort to show continued investigator oversight, physician investigators have long been tasked with the requirement from sponsors to physically sign and date study subject lab reports originating from the electronic medical record (Epic), along with indicating clinical significance for any out-of-range value (Figure 1). This has put an undue burden on study staff, as this is often a duplication of effort. It is standard practice for the investigators to review patient labs in Epic prior to treatment, discuss with clinical research coordinators, and review against the study dose modification section. Often, it is not feasible for study staff to obtain a physical signature on printed labs prior to treatment, so signatures are often obtained days or weeks after treatment, providing little value to this process.

Contact

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414-805-8748

Methods and Materials

While experiencing rapid growth and limited budgets, like many U.S. cancer centers, the MCW Cancer Center Clinical Trials Office (CTO) has had to do more with less in many areas. The Cancer Center CTO needed to find a way to reduce the burden of these lab sign-offs, which had proved problematic for research nurses, coordinators, assistants, as well as investigators. The MCW Cancer Center CTO had to find a way to maximize productivity while still maintaining patient safety and proper study oversight. Signing off on laboratory reports that were days or weeks in the past was a hinderance to study staff, provided no value to the study or patients, and was taking time away from performing other meaningful safety-related tasks.

In 2017, the MCW Cancer Center CTO implemented a Standard Operating Procedure that eliminated sign-offs on individual study subject laboratory reports in Epic, citing duplicative effort. As a standard practice, the study coordinator and the subject's clinical team review patient laboratory results prior to treatment. These values are examined alongside the current protocol to check for any safety concerns, dose modifications, sponsor reporting, or other necessary actions. The investigator then approves the subject for treatment by signing the treatment orders. The study coordinator or research nurse determines clinical significance by reviewing the clinic documentation and establishing if any action resulted from the lab value (treatment held, transfusions or supplementation given, repeat lab draws, etc.). Only if a lab result is considered clinically significant, is it then reported as an adverse event on study case report forms.

If a study sponsor or auditor requests documentation that labs have been reviewed, the study staff provide documentation of the treatment plan sign offs in Epic (Figure 2).

ZzTRN0NC-004-013 - DOB: 3/31/1952 - Review Flowsheets

Component	Latest Ref Rng & Units	4/5/2016	W
WHITE BLOOD CELL COUNT		8.4	
RED BLOOD CELL COUNT		4.6	
HEMOGLOBIN		13.5	
HEMATOCRIT		36	
MEAN CORPUSCULAR VOLUME		89	
PLATELET COUNT		350	
MEAN PLATELET VOLUME		9.8	
EOSINOPHIL PERCENT		9	
LYMPHOCYTE ABSOLUTE		2	
GLUCOSE	80 - 120 mg/dl	185 (A)	
GLYCOHEMOGLOBIN		7.4	
TOTAL CHOLESTEROL/HDL RATIO		232	
AST/SGOT		36	
ALT/SGPT		35	
BLOOD UREA NITROGEN		20	
CREATININE		1.5	

NCS
MSJ
4/21/16

Figure 1: Lab report signed by investigator with clinical significance indicated (test patient)

Results

The MCW Cancer Center CTO has not collected and analyzed formal time saving data around this issue. However, MCW Cancer Center CTO study staff anecdotally report considerable time savings by no longer having to obtain physician signatures on labs. This SOP has also saved considerable time for staff since they are no longer recording labs as Adverse Events that are considered not clinically significant. This has been widely accepted by sponsors and auditors since the SOP's official approval in 2017. Investigators have not been burdened with signing these lab reports.

Conclusions & Discussion

Currently, study staff are still obtaining physician signatures on lab reports that come from central labs, since they are not in the medical record. MCW Cancer Center CTO is exploring the need for these signatures, since they are often received by sites in the days following treatment, and therefore, not being used for clinical and treatment-related decisions. These reports also typically ask for clinical significance to be recorded as well, another duplication of effort.

Chemotherapy

Investigational - nivolumab (51616) 80 mg in NaCl 0.9 % 100 ml bag at 108 mL/hr, IV, ONCL, Thu 1/23/20 at 1005, For 1 dose
Subject Number: 300059
80 mg (rounded from 78.7 mg = 1 mg/kg × 78.7 kg treatment plan recorded weight), Administer over 60 Minutes, 108 mL
Infuse through a 0.2 micron inline filter. Do not follow SoC administration duration.

Action	User	Time
Order Administered	Kempka, Kathryn, RN	1/23/2020 10:41 AM
Order Released	Nelson, Maggie, PharmD	1/23/2020 8:50 AM CST
Order Signed	Harker-Murray, Amy K, MD	1/21/2020 10:27 AM CST
Order Modified (Order Composer)	Harker-Murray, Amy K, MD	1/21/2020 10:13 AM CST

Nursing Orders

Nursing Communication
Starting Thu 1/23/20 at 1341, Until Specified
Parameters for treatment:

ANC greater than or equal to 1,500 cells/mm³;
Platelets greater than or equal to 100,000 pbs/mm³;
Hemoglobin greater than or equal to 8 g/dl;
Total bilirubin less than or equal to 2.5 x ULN (except if with Gilbert's syndrome);
AST/ALT less than or equal to 5 x ULN;
Serum creatinine less than or equal to 2 x ULN

If patient does not meet treatment parameters, contact physician. If the physician determines that the patient is okay to treat (for investigational protocols, after protocol/medical monitor verification), document conversation in a progress note, and enter order NUR860 ONCOLOGY TREATMENT PARAMETERS with the adjusted parameters.

Action	User	Time
Order Released	Kempka, Kathryn, RN	1/23/2020 1:41 PM CST
Order Signed	Harker-Murray, Amy K, MD	1/21/2020 10:27 AM CST

Figure 2: Investigator signing off on treatment plan in Epic

Acknowledgements

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

Optimizing Our Protocol Management System Data and Aiding Research Portfolio Decisions Through Use of Custom Dashboards

J. Migliacci, B. Seko, A. Bijwe, S. Hanley, K. Kaufman, J. Lengfellner, R. Cambria, A. Rodavitch

Memorial Sloan Kettering Cancer Center

1. Background

As the medical community continues to embrace digital transformation, it is important that institutions leverage new technologies that optimize real-time reporting and aid research portfolio decisions. Over the last decade, electronic data collection has been a focus of health care institutions and has made a significant impact on scientific research.

2. Goals

At Memorial Sloan Kettering Cancer Center (MSK), the Protocol Activation and Human Research Protection Program recognized that data could be utilized for real-time dashboard reporting to aid our review process in the following key areas of interest: institutional scientific prioritization of research, principal investigator (PI) performance, and annual review reporting as mandated by federal regulations. Additionally, these dashboards can be used by investigators and their departments to facilitate conversations about streamlining resources.

3. Solutions and Methods

In collaboration with MSK's Clinical Research Informatics and Technology group, we sought to utilize data captured in our homegrown institutional Protocol Information Management System (PIMS) to develop and integrate two user-friendly dashboards into our protocol prioritization, activation, review, and monitoring processes.

4. Outcomes

The Department/Service Portfolio dashboard (DSP) [Fig1a] allows services to visualize their research portfolio by showing volume at each stage of a protocol's life cycle, from submission to closed to accrual. Volume is broken down by protocol category (e.g., industrial) and type (e.g., therapeutic) allowing Service Chiefs and Department Chairs a comprehensive look at their active portfolio when managing new proposals. The DSP indicates the time it takes protocols to move through the activation process (and ultimately provide patients the benefit of new treatments) using two metrics: Time To Activation (TTA) and Time To IRB Approval (TTIA), defined as time from first review to when a protocol is opened to accrual or IRB approved, respectively. The DSP shows a Year-Over-Year median TTA and TTIA comparison for the service and all MSK. The DSP includes a count of protocols with accrual performance notices issued by our Protocol Review and Monitoring System (PRMS), which can alert leaders of accrual problems.

The PI Metrics Dashboard (PMD)[Fig1b] provides reviewers from departmental and PRMS committees with visual aids to evaluate the performance of a PI's active trials, which inform the committees' review determination. The PMD allows the PI to evaluate his/her own performance and department chairs to evaluate their service's performance. The PMD provides the following PI-specific metrics:

- Protocol volume
- Median TTA/TTIA
- Accrual details
- Retrospective deviations
- Monitoring visit deficiencies

5. Lessons Learned

The two dashboards are being integrated into our research community to allow PIs to self-evaluate and Service Chiefs or Department Heads to assess their own groups. We will also explore new ways to integrate the dashboards into the review process to aid institutional committee reviewers in assessing new proposals from PIs and services with extensive portfolios. Furthermore, the IRB will evaluate how to integrate PMD into annual review reports as a visual representation of how a PI is handling his/her portfolio and assist with protocol monitoring.



Optimizing our Protocol Management System Data and Aiding Research-Portfolio Decisions through Use of Custom Dashboards

Jocelyn Migliacci, MA, Brian Seko, Aditi Bijwe, Sara Hanley, MSW, Kristopher Kaufman, MS, Joe Lengfellner, Roy Cambria and Ann Rodavitch, MA
Memorial Sloan Kettering Cancer Center

BACKGROUND

- As the medical community continues to embrace digital transformation, it is important that institutions leverage new technologies which optimize real-time reporting and aid research portfolio decisions.
- At Memorial Sloan Kettering Cancer Center (MSK), the Protocol Activation and Human Research Protection Program Unit recognized that data could be utilized for real-time dashboard reporting to aid our review process and to help in the following key areas of interest:
 - Institutional scientific prioritization of research
 - Principal investigator (PI) performance
 - Annual review reporting as mandated by federal regulations
- Additionally, we lacked a way for investigators and their departments to review their individual and cumulative portfolios.

GOAL

- To create Tableau dashboards with real-time visualization of protocol metrics that are already captured in our homegrown institutional Protocol Information Management System (PIMS).
- Utilize metrics to allow investigators and leadership a comprehensive look at our research portfolio, which could help departments streamline resources and aid our protocol review and activation process.

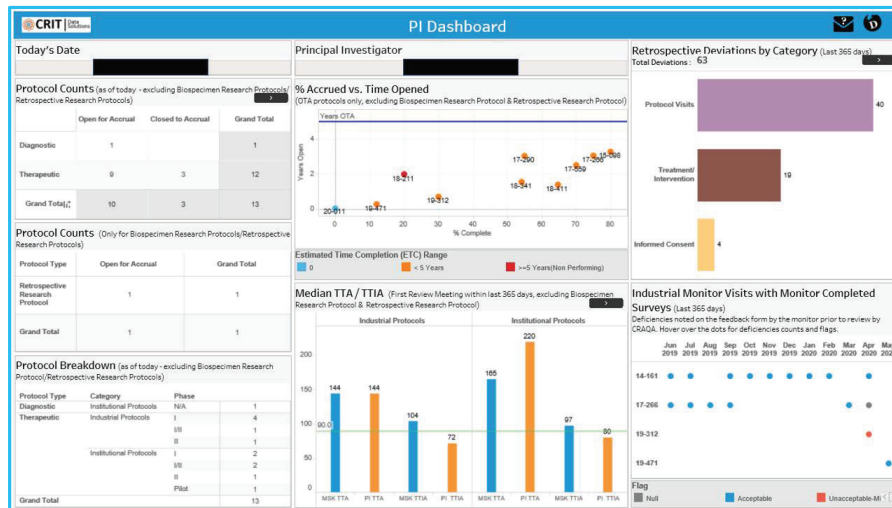
METHODS

- After identifying which metrics were the most informative to users, we collaborated with MSK's Clinical Research Informatics and Technology group to find an effective way to visualize the data.
- The development process included:
 - Creating detailed specifications prior to development
 - Working closely with developers to realign expectations throughout development
 - Extensive quality assurance review with comparison to raw data

Department/Service Portfolio Dashboard (DSP) →

- The Department/Service Portfolio dashboard (DSP) allows services to visualize their research portfolio by showing volume at each stage of a protocol's life cycle, from submission to closed to accrual.
- Volume is broken down by protocol category (e.g., industrial) and type (e.g., therapeutic) allowing Service Chiefs and Department Chairs a comprehensive look at their active portfolio when managing new proposals.
- The DSP indicates the time it takes protocols to move through the activation process (and ultimately provide patients the benefit of new treatments) using two metrics: Time To Activation (TTA) and Time To IRB Approval (TTIA), defined as time from first review to when a protocol is opened to accrual or IRB approved, respectively.
- The DSP shows a Year-Over-Year median TTA and TTIA comparison for the service and all MSK.
- The DSP includes a count of protocols with accrual performance notices issued by our Protocol Review and Monitoring System (PRMS), which can alert leaders of accrual problems.

Department/Service Portfolio												Department/Service (Multiple values)					
Institutional Trials: TTA/TTIA Medians				Industry Trials: TTA/TTIA Medians				National Group and Other Externally Peer Reviewed Trials: TTA/TTIA Medians				Department/Service					
MSK Current Median TTA	97	▼	MSK Current Median TTIA	104	▼	MSK Current Median TTA	49	▲	Median Key								
This Department/Service TTA	51	▼	This Department/Service TTIA	64	▼	This Department/Service TTA	56	▲	[▼] Lower than previous year	[▲] Higher than previous year	[=] Equal to previous year	[<-] No previous value for comparison	[X] No current value	[.] No comparison made			
MSK Current Median TTA	165	▼	MSK Current Median TTIA	144	▼	MSK Current Median TTA	81	▼									
This Department/Service TTA	123	▼	This Department/Service TTIA	119	▼	This Department/Service TTA	81	▼									
Median days for protocols in current pipeline	100	-	Median days for protocols in current pipeline	170	-	Median days for protocols in current pipeline	7	-									
Protocol Count by Category and Type: Therapeutic and Non-Therapeutic																	
Protocol Category	Protocol Type	Pre PAC	PAC	Department	Research Council	IRB	Approved Budget/Contract	Pending	Approved Pending	Open To Accrual	Closed To Accrual	Totals	Protocol Type	Open To Accrual	Closed To Accrual	In Pipe	Totals
Industrial Protocols	Therapeutic	0	0	3	4	3	0	1	63	52	87	136	Non-Therapeutic	9	8	0	17
Industrial Protocols	Non-Therapeutic	0	0	0	0	0	0	0	9	16	38	47	Therapeutic	136	107	23	266
National Group and Other	Therapeutic	0	0	1	0	0	0	0	21	16	38	47	Non-Therapeutic	9	8	0	17
Not Described	Therapeutic	1	3	0	0	0	0	0	0	0	0	4	Therapeutic	136	107	23	266
Not Described	Non-Therapeutic	0	0	0	0	0	0	0	0	0	0	0	Non-Therapeutic	9	8	0	17
Not Described	Not Described	0	0	0	0	0	0	0	0	0	0	0	Therapeutic	136	107	23	266
Grand Totals		1	3	7	5	3	1	2	145	115	282	282	Grand Totals	145	115	23	283
Protocol Count by Category and Type: Biospecimen and Retrospective																	
Protocol Category	Protocol Type	Pre PAC	PAC	Department	Research Council	IRB	Approved Budget/Contract	Pending	Approved Pending	Open To Accrual	Closed To Accrual	Totals	Number of Non-Performing Protocols				
Industrial Protocols	Biospecimen Research Prot.	0	0	0	0	2	0	1	17	4	24	24	11				
Industrial Protocols	Retrospective Research Prot.	0	0	0	0	0	0	1	52	3	56	56	11				
Not Described	Not Described	0	0	0	0	0	0	0	0	0	0	0	11				
Grand Totals		0	0	0	0	2	0	2	69	7	80	80	11				



← PI Metrics Dashboard (PMD)

- The PI Metrics Dashboard (PMD) provides reviewers from departmental and PRMS committees with visual aids to evaluate the performance of a PI's active trials, which informs the committees' review determination. The PMD allows the PI to evaluate his/her own performance and department chairs to evaluate their service's performance.
- The PMD provides the following PI-specific metrics:
 - Protocol volume
 - Median TTA/TTIA
 - Accrual details
 - Retrospective deviations
 - Monitoring visit deficiencies

FUTURE DIRECTIONS

- The two dashboards are being rolled out to our research community to allow PIs to self-evaluate and Service Chiefs or Department Heads to assess their own groups.
- We will also explore new ways to integrate the dashboards into the review process to aid institutional committee reviewers in assessing new proposals from PIs and services with extensive portfolios.

Registering 100% of Clinical Trial Participants: How Memorial Sloan Kettering Ensures Registration Accountability

R. Panchal, M. Buckley, B. Search, K.-H. Lin, D. Caron-Fabio, J. Yan, J. Lengfellner

Memorial Sloan Kettering Cancer Center

1. Background

Clinical trial participant registration is a manual step performed by research coordinators into each recruiting site's registration system. The accountability and accuracy of this step in clinical research participation is of utmost importance. Participant accrual reports are required quarterly to the NCI's Coordinating Center for Clinical Trials (CCCT) for all NCI-Designated Cancer Centers.

At Memorial Sloan Kettering (MSK), this process is being transformed as eConsent is implemented. eConsent is a web-based platform built by the Clinical Research Informatics & Technology (CRIT) team for electronic consenting, allowing for an automated data source, capturing real time consent data.

Given the ability to readily access the informed consent source data, we are reinventing how informed consent processes are systematically monitored and accounted for in the registration system, OnCore.

2. Goals

Our goal was to achieve 100% registration compliance by accounting for all informed consent processes taken place via eConsent into the MSK registration system, OnCore.

3. Solutions and Methods

The MSK CRIT team has established a quality assurance process to review all informed consents for one institutional protocol in the eConsent platform, in comparison with the registrations in OnCore. The ability to cross-reference both databases allows MSK to ensure full registration accountability and accuracy. The proof-of-concept process focused on one institution-wide protocol, which recruits approximately 180 participants per week, 13% of the total number of subjects consented weekly at MSK. Consents processes occurring in eConsent between March - December 2019 were monitored.

During the consent process for this trial, a set of five questions are answered. They are entered in the eConsent platform and this data is stored in the MSK's Clinical Research Database (CRDB), the same system that is also integrated with OnCore and receives its registration data. Any discrepancies between the two data sources are identified daily in CRDB. Weekly reviews of this discrepant data are performed. The eConsent user is notified of the delinquency and asked to rectify immediately.

4. Outcomes

Since the beginning of the weekly reviews in March/2019, on average, 9 discrepant records are identified, with a standard deviation of 5. This equates to approximately 5% of this clinical trial's weekly registration, ranging from 2-22 records. When the outstanding registrations are identified, the users and their managers are contacted to register the consented subjects in OnCore immediately. At each weekly reconciliation, an average of 7 unique users are notified.

5. Lessons Learned

The monitoring process initiated in 2019 was established as an initial effort to assess the number of outstanding consent processes that were not registered in OnCore. Once the rollout of eConsent is completed in 2020 for all protocols at MSK, the process can be scaled to all informed consents processes taken place in the MSK eConsent platform. This process will be automated with the implementation of the MSK Clinical Research Data Warehouse.

In the future, we foresee the ability to automate registrations by establishing an integration between eConsent and OnCore. This will effectively remove the need for manual data entry in OnCore, and significantly reduce clinical research coordinator's administrative time and effort and eliminate inaccuracy.



Registering 100% of Clinical Trial Participants: How Memorial Sloan Kettering Ensures Registration Accountability

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Background:

eConsent is a web-based platform built by MSK's Clinical Research Informatics & Technology (CRIT) for electronic consenting, allowing for an automated data source, capturing real time consent data.

eConsent digitalizes the consenting experience for patients through an educational engagement model.



eConsent platform has real time consent data stored in the MSK's Clinical Research Database (CRDB).

Patient registration is a manual process performed in OnCore by Clinical Research Staff, and is required entry within 2 business days of consent at MSK, as per internal SOP.

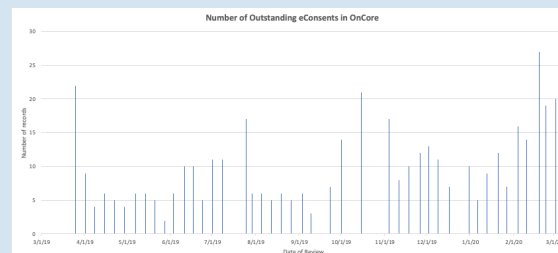
Goal:

To achieve 100% registration compliance by accounting for all informed consent processes taken place via eConsent into the MSK registration system, OnCore.

Methods for Proof-of-Concept:

- Piloting with one institutional protocol live in the eConsent platform.
 - Recruits ~180 subjects/week (~13% MSK wide)
- Cross review of eConsents records and registrations completed in OnCore was performed weekly.
- eConsent user is notified of delinquent registration in OnCore if outside of 2 business day window, as per MSK SOP, and instructed to rectify immediately.

Results:

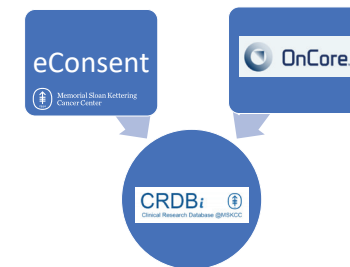


During Weekly Reviews:

- Average of 9 discrepant records found (SD: 5; 2-22)
- Average of 7 unique users are notified

Conclusions:

- Utilizing a monitoring effort between the eConsent platform and CTMS is valuable to enforce expected protocol patient registration requirements.
- Due to the positive results, once the rollout of eConsent is completed in 2020 for all MSK protocols, this process will be scaled to all informed consent processes occurring within the MSK eConsent platform



Future Directions:

- Automated process with implementation of the MSK Clinical Research Data Warehouse.
- Automate registrations by establishing an integration between eConsent and OnCore, removing the need for manual registration entry.

Staffing Model Reported Effort and Study Budgets: Are We In Sync?

E. Siglinsky, S. Goksu, H. Phan, K. Crane, M. Beg, E. Williams

Simmons Comprehensive Cancer Center, UT Southwestern Medical Center

1. Background

Over the past several years, clinical trials in oncology have increased in cost and complexity. The SCCC has developed a homegrown staffing model that measures the complexity of protocols to help determine the appropriate amount of staff to handle the workload. The staffing model is utilized across disease sites and studies in a consistent manner. Budgets are developed by individual teams. It is critical to ensure that the increase in workload is appropriately quantified and matched by budget.

2. Goals

We aimed to study the trends in trial complexity using the SCCC staffing model. Second, we investigated budgets and study complexity scores over the last six years to observe if there is a correlation between budget and complexity, in part to ensure that there is not a significant discrepancy.

3. Solutions and Methods

Our cancer center's protocol acuity model has been in use for six years, incorporating modifications over time, and aims to account for individual effort by measuring elements such as frequency of visits, quantity of study-related procedures, and data reporting. A static score is given for screening and enrollment of new subjects, which is retrospective, based on coordinator input. Utilizing the staffing model protocol acuity and corresponding budgets, we looked at change over time as well as their relationship. Specifically, we reviewed the numbers for industry studies, excluding investigator-initiated trials and cooperative group studies from the analysis. Total complexity score was used from the staffing model, and both total per-patient budget and screening per-patient budget were used in our analyses. A total of 120 studies were analyzed. Outliers greater than three times the standard deviation above the means were removed (n=2).

4. Outcomes

There was no significant correlation between per-patient study budget and study complexity score (Fig 1a). While the mean per-patient budget increased each year, including the portion of the budget dedicated to screening of potential patients, the total complexity score did not have a definitive trend over the years (Fig 1b). We believe this difference is a product of our acuity score not accounting for screening complexity; if the primary increase in study complexity is screening-related, the current protocol acuity score would not account for this change, yet budgets increased. The lack of a significant relationship between the total per-patient budget and total complexity score may also be attributed to differences in how managers calculate their budgets and negotiate with sponsors.

5. Lessons Learned

Legacy staffing models need to be reevaluated to keep up with changes in oncology clinical trial design. Based on our analyses, we hypothesize that the complexity of clinical trials has increased due to intense screening activities, however, more evaluation is needed. We have proposed a modification to our current staffing model to account for the screening period of studies in order to ensure that study complexity is inclusive of staff efforts during that time. Instead of a static number, the screening score would vary based on procedures and staff time before enrollment. Future research will review the increase in budgets versus inflation, to ensure that the complexity is matched by budget allocation.

Staffing Model Reported Effort and Study Budgets: Are We In-Sync?

Ellen Siglinsky, BS, CCRC, Suleyman Goksu, MD, Hannah Phan, MBA, MIS, Kimberli Crane, MS, CCRP Muhammad Shaalan Beg, MD, MS, Erin Williams, MBA

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

Background

Over the past several years, clinical trials in Oncology have increased in cost and complexity. The SCCC has developed a homegrown staffing model which measures the complexity of protocols to help determine the appropriate amount of staff to handle the workload. The staffing model is utilized across disease sites and studies in a consistent manner. Budgets are developed by individual teams. It is critical to ensure that the increase in workload is appropriately quantified and matched by budget.

We aimed to study the trends in trial complexity using the SCCC staffing model. Second, we investigated budgets and study complexity scores over the last six years to observe if there is a correlation between budget and complexity, in part to ensure that there is not a significant discrepancy.

Methods

- Our Cancer Center's protocol acuity model aims to account for individual effort by measuring:
 - frequency of visits,
 - quantity of study-related procedures
 - data reporting
 - A static score is given for screening and enrollment
- Utilizing the staffing model protocol acuity and corresponding budgets, we looked at change over time as well as their relationship in industry studies.
 - Total complexity score was used from the staffing model, along with total per-patient budget and screening per-patient budget
- A total of 120 studies were analyzed.
 - Outliers greater than three times the standard deviation above the means were removed (n=2).

Figures

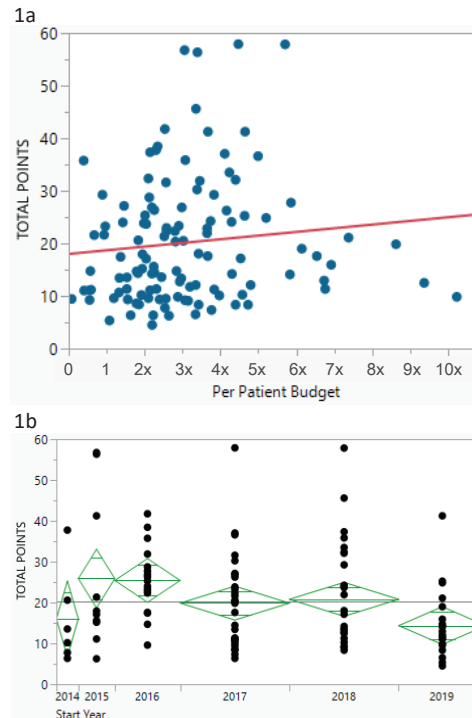


Figure 1a-b: Total complexity score versus per-patient budget and total complexity score by year.

Results

- No significant correlation between per-patient study budget and study complexity score (Fig 1a)
- Mean per-patient budget increased each year, including the portion of the budget dedicated to screening of potential patients
- Total complexity score did not have a definitive trend over the years (Fig 1b).

Discussion

- The discrepancy between increasing per-patient budget and stagnant complexity score could be a product of our acuity score not accounting for screening complexity.
- The lack of a significant relationship between the total per-patient budget and total complexity score may also be attributed to differences in how managers calculate their budgets and negotiate with sponsors.

Conclusion

- Legacy staffing models need to be reevaluated to keep up with changes in oncology clinical trial design.
- Proposed modifications to our current staffing model account for the screening period of studies in order to ensure that study complexity is inclusive of staff efforts during that time.
 - Instead of a static number, the screening score would vary based on procedures and staff time
- Future research will review the increase in budgets versus inflation, to ensure that the complexity is truly matched by budget allocation.

Utilizing the Clinical Trial Management System (CTMS) to Batch Load Accrual Data to the Clinical Trials Reporting Program (CTRP) System

M. Aguilar¹, S. Antony¹, E. Williams¹, S. Nonemaker-Cox²

¹Simmons Comprehensive Cancer Center, UT Southwestern Medical Center; ²Essex Management

1. Background

The Clinical Trials Reporting Program (CTRP) is a comprehensive database of information on all National Cancer Institute (NCI)-supported interventional clinical trials open to accrual as of January 1, 2009. A major benefit of the system is the consistent reporting to the NCI across centers, related to ongoing clinical trial activities funded by the NCI.

Accrual reporting is the responsibility of the lead organization for institutional, externally peer-reviewed, national (NCI-managed) studies or participating site for abbreviated/imported (e.g., industrial) trials. At UTSW, we utilize the effort of multiple people across the team to enter and report accrual in a timely manner.

Patient information is entered into our Clinical Trial Management System (CTMS) by the enrolling coordinator (any one of 60+ FTEs) and data is also required to be reported to CTRP. Reporting to CTRP can only be done by team members who are authorized CTRP users.

CTRP can accept accrual information in batched loads using the CTRP Accrual Batch File Tool, however, the system requires a specific format for submission to CTRP.

2. Goals

1. Reduce time/ effort taken to report accrual data on timely basis
2. Reduce incorrect data entry discrepancies due to human error
3. Create a reporting mechanism to push accrual from our CTMS to CTRP

3. Solutions and Methods

UTSW with the cooperation of the CTRP team implemented a semi-automated process to assist with the upload of accrual data for trials submitted to CTRP. The first step to achieving this task was to ensure that the data residing within the CTMS was in a format acceptable for receipt by the CTRP system. The next step was to create two separate batch files, one configured to assist with the complete (protocol provided) patient-level accrual update, and the second for abbreviated/imported trials. The final step was to email the de-identified files weekly to the UTSW CTRP Administrator who could then download the file and upload to the CTRP accrual website.

4. Outcomes

This new process eliminates the need to track what patient information was previously updated, as each upload ensures the most updated counts and/or information is loaded to CTRP for trials and patients referenced for that period. Doing so helps to have more timely reconciliation for important annual NCI-required Cancer Center Support Grant (CCSG) data tables, for example.

The time utilized to batch load the accrual data versus entering each accrual individually has been reduced from an average of 4.5 to 1.5 hours, including time and effort needed to investigate and correct error messages that may be received.

5. Lessons Learned

1. This process benefits from active collaboration between the CTRP administrators and center technical teams
2. To have a successful CTRP accrual batch load implementation, it is imperative to ensure the CTMS patient profile information is in a format acceptable by CTRP
3. In CTRP, once a trial is registered under a particular ICD code, the value cannot be changed without a data migration effort and/or nullification of the existing accrual data and submitted under a new ICD code

Utilizing the Clinical Trial Management System (CTMS) to Batch Load Accrual Data to the Clinical Trials Reporting Program (CTRP) System

Marcella Aguilar MBA¹, MHSM; Shiby Antony, MBA, MS¹, Erin Williams, MBA¹; Susan Nonemaker-Cox²

¹The University of Texas Southwestern Harold C. Simmons Comprehensive Cancer Center, Dallas, TX, ²Essex Management (Contractor to the National Cancer Institute)

Background

The Clinical Trials Reporting Program (CTRP) is a comprehensive database of information on all National Cancer Institute (NCI)-supported interventional clinical trials open to accrual as of January 1, 2009. A major benefit of the system is the consistent reporting to the NCI across centers, related to ongoing clinical trial activities funded by the NCI.

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Patient information is entered into our Clinical Trial Management System (CTMS) by the enrolling coordinator (any one of 60+ FTEs) and data is also required to be reported to CTRP. Reporting to CTRP can only be done by team members who are authorized CTRP users.

CTRP can accept accrual information in batched loads using the CTRP Accrual Batch File Tool, however, the system requires a specific format for submission to CTRP.

Metrics & Goals to be Achieved

Reduce time/ effort taken to report accrual data on timely basis.

Reduce incorrect data entry discrepancies due to human error.

Create a reporting mechanism to push accrual from our CTMS to CTRP.

Solutions and Methods

UTSW with the cooperation of the CTRP team implemented a semi-automated process to assist with the upload of accrual data for trials submitted to CTRP.

Step 1

- Ensure that the data residing within the CTMS was in a format acceptable for receipt by the CTRP system.

Step 2

- Create two separate batch files, one configured to assist with the complete (protocol provided) patient-level accrual update, and the second for abbreviated/imported trials.

Step 3

- Email the de-identified files weekly to the UTSW CTRP Administrator who could then download the file and upload to the CTRP accrual website.

Outcome

This new process eliminates the need to track what patient information was previously updated, as each upload ensures the most updated counts and/or information is loaded to CTRP for trials and patients referenced for that period. Doing so helps to have more timely reconciliation for important annual NCI-required Cancer Center Support Grant (CCSG) data tables, for example.

The time utilized to batch load the accrual data versus entering each accrual individually has been reduced from an average of 4.5 to 1.5 hours, including time and effort needed to investigate and correct error messages that may be received.

Lessons Learned and Future Direction

- This process benefits from active collaboration between the CTRP administrators and Center technical teams.
- To have a successful CTRP accrual batch load implementation, it is imperative to ensure the CTMS patient profile information is in a format acceptable by CTRP.
- In CTRP, once a trial is registered under a particular ICD code, the value cannot be changed without a data migration effort and/or nullification of the existing accrual data and submitted under a new ICD code.

UT Southwestern
Harold C. Simmons
Comprehensive Cancer Center



Conquering Resourcing

B. Broome, D. Pal Mudaranthakam

The University of Kansas Cancer Center

1. Background

Resourcing for clinical trials is a complex process, and achieving a balanced workload is a difficult task. Advocating for resources and ensuring all staff is working at capacity is a delicate balance that all clinical trial offices struggle to maintain. This is particularly difficult for clinical research coordinators and clinical data coordinator workloads. To balance workloads and ensure appropriate resourcing, leaders must consider trial types, complexity, ancillary department coordination, and visit types. With this as a goal, a workload algorithm was created to measure clinical and data coordinator resources objectively.

2. Goals

To evaluate current staffing capacity and needs, the KUCC workload algorithm was created:

1. To assess the current volume of work for individual clinical research coordinator and clinical data coordinator
2. For realignment of resources to balance workloads across staff
3. To quantify resourcing needs

3. Solutions and Methods

- Modifying the OPAL assessment to utilize subjective data to create objective data for supporting resources
- Collaborating with our clinical trial management system administrator to build a resourcing algorithm looking at actual hours of work based on trial type

4. Outcomes

Utilizing the methods implemented reviewing historical data specifically within the Early Phase program proved the resourcing algorithm to be on target for determining resourcing needs. With this confirmation, we moved forward with implementation across all trials.

5. Lessons Learned

Modifications to the algorithm were needed to capture work. We identified areas where we were not capturing the information needed to develop the algorithm. Tools to capture appropriate information were needed before testing the algorithm.

Future directions will be to utilize this reporting for ensuring staff is working at capacity, standardizing expectations, and realigning staff as needed. This resourcing tool will be used to justify additional staffing needs objectively, and support budgeting for trials. Eventually, we would like to incorporate the expected workload burden of a trial during disease working group review as a point for consideration when voting on trials.



Conquering Resourcing

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



Introduction

The University of Kansas Cancer Center (KUCC) Clinical Trials Office supports varying oncology clinical trials. Each trial is unique in design, complexity, accrual goals and deliverables with participants in varying stages participation. Ensuring appropriate resourcing across clinical research coordinators and clinical data coordinators is an every evolving challenge. Under or over utilization and resources leads to missteps in trial execution, data quality and timeliness, decline in morale, turnover and decreased participant satisfaction. To combat these challenges, The KUCC Clinical Trials Office has capitalized on existing resourcing tools and developed a robust resourcing algorithm.

GOALS

Develop an objective resourcing algorithm utilizing a clinical trials management system to allow:

- Assessment and alignment of workload
- Evaluation of staff performance
- Justification of staffing needs
- Appropriate budgeting for effort (pharma, grant, internal)
- Trial prioritization
- Transparency

Methods

Utilizing the Ontario Protocol Assessment Level² (OPAL) too as a guide to developing a protocol complexity score with a ranking scale of 1 (non-treatment/simplistic) through 8 (Phase I/CAR-T/highly complex), we modified the criteria to expand upon scoring criteria using “add-on” protocol requirements that can increase the complexity (i.e. requirement of multiple portal use).

From there we surveyed clinical research leaders, coordinators, and data managers with varying experience levels regarding overall amount of effort, measured by hours of work and visit type for each level of trial complexity. Thus turning objective data into subjective data. (Table 1).

Once hours of work were established, we incorporated all components of the calculation in to our clinical trials management system allowing for the automated calculation of hours of work for individual clinical and data coordinators.

Table 1

Visit Hours Based on Protocol Complexity and are calculated on a per visit basis (see additional sheet for justifications):									
Score (Based on Protocol Complexity and any add ons)	CRC Hrs Screen	CRC Hrs Actively On Tx	CRC Hrs F/U	CRC Hrs Survival Only		Data Hrs Screen	Data Hrs Actively On Tx	Data Hrs F/U	Data Hrs Survival Only
1	1	0.5	0	0		0.5	0.25	0	0
2	1	0.5	0	0		0.5	0.25	0	0
3	1	1	0.5	0.25		0.5	0.5	0.25	0.25
4	2.5	1	0.5	0.25		1	0.5	0.25	0.25
5	4	1.5	1	0.25		2	1	0.5	0.25
6	6	2	1	0.25		2	1	0.5	0.25
7	8	3	1.5	0.25		6	1.5	1	0.25
8	4	4	2	0.25		8	2	1	0.25
>8	10	5	3	0.25		9	3	1.5	0.25

²Smuck, B., Bettello, P., Berghout, K., Hanna, T., Kowaleski, B., Phippard, L., . . . Friel, K. (2011). Ontario Protocol Assessment Level: Clinical Trial Complexity Rating Tool for Workload Planning in Oncology Clinical Trials. *Journal of Oncology Practice*, 7(2), 80-84. doi:10.1200/jop.2010.000051

Results

In calendar year 2019, total number of study hours for Clinical Research Coordinators was 88,942 and clinical data coordinators 50,013. Considering the annual hours worked as 2080, this results in the need for 43 clinical research coordinators and 24 clinical data coordinators.

The algorithm’s calculations for resources needed almost mirrored the resources available (assuming all positions filled). This implies the need for better workload distribution among staff as there are areas in which acuity is higher and staff members are working increased hours.

Additional vetting is needed to solidify the algorithm as well as considerations for community site staff, program alignment and expected growth.

Future Directions

Once finalized, this resourcing report will be used to provide oversight of resources as a whole, ensure adequate budgeting for clinical trial effort, consideration in disease specific working groups on trial selection and justification for additional resources.

Adverse Event Reporting System

A. Annis, M. McAdoo, A. Hanlyn, Z. Feng, A. Smith, K. Simpson

UAMS Winthrop P. Rockefeller Cancer Institute

1. Background

Historically at our institution, adverse events were extracted from free text physician notes. As expected, all of the required elements were not documented and Common Terminology Criteria for Adverse Events (CTCAE) terminology was rarely used. The result of this method led to many queries which imposed a mountain of work upon our research staff who were tasked with determining the grade, attribution, start date, action(s) taken, and seriousness of the event.

With the implementation of electronic medical records we embarked upon the goal of establishing a more efficient and accurate way of capturing adverse events (AE). Our first attempts were successful in capturing some but not all of the required adverse event information. We still were not using CTCAE terminology consistently and properly.

Collectively our research staff partnered with our IT department and clinical staff representatives to develop an electronic application within our clinical trials management system (CTMS) to capture the required elements.

2. Goals

- Provide a user-friendly electronic system to capture all required data elements
- Decrease the workload associated with monitor/sponsor inquiries/queries
- Increase compliance of adverse event reporting

3. Solutions and Methods

Arkansas Adverse Event Reporting System (AR-AERS) is an application developed to allow clinical research staff to systematically collect AE information in order to increase compliance and inform research findings. AR-AERS allows the entry and review of new and ongoing AEs, as well as their resolution. AR-AERS uses the CTCAE version as determined by the study protocol.

There are many benefits of using AR-AERS:

- Improves the timeliness and accuracy of reporting
- Minimizes duplicate documentation and under-reporting of AEs
- Promotes subject safety
- Reduces the number of queries
- Provides a systematic, comprehensive way of capturing AE documentation and tracking ongoing AEs

Integration with our CTMS and the UAMS electronic medical records system allows AR-AERS to automatically enter and grade abnormal labs per the CTCAE criteria for active research subjects.

The research nurse, in collaboration with the patient and the physician, documents all adverse events.

In regards to CTCAE, AR-AERS:

- Allows for accommodation of multiple CTCAE versions
- Systematically separates CTCAE into symptoms and diagnoses
- Groups items for ease of finding the correct distinction to use when documenting AEs
- Alphabetizes lists for easy location

4. Outcomes

- Decreased number of AE-related queries
- Decreased time/effort in answering queries
- Increased understanding of adverse event reporting requirements
- Systematically captured all required data elements that can be easily reported to sponsors

5. Lessons Learned

- We underwent several rounds of modifications to get the workflow correct
- Clinical staff representation was vital to ensure accurate and efficient workflows
- Immediate physician workflow was complex and time consuming, but after much effort the process has been simplified extensively resulting in improved physician engagement



Adverse Event Reporting System

Missy McAdoo, RNP, BSN; Laura Hutchins, M.D., Sandy Annis, BA, CCRP;
Kacie Simpson, BS, CCRP; Andru Hanlyn, BS; Zhidan Feng, MS; Angela Smith, MS, PMP, CCRP;
Cancer Clinical Trials and Regulatory Affairs, Winthrop P. Rockefeller Cancer Institute,
University of Arkansas for Medical Sciences, Little Rock, AR

Background

Historically at our institution, adverse events were extracted from free text physician notes. As expected, all of the required elements were not documented and Common Terminology Criteria for Adverse Events (CTCAE) terminology was rarely used. The result of this method led to many queries which imposed a mountain of work upon our research staff who were tasked with determining the grade, attribution, start date, action(s) taken, and seriousness of the event. With the implementation of electronic medical records we embarked upon the goal of establishing a more efficient and accurate way of capturing adverse events (AE). Collectively our research staff partnered with our IT department and clinical staff representatives to develop an electronic application within our clinical trials management system (CTMS) to capture the required elements.

Metrics & Goals to be Achieved

- Goal 1: Provide a user-friendly electronic system to capture all required data elements.
- Goal 2: Decrease the workload associated with monitor/sponsor inquiries/queries
- Goal 3: increase compliance of adverse event reporting

Methods

Arkansas Adverse Event Reporting System (AR-AERS) is an application developed to allow clinical research staff to systematically collect AE information. AR-AERS allows the entry and review of new and ongoing AEs, as well as their resolution. AR-AERS uses the CTCAE version as determined by the study protocol.

The benefits of using AR-AERS has included improving timeliness and accuracy, minimizing duplicate documentation and under-reporting, promotes subject safety, reduces queries, and provides a systematic way of capturing AE documentation and tracking ongoing AEs.

AR-AERS Instance: Staging

Patient: [20190702] Test, AERS

ENROLLED in TREATMENT on study 20190702 Principal Investigator Hutchins, Laura Study Title: AERS Test

Summary | Ongoing AEs | Resolved AEs | New AE | No AE | Assess AE | Submit

This subject has:
2 Ongoing AEs, 1 Resolved AEs,
1 un-submitted Assessments in 1 AEs

Please click Ongoing AEs tab to process!
Flashing AEs to assess on Ongoing or Resolved tabs!

UAMS AR-AERS V3.4 © 2019 | IT Research | WPCR CCTRA

Outcomes

Implementation of this program has allowed us to decrease the number of AE-related queries, decrease time and effort in query resolution, increase understanding of AE reporting requirements, and systematically capture all required data elements that can be easily reported to sponsors. Integration with our clinical trial management suite and with EPIC has occurred. Lastly, we have recently implemented an automated lab grading feature that allows clinical lab results to be pulled in automatically for assessment when needed.

Grade Set Date	Assess Date	Action Taken	Action with Drug/Device	Status
2019-06-04	2019-06-04	Medication prescribed		X Onset AE awaiting assessment and sign off by investigator
AE Grade: Grade 1: Hemoglobin (Hgb) Less than LLN - 10.0 g/dL; Less than LLN - 6.2 mmol/L; Less than LLN - 100 g/L Comments:				
Baseline?	20190603:No	Solicited AE? Y/N	Expected AE? Y/N	Serious AE? Y/N
Does this Adverse Event increase risk to subjects/others? Y/N				
Related to study? -- select relatedness -- 20190603				

Lessons Learned & Future Directions

Several rounds of modifications happened before we were able to get the workflow correct. Clinical staff representation was vital to ensure accurate and efficient workflows existed. Immediate physician workflow was complex and time consuming but after much effort the process has been simplified extensively resulting in improved physician engagement.

Summary | Ongoing AEs | Resolved AEs | New AE | No AE | Assess AE | Submit

Abnormal Lab	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	No AE	Needs Assessment	New Assessment
Adverse Events	2018-12	2019-01	2019-02	2019-03	2019-04			
Blood and lymphatic syste...								
Extracocular muscle paresi...								
Palpitations								
Baselines								
Anemia								

Please assess flashing AEs

RESET | Zoom X4 | Zoom X8

Contact

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Arkansas-Patient Study Calendar

K. Simpson, A. Annis, C. Golden, Z. Feng, A. Smith, K. Zorn

UAMS Winthrop P. Rockefeller Cancer Institute

1. Background

Appropriately routing charges for services covered by research funding is a key concern for research staff. At UAMS, all research participants' generated charges must be reviewed against the research study protocol to assess study-relatedness. This finance review of all entries from each participant's medical record is very time-consuming, redundant to the tasks completed by study coordinators for case report form (CRF) entry, and can lead to errors during billing review.

2. Goals

Establish a mechanism to capture all known charges the study could generate and put them in a platform that would work with our electronic medical record system to decrease the time spent on billing review and streamline research accounting.

3. Solutions and Methods

- A detailed research study budget is built to capture administrative time, pharmacy, Institutional Review Board (IRB), reimbursement, and screening fees as invoiceable study expenses. All study-related activities are built in the research study budget matrix to mimic the protocol study calendar including alternate, conditional, and outside tests, and study communications. All items within the budget are then tied to a billing indicator to assist with routing charges as routine care or payable by the sponsor.
- The research study budget is imported to AR-Patient Study Calendar (AR-PSC). Study coordinators review the participant's medical record and mark all completed activities in AR-PSC for each protocol time point. Ideally, this review is done within 5 days of the visit and upon CRF completion.
- Information from AR-PSC is used for billing review and then imported to the Research Accounting System to assist the finance team with accounting.

4. Outcomes

AR-PSC has decreased redundant processes and duplicate data entry, significantly improved data quality, and increased revenue. AR-PSC is also a quick central location for research staff to review the location of participant within the research study.

5. Lessons Learned

Initially, we didn't have a solution for capturing unscheduled visits or additional treatment due to adverse events in AR-PSC because these items cannot be accounted for on the study level in the research study budget. Over time, a process was developed to manually enter this information into AR-PSC on the participant level as needed. We have also added some reporting features to AR-PSC that we hope will continue to evolve over time.



Patient Study Calendar

Kacie Simpson, BS, CCRP; Sandy Annis, BA, CCRP; Chris Golden, MS, CCRP;
 Zhidan Feng, MS; Angela Smith, MS, PMP, CCRP; Kristin Zorn, MD
 Cancer Clinical Trials and Regulatory Affairs, IT Research Systems,
 Winthrop P. Rockefeller Cancer Institute,
 University of Arkansas for Medical Sciences, Little Rock, AR

Background

Appropriately routing charges for services covered by research funding is a key concern for research staff. At UAMS, all research participants' generated charges must be reviewed against the research study protocol to assess study-relatedness. This finance review of all entries from each participant's medical record is very time-consuming, redundant to the tasks completed by study coordinators for case report form (CRF) entry, and can lead to errors during billing review.

Metrics & Goals to be Achieved

Establish a mechanism to capture all known charges the study could generate and put them in a platform that would work with our electronic medical record system to decrease the time spent on billing review and streamline research accounting.

Methods

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- Information from AR-PSC is used for billing review and then imported to the Clinical Research Accounting System to assist the finance team with accounting.

UAMS AR-CRIS AR-PSC Subject Calendar (Staging) logged user: Kacie Simpson

Presley, Ehis (PID-123456789, Male, 1935-01-08)
 This subject is registered in study: 123456 / 45212

- 2020-03-17 123456 / Pre-Registration / Screening / Screening / Day 1 (2 activities: 1 completed 1 dropped)
- 2020-03-24 123456 / Treatment / Arm 1 A, B, C-D / Cycle 1 / Day 1 (45 activities: 19 completed 6 dropped)
- 2020-03-31 123456 / Treatment / Arm 1 A, B, C-D / Cycle 1 / Day 5 (31 activities: 16 completed 5 dropped)
- 2020-04-06 123456 / Treatment / Arm 1 A, B, C-D / End of Treatment / Day 1 (2 activities: 2 completed)
- 2020-06-26 123456 / Follow up Prior to Progression / Follow up Prior to Progression / Follow up 1 / Day 1 (10 activities: 7 completed 3 dropped)
 - Misc (9 activities)
 - 00463 - Hospital outpt clinic visit / C / \$107.86 / cgt00463 / Notes
 - Misc - Disease Assessment - Disease Assessment / R / \$0.00 / Notes
 - Misc - PI Administrative Time / R / \$0.00
 - Misc - Research Nurse (Staff Time) / R / \$0.00
 - Misc - Study Coordinator (Staff Time) / R / \$0.00
 - PR CARDIOVASCULAR SYSTEM SERVICES (1 activities)
 - 36591 - Draw blood off venous device / See notes / R / \$99.14 / cgt36591
 - PR EVALUATION AND MANAGEMENT SERVICES (1 activities)
 - 99215 - Office/outpatient visit ext. / C / \$264.00 / cgt99215 / Notes
 - PR IMAGING (3 activities)
 - 71260 - Ct thorax w/dye / C / \$328.83 / cgt71260 / Notes
 - 74176 - Ct abd & pelvis w/o contrast / C / \$398.66 / cgt74176 / Notes
 - 74177 - Ct abd & pelv w/contrast / C / \$535.28 / cgt74177 / Notes
- 2020-07-28 123456 / Follow up Prior to Progression / Follow up Prior to Progression / Follow up 2 / Day 1 (9 activities: 9 planned)
- 2020-09-29 123456 / Follow up Prior to Progression / Follow up Prior to Progression / Follow up 3 / Day 1 (9 activities: 9 planned)

Note: Actual costs not represented

Intellectual Property of UAMS

Outcomes

AR-PSC has decreased redundant processes and duplicate data entry, significantly improved data quality, and increased revenue. AR-PSC is also a quick central location for research staff to review the location of the participant within the research study.

Lessons Learned & Future Directions

Initially, we did not have a solution for capturing unscheduled visits or additional treatment due to adverse events in AR-PSC because these items cannot be accounted for on the study level in the research study budget. Over time, a process was developed to manually enter this information into AR-PSC on the participant level as needed. We have also added some reporting features to AR-PSC that we hope will continue to evolve over time.

Contact

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UAMS AR-CRIS AR-PSC Template Management (Staging) logged user: Kacie Simpson

123456 A Phase III Randomized Trial of A, B, and C-D Versus A and B in Advanced Biliary Tract Cancers
 Current Version: Test again is released on 2020-05-27 Click Start to Manage button to manage the study. When completed, click End Managing button.

Preview Full Preview Hide deleted items Hide new change flags

Epoch	Arm/Segment	Length	Repeatable
Pre-Registration !	Screening		
Treatment !	Arm 1 A, B, C-D		
	Arm 2 _A, B		
Follow up Prior to Progression !	Follow up Prior to Progression		
Follow up after Progression !	Follow up After to Progression		

Intellectual Property of UAMS



Using Video Remote Interpretation to Overcome Language Barriers With Non-English Speakers in Clinical Trials

C. Garcia, J. Bourgeois, D. Harvey, C. Lewis

Winship Cancer Institute of Emory University

1. Background

In 2018, 67.3 million U.S. residents spoke a language other than English at home; of these, 25.6 million self-reported speaking English less than very well. Although about 20% of patients may be eligible to participate in cancer research studies, only about 3% of adults do. Those rates are even lower for ethnic minorities with one of the barriers to participation being language differences. Enrolling patients of different ethnicities in clinical trials is imperative to promote equity and ensure novel drugs/combinations have been evaluated in diverse populations. Inadequate interpreter services impact patients' quality of care, outcomes, and access to potentially lifesaving clinical trials.

The initial consent visit is done with an interpreter present; however, many subsequent visits may be done via telephone interpretation services which can be difficult due to phone access challenges. The cost of in-person interpreter services can be substantial, ranging from \$45–\$150/hour, while only \$1.25–\$3.00/minute for telephone, and \$1.95–\$3.49/minute for video remote interpreting. Documentation of the use of interpreter services is often not consistent and the incomplete documentation poses challenges for clinical trial standards resulting in possible regulatory implications. It is essential to promote equity by removing one of the barriers to underrepresentation of minorities in clinical trials and facilitate accurate reporting and documentation to ensure compliance.

2. Goals

Timely, accessible, professional medical translation services for over 200 languages with automatic record-keeping of call logs for documentation purposes.

3. Solutions and Methods

The Phase One Unit of the Winship Cancer Institute of Emory University acquired an iPad enabled with Video Remote Interpretation (VRI) which combines the benefits of face-to-face interpretation with the on-demand nature of Over-the-Phone Interpretation (OPI). With Stratus Video, there is now access to medically qualified interpreters with an average connection time of 30 seconds. There are 35 languages available over video, and Over-the-Phone Interpretation (OPI) service that is fully integrated with the Stratus Video solution in over 200 languages.

4. Outcomes

The translation iPad has allowed a reliable, easy to access way to provide language services to patients enrolled on clinical trials and allows for accurate reporting to be maintained in the patient's chart to ensure compliance. Clinicians and patients who have used it indicate ease of use, short wait time to be connected with interpreter, friendly and professional service, good quality of audio and video, and a large variety of languages available. Spanish and Korean have been the most used languages thus far.

It can be challenging to schedule an in-person interpreter for less commonly spoken languages within the protocol required appointment dates. The iPad has eliminated that barrier for all encounters after consent has been obtained with a live interpreter. It also automatically keeps a detailed log of all the sessions and provides interpreter information that is used for consistent documentation congruent with clinical trials expectations.

5. Lessons Learned

In the future, VRI could also be used to remotely obtain consent for tissue collection, and for remote check-ins to ensure proper communication of changes in clinical status for patients enrolled in clinical trials living in areas with low access to care and resources.

Using Video Remote Interpretation to Overcome Language Barriers with Non-English Speakers in Clinical Trials

Claudia Garcia, RN, BSN, BMTCN; John Bourgeois MMHC, BSN, RN, OCN, CCRP; R. Donald Harvey, PharmD, BCOP, FCCP FHOPA; Colleen Lewis, MSN, ANP-BC, AOCNP
Winship Cancer Institute of Emory University

Background

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Lessons Learned:

In the future, VRI could also be used to remotely obtain consent for tissue collection, and for remote check-ins to ensure proper communication of changes in clinical status for patients enrolled in clinical trials living in areas with low access to care and resources.

References

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Solutions and Methods

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Winship Clinical Trials Office CAPA Review Process – CAPA Review Team

P. Bourbo, C. Sharp, K. Nguyen, T. Kurilo, M. Hananel

Winship Cancer Institute of Emory University

1. Background

The Corrective and Preventative Action (CAPA) Review Team was originally developed in March 2018. The Winship Clinical Trials Office (CTO) needed a method to assess the design, implementation and effectiveness of CAPAs developed to address significant deviations and non-compliance in the conduct of cancer-related treatment clinical trials.

2. Goals

- Review all CAPAs to ensure they are appropriate, feasible and realistic
- Identify trends in deviation reporting
- Increase number of CAPAs successfully closed

3. Solutions and Methods

The CAPA Review Team is designed to ensure that CAPAs are appropriately developed based on a root cause analysis for significant findings, defined as deviations that require reporting to the IRB, other regulatory bodies, or sponsor.

The CAPA Review Team reviews CAPAs for all significant deviations occurring in interventional treatment trials including pharmaceutical, investigator-initiated, and NCTN trials. The scope also encompasses the review of trends in deviation reporting.

There are two levels of review: Significant deviations and less serious deviations.

Significant deviations that impact subject rights, safety, or welfare include, but are not limited to, consent process errors, eligibility process errors, drug dosing errors, missed safety labs, poor data quality, lapse in IRB approval, and other major deviations. Significant deviations may also include deviations that affect the integrity of the research data and the subject's willingness to continue participation on the study.

Significant protocol deviations are submitted and reviewed at the regularly scheduled CAPA Review Team meetings. The full review and any recommendations are captured in the meeting minutes.

Less serious deviations are reviewed by the team quarterly to track for trends in deviation reporting. The review and approval is presented quarterly at CAPA Review Team meetings.

4. Outcomes

In response to a recent NCI audit, Winship CTO created two CAPAs which focused on pharmacy orders to identify missing safety and protocol-specific laboratory values, as well as a pregnancy test audit to evaluate for testing compliance.

A recent FDA audit resulted in a classification of No Action Indicated (NAI) with a special mention from the auditor of Winship CTO lab compliance. The CAPA Review Team believes that this success can be attributed to effective CAPA development and implementation.

5. Lessons Learned

- Additional training is required on CAPA creation and root cause analysis.
- Once a CAPA is implemented, an assessment needs to be performed to determine the effectiveness of the CAPA. If not effective, a revision to the CAPA may be necessary.
- CAPAs need deadlines to ascertain if they can be closed out.
- The deviation reporting and assessment process needs to be streamlined. The team is currently investigating IT solutions.



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Comprehensive Cancer Center

Clinical Trials Office

Winship Clinical Trials Office CAPA Review Process

CAPA Review Team

Pam Bourbo, Michal Hananel, Tatiana Kurilo, Kim Nguyen, Cathy Sharp

Purpose

To assess the design, implementation and effectiveness of corrective and preventative action plans (CAPA) developed to address significant deviations and non-compliance in the conduct of cancer-related treatment clinical trials by Winship faculty. The CAPA Review Team performs assessments of CAPA plans to ensure the CAPA is appropriate, feasible and realistic and monitor CAPA implementation and effectiveness.

Scope

The CAPA Review Team is designed to ensure that the CAPA is appropriately developed based on a root cause analysis for significant findings, defined as deviations that require reporting to the IRB, other regulatory bodies or sponsor.

Objectives

The CAPA Review Team reviews the CAPA for all deviations occurring in treatment interventional trials including pharmaceutical, investigator-initiated and NCTN trials. The scope also encompasses the review of major deviations for major audits and inspections, and minor deviations where trends are seen. The focus is to provide the PI a review of a CAPA before the final version is submitted to a reviewing authority, including the IRB, sponsors or other external reviewers.

CAPA Tracking

CAPAs are tracked on a shared spreadsheet, and reviewed periodically to verify they are followed and determine when they can be closed.

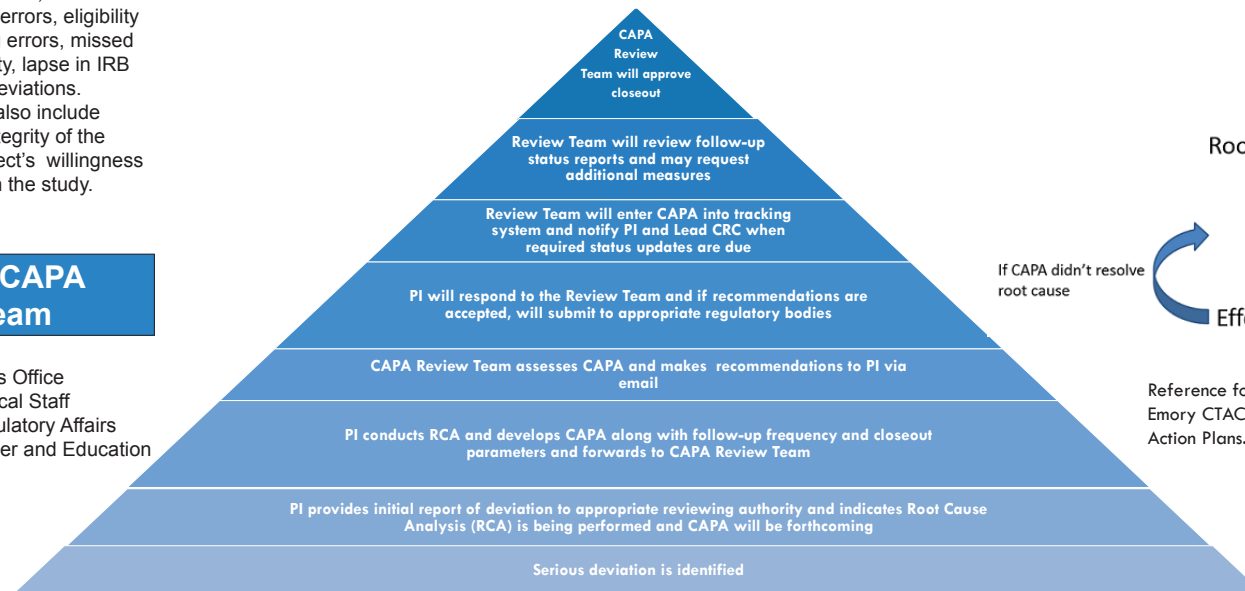
Deviations Review

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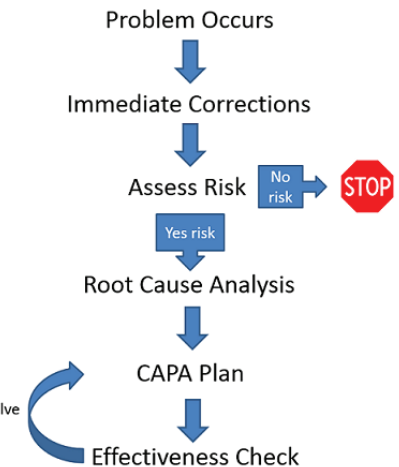
Members of CAPA Review Team

Director of the Clinical Trials Office
Assistant Directors for Clinical Staff
Assistant Directors for Regulatory Affairs
Manager for Quality Manager and Education
Manager for DSMC

CAPA Review Process



If CAPA didn't resolve root cause



Reference for RCA diagram.
Emory CTAC. (2020). Corrective and Preventive Action Plans. Emory University.

Metropolitan Management of Mitten-wide Clinical Trials: Coordination From Our Own Backyard

J. Ventimiglia, E. Doppel, B. Olsen

Barbara Ann Karmanos Cancer Institute, Wayne State University

1. Background

Karmanos Cancer Institute (KCI) merged with McLaren Healthcare Corporation to become Michigan's largest cancer care and research network aiming to increase access to transformative cancer care in communities throughout the state. The KCI Clinical Trials Office (CTO), based in Detroit, was tasked with developing and standardizing policies and procedures for conducting research across the subsidiaries, including patient enrollment, study coordination, and data management. To streamline training and operations, we developed a central data management (CDM) plan.

2. Goals

- Increase feasibility of clinical trial operations across the state
- Implement the research nurse role at each subsidiary to improve protocol compliance and data quality, based on KCI-Detroit model
- Centralize study coordination and data management to ensure data integrity across all sites and studies
- Expand the reach and responsibilities of CTO staff to ensure efficient utilization of current resources
- Facilitate the increase in industry, cooperative group, and investigator-initiated trial accruals

3. Solutions and Methods

- Constructed a comprehensive, step-by-step guide to CDM tasks (e.g., consenting process, patient eligibility, protocol deviations, serious adverse events, etc.)
- Developed process document to differentiate between the responsibilities of the research nurse at each network site and study coordinator at KCI-Detroit
- Dedicated a shared drive to CDM studies to securely and expeditiously transmit study-related documents
- Added a CDM module to the CTO New Employee Orientation program, mandatory for the onboarding of all KCI research staff
- Established a collaborative focus group, consisting of KCI-Detroit study coordinators and network staff, to regularly review CDM processes and procedures, and revise accordingly

4. Outcomes

Since the integration, the CTO has seen an increase in network accruals by ~500%, while utilizing the SCs at KCI-Detroit to manage network data collection and entry. This is the foundation of CDM, which has reduced discrepancies and error in data entry, retention, and management.

With the implementation of CDM, KCI-Detroit has seen a positive outcome by way of same-day communication of patient consents and study visits at network sites; instantaneous record-sharing through the shared drive and electronic health records (EHR); and a new role for network research nurses to facilitate the onboarding of patients to clinical trials. The CDM focus group meets monthly to discuss workflows and challenges in real time. These meetings provide a forum to identify problems and collaboratively work on solutions, as well as foster open discussions to prevent barriers.

5. Lessons Learned

One of the biggest hurdles in implementing the CDM process was navigating multiple EHRs at the different network sites. As this is a common problem in healthcare in general, KCI is working toward utilizing one standardized EHR software, accessible by all staff at all sites. This will improve the continuum of care for our patients as they seek to remain within the KCI network for their care, while simultaneously expediting the efficiency of CDM by storing true source in one internally universal, safe, electronic location.

As the landscape of oncology research evolves, we will continue to ensure our practices provide outstanding support to clinical trials with the goal of improving cancer therapy and patient quality of life through research.

The Dog Ate My Pill Diary and Other Stories From the Frontlines of Drug Accountability

C. Galasso, B. Dickow, C. Houde, J. Ventimiglia, M. Ventimiglia, C. Zack, C. Zuccaro

Barbara Ann Karmanos Cancer Institute, Wayne State University

1. Background

Karmanos Cancer Institute is an NCI-Designated Comprehensive Cancer Center and a Quality Oncology Practice Initiative (QOPI) certified site. In preparation for our QOPI re-certification we recognized we could apply those standards to enhance documentation and communication of drug accountability for our research patients. There was a need for more robust, real-time documentation of drug compliance that could be standard for all clinical trial patients. We created and implemented the Management of Oral Investigational Drug (OID) policy, workflow, and nursing documentation aid that met the needs of the hospital requirements and research standards. This included compliance, patient education, return visit instructions, clinic contact, and specific dosing instructions.

2. Goals

Primary goals in order to meet QOPI standards and research objectives:

- Monitor patient adherence to OID administered outside of the health care setting at clinically meaningful intervals
- Ensure documentation of dosing, education, and compliance is available in the electronic health record (EHR)
- Standardization of OID accountability across all Multidisciplinary Team (MDT) services
- Address and limit discrepancies between OID dispensed and OID returned to improve data accuracy

3. Solutions and Methods

Methods:

- Developed a working group consisting of Research Nurses (RN) and Study Coordinators (SC) to ensure the process met all needs
- Institutional standards, QOPI, and research requirements were utilized when creating the policy and workflow
- Accountability is performed at every study visit, uploaded in the EHR using the nursing documentation aid, and is completed independent of sponsor requirements
- Standardized pill diary templates were created for use when not provided by the sponsor
- New process was piloted for one month (approximately 100 patient visits) to identify potential issues
- Process was amended based on pilot experience, finalized, and formally implemented across all MDTs

4. Outcomes

Standardizing this process among patients receiving OID has created a notable positive effect on the patient experience, compliance, data quality, and documentation. This policy and workflow guide the RN in a conversation with the patient and clinician to review compliance and enhance patient safety. It enables the RN to clarify discrepancies between the diary and pill count and identify patient dosing errors contemporaneously. OID dosing is documented more frequently and enables timely data entry and query resolution. The development of the OID policy, workflow, and nursing documentation aid ensures consistency across all MDTs. Availability of the documentation in the EHR improves communication among all clinical and research staff.

5. Lessons Learned

We have observed an improvement in patient compliance and expectation when patients are mindful that their dosing will be reviewed at every study visit. In turn, patients are empowered to become active participants in their own care. This frequent interaction has strengthened the rapport between patient and staff. The future direction of our institution is to utilize a comprehensive electronic medical record (EMR). This process can be easily modified and incorporated into the EMR.

We may not be able to stop the dog from eating the pill diary, but this process has provided us with documentation of compliance that we otherwise would not have.

Improving Staff Engagement and Retention Through a Staff Engagement Committee and Subsequent Collaboration Between Staff and Management

A. Toth, K. Grimaldi, C. Light, N. Ross, S. Zamora, D. Cohen, E. Love

Laura and Isaac Perlmutter Cancer Center at NYU Langone

1. Background

The Clinical Trials Office (CTO) at New York University's Perlmutter Cancer Center recognizes the importance of staff retention and engagement to patient safety and successful operation of oncology clinical trials. In response to turnover of staff in the Clinical Coordination Unit (CCU) a survey of CCU staff was performed. The Staff Feedback Survey (SFS) showed room for improvement in key areas that impact staff retention and engagement.

2. Goals

The SFS sampled 29 of 29 CCU Staff. 20 CRNs, 8 CRCs, and 1 RA.

Survey Results related to retention and engagement:

In your current role do you feel supported?

Yes: 69% No: 31%

In your current role at the CTO do you feel valued?

Yes: 44.8% No: 55.2%

Do you have enough time during your work day/week to get everything that is required of you done?

Yes: 44.8% No: 55.2%

In your experience is your personal professional growth supported at the CTO?

Yes: 65.4% No: 34.6%

3. Solutions and Methods

A Staff Engagement Committee (SEC) was formed with members from both the CCU and senior management. The SEC carries out initiatives that address four key areas for improvement: engagement with leadership, staffing adequacy, teamwork expertise, and advancement opportunities.

4. Outcomes

A repeat of the SFS is planned for one year following SEC creation to measure initiative impact.

Selected initiatives:

Advancement: CCU staff collaborated with management to create a new clinical job ladder with three levels of CRN and three levels of CRC to improve career advancement opportunities and retention of experienced staff.

Staff Appreciation: We surveyed staff to collect feedback for an event that staff would enjoy and that would provide an opportunity to bring staff and management together outside of their normal daily routines. This culminated in a staff appreciation event with high levels of participation from CCU staff and management.

CCU Orientation and Standard Operating Procedures (SOPs): Feedback from CCU staff was incorporated into a standardized orientation program to improve the onboarding process for all staff and to ensure excellence across all groups. Standardization based on staff feedback addressed staffing adequacy through adoption of streamlined processes. SOPs that acknowledge current workflows and ensure patient safety were implemented with staff input.

CCU Support and Mentoring: A work group is tasked with the creation of additional support networks among staff members. The working group is in the process of creating a CCU buddy/mentor program that partners junior staff with more senior staff to help build an additional support network that supplements and complements those already available to employees through their managers and official channels.

5. Lessons Learned

Initial responses from staff have been positive and a large proportion of staff are involved with the SEC. The Committee has identified a need to be mindful to include new staff as the CCU grows in order to ensure that the SEC remains representative of all CCU staff. The SEC continuously elicits feedback from current CCU staff through regular meetings and feedback, in conjunction with the planned repetition of the SFS, will determine future SEC initiatives.

Optimizing Clinical Trial Conduct for CAR T Therapies Improves Trial Efficiency

J. Bruggeman, G. Bouska, K. Croghan, C. Grimont, M. Burt, C. DuBois, Y. Lin

Mayo Clinic Cancer Center

1. Background

There is exponential growth in clinical trials investigating chimeric antigen receptor (CAR) T-cell therapy to treat cancer in the recent years. At Mayo Clinic, the number of trials has grown six-fold over the last 4 years with more on the way. CAR T trials have complexities not traditionally found with other pharmaceutical protocols due to the multi-disciplinary teams involved with the individualized manufacturing of CAR T cells, the highly specialized expertise for clinical management, and complex data reporting.

2. Goals

We created a CAR T clinical trial standardized operation process (SOP) with the intent of improving efficiency in the trial conduct and improving the overall experience for the study team and clinical providers. We examined CAR T trial cases prior to 2019 in order to identify areas of need for a CAR T trial SOP, and implemented the practice in January of 2019. Our goals were to reduce deviations and data reporting delays, as well as increase provider and sponsor satisfaction during the time period of January 2019 to July 2019.

3. Solutions and Methods

We examined trial requirements including data reporting time constraints and monitoring visits, and inspected trial outcomes such as coordinator efforts for each stage of the trial conduct, the number of deviations, and effort spent clearing queries. We interviewed study monitors, sponsors, and clinical providers regarding challenges for efficient patient care and study conducts. In our assessment, we identified challenges in these common areas: scheduling logistics, meeting study specific requirement in addition to complex standard of care practice, and complex data entry. We worked with the CAR T program medical director, clinical lab personnel, and providers to develop an SOP for CAR T trial conduct. This SOP documents the expectations and responsibilities of the different roles in CAR T trial conduct. Contracts have been updated to allow more monitors per visit, increased number of visits, and additional monitor rooms at our site. In order to continually advance the practice, touch point meetings with key members of the inpatient clinical staff are scheduled monthly.

4. Outcomes

Deviations per accrual decreased from 2.24 for CAR T trials prior to 2019 to 0.857 after implementation in January 2019 ($p = 0.031$). The data entry efficiency improved along with query responses, and we are able to more effectively stay on schedule for task completion. Better reporting outcomes led to an increase in the sponsor and monitor satisfaction. Providers reported an increase in satisfaction due to improved communication among the inpatient and outpatient clinical staff, as well as the reduction in repetitive communication amongst the care team.

5. Lessons Learned

Despite the novel complexities involved with CAR T, we discovered ways to standardize the approach and improve trial efficiency. The standardization of communication practices and continual meetings with all involved departments proved to be necessary for the success of a CAR T trial. Lessons learned from this practice can be extended to other trials with complex processes. The SOP, in fact, is being implemented at our institution to other trials requiring coordinated inpatient and outpatient care and serves as the groundwork for new complex trial development in the immunotherapy space.

Clinical Research Strategic Partnerships (CRSP) Program Initiatives and Future Goals

S. Salvati, S. Yoon

Memorial Sloan Kettering Cancer Center

1. Background

The Clinical Research Strategic Partnership Program mission is to expand access to clinical trials and cutting-edge cancer research, raising standards of care at community-based hospitals and academic centers. To address programmatic needs and ensure protocol compliance, two initiatives were implemented in May 2019.

The first initiative restructured the team. The initial structure could not maintain increased numbers of sites and protocols. Furthermore, as the number and complexity of protocols increased, roles focused on protocol start-up, operations, and quality assurance were created.

The second initiative ensures compliance by confirming site protocol capabilities. We ensure sites have the target population and resources needed to conduct protocols. Previously, the protocol review was not standardized, leading to gaps in resources and capabilities.

2. Goals

The initiative's goals were to provide dedicated protocol support by restructuring the team and to increase protocol compliance by conducting feasibility reviews.

3. Solutions and Methods

Until May 2019, the team consisted of two Program Managers, a Protocol Activation Manager, Research Project Manager and two Research Project Associates. The Program Managers divided the portfolio and oversaw protocol and patient management and provided monitoring. The Activation Manager oversaw start-up; the Research Project Manager conducted source verifications for site participants; and the Research Project Associates managed protocol identification and finances.

Since implementation, there are teams for each protocol phase. The Activation team manages start-up by identifying protocols of interest, gaining stakeholder approval, executing subcontracts, receiving IRB approvals and opening protocols. The Operations team oversees regulatory items and manages protocol and patient activity. The Quality Assurance team ensures program quality via source verification for participant eligibility, quarterly onsite visits, and regulatory document oversight.

Prior to May 2019, there was no formal feasibility review. Now, MSK and site leadership calls into a monthly meeting to review protocols opening in the MSK pipeline. A formal feasibility process is then conducted before sending a protocol of interest into the activation process.

4. Outcomes

The team reorganization enables our team to provide specialized guidance to the sites. Because we have staff for each space, the sites know who to reach out to with their questions. The reorganization strengthened our collaboration with the sites, decreasing the number of issues related to protocol management.

The feasibility workflow has increased the site's protocol review from the inception of protocol start-up, and we have been able to address feasibility questions prior to activating a protocol. This has led to decreased roadblocks and an increased ability to seamlessly open protocols.

5. Lessons Learned

With the reorganization, there was a learning curve. We provided information sessions and distribute resources to sites. The sites also restructured their programs to support their infrastructures. The benefits of these restructures increased program success. We maintain open lines of communication to address changes.

We learned MSK Investigator Initiated Protocols oftentimes do not include instructions for external site specimen collection. This can cause a significant bottleneck in feasibility and site activation. In the future, we anticipate the development of a lab manual repository will alleviate such issues.

Creating a Culture of Continuous Improvement in a Cancer Clinical Trials Office

E. Anderson, Y. Pang, L. Craveiro, B. Hann, A. Nika
Stanford Cancer Institute

1. Background

Central cancer clinical research infrastructure is relatively nascent at Stanford with centralization initiated in 2013 through a leadership mandate. The broad organizational culture is one of autonomy through department-driven work. As this central infrastructure was separate from the departments, significant system and process development and implementation was required. Many improvement efforts were undertaken over the years, often missing elements for sustained success.

2. Goals

There is a singular, bold goal to build competency with continuous improvement and inculcate within our organizational fabric so that it is automatically instilled in all we do. Daily translation of this goal is multidimensional, including group communication and engagement through huddles, huddle boards, and structured team meetings; leader standard work through 1:1 meetings, leader rounding, and initiative oversight; and project definition, planning, execution and sustainability.

3. Solutions and Methods

Continuous improvement was deeply embraced by the Stanford Cancer Institute and Cancer Clinical Trials Office (CCTO) in 2017 and the position of Director, Strategic Initiatives for Cancer Clinical Research was created. This novel position leads the organizational culture building through training, mentoring, behavioral modeling, tool development, day-to-day management and oversight of key initiatives, and strategic goal setting. Work started with a series of foundational manager group trainings, and some managers and leaders have since incorporated the tools and practices into their daily work and projects. The adoption occurred along with expansion and elevation of our leadership structure.

4. Outcomes

Since the initiation of this work, 10 formal trainings have introduced progressively complex concepts of continuous improvement.

Daily management activities have expanded with 14% increase in groups with routine huddles and 32% increase in groups utilizing huddle boards. Manager/employee engagement has improved with 16% increase in regular 1:1 meetings, with added value of routine rounding by director-level leaders.

Continuous improvement methodology has been employed with many high-impact initiatives. Examples include improving turnaround for regulatory services by 50%, and pre-award industry study budget work by 29%. The approach is customized to support various initiatives from cross-institutional efforts such as centralized coverage analysis, to local efforts exemplified by workload management tool development and implementation. Extensive planning and communication enables smoother and more effective rollouts of these programs.

In addition, a 14% increase in satisfaction was noted among groups deeply involved with continuous improvement work in the 2019 CCTO engagement survey. Annual retention has remained stable but with 2.1% local unemployment rate, stability is positive.

5. Lessons Learned

Culture change and capacity building are non-linear and require long-term investment. Two years into this commitment, measurable and meaningful results are evident.

Dedicated expertise is critical given the time and attention required for successful implementation and continued advancement, as is relationship building. Role modeling instills in our leaders the value of respect, critical thinking, organizational empathy, and meeting people and groups where they are.

We continue the cyclical improvement journey through training, adoption, planning, and execution—repeat... keeping in mind regular reevaluation of processes and goals is required as services for our patients, researchers, and staff evolve.

New Study Feasibility: Harnessing the Power of REDCap

M. Ashland, L. Craveiro

Stanford Cancer Institute

1. Background

Stanford Cancer Clinical Trials Office (CCTO) policy required the conceptualization and feasibility of new clinical trials to be captured in a New Trial Feasibility Form. Study feasibility review is essential for illuminating and resolving the intricacies and challenges of a proposed clinical trial at a finite level. This includes identifying locations of research, services, and resources needed inside and outside the institution; funding methods; and distribution of staffing resources. If deemed feasible, trials will then move into the initiation phase. The previous New Trial Feasibility Form, in paper format, presented many operational challenges: lack of workflow for feasibility approval from managers; out-of-date questions; inaccessibility to form responses by upper management; and incompleteness of feasibility as seen by issues arising after the trial had opened.

2. Goals

Our goal is to increase transparency and communication across the institution through: (1) visibility and forecasting of required study resources; (2) the creation of a feasibility workflow with managers and research staff; (3) providing a preliminary evaluation of workload distribution, thereby creating strategic planning resources for management; (4) integration of OPAL feasibility scores into the assessment. Utilizing an electronic database will allow CCTO to easily collect and analyze study feasibility metrics including compliance, workload distributions, identify QI projects, and predict workforce needs.

3. Solutions and Methods

Launched on January 20, 2020, the web-based, PHI-secure, REDCap form and database are currently utilized by more than 20 Clinical Research Groups (CRGs) within the CCTO. Extensive review, updates and beta-testing were utilized to incorporate feedback from all entities across the institution. Field entries include fill-in text boxes, single & multiple choice responses, calculated fields based on entered data, document uploads and document downloads. The feasibility form can be completed by any research staff member, and once submitted, CRG managers must review and approve study feasibility within the database side of the form. As of March 3, 2020, 14 feasibility forms have been completed institution wide.

4. Outcomes

While further data is needed, Figure 1 depicts the recent launch of the Feasibility Form in REDCap on January 20, 2020. Figure 1 show moderate amenability with the new format: 66.67% compliance in February 2020, the first full month of use. Note that compliance in January 2020 is disproportional to CCTO Intake Submissions due to the mid-month launch, however, increased compliance is anticipated as 2020 continues.

5. Lessons Learned

At the one-year benchmark, future analysis of the feasibility form submissions will include: (1) evaluation the preliminary versus actualized OPAL scores, which would allow the identification of significant differences in initial feasibility with accruing study protocol requirements, illuminating discrepancies and areas of focus to resolve; (2) investigating if the type of staff, PI Credentials, or CRG who completes feasibility forms for new studies associates with larger differences in initial versus final OPAL scores, thus showing areas of QI improvement; (3) analyses with other significant variables, e.g. time to complete feasibility, type of patient population being targeted with new studies, type(s) of proposed trials (Phase I – III, Industry vs. Investigator-Initiated), physical locations of research within the institution and issues therein, and trial funding diversity.

Connecting the Clinical Research Supply Chain – Part Two

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¹The University of Kansas Cancer Center; ²nCoup Inc.

1. Background

There is considerable redundant work being performed today at both cancer centers and trials sponsors as a result of a lack of systems and data integration both within cancer centers and their related hospital Electronic Medical Record systems and Clinical Trial Management Systems as well as between cancer centers and trial sponsors. In a 2019 AACI-CRI Poster Session, we described a project in which we were able to reduce the time required for trial data collection by approximately 50% on three studies piloted by pulling data directly from the source medical record system into the electronic data capture (EDC) system. In this follow-up poster session, we will drill down on specific aspects of data collection where time and costs savings are achieved; the types of visits and studies that can particularly benefit; benefits related to facilitating access to unstructured data in the EMR; and other benefits such as easier source data verification and reduced data queries.

2. Goals

The key metrics we will focus on are a) time and cost savings by visit type, b) differences across study types (e.g. Phase I, II, and III), and c) other benefits in such areas as reduced queries.

3. Solutions and Methods

KUCC implemented a clinical trial fulfillment solution that integrates EMR data, its local clinical trial management system and related operations, and a sponsor's EDC system. The solution automates multiple aspects of clinical trial operations for study teams at the site; then leverages EMR data to populate case report forms directly into our local clinical research management system; then in turn electronically push the case report form data directly into the sponsor's EDC system.

4. Outcomes

The major finding of the project is multiple hours of time savings for study coordinators to complete study data requirements on patient visits in this sponsor-funded proof of concept. For each study tested, the time savings was significant. For one study, the average time savings for one screening visit was about four hours. The time savings for other recurring visits was about two hours per patient per visit. In addition, there were fewer queries and improved capabilities for source data verification.

5. Lessons Learned

The lesson learned is that significant time savings can be achieved through integration of EMRs, local clinical trial management systems, and sponsor EDC systems. The future direction, now that the proof and concept is complete, is to scale the solution and bring in other cancer center and study sponsors collaborators to both improve and benefit from the solution.

Piloting a “Just-in-Time” Model to Improve Efficiency and Accuracy in Phase I Clinical Trials Pharmacy Order Creation Process

E. Judson-Barton, M. Williams, C. Belmore

Winship Cancer Institute of Emory University

1. Background

Safe care delivery, accurate data collection, and efficient order creation is essential to the success of clinical trials. Research protocols provide the guidelines necessary to implement the schedules of events and drug administration. It is up to the participating institution to translate those requirements into an effective pharmacy order(s) and a data collection document(s). Prior to 2014, the process of order creation was pharmacist and primary investigator (PI) driven. Often, order creation was delayed due to pharmacist workload, preventing timely study enrollment for potential patients. In January 2014, a systematic and multidisciplinary approach to creation and implementation of research orders was conceived in the form of the research order committee. Clinical trials infusion nurses collaborated with clinical research coordinators to create the tables that outline patient care tasks and data collection time points as specified in the research protocols.

In 2016, to further refine the order creation process and increase efficiency of document completion, the research pharmacy order was split into two working documents: pharmacy order and nursing considerations. This substantially improved formatting and provided additional space for pertinent nursing care guidelines. With the new process in place, the time from Scientific Review Committee approval and committee notification to first draft creation decreased by 18 days (54%) and total time required for order completion and approval decreased by 52 days (55%) in 2017.

2. Goals

However, as committee participation increased and workflow efficiency improved, a new challenge emerged. The backlog of orders that had once existed was eliminated but protocol assignments were now completed months in advance of SIVs study opening and patient enrollments to treatment (averaging 7.6 months). Often multiple amendments and/or changes to phases or cohorts would go into effect prior to document utilization, requiring multiple edits before patient enrollment. This increased the challenges faced with Phase I studies that often require documents for multiple cohort and as a result several unnecessary documents are often created and never utilized.

3. Solutions and Methods

Due to these challenges, a “just-in-time” model was proposed as the new work flow model for research order creation. The collaborative team, plans to adjust the deadlines for pharmacy order creation to be completed two weeks from the SIV. The goal is pharmacy orders will be completed in this time frame with nursing considerations completed once a patient has been identified. The intention of this timeline is to ensure that the most accurate documents are created from the most current protocol versions and sponsor information. The goal being to reduce the number of order sets that need revision while reducing the need for repetitive review/approval by the PI.

4. Outcomes

The Phase I team at Winship Cancer Institute of Emory University is currently piloting the “just-in-time” model for several of our multi-cohort studies. We began this process by first focusing on two of our programs’ more complex trials. These trials include multiple cohorts with various dosing schedules.

5. Lessons Learned

This process is allowing us to test out our efficiency and accuracy as we move to generate orders with potential patient identification as the trigger.



FINANCE / CCSG / PRMS

Capturing Metrics for the First Stage of Protocol Review at a Consortium Cancer Center

K. Hoy¹, A. Firstencel¹, H.J. Pounardjian¹, J. Chan¹, K. Jenkins², L. Mooney², M. Kilbane²

¹Case Comprehensive Cancer Center; ²Cleveland Clinic Cancer Center

1. Background

In November of 2019 new CCSG P30 guidelines were published. These guidelines changed the reporting requirements for the PRMS for the first time in over 10 years. The FOA delineated two stages of protocol review; the first stage is at the disease team/hospital level and the second stage is at the PRMC level. Though the first stage of review was happening before the most recent FOA, the formal documentation of this process is novel.

Cleveland Clinic implemented formal, first stage, disease-focused scientific review through a feasibility process with an approved Standard Operating Procedure (SOP) on October 15, 2009. University Hospitals implemented formal, first stage disease-focused scientific review through a feasibility process with an approved Standard Operating Procedure (SOP) on January 8, 2018. The lead, non-clinical research coordinator (RC) distributes the protocol and associated documents to the entire research team, inclusive of research nurses (RN) and non-licensed clinical coordinators (CRCs and CRAs), pharmacy personnel, additional non-clinical research coordinators (RC), all disease team physicians, and financial analysts, at least 2 weeks prior to the regular Disease Oriented Group (DOG) meeting in which first review will occur. At the DOG meeting the PI presents the trial and physicians each have time to comment on the scientific merit and viability of the trial. In addition, all team members have time and are expected to discuss any issues discovered. The Program Leader then has authority to approve or deny opening the clinical trial. Implemented in 2019, team members are expected to have identified the issues, reported them to the lead RCs, and developed solutions as appropriate before the meeting. The meeting then consists of discussion about both issues and solutions and decisions on whether it is feasible or not to open the study. Many of the teams have implemented PowerPoint presentations of the potential trials to support the discussion of feasibility.

2. Goals

- What percentage of trials are rejected at each stage of the process?
- How effective is each stage?
- What is the best practice to capture all of the studies being offered at each consortium partner?
- Can the first stage of review be used to further joint trials?

3. Solutions and Methods

- Engaged CTUs and disease teams from both consortium partners to develop standard metrics
- Developed common timelines for data collection
- Shared best practices among consortium members to provide best practices

4. Outcomes

- Data collection is ongoing.
- Metrics will be established for each step in the process: Pre-CDA, CDA, Feasibility, Disease Group

5. Lessons Learned

- Develop standard review processes across disease teams.
- Track which trials are being offered at each site.
- Use descriptive statistics to show how selective the vetting process is for each step of the first stage of review.



Capturing Metrics for the First Stage of Protocol Review at a Consortium Cancer Center

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Background

The Case Comprehensive Cancer Center (Case CCC) is a consortium of Case Western Reserve University, The Cleveland Clinic, and University Hospitals of Cleveland. Though there is a collaborative relationship among all the consortium partners, each system has their own departmental structure, IRB, and Clinical Trial Units. The entire cancer center utilizes the same OnCore™ clinical trials database, a single PRMC, and a single Data Safety & Toxicity Committee. When the new FOA requirements were announced in November of 2019, we developed a way to capture our phase 1 review processes as it already existed in order to fulfill the new grant requirements.

In November of 2019 new CCSG P30 guidelines were published. These guidelines changed the reporting requirements for the PRMS for the first time in over 10 years. The FOA delineated two phases of protocol review, the first phase is at the disease team/hospital level and the second stage is at the PRMC level. Though the first stage of review was happening before the most recent FOA, the formal documentation of this process is novel.

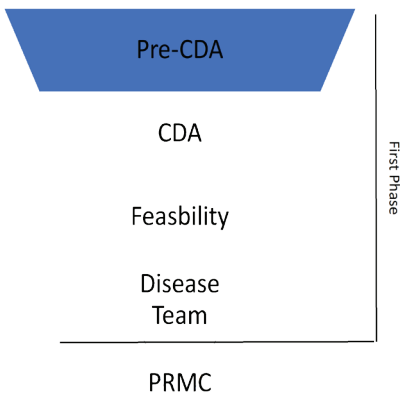
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Feasibility

The lead, non-clinical research coordinator (RC) distributes the protocol and associated documents to the entire research team, inclusive of research nurses (RN) and non-licensed clinical coordinators (CRCs and CRAs), pharmacy personnel, additional non-clinical research coordinators (RC), all disease team physicians, and financial analysts, at least 2 weeks prior to the regular Disease Oriented Group (DOG) meeting in which first review will occur. At the DOG meeting the PI presents the trial and physicians each have time to comment on the scientific merit and viability of the trial. In addition, all team members have time and are expected to discuss any issues discovered. The Program Leader then has authority to approve or deny opening the clinical trial. Implemented in 2019, team members are expected to have identified the issues, reported them to the lead RCs and developed solutions as appropriate before the meeting. The meeting then consists of discussion about both issues and solutions and decisions on whether it is feasible or not to open the study. Many of the teams have implemented PowerPoint presentations of the potential trials to support the discussion of feasibility.

Phase 1 Review

Figure 1. This depicts a graphical representation of the phase 1 review process. This shows how the largest number of studies are rejected prior to PRMC review.



Pre-CDA and CDA Process

During regular disease team research meetings, all MDs present are asked to recount how many trials they personally rejected since the last meeting (meetings are typically every 2 weeks). These are trials that based on the title or concept alone, the MDs have no interest in learning more about. Results are tallied and recorded in meeting minutes. Brief email surveys are also periodically asked of the program leaders to confirm the % of trials rejected pre-CDA across their disease team.

If an MD is interested in pursuing a CDA and receiving a protocol, they will ask the research contract analyst to process the CDA. The contract analyst meticulously tracks these details for every disease team. Information such as PI, sponsor and dates of processing are entered onto a spreadsheet and are tracked at the research disease team level and at a macro level.

Data for 2020

Table 1. 2020 up-to-date rejection rates for each disease team at one of our consortium partners. The highest rejection rate is at the disease team

DOG	MD rejection pre-CDA	Rejection at Disease Team	Rejection at Feasibility
Brain	0%	36%	0%
Breast	0%	0%	0%
GI	11%	0%	0%
GU	17%	0%	0%
GYN	0%	20%	10%
H&N	0%	25%	0%
Heme	4%	20%	0%
Melanoma	0%	25%	0%
Peds	0%	0%	0%
Sarcoma	0%	0%	0%
Phase 1	0%	13%	0%
Thoracic	4%	18%	0%
Average	3%	13%	>1%

DOG	MD rejection pre-CDA	MD rejection at CDA	Rejection at Feasibility
Phase 1	7%	10%	0%
GI	20%	13%	33%
Lung	33%	20%	0%
Breast	10%	17%	0%
RadOnc	10%	0%	0%
Melanoma	10%	0%	0%
GU	45%	60%	0%
H&N	55%	100%	0%
Phase 1	7%	10%	0%
GI	20%	13%	33%
Lung	33%	20%	0%
Breast	10%	17%	0%
BMT	45%	0%	0%
Lymphoma	62%	50%	0%
Leukemia	40%	11%	21%
MM	50%	25%	0%
Benign Heme	30%	0%	0%
BTI	10%	28%	0%
Average	31%	24%	4%

Table 2. 2020 up-to-date rejection rates for each disease team at one of our consortium partners. The highest rejection rate is at the CDA review by the investigating physicians.

Disease Team Sign Off

In order to promote collaboration within the consortium, communication between each hospital's disease team is required prior to PRMC study submission. Lead hospital disease team sends protocols to the non-lead hospital to see if they have interest in participating in the study. For sponsored studies, the study team explains our consortium to the sponsor and ask if both hospitals can participate on the study. For IIT studies, opportunity for both hospitals to participate is discussed between the disease team and Cancer Center leadership. For National Group studies each hospital communicates to the other side that they are participating in the study and the study can be found on the CTSU.org website.

Conclusions

- Capturing phase 1 reviews of protocols can be completed using existing hospital SOPs.
- Best practices are shared amongst consortium partners even though the structures and reviews are not identical.
- Documenting all levels of review, Pre-CDA, CDA, Disease Team, and Feasibility allows for specific data points to fulfill reporting requirements.

Memorial Sloan Kettering's Protocol Review Core: A Specialized Approach to Protocol Review Committee Management

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Memorial Sloan Kettering Cancer Center

1. Background

Prior to 2018, Memorial Sloan Kettering Cancer Center's (MSK) pre- and post-activation protocol review system was fragmented. Each departmental and institutional regulatory group had independent staff and unique leadership and processes to manage their review committees. Committees were siloed with little communication between groups, causing unclear review scope and inefficiencies for both new reviews and monitoring of protocols. This was further complicated by MSK's large research portfolio with 800+ active prospective protocols and 1,200+ retrospective and biospecimen clinical research studies; 552 total protocols entered the review and activation process in 2019.

2. Goals

To improve overall institutional protocol review process, MSK's major goals were to:

- Create a specialized team to manage complex review processes throughout protocol lifecycle
- Standardize pre- and post-activation reviews while simultaneously customizing best practices based on individual committee needs
- Provide high-level customer service to enhance varied users' experiences
- Decrease Time to Activation (TTA) and Time to IRB Approval (TTIA), defined as the number of days from the first review to when a protocol is open for patient enrollment and IRB approval, respectively

3. Solutions and Methods

In 2017, the Protocol Review Core (PRC) was created to manage all non-IRB protocol reviews at MSK. This specialized team of 10 full-time employees is responsible for managing 29 departmental and institutional committees. PRC committees review new protocols, amendments, regulatory submissions, and conduct accrual and data and safety monitoring. PRC has developed best practices for protocol review and monitoring committee management which includes:

- Defined scope through committee review letters and reviewer checklists
- Standardized routine reporting of metrics to inform committees on effectiveness, progress and volume
- Active PRC participation in all aspects of protocol reviews
- Increased transparency and communication across committees
- Expanded review space to include feasibility committees for multi-site and regional site participation
- Leveraging home-grown technology for data capture and tracking to benefit the research community
- Customized review requirements and monitoring criteria, including varied review flows and flexible deadlines
- Standardized administrative approach for all protocols entering review process to provide comprehensive information for committee reviews and allow for cross coverage

4. Outcomes

PRC's integration into MSK's protocol review process has resulted in a standardized approach to protocol reviews while simultaneously increasing efficiencies and enhancing the user experience. This centralized structure has resulted in:

- PRC actively managing the review of protocols from initial review to study closure
- Decrease in institution's median TTA, TTIA, and departmental time to approval (DTTA) for all protocol types from 2017 to 2019
 - o TTA: 177 to 137
 - o TTIA: 132 to 86
 - o DTTA Industry: 32 to 17
 - o IIT: 64 to 49
 - o NCI: 37 to 22

5. Lessons Learned

Lessons Learned:

- PRC is an essential component of optimizing the protocol review process at MSK
- Customizing our approach has enhanced our engagement of previously siloed, independently managed groups
- Formalized best practices support PRC's mission in quality and efficient protocol reviews

Future Directions:

- Define/triage high priority, complicated, unique protocols
- Broaden scope of feasibility committees to capture additional groups (e.g. information technology, infection control)
- Data visualization technology
- Standard Operating Procedures to share with external groups

MSK's Protocol Review Core: A specialized approach to protocol review committee management

Sara Hanley, MSW, Jocelyn Migliacci, MA, Carly Ryan, Xhenete Lekperic, Krista Napolitano, MA, Katherine Rolla Simpson, Ann Rodavitch, MA

BACKGROUND

Prior to 2018, Memorial Sloan Kettering Cancer Center's (MSK) pre- and post-activation protocol review system was fragmented. Each departmental and institutional regulatory group had independent staff and unique leadership and processes to manage their review committees. Committees were siloed with little communication between groups, causing unclear review scope and inefficiencies for new reviews, amendment reviews and monitoring of protocols. This was further complicated by MSK's large research portfolio with 800+ active prospective protocols and 1200+ retrospective and biospecimen clinical research studies at any given year; most recently 552 total protocols entered the review & activation process in 2019. Beginning in October 2017, the Protocol Review Core (PRC) was formed within the Protocol Activation and Human Research Protection Program (HRPP) Unit to work alongside the Protocol Activation Core (PAC) and the HRPP in improving protocol monitoring, review and activation at the Center.

GOALS

- To improve the overall institutional protocol review process, PRC's major goals were to:
- Create a specialized team to manage complex review processes throughout the protocol lifecycle
 - Standardize pre- and post-activation reviews while simultaneously customizing best practices based on individual committee needs
 - Leverage technology using our homegrown Protocol Information Management System (PIMS) and external resources to increase transparency and efficiencies
 - Provide collaborative approach to protocol review and activation in order to provide high-level customer service to enhance varied collaborators' experiences
 - Decrease Time to Activation (TTA) and Time to IRB Approval (TTIA), defined as the number of days from the first review to when a protocol is open for patient enrollment and IRB approval, respectively

CHANGES IMPLEMENTED

Figure 1: PRC Oversight of Protocol Life Cycle

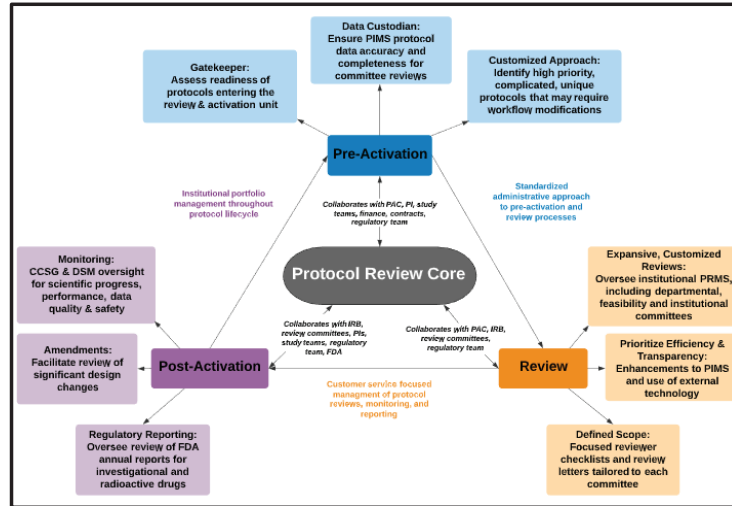


Figure 2: Protocol Activation & HRPP Unit Organization Chart

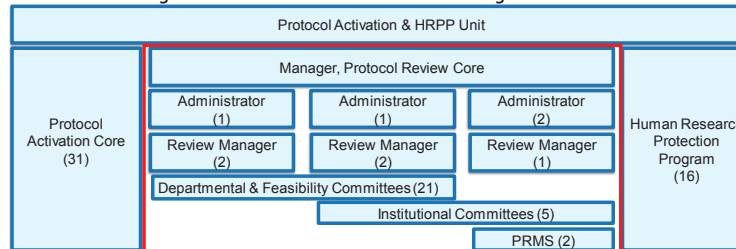
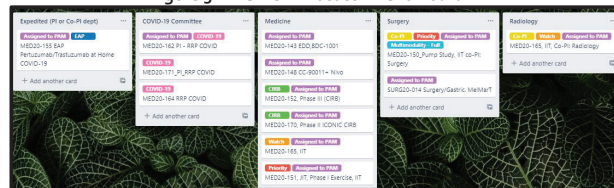


Figure 3: PRC New Protocol Trello Board



IMPACT

PRC's integration into MSK's protocol review process has resulted in a standardized approach to protocol reviews while simultaneously increasing efficiencies and enhancing user experience. This centralized structure has resulted in:

- Streamlined oversight of protocol life cycle (Figure 1)
- Collaborative culture and workflows within our unit: PRC, PAC, HRPP (Figure 2)
- PRC actively managing the review of protocols from initial submission to study closure, including 19 departmental, 2 feasibility, 5 institutional and 2 PRMS committees (Figure 2)
- Leveraging technology to define/triage high priority, complicated, and/or unique protocols to facilitate protocol review & activation (Figure 3) and to obtain electronic approvals from service chiefs (Figure 4) prior to entering the review & activation unit
- Decrease in institution's median TTA, TTIA, and Departmental Time to Approval (DTTA) for all protocol types from 2017 to 2019
 - TTA: 177 to 137
 - TTIA: 132 to 86
 - DTTA: Industry: 32 to 17, IIT: 64 to 49, NCI: 37 to 22

Figure 4: PIMS Research Protocol Submission Form (RPSF)

Designation	Department/Service	Name	Approval Date	Comments
Service Chief, Division Head	Medicine		15/10/2020	
Service Chief, Division Head	Medical Oncology/Onc		15/10/2020	
Service Chief, Division Head	Medicine/Laboratory Onc		15/10/2020	
Service Chief, Division Head	Medicine/Laboratory		15/10/2020	
Service Chief, Division Head	Surgery/Head&Neck/Oral&Max		15/10/2020	

DISCUSSION

Lessons Learned:

- PRC is an essential component of optimizing the protocol review process at MSK.
- Customizing our approach has enhanced our engagement of previously siloed, independently managed groups.
- Formalized best practices support PRC's mission in quality and efficient protocol reviews.

Future Directions:

- Broaden scope of feasibility committees to capture additional groups (e.g. information technology, infection control)
- Data visualization technology
- Standard Operating Procedures to share with external groups

Clinical Research: Following the Money

C. Golden, A. Annis, L. Hutchins, D. Drum, R. Geary, A. Smith, Z. Feng, N. Pruss

UAMS Winthrop P. Rockefeller Cancer Institute

1. Background

Prior to the development of the Clinical Research Accounting System (RAS) at UAMS, there was no consistent or efficient method to determine clinical trial revenue or expenses. Although in-depth budgets were developed for each clinical trial, there lacked streamlined accounting processes across all clinical research departments for tracking revenue or expenses. We required a system that could efficiently track invoiceable and milestone revenue while following accrued expenses for clinical trials to allow appropriate reconciliation of clinical trial expenses. We were not suitably tracking money that was owed to our institution for the services completed on the clinical trial. Lastly, we had no way to answer campus leadership financial questions without tedious and manual collation of data.

2. Goals

Our goal was to create streamlined processes for efficiently tracking billable items through robust integration with our clinical trials management system (CTMS), managing receipt of payments, facilitating fund transfers between departments, and reporting clinical trial revenue and expenses. Metrics used to evaluate milestones were: 1) revenue from invoiced procedures, 2) revenue from milestone procedures, 3) Institutional expenses posted to the clinical trials, and 4) expenses for unfunded procedures. Based on these four criteria, reports can be generated by individual clinical trial, principal investigator, disease group, clinical trial type, payee, etc.

3. Solutions and Methods

Our Information Technology Research Systems team, through in-depth collaboration with multiple teams from clinical research billing, finance, and grants accounting developed the RAS to capture financial activity associated with clinical trials. RAS is integrated with our CTMS importing completed subject-level and regulatory procedures with the contractual rate for the specific clinical trial as well as any defined milestone payment methods per the clinical trial's contract. RAS generates customizable invoices, which can be sent to the sponsor for payment and through integration with the existing UAMS enterprise finance system (SAP), allows us to track receipt of payment. Incorporation of reporting capabilities allows accurate tracking of clinical trial accounting methods to preserve financial profitability.

4. Outcomes

Since the inception of this program, we have been able to successfully track, report and post revenue and expenses for our clinical trials in an electronic system. Comprehensive integration with SAP and the CTMS reduced routine and often duplicative manual processes. We are now financially managing 220 Oncology clinical trial accounts (Industry, Cooperative, and Investigator Initiated) and have been able to adequately track revenue and report expenses related to clinical trials.

5. Lessons Learned

Phase 1 of this project has been implemented and we have made great strides in capturing our expenses, revenue gain as contractually obligated, and report clinical trial financials to leadership. Enhancements are ongoing and additional features will be implemented as we progress forward.



Clinical Research: Following the Money

Chris Golden, MS, CCRP¹, Laura Hutchins, MD¹, Alexandra Annis, BA, CCRP¹, Dylan Drum, MA¹,
 Ronni Geary, MBA, CCRP¹, Angela Smith, MS, PMP², Zhidan Feng, MS², Nicholas Pruss, BS²,
¹Cancer Clinical Trials and Regulatory Affairs, Winthrop P. Rockefeller Cancer Institute
²IT Research Systems, University of Arkansas for Medical Sciences, Little Rock, AR

Background

Prior to the development of the Clinical Research Accounting System (RAS) at UAMS, there was no consistent or efficient method to determine clinical trial revenue or expenses. Although in-depth budgets were developed for each clinical trial, there lacked streamlined accounting processes across all clinical research departments for tracking revenue or expenses. We required a system that could efficiently track invoiceable and milestone revenue while following accrued expenses for clinical trials to allow appropriate reconciliation of clinical trial expenses. Lastly, we had no way to answer campus leadership financial questions without tedious and manual collation of data.

Metrics & Goals to be Achieved

Our goal was to create streamlined processes for efficiently tracking billable items through robust integration with our Clinical Trials Management System (CTMS), managing receipt of payments, facilitating fund transfers between departments, and reporting clinical trial revenue and expenses. Metrics used to evaluate milestones were: 1) revenue from invoiced procedures, 2) revenue from milestone procedures, 3) Institutional expenses posted to the clinical trials, and 4) unfunded procedures. Based on these four metrics, reports can be generated by a number of criteria.

Methods

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

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DESCRIPTION	Date	Unit	Cost	AMOUNT
IRB Fee	XXXXXXXXXX	1	\$XXXX.XX	\$XXXX.XX
Original/Initial Submission	XXXXXXXXXX	1	\$XXXX.XX	\$XXXX.XX
Pharmacy Fee	XXXXXXXXXX	1	\$XXXX.XX	\$XXXX.XX
IRB Fee	XXXXXXXXXX	1	\$XXXX.XX	\$XXXX.XX
Pharmacy Fee	XXXXXXXXXX	1	\$XXXX.XX	\$XXXX.XX
Amendment Protocol A7	XXXXXXXXXX	1	\$XXXX.XX	\$XXXX.XX
SUB-TOTAL				\$XXXX.XX
TOTAL				\$XXXX.XX

Type	Name	ID	Study IRB	Date	SAP ID	SAP Date	Total Amount	Paid	Unreconciled	Not Paid Yet
Standard Invoice	XXXXXXXXXX	XXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX
Payment	XXXXXXXXXX	XXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX
Standard Invoice	XXXXXXXXXX	XXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX
Payment	XXXXXXXXXX	XXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX
Consolidated ID	XXXXXXXXXX	XXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX
SAP Closure/Pending ID	XXXXXXXXXX	XXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX
Partially Paid ID	XXXXXXXXXX	XXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX
Waiting for Payment ID	XXXXXXXXXX	XXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX
Draft Invoice ID	XXXXXXXXXX	XXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX	\$XXXX.XX

ID	Subject IRB#	Subject IRB ID	Activity Type	Activity Name	Contract Term	Charge Type	Payees	Epoch Segment, Cycle	Date Completed	Activity Details	To Be Invoiced	This Invoice	Not Invoiced Yet	Paid To This Invoice	YTD To Be Paid
XXX (E)			Submission	IRB Fee	1	0			XXXX-XX-XX		\$XXX.XX	\$XXX.XX	0.00	\$XXX.XX	0.00
XXX (E)			Submission	Original/Initial Submission	1	0			XXXX-XX-XX		\$XXX.XX	\$XXX.XX	0.00	\$XXX.XX	0.00
XXX (E)			Submission	Pharmacy Fee	1	0			XXXX-XX-XX		\$XXX.XX	\$XXX.XX	0.00	\$XXX.XX	0.00
XXX (E)			Annual	IRB Fee	1	0			XXXX-XX-XX		\$XXX.XX	\$XXX.XX	0.00	\$XXX.XX	0.00
XXX (E)			Annual	Pharmacy Fee	1	0			XXXX-XX-XX		\$XXX.XX	\$XXX.XX	0.00	\$XXX.XX	0.00
XXX (E)			Amendment	Amendment Protocol A7	1	0			XXXX-XX-XX		\$XXX.XX	\$XXX.XX	0.00	\$XXX.XX	0.00

Lessons Learned & Future Directions

Phase 1 of this project has been implemented and we have made great strides in capturing our expenses, revenue gain as contractually obligated, and reporting clinical trial financials to leadership. Enhancements are ongoing and additional features will be implemented as we progress forward.

Contact

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An Approach to Revitalizing PRMS Scientific Progress Reviews

S. Brogan, D. Martinez

Yale Cancer Center, Yale School of Medicine

1. Background

National Cancer Institute (NCI) Cancer Center Support Grant (CCSG) Guidelines call for a mechanism for assuring adequate internal oversight of the scientific aspects of cancer trials. The Protocol Review and Monitoring System (PRMS) has the authority to terminate protocols that do not demonstrate scientific progress. Yale Cancer Center (YCC) PRMS had a process in place whereby demonstration of scientific progress was determined based upon biannual presentations by the Disease Aligned Research Team (DART). The DART Leader presented the portfolio to the Protocol Life Cycle Subcommittee (PLCS) of the Protocol Review Committee (PRC), a component of Yale's PRMS. It was logistically challenging to coordinate the presentation of 14 DARTs biannually. As a result, DART presentations were infrequent and evaluation of protocols was primarily based upon low accrual.

2. Goals

The goal was to develop a robust process for consistent reviews of scientific progress in an expedited and structured manner while minimizing the burden on the DART Leaders and PLCS members.

3. Solutions and Methods

PLCS staff developed and implemented a revised process for scientific progress reviews. PLCS evaluates the scientific progress of interventional trials that are open to accrual or temporarily suspended at the time of IRB renewal. Trials that are not scientifically relevant or will not meet their scientific objective(s) may be recommended to the PRC for closure.

We outlined the policy and procedures for scientific progress reviews and developed submission and reviewer forms and submission instructions. We utilized the ePRMS Console of Yale School of Medicine's Clinical Trials Management System, OnCore, for submission. We generated reports within OnCore to determine which studies are due for submission. We educated and trained the research teams, PRMS members and PRMS staff on the process, communicated with key stakeholders, and announced the implementation plan.

4. Outcomes

DART portfolio reviews were presented annually in 2015-2017 despite the expectation for biannual presentation. In 2016, three of 14 DARTs did not present and in 2018, 13 DARTs did not present their portfolios, which prompted suspension of portfolio reviews in June 2018. Since October 2019 when the new process was implemented, 13 of 14 DARTs have had individual protocols reviewed.

We do not yet have sufficient data to demonstrate the impact of the process on the rate of closure due to lack of scientific progress.

5. Lessons Learned

We encountered studies where closure to accrual was imminent and a review of scientific progress was not necessary. Submitters communicate the expected closure date, provide supporting sponsor correspondence and review is waived.

We faced system limitations in the ePRMS console. Submitters cannot create another review of a different type when a review is in progress. To resolve, we withdrew the scientific progress report to allow submission of another type (i.e., an amendment), then resubmitted the scientific progress report when the other review was complete.

We have experienced delays in submission. PLCS members are determining how to handle late submissions and the appropriate action after sufficient follow-up attempts are made. We are considering using the IRB renewal report in lieu of a scientific progress report.



An Approach to Revitalizing PRMS Scientific Progress Reviews

Stephanie Brogan, CCRP and Dismayra Martinez, MHE, CCRP
Yale Comprehensive Cancer Center

Yale CANCER CENTER
A Comprehensive Cancer Center Designated by the National Cancer Institute

BACKGROUND

National Cancer Institute (NCI) Cancer Center Support Grant (CCSG) Guidelines call for a mechanism for assuring adequate internal oversight of the scientific aspects of cancer trials. The Protocol Review and Monitoring System (PRMS) has the authority to terminate protocols that do not demonstrate scientific progress. Yale Cancer Center (YCC) PRMS had a process in place whereby demonstration of scientific progress was determined based upon biannual presentations by the Disease Aligned Research Team (DART). The DART Leader presented the portfolio to the Protocol Life Cycle Subcommittee (PLCS) of the Protocol Review Committee (PRC), a component of Yale's PRMS. It was logistically challenging to coordinate the presentation of 14 DARTs biannually. As a result, DART presentations were infrequent and evaluation of protocols was primarily based upon low accrual.

AIMS

To develop a robust process for consistent reviews of scientific progress in an expedited and structured manner while minimizing the burden on the DART Leaders and PLCS members.

METHODS

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We educated and trained the research teams, PRMS members and PRMS staff on the process, communicated with key stakeholders, and announced the implementation plan.

Figure 1.

SCIENTIFIC PROGRESS REPORT FORM
Version 3.0
Page 1 of 2

DART Team: [] IRB Expiration Date: [] Submission Date: []

Instructions: Please complete this form for each open to accrual and suspended interventional trial within your DART portfolio that is due for scientific progress review. Submit form and supporting documentation within 15 business days of receipt of this request via ePRMS Continuation Review.

HC # [] Principal Investigator []

Study Title: []

1. Current Enrollment Status: []

2. Actual Months Open to Accrual: []

3. Yale Open to Enrollment Date: []

4. Percentage of Target Accrual Rate: []

See Figure 1.2 for the percentage of target accrual rate formula.

5. Percentage of Target Accrual Rate Status per Accrual Monitoring Policy for Non-Rare Trials or per Guidance for Rare Diseases and Rare Molecular Subtypes. []

See Figure 2.0 for the Accrual Monitoring Guidelines.

On above target
 Below target

6a. If accrual is below target, what strategies will be implemented to increase accrual? []

6. Does the study enroll a rare patient population or rare molecular sub-type?
Per the NCI, incidence rate \leq 6 newly diagnosed persons out of a population of 100,000 persons per year (\leq 6/100,000 per year).
 Yes
 No

SCIENTIFIC PROGRESS REPORT FORM
Version 3.0
Page 2 of 2

6a. If yes, has there been a change to the rare designation since the last scientific progress review or initial PRC review? Please explain. []

7. Has progress in the field impacted the scientific relevance of the study since the last scientific progress review / initial PRC review?
 Yes
 No

7a. If yes, how? Provide any supporting documentation from the sponsor or Biostat. []

8. Why should the study remain open to accrual? []

9. Are there competing protocols? (If yes, complete the table below for all competing protocols.)
 Yes
 No

HC #	Short Title	Date Open to Accrual	Accrual Goal	# Enrolled to Date	Expected Closure	Comments on how priority will be assigned.

Figure 2.

SCIENTIFIC PROGRESS EXPEDITED REVIEWER FORM
Version 3.0
13-Mar-2020

HC # [] Study Title: []

PLCS Reviewer: [] Date of Review: []

I. Background

1. If enrollment rate is below target, are the strategies to increase accrual realistic and expected to increase (R) or not expected (N)?
 Yes
 No
 Not applicable, study is at or above target enrollment rate

2. If the study was not previously designated as rare for rare events (per the NCI, incidence rate \leq 6 newly diagnosed persons out of a population of 100,000 persons per year), do you agree with the rare designation?
 Yes
 No
 Not applicable, rare designation has not changed

Additional comments regarding enrollment: []

II. Scientific Progress

1. Does the study demonstrate continuing scientific relevance?
 Yes
 No

Additional comments regarding scientific progress: []

III. Competing Protocols Section 104 Applicable (for competing studies)

1. If there are competing protocols, is the presentation plan adequate?
 Yes
 No

2. If there are competing protocols, does the information provided indicate the DART has the ability to enroll to all competing studies within patient populations?
 Yes
 No

Additional comments regarding competing protocols: []

IV. Reviewer's General Comments []

V. Reviewer's Determination

No further action is required
 Review at the time of the next continuing review
 Re-evaluate prior to the next continuing review
Provide timeframe for re-eval and rationale: []

Request full board PLCS review
Provide justification: []

Recommend study for closure to PRC
Provide justification: []

RESULTS

DART portfolio reviews were presented annually in 2015-2017 despite the expectation for biannual presentation. In 2016, three of 14 DARTs did not present and in 2018, 13 DARTs did not present their portfolios, which prompted suspension of portfolio reviews in Jun-2018. Since Oct-2019 when the new process was implemented, 13 of 14 DARTs have had individual protocols reviewed.

We do not yet have sufficient data to demonstrate the impact of the process on the rate of closure due to lack of scientific progress.

CONCLUSIONS

We encountered studies where closure to accrual was imminent and a review of scientific progress was not necessary. Submitters communicate the expected closure date, provide supporting sponsor correspondence and review is waived.

We faced system limitations in the ePRMS console. Submitters cannot create another review of a different type when a review is in progress. To resolve, we withdrew the scientific progress report to allow submission of another type (i.e., an amendment), then resubmitted the scientific progress report when the other review is complete.

We have experienced delays in submission. PLCS members are determining how to handle late submissions and the appropriate action after sufficient follow-up attempts are made.

We are considering using the IRB renewal report in lieu of a scientific progress report.

Building the NCI Network Program

L. Gaffney, J. Mohr, M. Warren, C. Aghajanian, P. Sabbatini, E. Cottingham, L. Deen, B. Zakrzewski, J. Klinger, S. Dominguez, C. Houston
Memorial Sloan Kettering Cancer Center

1. Background

As an NCI-Designated Comprehensive Cancer Center MSK receives funding via the Cancer Center Support Grant (CCSG). One of the expectations is to collaborate and coordinate NCI research efforts. MSK meets this expectation largely through participation in and enrollment to NCI-sponsored group studies. As part of the CCSG renewal process, we examined our NCI-sponsored group portfolio and noted there were quality concerns (i.e., audit findings), siloed physician leadership, and limited financial support.

2. Goals

As a first step, we created a central team of NCI experts to ensure the most efficient and effective regulatory management of our NCI sponsored group studies, known as the NCI Network Team. Next, we assembled the NCI Group and Grant Leaders at MSK to ensure oversight of MSK's participation in NCI studies, known as the NCI Network Committee. Together, these groups make up the NCI Network Program.

3. Solutions and Methods

We centralized the NCI subject matter experts onto a central team and made this institutional resource available to all departments that participate in NCI Group protocols. We transitioned regulatory tasks from the departments to the central team and added in QA/QC measures as these trials are not externally monitored. We've tracked our data entry and regulatory metrics in order to evaluate our intervention.

To form the NCI Network Committee, we assembled our grant and NCI group PIs in addition to identifying disease champions. We implemented a monthly meeting of Committee members to review protocols being activated by the various NCI groups and standardize ways to utilize our grants to best support departments participating in this work. The monthly meetings also serve as an opportunity to monitor accruals, grant and data metrics, and non-performing studies, and to track spending to grants and to our institution.

In an effort to address the limited financial support it was determined at the institutional level that the centralized team would be supported by grant funding received by MSK and MSK-established Institutional Cost Sharing for study expenses, i.e., financial support for the staff working on the individual clinical trials.

4. Outcomes

Our site has made improvements in data reporting timeliness. In addition, we've added a number of new NCI studies to our portfolio and are providing financial support to existing trials such that the portfolio is fully funded.

5. Lessons Learned

Together the NCI Network Team and Committee make up MSK's NCI Network Program. The Program is necessary for ensuring the focus, direction and efficient use of institutional resources.

Future plans:

- Develop REDcap database to track protocol activations and grant personnel; this should streamline grant reporting requirements
- Develop Tableau report to eliminate manual tracking of accrual information

* **Time is Money: The Impact of Clinical Research Finance Centralization**

C. Sanford, B. Zakrzewski

Memorial Sloan Kettering Cancer Center

1. Background

Compounded by the complex schedule of assessments and Medicare Coverage guidelines, the financial management of clinical trials requires qualified and trained research administrators supported by a sophisticated system, capable of tracking intricate details and producing enterprise level reports. Prior to 2017, clinical research financial management at Memorial Sloan Kettering (MSK) was performed at the department or service level without centralized resources resulting in incomplete budgets, difficult payment terms and under-recovered revenue. Data was tracked on Excel trackers and could not be easily reported.

2. Goals

Our goal was to streamline the time to budget approval measures and time spent developing an internal budget, performing a formal Medicare Coverage analysis, and negotiating external payment terms with the sponsor(s). Reducing time to budget approval is a goal of centralization that can help improve overall protocol time to activation.

Max contract value negotiated is anticipated to increase with trained Budget Analysts managing this responsibility for the entire research portfolio.

An increase in annual industrial revenue (per therapeutic accrual) is expected given a specialized Revenue Management team managing the research portfolio.

3. Solutions and Methods

In 2017, a modernized approach to clinical research operations was implemented to streamline clinical research financial activity to a centralized system and one responsible unit. A Clinical Trial Management System (CTMS) with predictive capabilities and reporting functionality was purchased for patient tracking and financial management. A phased roll-out consolidated all budget development and negotiation, Medicare Coverage Analysis and revenue management responsibilities to the Clinical Research Finance (CRF) unit.

This roll-out allowed clinical staff to focus on patient care responsibilities, while ensuring research administrative experts maintain efficient and research compliant operations. CRF initiated phased centralization of budget development and standard operating procedures were created to streamline daily operations and reduce billing compliance issues.

4. Outcomes

MSK's adoption of a centralized CRF unit and the use of CTMS has resulted in robust and accurate budgets and increased industrial revenue. A total of six departments and 46 services have been centralized.

The budget centralization processes resulted in comprehensive and defensible budgets representing a fair market value, improved negotiations with optimal payment terms while also meeting time to activation expectations. Budget development centralization incorporates research tests in compliance with Medicare and institutional guidelines via a formal Medicare Coverage Analysis process.

Improved productivity of clinical research finance centralization is evident in the ability to secure yearly increased average total budget values per contract. In 2019, a total of 386 budgets were approved, 196 of which were industry sponsored. Revenue increased consistently over the past two years, with a 27.6% increase in 2018 and an additional 14.2% increase in 2019.

5. Lessons Learned

Three-month learning curves were identified, and additional role-based trainings were created to support transitions. Data quality has impacted accounts receivable aging with ongoing efforts to improve and maintain CTMS data.

Utilizing OnCore Capabilities to Automate Annual Continuation Review Submissions to PRMC

S. Phillips

Siteman Cancer Center

1. Background

Siteman Cancer Center's Protocol Review and Monitoring Committee (PRMC) reviews all active cancer research studies on an ongoing basis by assessing progress at regular intervals. Study teams must submit their continuation review/annual documentation within the OnCore Clinical Trials Management System (CTMS), to include the Institutional Review Board (IRB) application (or proof of approval from external IRB) along with a completed PRMC Continuation Review (CR) Request Form, at the time of IRB approval of the continuing review. Missing and late annual renewal submissions represent noncompliance and can be a challenging obstacle to overcome without quality control mechanisms in place to assure ongoing capture of research activity. The Siteman PRMC Office, in collaboration with the Cancer Center Informatics (CCI) team, has employed the capabilities of the OnCore CTMS to develop new automation processes to address this challenge: creation of an auto-populated PRMC CR Request Form and distribution of automated email notifications to research teams.

2. Goals

Our goal is to streamline the submission process for annual renewals of cancer-relevant research studies, thereby decreasing submitter burden and increasing compliance of timely submissions. We will accomplish these goals by automating the completion of continuation review forms within OnCore and generating automatic email reminders for study teams when an annual renewal is due to PRMC.

3. Solutions and Methods

The Siteman PRMC and CCI teams have been developing an automated CR Form, which will mimic and replace the current manually-completed form, whereby OnCore CTMS auto-populates the majority of required information directly into the form for PRMC submission and review. To assist with improving compliance rates for annual CR submissions, we have also implemented over the past year automatic, repeated email notifications to study teams via OnCore to cue that a CR is due for submission. The automated CR Form has been pilot tested with six seasoned regulatory coordinators who routinely provide submissions via OnCore and will be rolled out to all cancer center submitters in Spring 2020.

4. Outcomes

Since implementing the CR email reminder system in early 2019, the Siteman PRMC Office experienced a 47% increase in the number of CR submissions received (number of submissions approved between January – June, 2019 = 109 and number approved between July – December, 2019 = 229).

The pilot testers have provided very positive feedback regarding the new CR Form and reminder system.

- Less time is spent by the submitters collating the information needed for a CR
- With large volumes of studies managed by each coordinator, the email reminders have greatly assisted with managing their workflows and preventing late submissions
- The reminders are reaching study teams who are not as accustomed to submitting via OnCore, thus facilitating educational opportunities for the PRMC Coordinators to train novice submitters who conduct either a minimal amount of studies or primarily non-oncology research

5. Lessons Learned

Future directions include:

- Expanding the automated process to incorporate PRMC change review/modification submissions
- Potentially automating PRMC initial study submissions via OnCore interfacing with the electronic IRB system to capture pertinent data for the PRMC application

Building the Post-award Management Infrastructure and Process Support to Reduce Turnaround Time to Collect Study Invoice(s) for Sponsor Clinical Trials

P. Chang

Stanford Cancer Institute

1. Background

Slow and delinquent sponsor payments have been a longstanding operational concern for Stanford Cancer Institute (SCI) Cancer Clinical Trials Office (CCTO). A post-award pilot program of Clinical Research Groups found the range of time from invoice(s) to payment is 180 -240 days, more than double of contractual clauses.

Payment management stress negatively affects the conduct of clinical trials by hampering appropriate staffing, employee satisfaction, and regulatory compliance, all of which impede patient recruitment and safety. It is critical to identify pain points and streamline the study payment process.

2. Goals

CCTO established a post-award pilot program of two CRGs (Breast Oncology and Urology Oncology) last year, to:

- Develop method to identify past-due account receivable invoices, follow-up timeline, and escalation process that helps verify unpaid payment
- Decrease past due payment (over 180 days) through more timely reconciliation in the first year
- Obtain dedicated financial support staff (Clinical Research Financial Specialist)

3. Solutions and Methods

For the short-term, the new method implemented below offered the best opportunity to identify past due payments in a timely manner.

- Create a master budget calendar listing all categories of billable work/items, data points demonstrating activity completion, and information from the detailed remittance notification
- Create a mechanism for flagging past due invoice(s) to provide snapshots of the outstanding money and our receivables portfolio
- Establish strong tracking (such as Sponsor/CRO Contact History Report and ongoing risk identification) to minimize risk of having a cash deficit in a sponsored project
- Develop a timeline of follow-up actions/escalation to be taken based on the number of days the payment is past due for routine collection items

We launched the new method on March 13, 2019. Baseline metrics were established for turnaround times to collect study invoice(s). Survey data was collected pre- and post- the launch to capture Principal Investigators (PIs) and CCTO Staff satisfaction with the post-award management support.

4. Outcomes

The baseline average time from invoice(s) to payment was 180 -240 days. Since implementation of the pilot program, average turnaround time to collect study invoice(s) for Urology Oncology (23 studies) and Breast Oncology (19 studies) is 48.5 days. The overall pilot PIs and CCTO Staff satisfaction with post-award management support increased by 65%.

The results demonstrated value of the pilot, and enabled us to hire a dedicated Clinical Research Financial Specialist in November 2019. This position was fully integrated into CRGs under the direction of CCTO, and serves as liaison between PIs, study team, Stanford Office of Sponsored Research, and department/division responding to sponsor inquires.

5. Lessons Learned

- Critical to listen to all parties involved to understand their perspectives and ideas, and keep the dialogue open with internal and external stakeholders
- Valuable to hold weekly huddles to review data, set goals, and solve problems

Future directions for this program include:

- Improve metrics and continue data analysis to guide future changes
- Continue to streamline post-award management workflows and further decrease turnaround time to 30 days
- Continue to perform ongoing risk identification and identify risk factors, allowing us to develop targeted intervention that may minimize the likelihood of the risk occurring

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

C. Vollmer, N. Kurtzweil, C. Allen, E. Kantemneni, T. Herzog

UC Cancer Center

1. Background

The University of Cincinnati Cancer Center (UCCC) re-examined its processes to ensure that we are improving our research and patient care, in preparation to seek NCI designation. In 2018, UCCC's Protocol Review and Monitoring Committee (PRMC), in conjunction with the Clinical Trials Office staff, reviewed and extensively revised the existing PRMC Charter to bring the processes and practices of the UCCC PRMC in line with those of other NCI-Designated Cancer Centers.

2. Goals

It was anticipated that many of the procedural changes would also promote greater efficiency within our PRMS, especially with respect to member review time per protocol and number of MD PRMS member reviewers required at each meeting.

3. Solutions and Methods

The following specific updates were made to the UCCC PRMC Charter: 1. Creating an expedited administrative review process, 2. Allowing for deferral to a single PRMS of a multi-center trial, 3. ensuring accrual review expressly defines and takes rare cancers into account, 4. Adding Data Table 4 study type definitions, 5. Defining member roles and responsibilities and 6. Clarifying the PRMC's authority to open and terminate protocols.

4. Outcomes

Turnaround time is defined as the numbers of days between submission date and approval date. Average (mean) number of days for turnaround time for previous charter was 18.45 days (SD = 8.69) whereas current charter averaged 15.42 days (SD = 12.66) (Table 1, Figs. 1 & 2). This yields a 16% decrease or ~3 days. While this is not a statistically significant difference ($W = 926.5$, $p = 0.665$) it's real added value to our physician reviewers allowing them to devote more time to patients and research.

Number of protocols discussed at each meeting was defined as ratio of total studies each month to how many studies underwent full PRMC review at meeting (see Figure 3). Average ratio between all studies to the full review for current charter is 1.90 whereas previous charter is 1.69. These are similar results as the total number of studies under review has increased under the new charter by 106%.

Figure 4 illustrates average number of reviewers/meeting has increased in new charter, explained by increase in number of protocols coming to PRMC. But Figure 5 shows more specifically that 33 of the 112 reviews under the current charter were achieved administratively, requiring no MD review. Previously, 0% of studies were administratively reviewed; 32% are now reviewed administratively. The administrative review type averages TAT of 4.42 days. This facilitates a decrease in TAT for fast track (11.22 days vs. 9.90 days). While the difference between full review type is minimal, the new changes allow more studies to be reviewed at full review.

5. Lessons Learned

Our data demonstrates, implementing the NCI's PRMS requirements resulted in a PRMC that was more efficient in terms of reviewer time and volume of studies reviewed. As we continue to obtain additional data, we anticipate increasing efficiencies to support our physicians and increased overall volume of new protocols. Driving this continued effort to better our PRMC charter is our center's goal to expand options for cancer patients and continue to pursue NCI designation.

Streamlining Feasibility Assessment Within the Scientific Review Process

A. Anderson, A. Ivey, T. Guinn, T. George

University of Florida Health Cancer Center

1. Background

The University of Florida Health Cancer Center (UFHCC) Clinical Research Office (CRO) is committed to facilitating the conduct of clinical trials that are feasible, scientifically meritorious and ethically sound. To minimize activation of trials that will poorly perform and encumber significant resources (personnel, financial, material), the CRO Feasibility Group (FG) was created. The FG review includes assessment of tumor registry and clinical records for enrollment within similar patient populations. The success of the group was seen as fewer trials have been terminated due to low accrual by the Scientific Review and Monitoring Committee (SRMC) since the group's inception.

For interventional trials utilizing CRO resources, the FG review was built into the protocol activation process. However, this review did not extend to all research groups on campus. Additionally, the FG was a separate committee with specific submission deadlines for review. To combat investigator frustrations related to delayed processing, confirm compliance with the updated CCSG guidelines and ensure comprehensive review of the UFHCC interventional trial portfolio with a focus on catchment area impact, a streamlined review was established.

2. Goals

- Minimize logistical barriers to rapid study activation;
- Standardize feasibility review across all research units to minimize study termination due to low accrual

3. Solutions and Methods

In early 2020, a combined review process was created that allowed feasibility review to be incorporated into the SRMC workflow for all interventional trials. Dynamic discussions were held between UFHCC CRO administration and SRMC leadership to map out the review process. As part of the initial SRMC review process, the feasibility review component provides non-binding recommendations, which ultimately are taken into consideration during the final SRMC determination vote. Feasibility review focuses on trial logistics and subject availability. A feasibility re-assessment is also conducted at continuation reviews for trials that do not meet local accrual targets. This review helps ensure the projected goal is reasonable based on current patient volumes and provides recommendations for recruitment resources.

The SRMC administrative team utilizes a Clinical Trials Management System (OnCore) for tracking and meets regularly to ensure all reviewer comments and reviews are received and responded to in a timely fashion. All SRMC Full Committee reviews require reviewer comments within 7 (non-IIT) to 14 (IITs) days; expedited SRMC reviews are to be received within 72 hours of submission. These expectations were initially viewed as laborious; however, with dedicated CRO staff conducting the feasibility reviews, this innovative review process has proven successful.

4. Outcomes

The collaboration resulting from these combined reviews have strengthened the interactions throughout the CRO and research teams. Ongoing discussions will continue in order to enhance the data collection and review process.

Metrics are pulled on a semi-annual basis to determine review and activation timelines related to how long it takes a trial to officially open to accrual as well as assessing subject enrollment and encompassing catchment area.

5. Lessons Learned

This innovative approach to comprehensive review is still relatively new. As the number of trials reviewed increases, a deeper dive into metrics and relationship to our research portfolios is expected to develop.





INVESTIGATOR-INITIATED TRIALS

The Sample Collection and Tracking Process for Multisite Investigator-Initiated Trials

A. Bauchle, L. Sego

Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. Background

Correlative samples are an important component of many trials. They often contribute to the trial objectives and end points used to make important scientific discoveries in oncology research. However, these samples can often be difficult to track even in a single-center trial. After samples are collected, they often change hands many times before they are analyzed and/or sent for long-term storage. The process complexity increases exponentially with the addition of each site and each processing and/or analyzing laboratory. Currently, there is not an efficient system for tracking the location of these samples at any given time for studies where Indiana University is the lead site. We rely exclusively on sites to inform us when specimens are shipped or on labs to let us know when they receive samples. FedEx tracking is used for institution-to-institution transfers however, this does not allow for internal tracking between labs on the same campus. This can leave much room for error including misplaced samples.

2. Goals

- To know the location of specimens at any given time through a centralized online system
- To avoid future deviations or decrease deviations and the number of misplaced samples by identifying lost specimens in real time, which would increase the chances of these samples being located

3. Solutions and Methods

Propose using Biospecimen Management (BSM), an application within OnCore is a web-based, Clinical Trial Management System developed by Forte, Inc. In conjunction with BSM propose using BarTender, a barcode label software, which will connect to BSM and extract data to print study-specific barcoded specimen labels. The barcodes will be scanned, using a hand-held barcode scanner, tracking all samples from collection through final storage location/analysis. At any given time, the exact location of a specimen can be viewed in BSM.

Training sites and labs on proper usage of labels and the barcode scanners will be imperative. The logging and tracking of samples within BSM will need to be reviewed on an ongoing basis as well as reaching out to the sites or labs as soon as misplaced or mishandled specimens are discovered.

4. Outcomes

While this system is currently used locally at Indiana University for a few select labs it has not been utilized in the Clinical Trials Office or in the multisite setting. This idea has just been proposed. Indiana University Clinical Trials Office is currently researching costs associated with using such a tracking system as well as advantages of using in the multisite setting. Once the equipment, which includes a barcode label printer, BarTender license, barcode labels, and barcode scanners, is purchased it can be used for multiple projects. Therefore the overall cost can be minimized when distributed among the many projects.

5. Lessons Learned

We plan to pilot this system on a single study. Once the process has been refined we can use this institution-wide and in the multisite setting. This change has the potential to make the data collected from the samples stronger, allowing the objectives and end points to be met effectively, making the analysis more accurate and the science more beneficial.



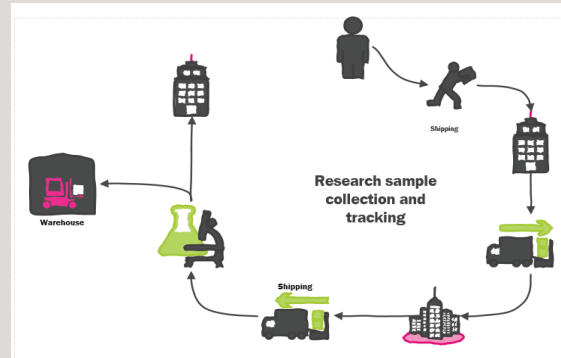
The sample collection and tracking process for multisite Investigator Initiated Trials.

Amber Bauchle BS CCRP, Lina Segó BA CCRP

Indiana University Melvin and Bren Simon Comprehensive Cancer Center

Background

Correlative samples are an important component of many trials. They often contribute to the trial objectives and end points used to make important scientific discoveries in oncology research. However, these samples can often be **difficult to track** even in a single-center trial. The process complexity increases exponentially with the addition of each site and each processing and/or analyzing laboratory. Currently, there is not an efficient system for tracking the location of these samples at any given time for studies where Indiana University is the lead site. We rely exclusively on sites to inform us when specimens are shipped or on labs to let us know when they receive samples. FedEx tracking is used for institution-to-institution transfers however, this does not allow for internal tracking between labs on the same campus. This can leave much room for error including **misplaced samples**.



Goals

- Ability to know the location of specimens at any given time through a centralized online system.
- Avoid future deviations or decrease deviations and the number of misplaced samples by identifying lost specimens in real time, which would increase the chances of these samples being located.

Solutions

- Propose using **Biospecimen Management (BSM)**, an application within OnCore™ is a web-based, Clinical Trial Management System developed by Forte, Inc. In conjunction with BSM propose using **BarTender**, a barcode label software, which will connect to BSM and extract data to print study-specific barcoded specimen labels. The barcodes will be scanned, using a hand-held barcode scanner, tracking all samples from collection through final storage location/analysis. At any given time, the exact location of a specimen can be viewed in BSM.
- **Training sites and labs on proper usage of labels and the barcode scanners.** BSM will need to be reviewed on an ongoing basis. Reaching out to the sites or labs as soon as misplaced or mishandled specimens are discovered.

Future Hopes

While this system is currently used locally at Indiana University for a few select labs it has not been utilized in the Clinical Trials Office or in the multisite setting. This idea has just been proposed. Indiana University Clinical Trials Office is currently researching costs associated with using such a tracking system as well as advantages of using in the multisite setting. Once the equipment, which includes a barcode label printer, BarTender license, barcode labels, and barcode scanners, are purchased it can be **implemented for multiple projects**. Therefore the overall cost can be minimized when distributed among the many projects.

Future directions:

We plan to pilot this system on a single study. Once the process has been refined we can use this institution-wide and in the **multisite setting**. This change has the potential to make the data collected from the samples stronger allowing the objectives and end points to be met effectively making the analysis more accurate and the science more beneficial.

Investigator-Initiated Trials – Completed Project

* Investigator-Initiated Trials in the Wild, Wild West: Implementation of the Oncology Clinical Research Support Team at the University of Colorado Cancer Center

S. Grolnic, T. Cull

University of Colorado Cancer Center

1. Background

Investigator-Initiated trial accruals lagged below targets for the CU Cancer Center and were a critique from NCI during CCSG site visit. The clinical trial office(s) did not have expertise to assist PIs in developing protocols and supporting FDA submissions. In order to improve chances of success for IITs, a central support office (Oncology Clinical Research Support Team – OCRST) was established in 2015 to provide regulatory expertise, clinical project coordination, and data monitoring for interventional investigator-initiated trials.

2. Goals

Goals of the central office included:

- Increase IIT accruals for CCSG competitive renewal
- Reduce burden to clinical trials office in managing FDA submissions and project coordination
- Develop infrastructure necessary to conduct high quality investigations including provision of clinical data monitoring

3. Solutions and Methods

IIT Incubator meeting was established to foster peer feedback for trial design and provide preliminary feedback to guide development and recommend additional preclinical studies needed. Once a concept is developed further, projects were submitted to the IIT Review Committee for approval of staff and/or funding support. Projects approved by the IIT Review Committee were provided with an OCRST project team with expertise in protocol development, regulatory, clinical project management, and clinical data monitoring. OCRST developed protocol templates and instructions for interventional- drug, non-drug interventional and chart review projects. Multicenter research project support was developed including a process to assess site qualifications and provide multicenter coordination.

The OCRST project team developed electronic case report forms using templates that can be customized for each study. Procedures were established to ensure study conduct and data quality by hiring clinical data monitors to validate data throughout the study. In addition, SOPs and guidance documents were developed to support regulatory and operational management of all IITs.

4. Outcomes

- IIT Interventional treatment trial accruals increased from 21 in FY2014 to 197 in FY2019.
- The number of IITs open to accrual has increased each year since OCRST was established. In 2016, 5 trials were opened to accrual, 10 in 2017, 14 in 2018 and 10 in 2019, with the OCRST currently managing over 30 active interventional IITs, 10 of which required INDs and 13 multisite trials
- SOP and guidance documents (n=13) for unique work of coordinating IITs, including multicenter IIT coordination and conduct. This is part of larger effort to establish SOPs governing all oncology research (N=34)
- Fee schedule for IITs that secure external funding support
- Current IIT staff include 14 FTEs (3 Managers, 2 Clinical Project Coordinators, 4 Regulatory Affairs Coordinators, 5 Clinical Research Monitors)

5. Lessons Learned

- Volume and complexity of projects much higher than was first envisioned
- IIT prioritization scoring being implemented to align approval with CC strategic plan
- Monitoring is largest resource requested/needed to ensure quality study conduct and data entry; work underway to implement risk based/targeted monitoring approach
- Protocols undergo a high number of amendments; in response, OCRST is developing a protocol review checklist to include items that may get missed in initial review processes to minimize future amendments
- Implement ForteEDC and electronic regulatory binder solution to improve efficiency and provide tools to streamline tasks



INVESTIGATOR INITIATED TRIALS IN THE WILD, WILD WEST: Implementation of the Oncology Clinical Research Support Team at the University of Colorado Cancer Center

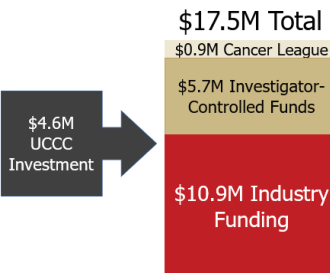
ONCOLOGY CLINICAL RESEARCH SUPPORT TEAM (OCRST)

The Oncology Clinical Research Support Team (OCRST) serves as a central resource for CU Cancer Center Consortium members.

The resources and services provided are aimed at supporting clinical research across the CU Cancer Center research enterprise.

Areas of expertise include: Investigator Initiated Trial (IIT) development and support, data quality and reporting, education and training, NCTN/LAPS trial support and Oncology Research Information Exchange Network (ORIEN).

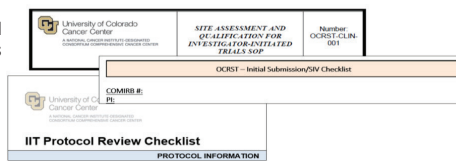
FUNDING: LEVERAGING UCCC INVESTMENT



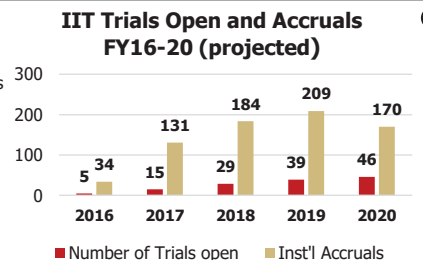
BACKGROUND: Investigator Initiated Trial (IIT) accruals lagged below targets for the CU Cancer Center and were a critique from NCI during CCSG site visit. In order to improve chances of success for IITs, a central support office (Oncology Clinical Research Support Team – OCRST) was established in 2015 to provide regulatory expertise, clinical project coordination, and data monitoring for interventional IITs.

- GOALS** of the central office included:
- Increase IIT accruals for CCSG competitive renewal
 - Reduce burden to clinical trials office in managing FDA submissions and project coordination
 - Develop infrastructure necessary to conduct high quality investigations including provision of clinical data monitoring

- METHODS:**
- Establish IIT Incubator and IIT Feasibility Review/Approval
 - OCRST team of regulatory, clinical and monitoring experts
 - IIT specific protocol templates
 - Multicenter project assessment
 - Case Report Form development
 - Clinical monitoring
 - SOP and Guidance document development

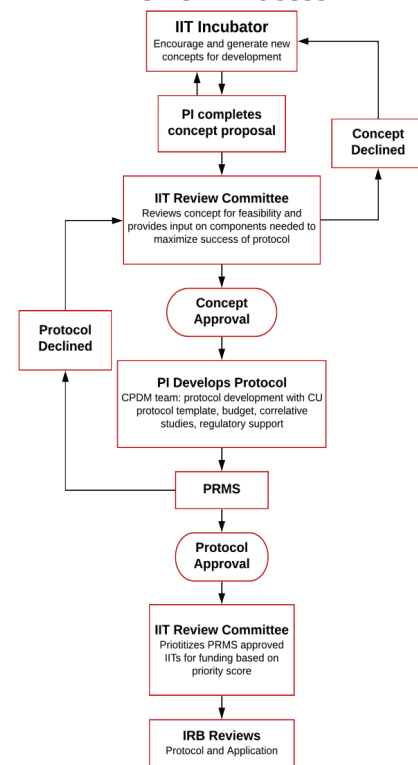


- RESULTS/CONCLUSIONS:**
- Accruals to IITs increased by 6x since 2016
 - Increase number of active trials from 5 in 2016 to 46 in 2020
 - >30 active interventional IITs; 10 with INDs; 13 multisite trials
 - Implemented IIT specific SOPs and Guidance documents
 - Increased OCRST dedicated resources from 6 FTEs in 2016 to 14 FTEs in 2020
 - Implemented fee schedule to secure revenue on externally funded projects for OCRST services
 - Leveraged UCCC funding support paired with industry and philanthropy to support IITs
 - Conducted 161 monitoring visits in CY2019



- FUTURE DIRECTIONS/LESSONS LEARNED**
- Volume and complexity of projects much higher than was first envisioned, multiple amendments
 - IIT scoring being implemented to align approval with CC strategic plan
 - Monitoring team underway to implement risk based/targeted monitoring approach for most requested resources
 - OCRST developed tools and processes to minimize amendments, enhance protocol review, interim/safety analysis, and study closeout
 - Implement electronic solutions to improve efficiency (ECRF, e-regulatory platform)

Investigator-Initiated Trials Review Process



Prevent and conquer cancer. Together.



Stimulating Investigator-Initiated Trial Development: A Comprehensive Approach to Provide Guidance, Mentorship, and Logistical Support for Principal Investigators

A. Anshu, B. Oleson, B. Brito, M. Larson, A. Szabo, K. Marquardt, E. Gore, H. Rui, J. Thomas, B. Shaw, S. Wong

Medical College of Wisconsin Cancer Center

1. Background

Academic cancer centers face many demands that necessitate accelerated development of high-quality, innovative, and well-designed investigator-initiated trials (IIT). Early career clinician scientists have many competing responsibilities that distract from the efficiency of IIT concept development. PIs have widely varying clinical trial experience, which poses an additional obstacle for efficient IIT development. In response, the MCW Cancer Center developed a comprehensive infrastructure to assist investigators in IIT development. We report here preliminary outcome metrics of this new initiative.

2. Goals

A new infrastructure was implemented with the following goals: 1) To provide direction and mentorship, particularly to junior faculty, early in the process of concept development; 2) Target two barriers in the successful opening of the IITs: a) time it takes to complete the protocol and, b) the timeline of Scientific Review Committee (SRC) review and subsequent approval; and 3) Assess the satisfaction of the investigators utilizing this infrastructure.

3. Solutions and Methods

In May 2018, the MWC Cancer Center instituted a new IIT development infrastructure directed by a steering committee. A protocol development coordinator (PDC) oversees the day-to-day operations of the committee and the development of the clinical trial project, along with the CTO team (Budget, Regulatory, and Research Manager).

Metrics of concept development, activation, and return on investment are monitored by a comprehensive REDCap-based system. A Disease Oriented Team (DOT) approved concept is submitted to the committee through REDCap and is scheduled for concept presentation. Feedback is then provided to the investigators. The PDC, along with the committee chairs, periodically reviews the status of concepts presented and acts accordingly.

4. Outcomes

As of March 2020, of 26 concepts (22 investigators) presented to the IIT Steering Committee, four are open for accrual while two have been abandoned. Of 22 investigators, 10 were junior investigators, and five senior investigators were developing an IIT for the first time. Substantial changes based on feedback that enhanced the project include scientific design change, correlative study identification, statistical changes, knowledge of funding opportunities, and recommendations for collaboration with other investigators.

Since February 2018, we completed 31 IIT protocols, while five are under development (including protocols not going through IIT Steering Committee). Protocol development was completed in a mean of 52 days (range: 10-105). This is better than the time given by pharmaceutical companies to complete an industry sponsored IIT protocol which on average is 90 days. We reduced the SRC approval timeline from 4 to 49 days (mean of 27 days). Based on the data from August 2013- May 2018, the average time it took from initial SRC review to final SRC approval varied 32 to 441 days (mean of 113 days).

5. Lessons Learned

We collected and reviewed the satisfaction of the investigators utilizing the IIT Steering Committee and our project development team. Overall satisfaction with the IIT Steering Committee was 92%, while it was 95% with the protocol development team. 93% investigators indicated that they were either extremely or moderately satisfied with the overall support provided by the cancer center.

A Risk-Based Approach to Monitoring and Auditing Multicenter Investigator-Initiated Trials

K. Muenkel, S. Hughes, J. Walkley, M. Warren, A. Granobles, F. Puma, S. Puleio, K. Yataghene, C. Houston

Memorial Sloan Kettering Cancer Center

1. Background

In 2019, the Multicenter (MCT) Office, a team within the Multi-Site Compliance Unit at Memorial Sloan Kettering (MSK), implemented the MSK Clinical Research Quality Assurance risk-based approach to monitoring and auditing multicenter therapeutic investigator initiated trials (IITs). According to the FDA, the risk-based approach ensures quality data by identifying critical data points, which are the most important study elements that need to be reviewed to assess patient safety and a trial's primary and secondary objectives. Data for open to accrual MCT IITs was monitored, while data for closed to accrual MCT IITs was audited.

2. Goals

The MCT team aims to identify the most common deficiencies found during risk-based monitoring and auditing visits for multicenter IITs, as well as the sub-categories of findings within these common deficiencies, to improve workflows and future trainings.

3. Solutions and Methods

To date, the MCT team conducted 26 remote monitoring and auditing visits (22 monitoring; 4 auditing) for 9 MCT IITs. This comprises ~20% of the multicenter portfolio with another ~50% transitioning to the risk-based approach and ~30% following the original quality assurance plan in the protocol. During these visits, critical data points for 86 patients were reviewed and 335 deficiencies were identified.

4. Outcomes

Deficiencies were most common in the following sub-categories:

- General Data Quality (~25%)
- During Study (~20%)
- Protocol Therapy Diaries (~14%)
- Study Treatment/Intervention Administration (~14%)

Deficiencies within categories of Eligibility, Toxicity, Regulatory, Baseline, Informed Consent, Treatment Modification, and Outcome/Response were found in frequencies under 10% each.

The most common deficiencies listed above were comprised of the following sub-categories of findings (Figure 1):

- General Data Quality: 58% Missing/Delinquent Data, 30% Errors in Submitted Data, and 12% Entered Data Not Supported by Source Documentation in EMR
- During Study: 36% Protocol Test Not Done, 23% Missing Source Documentation in EMR, 18% Protocol Test Done Outside of Protocol Timeline, 8% Specimen Samples Not Collected, 8% Assessment Not Done Per Protocol, 6% Documentation Incomplete/Completed Incorrectly, and 1% Wrong Test Performed
- Protocol Therapy Diaries: 56% Diary Incomplete or Completed Incorrectly, 32% Intervention Not Administered, 6% Information Recorded Not Contemporaneous, 2% Diary Missing in EMR, 2% Diary Mislabeled, 2% Corrections Not Made Per GCP

- Study Treatment/Intervention Administration: 46% Treatment Administration by Participant Missed; 25% Documentation Incomplete or Completed Incorrectly; 15% Dose Administration Not Documented, 6% Administration by Study Team Missed, 6% Unjustified Delays in Treatment, and 2% Intervention Not Administered

5. Lessons Learned

An analysis of these findings provides insights into current workflows and opportunities for improvement. The MCT team's participation in an Eligibility Verification Program, developed by MSK's CRQA team, likely decreased the number of eligibility deficiencies in 2019. No ineligible patients were enrolled and 7% of total deficiencies were administrative eligibility findings. Going forward, the MCT team will distribute monthly database reports to external participating sites to ensure data is entered in real-time and improve overall General Data Quality. The MCT team will also improve Site Initiation Teleconferences and multicenter staff trainings to focus on sub-categories of findings where the most deficiencies were identified, including frequently missed protocol tests and common pill diary errors.

Increasing Interventional Treatment IITs in the Study Start-up Pipeline With an IIT Committee Approach

N. Kurtzweil, S. Palackdharry, M. Racic, T. Wise-Draper

UC Cancer Center

1. Background

In preparation to seek NCI designation, the University of Cincinnati Cancer Center (UCCC) recognized the need to increase our volume of interventional treatment investigator initiated trials (IITs). In 2017, UCCC's Investigator Initiated Trials Committee (IITC) was formed to lower the barriers to entry for developing interventional treatment IITs for new PIs. The IITC acts as a centralized resource, providing protocol writing and feasibility support to new PIs to help make developing interventional treatment IITs achievable.

2. Goals

It was anticipated that by centralizing resources for developing IITs this would increase the number of interventional treatment IITs in our start-up pipeline, and increase the number of PIs supported by the UCCC CTO. Only interventional treatment IITs were analyzed for this project, although the IITC supports the development of non-treatment, non-interventional IITs.

3. Solutions and Methods

The NCI's protocol template was modified for institutional use and provided to PIs by the UCCC CTO staff who also coordinate monthly IITC meetings of key stakeholders (experienced physician-researchers/coordinators/statisticians/pharmacists/administrators). At the IITC the PI presents their protocol initial concept (no written protocol) or fully written protocol. The IITC sets realistic expectations around staffing, finances, and regulatory submission timelines and CTO staff facilitate protocol editing. The PRMC Charter was amended in 2019 to require IITC approval before PRMC review for interventional treatment IITs.

4. Outcomes

We focused our analysis on protocols that at least entered the start-up pipeline, rather than benchmarking against whether such protocols went on to receive IRB approval because many post-2017 IITs are still pending IRB review; and, because our goal was to establish whether IITC impacted new PI participation in IIT development. Pre-IITC data analyzed represent interventional treatment IITs that were at least submitted to PRMC. Post-IITC data analyzed represent interventional treatment IITs with at least an initial concept IITC submission. Non-Interventional/Treatment IITs, single patient INDs, and IITs where UC was a sub-site were excluded from both pre/post-IITC analysis.

After implementing centralized IITC review our data show a ~33% increase in total interventional treatment trial concepts proposed by PIs in our pipeline (from 12 to 16, Fig. 1). Although the total number of interventional treatment IITs per year remains similar to pre-IITC levels at ~4 per year (Fig. 2) we experienced engagement from a new cohort of unique PIs post-IITC (Fig. 3). Finally, because we are now tracking IITC support services in the form of informal PI requests for protocol templates and pre-IITC consults we saw an overall increase in PIs supported post IITC (Fig. 3).

5. Lessons Learned

As our data show, providing PIs with centralized resources has increased the interventional treatment IITs in our pipeline and number of unique PI's supported. We learned it is important to have: a dedicated coordinator for the IITC to project manage; PI mentors to provide candid advice; and a shared online editing platform for documentation review. In the future we will examine time to opening, if these IITs enroll patients sooner, if the number of amendments are reduced, and completion & publication metrics. We hope to engage new PIs by increasing our online availability of resources and by conducting workshops on protocol development.



REGULATORY

* Redesigning the Delegation of Authority Log for the Modern Cancer Center

J. Wurth, T. Presley, J. Feola, A. Vogt, D. Bullock, D. Berkow, E. Orcholski

Masonic Cancer Center, University of Minnesota

1. Background

For a large cancer center with blended clinical and research staff, maintaining the traditional format of delegation of authority log (DOA) has proven difficult. Obtaining signatures from 20+ staff members in a timely fashion is nearly impossible, and the need to send pages to offices all over campus inevitably leads to missing documentation. Additionally, using the varied industry sponsor templates makes it hard to capture the workflow of our local clinical research staff accurately.

FDA auditors have pointed out this issue. Nearly 20% of all monitor findings over the last two years relate to the DOA. With these things in mind, the Masonic Cancer Center Clinical Trials Office regulatory staff and management set out to reimagine the DOA to simplify the process while still documenting all pertinent information needed to conduct a study under Good Clinical Practice.

2. Goals

- Reduce time needed to obtain a completed DOA during start-up
- Reduce opportunities to misplace individual pages of the DOA
- Accurately reflect the delegations given to local staff members across studies

3. Solutions and Methods

- Only the principal investigator's signature is needed for each delegation. This satisfies our first two goals. It allows regulatory staff to obtain a complete DOA at the study initiation visit, and eliminates the need to send separate pages to individual staff members.
- All research staff completed Master Signature Log pages, which are available to all monitors and auditors via Box for handwriting comparisons.
- The delegation categories are tailored to our site, and are highly customizable to fit any type of study (e.g., therapeutic vs non-therapeutic, transplant vs chemotherapy, primary intervention vs supportive care).

4. Outcome

- Fewer monitor findings for missing pages or signatures.
- DOA can be uploaded to the research database prior to study opening for immediate study staff needs; i.e., investigational pharmacy staff verifying authorized drug prescribers.
- Study delegations are easier to comprehend, and it is easy to work with sponsors to add study-specific needs.

5. Lessons Learned

Results have been ultimately positive; however, some concerns have yet to be addressed, including:

- How do individual staff members know they have been delegated to work on the study if they do not sign the DOA?
- Differences between delegated start date and initial protocol training date.
- Balancing industry sponsors' desire for consistency between sites vs. MCC CTO's unique challenges.

MCC CTO will transition to an electronic regulatory system in late 2020. We will collaborate with the larger University of Minnesota research community, using the lessons learned during this project to implement an electronic DOA system that meets the needs of not only the MCC CTO, but also the university research community at large.

Authors: Jaime Wurth, CCRP; Ashley Vogt, CCRP; Julianne Feola, PhD, CCRP; Dinah Bullock; Danielle Berkow-Schwartz; Erica Orcholski, CCRP

Background: For a large cancer center with a multidisciplinary team of clinical and research staff, the traditional format of delegation of authority log (DOA) poses limitations. These limitations include: obtaining signatures from 20+ staff members in a timely fashion; the need to send pages of the log throughout campus, leading to missing documentation; and lack of consistency in capturing the workflow of clinical research staff.

Goals

Goal: Reduce the time needed to obtain a completed delegation of authority (DOA) log after a study's site initiation visit (SIV). When reviewing the process, the step that took the greatest amount of time was collecting each research staff's signatures, with collection times varying over several weeks.

Approach: Only require the Principal Investigator's (PI) initials and eliminate the need for research staff to sign the DOA log for each study. The purpose of signature collection is to verify who the work is attributable to. Instead of completing the signatures for each log, a master signature log was created for each research staff member and made electronically accessible for all studies. See figure below.

Result: With the elimination of research staff signatures for individual studies, only the PI signature is required to be collected for DOA log completion. With the PI available at nearly all SIVs, DOA logs were able to be signed and uploaded to Oncore CTMS same day or next day from SIV.

Master Signature Log

Name of research staff: [enter name]

This form will be used to identify signatures and handwritten notes on clinical trial records.

Please complete all fields below:

Printed Name	
Signature	
Signed Initials	
Printed Numbers (0, 1, 2, 3, 4, 5, 6, 7, 8, 9)	

Goal: Reduce opportunities to misplace individual pages of the delegation of authority (DOA) log. With multiple research staff signature requests circulating, many pages were out for signature at a time instead of on file in the investigator's regulatory file, leading to monitor findings for pending signatures.

Approach: As noted in the previous approach, only require Principal Investigator (PI) signature and eliminate the need for research staff to sign a DOA log for each study. See figures below.

Result: With the elimination of staff signatures, the log only had to be circulated to one individual (the PI) instead of multiple.

Original DOA Log Columns:

NAME (printed)	SIGNATURE	ROLE	STUDY RESPONSIBILITY (GOOD)	DATE STARTED WITH TRIAL	DATE ENDED WITH TRIAL	PI INITIALS

Updated DOA Log Columns:

NAME (printed)	START DATE	STOP DATE	ROLE	STUDY RESPONSIBILITY (GOOD)	PI INITIALS

Goal: Reduce the variability of delegated tasks.

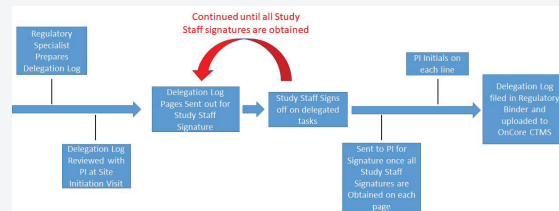
Approach: Customize set delegated tasks and determine which tasks are typical per role (PI, Sub-Investigator, Clinical Research Coordinator Nurse (CRC-RN), Clinical Research Coordinator (CRC), Advanced Practice Providers (APP), Treating Providers (TP), Investigational Drug Services (IDS), and Regulatory Specialist (RS)). See figure below.

Result: Created a policy to require use of our own site delegation of authority log template whenever possible, which included customized tasks as well as an option to add other tasks. Using our own template eliminated the variability from using Sponsor logs. Created a key with suggested tasks for each study role.

The following delegated tasks are typically linked to the responsible roles listed:

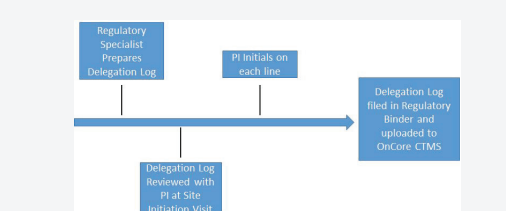
Delegated Task	Responsible Role
A. Determine subject eligibility	Sub-I
B. Obtain subject informed consent	Sub-I, CRC-RN, TP
C. Perform Physical Exam	Sub-I, TP, APP
D. Perform Drug Accountability	IDS, CRC-RN, CRC
E. Prepare and dispense study drug	IDS
F. Instruct subject on study drug administration	CRC-RN, Sub-I, TP, APP
G. Disease assessment evaluation	Sub-I, TP*
H. AE/SAE attributions	Sub-I
I. Safety/deviation reporting	CRC-RN, CRC, RS
J. CRF completion/query resolution	CRC-RN, CRC
K. Provide regulatory support	RS
L. Handle/ship research laboratory samples	CRC
M. Signing treatment plans	Sub-I, APP (non-CTEP studies), TP
N. Initial Protocol Training	Sub-I, CRC-RN, CRC, PM
O. Other (specify, if applicable)	[see below examples]

Previous Flow Summary



Several Weeks

Current Flow Summary



Same or Next Day

Limitations and Future Directions

- Uncertain if individual research staff know they have been delegated to work on the study if they do not sign the DOA log.
- Differences between delegated start date and initial protocol training date.
- Balancing Sponsors' desire for consistency of DOA logs between sites vs. our site's requirement to use internal DOA log.

University of Minnesota research teams will transition to an electronic regulatory system in summer 2020. Masonic Cancer Center Clinical Trials Office is collaborating with the larger research community, using the lessons learned during this project to implement an electronic DOA system that meets the needs of not only our program, but also the University's research community at large.

MSKCC INDs Multicenter IITs: A Centralized Model in Regulatory Oversight

H. Pham, W. Blouin, S. Yoon, J. Walkley, R. Ellis, M. Warren

Memorial Sloan Kettering Cancer Center

1. Background

Multicenter clinical trials require extensive management and oversight. The use of Investigational New Drug (INDs) in trials require additional reporting and regulatory requirements set forth by the Food and Drug Administration (FDA). Historically, expansive IND multicenter clinical trials were industry-sponsored, and the only feasible option for many investigators to participate in. However, these industry-sponsored trials, focused on commercialized drug development, largely overlooked research questions focused on clinician-based interests and needs. In addition, participation in industry-sponsored trials are costly for sites, which includes adequate clinical research staffing, training, monitoring and data management needs. As a result, investigator-sponsored IITs have become an attractive option for clinicians.

Here, we discuss how MSKCC's Clinical Research Administration has implemented a structured centralized model in the management of MSKCC INDs multicenter IITs and the challenges faced on an increasingly robust and expanding research portfolio.

2. Goals

MSKCC has two dedicated offices in the management of MSKCC INDs multicenter IITs: the IND Office and Multicenter Compliance. Together, the offices' goal is to provide centralized regulatory oversight and quality management of MSKCC INDs multicenter IITs through several measures:

- Streamline FDA communication amongst MSKCC, investigators and participating sites through a centralized IND office
- Reduce reporting lag and maintain consistency in regulatory reporting, including amendment posting and adverse reporting events
- Increase trial activations at participating sites, including community health centers through the MSK Clinical Research Strategic Partnership Program

3. Solutions and Methods

As lead coordinating site and the sponsor of the IND, MSKCC reduces the burden of regulatory oversight on participating sites, allowing them to focus on other components of trial management, including patient accrual and protocol operations.

- We have performed gap assessments and identified areas of improvement within the quality and compliance programs for both the IND Office and Multicenter compliance office
- We have developed a risk-based monitoring quality system to provide proactive multicenter support in: research staff training, Corrective and Preventive Actions (CAPA), audits and inspection preparedness
- Introduction of new technological enhancements in MSK's protocol information system for real-time reporting, such as electronic submission of documents rather than e-mail attachments, as well as automatically generated notifications to study teams on protocol status updates

4. Outcomes

Since implementing the strategies, we have preliminary data to demonstrate the following trends:

- Increased volume of MSKCC INDs multicenter IITs activations
- Increased number of participating sites, including MSK Clinical Research Strategic Partnership Program
- Expected decrease time in regulatory reporting processing, such as adverse event reporting and annual reports to the FDA

5. Lessons Learned

- Apply our knowledge and experience to recognize areas of growth, adjust and recommend changes to infrastructure model structure
- As our multicenter partnerships continue to expand internationally, streamlining adherence to the EU's General Data Protection Regulation (GDPR) enacted in May 2018.
- Continue to enhance our information technology systems, including automated data collection for study accrual breakdown in annual reports
- Capture important clinical, regulatory or scientific milestones that aid in the transition of products to our industry partners



Multicenter IND IITs – A Centralized Model in Regulatory Oversight

Hanh Pham, MS, CCRP, William Blouin, MBA, CCRP, Seo Yoon, MPH, Richard Ellis, CCRP; Janelle Walkley, Mary Warren

INTRODUCTION

Multicenter clinical trials require extensive management and oversight. In addition, the use of Investigational New Drug (INDs) in trials require additional reporting and regulatory requirements set forth by the Food and Drug Administration (FDA). Historically, expansive IND multicenter clinical trials were industry-sponsored, and the only feasible option for many investigators to participate in. However, these industry-sponsored trials, focused on commercialized drug development, largely overlooked research questions focused on clinician-based interests and needs. In addition, participation in industry-sponsored trials are costly for sites, additional considerations have to be made for adequate clinical research staffing, training, monitoring and data management. As a result, investigator-initiated multicenter trials have become an attractive alternative for clinicians.

MSKCC's Clinical Research Administration has implemented a structured model in the management of MSKCC Multicenter IND IITs, which has led to a continuous and successful growth of our research portfolio.

CENTRALIZED REGULATORY MODEL

IND Office (INDO)
Responsible for all investigational Drugs, devices and biologics, including INDs that are MSKCC manufactured

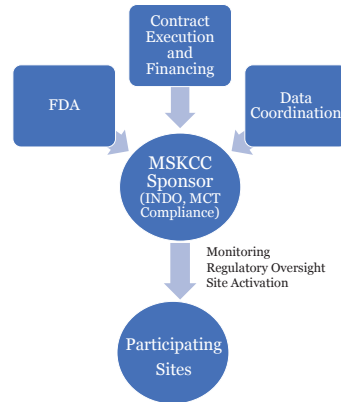
- Ensuring adherence to institutional standards and federal regulatory requirements set forth by the FDA, NIH, and OHRP
- Liaison for all FDA communications
- Providing expert guidance to MSK investigators on FDA trends and regulatory strategy

Multicenter Trials (MCT) Office
Oversees multicenter protocols on which MSK is the sponsor and data coordinating center

- Managing external site review and IRB approval, including budget and contract execution
- Monitoring, auditing and overseeing external site compliance
- Streamlining communications between MSK and participating institutions

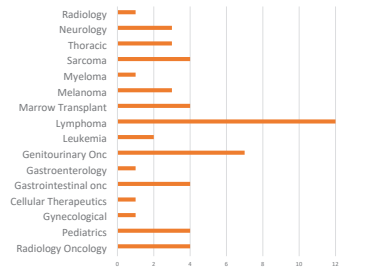
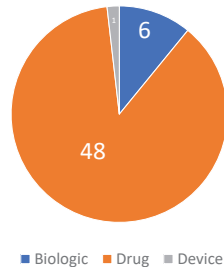
Clinical Research Strategic Partnerships (CRSP)
Expands MSKCC's participating sites to community healthcare providers

- Fostering the rapid adoption of the newest standards in the community setting
- Improving the quality of care and outcomes for cancer patients in an accelerated and cost-effective model that does not require building new facilities
- Expanding access to MSKCC's clinical trials, cutting-edge cancer research, and conduct multicenter trials amongst CRSP members



ACTIVE IND PORTFOLIO

MSKCC is the sponsor of 55 active INDs that involve several participating sites. These INDs include both drugs and biologics and devices. The majority of these INDs are for lymphoma indications.



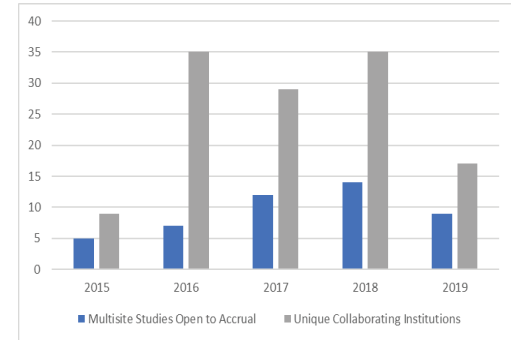
SOLUTIONS & METHODS IMPLEMENTED

MSKCC reduces the burden of regulatory oversight on participating sites, allowing them to focus on other components of trial management, including patient accrual and trial activation and operations. We have performed gap assessments and identified areas of improvement within the quality and compliance programs in Clinical Research Administration to continue to expand and successfully grow our research portfolio.

In 2018, MSKCC restructured specialized units to focus on specific components of the clinical trial life cycle, including study development, activation, finance, and streamlined centralized clinical trial management. These enhancements have resulted in an increase in partnering site collaborations, successful trial activations and a decrease in time to study activation.

MULTICENTER TRIAL ACTIVATIONS

Since 2015, there has been a generally steady increase in multicenter MSKCC IND IITs open to accrual activations, as well as an increased unique collaborating institutions. These numbers are inclusive of trials that are opened at Strategic Partnership sites.



IRB APPROVAL TO FDA APPROVAL

The introduction of a streamline clinical trial activation approach in 2018 reduced the time between initial MSKCC IRB approval to FDA IND approval in multicenter trials.

Year	Average days
2016	100
2017	98
2018	81
2019*	45

*Data does not include 2019 trials that were FDA approved in 2020

CONCLUSIONS AND FUTURE DIRECTIONS

As we continue to expand our robust portfolio, we aim to implement the following goals

- Apply our knowledge and experience to recognize areas of growth, including protocol volume and staffing needs. We will continue to reevaluate these areas, and recommend changes to infrastructure model structure as appropriate
- As our multicenter partnerships continue to expand internationally, streamlining adherence to the EU's General Data Protection Regulation (GDPR) in May 2018
- Continue to enhance our information technology systems, including automated data collection for study accrual breakdown in annual reports
- Capture important clinical, regulatory or scientific milestones that aid in the transition of products to our industry partners

The Regulatory and Product Development Road to the Future of Cancer Care

A. Yadav, R. Ellis, Z. Shabani, D.A. Ho, L. Shrestha, M. Varghese, H. Pham

Memorial Sloan Kettering Cancer Center

1. Background

The world around cancer research and treatment is evolving rapidly. While unmet medical need will continue to drive future cancer research and development, the core values of any cancer treatment will remain the same – Safety, Efficacy, and ultimately Cure. Advances in cancer research to terminal disease prevalence are causing a shift in paradigm, for both regulatory and product development teams within the organizations. At MSKCC, the Investigational New Drug & Device office (INDO) and Product Development (PD) Units review regulatory trends, advancing science and technology to develop the study drug candidates from the bench to first-in-human trials

2. Goals

- Regulatory balance – It is important to understand the regulatory standards and guidelines at an early stage of drug development for any cancer therapy. Regulatory surveillance will ensure balancing change in regulatory trends with advancing technological and scientific breakthroughs.
- Product Development (PD) – The product development team at MSKCC translates the investigator’s therapeutic discovery to required clinical, non-clinical, and critical quality attributes of the medical product that will be used in our IND applications.
- Communication – The INDO and PD team is involved with the investigators at early stages of the preclinical drug development process to explain the regulatory requirements that will drive innovative therapy in the right direction to obtain regulatory approvals and to meet crucial milestones.
- Time - Time is a critical factor while developing cancer therapies to ensure that treatment is accessible to patients as early as possible in a clinical trial.

3. Solutions and Methods

- IND oversight and strategy – The INDO’s comprehensive regulatory strategy helps to eliminate all the potential hurdles that could impact the successful IND application from submission to approval stage.
- Product development collaboration - The PD team’s collaboration with our core facilities, investigators, and regulatory team helps to achieve all the preclinical requirements for MSK’s IND/IDE studies including the preparation of IND applications/technical documents for regulatory submissions.
- Internal review committees – The Investigational New Drug and Device committee reviews and addresses both the clinical and regulatory component of the new IND application that is submitted to the FDA.
- Expedited drug development programs – MSKCC continues to effectively utilize FDA’s expedited drug development programs such as breakthrough therapy drug designation, orphan drug designation, and rare pediatric disease designation to expedite development of therapies for unmet medical needs.
- Developing internal SOP’s and regulatory resources for investigators.
- External collaborations with biotechnology partners.

4. Outcomes

- Improved regulatory compliance and decision-making process - We continue to learn from FDA’s feedback during IND review process and have successfully managed to improve our IND submission for both clinical and regulatory components of IND applications.
- Enhanced pace of product development – Effective regulatory strategy and cross-functional collaborations have helped us to reduce the time-lag between “aha” moment of an idea for a therapy to development of the medical product in a clinical trial.
- Return on Innovation (ROI) - MSKCC continues to deliver ROI and utilize it to support the INDO and PD unit.

5. Lessons Learned

- Supporting innovation.
- Enhancing the current protocol management systems to streamline regulatory operations.
- Digital solutions to internal tracking systems.



Regulatory and Product Development Road to the Future of Cancer Care

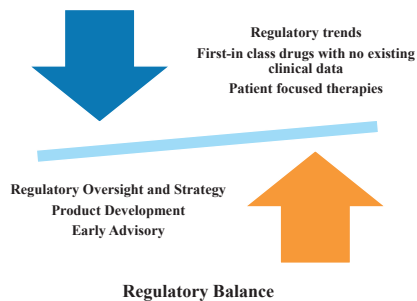
Anil Yadav, MS; Liza Shrestha, PhD; Zaher Shabani, MA; Richard Ellis; Hanh Pham, MS; Melissa Varghese; Alan Ho, MD

Introduction

- The world around cancer research and treatment is evolving rapidly. While unmet medical need will continue to drive future cancer research and development, the core values of any cancer treatment will remain the same – Safety, Efficacy, and ultimately Cure
- The exponential advancement of science and technology, alongside fast-paced regulatory changes and requirements impacts development of new cancer therapies
- Regulatory compliance and product development are key enabling factors that facilitates the movement of innovative therapies through investigative and regulatory processes
- At MSKCC, the Investigational New Drug & Device office (INDO) and Product Development (PD) Units review regulatory trends, utilizing technology and scientific expertise which guide the decision making process for novel agents

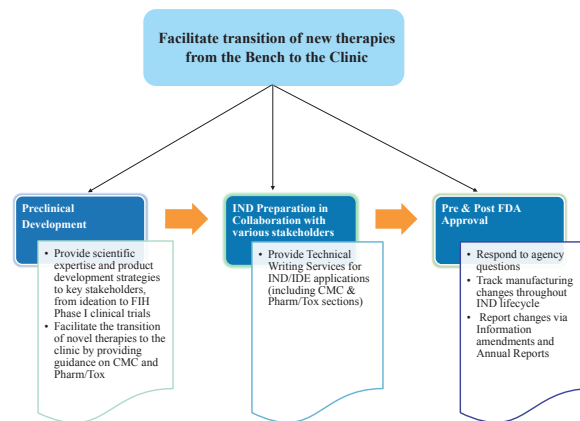
Regulatory Oversight

- It is important to understand the regulatory standards and guidelines at an early stage of drug development for any cancer therapy
- Regulatory surveillance will ensure balancing change in regulatory trends with advancing technological and scientific breakthroughs
- The INDO's comprehensive regulatory strategy helps to eliminate all potential hurdles that could impact successful IND applications from pre-clinical to IND approval



Product Development

- The product development team (PDT) at MSKCC facilitate translation of therapeutic discoveries to clinic by providing scientific expertise and strategy to meet the required clinical, non-clinical, and critical quality attributes of the clinical product for FIH clinical trials



Roles of MSK product development team at pre and post IND approval stages

- The PDT collaborates with our core facilities, investigators, and regulatory team to achieve all the preclinical requirements for MSK's IND/IDE studies in the pipeline including the preparation of IND applications/technical documents for regulatory submissions

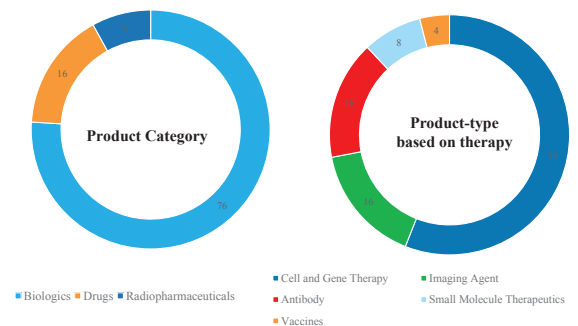
Key Resources

INDO & PD team continues to utilize the following internal resources and FDA's drug development programs to develop new therapies:

- FDA's expedited drug development programs such as breakthrough therapy drug designation, orphan drug designation, and rare pediatric disease designation to accelerate development of therapies for unmet medical needs
- Internal review committees – The Investigational New Drug and Device committee reviews and addresses both the clinical and regulatory component of the new IND application before FDA submission
- External collaborations with biotechnology partners
- Internal SOP's and regulatory resources for investigators

Outcomes

- Improved regulatory compliance and decision-making process - We continue to learn from FDA's feedback during IND review process and have successfully managed to improve our IND submission process for both clinical and regulatory components of IND applications
- Return on Innovation (ROI) - MSKCC continues to utilize FDA's expedited drug development programs for unmet medical needs to contribute towards ROI
- Enhanced pace of product development – Effective regulatory strategy and cross-functional collaborations have helped us reduce the time-lag between "aha" moment of ideation for a therapy to its clinical development



Current project pipeline of MSK manufactured products

Future Directions

- Enhancing the current protocol management system to streamline regulatory operations
- Develop commercialization pathways transitioning MSK manufactured products to biotech collaborators
- Continue to improve record of regulatory successes and drug approvals
- Regulatory Intelligence
 - Continue to develop creative regulatory pathways and solutions
 - Optimize digital solutions
 - Use data to create actionable regulatory information

Electronic Regulatory Binders – A Homegrown System

M. Kovak, D. Wade, B. Scanlon, B. Lehman, J. Holley, P. Newman, L. Hutchins, A. Annis

UAMS Winthrop P. Rockefeller Cancer Institute

1. Background

Record storage for our office had become a challenge. We were out of space and out of money. All of our regulatory records were maintained on paper for close to 300 studies. Paper binders were taking up physical space and printing and binding materials were costly.

2. Goals

The electronic system is a shared folder on the University's Network Server that is accessible only to those in the Cancer Clinical Trials and Regulatory Affairs Office (CCTRA). This project needed to address these goals:

Goal 1: Establishing a consistent method of storing regulatory binders electronically.

Goal 2: Establishing an official process for monitoring access.

3. Solutions and Methods

An organizational system for the electronic binders was created by the CCTRA regulatory team. This organizational system included the following:

- Creating trial folders with consistent naming conventions
- Creating an SOP for monitors

Once these items were created, setting up prospective trials that hadn't started yet were implemented into this structure at the time of study start-up. Space was a clear concern for us. We decided we needed a stopping point for all ongoing clinical trials. This allowed us to have a uniform mechanism for accessing regulatory binders. We chose an implementation date and then took the following steps:

- Placing a note to file for every trial that had a paper binder
- Training all regulatory team members on the new format
- Reviewing the new system at a staff meeting for all staff
- Creating an SOP for external monitors.

During the initial transition, monitors struggled with the new concept but adapted with time. We are now completely electronic except for the few items that are stored with original signatures.

4. Outcomes

We went from a file room with several hundred binders of regulatory documents to using manila folders to hold all wet signature documents must still be kept on paper at this time. The regulatory team can keep these files in one locked drawer at their desk. Although the project had an initial increase on staff workload during the transition, staff are now fully engaged. Many of the records they receive are already in an electronic format and can be saved rather than printing and filing. Costs are significantly lower for supplies and the electronic storage costs have been minimal.

5. Lessons Learned

It was not a quick process for transitioning all paper documents to the electronic format; the process took several months for the full regulatory team to complete (5 FTEs). Since then, we have participated in several demonstrations for companies who supply electronic regulatory binders. We have found that these systems are costly and not as easy to manage as our homegrown system. We feel that we saved



Electronic Regulatory Binders – A Homegrown System

Matthew Kovak, M.S., C.C.R.P., Laura Hutchins, M.D., Daisy Wade, B.A., C.C.R.P., Beth Scanlan, M.A., C.C.R.P., Brittany Lehman, B.S., C.C.R.P., Aaron Holley, B.S., Priscilla Newman, Sandy Annis, B.A., C.C.R.P.
Cancer Clinical Trials and Regulatory Affairs, Winthrop P. Rockefeller Cancer Institute, University of Arkansas for Medical Sciences, Little Rock, AR

Background

Record storage for our office had become a challenge. We were out of space and out of money. All of our regulatory records were maintained on paper for close to 300 studies. Paper binders were taking up physical space and printing and binding materials were costly.

Metrics & Goals to be Achieved

The electronic system is a shared folder on the University's Network Server that is accessible only to those in the Cancer Clinical Trials and Regulatory Affairs Office (CCTRA). This project needed to address these goals:

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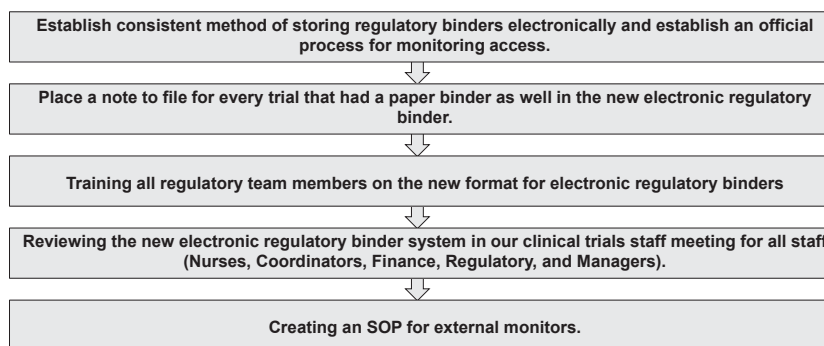
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Figure 1 – UAMS CCTRA E-Reg Schema



Lessons Learned & Future Directions

It was not a quick process for transitioning all paper documents to the electronic format; the process took several months for the full regulatory team to complete (5 FTEs). Since then, we have participated in several demonstrations for companies who supply electronic regulatory binders. We have found that these systems are costly and not as easy to manage as our homegrown system. We feel that we saved significantly with our homegrown process.

Contact

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Assessing an ASCO Decision Aid for Improving the Accuracy and Attribution of Serious Adverse Event Reporting From Investigators to Sponsors

L. Byatt¹, K. Mileham², S. Bruinooge³, C. Davis³, E. Garrett-Mayer³, P. Hurley³, L. Levit³, C. Schenkel³, M. Chuk⁴, A. Buchmeier⁵, R. Perez⁶, J. Vose⁷

¹University of New Mexico Comprehensive Cancer Center; ²Levine Cancer Center, Atrium Health; ³American Society of Clinical Oncology;

⁴U.S. Food and Drug Administration; ⁵Sarah Cannon Research Institute; ⁶Bristol Myers Squibb; ⁷University of Nebraska Medical Center

1. Background

Investigators often send adverse event (AE) reports to sponsors that are incorrectly categorized as serious or misattributed to the investigational drug, contrary to published guidance from the U.S. Food and Drug Administration (FDA). Such errors contribute to a high volume of uninformative Investigational New Drug (IND) safety reports that sponsors submit to FDA and all participating investigators, straining stakeholder resources and impeding the detection of valid safety signals.

2. Goals

To improve the quality of AE reporting, ASCO developed and tested a Decision Aid Tool (DAT). The DAT is an educational tool (one page flowchart) that is designed to improve the accuracy of physician investigator and research staff decision-making about whether an AE should be (1) reported to the sponsor as a serious adverse event (SAE) and (2) attributed to the investigational drug.

An effective DAT would reduce the number of uninformative safety reports that are submitted to trial sponsors, the FDA, and participating investigators. Reducing the number of uninformative reports would reduce administrative burden on the FDA, sponsors, trial sites, and clinical research teams, and would increase the efficiency of clinical trials. The time and cost savings associated with increased efficiency would allow for expanded clinical trial participation by individual investigators, research sites, and sponsors. Moreover, reducing uninformative reports would protect patient safety by improving the detection of valid safety signals from clinical trial data.

3. Solutions and Methods

A preliminary study with a cross-over design was conducted to test the DAT. Physician investigators and research staff were randomized to receive clinical case studies. Cases were assessed by participants for seriousness and attribution to the investigational drug, first unassisted and then with the DAT. Participants also completed a feedback survey about the DAT. Effectiveness of reporting and attribution were assessed using logistic regression.

4. Outcomes

Most of the 29 participants reported that the DAT was helpful (93%), improved their decision-making time (69%) and confidence in reporting (83%), and that they would use it in practice (83%). The DAT significantly increased accuracy of attributing a serious AE to a drug (OR, 3.60; 95% CI: 1.15, 11.4), but did not significantly affect accuracy of determining seriousness (OR, 0.87; 95% CI: 0.31, 2.46). The lack of improvement in determining seriousness is likely due to the fact that seriousness was generally well-understood by the participants prior to exposure to the DAT.

5. Lessons Learned

The DAT shows promise as a method to improve the quality of SAE attribution by investigators and research staff, which may improve the detection of valid safety signals and reduce the administrative burden of uninformative IND safety reports. The DAT and a corresponding educational toolkit are being disseminated to the broader research community and are available on the ASCO Research Community Forum website (asco.org/research-community-forum). A JCO Oncology Practice manuscript highlights the DAT and these findings.



TRAINING & QUALITY ASSURANCE



Standardized and Personalized Training Results in Increased Job Satisfaction and a Reduction in Turnover

K. Jenkins, J. Workman, L. Mooney, M. Kilbane
Cleveland Clinic Cancer Center

1. Background

Disorganized training leads to disengaged new hires and an increase in turnover. Training and onboarding methods at the Taussig Cancer Institute had an opportunity to be evaluated. The main approach was peer to peer training led by busy research coordinators (RC) with time constraints due to competing workloads. Feedback from new hires revealed that training was inconsistent and not robust. Dating back to 2016, Cleveland Clinic employee satisfaction surveys as well as exit interview data showed that the lack of extensive training contributed to turnover and job dissatisfaction. The financial cost of RC turnover was high and turnover averaged around 33.7% between 2016 and 2018.

2. Goals

- Reduce turnover to 22% annually
- Increase morale
- Standardize training

3. Solutions and Methods

Essential to the success of any clinical trial unit is effective and robust training for non-clinical, research coordinators. We justified the need for a dedicated trainer position based on the low survey scores surrounding training, the exit interview data and the financial impact of turnover. A dedicated trainer was hired into the role in Feb. 2019. We standardized training by creating a 30 day, rotating curriculum introducing people to oncology clinical research, data and regulatory roles and responsibilities. The training curriculum includes 33 distinct training modules presented in small group, interactive live sessions with continuously updated tools for reference. This training is complimentary to the existing, online, Clinical Trial Management Tool (CTMT) developed in 2014.

4. Outcomes

11 new hires have completed the full training program in 2019. All 11 trainees have completed a post training, new hire feedback survey indicating that they have the tools to do their job and feel the training was effective and successful. (See attached graphics.) Turnover has decreased from 33.7% (2016 through 2018 combined years) to 26.5% in 2019. Improved engagement was also demonstrated via the feedback survey illustrated by positive comments and/or informed, creative suggestions in the open feedback section.

5. Lessons Learned

- Training must include a multi-faceted approach to be effective in a large scale setting
- It is critical to connect every new hire with a dedicated mentor within their specific disease area
- Supervisor engagement is vital to the success of the program
- 2 skill assessments currently in development are focused on:
 - o Confirming that new hires are properly learning and retaining key information
 - o Assessing the appropriate timing of training modules
- Also in development is an investigator initiated trial (IIT) training module led by the lead of our multisite IIT department

Standardized and Personalized Training Results in Increased Job Satisfaction and a Reduction in Turnover

Joshua Workman, Lindsey Mooney, BS, CCRC, Megan Kilbane, MBA, Kimberly Jenkins, MSNM
 Taussig Research Staff, Cleveland Clinic, Cleveland, OH



BACKGROUND

Disorganized training leads to disengaged new hires and an increase in turnover. Training and onboarding methods at the Taussig Cancer Institute had an opportunity for evaluation. The main approach was peer to peer training led by busy research coordinators (RC) with time constraints due to competing workloads. Feedback from new hires revealed that training was inconsistent and not robust. Dating back to 2016, Cleveland Clinic employee satisfaction surveys as well as exit interview data showed that the lack of extensive training contributed to turnover and job dissatisfaction. The financial cost of RC turnover was high and turnover averaged 36% between 2016 and 2018.

GOALS AND METHODS

Our goals are to:

- Reduce turnover to 22%⁽¹⁾ annually
- Increase morale
- Standardize training

Essential to the success of any clinical trial unit is effective and robust training for non-clinical, research coordinators. We justified the need for a dedicated trainer position based on the low survey scores surrounding training, the exit interview data and the financial impact of turnover – calculation below. A dedicated trainer was hired into the role in Feb. 2019. We standardized training by creating a 30 day, rotating curricula introducing people to oncology clinical research, data and regulatory roles and responsibilities. The training curriculum includes 33 distinct training modules presented in a small group, interactive live session with continuously updated tools for reference. This training is complimentary to the existing, online, Clinical Trial Management Tool (CTMT) developed in 2014 and traditional mentor based training

Cost of Turnover - Calculated through sunk salary costs (includes fringe)			
New Hire (RC ts)	Cost/Nr	Average # of training hours in 3 mos*	Cost of training
1	X	400	X(400)
New Hires (trainers)			
Cost/Nr	No of hours in 3 mos**	Cost of training	
1.00	120	120	Y(120)
* 3 months = 480 hours. Per region average of 400 hours = new hire training/admin			
** 120 hours, across 3 months is the total time invested behind each new hire.			
Turnover Cost per RC			X(400) + Y(120)

Turnover equation:
 # employees present who leave by year's end divided by the # employees present at the start * 100

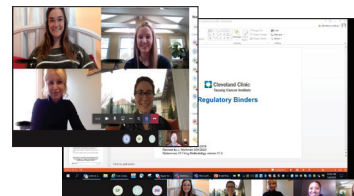
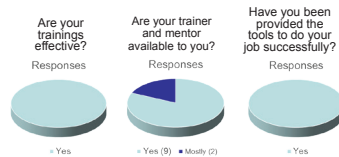
RESULTS

11 new hires completed the full training program in 2019. All 11 trainees have completed a post training, new hire feedback survey indicating that they have the tools to do their job and feel the training was effective and successful. (See graphs below.) Turnover has decreased from 36% (2016 through 2018 combined years) to 26.87% in 2019. Turnover to date in 2020 is at 9% which is projected to be at 18-19% by the end of the year. Improved engagement was also demonstrated via the feedback survey illustrated by positive comments and/or informed, creative suggestions in the open feedback section.

Training topics, New Hire Survey results and a screen shot of a remote class in session:

Research 101/Welcome	PRMC Submissions	Amendments	Monitoring Visits
Email/Calendar Use	Navigating IRB Interface	Deviations	Budget / Research Billing (MyCT)
Time Tracking System – How To	New IRB Applications	Regulatory Binders	Research Meeting – Expectations
CTMT Navigation	Regulatory Documents	Source Binders	Eligibility/Enrollment
Trial Feasibility Pt 1	ICF Writing	CRFs/Queries	Terminating Archiving
Trial Feasibility Pt 2	SIV/Open to Accrual	EPIC	Cooperative Group Trials- miniseries
How to read a Protocol	Continuing Reviews	Internal/External SAEs	Managing IIT Trials - miniseries

New Hire Feedback - 11 new hires throughout 2019:



CONCLUSIONS

- Training must include a multi-faceted approach to be effective in a large scale setting
- It is critical to connect every new hire with a dedicated mentor within their specific disease area
- Supervisor engagement is vital to the success of the program
- 2 skill assessments currently in development are focused on:
 - Confirming that new hires are properly learning and retaining key information
 - Assessing the appropriate timing of training modules
- Also newly created is an investigator initiated trial (IIT) training module led by the lead of our multistie IIT department

References/Resources:

- 1: 22% annual turnover goal is based on an informal survey conducted in Dec 2019, of AACI member respondents combined with turnover reported in the healthcare industry obtained from various sources including:
 - Owens Pickle, EE, et al., 2017. The Clinical Research Associate Retention Study: A Report From the Children's Oncology Group. J Pediatr Oncol Nurs. 2017 Nov-Dec; 34(6): 414-421.
 - Saulet, D. and Venner, E., (2019, October 7) *Oncology staff burned out? Engage and retain your staff with these targeted strategies.* Retrieved from www.advisory.com
 - Rosenbaum, M, (2018, January 16) *Will 2018 be the year healthcare addresses its turnover problem?* Retrieved from www.beckershospitalreview.com
 - NSI Nursing Solutions Inc. (2020), *2020 NSI National Health Care Retention & RN Staffing Report.* Retrieved from www.nsinursingsolutions.com

There are no relevant conflicts of interest to disclose.

“Who Cares? It’s Just a Minimal Risk Study”: The Case for Research Compliance Oversight of Cancer Population Sciences (CPS) Research

E. Beck, K. Thorne

Huntsman Cancer Institute, University of Utah

1. Background

Cancer Center Support Grant eligibility for NCI-Designated Cancer Centers lists “Prevention, Control, and Population Science Research” amongst the three major research areas to be found at qualifying centers[1]. While many centers are working to grow this area of research at their facility, there is minimal guidance surrounding the research compliance oversight of cancer population sciences (CPS) research. Although these studies are required to adhere to 45 CFR 46, which contains regulations for IRB oversight and informed consent, the Food and Drug Administration (FDA) and the International Council on Harmonisation (ICH) Good Clinical Practice (GCP) E6(R2) have little to say about CPS non-pharmaceutical research. At Huntsman Cancer Institute (HCI) at the University of Utah (U of U), we discovered that this lack of GCP guidance resulted in inconsistent and minimal to non-existent research compliance oversight.

As an NCI Comprehensive Designated Cancer Center, HCI is committed to cancer research including but not limited to laboratory research; clinical research; and prevention control and population-based research. While the Data and Safety Monitoring Committee (DSMC) at HCI is tasked with oversight of primarily interventional treatment clinical trials, there remains a need to ensure patient safety and data quality for CPS research which may not be subject to this rigorous monitoring oversight.

[1] Cancer Center Support Grants (CCSGs) for NCI-designated Cancer Centers (P30 Clinical Trial Optional): <https://grants.nih.gov/grants/guide/pa-files/PAR-20-043.html>

2. Goals

Our goal at HCI was to create a method of oversight for CPS studies in order to ensure research compliance to higher institutional standard.

3. Solutions and Methods

Standard Operating Procedures (SOPs) with a reasonable set of expectations based on ICH GCP were developed in collaboration with the U of U for all trial types. The HCI’s Research Compliance Office (RCO) developed a role specific for CPS based auditing. The auditor has been conducting audits of CPS studies for 5 years and ensures adherence to these SOPs.

Audit prioritization is given to studies which are:

- Greater than minimal risk
- Grant funded, and/or
- Interventional

The audit process closely mirrors that of our treatment clinical trial auditing, with specific focus on:

- Informed consent form process and consent process (including version check)
- Eligibility documentation
- Protocol and SOP compliance
- Source documentation
- Safety reporting requirements (as applicable)
- Data completion and accuracy
- Regulatory binder/essential documents

Audit findings are reviewed and discussed with study teams. When all queries are resolved, an abbreviated audit report is provided to the study team and filed with the U of U IRB.

4. Outcomes

The process has provided the following benefits:

- Overall improvement in compliance and data quality.
 - Over a three-year period we saw a 30% increase in “Outstanding” audits.
- Increased communication between the RCO and CPS study teams.
 - More teams are reaching out for guidance and preventative trainings.
- Direction for development of SOPs to support future compliance.

5. Lessons Learned

- How can we increase Principal Investigator (PI) and study team support for compliance oversight of CPS studies?
- How can we create a standard which is rigorous, but not preventative of institutional research projects?
- What metrics can we develop to gauge efficacy of CPS auditing?

“Who Cares? It’s Just a Minimal Risk Study.” THE CASE FOR COMPLIANCE OVERSIGHT OF CANCER POPULATION SCIENCES (CPS) RESEARCH

Erin Beck, MPH, CCRC; Kelli Thorne, MPH, CCRP
Huntsman Cancer Institute at the University of Utah



BACKGROUND

Cancer population sciences (CPS) research is an expanding area for many cancer centers; however, there is little guidance regarding compliance oversight of these studies.

Huntsman Cancer Institute (HCI), an NCI Comprehensive Designated Cancer Center, houses a Cancer Control and Population Sciences Research Program. Our goal at HCI was to create a method of oversight for our CPS research in order to ensure research compliance to a higher institutional standard.

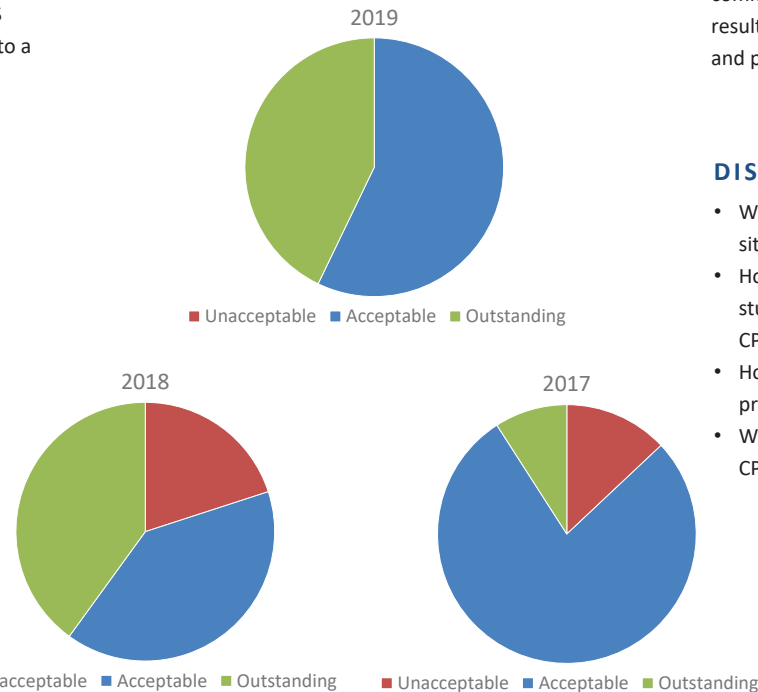
METHOD

- HCI developed a role specific to CPS based auditing. This role has been a part of HCI’s Research Compliance Office (RCO) for 3 years.
- CPS research is audited annually, with prioritization given to studies which are
 - greater than minimal risk,
 - grant funded,
 - and/or interventional.
- The audit process closely mirrors that of our clinical trial audits.
- Standard Operating Procedures (SOPs) based on ICH GCP were developed for all trial types.

OUTCOME

We have seen the following benefits:

- Overall improvement in compliance and data quality
- 30% increase in “Outstanding” audits over a three year period
- Increased communication between RCO and CPS study teams
- Direction for development of future SOPs to further support research compliance



CONCLUSIONS

The combination of a reasonable standard with routine auditing has greatly improved compliance amongst our CPS research. Repeat annual audits allow study teams to identify areas for improvement, develop tailored trainings, and refine their processes.

The audit process also facilitates increased communication between RCO and CPS study teams, resulting in more requests from teams seeking guidance and preventative trainings.

DISCUSSION POINTS

- What does CPS compliance oversight look like at other sites? What challenges have they seen?
- How can we increase Principal Investigator (PI) and study team support for compliance oversight of CPS studies?
- How can we create a standard that is rigorous but not preventative of institutional research projects?
- What metrics can we develop to gauge efficacy of CPS auditing?

* Development of a Competence-Based Quality Assurance Program

R. Kingsford, J. Espinosa, S. Sharry, J. Moehle, L. Lujan, T. Werner
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1. Background

One of the largest challenges plaguing cancer centers is turnover among coordination staff. Oncology clinical trials are becoming increasingly complex in an industry that is already highly regulated. In our experience, it is difficult to recruit coordinators who have previous experience in oncology. Over the past 5 years, we have focused on developing a robust and comprehensive training program to get new coordinators able to function in their roles as soon as possible. Given the volume of information in the form of regulations, standard procedures, and institutional policies relayed in the training program, it is not possible for new staff to retain all of the necessary concepts. In order to address gaps in retention, Huntsman Cancer Institute (HCI) Clinical Trials Office (CTO) leadership is in the process of developing a competence-based quality assurance program.

2. Goals

There are 4 primary goals of the HCI CTO's competence-based quality assurance program:

1. Create a culture shift of proactive process improvement rather than reactive corrective action plans.
2. Identify retention gaps to provide re-training.
3. Highlight necessary modifications to the training program.
4. Provide opportunities for professional development for our coordination teams.

3. Solutions and Methods

The Competence-Based Quality Assurance Program consists of 3 phases:

1. Administration of a general competence exam. The competence exam will be administered to new employees at approximately 3 months from hire. The exam is delivered in an open-book, proctored, online format and consists of general questions surrounding key concepts of Good Clinical Practice, HCI CTO standard operating procedures, and institutional policies. The exam is mapped to the individual training courses. If a coordinator misses the majority of the questions on a specific content area, the coordinator will be required to attend the associated training class again with additional mentorship in this area.
2. Task-based competency assessments. New staff will be required to demonstrate competence on individual tasks (i.e., scheduling a monitoring visit, conducting and documenting informed consent, etc.) prior to being authorized to complete them autonomously. Competence assessments for new staff will be completed by senior staff who have demonstrated competence.
3. Quality assurance chart reviews. New coordinators will have 5 charts per month reviewed for months 3-6 of the new employee's hire. All coordinators past the 6-month mark will have 2 charts per month reviewed on a continuing basis. Chart reviews consist of review of the database including metrics such as number of queries, data completion percentage, etc. The reviews will also include assessment of adherence to departmental documentation and Good Clinical Practice standards.

4. Outcomes

Development and refinement of this important project is ongoing. Determining the important concepts and procedures considered to be essential for coordinator competence has led to some modifications of the training program.

5. Lessons Learned

Identification of staffing resources to create and maintain this program is challenging, but the HCI CTO is committed to the investment. As the program is further developed, adjustments will be made to the training program to address deficiencies as they are identified. We look forward to reporting progress on this critical project in a future abstract.

Development of a Competence-Based Quality Assurance Program

Rachel Kingsford, MS, CCRP; Janna Espinosa, CCRP; Susan Sharry, CCRP; Jessica Moehle, CCRP; Leanne Lujan, CCRP; Theresa L. Werner, MD
Huntsman Cancer Institute at the University of Utah

BACKGROUND

Coordinator turnover is a challenge that plagues many cancer centers, including the Huntsman Cancer Institute (HCI) Clinical Trials Office (CTO). The ability recruit experienced staff is limited. Trials are increasing in complexity and there are many regulations. We have developed a robust comprehensive training program, however, volume of information and retention issues plague our staff. To mitigate this, we are in the development process of a competence-based quality assurance (QA) program.

METHOD

- The QA program consists of three phases:
 1. A computer-based, proctored exam mapped to topics covered in the training program and GCP principles. The exam administered at the 3-month mark. Retraining and additional mentoring for identified deficiencies.
 2. Task-based competence assessments conducted by senior staff who have previously demonstrated competence. New staff are only allowed to complete tasks autonomously after demonstrated competence.
 3. Five charts will be QA reviewed for new employees for months 3-6 and then two charts per month thereafter. These checks will confirm adherence to best practices and standard policies.

OUTCOME

We are still in the early development of the program. We anticipate the following four benefits:

1. Create a paradigm shift to proactive quality assurance away from reactive corrective actions.
2. Identify retention gaps to address with re-training and added mentoring.
3. Highlight needed modification to the training program.
4. Provide professional development opportunities for mentors.

CONCLUSIONS

- Development is still ongoing.
- Drafting competence-based exam questions has already led to some modifications to the training program.

LESSONS LEARNED

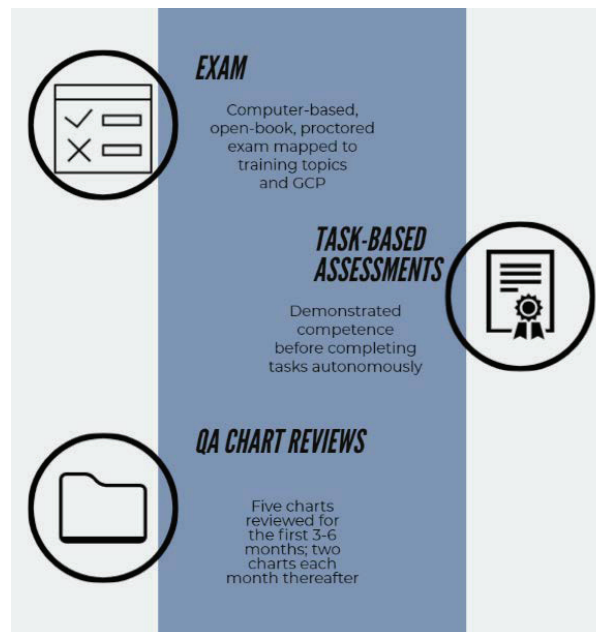
- Dedicating staffing resources for a project this large has been challenging.
- Administrative burden for tracking will be large.

CONTACT

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Advising and Trial Guidance for Investigators

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Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. Background

When investigators in departments outside the Clinical Trials Office (CTO) want to conduct institutional trials on a cancer patient population with a multicenter component, it is the responsibility of the CTO Multicenter team to provide guidance and ensure institutional policies and federal regulations are being followed. Since these investigators do not routinely conduct these types of trials and lack the appropriate infrastructure, they can be inexperienced or unfamiliar with specific requirements of multicenter, investigator-initiated trials. They may also be unaware of the resources available to them.

2. Goals

- Provide support and guidance to investigators outside the CTO that conduct multicenter trials
- Direct investigators to the resources available to them
- Ensure all trials are conducted in accordance with local institutional policies and federal regulations.

3. Solutions and Methods

Starting at protocol development, investigators are introduced to CTO Multicenter Clinical Research Coordinators (MCRC) for education and guidance. Over the course of several meetings, the MCRCs discuss multiple topics essential to multicenter trials such as:

- Multicenter template language for the protocol
- Contract requirements
- Use of IRBs
- Data collection and entry requirements
- Required regulatory document collection from sites
- Monitoring and auditing of the trial
- Sponsor-Investigator oversight
- Site training

4. Outcomes

Prior to the current practice listed above, MCRCs would conduct ongoing monitoring on trials to provide appropriate oversight. However, the MCRC would not monitor these trials until after they were already opened and had subjects accrued. During this early process, the cancer center did not have sufficient staffing available to provide additional guidance and audited, usually for cause only. As the need arose, the cancer center approved additional staffing to provide support earlier in the start-up process. MCRCs now meet with investigators and their study teams early in the trial start-up to guide them on the many important factors involved in multicenter trials. It was determined that earlier intervention was beneficial to minimize audit findings. These trials have an elevated risk level due to the involvement of outside participating sites. At any given time, MCRCs are assisting 4-8 investigators from other departments with starting their multicenter trials. This proactive approach with the guidance and ongoing teaching/training of the MCRCs, have reduced the number of deviations and the monitoring and audit findings on multicenter trials from outside departments. The ability to utilize the MCRCs as a resource has aided in building trust, rapport, and relationships with outside departments.

5. Lessons Learned

This newer process has only been in effect for a short time. It is still too early to know the full benefit of early guidance for investigators and their staff. The cancer center and MCRCs have encountered some resistance by investigators and staff in outside departments, however, we have found that early introduction to the process has proven to be more successful than waiting until after a trial is open to accrual. Often, investigators and their staff are hesitant to reach out with their questions but when encouraged by MCRCs, the trial staff is more willing to ask questions and reach out in the future with additional concerns.



Advising and Trial Guidance for Investigators

Lina Sego, BA, CCRP; Amber Bauchle, BS, CCRP; Sara Edwards, MSc CCRC
Indiana University Melvin and Bren Simon Comprehensive Cancer Center

Background

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Contact

Lina Sego: lmsego@iu.edu, 317-278-5624

Solution

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INDIANA UNIVERSITY MELVIN AND BREN SIMON COMPREHENSIVE CANCER CENTER

New Employee Orientation – Joining the 21st Century

F. Kerr, M. Cheviron, S. Edwards, S. Asche

Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. Background

At the Indiana University Melvin and Bren Simon Comprehensive Cancer Center, the Quality and Education Team is responsible for the training of newly hired and promoted employees; as well as mentoring, writing and updating SOPs, managing continuing education, quality improvement projects, and routine data checks and audit preparedness. The typical orientation schedule for a newly hired employee prior to implementing electronic modules was 48 hours of in-person presentations over the course of 4 weeks, approximately 5 hours per new employee of grading assignments, and approximately 3 hours per new employee of schedule creation. Periods of high turnover have significantly inhibited the availability of the Quality and Education Team to manage the full breadth of their workload, requiring the team to prioritize training and mentoring over other important quality projects.

2. Goals

- Design a web-based orientation program to provide a full training agenda to newly hired and promoted employees
- Identify key aspects of training that benefit from remaining in-person, versus those that can be electronic
- Resolve the conflict created by prioritizing orientation and mentoring over quality improvement and audit readiness

3. Solutions and Methods

- Prepare standardized scripts and slide presentations for all orientation topics
- Create multimedia recordings of training topics and corresponding course assessments
- Utilize the electronic Canvas application to house electronic training modules and course assessments

4. Outcomes

The Quality and Education Team began implementing the first Canvas-based electronic training modules in December 2019. Since its introduction, 18 of 46 modules (39%) have been converted into an electronic format, along with 15 automatically graded course assessments to evaluate topic understanding. An additional 14 modules are in-progress. Targeted assessments have shown student comprehension is equal to that of modules presented in-person, while reducing training time by 22.72 hours (39% + 4 hours grading) per orientation cohort, with a target reduction of 37.6 hours per orientation cohort. The platform has also allowed current employees access to training topics at any time for re-training or topic refresher, further reducing the mentoring burden of the Quality and Education Team.

5. Lessons Learned

The Quality and Education Team attended the IU Online conference on e-learning techniques and available programs, held Zoom meetings with IT instructors on campus, and spent hours learning how to record, edit, and host videos online. Each module required hours of preparation, from determining which topics qualified for electronic training, modifying and editing existing training documents, and writing and recording scripts to go with each. While the upfront cost to this project has been large, the team has already noticed a difference in the workload involved in training staff. The flexibility of this system has also allowed the team to identify new modules for creation that were previously avoided due to time burden. A plan still needs addressed on when and how to update modules as office processes and international policies change.



New Employee Orientation – Joining the 21st Century

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Indiana University Melvin and Bren Simon Comprehensive Cancer Center

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Goals

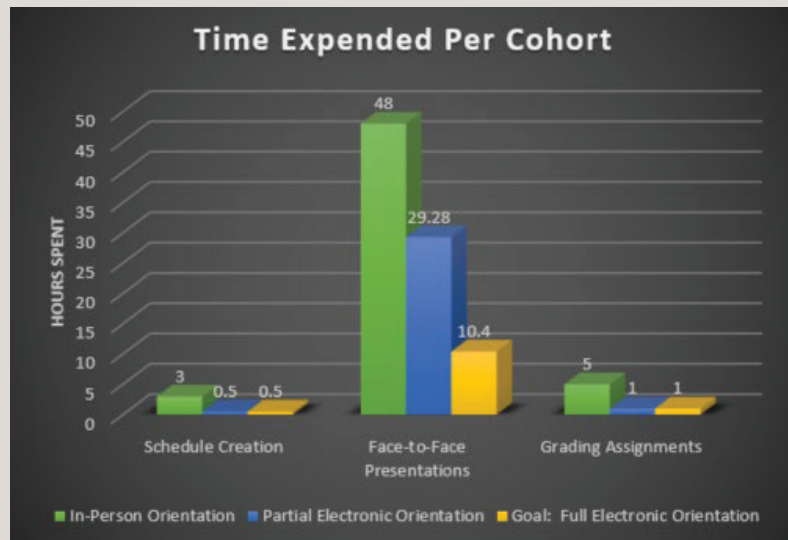
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Methods Implemented

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Results

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Training the Masses – Electronic Protocol Training

J. Norfleet, F. Kerr, S. Asche, J. Nichols

Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. Background

Maintaining a complete Trial Master File can be challenging for any study team. When working at a Comprehensive Cancer Center with dozens of investigators across multiple satellite sites, collecting training documentation in real time can be especially difficult. At the Indiana University Melvin and Bren Simon Comprehensive Cancer Center, monitoring and auditing reports notably include at least minor findings related to protocol training documentation.

2. Goals

- Utilize an electronic training platform to allow more efficient documentation of protocol training attestation
- Reduce instances of missed protocol training documentation
- Minimize the burden on research staff by eliminating the need to obtain physical signatures to capture training

3. Solutions and Methods

The Quality and Education Team partnered with the IT department to develop an application to assist in training documentation. The app is able to house protocol portals, and within each portal a designated study team. Clinical Research Specialists, who are responsible for study maintenance at the Indiana University Melvin and Bren Simon Comprehensive Cancer Center, can designate study team member roles and add or delete team members as a study progresses and team members change. Once defined, IRB approved documents can be uploaded and automatic e-mail notifications will be sent to the members listed within the defined protocol. The app is designed so that: all supporting documents must be opened before a staff member can attest; and any related versions can be linked. For instance, if a staff member logs in to attest to study start-up training and a new amendment has since been approved, the staff will also be directed to the most recent documents.

4. Outcomes

Currently we have been piloting this app with a single disease-oriented team, refining the process as problems present themselves. When the app runs smoothly it makes obtaining protocol training significantly less time consuming. We've found that the primary challenge associated with the app is that documents do not show up for the reviewer however, IT has been able to resolve this issue when it occurs. Secondly, the app does not send recurring reminders to attest to training at this time, which in turn requires the CRS to send out training reminders multiple times. Lastly, we do not have enough information to understand every aspect of the protocol training app and how to utilize it most effectively at the present time.

5. Lessons Learned

Moving forward, we will adjust the app to send out automatic reminders weekly for two weeks followed by daily until the trainee has reviewed the relevant protocol documents. Also, we plan to add the function to allow monitors to review training attestation electronically, eliminating the need to house training in regulatory binders for review. Finally, we plan to expand the pilot to multiple disease oriented teams in order to gather more feedback and address issues with the app before expanding to the Clinical Trials Office in its entirety.



Training the Masses – Electronic Protocol Training

Jessica Norfleet, BS, CCRP; Fyalon Kerr, BA, CCRP; Sarah Asche, MS, CCRP
Indiana University Melvin and Bren Simon Comprehensive Cancer Center

Background

Maintaining a complete Trial Master File can be challenging for any study team. When working at a Comprehensive Cancer Center with dozens of investigators across multiple satellite sites, collecting training documentation in real time can be especially difficult. At the Indiana University Melvin and Bren Simon Comprehensive Cancer Center, monitoring and auditing reports notably include at least minor findings related to protocol training documentation.

Goals

- Utilize an electronic training platform to allow more efficient documentation of protocol training attestation
- Reduce instances of missed protocol training documentation
- Minimize the burden on research staff by eliminating the need to obtain physical signatures to capture training

Methods Implemented

The Quality and Education Team partnered with the IT department to develop an application to assist in training documentation. The app is able to house protocol portals, and within each portal a designated study team. Clinical Research Specialists, who are responsible for study maintenance at the Indiana University Melvin and Bren Simon Comprehensive Cancer Center, can designate study team member roles and add or delete team members as a study progresses and team members change. Once defined, IRB approved documents can be uploaded and automatic e-mail notifications will be sent to the members listed within the defined protocol. The app is designed so that all supporting documents must be opened before a staff member can attest, any related versions can be linked, for instance, if a staff member logs in to attest to study start up training and a new amendment has since been approved, the staff will also be directed to the most recent documents.

Results

Currently we have been piloting this app with a single disease oriented team, refining the process as problems present themselves. When the app runs smoothly it makes obtaining protocol training significantly less time consuming. We've found that the primary challenge associated with the app is that documents do not show up for the reviewer however, IT has been able to resolve this issue when it occurs. Secondly, the app does not send recurring reminders to attest to training at this time, which in turn requires the CRS to send out training reminders multiple times. Lastly, we do not have enough information to understand every aspect of the protocol training app and how to utilize it most effectively at the present time.

Future Direction

Moving forward, we will adjust the app to send out automatic reminders weekly for two weeks followed by daily until the trainee has reviewed the relevant protocol documents. We also plan to expand the pilot to multiple disease oriented teams in order to gather more feedback and address issues with the app before expanding to the Clinical Trials Office in its entirety

CTO Protocol Training

BTCRC-LUN17-139

Versions

Type	Effective Date
Protocol Version: BTCRC-LUN17-139 amendment V.29MAR2019	06/06/2019

Attestation Status

Name	Attestation Date
A . N	06/17/2019 03:38:16 PM
A . A	01/31/2020 12:52:14 PM
B . J	06/17/2019 03:30:42 PM
D . G	06/18/2019 10:24:17 AM

Approaching Goals With a Plan: Application of MSK Resources for Internal Audit Process Improvement

C. Duarte

Memorial Sloan Kettering Cancer Center

1. Background

The internal audit process, utilized by Clinical Research Quality Assurance (CRQA) unit at Memorial Sloan Kettering Cancer Center (MSK), due to the lack of suitable platform, incorporates tasks that are repetitive, time-consuming and involve manual steps for report generation. A project was initiated to design a more practical solution for generating automated audit reports. REDCap, a secure web-based application, commonly used for data capture and survey creation, was used to satisfy this goal.

2. Goals

The primary objective was to design a more practical solution for generating audit reports. Additionally, by ensuring the design included automated areas, the CRQA unit intended to improve efficiency in the review time of finalizing the audit reports for distribution to Principal Investigators (PIs) and research staff.

3. Solutions and Methods

A systematic approach was used for effective resource allocation and skills acquisition to create an efficient project breakdown. The MSK Learning and Organization Development's (L&OD) course, 'Introduction to Project Management', was attended to ensure a successful project management outcome for both designer and end users. Data elements were defined by review of existing templates. Surveys were completed by end users (i.e., Clinical Research Auditors responsible for generating the audit report) to gather useful insights on individual auditing styles that influenced how the database was built. User-friendliness of REDCap was assessed together with the database building using mock audit finding data.

4. Outcomes

Project management was primarily spent on the defining and planning phases, resulting in the gathering of necessary and significant skills from participation in the MSK L&OD course. Different viewpoints collected from the survey results contributed to the decision-making for the REDCap database architecture. Furthermore, over 200 formulas were added, where possible, for efficiency and accuracy. Achieving optimal balance between the cosmetics of the exported audit report and preserving ease of use was challenging, but time-worthy.

5. Lessons Learned

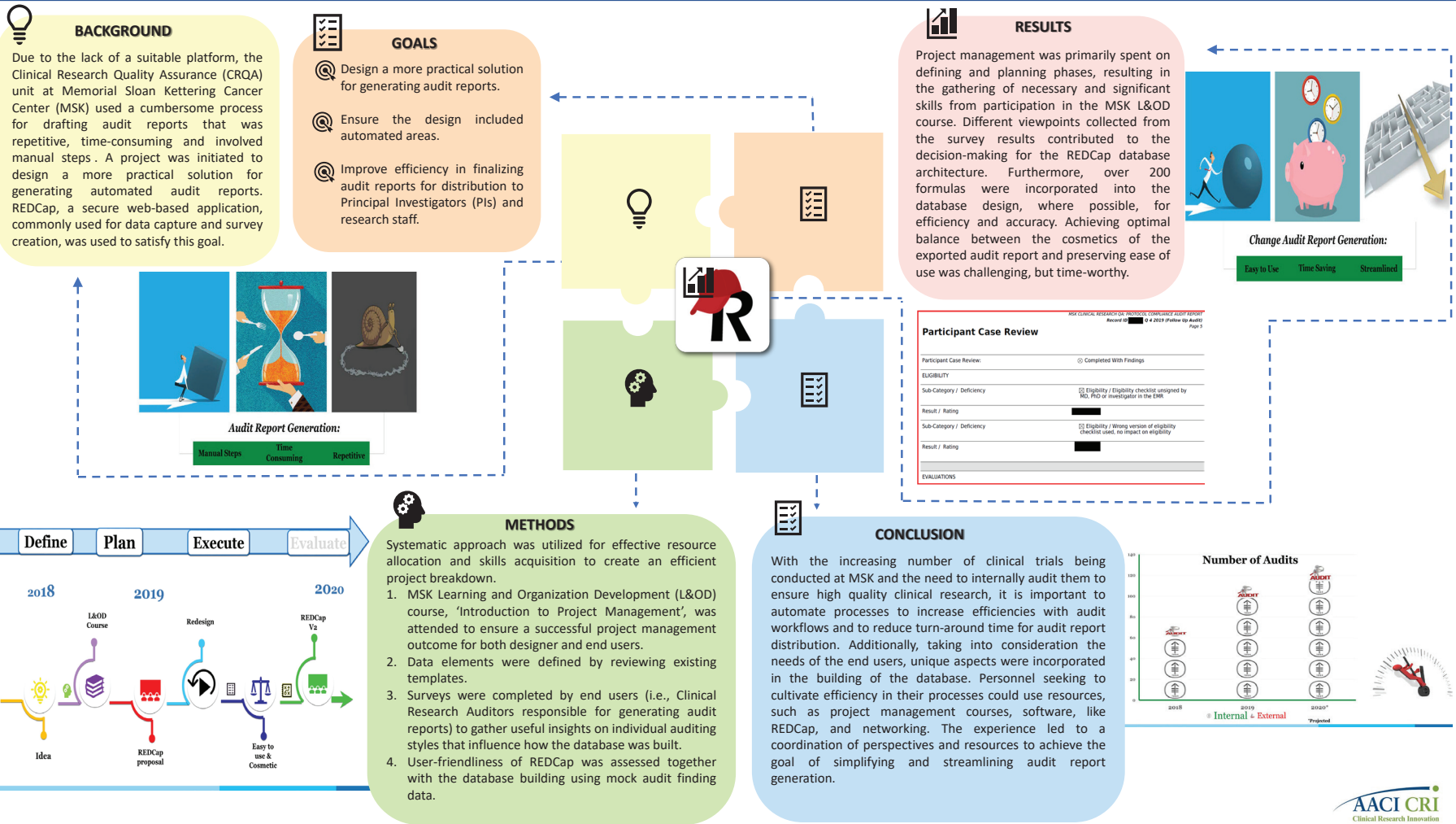
With the increasing number of clinical trials being conducted at MSK and the need to internally audit them to ensure high quality clinical research, it was important to automate processes to increase efficiencies with audit workflows and to reduce turn-around time for audit report distribution. Additionally, taking into consideration the needs of the end users, unique aspects were incorporated in the building of the database. Personnel seeking to cultivate efficiency in their processes could use resources, such as project management courses, software, like REDCap, and networking. The experience led to a coordination of perspectives and resources to achieve the goal of simplifying and streamlining audit report generation.

Approaching Goals with a Plan: Application of MSK Resources for Internal Audit Process Improvement

Charina O. Duarte, MD, MS



Memorial Sloan Kettering Cancer Center



Acknowledgements: Karima Yataghene MD, Susan Puleio, Nara Chhua, Jacqueline Simpronio, Debbie Marcellus-Duval, James Lozada, Jennifer Tom, Michael McGinn, Danae De Blasi, Reena Dholakia, Ashley Soh and Andrew Zarski



Let It Go! One Strategy to Maximize Limited QA Resources

A. Gateman, E. Smas

Yale Cancer Center, Yale School of Medicine

1. Background

The Yale Center for Clinical Investigation (YCCI) Quality Assurance (QA) team conducts internal reviews of clinical research across the Yale School of Medicine, including the Yale Cancer Center. Balancing resources between conducting internal reviews and working with investigators and research staff on corrective and preventative actions (CAPAs) is critical to ensuring a robust quality assurance program. The QA team found that trials with significant observations and more extensive CAPAs were consuming greater QA resources than originally allocated. This was hindering the QA team's ability to conduct routine reviews and support the broader portfolio.

2. Goals

To balance the QA team's time spent between conducting reviews across the entire research portfolio and overseeing the execution of trial specific CAPAs, a more efficient use of available systems, resources, and trainings was instituted.

3. Solutions and Methods

Upon identification of a review with significant observations, the QA team works with the Principal Investigator (PI) and research team to identify the root causes. Once the root causes are determined, a CAPA is developed. Ideally, the CAPA items are matched to existing and/or new internal systems and resources available. Instead of implementing, executing, and tracking the CAPA within the QA team, the QA team now works collaboratively to pair the PI and research team with Subject-Matter Experts (SME) and system resources. For example, if an observation related to managing essential documents is found, and the root cause identified is lack of systems or process to maintain regulatory files, the internal team who supports Forte's eReg®, the electronic regulatory file maintenance system used at Yale, and the YCCI Director of Training are paired with the PI and research team to assist with education, training and eReg system implementation.

4. Outcomes

Extending beyond the QA team and utilizing existing SMEs and system resources has multiple benefits. The QA team has created a clear process for hand-offs and completion of reviews, allowing allocation of more time to review trials across the School. Also, by pairing PIs and research teams with support systems, researchers have gained an awareness of available resources for not only their current studies but for future studies as well. The PIs and research teams are more aware of who to contact and system supports are established prospectively at study start-up versus deficiencies being discovered and addressed at the time of quality reviews. Researchers now are more aware of their access to receive answers, guidance, and education directly from SMEs.

5. Lessons Learned

Establishing clear communication is essential for a smooth, coordinated team approach of support when involving multiple stakeholders. The QA team remains involved and works closely with collaborators to track the process, ensuring that work is completed and delivered in a timely manner.

Both methods have been successful in providing reviews and addressing CAPA plans but letting go and collaborating with SMEs is much more efficient for the QA team and, ultimately, the PIs and research teams.



Let It Go! One Strategy to Maximize Limited QA Resources

Alyssa K Gateman, MPH, CCRP and Elzbieta Smas, BS, CCRP
Yale Comprehensive Cancer Center



BACKGROUND

The Yale Center for Clinical Investigation (YCCI) Quality Assurance (QA) team conducts internal reviews of clinical research across the Yale School of Medicine, including the Yale Cancer Center. Balancing resources between conducting internal reviews and working with investigators and research staff on corrective and preventative actions (CAPAs) is critical to ensuring a robust quality assurance program. The QA team found that trials with significant observations and more extensive CAPAs were consuming greater QA resources than originally allocated. This was hindering the QA team's ability to conduct routine reviews and support the broader portfolio.

AIMS

To balance the QA team's time spent between conducting reviews across the entire research portfolio and overseeing the execution of trial specific CAPAs, a more efficient use of available systems, resources, and trainings was instituted.

METHODS

Upon identification of a review with significant observations, the QA team works with the Principal Investigator (PI) and research team to identify the root causes. Once the root causes are determined, a CAPA is developed. Ideally, the CAPA items are matched to existing and/or new internal systems and resources available. Instead of implementing, executing, and tracking the CAPA within the QA team, the QA team now works collaboratively to pair the PI and research team with Subject-Matter Experts (SME) and system resources. [Figure 1]

For example, if an observation related to managing essential documents is found, and the root cause identified is lack of systems or process to maintain regulatory files, the internal team who supports Forte's eReg®, the electronic regulatory file maintenance system used at Yale, and the YCCI Director of Training are paired with the PI and research team to assist with education, training and eReg system implementation.

Figure 1.

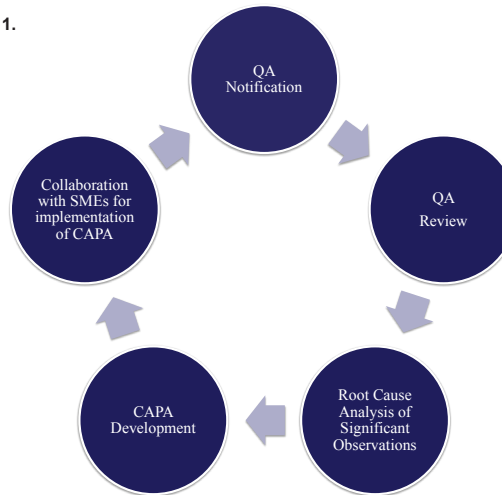
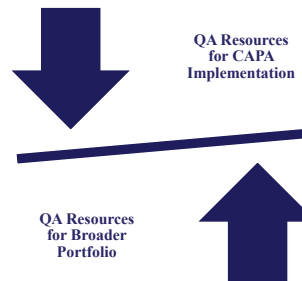


Figure 2.



RESULTS

Extending beyond the QA team and utilizing existing SMEs and system resources has multiple benefits. The QA team has created a clear process for hand-offs and completion of reviews, allowing allocation of more time to review trials across the School. Also, by pairing PIs and research teams with support systems, researchers have gained an awareness of available resources for not only their current studies but for future studies as well. The PIs and research teams are more aware of who to contact and system supports are established prospectively at study startup versus deficiencies being discovered and addressed at the time of quality reviews. Researchers now are more aware of their access to receive answers, guidance, and education directly from SMEs. [Figure 2]

CONCLUSIONS

Establishing clear communication is essential for a smooth, coordinated team approach of support when involving multiple stakeholders. The QA team remains involved and works closely with collaborators to track the process, ensuring that work is completed and delivered in a timely manner.

Both methods have been successful in providing reviews and addressing CAPA plans but letting go and collaborating with SMEs is much more efficient for the QA team and, ultimately, the PIs and research teams.



Use of REDCap Database to Identify Trends in Non-compliance

A. Kale, N. Cassim

City of Hope Comprehensive Cancer Center

1. Background

Given the growing number of investigator initiated trials, expansion of participating sites and increasing trial complexity (cellular therapy, transplant, CAR T, vaccine, stem cell, gene therapy) there is no reliable method to capture and compile the aggregate findings from internal auditing and monitoring visits. Monitoring findings from each report are presented to the individual study teams; however, they are not used to categorize trends across the entire investigator initiated trial portfolio. To improve audit readiness and data quality, it is crucial for the Clinical Trials Office Leadership to have a mechanism in place in order to track trends in non-compliance and to develop targeted reeducation sessions.

2. Goals

1. Create a user-friendly tool to identify the trends in non-compliance (GCP gaps, trial conduct, protocol and policy deviations etc.) across all investigator initiated trials.
2. Capture all findings from monitoring reports and classify according NCI categories (regulatory, informed consent, eligibility, general data quality, treatment, disease outcome, adverse events and patient case review).
3. Perform severity assessment for these findings per NCI guidelines (critical, major, and lesser).

3. Solutions and Methods

This project utilized REDCap which is a secure, web-based application for building and managing online surveys and databases. The authors composed a series of questions to create the data collection instrument in the form of REDCap survey. The survey function in REDCap was used to easily enter key information from monitoring reports, export these data instantly into excel, pdf, SAS, and SPSS (trend analysis), create reports, and present captured data.

Questions were designed to capture prominent findings in each of the NCI categories as defined above. Additional information including study PI, disease group, monitor name, site, and severity assessments was also collected. This survey link was distributed through REDCap to monitors via email. After every monitoring visit, each monitor entered their findings around the key categories by answering survey questions.

4. Outcomes

Monitors were directed to enter 6 months of data from previous monitoring reports (48 studies, 20 disease teams) and classify findings per NCI guidelines to gather baseline information. These data were used to identify areas improvement to develop targeted education materials. The baseline data also allowed the institution to highlight the successes and knowledge gaps amongst the individual disease teams creating opportunities for knowledge transfer and improvement in work instructions, SOPs and policies.

5. Lessons Learned

While this project is currently in the pilot phase, we have collected baseline information on compliance and current regulatory practices. The project identified the gap between the institutions deviation policy and the NCI deviation categories, resulting in a policy change to better align with the NCI guidelines. We anticipate that this project will create transparency among the disease teams to identify systemic issues across study teams. These observations will enable the institution to implement focused re-audits and appropriately develop educational programs to support the needs of the research community, for example, new staff onboarding, continuing professional development/ knowledge transfer, create resources, and better communication of new regulations pertaining to research operations.

The Case for Physician-Led Education Sessions for Research Coordinators

L. Waitkus

Cleveland Clinic Cancer Center

1. Background

Research Coordinators (RCs) play a vital role in a site's successful management of clinical trials. The majority of skills and education that are needed to be a successful RC are often learned "on-the-job" as opposed to the prospective training and education that defines many other disciplines. As such, there is a continued need for new and continued education opportunities for RCs. Additionally, the research coordinators' offices at Cleveland Clinic (CC) are located multiple blocks away from the Taussig Cancer Institute so the physical interaction between RCs and physicians is typically limited to a few meetings each month. This can lead to feelings of exclusion amongst RCs which can lead to disengagement and poor job satisfaction.

2. Goals

The goals of implementing an education model centered on physician-led education sessions were to increase RC knowledge and thereby increase confidence in job performance, improve research coordinator communication with physicians and increase job satisfaction and engagement.

3. Solutions and Methods

Throughout the last 12 months varying types of physician-led education opportunities were made available to research coordinators. These included:

- Clinical Education Speaker Series: Physicians present a monthly in-person education session on a topic of their choice.
- Clinical Trial Results Overviews: Physicians presented on the results of a clinical trial that was conducted at CCF, what impact the results have on the field of medicine, and what research is being developed as a result of the trial.
- Disease Specific Education Sessions: Physicians led a discussion amongst the RCs in their specific disease group on a disease, treatment, or problem facing a patient population.

4. Outcomes

37 RCs completed a survey regarding the effect the education sessions had on their communication with physicians, confidence in job performance, and their job satisfaction and engagement. These results show that there is a positive correlation between the number of education sessions attended and an increase in job performance confidence, job satisfaction and engagement, and improved communication with physicians.

The graph below shows that the greatest impact the education sessions had was improving RC confidence in their job performance. There was a 43% increase in the rating on the impact of the education sessions on confidence in job performance in those who attended five or more education sessions compared to those who attended two.

The survey results also showed attending physician-led education sessions that are specific to RCs primary disease group has the greatest impact on RC communication with physicians. There was a 22% increase in improvement of communication with physicians for RCs who attended five or more education sessions that were specific to their primary disease group compared to those who attended no education sessions that were specific to their primary disease group.

5. Lessons Learned

Taussig Cancer Institute has 67 RCs who manage hundreds of clinical trials. Improving confidence, communication, engagement, and job satisfaction through physician-led education sessions has a notable impact on the entire research department. Future directions include increasing the overall number of physician-led education session opportunities and studying what impact these education sessions have on the physicians who lead them.

Improving Clinical Research Quality and Efficiency Through the Implementation of a Risk-Based Audit Approach

S. Puleio

Memorial Sloan Kettering Cancer Center

1. Background

In 2017, the Clinical Research Administration (CRA) was formed at Memorial Sloan Kettering Cancer Center (MSK). A primary goal was to increase the quality and efficiency of clinical research conducted at MSK.

2. Goals

As part of the CRA initiative, the Clinical Research Quality Assurance (CRQA) Unit, under the Clinical Research Compliance division of CRA, was charged with increasing the number of yearly clinical trial audits to provide a more comprehensive understanding of the issues encountered during study conduct so, in turn, they could be adequately and successfully addressed.

3. Solutions and Methods

A risk-based audit approach was adopted, which identifies and targets critical findings within clinical trials conducted at MSK. Similar to the approach utilized by regulatory agencies (e.g., FDA), CRQA audit staff conduct efficient, high-quality audits of assigned clinical trials within ~5 business days. To accomplish this, 4-6 research participants are randomly selected, using selection process and tools. Additionally, the clinical trial is analyzed to identify critical time and data points (e.g., informed consent documentation and procedures, eligibility, baseline/screening assessments, adverse events/serious adverse events). A risk-based audit approach is also utilized to target critical regulatory documents for review during the audit.

4. Outcomes

In 2016, prior to the risk-based audit approach implementation, only 22 audits were conducted on MSK clinical trials. Contrastingly, in 2019, following the implementation of the risk-based audit approach, 98 audits were conducted, which is a 345.5% increase. The impact of this approach has allowed an increase in the number of clinical departments and services, conducting clinical trials, to be audited, exposing issues experienced across the MSK Clinical Research portfolio and, in turn, for those issues to be analyzed and addressed. Additionally, this has led to an increase in collaboration across CRA to effectively improve: (1) processes and workflows related to regulatory and participant management, (2) audit databases and clinical systems, (3) education on targeted/common issues and improve knowledge and implementation of root cause analysis, and (4) external audits and inspection results.

5. Lessons Learned

Ultimately, through the implementation of the risk-based audit approach, CRA has been able to target issues that significantly impact clinical research at MSK. As a result, initiatives have been implemented or are in the process of being developed to successfully address these issues with the overall goal of increasing the quality and efficiency of clinical research conducted at MSK.

Expanding the Scope of an Internal Quality Assurance Program to Initiate Change on a Mezzo- and Macro-level

E. Harms, N. Borrer, K. Williams
Siteman Cancer Center

1. Background

Protocols are increasingly more complex, staff turnover is high, and industry standards can be a moving target. Performing comprehensive quality audits on new protocols establishes a proactive approach to quality assurance (QA) and ensures corrective action plans are set into motion early on.

Our internal QA program was established in 2014, with an emphasis on micro-level clinic processes, such as informed consent and serious adverse event identification. Early audits did not include reviews of data entry or regulatory compliance, but instead focused on correcting study-specific clinic issues. This narrow focus could cause other aspects of clinical trials to be overlooked, such as accurate reporting of response data or documentation of amendment training. Without analysis of operational errors occurring within disease teams (mezzo-level) and across our Division as a whole (macro-level), we were missing an opportunity to identify areas that could improve with team- or Division-wide education.

2. Goals

Our goal was to develop a more comprehensive QA program that quickly identifies process issues, trends, and educational gaps that could jeopardize patient safety, data integrity, and regulatory compliance.

To establish a broader review of our Division, the scope of the QA program expanded in 2018 to include reviews of regulatory, policies, and processes. We also set 3 goals for 2019:

- Launch a data audit program and complete 45 audits in the first year
- Identify audit trends
- Work with the Education team to combat trends identified

3. Solutions and Methods

We worked with experienced data managers to establish priorities and determine the scope of data audits. We focused efforts on institutional and cooperative group trials for three reasons:

- We have limited resources (2-person QA team).
- Industry studies undergo extensive external data monitoring.
- Industry studies utilize many different EDC systems.

We presented the finalized data audit plan to a group of ~40 supervisors and senior coordinators and collected feedback prior to implementation. We began conducting data audits in September 2019.

In December 2018, we created an audit tracker that catalogues completed audits, upcoming audits, and audit findings.

We implemented monthly meetings with the Education Manager to review policies, audit findings, and education strategies.

4. Outcomes

We completed 15 data audits and presented preliminary clinic and regulatory results to Division team leads. After 83 clinic audits and 71 regulatory audits, we identified Division-wide and disease team trends, including issues related to oral medication compliance and obstacles to collecting protocol-specific training. We worked with Education to improve our tools and processes related to these trends.

5. Lessons Learned

Open communication with teams and supervisors is imperative to ensure audits capture useful data that can impact positive change. Interim reviews helped us determine more specific categories were needed to better understand aggregate data. As a result, we re-evaluated our goals and are piloting new audit processes.

We will summarize findings every 6-12 months to assess trends and determine if the categories we are tracking tell us what we want to know. Adding to our scope without growing our team requires constant re-evaluation of priorities. By eliminating categories without findings we may be able to narrow our scope in different areas in the future.

A Process for the People: Updating Oral Medication Compliance Policy, Guidelines, and Tools

N. Borrer, E. Harms, K. Williams, L. Menne

Siteman Cancer Center

1. Background

With all the complexities of oral medication studies, including variable dosages, ramp-up periods, interval dosing, multiple medications, and dose holds or reductions, it is increasingly complicated for patients to remain compliant, even with their best efforts.

In 2016, our Division implemented a policy and tool to aid non-clinicians in assessing patient compliance with oral medications. While our Education Team has been continuously training new staff on the importance of patient compliance and how to assess this compliance, we had not re-evaluated our policy and tools, or provided formal refresher training to existing staff.

After reviewing the results of approximately 60 quality assurance (QA) audits, we learned that the existing tools and policy developed were misunderstood and misused. There was frequent miscommunication between clinic coordinators completing medication compliance forms and data coordinators entering data into Electronic Data Capture (EDC) systems. The forms were not completed consistently and the process for notification was not always followed.

2. Goals

Through reframing our approach to oral medication compliance we hoped to accomplish the following:

- Evaluate and update our policy to provide clarity to sponsors and staff
- Provide updated tools and guidelines that are more clear, concise, and functional in a clinic setting
- Re-educate coordinators on the importance of compliance and provide real-life examples
- Establish an open line of communication, allowing coordinators to bring complex problems to light
- Minimize repeat issues with patient compliance
- Decrease the number of findings on QA audits related to the completion of the oral medication compliance form

3. Solutions and Methods

We held focus group meetings to gather insight from coordinators involved in assessing oral medication compliance. We reviewed specific examples of problems coordinators faced with these studies to establish a framework of what was working and what wasn't. In addition, we looped in pharmacy, management, and education specialists to provide a comprehensive approach.

4. Outcomes

This plan is still in its implementation phase. Thus far, we have developed an updated policy, comprehensive guidelines, clear and practical resources, and an education plan to share with staff.

5. Lessons Learned

With all the complexities of running a clinical research trial, many individuals play a part in patient compliance with oral medications. It is important to obtain their perspective and feedback when developing or updating policies, rather than excluding these individuals in favor of exclusively management level decision-making.

Seeking input from multiple perspectives, including pharmacists, inpatient staff, clinic coordinators, and data coordinators has led to more comprehensive set of guidelines.

Using real life examples was key to developing impactful staff tools. Piloting new tools with actual protocols generated questions we had not considered, and led to a more thorough set of guidelines.

One standard tool cannot address every possible scenario. Instead, address complex issues through education, customizable guidelines and tools, and communication across roles.

Having input from the staff on the ground leads to increased staff buy-in, and provides an incentive to use the tools they contributed to.

Protocol-Specific Training in a Commercial IRB World: Adjusting the Process to Ensure Training Keeps Up

L. Menne, E. Harms, N. Borrer

Siteman Cancer Center

1. Background

Protocol-specific training is essential for staff delegated study-specific duties on clinical trials. Training prior to study activation and amendment implementation is imperative to protect patient rights and safety, to ensure staff understand their roles, and to avoid protocol deviations.

Historically, our training timelines have been based on the rate at which our institutional IRB processes approvals. Staff were first trained on a protocol after initial IRB approval and prior to working on a trial. Amendment training was administered after IRB submission, and the orders and budget teams were often notified of an amendment after approval.

Amendments are implemented within 2 business days of IRB release. However, with the speed at which commercial IRBs are processing amendments, the submission to implementation windows have greatly diminished. Furthermore, when a commercial IRB acts as the central IRB, our site is often notified of an amendment at the time of approval. Our system did not allow adequate time to revise treatment orders, train delegates, or update study budgets prior to amendment implementation.

2. Goals

- Identify barriers to meeting protocol-specific training objectives
- Decrease the number of staff without training prior to study activation and with delayed amendment training
- Eliminate late modifications to orders and budgets
- Develop tools for consistent documentation of training
- Educate on staff responsibilities
- Assess staff compliance with the updated process

3. Solutions and Methods

We formed a task group of education, quality assurance (QA), clinic, regulatory, finance, and orders staff to discuss current workflow and obstacles. We determined that the swift approvals from commercial IRBs requires earlier communication and training.

Initial training is now administered as soon as training materials (e.g. training slides) are available. Staff are not added to the DOA log until initial training is complete. Within 2 days of amendment receipt, we initiate an OnCore Task List to facilitate communication between the regulatory, clinic, budget, and orders teams. If required, delegates are trained on an amendment within 5 business days of OnCore Task initiation. When we receive an amendment at the same time as IRB approval, training is distributed immediately.

We created standardized tools and templates to communicate and document training. We created work instructions outlining the responsibilities of each staff member. We educated staff on process changes during in-person education sessions, followed by an online module and assessment.

In order to assess staff adherence to the process updates, QA added reviews of the process to routine audits, and supervisors were trained to run OnCore Task reports.

4. Outcomes

The orders team is now able to review amendments within 24 hours of the OnCore Task initiation. The budget team has seen a marked improvement in how quickly they can complete updates. Regulatory has noted an increase in staff trained prior to study activation.

5. Lessons Learned

- Training staff with entrenched habits is difficult.
- Staff and faculty feedback facilitates streamlined workflows.
- Simpler and concise tools are more useful to staff.
- More data from supervisor reports and QA audits will inform next steps.

We will continue to assess the feasibility of the process and the utility of the tools, and work to develop innovative ways to administer continuing education.

UF Health Cancer Center (UFHCC) Research Fantasy League: A Novel Approach to Employee Engagement

T. Guinn, A. Anderson, A. Ivey, R. Houlihan
University of Florida Health Cancer Center

1. Background

The University of Florida Health Cancer Center (UFHCC) Clinical Research Office (CRO) supports diverse research projects from several colleges across campus. In 2017, UFHCC began a strategic realignment of the research portfolio to support increased enrollments to interventional trials. As a result, the CRO expanded by 30 FTE and created new partnerships with research offices throughout the enterprise. With the growth of research operations, the need for improved communication became apparent to ensure all research activities aligned with UFHCC priorities and collapsed existing cultural barriers between research units.

2. Goals

- Increase employee engagement and awareness of overarching UFHCC priorities and strategic goals across all clinical research units;
- Enhance awareness of ongoing research activities across and between units;
- Encourage timely entry of study status and enrollment data into the Clinical Trial Management System, OnCore;
- Improve CTMS data quality and employee communication to facilitate smoother data locks and metric reporting.

3. Solutions and Methods

The UFHCC Research Fantasy League (RFL) was created based on basic structure of the globally popular fantasy sports leagues. Research has shown that “engaging in play has implications for employee well-being, as play has been shown to reduce stress and burnout (DesCamp & Thomas, 1993; Sørensen & Spoelestra, 2011), increase job satisfaction and sense of competence (Abramis, 1990)” (Petelczyc et al. 2017). The RFL focuses on uniting individuals across research units to manage their respective teams. Teams of 6-8 staff, assigned from units which don’t typically interact, allow for unique communication opportunities and knowledge sharing of cancer research activity.

The RFL point scoring structure is based on the UFHCC’s study prioritization system. Points are awarded for each subject in an “on study” status. These points are distributed between the enrolling Investigator and Principal Investigator, and weighted to emphasize treatment trials. Seasons consist of 4, 3 week-long matchups, between two randomly assigned teams, culminating in one team being crowned RFL champion.

The RFL also includes a quality assurance component as the CRO has well-defined requirements for reporting interventional enrollments. Through weekly analysis of data and scoring, teams gain a better understanding of the reporting expectations for study status updates, including timely submission of enrollment data.

Among study coordinators, knowledge of providers and subjects in screening is enhanced as teams track their point systems and ensure each enrollment is accounted for throughout the RFL matchups amid friendly team competition.

4. Outcomes

Over 65 members of research staff and leadership participated in the inaugural season of the RFL. Feedback has been overwhelmingly positive from participants to date. The exercise has resulted in quicker resolution of data queries and enhanced understanding of OnCore data elements.

5. Lessons Learned

Gauging collaboration (and declined reasoning) of staff participation, has allowed for unique insights into the cultural cohesiveness of the UFHCC. UFHCC leadership endorsement has allowed for more desirable rewards for participants which is anticipated to increase overall participation willingness for future seasons.

References:

Petelczyc, C. A., Capezio, A., Wang, L., Restubog, S. L. D., & Aquino, K. (2018). *Play at Work: An Integrative Review and Agenda for Future Research. Journal of Management, 44(1), 161–190.* <https://doi.org/10.1177/0149206317731519>

Minimizing Clinical Trial Deviations Through Lean Six Sigma and a CRO Compliance Committee

A. Barkman, T. Cummings, J. Kessler

University of Maryland Marlene and Stewart Greenebaum Comprehensive

1. Background

The University of Maryland Greenebaum Comprehensive Cancer Center Clinical Research Office (UMGCCC CRO) Compliance Committee reported an abundance of re-occurrences and similar occurrences of clinical trial deviations deriving from research specimen collections and sample management. The purpose of this project was to analyze and determine the root causes of lab and sample deviations, to improve sample collection, and minimize research lab errors and deviations. In a root cause analysis conducted at UMGCCC by a Lean Six Sigma Green Belt, we determined the following were the most significant and impactful contributors to sample management deviations: inconsistent performance of procedures, lack of quality control processes, inconsistent usage of the calendar of events, and staffing of the lab and medical assistant teams.

2. Goals

- Improve lab collection and minimize research lab errors and deviations
- The immediate goal was to determine the root causes of sample collection RNIs and deviations.
- The long-term goal is to reduce the sample management error rate by at least 50% 6 months after implementing solutions.

3. Solutions and Methods

- Define: Using Lean Six Sigma (LSS), we defined the problem statement that the amount of lab deviations in 12 months (n=82) was too high and set a goal to minimize deviations.
- Measure: Created a “current state” process map of the sample management process. The process map identified the path of sample collection and defined value-added activities.
- Analyze: By creating a fishbone diagram, we identified the effect (Y): research lab deviations and identified the Critical (X)s: root causes. We then prioritized the root causes and proposed quick wins and rapid improvements.
- Improve: Through identifying the root causes, we then prioritized a list of solutions. A “future state” process map was created and a pilot plan was formed.
- Control: We revised process documentation, updated SOPs and training plans, and planned to transition sample management to the process owner.

4. Outcomes

- Updated the Research Specimen & Procedure Management SOP and implemented quality control training
- Updated the processes for calendar entry of research specimen collection requirements
- Provided supporting evidence and documentation that a Clinical Lab Coordinator management position was necessary for the CRO. This position was filled and the coordinator took over as the “process owner”
- As this is currently an active project, a full 12 months of data is not yet available. However, in the past four months post implementation, we have seen a mean of 4.5 lab deviations per month, which would extrapolate to 54 deviations over 12 months post implementation. This represents a 34% reduction in errors.

5. Lessons Learned

This work demonstrates that LSS methodology can be applied to operational issues in clinical research, including clinical trial deviations. By identifying root causes and prioritizing solutions, the UMGCCC CRO Compliance Committee was able to review and discuss the deviation report descriptions, brainstorm causes for deviations, discuss possible solutions, and mitigate strategies to be relayed by the CRMO leader representative. Future directions for GCCC include creating a monthly compliance report and quarterly reviews of research specimen and management deviations by the Compliance Committee.

Research Staff Orientation and Training

M. Horak, D. Cleary, B. Pappu
UPMC Hillman Cancer Center

1. Background

Staff turnover, hiring, and onboarding is a time-consuming and costly process. Common complaints during staff exit interviews included a lack of a structured and detailed orientation process. With the prior process, new staff were assigned a mentor and began hands-on training immediately, without an introduction to research concepts and processes. This led to staff confusion and dissatisfaction with the training process. Additionally, the training process was not well supervised, and it was difficult to ensure that new staff were meeting all expectations.

2. Goals

The goal of the updated orientation and training process was to help improve new staff training and satisfaction.

3. Solutions and Methods

New staff training now includes a thirteen-day orientation period with the Quality, Education, and Compliance (QA) team to learn basic research principles prior to training with a mentor in an assigned disease center. Each day of the thirteen-day orientation period includes one-on-one training regarding specific components of the research process. The intent is to give an overview of the start-to-finish research process. Each day of the orientation builds on content reviewed during prior trainings. Trainees are given PowerPoint presentations of material that outline processes which are used as reference once orientation and mentorship end.

Companion Skills Labs are completed by the trainees for the topics reviewed with the QA team. The Skills Labs are formatted as either a quiz or are a task-based exercise related to the material and topics reviewed. Once the initial thirteen-day orientation is completed, the trainees begin training directly with an assigned mentor in a specific disease center for 10 weeks. “Touch Base Meetings” are held biweekly for 12 weeks from the initial start date with the trainees, manager/supervisor, and mentor with a QA team member to facilitate. The trainee’s experiences are reviewed, and goals are set for the next weeks.

An “Orientation Checklist” is used to track training during the QA Orientation. A “Skills Checklist” is used to track experiences during the mentorship and is signed off by the mentor and trainee as skills and tasks are completed. The Skills Checklist is reviewed during the Touch Base Meetings to ensure compliance with the process and to ensure trainees are meeting expectations.

4. Outcomes

The improved orientation and training process has increased staff satisfaction. The trainees feel more supported and have a better understanding of the research process prior to training with a mentor. Additionally, mentor satisfaction has increased as they have noted that the trainees learn the job faster. The mentors also feel that they do not have to spend as much time teaching the trainees research concepts, as they have already reviewed the concepts with the QA team.

5. Lessons Learned

The Clinical Research Services leadership continues to review the orientation and training process for effectiveness. The training and orientation documents are updated in real time to reflect changes to processes. The next steps include a mentor training program to ensure all mentors are training staff in the same manner. We are also working to implement standard “refresher” training courses which will be available to all staff.

Development of an Integrated Orientation Program Using the Joint Task Force Core Competencies for Research Professionals

E. Gainey, G. Beals

Vanderbilt-Ingram Cancer Center

1. Background

Orientation and onboarding are critical components in the long-term success and retention of new staff. This is especially true in clinical research which requires not only a unique skill set but is also constantly evolving as the complexity of clinical trials increases. Historically, the Clinical Trials Office (CTO) at the Vanderbilt-Ingram Cancer Center has not offered a competency-based orientation and onboarding program, but rather relied heavily on peer-to-peer training. This resulted in inconsistent performance, a lack of clear understanding of the research process, decreased staff satisfaction, and retention challenges.

2. Goals

The goal of this project was to develop and implement an orientation and onboarding program based on the Joint Task Force (JTF) core competencies appropriate for all new staff regardless of their role within the organization. Measuring the success of the program is ongoing and should be reflected in increased staff satisfaction, lower employee turnover, more consistent practices, and a better understanding of clinical research and how each role impacts the success of clinical trials.

3. Solutions and Methods

Utilizing the JTF model, competencies were mapped to staff roles and responsibilities using a cross-functional and multi-level group of staff from the CTO. The entry level competencies were then used to develop the framework for the integrated orientation program. Training was developed using both existing resources and, if unavailable, new material created based on institutional standards, federal regulations, and international guidelines. After approval by CTO leadership, the first cohort of new employees completed integrated orientation in February 2019.

4. Outcomes


While quantitative data are still pending, qualitative data in the form of staff and manager feedback obtained via surveys and one-on-one meetings have been overwhelmingly positive. Staff have reported the integrated orientation program enabled them to become familiar with the organization, feel prepared when they assumed their new roles, and afforded them ample opportunity to ask questions. Additionally, many new staff members felt the time spent in orientation allowed them to begin developing a workplace support system. Managers also noted new staff members were well-equipped to enter the preceptorship portion of orientation and had a better understanding of the research process.

5. Lessons Learned

From the beginning, the implementation of this program required clear and concise communication ensuring buy-in from all stakeholders. Establishing expectations for both preceptors and managers has been essential for the success of the program and has helped to ensure that everyone involved has had the tools they need.

Although the feedback has been positive, we recognize the need for standardized tools to assess staff satisfaction and the effectiveness of orientation. Moving forward, the data gathered from these tools will help ensure integrated orientation continues to meet the needs of new staff members, contributes to the well-being of the organization, and positively impacts the future of clinical research.





**TRIAL RECRUITMENT & COMMUNITY
OUTREACH AND ENGAGEMENT**

Crack the Walnut! How Community Outreach Research Coordinators Can Empower African American Men to Come Out of Their Shell to Make an Informed Decision About Prostate Cancer Screening, a Cancer Prevention Project

C. Chapman, K. Hunt, E. Meisler, D. Allen, S. Abraksia, A. Seals, N. Anderson, K. Sanders
Cleveland Clinic Cancer Center

1. Background

American Cancer Society acknowledges the importance of an informed decision-making (IDM) process for prostate cancer screening (PCS). Prostate cancer incidence is 1.6 times higher in African American (AA) men compared to Caucasians, with mortality rate 2.4 times higher. AA men are frequently diagnosed with an advanced stage because they're less likely to have screenings. Discussing the advantages/disadvantages of PCS increases awareness, but many physicians find it difficult to provide comprehensive, unbiased education to patients. PCS outreach programs with an investment in patient navigation are needed to empower AA men about their choices and increase informed decision making. To reach these objectives, a project was developed to assess "Education and informed decision making for prostate cancer screening in a high-risk African American community".

2. Goals

- A. To improve knowledge of prostate cancer in a high-risk population.
- B. To empower men to make an informed decision about prostate cancer screening and provide information about the risks/benefits of PCS.

3. Solutions and Methods

Hosting the research project:

- Research Coordinator was responsible for overseeing different aspects of the program. Working closely with medical residents, researchers, physicians, navigators, patients, and managing data entry.
- A research project was conducted during the "For Men Only" health fair, where only men can participate to foster an environment of comfort and safety.
- South Pointe Hospital is located in a high-risk community, has free parking and is on a bus line. South Pointe Hospital has a positive reputation within the community with an emphasis on addressing health and wellbeing in Warrensville Heights, OH, and surrounding communities.
- The event was marketed/advertised using community favored stakeholders and various media platforms (radio, flyers at barbershops and other trusted community organizations, mailers).

Protocol:

- All patients were given an educational presentation about PCS, including all aspects of IDM, aimed at increasing the patient's ability to make an informed decision regarding PCS.
- Pre/post-tests were given to evaluate improved knowledge about PCS.
- After the educational intervention, patients had the option to complete free (grant-funded) same day screening (PSA/ DRE) onsite.
- Patients were navigated after the event to ensure appropriate follow-up according to screening results.

4. Outcomes

1. The test consisted of 15 questions to give information about the risks/benefits of PCS. The analysis resulted in a median improvement of +3. (Median Pre=9 Post=12)
2. The majority of patients (85%) indicated they wanted screening.
3. Overall, 82% of patients favored IDM before screening.
4. Most patients (73%) found the information "very helpful" (within a 5-point Likert scale) in decision-making.

5. Lessons Learned

Lessons Learned:

- The Research Coordinator is vital to the success of community outreach studies.
- AA men are willing to participate in research studies when they understand study objectives and feel supported.
- Our education-based IDM model led to significant improvement in knowledge about prostate cancer screening.
- Most patients preferred education prior to screening. Our approach, paired with the use of a navigation program, is feasible and was positively received by a large high-risk group.

Future Directions:

- Offering studies that compare the IDM model to shared decision making among high-risk AA communities.
- Use this research model at other locations and tailor it to address other disease sites.



CRACK THE WALNUT! How Community Outreach Research Coordinators Can Empower African American Men To Come Out Of Their Shell To Make An Informed Decision About Prostate Cancer Screening, A Cancer Prevention Project.

Kimberlee Hunt, M.S.; Carol Moss Chapman; Eileen Meisler, RN; Debra Allen; Aqeel Seals; Nasheema Anderson; Kimberly Sanders, MPA; Samir Abraksia, MD | Cleveland Clinic Taussig Cancer Institute



BACKGROUND

American Cancer Society acknowledges the importance of an informed decision-making (IDM) process for prostate cancer screening (PCS). Prostate cancer incidence is 1.6 times higher in African American (AA) men compared to Caucasians, with mortality rate 2.4 times higher. AA men are frequently diagnosed with advanced stage, because they're less likely to have screenings. Discussing advantages/disadvantages of PCS increases awareness, but many physicians find it difficult to provide comprehensive, unbiased education to patients. PCS outreach programs with an investment in patient navigation are needed to empower AA men about their choices and increase informed decision making. To reach these objectives, a project was developed to assess "Education and informed decision making for prostate cancer screening in a high-risk African American community".



GOALS

- (A). To improve knowledge of prostate cancer in a high-risk population.
- (B). To empower men to make an informed decision about prostate cancer screening and provide information about risks/benefits of PCS.

SOLUTIONS/METHODS

Hosting the research project:

- Research Coordinator was responsible for overseeing different aspects of the program. Working closely with medical residents, researchers, physicians, navigators, patients and managing data entry.
- A research project was conducted during the "For Men Only" health fair, where only men can participate to foster an environment of comfort and safety.
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Protocol:

- All patients were given an educational presentation about PCS, including all aspects of IDM, aimed at increasing the patient's ability to make an informed decision regarding PCS.
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OUTCOMES

1. The test consisted of 15 questions to give information about risks/benefits of PCS. Analysis resulted in median improvement of +3. (Median Pre=9 Post=12)
2. Majority of patients (85%) indicated they wanted screening.
3. Overall, 82% of patients favored IDM before screening.
4. Most patients (73%) found the information "very helpful" (within a 5-point Likert scale) in decision-making.



LESSONS LEARNED

	<p>The Research Coordinator is vital to the success of community outreach studies.</p>
	<p>African American men are willing to participate in research studies when they understand study objectives and feel supported.</p>
	<p>Our education-based IDM model led to significant improvement in knowledge about prostate cancer screening.</p>
	<p>Most patients preferred education prior to screening. Our approach, paired with the use of a navigation program, is feasible and was positively received by a large high risk group.</p>

FUTURE DIRECTIONS

- Offering studies that compare IDM model to shared decision making among high-risk AA communities.
- Use this research model at other locations and tailor it to address other disease sites.

* **Completing the Circle: Lay Summary of Protocol Results for Study Participants**

V. Santana, D. Wallace, D. McGarry, E. Walker, L. Tanner, J. English

Comprehensive Cancer Center, St. Jude Children's Research Hospital

1. Background

The success of clinical trials includes developing strong, valued partnerships with participants and their families through the life cycle of a study. Our Patient Family Advisory Council (PFAC) which embodies our community of patients and families identified the inability to communicate study results to participants as an important gap in this relationship. We developed and implemented a project to provide a lay summary of study results to patients and families through the St. Jude web portal.

2. Goals

Our goal was to define a process that would result in a web-based solution working with multiple stakeholders that included the Communications Department, the Patient Experience Office, the Biomedical Library, the St. Jude clinicaltrials.gov coordinator, the Internet Team and investigators. The initial scope was limited to St. Jude-initiated clinical trials that have published peer-reviewed results and have an NCT number. The aim was to provide lay summaries of study results that were consistent in format and content, written in lay language and that outlined the study's key findings. We sought the input of the PFAC in assessing the relevance of the content structure and how well it would communicate information that was understandable and aligned with their needs. To address the ethnic diversity of our patient population, we also aimed to have the lay summaries posted in English and Spanish.

3. Solutions and Methods

We defined a structured content for each summary, which included the following domains: why the study was done, when it was done, what the study consisted of, what we learned from it, what the next research steps were as a result of that study, how the study's findings affected the patient, whom should be contacted for more information, and where the results were published. We defined a stepwise process, including a decision tree of which studies would qualify for lay summaries and the stakeholder handoffs. See Figure 1.

4. Outcomes

The project was completed in 5 months. Currently, 18 lay summaries in both English and Spanish are available through the St. Jude website. We developed a communication strategy that included input from the Patient Family Advisory Council to bring awareness of this initiative and to alert parents about the availability of study results.

5. Lessons Learned

Working with the Internet Team, we plan to provide greater awareness and optimization of content by employing additional tools to provide a search-engine function based on study title/mnemonic, notification when there is a new posting, and monitoring metrics of impact (survey, website use, etc.).

Completing the Circle: Lay Summary of Protocol Results for Study Participants

Diane McGarry, M.S.B.I.; Elizabeth Walker, M.Ed.; Dana Wallace, M.S.; Leigh Tanner, M.S.; Janice English, M.S.N.; Victor M. Santana, M.D.

Why have lay summaries of protocol results?

The success of clinical trials (protocols) includes developing strong, valued partnerships with participants and their families through the life cycle of a study. Our Patient Family Advisory Council identified the inability to communicate study results to participants as an important gap in this relationship. We developed and implemented a project to provide a lay summary of study results to patients and families through the St. Jude website. Providing our families with a lay summary of protocol results not only meets a need, it also creates a deeper bond between our families and our research. Figure 1.

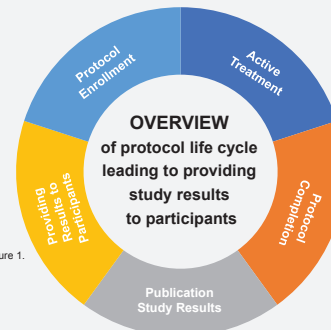
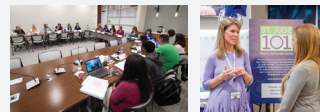


Figure 1.

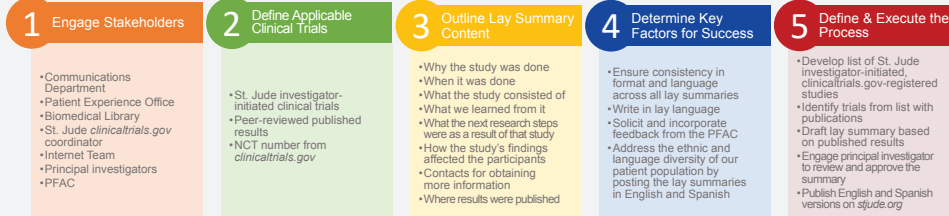


What is the Patient Family Advisory Council?

The Patient Family Advisory Council (PFAC), comprised of parents of St. Jude patients, represents the patient and family community and partners with our staff to enhance patient family-centered programs at St. Jude. The St. Jude Comprehensive Cancer Center works closely with the PFAC, seeking their input and feedback on research ideas, as well as community needs, and providing education about clinical trials.

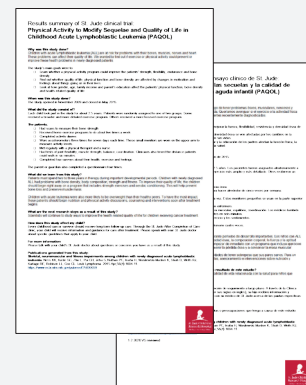


How did we do it?



What has been accomplished?

Currently, 18 lay summaries in both English and Spanish are available through the St. Jude website.



How are the lay summaries communicated to the study participants and their families?

- Surveyed PFAC members on their knowledge of this new initiative
- Featured in **Your Voice** parent newsletter
- Increased accessibility by providing information and links to the summary at multiple locations
 - a. Education section of the patient/parent app
 - b. Patient/Family Advisory Resource Section of the St. Jude website

What's next?

- Optimize our search engine on the St. Jude website so the results from a particular study can be easily found
- Explore ways to notify when there is a new clinical trial result posting
- Assess impact through surveys and website hits

A Quick Guide to Affiliate and Satellite Site Activation and Oversight Process

G. Nachaegari

Huntsman Cancer Institute, University of Utah

1. Background

In current clinical research scenario, there is an emerging need for Community Outreach and Engagement. The simplest way is to expand clinical research program to facilities within the same financial and legal entity (satellite sites) and to facilities that are financially and legally independent (affiliate sites). In implementing this process, parent sites often face several logistical challenges. After activating multiple satellite and affiliate sites, HCI has developed a step-by-step guide for successful site activation.

2. Goals

The main goals of this process are:

- Time: Faster activation
- Effort: Streamlined process with reduced resource burden
- Process: Defined process development
- Oversight: Ensuring quality, ethics and compliance

3. Solutions and Methods

HCI developed a quick guide as described below and established an Affiliate Site Committee to implement and oversee the process for National Cancer Institute (NCI) trial activation. Steps listed in the guide were followed during HCI's two most current NCI-aligned affiliate site activations, and were found efficient.

4. Outcomes

Utilizing this process resulted in

- Drastically reduced time to site activation
- A smoother and streamlined process for parent institution and other sites
- Quality clinical trials in compliance with regulations and requirements

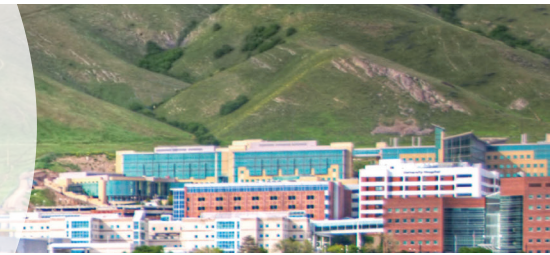
5. Lessons Learned

Future prospects

- Additional steps to streamline operational logistics
- Develop tools to quantify and assess parent and affiliate institute effort
- Utilize efficiency gained to venture into additional clinical trial opportunities (e.g. IIT and Industry trials at affiliate sites)

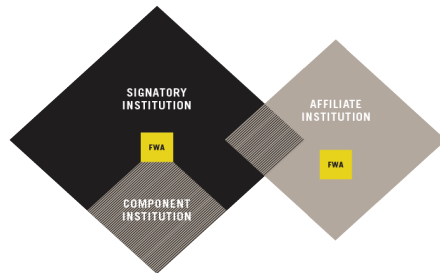
A Quick Guide to Affiliate and Satellite Site Activation and Oversight Process

Gayatri Nachaegari, M.Pharm, CCRP
Huntsman Cancer Institute at the University of Utah



BACKGROUND

In current clinical research scenarios, there is an emerging need for community outreach and engagement. The simplest way for a signatory/parent institution to achieve this would be to expand clinical research programs to satellite sites/component institution (facilities within the same financial and legal entity) and to affiliate sites (facilities that are financially and legally independent). In implementing this process, parent sites often face several logistical challenges. After activating multiple satellite and affiliate sites, HCI has developed a systematic guide for successful site activation.



GOALS

The main goals of this process are

- Time: Faster on boarding time
- Effort: Streamlined process with reduced resource burden
- Process: Defined process development
- Oversight: Ensuring quality, ethics, and compliance

STRATEGY IMPLEMENTED

HCI developed a quick guide as described below and established an Affiliate Site Committee to implement and oversee the process for National Cancer Institute (NCI) trial activation. Steps listed in the guide were followed during HCI's two most recent NCI aligned affiliate site activations and were found efficient.

Approximate Timelines/ Comments	Steps	Approximate Timelines/ Comments
Same legal entity so N/A	Establish legal agreement covering responsibilities of parent and affiliate sites relating to conduct of clinical trials	1- 2 months
Gather and assess information on resources and preparedness, provide direction to the site.	Ensure Adequacy of Key Infrastructure Adequate and qualified staff Facility and resources <ul style="list-style-type: none"> o Specimen processing capabilities o EMR compliance (21 CFR part 11) o Investigational pharmacy services o Radiation facility 	Gather and assess information on resources and preparedness, provide direction to the site.
1 month	Help sites fulfil clinical research requirements of Federalwide Assurance (FWA), Office for Human Research Protections (OHRP), NCI, Lead Protocol Organization (LPO) Membership (e.g. SWOG, Alliance or NRG)	3-4 months
Same as parent institute, so no lag phase	Support fulfillment of Regulatory requirements: NCI- CIRB affiliate site memberships: <ul style="list-style-type: none"> o CIRB authorization agreement o Annual signatory & PI worksheet submission o Boilerplate language addition o Ancillary policies and SOPs submission to CIRB: <ul style="list-style-type: none"> ▪ HIPAA ▪ Conflict of Interest ▪ Biosafety ▪ Radiation safety 	3-4 months
Same as parent institute, so no lag phase	Provide operational logistics <ul style="list-style-type: none"> o Training – Investigator & Research Staff o Policies and SOP development o Regulatory requirements o Finance management o Trial coordination support o Specimen processing 	6-9 months initially and ongoing support thereafter

OUTCOME

Utilizing this step by step process resulted in

- Drastically reduced time to site activation
- A smoother and streamlined process for parent institution and other sites
- Establishing quality clinical research in compliance with regulations and requirements

FUTURE DIRECTIONS

Works that are in progress:

- Additional steps to streamline operational logistics
- Develop tools to quantify and assess parent and affiliate institute effort
- Utilize efficiency gained to venture into additional clinical trial opportunities (e.g., IIT and Industry trials at affiliate sites)

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The Challenges and Successes of Enrolling Participants on the Tomosynthesis Mammographic Imaging Screening Trial (TMIST or study EA1151) in Hawaii's Minority/Underserved NCI Community Oncology Research Program (M/U NCORP)

S. Cheng¹, S. Wakuk¹, S. Lieu¹, N. Ramos¹, K. Bryant-Greenwood¹, K. Cassel¹, J. Berenberg¹, M. Ka'aihue², R. Lee², E. Capps²

¹University of Hawai'i Cancer Center, University of Hawai'i at Mānoa; ²Queen's Medical Center

1. Background

The University of Hawaii Cancer Center (UHCC) and our M/U NCORP does not have its own hospital or ambulatory treatment facility and instead enrolls patients through a formal affiliation with local hospitals (Hawaii Cancer Consortium). ECOG-ACRIN EA1151 "TMIST" (digital mammography vs tomosynthesis) is one such enrolling trial currently open at a single consortium site, the Women's Health Center (WHC) of The Queen's Medical Center (QMC) in Honolulu. Hawaii's population is highly diverse and ethnic minority enrollment to TMIST ensures study findings are universally applicable. It is of particular interest for our team to enroll as many women in our community as possible, especially Native Hawaiians and other Pacific Islanders. Accrual barriers that we overcame included increased workload vs staff available, cultural sensitivity, language, and lack of access to healthcare.

2. Goals

- Increase number of participants enrolled onto the study
- Enroll more Micronesian participants as these groups have the lowest frequency of mammography screenings in Hawai'i
- Provide resources to those who are uninsured or without a primary care provider (PCP)
- Provide education about clinical trials and the TMIST study within our community

3. Solutions and Methods

- Increase recruitment efforts by soliciting help from volunteers, engaging CRAs, and calling patients a few days before their scheduled mammogram.
- Work closely with the WHC Patient Navigator/ BCCCP Coordinator to ensure participant's coverage for tomosynthesis and referral to a PCP.
- Partner with the National Cancer Institute's Center to Reduce Cancer Health Disparities and administrative supplement P30 to further assist underserved populations.
- Collaborate with a community health educator and focus on three implementation methods:
 - o One-on-one recruitment
 - o Collaboration with community leaders to plan educational events
 - o Hand out flyers and provide flip chart presentations at community events
- Use of translated documents (consent form and powerpoint) in Marshallese and Chuukese

4. Outcomes

Since the trial opened in June 2018, our site enrolled 241 participants. About 46% of enrollees are Asian, 23% are Caucasian, 19% are Native Hawaiian or Pacific Islander, and most of the remaining 12% identify with two or more ethnic groups. Initially, recruitment procedures consisted of inserting a TMIST information and interest form into reminder letters for women to schedule routine mammograms. With this method, only 13% of recipients expressed interest and 3% enrolled onto the study. At that time, only 1 Micronesian woman had enrolled. After phone contact protocols were put in place in August 2019 to combat the low recruitment rate, the number of accruals increased by 42%. Additionally, our team conducted TMIST presentations at 15 events within the Micronesian community. As a result, 45 Micronesian women expressed interest, 6 have enrolled on the trial, and 6 are scheduled for their mammogram pending enrollment.

5. Lessons Learned

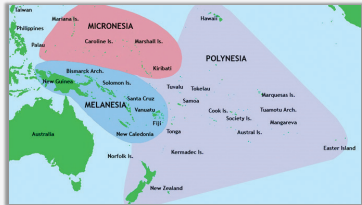
Creating a strong working structure among collaborators involved was crucial to enrolling a large number of women onto the study. Building good relationships with community leaders reinforced disease awareness and prevention. The TMIST team will continue to work towards increasing the number and diversity of TMIST participants in Hawaii as it offers an opportunity to enhance their access to screening and level of care.

The Challenges and Success of Enrolling Participants on the Tomosynthesis Mammographic Imaging Screening Trial (TMIST or study EA1151) in Hawaii's Minority/Underserved NCI Community Oncology Research Program (M/U NCORP)

Shirley Cheng, BS¹ ; Srue Wakuk, BA¹; Michelle Ka'aihue, BA²; Suzanna Lieu, BS¹; Nathan Ramos, BA¹; Kate Bryant-Greenwood, JD¹; Kevin Cassel, DrPH¹; Jeffrey Berenberg, MD¹; Rochelle Lee², Erin Capps, MD²
¹ University of Hawaii Cancer Center ² The Queen's Medical Center

Background

The primary aims of the EA1151-TMIST study is to compare 2D and 3D mammography in the detection of advanced breast cancer and develop ways to personalize breast cancer screening. The University of Hawaii Cancer Center is currently enrolling participants at the Women's Health Center housed in The Queen's Medical Center. The site on average conducts 400 screenings per week in the heart of Honolulu, Hawaii. Any woman between the ages of 45-74 with no history of breast cancer can participate.



In Hawai'i, a new wave of immigration is taking place as a result of the Compact of Free Association. These new immigrants, such as Micronesians, come from other parts of the Pacific and are under presented in clinical trials.

Despite Hawaii having no majority population, Micronesian populations experience disadvantages when accessing healthcare services, especially in breast cancer screening.

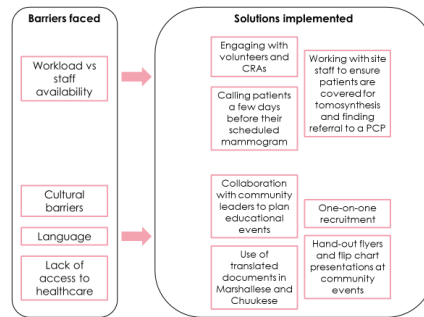
Breast Cancer Burden in Hawaii

- From 2012-2016, Hawaii had the 5th highest incidence rate of breast cancer (female) in the US². In the same time period, breast cancer incidence and mortality rates in Hawaii were highest in Native Hawaiians³.
- Other Pacific Islanders followed by Native Hawaiians represent the highest percentage of women that have never had a mammogram⁴.
- Only 26% of Micronesian women 40 and older had ever had a mammogram¹.

Goal

Increase the overall accrual of participants onto the TMIST study and the accrual of minority women focusing on the Micronesian population.

Methods

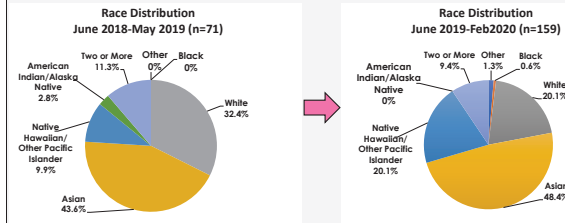


A. Numbers of Accruals Before (n=71) vs After Community Outreach and Phone Contact Project Initiated (n=159)

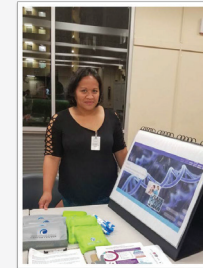
Jun 2018	Jul 2018	Aug 2018	Sep 2018	Oct 2018	Nov 2018	Dec 2018	Jan 2019	Feb 2019	Mar 2019	Apr 2019	May 2019
1	10	4	1	0	2	4	6	8	12	13	10

Jun 2019	Jul 2019	Aug 2019	Sep 2019	Oct 2019	Nov 2019	Dec 2019	Jan 2020	Feb 2020	Mar 2020	Apr 2020	May 2020
4	34	24	15	12	7	16	28	19			

B. Accruals by Race Before vs After Community Outreach and Phone Contact Project Initiated (n=230)



Results



Since the trial opened in June 2018 until February 2020 our site enrolled a total of 230 participants. During the first year of recruitment, responses and accruals were relatively low. After community outreach efforts (C) were initiated in June 2019 and phone contact protocols began in August 2019 the diversity of participants expanded (A) and the number of accruals increased (B). The picture on the left is Srue Wakuk, community health educator, at a Chuukese community gathering.

C. Community Outreach Outcomes



Summary

- Collaborating with a community health educator with the same cultural background as the population that you are working with provides patients with improved access to healthcare services and may increase the likelihood of enrolling patients onto a clinical trial.
- Building a strong network with our partner site and community leaders was essential to recruiting minority women and providing health education and disease awareness.
- We will work towards expanding our community outreach efforts along with utilizing translated documents and increasing the number and diversity of TMIST participants.

References

- Aifaoto N et al. Design and results of a culturally tailored cancer outreach project by and for Micronesian women. *Prev Chronic Dis*. 2012;9:E82. doi:10.5888/pcd9.100262
- Breast Statistics. American Cancer Society - Cancer Statistics Center. [cancerstatisticscenter.cancer.org/#/cancer-site/Breast](https://www.cancerstatisticscenter.cancer.org/#/cancer-site/Breast)
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- Mammogram - had mamm, for the State of Hawaii, for the Year(s) - 2011, 2012, 2013, 2014. Hawaii Health Data Warehouse; Hawaii State Department of Health, Behavioral Risk Factor Surveillance System.

The Reinvigoration of Alliance Membership and Accrual: From Almost Losing Membership to a High-Performing Site in 2 Years

M. Russell, D. Kitterman, O. Danciu, J. Quigley
University of Illinois Cancer Center

1. Background

The University of Illinois Cancer Center (UICC) experienced repeated years of low accruals. Over calendar year 2017, as part of an effort to apply for cancer center designation, the UICC Clinical Trials Office (CTO) underwent a complete reorganization. In January 2018, the UICC received a warning letter for not meeting required minimum accrual to maintain Alliance membership. The UICC was given until the end of 2018 to increase accrual to the required three (3) year minimum or lose main membership and have to affiliate with another main site.

2. Goals

Increase accrual to Alliance trials from an average of approximately 5 accruals per year to a three year total of 45 accruals over a 3 year period (representing a minimum of 15 accruals per year, or 35 accruals in a single year to make up for low accrual in the previous 2 years).

3. Solutions and Methods

In response to the warning letter, the UICC CTO implemented an action plan to increase accrual. Changes implemented included opening all appropriate Alliance and AFT trials, re-focusing principal investigators on Alliance and AFT trials already open, and carefully selecting the right trials for the UICC patient population. Additional changes implemented, both in response to the warning letter and as part of structural changes in anticipation of applying for NCI designation included: Increasing CTO resources and decreasing CTO staff turnover, decreasing study start time through concentrating study start-up with a start-up analysis and making process and policy changes, implementing disease teams, PRC accrual monitoring and feasibility reviews to assure the appropriate studies are opened and to review barriers to accrual, address accrual barriers for the UICC subject population such as providing transportation and meal vouchers to participants, and implementing screening processes to assure that all patients are screened for available studies.

4. Outcomes

In January 2019 the UICC was approved to maintain membership after increasing accrual from 4 in 2016 and 5.5 in 2017, to 29.2 in 2018. This was a 430% increase between 2017 and 2018. Approval to continue Alliance membership was contingent upon achieving 15 or more accruals in 2019. In 2019, the UICC was credited with 33.75 Alliance accruals for a 3 year total of 80.45 for 2017, 2018, and 2019 representing a 387% increase from the total enrolled in the previous two years. In October 2019, NTCN designated UICC as a high performing Alliance site.

5. Lessons Learned

Lessons learned:

- Regular meetings/discussions with PIs is critically important as is having a dedicated clinical trials office staff.
- Adequate resourcing is critical
- Centralization of start-up tasks and disease focused teams is a more efficient organizational structure
- Data driven decision making, and assuring correct data used for all decision making, allows corrections to be made prior to major effects experienced
- Meaningful faculty discussion at disease team meetings is critical to decision making and implementation of studies

Future directions:

- Further adjustments to organizational structure
- Maintain adequate staffing in the face of space challenges
- Further pair down and be more selective with studies opened
- Apply lessons learned to develop a vigorous AYA program

Minority Accrual to Therapeutic Clinical Trials

M. Russell, D. Kitterman, O. Danciu

University of Illinois Cancer Center

1. Background

The demographics of newly diagnosed cancer patients in the catchment of the University of Illinois Cancer Center (UICC) is 24% African American and 11% Hispanic. Nationally, treatment clinical accrual to these two groups is very low with 6% for African Americans and 3% for Hispanic populations. UICC strives to have therapeutic accrual demographics at least as diverse as the demographics of cancer patients in the UICC catchment area, with a goal to match the diversity of UICC's patient population.

2. Goals

In 2016, the UICC clinical trials office enrolled 29% African American and 15% Hispanic patients into therapeutic clinical trials. Though nationally the demographics of clinical trial participants is far less diverse than the population diagnosed with cancer (Duma N, et al. Representation of Minorities and Women in Oncology Clinical Trials: Review of the Past 14 Years. Journal of Oncology Practice, January 1, 2018), UICC's goal is to enroll a proportion of participants into our therapeutic clinical trials at least as diverse as our patient population.

3. Solutions and Methods

Strategies implemented to increase the diversity of UICC's therapeutic clinical trial population include:

- Maintaining a diverse workforce, including native Spanish speakers
- Providing transportation to study visits
- Selecting and designing trials appropriate for the characteristics of UICC's patient population:
 - o Greater proportion of latter stage disease
 - o Finding trials for specific types of diseases (more triple negative breast cancer, etc.)
 - o Not taking studies with limits on comorbidities/life style issues which do not significantly affect study outcomes (HIV, upper age if otherwise healthy, etc.)
- Development and implementation of clinical trial education materials specifically highlighting the importance of the diverse participation in clinical trials.

4. Outcomes

In 2016, the participants enrolled into UICC therapeutic clinical trials was 22% African American and 20% Hispanic. By 2019, the proportion of African American therapeutic clinical trial participants increased to 41% and Hispanics had increased to 27%, which exceeds the diversity of newly diagnosed cancer patients in our catchment area (24% African American and 11% Hispanic) and approximates the diversity of UICC newly diagnosed cancer patients (42% African American and 18% Hispanic).

5. Lessons Learned

- Ensure that we are picking the right trials for our population
- Continue and expand clinical trial education efforts
- Ensure proper support of non-English speaking patients including multi-lingual clinical trial staff and other resources
- Shift focus to increasing the retention





TRIAL START-UP AND ACTIVATION

* The Road to 90

M. Kelley, K. Donahue, M. Gorno, S. Bigelow, R. Jarrard, P. Dykema, R. George, V. Davis, V. Gorden
Barbara Ann Karmanos Cancer Institute, Wayne State University

1. Background

Study activation within 90 calendar days has been a priority for the KCI Clinical Trials Office (CTO) since the NCI Operational Efficiency Working Group (OEWG) directive was released in the 2000s. In early 2019, a task force was established to evaluate the activation process with a goal of modifying current workflows to maintain a consistent 90 day activation median for new studies. In order to make these changes, the task force recognized the need for institutional leadership support for interdepartmental workflow changes.

2. Goals

The primary goal was to decrease the activation timeline to 90 calendar days as defined by Protocol Review and Monitoring Committee (PRMC) submission to activation (open to accrual). Rate limiting steps needed to be defined and categorized by responsible department. In addition, the task force aimed to increase interdepartmental communication and collaboration.

3. Solutions and Methods

The CTO reviewed a diverse subset of the KCI study portfolio activated in 2018. The rate limiting steps were identified, which included: receipt of required documents, consent preparation and review, IRB review, budget & contract review and Site Initiation Visit (SIV) requirements. Data related to these steps was used to develop recommendations and subsequently presented to institutional leadership. The presented recommendations were approved and introduced to the CTO as the “Road to 90” initiative in April 2019.

The following changes were implemented:

- Enforced receipt of necessary study documents prior to PRMC submission
- Consent, budget and contract study activation processes were amended
- Expanded use of OnCore® task lists across departments to track key milestones
- Addition of two activation coordinators to facilitate communication and timely completion of required steps
- Streamlined and optimized the activation of protocols throughout the KCI Network
- Increased frequency of collaborative meetings with the local IRB to communicate newly defined goals and review progress
- Developed and revised policies and procedures to support this initiative

4. Outcomes

The changes implemented resulted in a dramatic decrease in the CTO’s monthly activation timeline (Attachment 1). Additionally, the initiative improved internal and external communication and collaboration. The “Road to 90” initiative has been adopted as an institutional goal and continues to be supported by leadership throughout the KCI Network. A welcomed outcome that resulted from this initiative included a well-defined “Road Map” to support the activation of studies in the required timeframe. The addition of protocol activation coordinators allowed the CTO to globally track specific steps of activation using enhanced task lists within OnCore® and identify potential roadblocks.

5. Lessons Learned

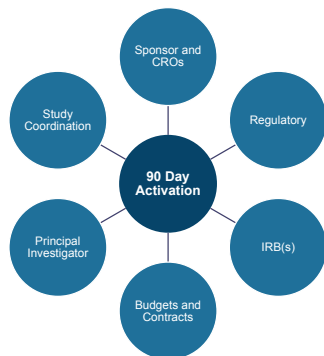
Optimal staffing levels and qualifications played a pivotal role in the success of the initiative. In addition, institutional leadership support was abundant since the inception of the proposed process changes. Real time task list completion allowed for accurate tracking of activation metrics. These metrics provide the CTO with a plethora of data to aid in continued efforts to improve collaboration between all involved stakeholders. The CTO established specific timelines to successfully activate trials within 90 days; however, unanticipated sponsor delays continue to impact these efforts. The CTO continues to track these trends and review the robust data accordingly for continued process improvement.

Background

Study activation within 90 calendar days has been a priority for the KCI Clinical Trials Office (CTO) since the NCI Operational Efficiency Working Group (OEWG) directive was released in the 2000s. In early 2019, a task force was established to evaluate the activation process with a goal of modifying current workflows to maintain a consistent 90 day activation median for new studies. In order to make these changes, the task force recognized the need for institutional leadership support for interdepartmental workflow changes.

Metrics and Goals

The primary goal was to decrease the activation timeline to 90 calendar days as defined by Protocol Review and Monitoring Committee (PRMC) submission to activation (open to accrual). Rate limiting steps needed to be defined and categorized by responsible department. In addition, the task force aimed to increase interdepartmental communication and collaboration.

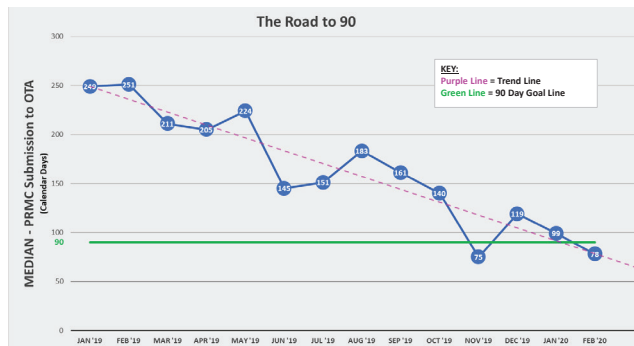


Solutions and Methods Implemented

The CTO reviewed a diverse subset of the KCI study portfolio activated in 2018. The rate limiting steps were identified, which included: receipt of required documents, consent preparation and review, IRB review, budget & contract review and Site Initiation Visit (SIV) requirements. Data related to these steps was used to develop recommendations and subsequently presented to institutional leadership. The presented recommendations were approved and introduced to the CTO as the “Road to 90” initiative in April 2019.

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Outcome

The changes implemented resulted in a dramatic decrease in the CTO’s monthly activation timeline. Additionally, the initiative improved internal and external communication and collaboration. The “Road to 90” initiative has been adopted as an institutional goal and continues to be supported by leadership throughout the KCI Network. A welcomed outcome that resulted from this initiative included a well-defined “Road Map” to support the activation of studies in the required timeframe. The addition of protocol activation coordinators allowed the CTO to globally track specific steps of activation using enhanced task lists within OnCore® and identify potential road blocks.



Lessons Learned and Future Direction

Optimal staffing levels and qualifications played a pivotal role in the success of the initiative. In addition, institutional leadership support was abundant since the inception of the proposed process changes. Real time task list completion allowed for accurate tracking of activation metrics. These metrics provide the CTO with a plethora of data to aid in continued efforts to improve collaboration between all involved stakeholders. The CTO established specific timelines to successfully activate trials within 90 days; however, unanticipated sponsor delays continue to impact these efforts. The CTO continues to track these trends and review the robust data accordingly for continued process improvement.

Redefining Clinical Trial Start-up Through Continuous Improvement

A. McCorkle, L. Mooney, M. Kilbane
Cleveland Clinic Cancer Center

1. Background

Clinical trial start-up is a multifaceted process that occurs across a diversity of disciplines. Health systems must support caregivers by providing the appropriate tools, resources and training to promote timely execution of study activation. Eliminating bottlenecks in the activation process is critical to opening new studies quickly and efficiently and to providing patients the best possible treatment options. The objective of this project was to identify barriers within the current state activation process; then create new processes, tools, standards and trainings for an ideal state; and finally implement a future state workflow designed to reduce the total time to open a clinical trial.

2. Goals

A new activation target of 90 days (median) for all trial types, represents a 49% reduction from the baseline target of 175 days. A committee of 15-20 multidisciplinary research staff functioned as change agents and met bi-weekly for project updates, ideation and discussion. The project sponsor, owners and project manager collaborated with the committee to create a portfolio of 10-15 sub-projects with 90 day deadlines. These sub-projects addressed risks and concerns of the new activation process. A diagram aligned sub-projects to stakeholder feedback and monthly departmental meetings of 100+ research staff provided a platform for project updates and discussion.

3. Solutions and Methods

The project was completed in three phases. Phase One utilized value stream mapping to identify current workflows and highlight waste, processing time and lead time. Phase Two replaced the current linear workflow with three new workflows, one for each clinical trial type: Cooperative Group, Industry Sponsored and Investigator Initiated. These workflows were given new timelines of 60, 90 and 150 days, respectively. Phase Three involved the collection of feedback across the research department. Means of data collection included Crawford Slip Methodology, informal surveys, 1:1 meetings, team rounding, department meetings and a Kaizen event for new process roll out.

4. Outcomes

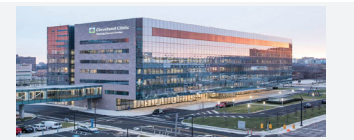
Results after the soft launch (Q3, 2019) showed a reduction to 178 days for the quarter, down from 210 days at baseline (Q1, 2019), a 15% decrease when comparing Q1 to Q3. Results after the full launch (Q4, 2019) showed a reduction to 150 days for the quarter, showing a near 29% reduction from baseline when comparing Q1 to Q4. The raw number of clinical trials that were activated in ≤ 90 days grew by 200% after full launch.

5. Lessons Learned

At the Cleveland Clinic Taussig Cancer Institute improving clinical trial start-up is a balance of meeting sponsor expectations, remaining competitive with comparable cancer centers and evaluating the internal needs of our stakeholders. The process of reaching an ideal state is iterative. Although the project is completed, we will continue to phase through the Plan Do Check Act cycle to evaluate gaps. Key components of the future strategy include 1) establishing a dedicated start-up team 2) developing a rewards and recognition system for meeting or exceeding targets 3) using clinical trial schemas to focus on gaps within disease groups 4) evaluating predictive tools for clinical trial accrual.

REDEFINING CLINICAL TRIAL START UP THROUGH CONTINUOUS IMPROVEMENT

Aaron McCorkle, Lindsey Mooney, Megan Kilbane



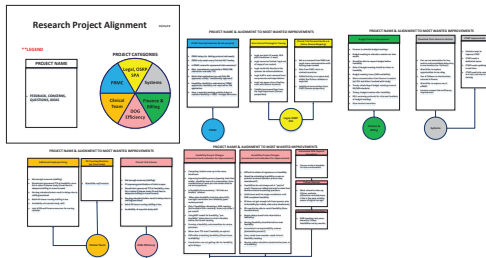
Background

Clinical trial start up is a multifaceted process that occurs across a diversity of disciplines. Health systems must support caregivers by providing the appropriate tools, resources and training to promote timely execution of study activation. Eliminating bottlenecks in the activation process is critical to opening new studies quickly and efficiently and to providing patients the best possible treatment options. The objective of this project was to identify barriers within the current state activation process; then create new processes, tools, standards and trainings for an ideal state; and finally implement a future state workflow designed to reduce the total time to open a clinical trial.



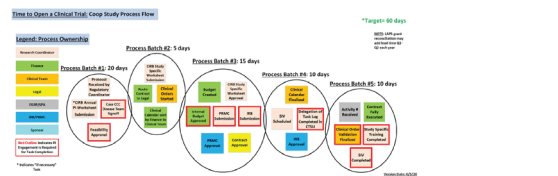
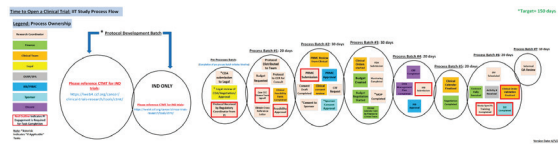
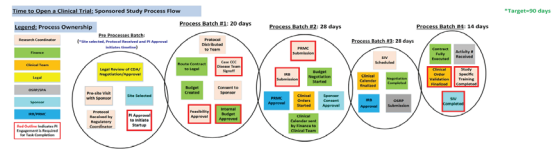
Metrics

- Set new activation target of 90 days (median) across all trial types (49% reduction from the baseline target of 175 days)
- Establish a committee of 15-20 multidisciplinary research staff
- Develop portfolio of 10-15 sub-projects for risk management
- Create diagram aligning sub-projects to stakeholder feedback



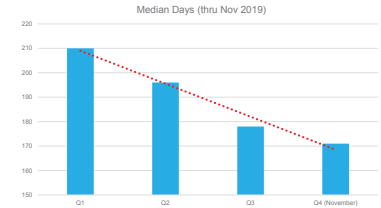
Methods

- The project was completed in three phases:
- Utilize value stream mapping to identify current workflows and highlight waste, processing time and lead time.
 - Replace current linear workflow with three new workflows: Cooperative Group, Industry Sponsored and Investigator Initiated clinical trials (60, 90 and 150 days, respectively)
 - Collect data across research department using Crawford Slip, informal surveys, 1:1 meetings, team rounding, department meetings and a Kaizen event for new process roll out.



Outcomes

Results after the soft launch (Q3, 2019) showed a reduction to 178 days for the quarter, down from 210 days at baseline (Q1, 2019), a 15% decrease when comparing Q1 to Q3. Results after the full launch (Q4, 2019) showed a reduction to 150 days for the quarter, showing a near 29% reduction from baseline when comparing Q1 to Q4. The raw number of clinical trials that were activated in ≤ 90 days grew by 200% after full launch.



Lessons Learned

At the Cleveland Clinic Taussig Cancer Institute improving clinical trial start up is a balance of meeting sponsor expectations, remaining competitive with comparable cancer centers and evaluating the internal needs of our stakeholders. Although the project is completed, we will continue to phase through the Plan Do Check Act cycle to evaluate gaps. Key components of the future strategy include:

- Establishing a dedicated start up team
- Developing a rewards and recognition system for meeting or exceeding targets
- Using clinical trial schemas to focus on gaps within disease groups
- Evaluating predictive tools for clinical trial accrual



Improving Study Start-up Timelines: A Comprehensive, Multidisciplinary, Process-Improvement Initiative

S. Skendzel, E. Orcholski, D. Krishnadas, R. Nicklow, M. Lindemann, M. Morris, J. Bruan

Masonic Cancer Center, University of Minnesota

1. Background

In the current era of rapid medical advancements in the treatment of oncologic disorders, there is increasing emphasis on shortening clinical trial study start-up (SSU) timelines in order to remain competitive. Consequently, the University of Minnesota Masonic Cancer Center Clinical Trials Office (CTO), like other large academic CTOs, faced increasing pressure from key stakeholders to shorten SSU. Underlying drivers have been limited enrollment opportunities for multicenter early phase trials, timely publication of investigators' novel therapeutic approaches, and pressure to move new drugs to market in advance of our sponsors competitors (Sertkaya, Birkenbach, Berlind, & Eyraud, 2014). Unfortunately, our SSU phase remains > 300 days, nearly twice the national target.

Shortening the SSU timeline is a multifaceted and largely heterogeneous problem across CTOs (Abbott D, Califf R, Morrison BW, Chakraborty S. 2013). In addition, there is very little published research regarding specific barriers to SSU, preventing identification of umbrella solutions from literature sources alone. Therefore, our multidisciplinary team of clinical research coordinators (CRC), registered nurses (CRC-RN), regulatory specialists (RS), program managers (PM), and administrative leadership conducted an internal root cause analysis (RCA) focused on critical time points in the start-up process. Several areas for improvement were identified. Presented here are recognized opportunities for change, critical timepoints, target timelines, collaborative process improvement strategies, and our evaluation metrics.

2. Goals

The primary objective of this quality improvement (QI) initiative was to improve SSU for complex investigator initiated clinical trials to < 180 days, and sponsor initiated or lower complexity trials to < 150 days. To achieve this, our multidisciplinary CTO team developed target timelines for each segment of the trial start-up phase of the project lifecycle.

3. Solutions and Methods

We discovered several barriers to efficient study activation. Once identified, focus groups were created to set goals and implement QI initiatives targeting each barrier. Groups consisted of collaborators from a wide cross section of our CTO; allowing team members to provide expertise based on their unique practice ontology and experiential knowledge base. Projects identified as having the greatest potential impact on SSU are outlined here.

- Enhanced collaboration to define the breadth of trial complexity early in the SSU process
- Identification of common barriers leading to prolonged hold times
- Optimization of site initiation visits (SIV) schedules
- Improved workflow to develop multi-linear approaches, split executions, and parallel conduction of SSU processes
- Enhanced investigator education regarding available resources, facilities and infrastructure for project development
- Standardized workflows and defined SSU document checklists
- Identification of minimally required sponsor documents critical to advance projects through SSU steps

4. Outcomes

Preliminary outcomes will be presented at the AACI CRI meeting in July, 2020

5. Lessons Learned

Collaboration, real-time communication, transparency, and standardized practices were fundamental to our collective improvement in SSU timelines, ultimately leading to the consideration of advanced technology based platforms for real-time communication between clinical staff and within our community of research staff. Furthermore, establishment of an agreed upon SSU timeline was a pivotal milestone in our progress towards shortening SSU. Finally, this extensive CTO-wide initiative also heightened our regard for transparency as we sought to align our shared paths.

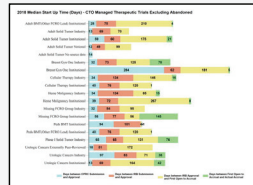
Authors: Sasha Skendzel, DNP, MSN, APRN, Erica Orcholski, CCRP, Deepa Krishnadas, Ph.D., Roby Nicklow, RN, Matthew Lindemann, RN, BAN, Markco Morris, Jennifer Braun, DNP, APRN

Objective

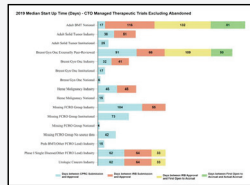
Objective: The primary objective of this quality improvement (QI) initiative was to improve Study-Start-Up (SSU) for complex investigator initiated clinical trials to < 150 days, and sponsor initiated or lower complexity trials to < 120 days. To achieve this, our multidisciplinary CTO team developed target timelines for each phase of SSU, then identified areas for improvement and methods by which we could target those barriers to improve SSU efficacy.

Background

Background: Shortening the SSU timeline is a multifaceted and largely heterogeneous problem across CTO's¹. In addition, there is very little published research regarding specific barriers to SSU, preventing identification of umbrella solutions from literature sources alone. Therefore, our multidisciplinary team of clinical research coordinators (CRC), registered nurses (CRC-RN), regulatory specialists (RS), program managers (PM), administrative leadership, and the Cancer Research Translational Initiative (CRTI) team conducted an internal root cause analysis (RCA) focused on critical activities in the SSU process. Several areas for improvement were identified. Presented here are recognized opportunities for change, critical time points, target timelines, collaborative process improvement strategies, and our evaluation metrics.



2018 Median SSU (Days)



2019 Median SSU (Days)

Approach

Approach: We discovered several barriers to efficient study activation. Once identified, focus groups were created to set goals and implement quality improvement initiatives targeting each barrier. Groups consisted of collaborators from a wide cross section of our CTO, allowing team members to provide expertise based on their unique practice ontology and experiential knowledge base.

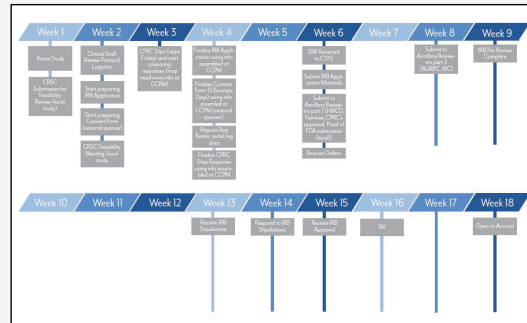
Cross-Functional Working Groups:

- **Reducing SSU Timelines:** Collaborate with internal and external CTO stakeholders to recommend and implement methods to reduce SSU
- **CRTI:** Translational mechanism connecting interdisciplinary teams across the Cancer Center and University to move translational studies from bench to bedside
- **Campus Wide Collaborators:**
 - Clinical Research Support Center: 360 feasibility review
 - Health Information Technology (HIT): Epic order production
 - Sponsored Projects Administration (SPA): Budgets and Contracts
 - Internal Review Board (IRB): Methods to reduce review timeline
- **Disease Focused Interdisciplinary Site-Specific Care (ISC) Teams:** Faculty-lead disease-focused groups to prioritize studies, identify & eliminate barriers, etc. including clinical and research representation.
- **Opening the Right Studies:** Establish guidelines for the CTO to follow when opening a trial to ensure successful implementation and conduct.

References

Choi YJ, Beck SH, Kang WY, et al. Knowledge and Perception about Clinical Research Shapes Behavior: Face to Face Survey in Korean General Public. J Korean Med Sci. 2016;31(5):674-681. doi:10.3346/jkms.2016.31.5.674

Process-Improvement



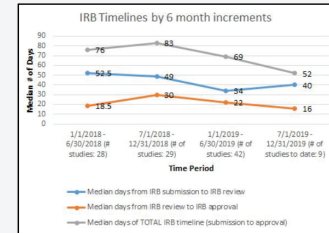
Goal Timeline for Study Activation (120 Days)

Initiatives

Initiatives: Established best practices with expected timelines for typical SSU tasks. Projects identified as having the greatest potential impact are outlined below.

- **Established Timelines:** Each new study is assigned a project timeline for major milestones during start-up.
- **Contingency Planning:** Implemented a contingency plan to obtain required information for regulatory applications if the investigator planning meeting is delayed.
- **Sponsor FAQ:** Assembled frequently asked questions from sponsors to provide SOPs and site information up front.
- **Timely Document Preparation:** Optimized timing of regulatory documents assembly, with the goal to prevent downstream delays due to pending signatures.
- **Optimized Timing of Ancillary Reviews:** Improved timing of departmental ancillary reviews which require sign-off prior to IRB review.
- **Engagement of Stakeholders Outside CTO:** Established mechanisms for setting priorities for efforts performed outside of the CTO
 - **HIT:** Partnered with HIT to improve timely Epic® order builds and production.
 - **SPA:** In collaboration with SPA developed standardized budget assumptions, built budget tools, and established labor guidelines to reduce time in negotiations.
 - **IRB:** Worked with IRB leadership to accelerate review timeline
- **Improved LOI Template:** Enhanced the draft letter of intent (LOI) template to reduce time spent in the budget and negotiations phase of SSU.
- **Targeted Preventable Amendments:**
 - **Investigator Initiated Trials:** Leveraged expertise of experienced Clinical Research Coordinators when developing local protocols to prevent delays caused by protocol amendments during start-up.
 - **Sponsored Studies:** Changed our policy to request holds on amendments that can wait until after initial IRB approval to avoid retraction and revision of the initial application.
- **Leveraged Technology:** Implemented FDA IND/IDE submissions, electronic signatures for regulatory documents, and invested in Electronic Data Capture Part 11 compliant technology.

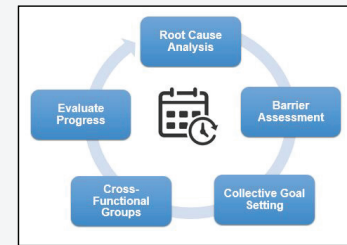
Evaluation



Median Change IRB Timelines: 01/01/2018-12/31/2019

Evaluation Metrics:

- Biannual evaluation of timelines
- Review of IRB specific time points
- Quarterly review of working-group project specific metrics and progress towards shared goals



Implementation and Evaluation Cycle

Key Insights

Lessons Learned:

- **Collaboration:** Integration of clinical and research teams for real-time communication, transparency, and standardized practices were fundamental to our collective improvement in SSU timelines.
 - Development of cross-functional working-groups
 - Development of organized ISC team structure as a multidisciplinary venue to discuss trial portfolios by disease
- **Technology:** Consideration of advanced technology based platforms for real-time communication between clinical staff and within our community of research staff.
 - Grant for SmartSheet®
 - Portable workstations for timely, remote communication
- **Goal Alignment:** Establishment of an agreed upon SSU timeline was a pivotal milestone in our progress towards shortening SSU.
- **Transparency:** This extensive CTO-wide initiative also heightened our regard for transparency as we sought to align our shared paths.

Enhancing Productivity: Utilizing the ONBASE Application and Pharmacist Created Order Sets to Streamline the Trial Launch Process

B. Secor, I. Reveles, D. Yzquierdo, A Rodriguez, M. Nashawati, M. Tomasini, P. Manea

Mays Cancer Center, UT Health San Antonio

1. Background

In the last year the University of Texas Health Science Center has experienced a substantial increase in the volume of clinical trials being submitted to the IRB, with each protocol requiring onboarding and EMR protocol validation. As a result, the process for protocol activation required restructuring to increase productivity and decrease time spent on order set approval. After breaking down each step in the workflow, two key processes were found to be the major contributors to inefficiency and errors:

- non-clinical staff developing medication order sets requiring multiple revisions by pharmacy
- using email to transmit and store trial related documents

The strategy was to remove these practices and replace them with more constructive means of communication and order development.

2. Goals

- Decrease time from IRB approval to protocol activation
- Reduce errors during order set development
- Improve ease of process and overall staff satisfaction

3. Solutions and Methods

A committee including members from Quality Assurance, the Investigational Drug Section, and Clinical Research team convened to establish a streamlined workflow for trial activation. The first task was to transition order set development from research coordinators to a dedicated research pharmacist. This allowed an individual with medication expertise to review protocols and build more precise medication order sets. An order template was created and required to be used for all protocol builds; this assured consistency and reduced errors caused by varying order form appearance and omission of critical information. The second step was to shift the management of all trial build requests and supporting documents to a single, trackable database. The application OnBase was selected for its ability to build a customized environment based on our desired workflow (flow chart attached). The application underwent testing to ensure all required information was captured and that the forms functioned properly prior to implementation.

4. Outcomes

The new process went live January 8th, 2020. Data collection to assess efficiency is still ongoing; however, four protocol activations have been completed under the new workflow. When compared to data from 34 studies initiated in 2019, the average time from order form submission to protocol activation has dropped by 23% (35 to 27 days). In addition, time from order form submission to approval has decreased by 60% (15 to 6 days). This suggests that pharmacist-created order sets require less revisions, and thus, result in faster approval times. We expect that as we continue to refine the process and collect additional metrics, we will be able to show a significant reduction in time from IRB approval to activation. A survey was conducted to assess staff satisfaction in the areas of efficiency, time consumption, error reduction, and submission ease. All areas scored 4.8/5 (5 being significantly better) except for error reduction, which scored a 4.5/5.

5. Lessons Learned

We learned that metric tracking is crucial in assessing the performance of process improvement measures. Historically this information wasn't adequately documented or pursued. In the future, Onbase use will be expanded to capture and provide automated metrics that will be reviewed on a quarterly basis to further improve the process.

Enhancing Productivity: Utilizing the ONBASE Application and Pharmacist Created Order Sets to Streamline the Trial Launch Process.

Britni Secor, PharmD; Ivan Reveles, PharmD; David Yzquierdo, CPhT;
 Angela Rodriguez; Melissa Nashawati; Patricia Manea, RN; Maggie Tomasini, RN

Background

In the last year, the University of Texas Health Science Center has experienced a substantial increase in the volume of clinical trials being submitted to the IRB, with each protocol requiring onboarding and EMR protocol validation. As a result, the process for protocol activation required restructuring to increase productivity and decrease time spent on order set approval. After breaking down each step in the workflow, two key processes were found to be the major contributors to inefficiency and errors:

- non-clinical staff developing medication order sets requiring multiple revisions by pharmacy
- using email to transmit and store trial related documents

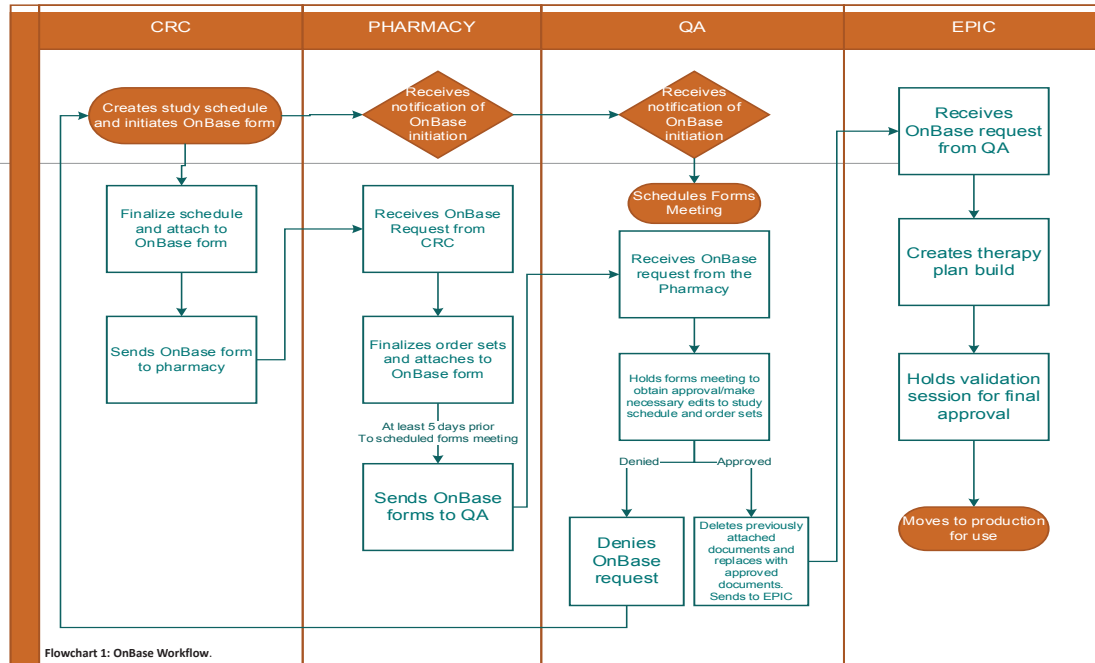
The strategy was to remove these practices and replace them with more constructive means of communication and order development.

Goals

- Decrease time from IRB approval to protocol activation
- Reduce errors during order set development
- Improve ease of process and overall staff satisfaction

Methods

A committee including members from Quality assurance, the Investigational Drug Section, and Clinical Research team convened to establish a streamlined workflow for trial activation. The first task was to transition order set development from research coordinators to a dedicated research pharmacist. This allowed an individual with medication expertise to review protocols and build more precise medication order sets. An order template was created and required to be used for all protocol builds; this assured consistency and reduced errors caused by varying order form appearance and omission of critical information. The second step was to shift the management of all trial build requests and supporting documents to a single, trackable database. The application OnBase was selected for its ability to build a customized environment based on our desired workflow (see flowchart). The application underwent testing to ensure all required information was captured and that the forms functioned properly prior to implementation.



Flowchart 1: OnBase Workflow.

Results

The new process went live January 8th, 2020. Data collection to assess efficiency is still on-going; however, four protocol activations have been completed under the new workflow. When compared to data from 34 studies initiated in 2019, the average time from order form submission to protocol activation has dropped by 23% (35 to 27 days). In addition, time from order form submission to approval has decreased by 60% (15 to 6 days). This suggests that pharmacist created order sets require less revisions, and thus, result in faster approval times. We expect that as we continue to refine the process and collect additional metrics, we will be able to show a significant reduction in time from IRB approval to activation. A survey was conducted to assess staff satisfaction in the areas of efficiency, time consumption, error reduction, and submission ease. All areas scored 4.8/5 (5 being significantly better) except for error reduction, which scored a 4.5/5.

Future Directions

We learned that metric tracking is crucial in assessing the performance of process improvement measures, something that wasn't adequately documented with the old process. In the future, Onbase use will be expanded to capture and provide automated metrics that will be reviewed on a quarterly basis to further improve the process.

Time to Activation: Are We Comparing Apples to Apples?

A. Skafel, K. Shumate

UCSF Helen Diller Family Comprehensive Cancer Center

1. Background

Time-to-activation is a key metric that the National Cancer Institute (NCI) and Sponsors use to evaluate centers when determining their ability to conduct and be successful in clinical trials. While centers aim to activate trials in 90-120 days, the literature reveals that majority of centers activate trials in around six months. Clinical Trials Office (CTO) staff are constantly seeking to learn practices from other institutions to improve time-to-activation, but it is difficult to understand where your center sits, compared to the targets, when definitions of time-to-activation, and methodologies to count days in the activation definition differ across centers. Through a survey to Cancer Center CTO staff, we sought to investigate the differences in time-to-activation definitions and metrics across the country.

2. Goals

1. Determine commonalities and differences in time-to-activation metrics used at Cancer Centers
2. Understand the situations where Cancer Centers may manipulate the time-to-activation calculations
3. Suggest best practices for time-to-activation definitions

3. Solutions and Methods

In February 2020, we sent a survey to the AACI-CRI listserv asking one representative to complete the 22-question survey about time-to-activation at their center. The survey inquired about time-to-activation definitions and goals for industry, institutional, national and externally peer reviewed trials. In addition to definitions used, questions included targets for time-to-activation, use of central or Cancer Center controlled resources for activation processes and, reasons for 'pausing' the time-to-activation clock e.g. FDA holds, sponsor delays, etc.

4. Outcomes

To date, 26 centers completed the survey. The majority of the centers were NCI-Designated Comprehensive Cancer Centers (76%) and operated a matrix unit within their institution (88%). 72% who responded activated more than 75 interventional trials in 2019.

For industry trials, 81% of responding centers started the clock at Protocol Review Committee/Scientific Review Committee (PRC/SRC) submission. The end time varied between receipt of sponsor activation letter, Institutional Review Board (IRB) approval, site initiation visit, and enrolment ready. All centers are targeting between 90-120 days to activate industry trials. Similar data was collected on institutional, national and externally peer-reviewed trials.

Almost half the centers (46%) remove extended holds (e.g. FDA), sponsor delays and PRC/SRC exempt studies (e.g. registries). Holds and sponsor delay criteria vary anywhere from 5-30 days depending on the center.

5. Lessons Learned

Given the inconsistency in time-to-activation definitions and methodologies used to count days in the activation definition, we are proposing a working group of NCI-Designated Cancer Centers to develop a best practice definition for time-to-activation, which can be endorsed by the NCI and reported by centers. The definition needs to use data points that are measurable at all NCI-Designated Cancer Centers and not be onerous on centers to collect. Additionally, the definition needs to reflect the true reality of opening a trial. Delays from all parties are inevitable, and the aim should be to implement practices to reduce delays where feasible. Ultimately, opening trials as quick as possible is a benefit to patients and science, but manipulating the metrics simply to demonstrate that you can meet arbitrary goals is an exercise in futility if the trial is not available to patients.

Time to Activation: Are we comparing apples-to-apples?

Andrea Skafel¹ MSc CCRP, Kate Shumate¹ MPA CCP

¹University of California San Francisco, Helen Diller Family Comprehensive Cancer Center



Background

Time-to-activation is a key metric that the National Cancer Institute (NCI) and Sponsors use to evaluate centers when determining their ability to be successful in clinical trials. While centers aim to activate trials in 90 to 120 days, the literature reveals that majority of Centers activate trials in around six months (1). Clinical Trials Office (CTO) staff are constantly seeking learned practices from other institutions to improve time-to-activation, but it is difficult to understand where a center sits, compared to the targets, when definitions for time-to-activation, and methodologies to count days in the activation definition, differ across centers.

Methods

In February 2020, we sent a survey to the AACI-CRI *listserv* asking centers to complete a 22-question survey about their methods to calculate time-to-activation at their center.

Table 1: Responding Center Characteristics

Characteristics of centers who responded to the AACI-CRI *listserv* survey

Center Characteristics	N=32
NCI designation	
Comprehensive Cancer Center	80%
Cancer Center	10%
No NCI Designation	10%
Cancer center structure	
Matrix	79%
Free-standing (with or without network sites)	21%
Number of Interventional trials opened (2019)	
< 50	10%
51-75	17%
>76	73%

Activation Definitions

For industry trials, 65% of responding centers start the clock at **Protocol Review & Monitoring Committee/Scientific Review Committee (PRMC/SRC) submission** and stopped the clock at **Open to Accrual**.

The remaining centers started at full-regulatory package received (18%), first-stage/disease committee review (6%), date of PRC/SRC acceptance (3%), date of PRC/SRC meeting (3%), and PRMC/SRC approval (3%). The end time varied between receipt of sponsor activation letter, Institutional Review Board (IRB) approval, site initiation visit, and enrolment ready.

Similar definitions are used for other sponsor trial types e.g. Investigator Initiated Trials. 94% of centers report time-to-activation in calendar days.

Centralized Activation

81% of centers (83% of matrix cancer centers) use a centralized office for pieces of the activation process. Only 44% of centers use the same activation definition as the rest of campus (i.e. centralized unit definition). Most centralized units calculate time-to-activation as intake into central unit to date contract signed, or do not track the overall metrics, and only track the time for individual components e.g. draft budget preparation and negotiation timelines.

Table 2: Centralized Resources for Matrix Cancer Centers
Percentage of responding matrix centers who use a centralized (campus) resource for components of the activation process.

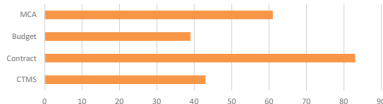


Table 3: Time to Activation Goals

Targets for time-to-activation by sponsor type

Time to Activation Goals	N=32
Industry Sponsored	
90 days	50%
90-120 days	42%
Other	8%
Institutional	
90 days	39%
90-120 days	45%
121-180 days	10%
Other	6%
National	
<90 days	52%
90 days	41%
>90 days	7%

Future Directions

Further exploration is required to understand how centers use the term "open to accrual". The data suggests that each center may interpret this phrase slightly differently e.g. time of site initiation visit, sponsor approval, or ability to accrue patients.

Given the inconsistency in time-to-activation definitions and methodologies used to count days in the activation definition, we are proposing a working group of NCI designated Cancer Centers to develop a best practice definition for time-to-activation, which can be endorsed by the NCI and reported by centers. The definition needs to use data points that are measurable at all NCI designated Cancer Centers and not be onerous on centers to collect. Additionally, the definition needs to reflect the true reality of opening a trial. Delays from all parties are inevitable and the aim should be to implement practices to reduce delays where feasible.

Reference:

¹Stewart S and Tate W (2019). Perspectives on Cancer Community Activation Timelines. Forte Ensemble Conference. Madison, USA.

Removing Studies

Centers remove trials (or a defined period) from their time-to-activation definition. Figures 1-3 below detail the common reasons to remove trials (or time periods) from their definitions. Other reasons include: abandon studies (remove data from metrics); extended holds causing re-review at PRMS are removed from timelines and re-started; and IITs with multiple sponsors (due to contracting difficulties).

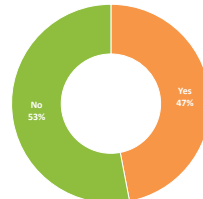


Figure 1: Extended Holds

Q. Do you remove extended holds (e.g. FDA) from the reported time-to-activation? For those centers who do remove holds, the majority of centers remove holds when the hold is outside of the cancer center's control e.g. drug delays, FDA holds, unresponsiveness from the sponsor.

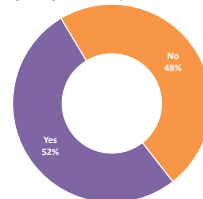


Figure 2: Exempt Studies

Q. Do you remove Protocol Review and Monitoring System (PRMS) exempt studies (e.g. registries) from your time-to-activation metric?

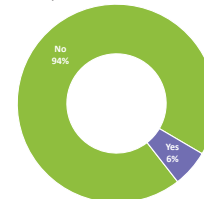


Figure 3: Mid-Activation Amendments

Q. Do you 'restart the clock' when mid-activation amendments arrive and the initial protocol has not been activated yet?

Reducing Burdens of Site Feasibility Assessments for Conducting Clinical Trials

L. Byatt¹, P. Hurley², C. Davis², J. Hofacker³, E.S. Kim⁴, D.M. Waterhouse⁵, G.S. Nowakowski⁶, D. Kurbegov⁷

¹University of New Mexico Comprehensive Cancer Center; ²American Society of Clinical Oncology; ³Association of American Cancer Institutes;

⁴Levine Cancer Institute, Atrium Health; ⁵Oncology Hematology Care, Inc.; ⁶Mayo Clinic Cancer Center; ⁷Sarah Cannon Research Institute

1. Background

Current methods to assess trial site feasibility for industry-funded clinical trials are onerous. Industry sponsors and contract research organizations (CROs) often probe for unnecessary and/or duplicative information and requests. There are initiatives underway that aim to streamline these assessments. However, the immediate benefit for trial sites is questionable. Centralized portals, for example, have potential but have imitations across clinical research scenarios and are facing increasing competition. The inefficiencies and variability across trials will continue to place undue burden on trial sites, particularly those with limited resources. Ultimately, patient access to novel treatment options is at risk.

2. Goals

The American Society of Clinical Oncology (ASCO) Research Community Forum convened a task force to assess the problem and develop strategies to address feasibility assessment challenges. This initiative provided an opportunity to develop an evidence base and leverage existing momentum in the broader research community to establish more effective approaches for qualifying trial sites.

3. Solutions and Methods

Data were collected in 3 initial steps: 1) survey to assess the extent of site burden, 2) database of sample feasibility questionnaires (FQs), and 3) stakeholder meeting to discuss potential solutions. The task force then developed recommended best practices and obtained stakeholder feedback through a survey.

4. Outcomes

113 oncology practices (66 community, 47 academic) reported completing 11 FQs and 4 pre-study site visits (PSSVs) on average per month. Each FQ took 4 hours and PSSVs took 10 hours on average to complete. All combined, respondents spent 113,904 staff hours on feasibility assessments per year. Most considered FQ and PSSV content redundant to information previously provided (81% and 91%, respectively); and FQs similar between different sponsors (86%). Insufficient trial documentation from sponsors and CROs pose challenges for sites completing FQs. The average time from first contact to first patient enrolled was 7 months.

There were 40 respondents to stakeholder feedback survey about recommendations for process improvements (Figure 1). Respondents represented 19 academic- and 9 community-based sites, 8 industry sponsors, and 4 CROs. Most preferred a model with a short FQ plus a PSSV when there was not a prior relationship. If there was a prior relationship, a PSSV or teleconference (only) was preferred. CRO respondents were the least supportive of these approaches. All stakeholders identified time savings, expedited start-up, fewer staff resources, and cost savings as the greatest benefits. The greatest barriers to adoption were buy-in from sponsors and CROs and insufficient site information.

5. Lessons Learned

Site feasibility assessments for industry-sponsored trials are important for all stakeholders. However, current methods are inefficient and time and resource intensive. Patient access to novel treatment options are hindered with trial delays and when sites are unable to participate in clinical trials due to resource constraints. This initiative helped elucidate challenges for sites and provided insights about the viability of a fundamental change with site feasibility assessments. In 2020, ASCO will release formal recommendations to address feasibility assessment burdens, including improving processes, standardizing and minimizing questions, and using portals that are effective across all trials and clinical research scenarios.

Reducing Burdens of Feasibility Assessments for Conducting Clinical Trials

Leslie Byatt¹, Patricia Hurley², Janie Hofacker³, Edward S. Kim⁴, David M. Waterhouse⁵, Grzegorz S. Nowakowski⁶, Courtney Davis², Dax Kurbegov⁷

¹University of New Mexico Comprehensive Cancer Center; ²American Society of Clinical Oncology; ³Association of American Cancer Institutes; ⁴Levine Cancer Institute, Atrium Health; ⁵Oncology Hematology Care, Inc.; ⁶Mayo Clinic; ⁷Sarah Cannon

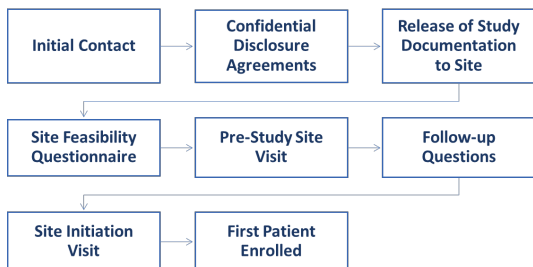
BACKGROUND

Current methods to assess trial site feasibility for clinical trial participation are perceived to be onerous. Figure 1 shows the key elements of the current feasibility assessment process. Industry sponsors and contract research organizations (CROs) often probe for unnecessary and/or duplicative information and requests. There are initiatives underway that aim to streamline these assessments. However, the immediate benefit for trial sites is questionable.

Centralized portals, for example, have potential but have limitations across clinical research scenarios and are facing increasing competition. The inefficiencies and variability across trials will continue to place undue burden on trial sites, particularly those with limited resources. Ultimately, patient access to novel treatments is at risk.

The American Society of Clinical Oncology (ASCO) Research Community Forum Task Force was formed to assess the problem and develop strategies to address feasibility assessment challenges. This initiative provided an opportunity to develop an evidence base and leverage existing momentum in the broader research community to establish more effective approaches for qualifying trial sites.

Figure 1. Current Key Elements of Site Feasibility Assessments



METHODS

Data were collected in 3 initial steps: 1) survey to assess the extent of site burden, 2) database of sample feasibility questionnaires (FQs), and 3) stakeholder meeting to discuss potential solutions. The task force then developed recommended best practices and obtained stakeholder feedback through a survey.

RESULTS

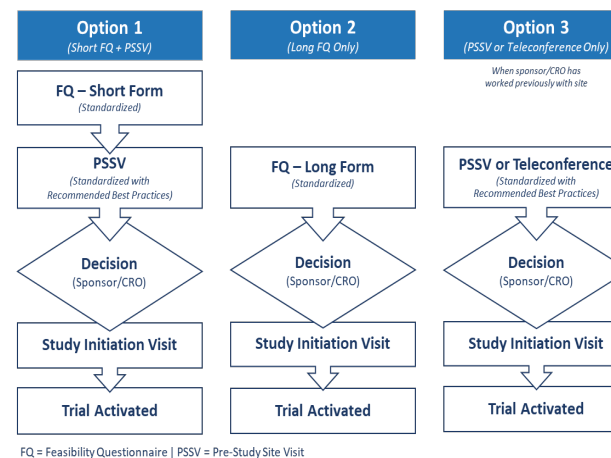
The Burden of Feasibility Assessments

- 113 research sites (66 community, 47 academic) reported completing 11 FQs and 4 pre-study site visits (PSSVs) on average per month. Each FQ took 4 hours and PSSVs took 10 hours on average to complete. All combined, respondents spent 113,904 staff hours on feasibility assessments per year.
- Most considered FQ and PSSV content redundant to information previously provided (81% and 91%, respectively) and FQs were similar between different sponsors (86%).
- Insufficient trial documentation from sponsors and CROs posed challenges for sites completing FQs.
- The time from first contact to first patient enrolled was 7 months on average.

Improving the Feasibility Assessment Process

- There were 40 respondents to stakeholder feedback survey about recommendations for process improvements (Figure 2).
- Respondents represented 19 academic- and 9 community-based sites, 8 industry sponsors, and 4 CROs.
- Most respondents preferred a model with a short FQ plus a PSSV when there was not a prior relationship.
- If there was a prior relationship, a PSSV or teleconference (only) was preferred. CRO respondents were the least supportive of these approaches.

Figure 2. Recommended Feasibility Assessment Process Improvements



- All stakeholders identified time savings, expedited start-up, fewer staff resources, and cost savings as the greatest benefits.
- The greatest barriers to adoption were buy-in from sponsors and CROs and insufficient site information.

CONCLUSIONS

The current approach to identifying and qualifying sites for clinical trials poses a tremendous burden on oncology clinical practice resources. Inefficiencies delay time to enrollment and represent a significant barrier to community site participation in clinical trials. New methods that standardize, harmonize, and streamline site assessment, selection, and activation will expedite clinical trial enrollment, broaden trial access for patients and sites, and reduce costs.

Sponsor and Collaborator Content Management System

G. Balagot, N. Cassim

City of Hope Comprehensive Cancer Center

1. Background

Cancer Centers have a wealth of knowledge that spans across various individuals and teams within their institute regarding industry partners/sponsors and other collaborators. This knowledge has accumulated over years of dedicated hard work that fosters innovative thinking and industry leading treatments. Many Cancer Centers would benefit from a centralized Content Management System (CMS) where knowledge can be stored, shared and viewed by other key team members. This will create transparency between the parties involved in conducting clinical trials and aid in avoiding contradicting previous practices and inefficiency.

City of Hope Research Operations (COH RO) is creating a CMS that will allow for teams and individuals to provide their experiences in a central location where others in the institute's research community can view and reference.

2. Goals

With a Content Management System, our goals are to be able to:

- Access collaborator information from a central location and is organized in a structured fashion. This will make it easier to view consistent information by various teams conducting the trial in the institution.
- Assess collaborators that will be engaged in any given project and identify/minimize risks prior to engagement. This will help in avoiding poor performing collaborators.
- Predict data quality and performance of our external collaborators, based on our previous experience and scoring of external sites during our monitoring visits.
- Aid in forecasting project timelines. With information that external sites are able to enroll at the rate of what they are contracted, we can continue to engage with these sites.

3. Solutions and Methods

Our project has identified key milestones:

- Identify key information that has already been collected that can be used to aid in assessing external collaborators. Additionally, identify key information that may not be currently captured in any system and decide the appropriate platform to enter the information.
- Structure the data so that it can provide meaningful reports/outputs that aid in assessing
- Determine an appropriate system/platform that will bring these data points together. We will then begin the build of the CMS, with the help of our Research Data Management and Analysis colleagues.
- Create work instructions so that users are optimizing the system and information is kept consistent.

4. Outcomes

We are looking at our current systems that are already being used and assessing if those systems can be leveraged to house the data. We would like to be able to have the CMS pull data from various systems already in use (REDCap, OnCore, Florence, etc.) into a central location that will allow teams to run reports or view a wide range of data in one system. We are also exploring having the system allow for entry of data that other systems may not be able to capture.

5. Lessons Learned

We have learned that much of the information we would like to use to assess collaborators is currently not housed in any systems. It is in team members' emails or brains. With the roll out of the CMS, this information will be captured and categorized and become available for future reference.

The project completion is targeted for September 2020.

Clinical Trials Time to Activation: The Process, Structure, and People

Y. Suri, M. El Shayeb

O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham

1. Background

The accessibility of unique clinical trials attracts new patients to the institution, leading to higher accrual numbers, and better patient access to new, novel agents. However, activating clinical trials in large academic institutions, such as UAB, is a long, arduous, and costly process. This process involves communication and collaboration between many stakeholders across numerous departments. Consequently, many trials do not open soon enough to accrue patients at an optimal rate or the trial closes nationally by the sponsor as soon as it becomes active, leading to loss of time and effort, and a negative financial impact. We aimed to perform a preliminary analysis to describe trials activation process at UABCCC, as well as identify the length of time that a new trial takes to become activated, and determine the rate limiting steps and processes.

2. Goals

We mapped the current operational/administrative process for activation in our Cancer Center. Using the dates available for industry sponsored protocols activated between 2016 and 2019, the number of days to complete each step in the activation process was calculated. The length of Time to Activation will be compared from 2016 to 2019, and after 2019, with the introduction of new administrative processes.

3. Solutions and Methods

In recognition of the higher TTA at UAB, a new SOP was established that included a new process that protocols would be concurrently submitted to PRC, Budget, and Regulatory. There was also the introduction of distinct trial navigators for all disease groups across the cancer center.

4. Outcomes

Our retrospective analysis showed that, overall, the median complete activation process from WG approval to conducting the study initiation visit (SIV) takes 311 days. However, it took a median and average time of 188.5, and 196.8 days, respectively, from Protocol Review Committee review to SIV during the same time period. The median time it took from PRC approval to completing all administrative submissions (FAP, Budget, OSP, IRB, WIRB) was 149.5 days, and the review process from administrative submission to approval was 35 days. Finally, the median time from Contract Execution to SIV was 21 days. From 2016 to 2017 and 2017 to 2018, there has been an increase in total time to activation each year, by 17.1% and 13.5%, respectively.

5. Lessons Learned

Though the overall process of trial activation is long, there are external factors that influence the first part of the trajectory (CDA receipt, regulatory documents receipt, feasibility assessments by the sponsors, etc.). Since availability of regulatory package is the time when all essential documents required for activation are available, defining the starting point of activation is critical, and the NCI has recommended the PRC review to be the best proxy for the start of activation. This study should provide the framework for future studies, to better understand each process in the activation process, and the current system gaps to re-engineer workflows to improve time to activation. The new process implemented will take time to create a positive impact on TTA, but the investigator satisfaction and communication between the departments has increased, to improve the process flow.

C3OD User Interface – A Simple and Intuitive Solution to Feasibility Analysis for Clinical Trials

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The University of Kansas Cancer Center

1. Background

With a variety of recruiting and feasibility challenges, organizations and researchers have been either developing or have implemented several solutions to support feasibility analysis for clinical trials. One of the conventional techniques involves retrieving information from the electronic health record and other sources to provide aggregate numbers for how many subjects could be expected that match a specific set of inclusion/exclusion criteria for a proposed trial. However, many of these solutions are not intuitive and require a fair amount of training to maximize tools utility. Given the busy schedules of most researchers involved in clinical trials, this can present an obstacle to the adoption of these tools, which can lead to inaccurate assessments of trial feasibility and trial failure. Furthermore, many of these tools are expensive, adding to the budget of clinical trials. Therefore, there is a need for a simple, intuitive tool for trial feasibility analysis that is provided open-source, so that cancer centers can adopt it without unreasonable additions to clinical trial costs and so that they can modify it to meet the needs of their institution.

2. Goals

We are using a validated survey instrument for measuring the impact of a new software tool to assess the effect it is having on researchers involved in planning clinical trials at our institution.

3. Solutions and Methods

We have implemented a simple, intuitive user interface to our data warehouse, which we call the Curated Cancer Clinical Outcomes database. The user interface is implemented in Angular, making the software widely available through a web browser over an institution's intranet. A middleware layer disconnects the user interface from the data warehouse, making it easier to connect the software to different data warehouse implementations. The software will soon be made available as an open-source tool to all institutions that would like to investigate its utility.

4. Outcomes

Preliminary data show that the user interface to C3OD is having a positive impact on clinical trial design and assessment at KU Cancer Center.

5. Lessons Learned

Soon, we will be requiring all studies going through the Protocol, Review, and Monitoring Committee (PRMC) to demonstrate that they used C3OD to determine the feasibility of a trial.

Automatic Study Cost-Outs: A Tool Designed to Objectively Assess Trial Operations Costs for More Standardized and Efficient Budget Negotiations While Improving Overall Study Time to Activation

J. Plassmeyer, M. Yarkowski, G. Hickman, B. Crocker, K. Richter, K. Yee

UPMC Hillman Cancer Center

1. Background

One aspect considered for protocol time to activation includes the preparation, development and negotiation of the budget. During budget preparation clinical research managers must prepare an operations cost-out to determine the amount of staff hours required for each visit. The current cost-out process is subjective and has demonstrated, on occasion, to over or underestimate staff efforts on the studies, and cause delays as clinical research managers try to open an increased number of protocols relevant to the catchment area's needs. The lack of detail and standardization also negatively impacts the timeline for budget negotiation when sponsors request justification for requested costs. An automatic and objective summary of operational efforts standardized across the Hillman Cancer Center Clinical Research Services (HCC CRS) trial portfolio can significantly improve each of the aspects referenced above.

2. Goals

Our automatic cost-out evaluates specific tasks described in protocol study calendars and assigns those study related tasks a pre-determined level of effort. This calculation allows our clinical research fiscal team to objectively prepare comprehensive and accurate budgets. The automation can generate time savings in many aspects of budget preparation and negotiation. Primarily, it will eliminate the time required to prepare a manual cost out; likewise, the fiscal team will no longer need to wait for the cost out to prepare the study budget. Automation will also streamline communication between the fiscal team and the clinical research managers by providing additional task-specific details to justify budget requests to sponsors. Our expectation is that the above will result in a decrease in our overall trial activation time at the Hillman Cancer Center and a comprehensive, detailed and consistent reflection of time needed for each task.

3. Solutions and Methods

Our home-grown database, Clinical Trial Management Application (CTMA), is populated during study start-up with a study schema that includes each assessment required at each time point per the protocol calendar of events. Each assessment is given a specific code that is associated with an allotment of time that will be multiplied by the hourly budget rate relevant to the study team member performing the task. The clinical research fiscal team is then able to run an automated report that will produce a study specific cost out with calculated efforts for nurse coordinators, data coordinators, and clinical research managers.

4. Outcomes

The outcome of this automated process will allow HCC CRS to reduce the number of days it takes for a cost-out to be developed, prepared for submission and negotiated. Its implementation will give clinical research managers vital time back to focus on staff and protocol execution and provide the fiscal team with a more objective and consistent budget for efficient budget negotiations.

5. Lessons Learned

The Hillman Cancer Center is currently assessing many aspects of trial activation including contracts, IRB review, and implementation. A key element and identified sticking point are budget negotiations. The Automatic Study Cost-Out tool will assist in reshaping how study start-up is organized and carried out leading to improved time to activation, comprehensive and consistent budget detail, and the ability to process more studies in a shorter timeframe.



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