

**STRATEGIES TO MAXIMIZE
INNOVATION**
TO ADVANCE CANCER CLINICAL RESEARCH

2019 ABSTRACTS AND POSTERS

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11th Annual AACI CRI Meeting: Strategies to Maximize Innovation to Advance Cancer Clinical Research

In 2019, AACI's Clinical Research Innovation (CRI) convened its 11th annual meeting in Chicago. A record-breaking 431 clinical research office leaders, medical directors, cancer center administrators, patient advocates, and representatives from the National Cancer Institute (NCI) and industry attended the three-day meeting, titled *Strategies to Maximize Innovation to Advance Cancer Clinical Research*.

Participants engaged in sessions on topics including conducting multicenter trials, recruiting diverse populations, using electronic solutions to match patients to trials, making the business case for a compassionate use program, maximizing financial resources, and preparing for the NCI Cancer Center Support Grant (CCSG).

"How to Capitalize on Conducting Multicenter Trials" focused on setting clear expectations, operationalizing investigator-initiated trials, and managing multiple sites under a single institutional review board to ensure that multicenter trials are run effectively.

In the session, "Getting to Know Your Patients: Enrolling Diverse Populations to Clinical Trials," panelists discussed innovative ways to recruit and enroll patients from minority groups in a cancer center's catchment area. They shared strategies for increasing the number of Hispanic and African-American patients involved in clinical research, including a clinical trials minority accrual task force and programs designed to empower individuals to make informed decisions about trial participation.

"Using Clinical Trial Matching to Enhance Enrollment" provided real-world examples of digital tools—including software driven by artificial intelligence and data from electronic health records—designed to increase clinical trials enrollment at the cancer centers.

Responding to the growing need for compassionate use programs at many cancer centers, panelists explored the rationale, policies, and procedures for developing and implementing these programs. They recommended assembling a dedicated team that meets regularly; quantifying compassionate use data that includes volumes and financial information specific to the institution; determining an "executive ask," which may include funding or staffing needs; and meeting with senior executives to present the business case for compassionate use programs.



L to R: Mallory Kock, MS, CCRP; Patricia Hurley, MSc; Jessica Rhee, MD, MS; and Kyusun Cha, CCRC, discuss posters at the CRI meeting.



CRI Steering Committee Chair, Carrie Lee, MD, MPH, welcomes attendees.

11th Annual AACI CRI Meeting: Strategies to Maximize Innovation to Advance Cancer Clinical Research



L to R: Robert Winn, MD; Chanita Hughes Halbert, PhD; Patricia Chalela, DrPh; and Tara Lin, MD, discuss enrolling diverse patients to clinical trials.

THE PURPOSE OF THE ABSTRACTS IS TO INFORM MEETING ATTENDEES ABOUT CLINICAL TRIALS OFFICE CHALLENGES AND THE INNOVATIVE SOLUTIONS IMPLEMENTED AT AACI CANCER CENTERS.

“Clinical Trial Finance Management: Matching CTO Resources With Innovative Therapies” offered creative strategies to address common challenges with creating trial budgets for immuno-oncology trials, collecting data to demonstrate downstream revenue generated from trials, and ensuring that trial budget costs align with efforts for conducting research. Solutions included implementing new clinical trials management systems to automate and centralize efforts, and reorganizing finance departments to reduce redundancies, support budget development, complete real-time invoicing for trials, and evaluate revenue received from clinical trial sponsors.

Henry Ciolino, PhD, director of the NCI’s Office of Cancer Centers, presented updates to the NCI CCSG program, as well as the new funding opportunity agreement, new catchment area definitions, and adjustments to community outreach and engagement (COE) reporting and protocol review and monitoring. Dr. Ciolino emphasized that centers would be encouraged in their CCSG reviews to describe the infrastructure that has been established to enhance outreach, for example, by establishing an office of COE, forging partnerships with health care plans and government agencies, and constituting community advisory boards. **Gisele Sarosy, MD**, of the NCI’s Coordinating Center for Clinical Trials, focused on modifications to the clinical trials reporting program (CTRP), including an update on the CTRP-Generated Data Table 4.

Raquel Jex Forsgren, founder of Front-Line Resilience Health and Living Yoga Therapy in Chicago, presented the keynote, “Strategies for Self-Preservation.” The interactive presentation provided attendees with tools for managing stress and building on six domains of resilience—vision, composure, reasoning, health, tenacity, and collaboration—to combat “compassion fatigue.”

Leading up to the meeting, AACI issued a call for abstracts to its membership. The purpose of the abstracts is to inform meeting attendees about clinical trials office challenges and the innovative solutions implemented at AACI cancer centers. This year, seven categories were provided to authors to guide the submission process: Regulatory, Training & Quality Assurance, Finance/CCSG/PRMS, Trial Recruitment & Disparities Research, Trial Start-up, Clinical Research Operations, and Investigator-Initiated Trials. The meeting's poster session provided another opportunity for abstract authors to informally share their findings.

Authors from 24 cancer centers submitted 66 abstracts. Submissions reflected an increase in collaboration between AACI members, vendors, and community partners. Three abstracts were presented individually during a formal meeting program session, and nine posters were discussed during breakout sessions at the meeting.

The three abstracts selected for presentation by the CRI Steering Committee and CRI Education Committee were submitted by authors representing Memorial Sloan Kettering Cancer Center; Hollings Cancer Center, Medical University of South Carolina; and Masonic Cancer Center, University of Minnesota.

During the breakout sessions, poster presenters discussed topics that corresponded with the seven abstract categories. The presenters represented Cleveland Clinic Cancer Center; Herbert Irving Comprehensive Cancer Center at Columbia University Irving Medical Center; Medical College of Wisconsin Cancer Center; Memorial Sloan Kettering Cancer Center; Princess Margaret Cancer Centre, University Health Network; The University of Texas MD Anderson Cancer Center; UCSF Helen Diller Family Comprehensive Cancer Center; and University of Florida Health Cancer Center.

Supporters worked with AACI to create a meeting environment conducive to learning, networking, and strategic innovation.

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

AACI CRI 2019 Steering Committee

Carrie Lee, MD, MPH – Chair

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

Theresa L. Werner, MD – Chair-Elect

*Huntsman Cancer Institute
University of Utah*

Tricia Adrales Bentz, MHA, CCRP

*Hollings Cancer Center
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Theresa Cummings, RN, MS, CCRP

*University of Maryland Marlene and Stewart
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Alex Zafirovski, MBA

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

2019 ABSTRACTS AND POSTERS

The background features a complex network of thin white lines connecting various sized white dots, creating a web-like structure. The color gradient transitions from a deep blue at the top to a bright, almost white light at the bottom, with a soft greenish glow at the very bottom edge.

CLINICAL RESEARCH OPERATIONS

The background features a network of white nodes connected by thin white lines, set against a gradient from dark blue at the top to light green at the bottom. A bright horizontal light flare is positioned across the middle of the image.

Multifunctional Staff Focus Groups as a Tool to Improve Employee Engagement of Clinical Trials Office Staff

L. Lange, S. Bigelow, C. Brown, P. Dykema, D. Erickson, L. Jakovski

Barbara Ann Karmanos Cancer Institute, Wayne State University

1. Background

Clinical Trial Offices (CTO) encounter common issues with low employee engagement and high employee turnover. This can impact the quality of the research as well as causing a financial strain on the organization because of the cost of onboarding and training new staff. Many health care organizations have started to measure employee engagement and to prioritize measures to improve employee engagement scores. The Barbara Ann Karmanos Cancer Institute (KCI) began measuring employee engagement on a yearly basis in 2016 utilizing a standardized survey. Despite several initiatives in 2017, the scores remained lower than desired. The KCI leadership team, including the CTO leadership, was charged with forming focus groups within their departments.

2. Goals

The goal of the focus groups was to encourage staff to take ownership of their department's employee engagement scores and culture, identify key issues affecting the staff's engagement scores, and develop plans that could be implemented by the staff to mitigate these issues. The ultimate goal of these groups was to improve annual employee engagement survey scores.

3. Solutions and Methods

In March 2018, the KCI CTO formed three focus groups consisting of 8-10 staff members each that included representatives of multiple departments involved in implementing clinical trials. The Vice President (VP) CTO identified three staff members who were high performers and "unofficial leaders" of the staff and approached them about leading these groups. Each manager or supervisor within the CTO provided the names of high-performing staff and this list of members was divided to form the three groups with broad representation. The areas represented included study coordinators, regulatory coordinators, research nurses, network sites, administrative, pre and post-award, and research informatics. The focus group leaders were provided with training by the VP CTO and were introduced to the group members. The initial meeting consisted of a "start-stop-continue" exercise to initiate discussion. The groups were tasked with choosing an area of concern to focus on and develop potential solutions. All three groups chose to work on improving communication and met every 2-4 weeks.

4. Outcomes and Future Directions

The focus groups began meeting in March 2018. The groups brainstormed several methods to improve communication and employee engagement. The ideas were presented to the VP CTO for approval and were then implemented. Some of these solutions included the development of: a CTO activities committee, a monthly newsletter (attached), and an anonymous electronic suggestion box for staff to submit their suggestions. The three CTO focus groups were recognized as some of the most active and successful at KCI. The CTO employee engagement survey scores were compared between 2017 to 2018.

The employee engagement category stayed essentially stable from 2017 to 2018, 3.62 to 3.61 on a 5 point scale. However, communication skills improved from 3.16 to 3.30. In addition, the overall employee experience score improved from 3.87 to 4.00. Based on the 2018 survey results, the groups are focusing on career development in 2019. The first initiative has been to have an educational session for the staff about SoCRA and ACRP certification.

Multifunctional Staff Focus Groups as a Tool to Improve Employee Engagement of Clinical Trials Office Staff

L. Lange, AOCN, ANP-BC; S. Bigelow, CCRP; C. Brown, CCRP; P. Dykema, CCRP; D. Erickson, CCRP; L. Jakovski
Barbara Ann Karmanos Cancer Institute, Wayne State University

Background and Significance

Karmanos Cancer Institute (KCI), a National Cancer Institute (NCI) designated Comprehensive Cancer Center (CCC), has continually strived for the best kind of environment for their patients and for their employees. The Clinical Trials Office (CTO) at KCI represents one of the four main pillars of KCI's mission and vision (Figure 1), and is comprised more than 160 individuals employed at the Institute. CTO staff play an important role in conducting clinical research. In clinical research, the staff perform 30% of the total work on the trial while the physicians perform 9% (Baer, Zon, Devine and Lyss., 2011). It was imperative for the CTO to focus on listening to their employees to avoid future employee burnout and ensure the success of KCI's nationally recognized Clinical Trial Program. Engagement helps to reduce the impact of work demands which can lead to burnout (García-Sierra, Fernández-Castro, Martínez-Zaragoza, 2016).



Figure 1: KCI visual representation of mission.

Employee Engagement surveys were disseminated to all employees at KCI beginning in 2016 utilizing a standardized survey. Employee engagement extends beyond measuring employee satisfaction. Employee engagement focuses on each individual's investment into their role in the workplace (Rich, Lepine and Crawford, 2010). Initiatives from KCI senior leadership were implemented after this initial survey was given, but scores remained lower than desired in the survey that was performed in September 2017. In response to these scores, the KCI leadership team charged each department in March 2018 with the task of forming focus groups comprised of high performing employees (Buxton, 2018). The CTO decided to form three groups that included representatives across all clinical trial departments in order to create change within their department and the CTO overall. The CTO focus groups were comprised of members of various departments and locations that contribute to the functions of clinical trials at KCI, these departments are depicted in Figure 2. It was important for the success of the groups that no leadership staff were involved in the groups to allow for open dialogue between staff. The management team was asked to identify their "high performers" to be a part of the groups and represent their department. The focus groups were tasked in March of 2018 with increasing employee engagement scores quantitatively prior to an employee engagement "Pulse Survey" that took place in June 2018. The focus groups were directed to choose one area of concern found in the 2017 Employee Engagement Survey. The groups chose from the lowest scoring items which were communication, career development, and compensation/benefits. The three CTO focus groups chose to work on improving communication. Focus group members were encouraged to voice their honest opinions and create measurable outcomes to boost morale in the CTO and create a positive work environment for all those involved.

Purpose

The objectives of the three Clinical Trials Office focus groups were to:

1. **Encourage** staff to take ownership of the department's employee engagement scores and culture
2. **Identify** key issues affecting staff engagement scores
3. **Develop** plans that could be implemented by staff to mitigate these issues.

The ultimate goal of these groups was to improve employee engagement.



Figure 2: Composition of Clinical Trials Office Focus Groups

Implemented Practice Changes

All three CTO focus groups chose to work on the low scoring employee engagement survey category of communication. The groups were taught techniques to assist staff to identify reasons for low scores. They then created 3 programs that helped improve communication between the department disciplines. Below is a brief description of each initiative.



Figure 3: Most recent CTO monthly newsletter

- ❖ **Monthly Newsletter:** A monthly newsletter is now implemented and highlights specific departmental updates, staff changes, open positions, one focus employee from the CTO and reminders about upcoming events/special projects. Staff are encouraged to post the newsletter in public areas because it acts as an interdepartmental liaison and a way for employees to get to know one another better. This initiative will be continued because leaders continue to hear feedback that the newsletter is enhancing communication within the CTO (Figure 3.)
- ❖ **Afternoon Walks:** To ease the stress of difficult conversations that can come with certain meetings in the office, CTO employees are encouraged to take a walk outside and confront these difficulties together in the fresh air. A simple walk in the middle of the day with fellow employees is a great way to get to know coworkers and foster a team-building atmosphere.
- ❖ **Anonymous suggestion box:** Employees are encouraged to utilize an anonymous suggestion box to suggest new initiatives, voice concerns, and create potential solutions in a concise way to directly communicate with management.

Outcomes

The employee engagement scores on the standardized survey were compared from 2017 to 2018. The overall employee engagement category was stable from 2017 to 2018. Communication scores and the overall employee experience improved during the same time period. Table 1 summarizes these results. The three CTO focus group leaders met with the larger group of KCI focus group leaders every few months. The CTO groups were recognized for their success in developing departmental initiatives.

Survey Category	2017	2018	Difference
Employee Engagement	3.62	3.61	-0.01
Teamwork	4.17	4.34	+0.17
Communication	3.16	3.30	+0.14
Overall Employee Experience	3.87	4.00	+0.13

Table 1: Selected data points from Employee Engagement Survey from 2017 and 2018

Future Directions

Based on the survey results found in 2018, the Focus Groups have chosen career development as the area of concern to address in 2019. One initiative that is currently underway is an educational lunch session offered to employees. A pilot session was offered to all CTO employees and lead by 2 high performing focus group members highlighting the important steps in which a coordinator needs to take to obtain their SoCRA certification. This session was attended by about 40 staff including coordinators at satellite sites across the state of Michigan.

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THAW – The Holistic Approach for Working in Cellular and Gene Therapy Clinical Trials

J. Gould, K. Shrestha, R. McCray, F. Brogan, D. Otap, M. Kelsen, M. Mapara, R. Reshef, A. Lassman

Herbert Irving Comprehensive Cancer Center, Columbia University Irving Medical Center

1. Background

Execution of cellular and gene therapy trials is highly complex and requires multidisciplinary interactions (cell therapy/transplant program, transfusion medicine, oncologic sub-disciplines, inpatient and outpatient patient care units) for which the research team is the core. The rapidly growing number of clinical trials in this area and their diversity across hematologic and solid tumor indications are some of the challenges that face an organization that wishes to operate in this innovative field. The Clinical Protocol and Data Management (CPDM) office began this cutting edge cancer and non-cancer research with its first gene therapy protocol in 2016. Since then, CPDM has developed a dedicated research team facilitating the execution of Cellular and Gene therapy protocols for varying indications from Sickle Cell to large cell carcinoma.

2. Goals

- Solidify processes with workflow guidance documents and standard operating procedures specific to cellular and gene therapy protocols
- Create a dedicated feasibility committee to thoroughly review potential studies to ensure success in clinical trial facilitation and selection
- Create a dedicated research cell therapy lab focused on clinical trials
- Further expand by placing CPDM personnel in partnering departments to facilitate collaboration
- Collaboration of different oncologists throughout the hospital and CPDM office

3. Solutions and Methods

CPDM recognized the need for a team dedicated to the cellular and gene therapy protocols. As such, a senior CRC position was created and a data coordinator was assigned to supplement the efforts of the initial research nurses, CRC, and CRM. Detailed tracking mechanisms were implemented by the Clinical Research Manager to monitor all protocol processes from start-up through overall trial progress. Weekly meetings to review the tracker and protocol progress supplement the weekly disease team meetings. Updates are discussed surrounding current patients as well as study start-up specifics for new trials.

Additionally, Outlook calendar entries were created to house all information pertaining to patient visits for cellular therapy/gene therapy protocols. All manuals, subject documents, protocol documents, and visit information are located on this calendar for cross-departmental simultaneous viewing. The calendar entry is distributed to all personnel (leukapheresis nurses, physicians, research nurses, CRCs, etc.) prior to the study visit.

Furthermore, a departmental SOP outlining the roles and responsibilities when facilitating cellular and gene therapy clinical trials was developed. The SOP references supplemental workflow documents created to assist and reinforce trial procedures.

4. Outcomes and Future Directions

Since its inception and implementation in 2016, 8 cellular therapy and gene therapy protocols have been opened, 17 patients have been enrolled, and 12 patients have been treated. With each enrollment, the study team continues to grow and assess the new processes set forth by the department. We anticipate opening 8 new trials in the coming year.

The implementation of the aforementioned processes streamlines communication, minimizes confusion, and provides structure for protocols with cross-departmental responsibilities. With that said, the processes are still in the beginning phases of execution. The cross-communication techniques will continue to be refined to ensure each subject's clinical trial experience goes as seamlessly as possible. In anticipation of opening protocols with solid tumor disease origin, we anticipate doubling those numbers by the end of 2020.

THAW–The Holistic Approach for Working in Cellular and Gene Therapy Clinical Trials

By Julia Gould, BA, Kayla Shrestha, MS, Rachel McCray, BS, Fran Brogan, MSN, RN, Daniel Otap, CCRP, Moshe Kelsen, MBA, Markus Mapara, MD, PhD, Ran Reshef, MD, Andrew Lassman, MD, MS

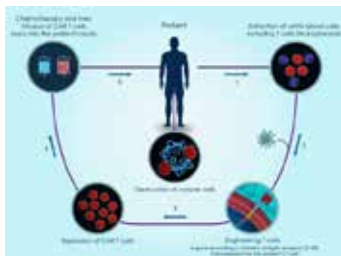
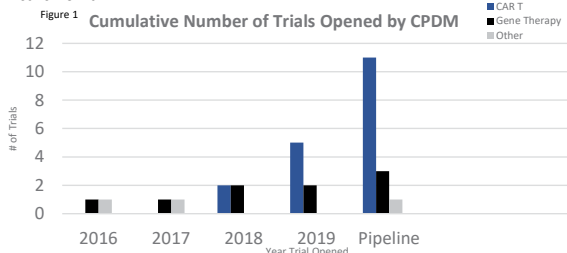


Photo obtained from Columbia Cancer Facebook page 201UN2019.

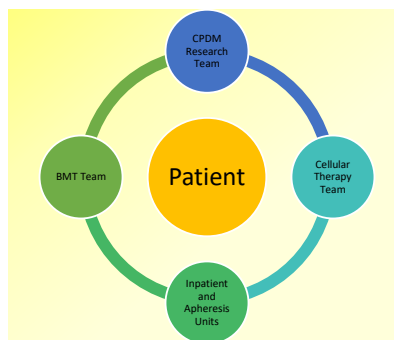
Background

Execution of cellular and gene therapy trials is highly complex and requires multidisciplinary interactions (cell therapy/transplant program, transfusion medicine, oncologic sub-disciplines, inpatient and outpatient patient care units) for which the research team is the core. The rapidly growing number of clinical trials in this area and their diversity across hematologic and solid tumor indications are some of the challenges that face an organization that wishes to operate in this innovative field. The Clinical Protocol and Data Management (CPDM) office began this cutting edge cancer and non-cancer research with its first gene therapy protocol in 2016. Since then, CPDM has developed a dedicated research team facilitating the execution of Cellular and Gene therapy protocols for varying indications from Sickle Cell to large cell carcinoma.



Methods

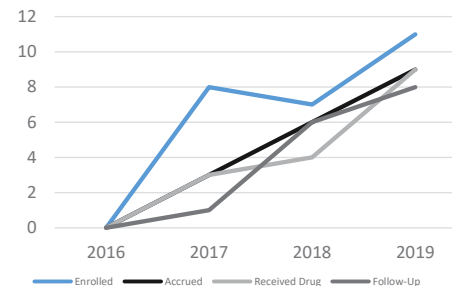
CPDM created a team dedicated to the cellular and gene therapy protocols. A senior CRC, a data coordinator, and a research nurse were assigned to supplement the efforts of the initial research nurses, CRC, and CRM. Detailed tracking mechanisms were implemented by the Clinical Research Manager to monitor all protocol processes from start-up through overall trial progress. Weekly meetings to review the tracker and protocol progress supplement the weekly disease team meetings. Furthermore, a departmental SOP outlining the roles and responsibilities when facilitating cellular and gene therapy clinical trials was developed. The SOP references supplemental workflow documents created to assist and reinforce trial procedures.



Results

Since its inception and implementation in 2016, 8 cellular therapy and gene therapy protocols have been opened, 28 patients have been enrolled, and 14 patients have been treated. With each enrollment, the study team continues to grow and assess the new processes set forth by the department.

Figure 2 Subject Progress from 2016 to Present



Conclusion

The implementation of the aforementioned processes streamlines communication, minimizes confusion, and provides structure for protocols with cross-departmental responsibilities. The processes are still in the beginning phases of execution. The cross-communication techniques will continue to be refined to ensure each subject's clinical trial experience goes as seamlessly as possible.

Next Steps

In anticipation of opening protocols with solid tumor disease origin, we anticipate doubling the numbers in Figure 1 and Figure 2 by the end of 2020.

Implementation of an Oncology Clinical Research Merit-Based Recognition Program for Physicians T. Adrales Bentz, C. Britten, D. Berrier, D. Marshall *Hollings Cancer Center, Medical University of South Carolina*

1. Background

Accrual to clinical trials, development and publication of investigator initiated trials (IITs), and staffing of important clinical research scientific and safety committees rely on clinical investigator engagement. However, in today's healthcare environment, the priority on achieving Relative Values Units (RVUs) targets add difficulty for physicians to participate in non-RVU generating clinical research activities. From CY2014 - CY2016, treatment trial accrual declined (CY14 = 248 pts, CY15 = 220 pts, CY16 = 176 pts). Increased accrual was imperative to meet CCSG goals.

2. Goals

From 10/1/2015 – 10/1/2016, HCC accrued 158 patients to treatment trials. Within 12 months, our goal was to increase treatment accrual by 25% (200pts).

3. Solutions and Methods

Four priority areas were selected by MUSC leadership: 1) treatment trial accrual; 2) treatment IIT activation; 3) treatment IITs publication; and 4) active participation in research infrastructure committees. From 10/1/2016- 9/30/2017, physicians would be eligible to earn for their department, 1% of their salary for "unit" of clinical research activities based on the following rubric: 1% for 1 treatment accrual; 4% for the activation and enrollment of a MUSC physician developed treatment IIT; 2% for IIT publication or 5% for an IIT publication in a high impact journal; 1% for participation of at least 80% of PRC, DSMC, or IRB meetings. The strategic investment estimated at \$870,000 would be split between HCC and the MUSC Provost. Funds were distributed to the department chair for future investment into oncology clinical research.

4. Outcomes and Future Directions

Treatment accrual at end of the 12 month period increased by 71.5% from 158 to 271 treatment accruals. Five treatment IITs were activated and accrued at least one patient. One treatment IIT was published in a high impact journal, and twelve physicians participated in research infrastructure committees. A total of \$863,984 was distributed, with the Division of Hematology Oncology receiving 59%, Radiation Oncology 11%, and other eight other divisions achieving <10% of the payout. The number of physicians participating in cancer research increased demonstrating a shared contribution towards the Center's accrual goal. Furthermore, physicians reported increased satisfaction and felt that the institution valued research activities. Providing financial resources to the departments to secure time and effort of clinical investigators is essential; however, the ability to maintain a funding source for the program presents a challenge.

Implementation of an Oncology Clinical Research Merit-Based Recognition Program for Physicians

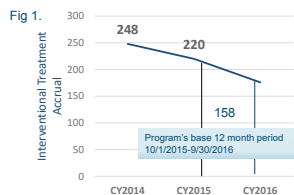
Tricia Adrales Bentz, MHA; Carolyn Britten, MD; David Marshall, MD; and Donna Berrier, MPA



Hollings Cancer Center
An NCI-Designated Cancer Center

Background

Accrual to clinical trials, development and publication of investigator initiated trials (IITs), and staffing of important clinical research scientific and safety committees rely on clinical investigator engagement. However, in today's healthcare environment, the priority on achieving Relative Values Units (RVUs) targets add difficulty for physicians to participate in non-RVU generating clinical research activities. Treatment accrual was declining significantly and action was needed to meet the Cancer Center's NCI Designation goals. As depicted in Figure 1, the baseline 12 month period, prior to the merit-based program implementation, treatment accrual was only 158. Furthermore, the pipeline of new IITs from MUSC faculty and publications from MUSC sponsored treatment IITs was down. During the base period, there were 2 IIT activations with accrual and 1 reported publication from a MUSC treatment IIT.



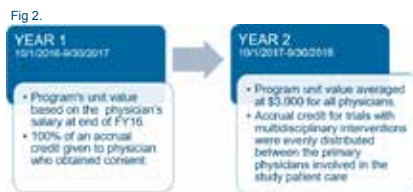
Method

Physicians earned funds for their department for completed research activities based on the rubric below (Table 1). The strategic investment estimated at \$1 million was funded by the Hollings Cancer Center. Activity was tracked by the HCC Clinical Trials Office (CTO). The CTO provided a detailed report to each department or division which was reviewed by HCC and the COM for accuracy. Fund distribution was expected quarterly to department or division for their future investment into oncology clinical research.

Priority Area	Program Year 1*	Program Year 2
Treatment trial accrual	1%	1 unit
Treatment IIT activation with at least 1 enrollment	4%	4 units
MUSC physician developed treatment IIT publication	2% or 5% for high impact	2 units or 5 units for high impact
Active participation in PRC, DSMC, or IRB (> 80% of meetings)	1%	1 unit

* Program Year 1 reimbursed at a percentage of the physician's total annual salary as of 8/1/2016)

The merit-based recognition program was continued with the same level of support through a second 12-month period. However, the program was slightly modified based on feedback from stakeholder focus groups. Figure 2 describes the two major changes made in the program.



Results

Table 2. Merit-Based Program Year 1 Detailed Results

Division	Payout Total by Division	% of Payout Total	Total Tx Accrual by Dept.	% of Tx Accrual Total	Total Tx IIT Activations with >1 accrual	MUSC sponsored Tx IIT Publications	Committee Members (excludes those with CCSG support)
Heme Onc	\$506,750	58.70%	169	62.40%	3	1	3
Rad Onc	\$97,746	11.30%	17	6.30%			3
Radiology	\$66,893	7.70%	27	10.00%			1
Surg Onc	\$54,786	6.30%	9	3.30%	1		1
Ped	\$43,124	5.00%	23	8.50%			
Neuro	\$27,400	3.20%	11	4.10%			2
Urology	\$25,565	3.00%	5	1.80%			1
Oto	\$21,552	2.50%	3	1.10%	1		1
Gyn Onc	\$17,670	2.00%	6	2.20%			
Derm	\$2,500	0.30%	1	0.40%			
Total	\$863,984		271 pts		5	1	12

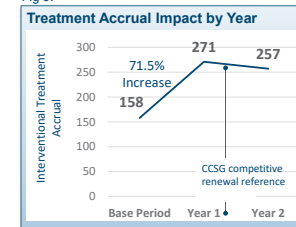
Table 3. Merit-Based Program Year 2 Detailed Results

Division	Payout Total by Division	% of Payout Total	Total Tx Accrual by Dept.	% of Tx Accrual Total	Total Tx IIT Activations with >1 accrual	MUSC sponsored Tx IIT Publications	Committee Members (excludes those with CCSG support)
Heme Onc	\$537,000	64.39%	164	63.81%	1	1	6
Surg Onc	\$106,500	12.77%	35.5	13.81%			
Rad Onc	\$57,000	6.83%	17	6.61%			2
Ped	\$39,000	4.68%	13	5.06%			
Neuro	\$39,000	4.68%	11	4.28%			2
Radiology	\$36,000	4.32%	11	4.28%			1
Oto	\$10,500	1.26%	3.5	1.36%			
Urology	\$9,000	1.08%	2	0.78%			1
Total	\$834,000		257 pts		1	1	12

Conclusion

- In light of the increasing prevalence of RVU-driven compensation plans for providers, cancer centers need to have well-defined incentives for providers to align their clinical activity with CCSG goals.
- The merit-based program was very effective in promoting treatment clinical trial accrual; however, additional factors such as clinical trial pipeline and investigator turnover may also impact accrual. Additional research is required to document that the funds allocated to departments from the merit-based program were actually used to promote activities that supported CCSG goals.

Fig 3.



- During the program, treatment accrual increased by 71.5% in the first year and sustained at 62.7% higher accrual in the second year compared to the base period.
- Other reported benefits included: a) the number of physicians participating in cancer research increased demonstrating a shared contribution towards the Center's accrual goal and b) physicians reported increased satisfaction and felt that the institution valued research activities.
- There was low - moderate impact on IIT activations and publications and committee participation.

Full Integration of the Gynecology Oncology Research Operations Under the IU Simon Cancer Center Clinical Trials Office

M. Contreras, S. Edwards, L. Vaughn, K. Miller

Indiana University Melvin and Bren Simon Cancer Center

1. Background

The Clinical Trials Office (CTO) continues to coordinate services, share standard operating procedures (SOPs), and maintain standards of quality for clinical trials with cancer-related studies. Although the CTO services are available to all departments seeking to conduct Cancer related studies, some departments prefer to use their own departmental resources. The GYN Oncology model poses a challenge for accrual goals, maintenance of standardization and quality of clinical research. Full integration of the GYN Oncology research staff under the Clinical Trials Office with the support of GYN Departmental Leadership and new Principal Investigator allows for improvement of clinical research operations.

2. Goals

Fully integrate GYN Oncology clinical trial operations under the direction of the Clinical Trials office:

- Develop a trusting relationship with GYN Oncology Leadership and PIs
- Provide regulatory, clinical and financial responsibilities under the CTO.
- Provide oversight of clinical research activity under the GYN Oncology program.
- Expand GYN Oncology Clinical Trial portfolio and increase clinical trial accruals
- Provide cross-coverage for staff support.

3. Solutions and Methods

- Met with GYN Oncology leadership to understand vision.
- GYN Oncology PI participated in training and overview of the clinical trials office operations.
- Initiated quarterly meetings with GYN Oncology Leadership to review current research activity and address current issues.
- GYN Oncology PIs play key leadership roles within the IUSCC clinical research management and oversight.
- Hired research staff under the CTO and participated in our onboarding and orientation process, which allows us to train on current SOPs.
- Disease oriented teams (DOT) [PIs, Clinical Research Nurses, Clinical Research Specialist, Data Coordinators, Regulatory and Finance] meet on a weekly and monthly basis to review GYN Oncology portfolio.
- Share specific clinical trials metrics to PI and DOT on a monthly basis.

4. Outcomes and Future Directions

- Since full integration the GYN Oncology research operations under the Clinical Trials Office, the clinical trial portfolio has expanded and therapeutic accruals have increased (multifactorial).
- Therapeutic accruals has increased 800% and patient's visits increased 485% for CY 2018.

While we fully integrated the GYN Oncology research operations under the CTO, we continue to monitor clinical research activity on a monthly basis to address workload and expectations. With the support of GYN Oncology leadership and PIs this has allowed for a smooth transition for both departments. We continue to monitor progress and are excited for two new GYN Oncology physicians to join the department in CY2018 and 19 with the goal of exceeding 2018 accrual goals.



INDIANA UNIVERSITY
SCHOOL OF MEDICINE

Full Integration of the Gynecologic Oncology Research Operations under the IU Simon Cancer Center Clinical Trials Office

Mario M. Contreras, MBA, MSN, RN¹ • Sara Edwards, M.S.c., CCRC¹ • Kathy D. Miller, MD¹

¹Indiana University School of Medicine, Indianapolis Indiana

Background

The Clinical Trials Office continues to coordinate services, share standard operating procedures, and maintain standard of quality for clinical trials with cancer-related studies. Although the Clinical Trials Offices services are available to all departments seeking to conduct cancer related studies, some departments prefer to use their own departmental resources. The Gynecologic Oncology model poses a challenge for accrual goals, maintenance of standardization and quality of clinical research. Full integration of the Gynecologic Oncology research staff under the Clinical Trials Office with the support of the Gynecologic Leadership and new Principal Investigator allows for improvement of clinical research operations.

Goals

- Fully integrate Gynecologic Oncology clinical trials operations under the direction of the Clinical Trials Office:
- Develop a trusting relationship with Gynecologic Oncology leadership and Principal Investigators.
 - Provide regulatory, clinical and financial responsibilities under the Clinical Trials Office.
 - Provide oversight of clinical research activity under the Gynecologic Oncology program.
 - Expand Gynecologic Oncology Clinical Trials portfolio and increase clinical trial accruals
 - Provide cross-coverage for staff support

Methods

- Clinical Trials Office Leadership met with Gynecologic Oncology Leadership to understand vision and future direction
- Gynecologic Oncology Principal Investigator attended training and overview of the clinical trials office operations.
- Initiated quarterly meetings with Gynecologic Oncology leadership to review current research activity and address current issues.
- Gynecologic Oncology Principal Investigators play key leadership roles within the Indiana University Simon Cancer Center clinical research management and oversight.
- Hired clinical research staff under the Clinical Trials Office and participated in our onboarding and orientations process, which allows us to rain on current standard operating procedures
- Disease oriented teams (Principal Investigators, Clinical Research Nurses, Clinical Research Specialist, Data Coordinators, Regulatory and Finance) meet on a weekly and monthly basis to review Gynecologic Oncology portfolio.
- Share specific clinical trials metrics to Principal Investigators and Disease-oriented teams on a monthly basis.

Results

Since fully integrating the Gynecologic Oncology Research operations under the Clinical Trials Office, the clinical trial portfolio has expanded and therapeutic accruals have increased (multifactorial).



Figure 1: The total number of Gynecologic Oncology Therapeutic accruals prior to and after full integration under the clinical trials office. **Therapeutic accruals have increased 800% from CY2017-18 and projected for 90% for CY2019.**



Figure 2: The total number of Gynecologic Oncology Therapeutic visits prior to and after full integration under the clinical Trials office. **Therapeutic visits have increased 485% from CY 2017-18.**

Future Direction

While we fully integrated the Gynecologic Oncology research operations under the Clinical Trials Office, we continue to monitor clinical research activity on a monthly basis to address workload and expectations. With the support of Gynecologic Oncology leadership and Principal Investigator has allowed for a smooth transition for both departments. We continue to monitor progress and are excited for two new Gynecologic Oncology physicians to join the department in CY2018 and 19 with the goal of exceeding 2018 accrual goals.



MELVIN AND BREN SIMON
CANCER CENTER
INDIANA UNIVERSITY

Developing an Automated Deviation Reporting and Electronic PI Attestation Process

L. Rohn, J. Nichols, A. Semla, S. Asche, J. Leiriao

Indiana University Melvin and Bren Simon Cancer Center

1. Background

Providing clear and consistent documentation of Principal Investigator (PI) oversight throughout a clinical trial is important element for trial management. Timely evaluation of protocol deviations is one way in which a study site can demonstrate effective PI oversight. In addition, effective protocol deviation management can help to improve protocol execution and minimize further deviations within a clinical trial.

2. Goals

- Establish a standardized method in which all Disease-Orientated Teams (DOTs) would report and review protocols deviations within the Clinical Trials Office (CTO)
- Develop an electronic process by which PIs could review and sign-off on deviations for each protocol, utilizing existing deviation entry process into the Clinical Trial Management System (CTMS)
- Create a reconciliation process to confirm that deviations are documented consistently between both the electronic PI Attestation application and the CTMS
- Provide a mechanism which will allow the Data Safety Monitoring Committee (DSMC) to review deviations across CTO, as well as confirm PI oversight

3. Solutions and Methods

- Developed resources for study staff on DOTs to utilize when reporting deviations and/or discussing deviations in team meetings
- Training Documentation for both study staff and PIs on process
- Templates for deviation reporting within CTMS
- Designed and implemented an electronic system to export documented deviations from CTMS into PI Attestation application
- Piloted with 2 DOTs prior to roll-out to entire CTO
- PI Attestation application used to supplement DOT meetings during which deviations are addressed and discussed
- Created features within PI Attestation application to view both CTMS documentation and PI determination in order to facilitate reconciliation
- Developed reports with PI Attestation application so that deviation outcomes and PI oversight could be reviewed at a site level

4. Outcomes and Future Directions

Outcomes:

- Roll-out of new deviation documentation across entire (CTO)
- Now have 100% deviation attestation occurring via electronic PI attestation application
- Including 45 PIs across all DOTs
- Audit trail of PI review for all deviations reported within CTMS and pulled into PI attestation application
- Including determination by PI for major vs. minor deviations
- Reports can be reviewed by PI, protocol, DOT or site level

Lessons learned:

- Determining what deviation template should contain earlier within process rather than later
- Developing a more effective method to reach out and train PIs in larger settings

Future directions:

- Rolling out to teams outside of the CTO that operate under the Cancer Center



Developing an Automated Deviation Reporting and Electronic PI Attestation Process

Liz Rohn, MS, CCRC, Josh Nichols, Amanda Semla, BA, CCRP, Sarah Asche, Jenny Leiriao, JD, CCRP
Indiana University

Background

Providing clear and consistent documentation of Principal Investigator (PI) oversight throughout a clinical trial is important element for trial management. Timely evaluation of protocol deviations is one way in which a study site can demonstrate effective PI oversight. In addition, effective protocol deviation management can help to improve protocol execution and minimize further deviations within a clinical trial.

Metrics & Goals to be Achieved

- Establish a standardized method in which all Disease-Orientated Teams (DOTs) would report and review protocols deviations within the Clinical Trials Office (CTO)
- Develop an electronic process by which PIs could review and sign-off on deviations for each protocol, utilizing existing deviation entry process into the Clinical Trial Management System (CTMS)
- Create a reconciliation process to confirm that deviations are documented consistently between both the electronic PI Attestation application and the CTMS
- Provide a mechanism which will allow the Data Safety Monitoring Committee (DSMC) to review deviations across CTO, as well as confirm PI oversight

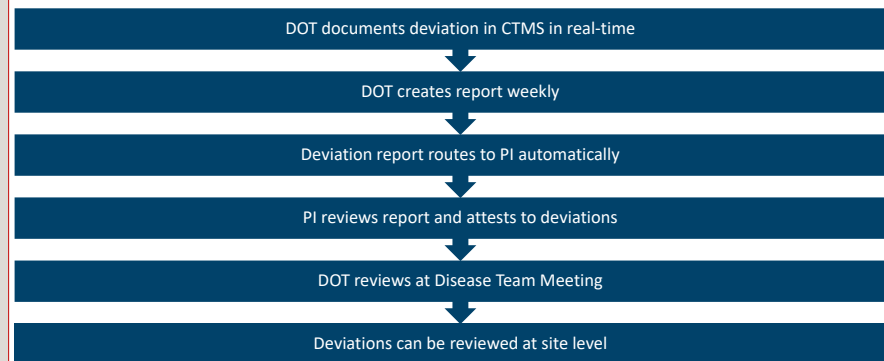
Solution or Methods Implemented

- Developed resources for study staff on DOTs to utilize when reporting deviations and/or discussing deviations in team meetings
 - Training Documentation for both study staff and PIs on process
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Outcome

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 - Now have 100% deviation attestation occurring via electronic PI attestation application
- Including 45 PIs across all DOTs
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 - Including determination by PI for major vs. minor deviations
 - Reports can be reviewed by PI, protocol, DOT or site level

Figure 1. Process for Deviation Reporting



Lessons Learned & Future Directions

Lessons learned:

- Determining what deviation template should contain earlier within process rather than later
- Developing a more effective method to reach out and train PIs in larger settings
- Creating a back-up paper process in case of technology issues

Future directions:

- Rolling out to teams outside of the CTO that operate under the Cancer Center

Development of a Systematic Review of Molecular Testing Increases Precision Medicine Based Clinical Trial Screening and Awareness

M. Lasowski, B. George, B. Oleson, J. Thomas

Medical College of Wisconsin Cancer Center

1. Background

Precision medicine testing is becoming more affordable and more widely used. Target therapy is rapidly changing as a result. But there is currently not a mechanism to review this testing to determine what treatment options are best, whether that is on or off clinical trials. Trial design has also shifted to basket or umbrella study design incorporating numerous cancers into one trial. This adds complexities and difficulties in identifying patients for these studies. The EAY131-Match protocol is an example of the complexity that the basket molecular based trial pose to sites. A systematic approach to manage the broad scope and range of studies like Match is needed to be successful.

2. Goals

- 1) Establish committee with adequate representation from medical oncology, geneticists, and clinical trial office to review all patients who undergo molecular testing for: trial eligibility, germline testing, and/or didactic value for Molecular Tumor Board.
- 2) Efficiently identify and screen patients for molecular targeted trials and germline testing through centralized screening with a lead coordinator at CCGRC
- 3) Develop a notification structure that allows for geneticists and coordinator to notify providers of qualifying patients.
- 4) Create a central clinical trial office contact that providers can reach out to regarding molecular testing. This contact can screen the molecular testing
- 4) Provide cases and expertise to the MCW Molecular Tumor Board to increase visibility of trial and treatment options based on precision medicine testing.

3. Solutions and Methods

The Medical College of Wisconsin has adopted a centralized approach to reviewing precision medicine testing. The first step was to establish the Cancer Center Genomic Review Committee (CCGRC) to review genomic data on all adult cancer patients who undergo comprehensive somatic mutation profiling. The membership of the committee includes medical oncologists, geneticists, and clinical trial coordinators. The goal is to identify candidates for biomarker enriched clinical trials and patients who may benefit from germ line testing based on somatic analysis. The CCGRC meets every 2 weeks and reviews all molecular testing.

Notifications are generated to providers to inform them a patient has a qualifying finding for a clinical trial or need germline testing. Coordinators of the targeted trials are also included on the notification to facilitate the communication between the Clinical Trials Office (CTO) and providers.

The CTO representative on CCGRC is the primary contact for questions regarding molecular testing eligibility for targeted trials such as Match. Providers only need to know one contact to inquire about eligibility.

4. Outcomes and Future Directions

The CCGRC was established in 2018 and meets every 2 weeks. Since October 2018, 236 cases have been reviewed by the CCGRC. 109 molecular findings potentially met eligibility for a trial.

A lead coordinator is a representative on the CCGRC and a resource for providers for eligibility and screening. All Match screening cases run through this single person and then referred out if they match to a treatment.

The Molecular Tumor Board meets monthly, often including cases from community-based hospitals. This provides an opportunity for patient's outside of our area to be identified for trials and have the opportunity to enroll.

Development of a systematic review of molecular testing increases precision medicine based clinical trial screening and awareness

Matt Lasowski, MS, CCRP; Ben George, MD; Betty Oleson, BSN, RN, CCRP; James Thomas, MD, PhD - Medical College of Wisconsin

Background

Precision medicine testing is becoming more affordable and widely used. Numerous companies now offer next-generation sequence (NGS) testing. Consequently, targeted therapy options are rapidly changing. However, there is currently not a mechanism to review this testing to determine which treatment options are best. Many clinical trials incorporate basket or umbrella study designs, focus on numerous cancers and use many treatments. This adds significant difficulty in identifying patients for these studies. The EAY131-Match protocol is an example of the complexity that a molecular-based trial with a basket design poses. A systematic approach to manage the broad scope and range of studies that are similar to Match is needed to be successful.

Goals

- 1) Establish a committee with adequate representation from medical oncology, genetics and the Clinical Trials Office to review all patients who undergo molecular testing for trial eligibility, germline testing and/or didactic value for the Molecular Tumor Board.
- 2) Efficiently identify and screen patients for molecular-targeted trials and germline testing through centralized screening, using a lead molecular research coordinator on the Cancer Center Genomic Review Committee (CCGRC).
- 3) Develop a notification structure that allows geneticists and the coordinator to alert providers of qualifying patients.
- 4) Create a central Clinical Trials Office contact whom providers can reach out to regarding molecular testing.
- 5) Provide cases and expertise to the MCW Molecular Tumor Board to increase visibility of trial and treatment options, based on precision medicine testing.

Solutions

The Medical College of Wisconsin adopted a centralized approach to reviewing precision medicine testing. First, the Cancer Center Genomic Review Committee (CCGRC) was created to assess genomic data on all adult cancer patients who undergo comprehensive somatic mutation profiling. Committee members include medical oncologists, geneticists and clinical trial coordinators. The committee's central goal is to identify candidates for biomarker-enriched clinical trials and patients who may benefit from germline testing, based on somatic analysis. The CCGRC meets every two weeks to evaluate all molecular testing.

A representative notifies providers that a patient needs germline testing or has a finding that qualifies him or her for a clinical trial. Coordinators of the targeted trials are also included on the notification to facilitate the communication between the Clinical Trials Office (CTO) and providers.

The CTO representative on CCGRC is the primary contact for questions regarding molecular testing eligibility for targeted trials, such as Match.

Contact

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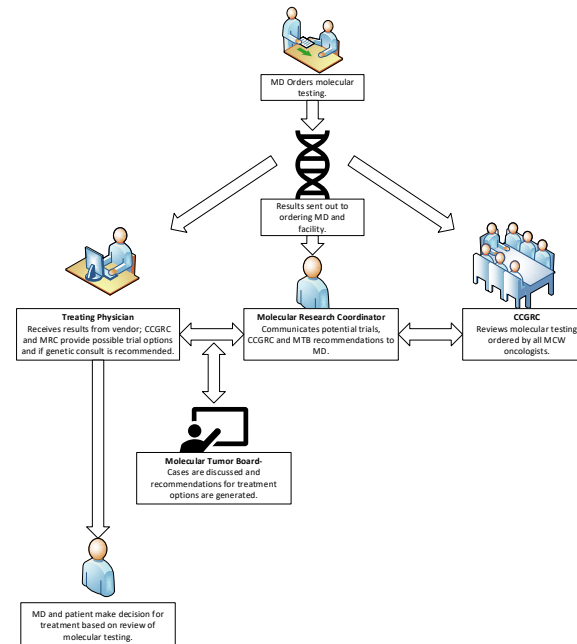


Figure 1. This illustrates the process the MCW Cancer Center uses to review molecular testing. The treating physician, molecular research coordinator (MRC) and Cancer Center Genomic Review Committee (CCGRC) review results. The patients are screened for molecular-targeted clinical trials that match their results. Then, treating physicians are notified.

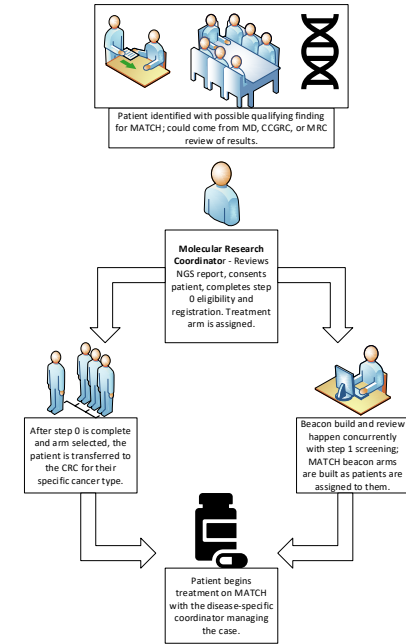


Figure 2. This outlines the MATCH screening process. The molecular research coordinator screens and completes Step 0. After the treatment arm is determined, the case is referred to the coordinator responsible for the patient's cancer type.

Outcomes

The CCGRC was established last year and meets every two weeks. Since October 2018, the committee reviewed more than 300 cases. More than 120 molecular findings met eligibility for a trial. The committee is investigating novel technology solutions to improve efficiency.

A lead molecular research coordinator is a CCGRC member and a resource for providers for eligibility and screening. This individual, who is a central point of contact for physicians, handles all Match screening cases. If patients are eligible, they are referred.

The monthly Molecular Tumor Board often reviews cases from community-based hospitals. This provides an opportunity for patients outside the area to be identified for trials.

Acknowledgements

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



Electronic Informed Consent (eIC) Platform for Clinical Trials: An Operational Model and Suite of Tools for Consent Authoring, Obtaining Informed Consent, and Managing Consent Documents

J. Lengfellner, M. Buckley, M. Koch, H. Pacheco, J. Levine, C. Hoidra, D. Damron, C. Houston, R. Cambria, A. Rodavitch, P. Sabbatini, E. Cottingham

Memorial Sloan Kettering Cancer Center

1. Background

The informed consent process is the foundation of human research subject protection, and studies have shown that enhancing the consent experience with introductory videos and visual aids, can improve participant engagement and comprehension. With this in mind, the MSK eIC platform was developed to augment educational alternatives for research participants, reduce administrative time and effort associated with paper-based consenting, improve the IC audit trail, and streamline consent document authoring.

2. Goals

To evaluate the pros and cons of the eIC platform versus the traditional paper-based consent process, we assessed: 1) the availability of the finalized consent document in the electronic health record (EHR), 2) processing time, and 3) the accurate completion of required data fields in the consent form. A standardized 5 question survey was used to assess participant's feedback on the eIC process. Free text responses were also reviewed for common topics.

3. Solutions and Methods

This web-based platform is device-agnostic and browser-independent; it is now used by 36 Services for 38 institutional and sponsored therapeutic and non-therapeutic clinical trials. Access to the platform is restricted to hospital WiFi (with off-site access via VPN). Three protocols in the platform have an educational video embedded in the eIC, and 5 have an embedded image flow that gives an overview of the protocol timeline for tests and clinic visits. The eIC platform was launched as a pilot program in January 2016; it went into use in our clinics in November 2016.

4. Outcomes and Future Directions

By March 2019, 93 active consenting professionals were using the module, 3,814 participants were consented, and 168 reams of paper were saved. Average eIC monthly accrual between January and March 2019 was 468 (STDEV +/- 142). Compared with paper-based consent forms, which take ~ 72h to post to the EHR (scanning, QA/QC), the signed eIC is sent to and stored in both the EHR and the Patient Portal (for MSK study participants) in < 2 minutes. The eIC platform decreases administrative effort (collating, printing, scanning) associated with paper-based consenting by 5-15 minutes/form. The eIC module has a robust audit trail that tracks the consent session and participant interactions via timestamps. We compared results of 170 patients consenting to one protocol during the same timeframe; 85 used the eIC platform, and 85 used the paper-based method. Use of the eIC platform increased the completion of required data fields in the consent form by 4%, versus paper.

Surveys were sent to 976 eConsent users, with 225 responses received (23%). The majority of respondents (186, 83%) indicated that electronic consenting was very easy (88), or easy (98) to use. Only 7 respondents (3%) noted that electronic consenting was somewhat difficult to use, 1 indicated that it was difficult (0.4%), and 31 were neutral. The majority of respondents (209, 95%) noted they would recommend electronic consenting to another patient at MSK. Free text responses to the open-ended questions were submitted by 116 respondents (52%), and surfaced the consistent themes noting the electronic process was simple, convenient, and user friendly.

Electronic Informed Consent (eIC) Platform for Clinical Trials: An Operational Model and Suite of Tools for Consent Authoring, Obtaining Informed Consent, and Managing Consent Documents

Joseph Lengfellner, Michael Buckley, Matthew Koch, Hector Pacheco, Joshua Levine, Carol Hoidra, Dorothy Damron, Collette Houston, Roy Cambria, Ann Rodavitch, Paul Sabbatini, Eric Cottingham

Background

The informed consent process is the foundation of human research subject protection, and studies have shown that enhancing the consent experience with introductory videos and visual aids can improve participant engagement and comprehension.^{1,2} With this in mind, the MSK eIC platform was developed to augment educational alternatives for research participants, reduce administrative time and effort associated with paper-based consenting, improve the IC audit trail, and streamline consent document authoring.



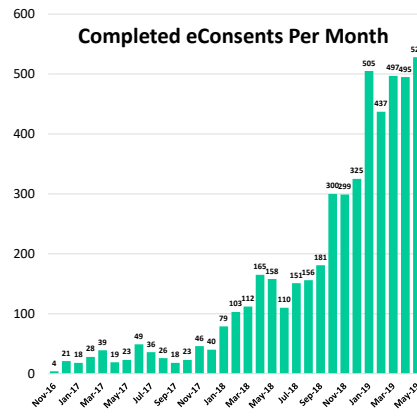
Methods

This web-based platform is device and operating system-agnostic, built by the Clinical Research Informatics & Technology (CRIT) team at MSK.

To evaluate the pros and cons of the eIC platform versus traditional paper-based consenting, we assessed: 1) the availability of the finalized consent document in the electronic medical record (EHR), 2) processing time, and 3) the accurate completion of required data fields in the consent form. A standardized 5-question survey was used to assess research participants' feedback on the eIC process. Free-text response fields were provided for common topics. **Participants always drive the decision to use electronic or paper consenting.**

Results

- >5,000 completed consents
- Used by 195 consenting professionals
- Across 36 different services

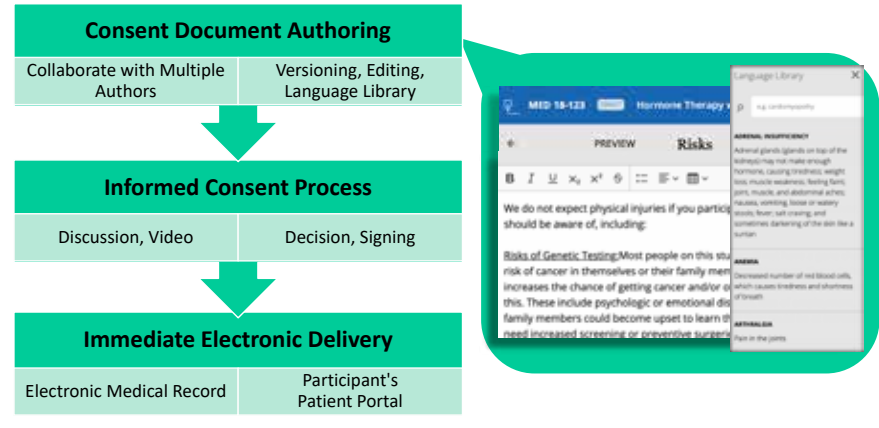


Improves Quality & Compliance

We compared the results of 170 research participants who consented to at least one protocol during the same timeframe; 85 used the eIC platform, and 85 used the paper-based method.

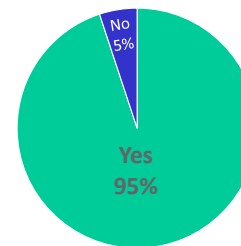
- **Use of the eIC platform increased the completion of required data fields in the consent form by 4%, versus paper-based consenting.**
- **The eIC platform decreases administrative effort** (collating, printing, scanning) associated with paper-based consenting by 5-15 minutes/form.
- **The platform delivers completed consent documents to the EMR within 2 minutes**, compared to up to 72 hours for paper consents.
- **The eIC module has a robust audit trail** that tracks the consent session and participant interactions via timestamps to indicate time spent in each section of the consent form.

A Seamless Digital Experience: Consent Authoring → Delivery



Patient Feedback

Would You Recommend eIC To Another Patient?



- **23% response rate** (365/1,577, as of 6/19/19).
- **81% of participants found the platform easy or very easy to use.**

Since February 2019, a standardized 5-question feedback survey was sent to each participant who completed a consent process using the eIC system.

Buy or Build?

Off-the-shelf and industry-specific solutions exist.

MSK decided to **build** a custom solution:

1. **Tightly integrate with MSK systems**
2. **One platform for all consents**
3. **Consistent MSK brand experience**

Future Platform Enhancements

- Multiple language support
- Ability to "hover" over term in consent to get further information
- Allow participant/provider to make notes on the electronic document during the consent discussion

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Reducing Overhead During Study Startup With System Integrations

N. VanKuren¹, R. Jones², A. Garcia²

¹Sidney Kimmel Cancer Center at Jefferson Health; ²Florence Healthcare

1. Background

NCI centers rely on a diversity of software systems to aid their clinical operations. Unfortunately, these systems create redundant tasks for research teams. For example, the process of adding a user in one system may have to be repeated in another. In this research project, the Jefferson and Florence technical teams combined traditionally disparate systems (CTMS and eReg) for an integrated process. Examples of administrative study setup tasks include creating a virtual trial binder workspace, inviting users to that workspace and configuring their permissions. This abstract describes a work in progress, shares preliminary results, and explores how this first effort can pave the way for future research.

2. Goals

The primary goal was to connect a popular oncology CTMS system to the Florence eBinders eRegulatory system in order to reduce administrative workload. Within that context, the teams held two goals:

1. Could the systems “talk” to one another? Could we automate study setup in the eBinders trial binder system by initiating the study in the CTMS? Metric: Completion of workspace setup to spec.
2. Did this integration actually save the study or administration team time? Metric: Time spent on key configuration tasks

3. Solutions and Methods

Solution:

The team sought to integrate CTMS and eRegulatory systems in order to automate six setup tasks

1. Create regulatory binder structure—deploy the workspace
2. Create roles—identify categories of users
3. Assign permissions—decide which categories may do which things
4. Assign users to roles—assign users those capabilities
5. Register and activate users—onboard users onto the system
6. Validation—ensure the setup was completed correctly

The result is that when a Study is created or modified in the CTMS the attributes of that study are sent to a middleware solution, configured programmatically, and are then established in the eRegulatory system. This results in a new set of binder structures, roles, and permissions that are immediately ready for use by the study team.

Methods:

Two categories of testing were used to measure performance of the solution against goals

1. Basic functionality: Would the system perform as desired against the specification developed?
2. Performance: Would this new integrated approach save time?

4. Outcomes and Future Directions

1. Basic functionality: The system ultimately satisfied the first functional goal. All six steps described above worked as designed when launched from the CTMS.

2. Performance: Our temporal analysis showed a reduction in system setup effort when eRegulatory workflows are initiated from the CTMS.

As the existing integrations free up resources from the most basic but critical activities, we are next exploring the possibilities of more complex workflows. These could include elaborate decision trees, as well as other systems such as IRB portals and electronic medical records. Ultimately, we seek to gain more efficiencies, reduce dependencies on scarce resources, and improve quality through technical integrations.

THE CHALLENGE



RESEARCH SITES FORCED TO COMPLETE REDUNDANT TASKS IN MULTIPLE TECHNOLOGY PLATFORMS

NCI centers rely on a diversity of software systems to aid their clinical operations. Unfortunately, these systems create redundant tasks for research teams. For example, the process of adding a user in one system may have to be repeated in another.

THE PROJECT



INTEGRATE CTMS & eREG SETUP TASKS INTO A SINGLE ADMINISTRATIVE PROCESS

In this research project, the Jefferson and Florence technical teams combined traditionally disparate CTMS and eReg administrative setup tasks into a single process.

Examples of administrative study setup tasks include creating a virtual trial binder workspace, inviting users to that workspace and configuring their permissions.

THE GOAL



REDUCE ADMINISTRATIVE WORKLOAD TO ELIMINATE DUPLICATE EFFORTS

The teams explored two questions:

1. Could the systems "talk" to one another, and could we automate study setup in the eBinders trial binder system by initiating the study in the CTMS?
Metric: Completion of workspace setup to spec.
2. Did this integration actually save the study or administration team time? **Metric:** Time spent on key configuration tasks
Metric: Time spent on key configuration tasks

8.3x Reduction of Administrative Overhead During Binder Setup Phase of Study Startup



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THE OUTCOME



PERMISSIONS AND ROLE SETUP TIME REDUCED FROM 27 MINUTES TO 3 MINUTES PER STUDY

9x Faster

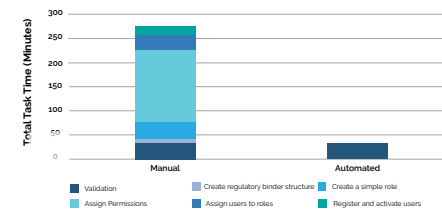


1) Basic functionality. The system ultimately satisfied the first functional goal. All six steps described below worked according to spec when launched from the CTMS.

2) Performance: Our temporal analysis showed a reduction in system setup effort when eRegulatory workflows are initiated from the CTMS.

The largest single improvement was found by automating permissions assignment, which encompass hundreds of configuration operations across dozens of users— the type of redundant task best done by software.

Time Savings Across 100 Studies from System Integration



THE METHOD

INTEGRATE CTMS AND eREGULATORY SYSTEMS IN ORDER TO AUTOMATE SIX SETUP TASKS

The result is that when a study is created or modified in the CTMS, the attributes of that study are sent to a middleware solution, configured programmatically, and are then established in the eRegulatory system. This results in a new set of binder structures, roles, and permissions that are immediately ready for use by the study team.



Create Binder Structure
Deploy regulatory binder workspace for study



Create Roles
Identify key categories of users for eReg and CTMS platforms



Assign Permissions
Identify key categories of users needed for both platforms



Assign Users to Roles
Assign users to appropriate roles and permission groups



Register and Activate Users
Activate and onboard users to the combined access system



Validate Deployment
Ensure setup was completed correctly by validating permissions

THE FUTURE



CONTINUE TO DRIVE EFFICIENCIES THROUGH TECHNICAL INTERGRATION

As the existing integrations free up resources from the most basic but critical activities, we are next exploring the possibilities of more complex workflows. These could include elaborate decision trees, as well as other systems such as IRB portals and electronic medical records. Ultimately, we seek to gain more efficiencies, reduce dependencies on scarce resources, and improve quality through technical integration.

Learn more at florencehc.com/AACIposter

This presentation provides a description of Jefferson's experience with a Florence Healthcare product and should not be construed as an endorsement of such product.

Connecting the Supply Chain

D.P. Mudaranthakam¹, J. Thompson¹, D. Streeter¹, G. Marikanti¹, R. Jensen¹, M. Mayo¹, A. Chahal¹, S. Yadav², J. McIlwain²

¹The University of Kansas Cancer Center; ²Velos

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. This is beginning to change as cancer centers and trials sponsors alike recognize the need and opportunity for transformation or to do what we call connecting the clinical research supply chain.

2. Goals

The goals were to test whether we could reduce the amount of time required to complete study tasks and case report form data entry and in the process accelerate the speed at which clinical trials can be completed. To cite one metric, according to a 2017 study completed by Tufts, it takes an average of eight days from the time a subject visit occurs for sponsors to receive visit data. The work KUCC has done, both within KUCC and between KUCC and a large clinical trial sponsor, demonstrates the material time savings that can be achieved through the integration of systems and study execution tasks both within our cancer center and between us and study sponsors.

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. This results in zero manual data entry for some data elements and reduces the time required to complete study requirements for other data elements. As a natural byproduct, study data accuracy also increased and source data became automatically available and connected to the study, both of which also save time and money for sites and sponsors alike.

4. Outcomes and Future Directions

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 visit. At scale, this translates to very substantial reductions in the amount of time and effort required to complete clinical studies and as a by-product the pace at which trials can be completed.

Address lessons learned and future directions:

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.



Connecting The Supply Chain

Dinesh Pal Mudarantthakam¹, Jeffrey Thompson¹, David Streeter¹, Goutham Marikanti¹, Roy Jensen¹, Matthew S. Mayo¹, Amar Chahal², Sunita Yadav², John McIlwain²



1. The University of Kansas Cancer Center, Kansas City, KS, USA
2. nCoup Inc, Fremont, CA, USA

INTRODUCTION

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Goals The goals were to test whether we could reduce the amount of time required to complete study tasks and case report form data entry and, in the process, accelerate the speed at which clinical trials can be completed. To cite one metric, according to a 2017 study completed by Tufts, it takes an average of eight days from the time a subject visit occurs for sponsors to receive visit data. The work KUCC has done, both within KUCC and between KUCC and a large clinical trial sponsor, demonstrates the material time savings that can be achieved through the integration of systems and study execution tasks both within our cancer center and between us and study sponsors

FUTURE DIRECTIONS

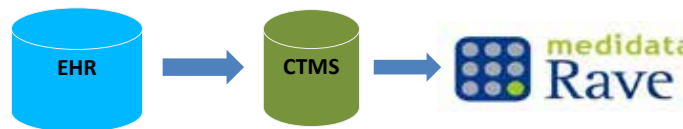
The lesson learned is that significant time savings can be achieved through integration of EMRs, local clinical trial management systems, and sponsor EDC systems. The future direction, now that the proof and concept is complete, is to scale the solution and bring in other cancer center and study sponsors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

KEY VALUE METRICS

3	Number of studies undertaken
380	Estimated data hours with manual data entry
190	Estimated data hours with structured data entry
\$24,700	Estimated cost with manual data entry
\$12,350	Estimated cost with structured data entry
50%	Estimated hours and cost reduction using structured data entry

METHODS

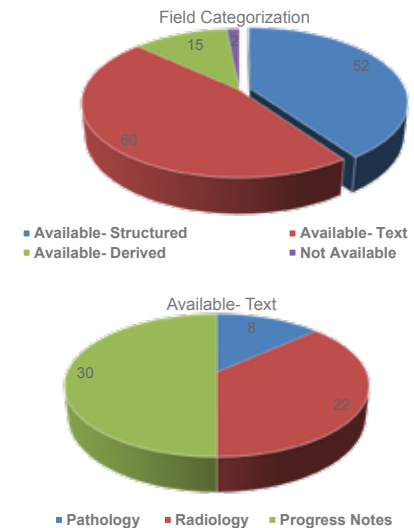
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Data Flow Diagram

RESULTS

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 visit. At scale, this translates to very substantial reductions in the amount of time and effort required to complete clinical studies and as a by-product the pace at which trials can be completed



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Data Analytics on Data Reporting: Building on Current Tools to Transform Available Data Into Useful Tools

K. Cha, A. Skafel, M. Kock, E. Pon

UCSF Helen Diller Family Comprehensive Cancer Center

1. Background

In 2016, a data reporting tool was created and implemented at the Helen Diller Family Comprehensive Cancer Center (HDFCCC). The tool tracks data entry completion rates by CRC, by study, and by type of event (e.g. study visit, query, SAE, etc.). The tool has been used to identify and focus study team efforts on specific areas with deficiencies, inform on staffing needs, help with workload assessments, and provide data for report-outs to senior leadership. Data completion (defined as outstanding data entered into the electronic data capture system) has improved year after year since implementing the tool (currently at 85% overall in 2018) and the report has allowed us to be proactive in taking the appropriate actions when goals are not met.

However, since the implementation, the tool had not undergone optimization; furthermore, there was no standardized method of transforming the raw data collected into a simple report to display key performance indicators and data trends in order to inform future strategies and prioritization.

2. Goals

1. Refine Elements: Scrutinize all data points from established data reporting tool for relevance in order to remove any non-value added elements
2. Automate process: Develop an automated process of data manipulation to prevent errors and to reduce effort
3. Develop Dashboard: Use data visualization tools to transform data into a simplified report for use by study teams

3. Solutions and Methods

1. Engaged study teams for feedback on areas of improvement for data report tool
2. Used Microsoft Excel as platform of choice for data analytics and visualization
3. Developed metrics and visualizations to highlight deficiencies

4. Outcomes and Future Directions

The data reporting tool was updated to become more streamlined, with elements both added and deleted.

- Staffing information was included in order to trend data completion vs staffing changes
- Tool was re-formatted to reduce file size and prevent breaks in Excel formulas
- Added in a calculation of total volume of study visits to help give additional context for each program's monthly data completion
- Automated the process of creating a monthly report through the use of pivot tables and formulas
- An interactive data dashboard was created in Excel for report-outs to study teams, in addition to senior leadership.
- Monthly reports that can be customized by program and month
- Data benchmarks against previous month as well as the Cancer Center average
- Includes tables, graphs, and tables

As of April 2019, Clinical Research Managers are now required to present monthly summaries from the data dashboard to their study teams and Program Leadership. This dashboard has helped in visualizing trends over time, becoming proactive in hiring, distributing workload, and troubleshooting specific areas of need, such as reducing the number of days to enter data.

Address lessons learned and future directions:

- Do not collect or request information beyond what is required; on the flip-side, present rationale and justification for the data points that are being requested
- Data dashboard can provide an efficient means of providing information to aid in business decisions
- Do not need expensive programs, Microsoft Excel allows for simple data analytics

Data Analytics on Data Reporting: Building on Current Tools to Transform Available Data into Useful Tools



Kyusun Cha CCRC CCRP, Mallory Kock MS CCRP, Elizabeth Pon CCRP, Andrea Skafel MSc CCRP

Background

In 2016, a data reporting tool was created and implemented at the UCSF Helen Diller Family Comprehensive Cancer Center (UCSF HDFCCC). The tool tracks data entry completion rates by Clinical Research Coordinator (CRC), by study, and by type of event (e.g. study visit, query, SAE, etc.). The tool has been used to identify and focus study team efforts on specific areas with deficiencies, inform on staffing needs, help with workload assessments, and provide data for report-outs to senior leadership. Data completion (defined as outstanding data entered into the electronic data capture system) has improved year after year since implementing the tool (currently at 86% overall as of May 2019) and the report has allowed us to be proactive in taking the appropriate actions when goals are not met.

In 2019, the tool underwent optimization in order to standardize the method of transforming the raw data collected into a simple report to display key performance indicators and data trends in order to inform future strategies and prioritization.

Goals to be achieved

The following goals were used to establish the scope of work

1. Refine Elements: Scrutinize all data points from established data reporting tool for relevance in order to remove any non-value added elements;
2. Automate process: Develop an automated process of data manipulation to prevent errors and to reduce effort; and
3. Develop Dashboard: Use data visualization tools to transform data into a simplified report for use by study teams

Methods Implemented

1. Engaged study teams for feedback on areas of improvement for data report tool
2. Used Microsoft Excel as platform of choice for data analytics and visualization
3. Developed metrics and visualizations to highlight deficiencies

The implementation of new changes spanned across 3 months, from initial feedback to official roll-out of updated tool. The feedback was received from daily users of the tool (CRCs) as well as the Clinical Research Managers (CRMs) from the cancer center.

Outcome

The data reporting tool was streamlined, with elements added and deleted.

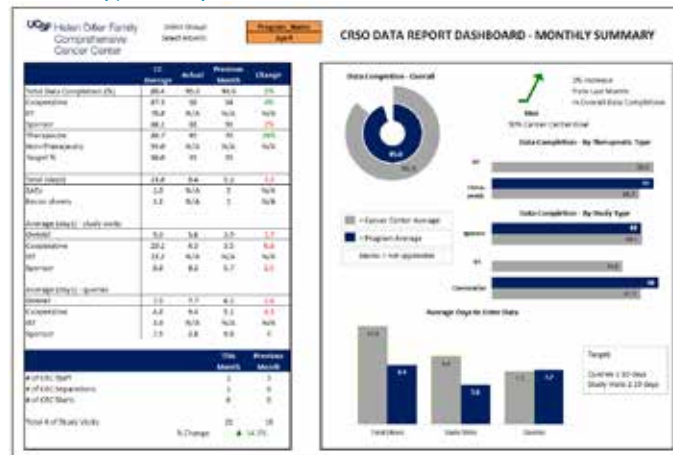
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- Added in a calculation of total volume of study visits to help give additional context for each program's monthly data completion
- Automated the process of creating a monthly report through the use of pivot tables and formulas

An interactive data dashboard was created in Excel for report-outs to study teams, in addition to senior leadership.

- Monthly reports that can be customized by program and month
- Data benchmarks against previous month as well as the HDFCCC average
- Includes tables, graphs, and tables

As of April 2019, CRMs are required to present monthly summaries from data dashboard to their study teams and Program Leadership. This dashboard has helped in visualizing trends over time, becoming proactive in hiring, distributing workload, and troubleshooting specific areas of need, such as reducing the number of days to enter data.

Program Specific Data Dashboard - Demo



Lessons Learned

- Do not collect or request information beyond what is required; on the flip-side, present rationale and justification for the data points that are being requested
- Data dashboard can provide an efficient means of providing information to aid in business decisions
- Do not need expensive programs, Microsoft Excel allows for simple data analytics

Future Direction

- Integration with OnCore and ability to run reports
- Calculation of % data completed within x days (i.e. within 5, 10, and 30 days)

Implementation and Application of the Ontario Protocol Assessment Level Tool at the Helen Diller Family Comprehensive Cancer Center

M. Kock, C. Aoun, K. Cha, A. Skafel

UCSF Helen Diller Family Comprehensive Cancer Center

1. Background

The Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) conducts over 460 clinical trials. These trials are conducted by 101 individual research staff, in 13 programs across 3 campuses. Due to the unpredictable nature of clinical trials and high turnover rate, clinical research programs struggle to adequately staff and assign clinical trial related work to their study teams.

The HDFCCC previously estimated workload based on patient accrual and/or the average percentage of data that was completed each month by Clinical Research Coordinators (CRCs). This excludes the complexity of a clinical trial in the workload assessment and results in a delayed feedback loop, as hiring managers are making staffing decisions after the data completion percentage dropped.

2. Goals

The goals were to develop and implement a workload assessment tool developed referencing the OPAL model developed by Smuck et. al (2011) so that the Clinical Research Manager (CRM) could determine a maximum and minimum workload assigned to a CRC. Once implemented, the workload assessment tool would provide a monthly score HDFCCC OPAL score. This score would begin to provide data and allow the CRMs to establish an HDFCCC OPAL score range that ensures the CRCs have adequate bandwidth to fulfil their job responsibilities of conducting their assigned clinical trials.

3. Solutions and Methods

The implementation of this project consisted of two key steps: development of the HDFCCC OPAL Tool scoring worksheet, followed by tracking the program's monthly HDFCCC OPAL score (Smuck et al., 2011). The Associate Director of Clinical Research Programs (ADCRP) and CRM of the HMRP met to review and tailor the OPAL Tool Scoring Worksheet developed by Smuck et al. in 2011. This scoring worksheet was created in Microsoft Excel and generated the HDFCCC OPAL base score specific to each clinical trial based on the complexity of the clinical trial. Monthly, the CRM modified the HDFCCC OPAL Program Report and incorporated the accrual information for each clinical trial, producing the program's cumulative HDFCCC OPAL score.

The Hematologic Malignancy Research Program (HMRP) was selected to pilot the project as the program had completed a mere 14% of their monthly data entry requirements in June 2016. As the program increased their overall data completion, the program struggled to consistently meet the HDFCCC goal of 85% monthly data completion due to fluctuations in accruals onto their complex clinical trials.

4. Outcomes and Future Directions

The CRM demonstrated that the program's cumulative HDFCCC OPAL score ranged from 847-898 and with a team of 7 CRCs, the average monthly HDFCCC OPAL score for CRC ranged from 121 to 128 (as demonstrated in Figure 2 and Figure 3). Ongoing data collection is taking place to further refine the maximum and minimum range using the HDFCCC OPAL values.

References:

Smuck, B., Bettello, P., Berghout, K., Hanna, T., Kowaleski, B., Phippard, L., Au, D., 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.

Implementation & Application of the Ontario Protocol Assessment Level Tool at the Helen Diller Family Comprehensive Cancer Center



Mallory Kock, MS, CCRP, Charlie Aoun, CCRP, Kyusun Cha, CCRC, CCRP, Andrea Skafel, MSc, CCRP

Background

The Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) conducts over 460 clinical trials. These trials are conducted by 101 individual research staff in 13 programs across 3 campuses.

The HDFCCC previously estimated workload based on patient accrual and/or the average percentage of data that was completed each month by Clinical Research Coordinators (CRCs). These estimates did not account for the complexity of a clinical trial.

This project aims to develop and implement the Ontario Protocol Assessment Level (OPAL) Tool originally developed by Smuck, et al., (2011) to address inadequate staffing in the Hematologic Malignancy Research Program (HMRP) at UCSF's HDFCCC.

The HMRP was selected to pilot this project as the program struggled to meet and maintain HDFCCC's goal of 85% monthly data completion due to the fluctuations in patient accruals onto their complex clinical trials.



Goals

The goal of this project was to:

- Develop and implement a workload assessment tool referencing the OPAL model developed by Smuck, et al., (2011).
- Provide each Clinical Research Manager (CRM) with a monthly cumulative HDFCCC OPAL score for their staff. This would allow the CRM to determine a minimum and maximum workload that can be assigned to a CRC and proactively identify staffing needs.

HDFCCC Opal Tool Development & Implementation

The implementation of this project consisted of two key steps: development of the HDFCCC OPAL Tool Scoring Worksheet, followed by tracking the program's monthly HDFCCC OPAL Score.

This scoring worksheet was based off of the original tool produced by Smuck, et al., and tailored to fit the needs of HDFCCC (2011). The HDFCCC OPAL Tool Scoring Worksheet generated the HDFCCC OPAL base score specific to each clinical trials based on the complexity of the clinical trial.

HDFCCC OPAL Tool Scoring Worksheet

The Associate Director of Clinical Research Programs (ADCRP) and CRM of the HMRP met to review and tailor the OPAL Tool Scoring Worksheet developed by Smuck, et al., (2011).

At this time, the HDFCCC CRC Job Description, performance goals and existing workflows were reviewed to identify key tasks performed by CRCs. These tasks, as well as special procedures unique to oncology trials were incorporated into the HDFCCC OPAL Tool Scoring Worksheet.

The scoring worksheet generated the HDFCCC Base OPAL score specific to each clinical trial based on the trial's complexity.

Special Procedures

Use of central lab	Yes
Pathology	No
Radiology (e.g. upload of scans)	Yes
Tumor banking	Yes
Archived tissue	No

PK sampling (pre & post infusions)	Yes
ECG (by CRC)	No
Serial lab or BCIs (in one visit)	No
Biomarker specimen collection	Yes
Blood banking (at UCSF)	No
Eligibility biomarkers (e.g. KRAS, FISH, HER2, PDx)	No

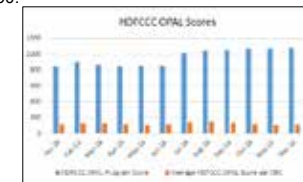
HDFCCC OPAL Program Summary

Monthly, the CRM updated the HDFCCC OPAL Program Report with current accrual information for each clinical trial, producing the HMRP's cumulative HDFCCC OPAL Score.

Study	Base OPAL	# patients assessed	Ineligible	Active Patients	Active Pts Off Treatment or In Surv R/L	# Patients in TRT	HDFCCC OPAL Score	Data % Completion
Study 12345	12.21	1	1	1	1	1	11.00	90.2%
Study 23456	1.20	10	10	0	0	0	11.00	90.2%
Study 34567	2.30	10	10	0	0	0	11.00	90.2%
Study 45678	3.40	10	10	0	0	0	11.00	90.2%
Study 56789	4.50	10	10	0	0	0	11.00	90.2%
Study 67890	5.60	10	10	0	0	0	11.00	90.2%
Study 78901	6.70	10	10	0	0	0	11.00	90.2%
Study 89012	7.80	10	10	0	0	0	11.00	90.2%
Study 90123	8.90	10	10	0	0	0	11.00	90.2%
Study 01234	9.00	10	10	0	0	0	11.00	90.2%
Total Active Worksheet for CRC #1	50.11	100	100	0	0	0	11.00	90.2%

Results

The HMRP's cumulative HDFCCC OPAL score ranged from 847-1091. The average monthly HDFCCC OPAL score per CRC ranged from 107-150.



After implementation of the HDFCCC OPAL Tool in February 2018, the HMRP effectively used the HDFCCC OPAL scores to assign CRCs a workload that allowed the program to consistently maintain their data completion percentage of 85% or more from March 2018 through December 2018.



Conclusions

This pilot project demonstrates that the OPAL tool can be developed and implemented to evaluate the varying complexities inherent to staffing clinical trials. The application of the HDFCCC OPAL tool allows CRMs to identify the workload required for a clinical trial and make staffing adjustments proactively in order to ensure all trials are audit-ready.

Reference

Smuck, B., Bettello, P., Berghout, K., Hanna, T., Kowaleski, B., Phippard, L., Au, D., 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. JOP.2010.000051.

Creating a Clinical Research Network

A. Yost, L. Curran, A. Skafel, M. Feng, E. Small

UCSF Helen Diller Family Comprehensive Cancer Center

1. Background

The Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) is located in the San Francisco Bay Area – a large urban area in which travel can be challenging and time consuming. Community oncologists deliver much of the cancer care in the area, but cancer advances can take years to be adopted in the community setting and these clinical groups and community hospitals typically don't have the resources or expertise to conduct clinical trials on their own. In order to increase access to innovative care through oncology clinical trials in the community setting, UCSF created the Clinical Research Network Office (CRNO) in 2017.

2. Goals

The primary objective of UCSF's CRNO is to help develop, streamline, and improve clinical research opportunities at regional affiliate sites. Together with our partners, our goal is to provide local access to innovative clinical trials for every patient, by removing the need for patients to travel to UCSF or other facilities.

- Eliminate redundancies in study activation and operations across network sites.
- Ensure the standards and quality of research being done is uniform across network sites.

3. Solutions and Methods

The network is currently comprised of two local hospitals in San Francisco proper, and three community hospitals located in the surrounding area. Affiliate sites can sign a UCSF IRB reliance agreement and utilize the UCSF IRB. The CRNO provides oversight and regular monitoring from the HDFCCC Data and Safety Monitoring Committee (DSMC). Training programs are provided for all study staff including research coordinators, pharmacy, regulatory, and investigators.

Investigators and staff at affiliate sites have access to HDFCCC disease specific clinical research working groups (termed "site committees") where they can be involved in preliminary discussions around study design and feasibility, to ensure the trials can be implemented at their sites. Site committees also review all safety events, and community oncologists that enroll patients on clinical trials are expected to participate in these reviews. Affiliate sites can participate in tumor boards and educational talks/conferences offered at the HDFCCC. The CRNO facilitates clinical trial portfolio management at the affiliate sites in order to leverage existing patient populations and identify/ fill in gaps in offerings at UCSF (i.e. frontline therapies).

4. Outcomes and Future Directions

The network is in its early stages, but to date has built positive interactions between UCSF and our affiliate sites. We have been able to enhance the research programs at the two local hospitals as well as build a new clinical research program from scratch at one of our affiliate sites. The CRNO developed a process for how trials are offered to affiliates, metrics they must meet to open new types of trials and how the affiliate sites will be monitored to ensure compliance and patient safety. We have expanded

UCSF's HDFCCC training program to be applicable to affiliate sites. Affiliate participation in site committees and tumor boards has increased. We will continue to build the CRNO by adding more network sites as well as streamlining processes and increasing the amount and complexity of clinical trials run at already existing sites.



Background

The Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) is located in the San Francisco Bay Area – a large urban area in which travel can be challenging and time consuming.

Community oncologists deliver much of the cancer care in the area, but cancer advances can take years to be adopted in the community setting and these clinical groups and community hospitals typically don't have the resources or expertise to conduct clinical trials on their own.

In order to increase access to innovative care through oncology clinical trials in the community setting, UCSF created the Clinical Research Network Office (CRNO) in 2017.

CRNO Objectives

- The primary objective of UCSF's CRNO is to help develop, streamline, and improve clinical research opportunities at regional affiliate sites.

Together with our partners, our goal is to provide local access to innovative clinical trials for every patient, by removing the need for patients to travel to UCSF or other facilities. Specific goals include:

- Eliminate redundancies in study activation and operations across network sites.
- Ensure the standards and quality of research being done is uniform across network sites.
- Provide infrastructure for review and prioritization of trials, conduct of trials, compliance, and monitoring.



Together with our partners, our goal is to provide local access to innovative clinical trials for every patient.

CRNO Support for Network Sites

Administrative/regulatory

- Address administrative burdens such as navigation of the many electronic portals, registrations, and applications required to conduct clinical trials
- Assist local sites navigate the clinical trial process as efficiently as possible

Clinical Trial Portfolio Management

- Assist sites in selecting the most appropriate clinical trials for their patients. This consists of first examining their most common cancer types and stages, the types of trials their patients and medical providers would find exciting, and reviewing the logistical requirements of trials to ensure they can be carried out within space, equipment, and staffing constraints

Policies and Procedures

- Assist in the development of standard operating procedures (SOPs) and policies for obtaining informed consent, calendaring and scheduling, documenting/reporting treatment and toxicity, and all other data requirements
- Ensure compliance with all regulatory requirements (federal and local)
- Customize to each affiliate's electronic medical record, work flow, and staffing

Monitoring Support

- Local Data Safety Monitoring, in order to ensure compliance with mandatory reporting and data management
- Provided by a dedicated CRNO-Data Safety Auditor who supports preparation for audits and inspections
- Audits are undertaken of the research records of early patients enrolled on every clinical trials and provide feedback for improvement

Personnel Training and Support

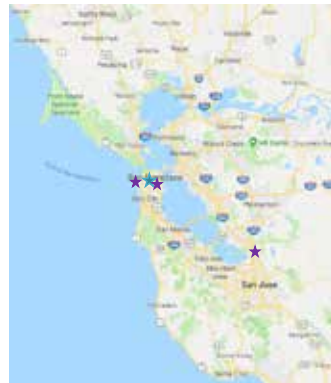
- Training, continuing education, certification, and mentoring of all research personnel
- Includes clinical research coordinators, pharmacists, and physicians
- Provides peer and mentoring resources to maximize job satisfaction and continuity

Infrastructure Support

For new research enterprises:

- Structural organization of research activities
- Developing space requirements
- Provide guidelines and infrastructure to ensure that the pharmacy meets investigational drug service requirements
- Provide guidelines and infrastructure for biologic specimen acquisition and processing

Current Network Status



Washington Hospital Healthcare System (WHHS)

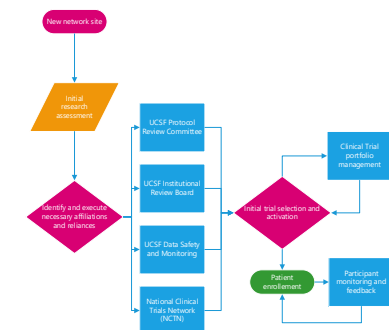
WHHS partnered with UCSF to build a brand new clinical research program. This included recruitment/training of staff, IRB reliance, cooperative group affiliation, SOP creation and portfolio management.

Zuckerberg San Francisco General Hospital (ZSFG)

ZSFG is a long standing satellite site of UCSF, utilizing UCSF scientific and ethical reviews as well as monitoring and training support. CRNO is working with their clinical trial team to grow their existing program and expand access to clinical trials to more of their patients.

San Francisco Veterans Affairs Medical Center (SFVA)

SFVA is also a long standing satellite site and NCTN affiliate. The CRNO is excited to partner with them to provide training and educational opportunities, clinical trial operations support and portfolio management.



Future Directions

- 3- 5 additional network sites in planning stages
- Streamlining processes and increasing the number and complexity of clinical trials run at existing sites
- Facilitation of ongoing learning opportunities and collaboration for all involved parties

Building a Clinical Career Ladder

S. Belanger, S. Ladd

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

1. Background

During interviews, most study coordinator (SC) candidates say they seek growth and upward mobility. The reality in our Clinical Protocol Office (CPO) was that once an SC wanted growth, they had three options: become a manager (limited opportunities), switch to another role laterally within the CPO, or leave altogether. Staff would often go to industry (common given our location within the Research Triangle) in search of more opportunities. Providing regular support for staff was also challenging. Our clinical branch consisted of two leadership positions overseeing approximately fifty staff across four buildings. Between physical barriers and numerous obligations, supervisor availability to all staff was insufficient. Staff need and deserve consistent resources for assistance and support.

2. Goals

We sought a way to provide SCs with support and growth opportunities. We posited that implementing a career ladder would embed more support within the office, resulting in greater protocol compliance. We also felt this would provide built-in growth and professional development opportunities, resulting in greater staff satisfaction and retention.

3. Solutions and Methods

In November 2017, we implemented phase one of our career ladder. SCs were designated to an SC1 or SC2 role. SC1s have one year of SC experience or one year of experience in oncology clinical trials; SC1s spend 100% of their time coordinating trials and learning the role. SC2s have two years of SC experience, one of which must be within oncology; SC2s spend most of their time coordinating trials, but also help train new staff, participate in advisory groups, facilitate site selection visits, etc.

In November 2018, we implemented phase two of our career ladder. We sought to identify SC3s to lead SC1s and SC2s. SC3s have three years of SC experience, two of which must be within oncology, and are certified through SOCRA or ACRP; SC2s meeting these qualifications could apply into the SC3 role. SC3s spend 50% of their time coordinating trials and 50% providing portfolio management and program support, as well as being a team lead for daily tasks like training, leave approvals, and being a resource. Once identified, SC3s were provided support, regular leadership meetings, and HR training, as we recognize that this new part of the role is vastly different than what they have previously experienced.

4. Outcomes and Future Directions

Though phase two of the career ladder is still new, we are already seeing positive effects, such as:

- More clinical staff are interested in obtaining professional certification
- More leaders who can provide mentorship, being closer to the work
- Staff feel more supported via daily interactions with their leads
- Better portfolio management (identifying trial needs, monitoring activation timelines, etc.)

Our SC3s are still new to their role, so we are gradually giving them more responsibilities in order to not overwhelm them. We continue identifying more HR trainings for them to attend and occasionally have HR leadership attend our meetings to help address specific areas of interest. We will also read a leadership book together and facilitate discussions. In the next several months, we also plan to hire additional managers to provide additional support and oversight.

Building a Clinical Career Ladder

Stefanie Belanger, BA, CCRP, Stephanie Ladd, BS, CCRP

Background

During interviews, most study coordinator (SC) candidates say they seek growth and upward mobility. The reality in our Clinical Protocol Office (CPO) was that once an SC wanted growth, they had three options: become a manager (limited opportunities), switch to another role laterally within the CPO, or leave altogether. Staff would often go to industry (common given our location within the Research Triangle) in search of more opportunities.

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Goals

We sought a way to provide SCs with support and growth opportunities. We posited that implementing a career ladder would embed more support within the office, resulting in greater protocol compliance. We also felt this would provide built-in growth and professional development opportunities, resulting in greater staff satisfaction and retention.

Phase 1: November 2017

- **Study Coordinator 1 (SC1)**
 - One year study coordinator experience or experience in oncology clinical trials
 - Duties: 100% study coordination; other duties as assigned
- **Study Coordinator 2 (SC2)**
 - Two years study coordinator experience, one year oncology trial coordination experience
 - Duties: study coordination; participating in advisory groups, precepting, SSVs, other duties as assigned

Methods

Clinical Structure Before



Clinical Structure After



Methods (cont'd)

Phase 2: November 2018

- **Study Coordinator 3 (SC3, Lead Study Coordinator)**
 - 3 years study coordinator experience, 2 years oncology trial coordination experience
 - Certification with SOCRA or ACRP required
 - Duties: 50% study coordination; portfolio management, team lead, program support, other duties as assigned

Once identified, SC3s were provided support, regular leadership meetings, and HR training, as we recognize that this new part of the role is vastly different than what they have previously experienced.

Though phase two of the career ladder is still new, we are already seeing positive effects, such as:

- More clinical staff are interested in obtaining professional certification
- More leaders who can provide mentorship, being closer to the work
- Staff feel more supported via daily interactions with their leads
- Better portfolio management (identifying trial needs, monitoring activation timelines, etc.)

Outcomes

Conclusions

Our SC3s are still new to their role, so we are gradually giving them more responsibilities in order to not overwhelm them. We continue identifying more HR trainings for them to attend and occasionally have HR leadership attend our meetings to help address specific areas of interest. We will also read a leadership book together and facilitate discussions. In the next several months, we also plan to hire additional managers to provide additional support and oversight.

Deployment of a Cancer Population Science Clinical Research Navigator to Improve Engagement With CPS Investigators

A. Anderson, A. Ivey, T. George

University of Florida Health Cancer Center

1. Background

The UF Health Cancer Center (UFHCC) Clinical Research Office (CRO) is responsible for tracking and reporting all cancer relevant research activity, including Cancer Population Science (CPS) research. Historically, the CRO had limited interactions with CPS investigators and study staff, and therefore CPS study activity was not routinely captured. In 2017, a new requirement for all cancer research to undergo Scientific Review and Monitoring Committee (SRMC) review lead to improved knowledge of new studies in the CPS area. However, obtaining ongoing updates for study progress proved difficult and some CPS investigators expressed frustration with navigating the regulatory processes. As a result, CRO established a designated CPS Navigator team to assist investigators with navigating study activation and ongoing review processes while simultaneously fostering working relationships with CPS staff.

2. Goals

- Improve the capture of protocol status and accrual information within the Clinical Trials Management System (CTMS), OnCore
- Enhance communications with CPS staff by providing support to navigate institutional research requirements to deploy and maintain study portfolios

3. Solutions and Methods

During SRMC review, periodic updates were sought by CRO staff by contacting CPS teams for protocol status and accrual updates. In early 2018, a dedicated Regulatory Specialist was hired to help navigate CPS trials through protocol activation and the IRB process. This incremental hire allowed management of IRB submissions for CPS investigators as long as accrual updates were provided on a regular basis. This hire also supported entry of accruals and study status updates into OnCore.

This dedicated resource subsequently led to increased requests for trial support. A second staffer was hired shortly thereafter who possessed both regulatory and study coordination experience, given the diversity of CPS-style studies conducted at UFHCC. Together, this CPS Navigator team utilizes a shared email address so that all messages are shared allowing for improved communication and cross coverage.

4. Outcomes and Future Directions

From January 2017 through May 2018, only 23 new CPS studies were known to the center and accrual updates were non-existent. Upon deploying the CPS Navigator team, we identified and logged roughly 750 accruals associated with these studies. An additional 16 new CPS trials were subsequently activated with cumulative enrollments exceeding 3800 subjects by the end of 2018. Through efforts of the CPS Clinical Research Navigator team, the number of studies identified and accruals tracked increased exponentially due to the CPS study accruals actively being entered into OnCore. Communications and engagement between the CRO and CPS investigators through the CPS Navigator Team have similarly improved.

Early on we discovered that many CPS and UFHCC CRO staff members did not share a common research lexicon. CPS Navigator staff had to modify messaging and reduce technical language/acronyms with CPS staff who were unfamiliar with UFHCC and NCI reporting requirements. Reciprocating, CRO staff needed to expand their working knowledge of clinical research study types and interventions. Clarity regarding accrual reporting was also provided, to prevent under and/or over reporting of accruals, especially for trials that were multisite. A future goal is to scale the program services to offer more bandwidth as CPS program faculty ranks expand.

Deployment of a Cancer Population Science Clinical Research Navigator to Improve Engagement with CPS Investigators

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

BACKGROUND

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SOLUTIONS & METHODS

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FUTURE DIRECTIONS

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A future goal is to scale the program services to offer more bandwidth as CPS program faculty ranks expand.

GOALS

- Improve the capture of protocol status and accrual information within the Clinical Trials Management System (CTMS), OnCore
- Enhance communications with CPS staff by providing support to navigate institutional research requirements to deploy and maintain study portfolios

OUTCOMES

From January 2017 through May 2018, only 23 new CPS studies were known to the center and accrual updates were non-existent. Upon deploying the CPS Navigator team, we identified and logged roughly 750 accruals associated with these studies. An additional 16 new CPS trials were subsequently activated with cumulative enrollments exceeding 3800 subjects by the end of 2018.

Through efforts of the CPS Clinical Research Navigator team, the number of studies identified and accruals tracked increased exponentially due to the CPS study accruals actively being entered into OnCore. Communications and engagement between the CRO and CPS investigators through the CPS Navigator Team have similarly improved.

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A Data Informed Approach to Staffing Using OnCore

L. Pettiford, A. Ivey, H. Koranne, W.J. Stokes, T. George

University of Florida Health Cancer Center

1. Background

The UF Health Cancer Center Clinical Research Office (CRO) is rapidly expanding and currently staffed with 24 Clinical Research Coordinators (CRCs). The CRC role continues to evolve with the increasing complexity of studies and growing administrative responsibilities. Historically, a CRC's assigned trials were aligned with their designated Disease Site Group (DSG) without taking into account staff workload. This led to workload imbalances and perceptions in inequity that had a negative impact on trial operations and subject management.

2. Goals

The Coordinator Workload Report was designed to provide objective and automated reporting of coordinator assignments with the ability to identify trends and predict future workload capacity. A major goal was to improve job satisfaction, protocol compliance, and subject safety by identifying and establishing acceptable workloads for CRCs. This report is used to inform staffing needs, including hiring of incremental staff and/or reassignment of existing staff. Reporting has also allowed leadership to quantitatively measure effort in a manner other than simply counting accruals.

3. Solutions and Methods

A CRO working group reviewed multiple existing tools including the NCI Trial Complexity Elements & Scoring Model, the Wichita Protocol Acuity Tool (WPAT), and the US Oncology Research Study Clinical Coordination Grading tool. The Ontario Protocol Assessment Level (OPAL) tool was chosen as a basis for our workload report as the CRO leadership team felt OPAL achieved a balance between specificity and ease of use when scoring trials. A modified OPAL score is calculated for each study and the score is entered in OnCore as a protocol-specific annotation. A protocol level workload is then assigned to the primary study coordinator with the flexibility to assign workloads at the subject level to the staffer managing each accrual. CRO leadership established designated ranges for staff based on internal benchmarking. New CRCs have a threshold of 120, established CRCs at 150, and experienced CRCs at a score of 180. Workloads are tracked on a weekly and ad hoc basis. In addition, projected workloads can be manually calculated using data entered in the accrual duration, lower accrual goal, and protocol status date fields.

4. Outcomes and Future Directions

Implementation of the workload report has allowed objective management of CRC assignments by CRO leadership and unit managers. This tool can be used from feasibility and study start-up through the lifetime management of the study. Unit managers have successfully used the tool to shift CRC assignments and justify the need for incremental hires during the last year based on data rather than perceived capacity.

The workload report is a tool that can help CRO leadership and unit managers make objective decisions about CRC assignments. However, the tool is limited in that the CRC workload is highly dependent upon accurate and timely study and subject enrollment updates in OnCore. Currently, the

Institutional Perspectives on Cancer Community Activation Timelines

S. Stewart¹, W. Tate², L. Hilty²

¹University of Wisconsin Carbone Cancer Center; ²Forte Research Systems

1. Background

Cancer centers have multiple competing deadlines coming from their institutions as well as from clinical trial sponsors, including pressure to decrease the time it takes to activate a study. However, there is a lack of information available to institutions on whether timelines requested by internal and external stakeholders are comparable to peer organizations. Without knowing whether shorter timelines are being achieved by peer organizations, institutions have a greater difficulty knowing if they are competitive in the activation space and whether shortening study activation timelines to a value set by sponsors (whether industry or NCI) are achievable.

2. Goals

Median turnaround times from the aggregated Forte Benchmarks cancer community will be generated. These include times to complete the PRMC, IRB, budgeting, contracting, and overall activation processes. Collaborating institutions will review these timelines and provide commentary and assessment of the community timelines, current requirements of the center by internal and external stakeholders, and what these metrics mean in the current landscape of activating clinical trials.

3. Solutions and Methods

The Benchmarks database will be queried by Forte to look at turnaround times for protocols that were activated in calendar year 2018. These timelines will be shared with the institutional partners for their analysis. Responses will be aggregated and presented for broader community discussion at the AACI CRI conference.

4. Outcomes and Future Directions

Analysis to be completed in Spring 2019. A similar analysis was performed by Forte in Fall 2018 for the AACI-CCAF conference and showed that the overall activation timelines for institutional protocols took approximately 20-30 days longer than industry, while national group protocols took about 60 days fewer than industry. The fastest of national group protocols met the NCI cutoff for activation of 60-90 days while; however, the majority of these protocols were above this requirement. Time to finalize study budgets has decreased over the last five years, while PRMC review times have remained steady.

Many organizations are in a vacuum when it comes to understanding where they stand in comparison to their peers in activation timelines. This puts them at a disadvantage when it comes to negotiating with sponsors or setting achievable process improvement goals. Analyses and discussions such as this remove the “black box” and allows institutions to come together to better the clinical research enterprise through the sharing of realistic and streamlined processes and timelines.

INSTITUTIONAL PERSPECTIVES ON CANCER COMMUNITY ACTIVATION TIMES



BACKGROUND

- Cancer Centers are under pressure to decrease trial time to activation
- NCI expects protocols to be activated in **8 to 12 weeks**
- Cancer Centers want to know
 - Are we competitive with our peers?
 - Are these timelines achievable?



METHODS

- Forte Benchmarks database queried:
 - Cancer Centers
 - Treatment Intervention Protocols
 - December 2018 – May 2019



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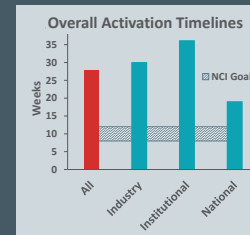


RESULTS

Activation Metric	Sponsor Type	# Orgs	# Protocols	Turnaround Times (days)		
				25 th %ile	Median	75 th %ile
Overall	All protocols	19	548	124	196	273
	Industry	18	267	153	210	278
	Institutional	17	79	178	253	378
	National	19	165	76	133	231
PRMC	All protocols	19	713	8	20	42
	Industry	19	370	13	28	47
	Institutional	18	100	8	22	64
	National	18	172	3	9	19
IRB	All protocols	19	556	6	21	61
	Industry	17	299	9	26	66
	Institutional	18	73	26	53	81
	National	19	145	1	3	22
IRB-Open	All protocols	19	530	21	57	127
	Industry	17	256	28	58	102
	Institutional	17	77	34	69	161
	National	19	161	10	46	152
Open-FPI	All protocols	18	375	27	70	189
	Industry	18	198	24	61	137
	Institutional	16	63	21	51	128
	National	17	93	30	122	383
Budget	All protocols	7	83	64	103	150
	Industry	7	78	72	106	152
Contract	All protocols	7	71	93	132	188
	Industry	7	56	101	136	189
Contract-Open	All protocols	10	119	14	54	91
	Industry	9	91	14	53	83

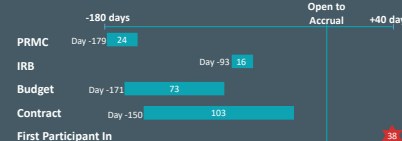
KEY TAKE-AWAYS

- Activation timelines are much slower than NCI goals



- **NO centers** have a median activation time under 12 weeks
- Fastest averages ~3 months
- 2/3 of centers have fewer than 10% activating in 12 wks
- Protocols with **concurrent** PRMC and IRB processes (9% of protocols) activated on average **53 days faster** than ones with sequential processes (161 v. 218)
- Of protocols that closed in this timeframe, **25% were zero-accruing**

- Median time between the last major process completed and the open to accrual date is **50 days**



*graph depicts protocols with all 4 processes represented



DISCUSSION

- 8-12 weeks is possible for **individual trials**, but it's not a realistic metric for Cancer Centers to achieve **TODAY**
- Significant effort spent on zero-accruing trials – for what gain?
- **What can Cancer Centers do?**
 - Decrease National Group study activation to **30 days** – possible?
 - Concurrent processes (e.g., PRMC/IRB)
 - Minimize 'gap time' between last major process and opening
 - SIV scheduling / sponsor activation
 - Institutional processes (e.g., financial, chemo orders, institutional review, calendar build)
 - Dedicated activation staff
 - Manage workload and number of trials in activation



FORTE
Benchmarks.

A Task-Based Automated Comprehensive Assessment Tool for Clinical Trial-Associated Workload

J. Plassmeyer, D. Cleary, C. Muniz, T. Doeblner, B. Crocker, K. Yee, K. Richter, B. Pappu

UPMC Hillman Cancer Center

1. Background

The accurate and efficient assessment of workload enables the effective deployment of research personnel to support clinical trials. Workload assessment enables managers to distribute workload among the research staff more evenly, which prevents staff burn-out and reduces turnover. However, this evaluation is intricate by the development of increasingly complex trials, more restrictive patient criteria, decreased funding, and subjective trial assessments. We have developed an objective, task-based acuity assessment tool that utilizes real-time data produced by our internally developed Clinical Trials Management Application (CTMA) to measure workload.

2. Goals

Our complexity assessment tool evaluates the time spent on various tasks performed over the course of the clinical trial life cycle including study start up, diagnostic testing requirements, scheduling, treatment day visits, safety, modifications, data gathering and entry, queries, monitoring/audit, and other administrative tasks. Using this information, we have analyzed the acuity of each employee (Research Nurses, Data Coordinators, Safety Specialists, and Regulatory Specialists), which has enabled our managers to make objective decisions on staffing and workload distribution while also monitoring compliance and efficacy. We have set 2,000 work hours ($\pm 5\%$) per year as the benchmark goal per full-time equivalent (FTE) and adjusted the study and patient assignment based on the real-time assessment of this benchmark.

3. Solutions and Methods

CTMA documents information related to all aspects of the clinical trial life cycle, including study start up, patient enrollment, study visits, queries and other administrative tasks. This information is linked to each staff member to accurately measure his/her workload. Real-time data is analyzed by a pre-designed algorithm that will automatically calculate time spent per task category.

The algorithm for each job category (Nursing, Data, Regulatory, Safety) was developed by employee working groups. The data is analyzed and made available to management, and can be drilled down to the staff, disease center, and department level.

4. Outcomes and Future Directions

The outcome will allow us to accurately assess cumulative workload, completed vs anticipated workload per employee based on existing studies and patient load. In addition, it will provide real-time compliance information that will improve corrective action effectiveness. Using this data, we have reassigned active patients evenly among the Research Nurses, and shuffled FTEs between disease centers based on complexity rather than number of open trials and accruals, which do not necessarily translate to increased workload. The data will also allow for a projection of time to any point throughout the year (quarterly, biannually, annually) so that the workload can be distributed appropriately by management. In addition, the information will enable management to make more informed decisions about overall staffing and budgeting of trials and provides a foundation for higher level financial and efficiency analyses.

The complexity assessment can be used to assess a variety of activities based on the information compiled. Our center is conducting a comprehensive analysis of a variety of critical areas in clinical research including time to activation, cost outs, invoicing, query analysis, and regulatory tracking. Most importantly, transparent assessment of workload has resulted in increased employee satisfaction based on internal HR surveys.

A task-based automated comprehensive assessment tool for clinical trial-associated workload

¹Joshua Plassmeyer, ¹Deidre Cleary, ¹Carrie Muniz, ²Tim Doebler, ²Brenda Crocker, ²Kristie Yee, ²Kelli Richter, ¹Bhanu Pappu
¹UPMC Hillman Cancer Center Clinical Research Services ²UPMC Hillman Cancer Center Information Services

Background

The accurate and efficient assessment of workload enables;

- the effective deployment of research personnel to support clinical trials
- even distribution of workload among staff
- Deploy strategies to prevent staff burnout and turnover

We have developed an objective, task-based acuity assessment tool that utilizes real-time data produced by our internally developed Clinical Trials Management Application (CTMA) to measure workload.

Goals

Our complexity assessment tool evaluates the time spent on various tasks including

- study start up
- diagnostic testing requirements
- scheduling
- treatment day visits
- safety
- modifications
- data collection, entry & queries
- monitoring/audit
- administrative tasks.

- Complexity Scale covers
 - Research Nurses
 - Data Coordinators
 - Regulatory Specialists
 - Quality Improvement & Safety Specialists
- 2,000 work hours ($\pm 10\%$) per year is the benchmark goal per full-time equivalent (FTE)
- Study and patient assignment is adjusted based on the real-time assessment of this benchmark.

Implementation

- CTMA documents trial life cycle information study start up, execution and closure
- Information is linked to each staff member to accurately measure his/her workload.
- Real-time data is analyzed by a pre-designed algorithm that will automatically calculate time spent per task category.
- The data is analyzed and made available to management, and can be drilled down to the staff, disease center, and department level.

Outcomes

- Accurately assess workload per employee based on existing patients and anticipated accruals
 - cumulative
 - completed vs anticipated
- Reassign patients or studies evenly among staff
- Reallocated FTEs within disease centers
- Use accurate task based workload assessment rather than number of open trials and accruals
- Provide real-time compliance that allows for prompt data completion
- Faster revenue realization
- Enable overall staffing and budgeting of trials
- Provides a foundation for higher level financial and efficiency analyses
- Hired schedulers to replace administrative duties of the research nurses

Data Coordinator Workload

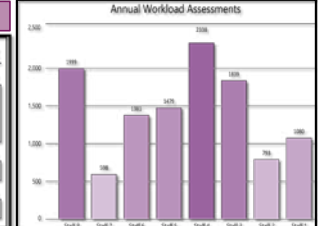
Tasks	Percent Effort
Projected Time (anticipated accruals)	34.62%
Data Entry	23.11%
Center Level Tasks	15.51%
Query	7.76%
Lab Time	5.49%
Monitoring	3.13%
Miscellaneous	3.07%
IT Issues	2.86%
Chart Prep	1.95%
Modifications	0.92%
Start Up	0.84%
Safety	0.72%

Research Nurse Workload

Tasks	Percent Effort
Projected Time (anticipated accruals)	31.41%
Center Level Tasks	25.86%
Patient Care	15.40%
Scheduling*	13.77%
Modification	3.75%
Start Up / Screening	3.15%
Miscellaneous	3.15%
Monitor/Audits	2.49%
Safety	1.03%

Regulatory Workload

Tasks	Percent Effort
Start Up	34.40%
Administrative (Documentation Compliance, Signatures, etc)	32.57%
Monitoring	15.00%
Center Level Tasks	8.17%
Modifications	5.41%
Miscellaneous	4.44%



Future Directions

The complexity assessment can be used to assess a variety of activities based on the information compiled. Our center is conducting a comprehensive analysis of critical areas in clinical research including time to activation, cost outs, invoicing, query analysis, and regulatory tracking. Most importantly, transparent assessment of workload has resulted in increased employee satisfaction based on internal HR surveys.

Creating the Standard for Specialized Nurse Training in the Phase I Clinical Trials Setting

C. Belmore, J. Bourgeois, J. Warren, C. Lewis, R.D. Harvey, T. Mann

Winship Cancer Institute of Emory University

1. Background

The complexity of phase I clinical trials requires specialized nurses dedicated to safe and compassionate care while obtaining quality data collection through a comprehensive understanding of clinical practice. A phase I clinical trial treatment visit consists of safety measures and research requirements including adverse event assessments, preventative interventions for toxicities, research lab requirements and frequent vital sign monitoring including electrocardiograms. These observations are paired with detailed documentation necessary in monitoring drug activity and patient safety. It is essential to have a nursing staff trained to navigate complex research protocols in an effective and efficient manner that benefits both patient and research study needs.

2. Goals

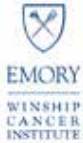
In January of 2019, The Phase I Unit at Winship Cancer Institute (WCI) of Emory University relocated to a new, larger, state of the art unit. To ensure excellent patient care and research conduct, the nursing team is required to complete comprehensive certifications and training. The phase I nurses at Winship are required to complete Collaborative Institutional Training Initiative (CITI), Good Clinical Practice Program (GCP), certification in oncology nursing through the Oncology Nursing Society (ONS), completion of the chemotherapy and biotherapy course through ONS, ACLS certification and completion of a Phase I clinical trials specific orientation. This orientation is an in-depth review of clinical trial design, protocol overview, principles of pharmacokinetics and documentation practices that allow grading of adverse events (AEs). The nurses are trained to review all phase one trial order sets for accuracy prior to trial initiation and meet with the research coordinator prior to cycle 1 day 1 to ensure the patient can be treated efficiently and accurately on day 1. The target nurse to patient ratio of 1:2 in the new unit is reflective of the need for specialized care.

3. Solutions and Methods

Deviations from protocol requirements can impact patient outcomes and facility integrity as a compliant research site. At WCI, once a research coordinator has become aware of a deviation, the report is entered into a database. A comprehensive review of deviation data from 2017-2018, revealed lower deviation rates within the Phase I Unit. This is due to the Phase I team's comfort with trial complexity, multidisciplinary care planning, patient acuity and specialized training, along with appropriate nurse to patient ratios.

4. Outcomes and Future Directions

Specialized nurse orientation and continued training within the phase I clinical trial field is imperative in creating a standard of practice and expertise. Development of acuity scales capturing specialized clinical trial conduct will better inform appropriate staffing with ideal staffing ratios that will positively impact treatment practices in the future. Consequently, clinical trials must be viewed as an area of expertise in oncology nursing. Future development of a standardized manual for nurse training as well as the development of a clinical trials nurse certification will drastically escalate the overall standard of practice of clinical trials nurses.



CREATING THE STANDARD FOR SPECIALIZED NURSE TRAINING IN THE PHASE I CLINICAL TRIALS SETTING

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WINSHIP CANCER INSTITUTE OF EMORY UNIVERSITY, ATLANTA, GA

Phase I Unit Overview

- 15 Private Treatment Rooms
- 4 Private Clinic Rooms
- 3 Fast Track Areas
- Collaborative Care Team Stations
- Translational Lab
- Multidisciplinary cohesive clinic and infusion care integration
- "One Stop Shop" Care Model
- Designed with unique integrated facility design emphasizing integration of high quality patient care and accurate research conduct
- 200 + patients enrolled to Phase I Trials annually



Phase I RN Role Summary

- Advanced certification required (i.e.: OCN, BMTCN)
- CITI Training and Good Clinical Practice (GCP)
- Phase I Trial specific orientation
- Comprehensive understanding of protocol navigation
- Detailed assessment and documentation to allow accurate CTCAE grading
- Conceptual understanding of the importance of quality data collection within mandated protocol time points



Advanced Training

- Collaboration during each patient visit: research coordinator, lab specialist, pharmacist, RN, APP, MD
- Creation of nursing considerations documents outlining data collection time points during treatment visits
- Required RN training prior to study opening
- Pre trial huddle with nursing staff and research team to review research procedures and pharmacy orders prior to first patient enrolled on a new study
- Comprehensive review of protocol navigation: contraindicated medications, windows within data collection time points and safety precautions associated with investigational drugs
- Review of study drug mechanisms of actions

Plans for Future Growth

- Further development of a standard training manual and training classes for phase 1 orientation
- Development of educator role, specific to phase 1 clinical trials
- Development and monitoring of metrics to track quality control, patient satisfaction and clinical practice



Designing a Phase I Clinical Trial Unit: A Multi-Disciplinary Collaborative Approach

C. Lewis¹, A. Kim², M. Childress¹, T.K. Owonikoko¹, M.A. Bilen¹, B. El-Rayes¹, J. Bourgeois¹, H. Collins¹, C. Belmore¹, T. Williams¹, J. Warren¹, M. Goodman¹, K. Culver¹, M. Williams¹, E. Barton-Judson², S. John², R.D. Harvey^{1,2}

Winship Cancer Institute of Emory University; ²Simpler Consulting, an IBM Company

1. Background

In 2009, the Winship Cancer Institute of Emory University opened its initial Phase I Clinical Trials Unit to integrate patient care and research for patients enrolled on translational early phase studies. As the Phase I program continued to grow and diversify, a need for a larger unit with greater capacity for groundbreaking trials emerged. In 2018, the team embarked on the creation of a new unit utilizing an integrated facility design (IFD) process. The IFD approach was selected as it is a multi-disciplinary, comprehensive process focused on creation of an ideal environment for patients, caregivers, researchers, providers and nurses. Patient and staff agreed comfort, safety and functionality needs should drive the design of the space using prior philosophies and the IFD method.

2. Goals

Project governance outlining the vision and goals for the creation of a new cutting edge phase I unit was established. A primary objective was to encourage people using the unit, especially staff and patients, to design a space that allows for translational research and excellent patient care with a focus on quality improvement initiatives for the future.

3. Solutions and Methods

Multidisciplinary teams including providers, nurses, research coordinators, pharmacists, patient family advisors, laboratory, and operations team members were assembled. Process mapping, time studies, voice of patient/staff/leadership interviews were conducted; and unit volume data were benchmarked to better establish current volumes and processes for future projections and improvement opportunities. Upon completion of the pre-work, multi-day workshops across 2 different weeks were conducted to brainstorm the ideal patient and staff experience in a phase I research program. The establishment of visionary patient care and research conduct processes as well as agreed-upon critical adjacencies laid the foundation for the physical unit design. Upon completion of several draft layouts, each version was vetted for team established adjacencies and flow needs.

A life size cardboard version of the proposed final unit rendering was built overnight. Multidisciplinary teams toured the mockup to provide critical feedback allowing for real-time changes to the cardboard layout. The team finalized the unit design, submitted it for leadership input and approval followed by the start of construction. The new unit features 15 private treatment rooms, 4 consult rooms and a 3 chair fast track area. Key tenets of the final design included patient and family comfort, patient line of sight for the nursing staff, a research lab that tripled in size and integrated multidisciplinary work stations throughout the unit allowing optimal communication and research conduct.

4. Outcomes and Future Directions

Design of a phase I unit focused on the ideal flow, functionality, safety and patient experience determined by patients and staff using the space, resulted in an environment that supports full integration of excellent patient care and precise research conduct.

BACKGROUND

In 2018, Winship Cancer Institute embarked on the creation of a new, larger phase I unit utilizing an integrated facility design (IFD) process. IFD is a multi-disciplinary, comprehensive process focused on creation of an ideal environment for patients, caregivers, researchers, providers and nurses. Patient and staff agreed comfort, safety and functionality needs drive the design of the space.

GOALS

- Project governance established vision for new cutting edge phase I unit
- People using the space, design the space
- Focus on implementing lean quality improvement initiatives

METHODS

- Process mapping, time studies, voice of patient/staff/leadership interviews conducted. Current and future unit volume benchmarking performed.
- Multidisciplinary teams: providers, nurses, research coordinators, pharmacists, patient family advisors, lab, and operations team members gathered.
- Visionary patient care and research conduct processes agreed-upon critical adjacencies laid the foundation for the physical unit design.
- A life size cardboard unit rendering was built overnight.

OUTCOMES

- Design of a dedicated phase one research unit focused on integration of excellent patient care and precise research conduct.
- The new unit features 15 private treatment rooms, 4 consult rooms and a 3 chair fast track area.

FUTURE IMPLICATIONS

Visual controls including a patient tracking board and patient status boards were incorporated as a part of the IFD process. Standard processes embracing lean tenets will guide the ongoing commitment of quality enhancements in the phase I program in the new space.





FINANCE/CCSG/PRMS

The background features a network of white nodes connected by thin white lines, set against a gradient from dark blue at the top to light green at the bottom. A bright white horizontal glow is positioned across the middle of the image.

CTO Financial Dashboard

A. Bowler, E. Bake, C. Ross

Huntsman Cancer Institute, University of Utah

1. Background

As clinical trials become more complicated, including genetic-based treatments, we found the effort needed to manage these trials was more than budgeted. Our negotiated reimbursements were not covering the actual visit costs.

In the past, we analyzed data for each Clinical Trial Research Group (CTRG). This involved manually preparing a yearly financial dashboard of combined data from spreadsheets and databases. Other key performance indicators such as effort expended by staff role/position, study type, CTRG, and physician also involved vast amounts of time for manual gathering of the data.

2. Goals

Our goal was to find a more effective way of determining the actual effort expended for every clinical trial visit, as well as the key performance indicators mentioned above.

Metrics needed to evaluate effort by trial:

- Clinical Trial Research Group (Disease) (CTRG)
- Study type
- Goals/actual accrual
- Visit count
- Coordinator/Data Manager/Specimen processors effort
- Effort charged or not charged by study
- Income statement from financial software

This data has been available from our clinical trials management software (CTMS), as well as financial data from our organization's financial software. We wanted to evaluate these metrics on three levels: individual trials, CTRG, and the Clinical Trials Office as a whole.

3. Solutions and Methods

Our in-house programmers designed a financial dashboard database to consolidate all the data mentioned above. It also performs calculations to provide us with the actual effort expended by trial, staff role, study type, physician, and per completed visit.

4. Outcomes and Future Directions

We prepared an executive summary that outlined all parameters required for the design of the database, including a detailed analysis of all fields and calculations. This proved to be very valuable. The financial and patient data is reported monthly, but effort is reported quarterly. We decided to display data quarterly, yearly, or total year to date. We load all data at the same time point, allowing users to see metrics up to the end of the last quarter.

With the data generated from the database, we identified areas where we need to negotiate increased hours of effort in our study budgets. This included trends in some CTRGs where negotiated budgets were consistently one-third of the actual effort expended. We plan to add a budget-to-actual comparison to the database.

The database still relies on manual processes, but now data can be prepared faster. The database also eliminates the need to repeatedly calculate the same totals.

We discovered CTRG managers also used the data we collected to prepare reports for CTRG meetings with physician leaders and staff. With this database, CTRG managers no longer need to prepare these reports manually. We plan to make this database available to all staff and clinical trials physicians, with different views based on the end user role.

Poster not available.

What's in a Pre-Review? Establishing a Streamlined Method for Ensuring Quality Submissions to Protocol Review Committees

J. Migliacci, A. McKeown, A. Motta, D. Diaz-Leyton, C. Kolenut, X. Lekperic, K. Napolitano, C. Ryan, S. Hanley, A. Rodavitch

Memorial Sloan Kettering Cancer Center

1. Background

The robust clinical research portfolio at Memorial Sloan Kettering Cancer Center (MSK) is vital to MSK's mission and provides novel treatment options to patients. Prior to opening for enrollment, protocols must undergo a series of committee reviews. Historically, separate groups were responsible for review committees. Protocols were reviewed by one committee at a time, which created vague and inconsistent review requirements, incomplete submissions, lack of transparency, unclear scope, inaccurate data entry and repetitive reviews which contributed to delays in the protocol review process.

In 2018, when MSK centralized protocol review and activation, one primary area of focus was to decrease time to Institutional Review Board (IRB) approval (TTIA). Two centralized cores, the Protocol Review Core (PRC) and Protocol Activation Core (PAC), were created with a mission of streamlining the review process. PRC is charged with managing 25 departmental/institutional review committees and increasing efficiencies within the review process while maintaining the quality of protocol reviews. PAC navigates protocols through the review process and serves as the liaison between investigators, research operations, and other departments.

2. Goals

One of PRC's major goals was to develop a new comprehensive pre-review process to increase efficiency, reduce bottlenecks and ensure protocols are ready for committee reviews.

Our sub-goals were to:

- Define review requirements
- Improve data quality
- Ensure complete submissions
- Focus committee scope/streamline review flows
- Increase transparency/communication
- Conduct pre-review within 24 hours

3. Solutions and Methods

PRC developed the following resources to aid implementation of the new standardized pre-review workflow shown in Figure 1:

- Pre-Review Guide (standardized requirements)
- Committee Determination Form (identifies required reviews)
- New functionality in MSK's homegrown Protocol Information Management System (PIMS)
- PIMS Library (defines data fields)
- Efficient review flows

4. Outcomes and Future Directions

PRC conducted 289 pre-reviews in 2018. Eighty percent of pre-review comments were sent to PAC within 24 hours of receipt, with a median time of 7.5 hours. The median time to pre-review approval (time between receipt and resolution of issues) was 2 days. This rapid turnaround decreased the time between protocol submission and committee reviews. PRC's new workflow and resources ensured consistent and high quality PIMS data, allowed for concurrent reviews, and improved compliance with institutional/regulatory requirements.

Notably, PRC saw a 52% increase in Committee on Radiation submissions, demonstrating success in determining appropriate committee reviews.

Discussion:

PRC's new process contributed to reducing MSK's median TTIA from 135 days in 2017 to 80 days in 2018 by streamlining workflows throughout the review process and across committees. Clear communication, adaptability, and continual improvement of shared resources were key to managing the launch of the new workflow successfully. Additionally, the improved quality of PIMS data ensures that institutional leadership utilizes accurate data in reporting and decision making.

Future goals:

- Utilize our experience to increase the percentage of pre-reviews completed within 24 hours, further decrease time to approval at committees, increase quality of submissions, and inform future collaborations within the clinical research community.
- Apply the knowledge/experience gained from developing/implementing the pre-review process to standardize other aspects of committee management.

What's in a Pre-Review? Establishing a Streamlined Method for Ensuring Quality Submissions to Protocol Review Committees

Jocelyn Migliacci, MA, Ashley Motta, Andrew McKeown, MPH, Diana Diaz-Leyton, MHA, Christina Kolenut, MPH, Xhenete Lekperic, Krista Napolitano, MA, Carly Ryan, Ann Rodavitch, MA, Sara Hanley, MSW

BACKGROUND

- Memorial Sloan Kettering Cancer Center (MSK) has a robust clinical research portfolio that is vital to MSK's mission.
- Before opening for patient enrollment, each protocol must undergo a series of committee reviews based on the participating investigators and resources needed to conduct the protocol.
- Approximately 300 new prospective protocols go through the review and activation process each year.
- Historically, individual clinical departments were responsible for managing their own protocol review committee (N=18) and additional groups were responsible for managing MSK's institutional committees (N=7).
- Protocols were reviewed in an asynchronous manner, one committee at a time.
- The previous structure inherently created vague and inconsistent review requirements, incomplete submissions, lack of transparency, unclear scope, inaccurate data entry and repetitive reviews from various committees. All these factors contributed to delays in the protocol review process.
- MSK leadership charged Clinical Research Administration with optimizing protocol review and activation to decrease Time to IRB Approval (TTIA).
- Two new centralized sub-units, the **Protocol Review Core (PRC)** and Protocol Activation Core (PAC) were created.
- PRC is charged with managing 25 departmental and institutional review committees, including MSK's PRMS, and increasing efficiencies within the review process while maintaining the quality of protocol reviews.

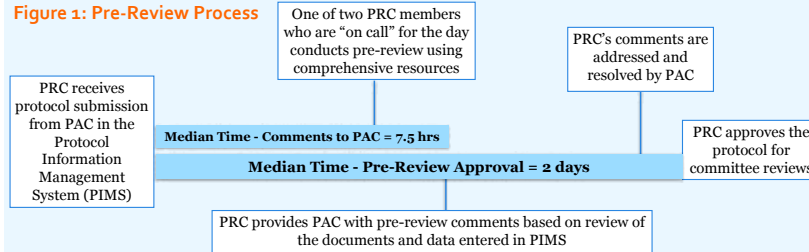
GOALS

- In support of the institution initiative to decrease TTIA, our goal was to develop and implement a new comprehensive pre-review process that increases efficiency, reduces bottlenecks, and ensures protocols are ready for committee reviews.
- In conjunction with this overarching goal, we identified the following sub-goals:
 - Define review requirements (i.e., required documents, required committee reviews)
 - Improve quality of regulatory protocol data in the Protocol Information Management System (PIMS)
 - Ensure complete submissions for committee reviews
 - Focus committee scope & streamline review flows
 - Increase transparency and communication
 - Conduct pre-reviews within 24 hours of receipt

CHANGES INTRODUCED

The Protocol Review Core developed and implemented a **comprehensive, standardized pre-review process:**

Figure 1: Pre-Review Process



RESOURCES

PRC developed multiple resources to ensure consistency and transparency to enable a standardized pre-review process.

- Committee Determination Form**, which is a smart form with guided questions to ensure protocols are reviewed by all appropriate departmental and institutional committees
- Best Practices** Guidelines
- PIMS Library** that defines data fields in our institutional database
- Pre-Review Guide**, which extensively details standardized requirements for pre-review, such as required documents and naming conventions (Figure 2)
- New PIMS Functionality**, including snapshots of required reviews/statuses available (Figure 3)
- Efficient Review Flows** that help maximize the number of concurrent reviews and minimize TTIA (Figure 4)

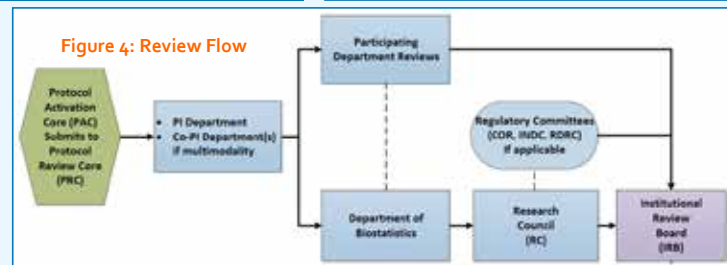
Figure 2: Pre-Review Guide

PRE-REVIEW CONTENTS	
PRE-REVIEW CHECKLIST TEMPLATE	7
FACE SHEET GUIDE	8
COMMITTEE DETERMINATION FORM	9
REQUIRED DOCUMENTS	11
DOCUMENT NAMING CONVENTIONS	13
RFP GUIDE	15
PIMS LIBRARY VERIFICATION GUIDE	24
FEASIBILITY REVIEWS	28
FLOWS	29

Figure 3: Protocol Summary Table

Department	Review Committee	Review Date	Review Date	Review Date	Review Date
Medicine	MSD Oncology	Approved by	02/08/2018	02/08/2018	Pat
Medicine	MSD Oncology	Approved by	02/08/2018	02/08/2018	Pat
Biostatistics	Biostat	Approved by	02/08/2018	02/08/2018	Pat
Pathology	PAC	Completed Review	02/08/2018	02/08/2018	Pat
Pharmacy	Pharmacy	Approved by	02/08/2018	02/08/2018	Pat
Immunology	MSK-IC	Approved by	02/08/2018	02/08/2018	Pat
IRB	IRB	Approved by	02/08/2018	02/08/2018	Pat

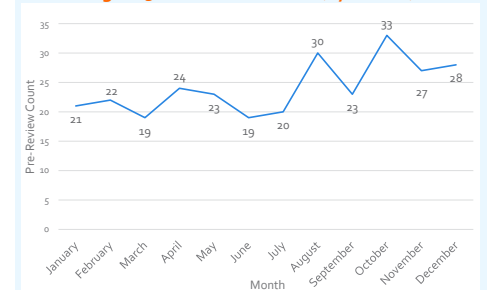
Figure 4: Review Flow



IMPACT

- PRC conducted **289** pre-reviews in 2018 (Figure 5).
- Eighty percent** of pre-review comments were sent to PAC within 24 hours of receipt, with a median time of **7.5 hours**. Median time to pre-review approval was **2 days** (Figure 1).
- Rapid turnaround results in prompt placement of protocols on committee meeting agendas.
- Revised workflows and resources developed by PRC expedites turnaround time, ensures consistent and high quality PIMS data, facilitates confirmation of review type (full or expedited) and allows for concurrent reviews.
- Improved compliance with institutional and regulatory requirements. One of the most notable examples has been the **52% increase** in Committee on Radiation (COR) submissions from 2017 to 2018, which demonstrates PRC's effectiveness in determining required committee reviews.

Figure 5: 2018 Pre-Reviews (by month)



DISCUSSION

- PRC's new pre-review process has contributed to **reducing MSK's median TTIA from 135 days in 2017 to 80 days in 2018** by streamlining workflows throughout the review process and across committees.
- Collaboration between centralized groups (PRC and PAC) as well as shared resources have been instrumental in our successful first year.
- Continual improvements and adaptability are essential with the ever-changing landscape of clinical research.
- Improved quality of PIMS data ensures institutional leadership is utilizing accurate data in their reporting and decision making.
- In the future, we hope to utilize our experience to increase the percentage of pre-reviews completed within 24 hours, further decrease time to approval at review committees, increase quality of protocol submissions, and inform future collaborations within the clinical research community.
- We will continually assess the needs of our stakeholders (PAC, PI, committee members) as well as the value added in our processes and incorporate changes to improve our workflows.

Re-Envisioning Memorial Sloan Kettering's Data and Safety Monitoring Committee

X. Lekperic, K. Napolitano, S. Hanley, C. Kolenut, A. Rodavitch, C. Houston, E.M. O'Reilly

Memorial Sloan Kettering Cancer Center

1. Background

Memorial Sloan Kettering Cancer Center's (MSK) Data and Safety Monitoring Plan includes the Data and Safety Monitoring Committee (DSMC) for non-phase 3 trials and the Data and Safety Monitoring Board (DSMB) for phase 3 randomized trials. These committees are essential for institutions like MSK, which has a portfolio of over 750 active protocols. In 2017, MSK created the Protocol Review Core (PRC) to optimize previously siloed processes. PRC provides centralized oversight and administration of MSK's protocol review committees, including DSMC and DSMB. Based on portfolio size, PRC prioritized streamlining DSMC's processes and identified several areas for improvement.

2. Goals

- Clarify DSMC monitoring criteria to appropriately identify protocols requiring DSMC oversight
- Update DSMC review processes
- Leverage technology to better coordinate DSMC reviews

3. Solutions and Methods

- Streamlined DSMC focus, review criteria, and processes
 - Focus on study conduct with emphasis on:
 - Safety
 - Unanticipated or excessive toxicity
 - Protocol-specific stopping rules
 - Data
 - Completeness
 - Accuracy
 - Database integrity
 - Progress and accrual
 - Review Criteria:
 - Eligible protocols:
 - MSK investigator-initiated trials
 - External studies where MSK is data coordinating center

- Ineligible protocols:
 - Retrospective, biospecimen, and specimen banking
 - Externally sponsored studies with an external monitoring plan
- Frequency of protocol monitoring is risk-based:
 - High – quarterly
 - Moderate – semi-annually
 - Low – annually (recently refined to focus on interventional protocols)
- Streamlined processes:
 - PRC identifies eligible protocols instead of study teams and DSMC members.
 - Reviews initiated following first accrual or after one year if no accruals.
 - Monitors until there are no active participants instead of ending when protocol has closed to new accruals.
 - Revamped DSMC monitoring form, a submission requirement, with specific questions to help identify potential issues.
 - Incorporated routine statistical reviews to evaluate stopping rules, interim analyses, etc.
 - Updated reviewer checklist to ensure focus, detail, and consistency across reviews.
 - Created tools such as guidance documents to aid study teams.
- Leveraged institutional Protocol Information Management System (PIMS) for reviews.
 - Enables electronic submissions.
 - Improves identification of protocols and tracking of submissions.
 - Allows electronic meeting minutes and review letters.
 - Includes "interim" approval so information requests can be handled promptly and outside of scheduled meetings.
- Increased communication with committees such as Institutional Review Board (IRB) and Protocol Review and Monitoring System (PRMS).
- Incorporated educational presentations at meetings to aid committee members.

4. Outcomes and Future Directions

Outcomes:

- Currently, approximately 270 protocols are under DSMC oversight.
- In 2018, DSMC conducted 495 reviews. DSMC submission and review workflow is more efficient.
- Simplified identification of eligible protocols.
- Eliminated overlap with external monitoring.
- Ensures adequate risk-based monitoring of MSK's complex and growing portfolio.
- Increased quality of reviews with renewed focus on active protocols.
- Transparency has increased amongst DSMC and other institutional committees.

Lessons Learned:

- DSMC should function as an institutional service to investigators and study teams.
- DSMC must communicate with IRB and PRMS for adequate portfolio management with minimal overlap.
- DSMC processes, review requirements, and resources should be clear and transparent.

Future Directions:

- Streamline data requirements for submission
- Incorporate data visualization
- PIMS enhancements
- Create educational materials and DSMC-specific SOPs

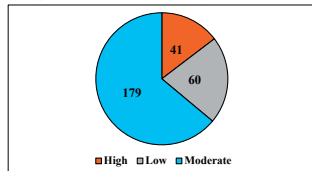
Re-envisioning Memorial Sloan Kettering Cancer Center's Data and Safety Monitoring Committee

Xhenete Lekperic, Krista Napolitano, MA, Sara Hanley, MSW, Christina Kolenut, MPH, Ann Rodavitch, MA, Collette Houston, Eileen M. O'Reilly, MD

Background

- Memorial Sloan Kettering Cancer Center's (MSK) Data and Safety Monitoring Plan includes two institutional committees—the Data and Safety Monitoring Committee (DSMC) for non-phase 3 trials and the Data and Safety Monitoring Board (DSMB) for phase 3 randomized trials.
- These committees are essential for cancer centers like MSK, whose active portfolio includes over 800 clinical research protocols.
- In 2017, MSK created the Protocol Review Core (PRC) that provides centralized oversight and administration of MSK's protocol review committees, including DSMC and DSMB.
- DSMC and DSMB were centralized through PRC to optimize previously siloed processes. Based on portfolio size, PRC prioritized streamlining DSMC's processes and identified several areas for improvement.
- DSMC's current portfolio consists of 280 protocols, 266 of which are MSK Investigator Initiated Trials (IITs). Figure 1 outlines the portfolio by risk level.

Figure 1: DSMC Portfolio by Risk Level



Goals

- Clarify monitoring criteria to appropriately identify protocols requiring DSMC oversight
- Update review processes
- Leverage technology to better coordinate DSMC reviews

Changes Implemented

	BEFORE	AFTER
Mission & Focus	<ul style="list-style-type: none"> Not clearly defined. Focused on study progress and accrual. 	<ul style="list-style-type: none"> Focus on safety (unanticipated or excessive toxicity, protocol-specific stopping rules), data (completeness, accuracy, and database integrity), and progress and accrual.
Review Frequency	<ul style="list-style-type: none"> Quarterly meetings. Risk-based monitoring (high=quarterly, moderate=biannually, low=annually). 	<ul style="list-style-type: none"> Added ad hoc meetings for flexibility. Risk-based monitoring is unchanged. Low risk focus is on interventional protocols.
Review Criteria	<ul style="list-style-type: none"> Monitored trials when external monitoring was less frequent than every 6 weeks. 	<ul style="list-style-type: none"> Eliminated overlap with external monitoring. <ul style="list-style-type: none"> Eligible: MSK IITs and external protocols for which MSK is the data coordinating center. Ineligible: retrospective, biospecimen, specimen banking, and external protocols.
Protocol Identification	<ul style="list-style-type: none"> Local study teams & DSMC identified eligible protocols once opened to accrual (OTA). 	<ul style="list-style-type: none"> Simplified identification of eligible protocols. Protocol Review Core identifies eligible protocols once OTA.
Monitoring Life Cycle	<ul style="list-style-type: none"> Monitoring initiated once a protocol OTA. Monitoring ends once closed to accrual (CTA). 	<ul style="list-style-type: none"> Monitoring initiated following 1st accrual or 1 year after OTA if no accruals. Monitoring continues until no active participants.
Submission Requirements	<ul style="list-style-type: none"> DSMC Monitoring Form had limited open-ended questions and lacked flexibility for the different types of trials. 	<ul style="list-style-type: none"> DSMC monitoring form revamped with questions to help identify potential issues. PI must provide more detail on matters such as serious adverse events, interim analyses, audits, etc. Protocol Review Core created tools to aid study teams in providing complete submissions.
Statistical Reviews	<ul style="list-style-type: none"> DSMC statistician did not conduct formal reviews. 	<ul style="list-style-type: none"> Incorporated routine statistical reviews to evaluate stopping rules, interim analyses, amendment trends, etc.
Reviewer Checklist	<ul style="list-style-type: none"> Reviewer checklist was vague and lacked focus. 	<ul style="list-style-type: none"> Updated reviewer checklist to ensure focus, detail, and consistency across reviews (Figure 2).
Reviewer Education & Experience	<ul style="list-style-type: none"> Limited to onboarding process. 	<ul style="list-style-type: none"> Incorporated ongoing educational presentations into DSMC meetings. Initiated member surveys to improve engagement and satisfaction.
Inter-committee Communication	<ul style="list-style-type: none"> Infrequent communication between the DSMC and other institutional committees. 	<ul style="list-style-type: none"> Increased communication with committees such as Institutional Review Board (IRB) and Protocol Review and Monitoring System (PRMS).
Leveraging Institutional Technology	<ul style="list-style-type: none"> Used MSK's home-grown web-based application called Protocol Information Management System (PIMS) for reviews, meeting minutes, and review letters. Submissions via email. 	<ul style="list-style-type: none"> Enhanced PIMS to improve identification of eligible protocols, enable electronic submissions, optimize tracking, and allow for expedited reviews. Implemented inclusion of IRB/PRMS documents for DSMC reference within centralized review tab (Figure 3).

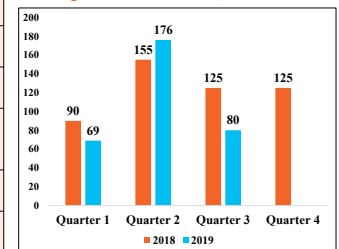
Figure 2: PIMS Reviewer Checklist

Figure 3: PIMS Review Tab

Outcomes

- Simplified submission and review workflows are more efficient.
- Transparency has improved amongst DSMC and other institutional committees.
- For quarters 1-3, 2019 volume has decreased 12% compared to 2018 due to thoughtful monitoring criteria.
- 495 reviews were conducted in 2018 and 325 have been conducted in 2019 to date for quarters 1-3 (Figure 4).
- The decreased volume ensures reviewers can conduct efficient, comprehensive reviews.

Figure 4: DSMC Volume, 2018-2019



Conclusions

- The committee functions as an institutional service to investigators and study teams.
- DSMC communicates with IRB and PRMS for adequate portfolio management with minimal overlap.
- Processes, review requirements, and resources are clear and transparent.

Future Directions

- Streamline submission data requirements
- Incorporate data visualization
- Implement a DSMC charter and SOPs
- Additional PIMS enhancements
- Create educational materials

Enhancing the Capture of Oncology Study Activity via Scientific Review and IRB Collaboration

A. Anderson, T. George, A. Ivey

University of Florida Health Cancer Center

1. Background

The UFHCC Scientific Review and Monitoring Committee (SRMC) is charged with review of all prospective cancer research conducted at the University of Florida. To facilitate capture of these studies, changes to institutional communication and research culture were required. In 2017, the University of Florida's (UF) research leadership, endorsed and mandated use of the SRMC for applicable studies prior to Institutional Review Board (IRB) approval. Prior to this directive, studies routinely reviewed by the SRMC were only those submitted by the UFHCC Clinical Research Office (CRO); units outside of the CRO did not receive a formal review. Therefore, there was no singular quality control mechanism to assure initial and ongoing capture of cancer relevant research activity.

2. Goals

- Enhance capture of cancer research activity including subject accruals
- Improved tracking of trial status within the Clinical Trials Management System
- Augment communication between the SRMC, study teams, and IRB

3. Solutions and Methods

UFHCC leadership held stakeholder meetings with key leaders from UF's Division of Sponsored Programs and UF's Health Science Center Colleges to support and drive the change in institutional review of cancer research. In summer 2017, UF's Vice President (VP) for Research and Senior VP for Health Affairs released a memorandum outlining the SRMC review requirement for all cancer research and enhancements to the IRB submission system to include a review trigger for SRMC. The memorandum also outlined that cancer relevant studies could not be IRB approved without SRMC approval.

To accomplish this, the IRB created a SRMC Oncology page with specific questions used to determine cancer relevancy. This page is deployed for all new and amendment submissions to the IRB. This facilitates the capture of both new and previously IRB approved studies. Contextual definitions and hyperlinks were added to educate study teams and email communication techniques were engineered to ensure timely SRMC reviews and responses. Below are the cancer relevancy questions that are used to trigger a SRMC review:

- Study specifies enrolling patients with a known or suspected diagnosis of cancer as part of the eligibility criteria; or
- Includes research endpoints related to cancer, associated symptoms or established cancer risk factors (including smoking and tobacco-associated studies, surveys, hepatitis or HPV vaccines, etc.); or
- The local PI plans to exclusively enroll current, former or potential cancer patients into the study

4. Outcomes and Future Directions

Prior to the interface, there was not one single mechanism to capture all cancer research studies conducted on campus, especially trials non-interventional in design. With the interface, the SRMC is now made aware of all studies identified as cancer-relevant at the time of IRB submission. Ultimately, this interface has supported tracking of accruals, status updates and/or study closures submitted for IRB review.

The number of studies requiring SRMC review proved to be much higher than projected; myriad of divisions (some previously unanticipated) and variations of studies were noted across campus. Moving forward, quarterly meetings with SRMC administrators and IRB leadership will be held to finesse the review processes. Additional enhancements to capture studies outside of study team initiated IRB submissions will also be explored.

Enhancing the Capture of Oncology Study Activity via Scientific Review and IRB Collaboration

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

BACKGROUND

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OUTCOMES

Prior to the interface, there was not one single mechanism to capture all cancer research studies conducted on campus, especially trials non-interventional in design. With the interface, the SRMC is now made aware of all studies identified as cancer-relevant at the time of IRB submission. Ultimately, this interface has supported tracking of accruals, status updates and/or study closures submitted for IRB review.

FUTURE DIRECTIONS

The number of studies requiring SRMC review proved to be much higher than projected; myriad of divisions (some previously unanticipated) and variations of studies were noted across campus. Moving forward, quarterly meetings with SRMC administrators and IRB leadership will be held to finesse the review processes. Additional enhancements to capture studies outside of study team initiated IRB submissions will also be explored.

CONTACT

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Establishment of a Zero Tolerance Policy to Eliminate Non-Performing Studies

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

University of Florida Health Cancer Center

1. Background

The UFHCC Scientific Review and Monitoring Committee (SRMC) is tasked with review of cancer relevant research studies conducted at the University of Florida (UF). The UFHCC Clinical Research Office (CRO) is primarily responsible for ensuring accurate protocol and accrual status entry within the Clinical Trials Management System (CTMS), OnCore, and notifying investigators of studies that are failing to meet minimum accrual benchmarks. Investigators and/or Disease Site Groups (DSGs) have long struggled with finding a balance between interesting science and feasibility of accrual resulting in portfolios that are misaligned with their patient population. The tax of resources to maintain trials (staffing, IRB support, contractual work, etc.) at a large academic cancer center, requires continuous review to ensure appropriate stewardship of limited resources. Evaluation of historic data illustrates that studies which fail to accrue within the first six months of site activation are unlikely to reach a successful completion.

2. Goals

- Closure of non-performing trials to allow for re-deployment of assigned resources
- Robust deliberations for trial selection within DSG portfolios, focusing on current patient needs and feasibility of trials

3. Solutions and Methods

In 2018, the SRMC developed the Zero Tolerance Policy to target interventional trials with no accrual activity. The initial implementation of the policy called for closure of a study if there were no patient accruals by 12 months post-activation. This policy was subsequently strengthened, placing studies on administrative probation at 3 months and requiring termination at 6 months if accrual remains at zero. As part of the probation process, the study undergoes a new feasibility review to determine if the appropriate patient population exists and if new recruitment strategies could be implemented. Investigators are also required to craft a Corrective Action Plan based on the feasibility findings. If the corrective actions fail, studies are administratively terminated by the SRMC if they are not electively closed by the investigator or DSG. Exceptions to this policy include studies involving a rare disease (modified NIH definition), pediatrics, highly-selected IITs and studies experiencing moderate, but temporary, closures to accrual.

4. Outcomes and Future Directions

In 2018, implementation of the Zero Tolerance Policy resulted in a higher percentage of studies placed on probation compared to 2017 (37% vs 20%). Ultimately, the number of studies closed with zero accrual in 2018 rose by 30% over the previous year. Due in part to this policy, the initial feasibility review process has become more robust and data driven. The CRO has since established metrics used to assess available patients in light of investigator stated accrual goals. The ratio of available patients to target accrual is now a key part of the feasibility review process. Clear expectations for early study enrollment is now pervasive across the UFHCC.

Future directions include incorporating the UFHCC Community Outreach and Engagement (COE) director in initial and probationary reviews of trials to determine if there are opportunities to enhance recruitment via COE resources.

BACKGROUND

The UFHCC Scientific Review and Monitoring Committee (SRMC) is tasked with review of all cancer relevant research studies conducted at the University of Florida (UF). The UFHCC Clinical Research Office (CRO) is primarily responsible for ensuring accurate protocol and accrual status entry within the Clinical Trials Management System (CTMS), OnCore, and notifying investigators of studies that are failing to meet minimum accrual benchmarks.

Investigators and/or Disease Site Groups (DSGs) have long struggled with finding a balance between interesting science and feasibility of accrual resulting in portfolios that are misaligned with their patient population. The tax of resources to maintain trials (staffing, IRB support, contractual work, etc.) at a large academic cancer center, requires continuous review to ensure appropriate stewardship of limited resources.

Evaluation of historic data illustrates that studies which fail to accrue within the first six months of site activation are unlikely to ever reach a successful completion.

GOALS

- Systematic closure of non-performing trials to allow for re-deployment of assigned resources
- Robust deliberations for trial selection within DSG portfolios, focusing on current patient needs and feasibility of trials

SOLUTION & METHODS

In 2018, the SRMC developed the **Zero Tolerance Policy** to target interventional trials with no accrual activity.

The initial implementation of the policy called for closure of a study if there were no patient accruals by 12 months post-activation. This policy was subsequently strengthened, placing studies on administrative probation at 3 months and requiring termination at 6 months if accrual remains at zero.

As part of the probation process, the study undergoes a new feasibility review to determine if the appropriate patient population exists and if new recruitment strategies could be implemented. Investigators are also required to craft a Corrective Action Plan based on the feasibility findings.

If the corrective actions fail, studies are administratively terminated by the SRMC if they are not electively closed by the investigator or DSG. All administrative terminations by SRMC through this policy are final and without an opportunity for appeal.

Exemptions from this policy include studies involving a rare disease (modified NIH definition), pediatric trials, highly-selected IITs and studies experiencing moderate, but temporary, closures to accrual.

CONTACT

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OUTCOMES

- Implementation of the Zero Tolerance Policy resulted in a higher percentage of studies placed on probation in 2018 compared to 2017 (37% vs 20%).
- The number of studies closed with zero accrual in 2018 rose by 30% over the previous year.
- Due in part to this policy, the initial feasibility review process has become more robust and data driven.
 - The CRO subsequently established metrics to assess available patients in light of investigator stated accrual goals.
 - The ratio of available patients to target accrual is now a key part of the feasibility review process.
 - Clear expectations for immediate study enrollment is now pervasive across the UFHCC with the Zero Tolerance Policy credited with establishing this culture.

FUTURE DIRECTIONS

Future directions include incorporating the UFHCC Community Outreach and Engagement (COE) Director in initial and probationary reviews of trials to determine if there are opportunities to enhance recruitment via COE resources and expanding the administrative closure policy to poorly, but not zero, performing studies.



INVESTIGATOR-INITIATED TRIALS

The background features a network of white nodes connected by thin white lines, set against a gradient from dark blue at the top to light green at the bottom. A bright horizontal light flare is positioned across the middle of the image.

Investigator-Initiated Trial Activation: Increasing Collaboration With a Protocol Navigator

K. Thorne, S. Clement

Huntsman Cancer Institute, University of Utah

1. Background

The challenges of timely writing, activation, and implementation of quality therapeutic oncology based investigator-initiated trials (IITs) has become a growing issue at Huntsman Cancer Institute (HCI) and nationally. Recent studies show activation of clinical trials is no faster today than 20 years ago.¹⁻² Protocol complexity contributes to these delayed timelines; however, fragmented, siloed operating processes also play a role¹⁻³.

At HCI, all new interventional treatment IITs go through a multistep institutional review process involving numerous groups (concept review, budgets, contracts, feasibility, scientific review, FDA, and more) before Institutional Review Board (IRB) submission. The review process involves many departments which have varying priorities, both within and outside HCI. As a result, the average time from protocol receipt by the CTO to trial activation was 215 days in 2017. The slow timelines were negatively affecting the quality of our research. New drug combinations were being approved sooner than we could activate institutional trials.

As a National Cancer Institute (NCI) Designated Comprehensive Cancer Center, enhancing clinical research by initiating and implementing scientifically relevant IITs is a strategic priority integral to our mission.

2. Goals

Our goal was to streamline the HCI administrative processes associated with protocol development to facilitate timely activation of IITs, while maintaining compliance with good clinical practice guidelines and federal regulations. In review of our data, we identified areas of the trial startup process where increased collaborations and coordination could decrease timelines. We reviewed the recent 2017 National Comprehensive Cancer Network (NCCN) benchmarking survey, and identified a set of activation goals based on historical data and internal expectations.

3. Solutions and Methods

We developed a protocol navigator position to work closely with departments and teams with the slowest timelines (for example, budgets, contracts, investigator engagement, regulatory approvals). This person would provide project management support and facilitate start-up activities for therapeutic oncology-based IITs. A protocol navigator was hired in June 2018. This position uses metrics to set milestones and track overall IIT development progress. The protocol navigator ensures the various areas of the start-up approval process move forward in parallel. If delays occur in one area—for example, contracts, the protocol navigator can show investigators how this delay affects the bottom line for protocol activation. The increased communication with study teams facilitates appropriate intervention when necessary to speed up timelines.

4. Outcomes and Future Directions

We have not yet gathered enough data to show whether the protocol navigator efforts have yielded statistically significant change. However, anecdotal review of HCI IIT activation timelines shows a reduction in the time for study start-ups. With continued collaboration and communication, we believe these times will continue to decrease.

Although we have seen a decrease in our protocol activation timelines, we have noticed an increase in the number of protocol amendments. Our future efforts will be geared towards continuing to improve IIT protocol activation timelines, while taking steps to improve the quality of the initial protocol.

Full references available

1. Watters, Julie, (November 2017) Transforming the activation of clinical trials.
2. Mohs, Richard, (July 2018) Innovations in clinical trials.
3. Getz, Kenneth, (May 2017) Trends in clinical trial design complexity.



Investigator-Initiated Trial Activation: Increasing Collaboration with a Protocol Navigator

Kelli Thorne, MPH, CCRP; Susan Clement, CCRP
Huntsman Cancer Institute at the University of Utah



BACKGROUND

The challenges of timely writing, activation, and implementation of quality therapeutic oncology based investigator-initiated trials (IITs) has become a growing issue at Huntsman Cancer Institute (HCI) and nationally. Recent studies show activation of clinical trials is no faster today than 20 years ago. Protocol complexity contributes to these delayed timelines; however, fragmented, siloed operating processes also play a role.

METHOD

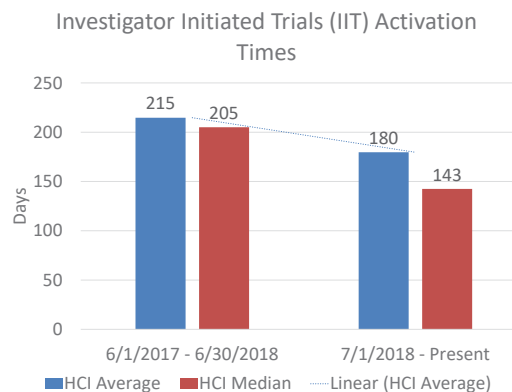
Streamline the HCI administrative processes associated with protocol development and start-up via a dedicated protocol navigator:

- Ensure approvals move forward in parallel
- Start contract/budget negotiations sooner
- Increase communication between groups (budgets, contracts, investigator, pharmaceutical companies, regulatory approvals)
- Use metrics to set milestones and track overall IIT development progress (Microsoft Project)

RESULTS

Protocol navigator resulted in these changes:

- Overall **decrease in IIT activation** timelines
- Areas where we saw the **biggest impact**:
 - PRMC submit to PRMC approval
 - IRB approval to study activation
- Facilitated **appropriate intervention** when necessary to speed up timelines
- Clinical investigator **satisfaction** with regulatory start-up process



CONCLUSIONS

Our goal was to streamline the HCI administrative processes associated with protocol development to facilitate timely activation of IITs, while maintaining compliance with good clinical practice guidelines and federal regulations. Anecdotal review of HCI IIT activation timelines shows a reduction in the time for study start-ups. With continued collaboration and communication, we believe these times will continue to decrease.

FUTURE PLANS

- Create an investigator-initiated-trial physician handbook describing the process for activation
- Track the number of IIT protocol amendment and timelines for amendments

References

1. Watters, J, et al. (Nov 2017) Transforming the activation of clinical trials. *Clinical Pharmacology and Therapeutics*, Volume 103, Issue 1, P43-46.
2. Mohs, R, et al. (July 2018) Innovations in clinical trials: improving study start up (SSU). *Alzheimer's & Dementia: The Journal of the Alzheimer's Association*, Volume 14, Issue 7, P819.
3. Getz, K, et al. (May 2017) Trends in clinical trial design complexity. *Nature Reviews Drug Discovery*, Volume 16, P307.

Multicenter Investigator-Initiated Trial Prioritization

L. Sego, A. Bauchle, M. Darling, K. Miller, P. Loehrer, S. Farag, S. Edwards

Indiana University Melvin and Bren Simon Cancer Center

1. Background

No process existed previously to determine what infrastructure would support institutional multicenter investigator-initiated trials (IIT) at Indiana University (IU). It was unclear to Sponsor-Investigators who would manage their multicenter IIT, the IU Simon Cancer Center (IUSCC) Multicenter infrastructure or an outside contract research organization (CRO). A clear guideline was also needed to prioritize use of the multicenter infrastructure to appropriately allocate resources to high priority trials.

2. Goals

The IUSCC Clinical Trials Office set out to establish a process and decision tree to assist Sponsor-Investigators in identifying the appropriate infrastructure to manage an institutional multicenter IIT. Criteria considered in the decision tree included:

- Funding source
- Number of participating sites
- Geographical location of sites
- Support by Cancer Center

3. Solutions and Methods

An SOP was established utilizing a clear process and well-defined criteria to determine when the IUSCC Multicenter infrastructure would be employed and when the IIT would be referred to an outside CRO. A process was instituted whereby institutional studies proposing to be opened through the Multicenter infrastructure required review and approval by the Administrator for Quality and Education, the IUSCC Associate Director or Clinical Research and if applicable, Cancer Center leadership. This process also incorporated discussion of the funding support for multicenter infrastructure. Sponsor-investigators were made aware that a percent effort of the budget may be required to support multicenter infrastructure if a protocol was approved for multicenter management by the institution.

4. Outcomes and Future Directions

Since execution of the SOP in February 2018, 6 studies have been opened using this process and have been successfully managed by the IUSCC multicenter team. This has provided Sponsor-Investigators and the institution with clear direction and guidelines when considering and opening institutional multicenter IITs. For example, the addition of international participating sites was requested by two Sponsor-Investigators. These requests were denied based on the SOP. A study without funding to support multicenter infrastructure was submitted to the Cancer Center leadership and was successful in obtaining leadership support to open as an institutional multicenter IIT.

While progress has been made in the decision process for institutional management of multicenter IITs, there are additional areas for growth and policy refinement. A process needs to be established for situations in which a study is opened under IUSCC Multicenter management but then exceeds the site criteria in the SOP. Three options can be considered in this situation. The IUSCC multicenter infrastructure can agree to manage the additional sites, reject the addition of new sites or transfer management of the study to an outside CRO. Other complications that have surfaced include the Sponsor-Investigators reaching out to a CRO for management and bypassing the process outlined in the SOP. This is primarily due to lack of understanding of this process by the Sponsor-Investigator. The Multicenter team will investigate additional collaboration with Indiana University's outside CRO partners to educate on this process. Additionally, providing the Multicenter IIT Prioritization SOP to Sponsor-Investigators earlier in the protocol development process as well as incorporating review of the SOP during new faculty orientation can aid in education.



Multicenter Investigator-Initiated Trial Prioritization

Lina Segó, BA, CCRP; Amber Bauchle, BS, CCRP; Michael Darling, MHA; Kathy D. Miller, MD; Patrick J. Loehrer, MD; Sherif S. Farag, MD, Sara Edwards, MSc, CCRC

Indiana University Melvin and Bren Simon Cancer Center

Background

No process existed previously to determine what infrastructure would support institutional multicenter investigator-initiated trials (IIT) at Indiana University (IU). It was unclear to Sponsor-Investigators who would manage their multicenter IIT, the IU Simon Cancer Center (IUSCC) Multicenter infrastructure or an outside contract research organization (CRO). A clear guideline was also needed to prioritize use of the multicenter infrastructure to appropriately allocate resources to high priority

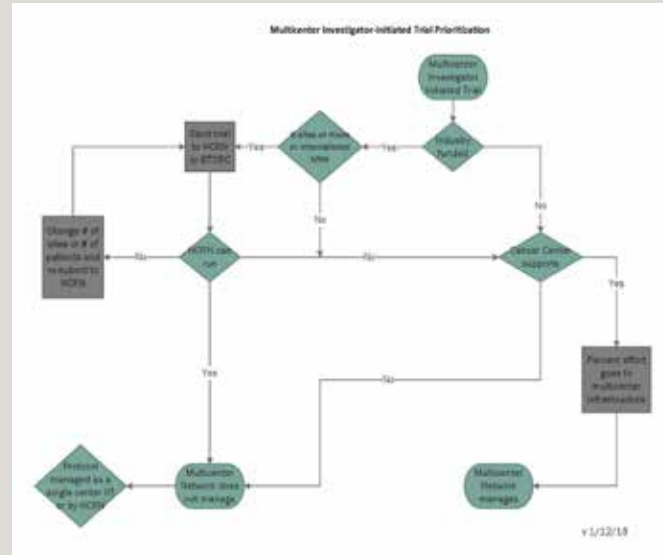
Goals

The IUSCC Clinical Trials Office set out to establish a process and decision tree to assist Sponsor-Investigators in identifying the appropriate infrastructure to manage an institutional multicenter IIT. Criteria considered in the decision tree included:

- Funding source
- Number of participating sites
- Geographical location of sites
- Support by Cancer Center

Solution

An SOP was established utilizing a clear process and well-defined criteria to determine when the IUSCC Multicenter infrastructure would be employed and when the IIT would be referred to an outside CRO. A process was instituted whereby institutional studies proposing to be opened through the Multicenter infrastructure required review and approval by the Administrator for Quality and Education, the IUSCC Associate Director or Clinical Research and if applicable, Cancer Center leadership. This process also incorporated discussion of the funding support for multicenter infrastructure. Sponsor-investigators were made aware that a percent effort of the budget may be required to support multicenter infrastructure if a protocol was approved for multicenter management by the institution.



Conclusions

While progress has been made in the decision process for institutional management of multicenter IITs, there are additional areas for growth and policy refinement. A process needs to be established for situations in which a study is opened under IUSCC Multicenter management but then exceeds the site criteria in the SOP. Three options can be considered in this situation. The IUSCC multicenter infrastructure can agree to manage the additional sites, reject the addition of new sites or transfer management of the study to an outside CRO. Other complications that have surfaced include the Sponsor-Investigators reaching out to a CRO for management and bypassing the process outlined in the SOP. This is primarily due to lack of understanding of this process by the Sponsor-Investigator. The Multicenter team will investigate additional collaboration with Indiana University's outside CRO partners to educate on this process. Additionally, providing the Multicenter IIT Prioritization SOP to Sponsor-Investigators earlier in the protocol development process as well as incorporating review of the SOP during new faculty orientation can aid in education.

Outcome

Since execution of the SOP in February 2018, 6 studies have been opened using this process and have been successfully managed by the IUSCC multicenter team. This has provided Sponsor-Investigators and the institution with clear direction and guidelines when considering and opening institutional multicenter IITs. For example, the addition of international participating sites was requested by two Sponsor-Investigators. These requests were denied based on the SOP. A study without funding to support multicenter infrastructure was submitted to the Cancer Center leadership and was successful in obtaining leadership support to open as an institutional multicenter IIT.



Implementation of a Concept Development Program for Investigator-Initiated Trials

A. Ivey, A. Daniels, T. George

University of Florida Health Cancer Center

1. Background

Investigator-Initiated Trials (IITs) are institutional priorities and represent the combination of intellectual property and scientific output from translational science programs. Therefore, a robust IIT concept development process is essential to the success of an academic cancer center. Prior to 2016, University of Florida Health Cancer Center (UFHCC) investigators lacked a formal system of resources and support in developing cancer-relevant interventional research concepts, often resulting in concepts deficient in scientific merit, statistical validity, and feasibility related to funding, staff support, and the Center's catchment area. To overcome these challenges, the UFHCC Clinical Research Office (CRO) established the IIT Concept Development Group (CDG).

2. Goals

1) Improve the feasibility, scientific merit and ultimate success in completing cancer relevant IITs, 2) Shorten the timeframe from concept approval to protocol activation and 3) Maximize staff and investigator effort in protocol development

3. Solutions and Methods

The CDG was created to provide a comprehensive review of all concepts managed by the CRO or otherwise supported by UFHCC resources. After soliciting key concept requirements from senior investigators, a standard concept form was developed for CDG submission to provide investigators guidance on the fundamental elements of a concept proposal. The IIT CDG approval process also involves documentation of provisional peer support through the respective Disease Site Group (DSG). As part of the formal CDG review, UFHCC experts review concepts and provide consultation to ensure there is a valid statistical plan, scientific rigor, appropriate institutional budget development, and confirmation of appropriate staff resources for conduct. The UFHCC Associate Director for Clinical Research (ADCR) ultimately provides final approval. Approved concepts may (only) then be developed into full protocols. This iterative CDG review process helps to ensure that protocols are built upon a solid scientific foundation in an effort to maximize the potential impact of the research and maximize limited resource utilization.

4. Outcomes and Future Directions

Since the implementation of the CDG a 42.0% decrease in obtaining SRMC approval has been observed with an average of 40 days for CDG reviewed trials to obtain approval compared to 69 days for non-CDG reviewed trials. When specifically looking at treatment trials, a 49.3% decrease was seen in SRMC approval with an average of 37.5 days for CDG reviewed trials and 74 days for non-CDG reviewed trials.

Within the next year, it is planned to evaluate the impact the CDG process has had on trial accrual goals, overall activation timelines, and merit scoring system for the Center's cancer-relevant interventional investigator-initiated trials compared to those trials which are not vetted through the CDG.

To date, positive reactions have been received from investigators, study staff, and SRMC committee members about improvements in the quality of trials developed and activated through this program. As the process is refined locally, the next step is to introduce strong concepts in a multi-site setting and expand the population-base of our trial portfolio.

BACKGROUND

Investigator-Initiated Trials (IITs) are institutional priorities and represent the combination of intellectual property and scientific output from translational science programs. Therefore, a robust IIT concept development process is essential to the success of an academic cancer center. Prior to 2016, University of Florida Health Cancer Center (UFHCC) investigators lacked a formal system of resources and support in developing cancer-relevant interventional research concepts, often resulting in concepts deficient in scientific merit, statistical validity, and feasibility related to funding, staff support, and the Center's catchment area. To overcome these challenges, the UFHCC Clinical Research Office (CRO) established the IIT Concept Development Group (CDG).

GOALS

- Improve the feasibility, scientific merit and ultimate success in completing cancer relevant IITs.
- Shorten the timeframe from concept approval to protocol activation.
- Maximize staff and investigator effort in protocol development.

SOLUTIONS & METHODS

The CDG was created to provide a comprehensive review of all concepts managed by the CRO or otherwise supported by UFHCC resources. After soliciting key concept requirements from senior investigators, a standard concept form was developed for CDG submission to provide investigators guidance on the fundamental elements of a concept proposal. The IIT CDG approval process also involves documentation of provisional peer support through the respective Disease Site Group (DSG). As part of the formal CDG review, UFHCC experts review concepts and provide consultation to ensure there is a valid statistical plan, scientific rigor, appropriate institutional budget development, and confirmation of appropriate staff resources for conduct (**Figure 1**).

The UFHCC Associate Director for Clinical Research (ADCR) ultimately provides final approval. Approved concepts may (only) then be developed into full protocols.

This iterative CDG review process helps to ensure that protocols are built upon a solid scientific foundation in an effort to maximize the potential impact of the research and maximize limited resource utilization.

Figure 1. CDG Workflow



OUTCOMES

- Since the implementation of the CDG a 42.0% decrease in obtaining SRMC approval has been observed with an average of 40 days for CDG reviewed trials to obtain approval compared to 69 days for non-CDG reviewed trials.
- When specifically looking at treatment trials, a 49.3% decrease was seen in SRMC approval with an average of 37.5 days for CDG reviewed trials and 74 days for non-CDG reviewed trials.

FUTURE DIRECTIONS

Within the next year, it is planned to evaluate the impact the CDG process has had on trial accrual goals, overall activation timelines, and merit scoring system for the Center's cancer-relevant interventional investigator-initiated trials compared to those trials which are not vetted through the CDG. To date, positive reactions have been received from investigators, study staff and SRMC committee members about improvements in the quality of trials developed and activated through this program. As the process is refined locally, the next step is to introduce strong concepts in a multi-site setting and expand the population-base of our trial portfolio.

CONTACT

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REGULATORY

The image features a dark blue background with a network of white nodes and lines. A bright, horizontal light flare is positioned across the lower middle of the image. The word "REGULATORY" is written in bold, yellow, uppercase letters in the upper center, with a thin white horizontal line above it.

SOP Implementation for Managing CIRB Studies in Data Analysis Only Status

S. Edwards, B. Johnson, I. SerVaas

Indiana University Melvin and Bren Simon Cancer Center

1. Background

The NCI CIRB does not have a policy or clear guidance for including institutional boilerplate language into amended consent forms for studies closed to accrual (CA) with all subjects off study. Our local IRB considers these studies to be in data analysis only status and does not require consent form updates for a study at this stage of IRB review. Furthermore, the resources required to include institutional boilerplate language into consent forms for use solely at the time of audit did not represent the best use of our staff resources.

2. Goals

Our goal was to develop a policy that would be accepted by the National Clinical Trials Network (NCTN) Groups at the time of audit for studies reviewed by the NCI CIRB. The policy would be provided during an audit in lieu of expending resources to add institutional boilerplate language to amended consent forms when studies were CA with all subjects off study.

3. Solutions and Methods

A helpdesk query was sent to NCI CIRB in October 2017 requesting the CIRB's policy on updating consents for studies closed to accrual with all subjects off study. The CIRB responded to the query in December 2017 stating it did not have a policy with respect to updating amendments for studies that are CA with all subjects deceased. The CIRB indicated we should follow our local policies regarding this matter. Our local IRB was consulted in January 2018 requesting its policy. The local policy stated our IRB would not accept amendments to informed consent documents as they would not have an impact where no living subjects are on study and the study is CA. After reviewing the CIRB and local IRB policies, an institutional SOP was written in May 2018 stating that CIRB trials CA with all subjects off study (in "data analysis only" by local IRB standards), will not be required to amend informed consent or HIPAA authorization documents. Late onset risk updates that may impact subject safety will be reviewed on a case-by-case basis. Other study documents will continue to be downloaded and stored in accordance to IUSCC CTO Regulatory SOPs and guidance documents. If a study is re-opened the study coordinator needs to verify the most current protocol is approved. If not approved, the study coordinator needs to submit the amendment to the regulatory team for IRB approval.

4. Outcomes and Future Directions

The site was cited in an NRG audit in February 2019 for not incorporating amendment changes or boilerplate language into the informed consent for a study closed to accrual with all subjects off study. The "Managing CIRB Amendments in Closed to Accrual Trials with all Subjects Off-Study" SOP was provided to the auditors in the audit response. The auditor queried the site asking if the site participated in the optional imaging sub-study. The site responded indicating it did not. The auditor removed the citations regarding incorporation of amendment and boilerplate language requirements from the final audit report. An SOP for termination of studies open for data queries and application to basket and umbrella trials is being explored.



SOP Implementation for Incorporation of Amendments and Local Boilerplate Language for CIRB studies in Data Analysis Only Status

Sara Edwards¹, MSc, CCRC, Bethany Johnson², JD, CIP, Ian SerVaas², MA, CCRP

¹Indiana University Melvin and Bren Simon Cancer Center, ²Indiana University

Background

The NCI Central Institutional Review Board (CIRB) does not have a policy or clear guidance for including institutional boilerplate language into amended consent forms for studies closed to accrual with all subjects off study. Our local IRB considers these studies to be in data analysis only status and does not require consent form updates for a study at this stage of IRB review. Furthermore, the resources required to include institutional boilerplate language into consent forms that would only be used at the time of audit did not represent the best use of our staff resources.

Goals

1. Develop a policy that would be accepted by the National Clinical Trials Network (NCTN) Groups (ECOG, NRG etc.) at the time of audit for studies reviewed by the NCI CIRB
2. Provide the policy at the time of audit in lieu of using resources to add institutional boilerplate language to amended consent forms when studies were closed to accrual with all subjects off study.

Solutions and Methods

Help Desk Query Submitted to NCI CIRB

- Requested CIRB's policy on updating consent forms for studies closed to accrual with all subjects off study
- CIRB stated it had no policy and that local policies should be followed

Local IRB Consulted

- The local IRB's policy stated it would not accept amendments to informed consent documents as they would not have an impact where no living subjects are on study and the study is closed to accrual

Institutional SOP Written

- SOP states CIRB trials closed to accrual with all subjects off study (in "data analysis only" by local IRB standards), will not be required to amend informed consent or HIPAA authorization documents....Other study documents will continue to be downloaded and stored in accordance with IUSCC CTO Regulatory SOPs and guidance documents.

Outcome



The site was cited in an NRG audit in February 2019 for not incorporating amendment changes or boilerplate language into the informed consent for a study closed to accrual with all subjects off study. The "Managing CIRB Amendments in Closed to Accrual Trials with all Subjects Off-Study" SOP was provided to the auditors in the audit response. The auditor queried the site asking if the site participated in the optional imaging sub-study. The site responded indicating it did not. The auditor removed the citations regarding incorporation of amendment and boilerplate language requirements from the final audit report.

Lessons Learned

Establishing an SOP for incorporation of institutional boilerplate language saved time and resources

Future Direction

The site would like to apply the policy to include basket trials and umbrella trials that have a screening protocol requiring subjects to be positive for a genetic variant. These trials can have numerous consent forms and amendments without ever accruing a subject. Using a "just in time" approach for these sub studies and only updating consent forms for arms that have a subject accrued will be explored. An SOP for termination of studies open for data queries and application to basket and umbrella trials is being explored.

References

NCI CIRB SOPs <https://www.ncicirb.org/about-cirb/sops>.
IU IRB SOPs <https://research.iu.edu/policies/human-subjects-irb/irb-review-process.html>



How to Implement a Master Delegation of Authority Process Across a Clinical Trials Office

L. Rohn, T. Detty, A. Semla, S. Asche, K. Ackermann

Indiana University Melvin and Bren Simon Cancer Center

1. Background

Maintaining an accurate and complete list of staff participating on a clinical trial is an important part of study conduct. However, the documentation of staff delegation can be cumbersome and is often repetitive. Additionally, this documentation often differs across various types of trials, making consistency across multiple studies difficult. Developing a method to facilitate study document compliance and standardize delegation of study roles across the Clinical Trials Office (CTO) would be useful in minimizing regulatory burden.

2. Goals

- Establish a standardized method in which all studies conducted within the Clinical Trials Office (CTO) are delegated in the same manner
- Align personnel roles with tasks on protocols appropriate to duties and training
- Create documentation to support the Master Delegation of Authority initiative

3. Solutions and Methods

- Master Delegation of Authority (mDOA) process created to standardize staff delegation across all CTO new trials, with option to move over existing trials to the new process
- Staff roles assigned tasks on the mDOA as appropriate to their duties within role
- Staff then assigned tasks by role on individual protocols as appropriate
- SOPs and templates created to explain the mDOA initiative and document delegation of authority appropriately with the CTO, as well as on individual protocols
- Master Delegation Profiles created per role and completed by personnel upon start of role and maintained throughout time in role
- Individual Protocol Delegation of Authority logs track staff assigned to specific protocols, along with dates active on the trial in role

4. Outcomes and Future Directions

Outcomes

- All new trials moving forward within the CTO have been opened utilizing the mDOA process (over 125 studies to date)
- Significant number of existing number of trials have been transitioned over to new mDOA as well
- Regulatory burden has decreased across protocols managed by the CTO

Lessons learned

- Maintaining clear communication with industry partners is important when not utilizing sponsor provided templates

Future directions

- Rolling out to teams outside of the CTO that operate under the Cancer Center



How to Implement a Master Delegation of Authority Process Across a Clinical Trials Office

Liz Rohn, MS, CCRC, Tammi Detty, BA, CCRP, Amanda Semla, BA, CCRP, Sarah Asche, Kayla Ackermann, MSc, CCRP
Indiana University

Background

Maintaining an accurate and complete list of staff participating on a clinical trial is an important part of study conduct. However, the documentation of staff delegation can be cumbersome and is often repetitive. Additionally, this documentation often differs across various types of trials, making consistency across multiple studies difficult. Developing a method to facilitate study document compliance and standardize delegation of study roles across the Clinical Trials Office (CTO) would be useful in minimizing regulatory burden.

Metrics & Goals to be Achieved

- Establish a standardized method in which all studies conducted within the Clinical Trials Office (CTO) are delegated in the same manner
- Align personnel roles with tasks on protocols appropriate to duties and training
- Create documentation to support the Master Delegation of Authority initiative

Solution or Methods Implemented

- Master Delegation of Authority (mDOA) process created to standardize staff delegation across all CTO new trials, with option to move over existing trials to the new process
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Figure 1. Example mDOA Role Profile

The form is titled 'DELEGATION OF AUTHORITY PROFILE' and includes fields for 'Role', 'Staff Name', 'Title/Position', and 'Signature'. It contains a table for 'Significant trial sponsor name' with columns for 'Role', 'Start Date', and 'End Date'. There are also sections for 'Signature' and 'Date'.

Figure 2. Example mDOA Documentation for Individual Trial

The form is titled 'Log of Study Personnel' and includes a table with columns for 'Personnel Number', 'Personnel Name', 'Role', 'Start Date', and 'End Date'. It also includes a section for 'Signature of Principal Investigator' and 'Date'.

Outcome

- All new trials moving forward within the CTO have been opened utilizing the mDOA process (*over 140 studies to date*)
- Significant number of existing number of trials have been transitioned over to new mDOA as well
- Regulatory burden has decreased across protocols managed by the CTO

Lessons Learned & Future Directions

Lessons learned:

- Maintaining clear communication with industry partners is important when not utilizing sponsor provided templates

Future directions:

- Rolling out to teams outside of the CTO that operate under the Cancer Center

Driving Innovation Through Regulatory and Product Development Magic

R. Ellis, A. Yadav, L. Shrestha, A. Ho, S. Oliver, O. Hauke

Memorial Sloan Kettering Cancer Center

1. Background

When it comes to regulatory and product development, innovation is the holy grail. The magic happens when barriers are eliminated, while maintaining institutional compliance and driving change within clinical research. The Regulatory Oversight and Product Development (ROPD) unit has developed a sustainable centralized model to provide expert guidance to investigators, clinical research staff and external collaborators throughout the Investigational New Drug (IND) lifecycle that enables us to also drive innovation within the space.

2. Goals

- Centralize communication within the regulatory and product development space
- Utilize regulatory and product development strategic tools to enhance decision making processes
- Develop a formal structure to utilize FDA fast track and accelerated programs

3. Solutions and Methods

Our recipe of innovation and success focused on four key areas to drive a culture of institutional innovation:

- (a) centralized IND office
- (b) streamlined FDA communication
- (c) established process for regulatory and product development strategies
- (d) culture of diversity and inclusion.

4. Outcomes and Future Directions

- We have established processes for regulatory and product development strategies for MSK-manufactured products.
 - We have developed a formal structure for requesting specialty designations such as breakthrough therapy, that helps to expedite the drug development process.
 - INDO has been able to decrease the time from FDA submission to activation by half, while increasing the number of IND/IDE applications submitted to FDA, resulting in patients having access to investigational products in record time.
- MSK has achieved a 66% success rate in applying for breakthrough therapy designations compared to industry 32% (for drug applications) and 34% (for biologics) based on current FDA data.
 - We utilize several strategic tools that support a return on innovation.
 - We continue to reinvest by supporting the infrastructure of the unit by optimizing the processes that drive the regulatory and product development space.
 - We are utilizing FDA fast track and accelerated programs, which were exclusively being used by industry to leverage our relationships with our biotechnology collaborators.



Driving Innovation Through Regulatory and Product Development Magic

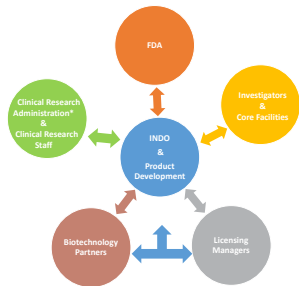
Richard Ellis, Anil Yadav, Liza Shrestha, Alan Ho, MD, Sheri Oliver, Odette Hauke

Memorial Sloan-Kettering Cancer Center

INTRODUCTION

When it comes to regulatory and product development, innovation is the holy grail. The magic happens when barriers are eliminated, while maintaining institutional compliance and driving change within clinical research. The Regulatory Oversight and Product Development unit at MSK has developed a sustainable centralized model to provide expert guidance to investigators, clinical research staff and external collaborators throughout the Investigational New Drug (IND) lifecycle that enables us to also drive innovation within the space.

CENTRALIZED REGULATORY MODEL

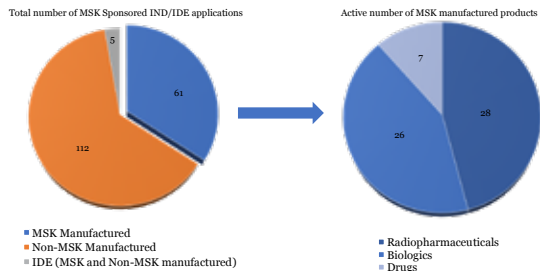


*Clinical Research Administration also includes HRPP, PAC and INOC

- This centralized communication model helps us to effectively liaise with our Human Research Protection Program (HRPP), Investigators, Clinical Research Staff, Core Facilities, Investigational New Drug Committee (INDC), Protocol Activation Core (PAC), Licensing Managers and external industry/biotechnology partners.
- The Regulatory Oversight and Product Development unit has streamlined communication with the Food and Drug Administration (FDA) where the Investigational New Drug Office (INDO) acts as MSK's primary liaison to the agency in answering questions and queries relating to MSK sponsored IND trials, decreasing the lag time in completing scientific and regulatory reviews.

PORTFOLIO MANAGEMENT

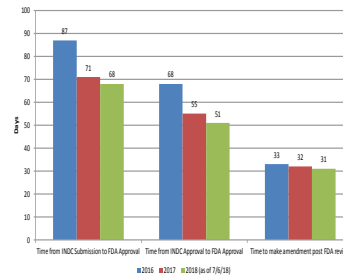
INDO manages one of the largest IND portfolio of any academic institution.



Cumulative FDA Approvals and Specialty Designations for 2014 and 2018



IND Time to Activation

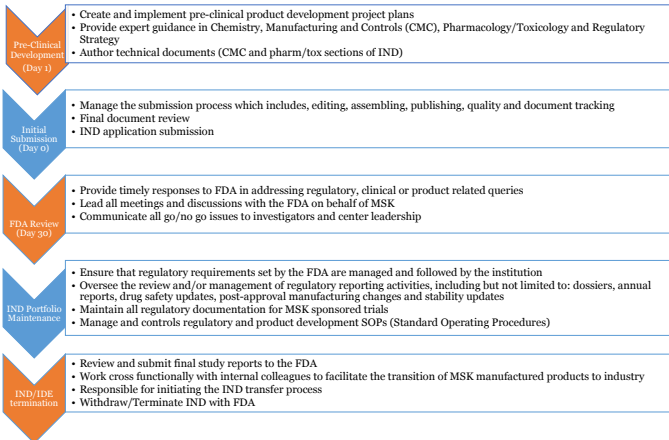


REGULATORY METRICS AND SUCCESSES

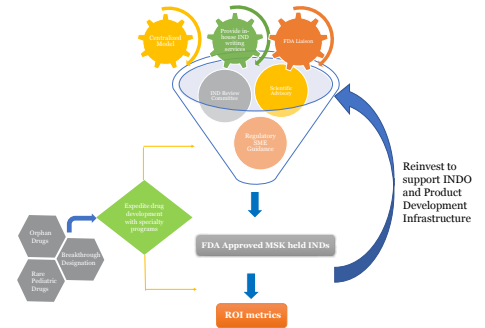
- We have established processes for regulatory and product development strategies for MSK-manufactured products.
- A formal structure has been developed for requesting specialty designations such as breakthrough therapy, that helps to expedite the drug development process.
- INDO has been able to decrease the time from FDA submission to activation by half, while an increased number of IND/IDE applications are being submitted to FDA, resulting in patients having access to investigational products in record time.
- MSK has a 66% success rate in applying for breakthrough therapy designations compared to industry 32% (for drug applications) and 34% (for biologics) based on current FDA data.

IND/IDE LIFECYCLE MANAGEMENT

The Investigational New Drug Office (INDO) is responsible for ensuring that investigators and clinical research staff adhere to institutional standards and federal regulatory requirements regarding investigational drugs, devices and biologics. The Product Development Team implements in-house writing services and consultancy to investigators, core facilities and biotechnology partners.



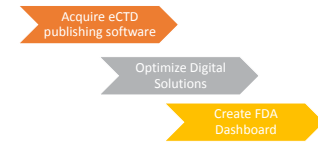
STRATEGIC TOOLS THAT SUPPORT RETURN ON INNOVATION



The return on innovation (ROI) is unique to the core of how the unit functions.

- We utilize several strategic tools that support a return on innovation.
- We continue to reinvest by supporting the infrastructure of the unit by optimizing the processes that drive the regulatory and product development space.
- Additionally, we are utilizing FDA fast track and accelerated programs, which were exclusively being used by industry to leverage our relationships with our biotechnology collaborators.

FUTURE GOALS



CONCLUSION

- The Regulatory Oversight and Product Development unit at MSK plays an integral role in developing innovation that occurs within the regulatory space.
- As one of the first academic institutions to have a centralized IND office, we continue to leverage our relationship with the FDA and utilize several strategic tools to enhance our decision-making processes involving MSK-sponsored IND trials.
- We focus on several factors that support a positive return on innovation in a field that is rapidly changing and growing increasingly complex.

GOING LIVE With an e-Regulatory System: Lessons Learned in Managing the Change Process During an e-Regulatory Rollout at a Comprehensive Cancer Center

A. Drawz¹, K. Akula¹, C. Passaglia¹, M. Hurley²

¹Robert H. Lurie Comprehensive Cancer Center of Northwestern University; ²Complion, Inc.

1. Background

Deciding to implement an eRegulatory system is one thing, but figuring out how to actually 'go live' when the time comes should be a thoughtful, step-wise process, taking into consideration all the teams that will be affected in order to successfully manage the change and ultimately foster adoption of the new system. This poster seeks to explore the Lurie Cancer Center's rollout of Complion, delving into how it was organized and when different teams were engaged in the process. Key issues:

- Size and structure of the teams
- Shifting workflows from a paper and server-based system to a compliant eRegulatory system
- Engaging the teams throughout the change

2. Goals

By exploring the rollout phase of switching to an eRegulatory system, we will share our experiences and lessons learned, especially as the first of several departments within the institution. The goal is to provide insight into how to approach similar transformational initiatives. Key considerations:

- Talking about the change vs. going live with it
- Impact of going-live on each team's workflows – quantitatively and qualitatively
- Targeted training for individual teams – When and How
- Common issues and unique challenges for various teams

3. Solutions and Methods

Our approach stratified research staff involved in roll-out as early users (regulatory, IT) or late users (study coordinators, finance, etc). The actual rollout took place in two main phases; early users participated in longer, more hands-on training. Having the Complion team on-site to provide hands-on troubleshooting and offer real-time solutions was critical for successful rollout. Roll-out with the investigators is still underway.

4. Outcomes and Future Directions

Within the first four months of roll-out:

- 110 binders built
- Approximately 1700 central binder documents filed
- Average of 8 different teams using the system daily, including personnel outside our clinical trials office from 5 of the 14 disease teams

As expected, we encountered somewhat slower adaptation from non-regulatory teams, as well as some degree of recoiling from others despite involvement prior to rollout. It is an on-going process to promote awareness and build confidence and trust in using the system.

Oftentimes when major changes are undertaken, there is a heavy focus on the decision-making and building phases. Final roll-out may seem like a seamless end to the process, but in looking back there have been some lessons learned:

- Involve the finance team earlier in planning the timing of roll-out.
- Create team-based user groups before roll-out.

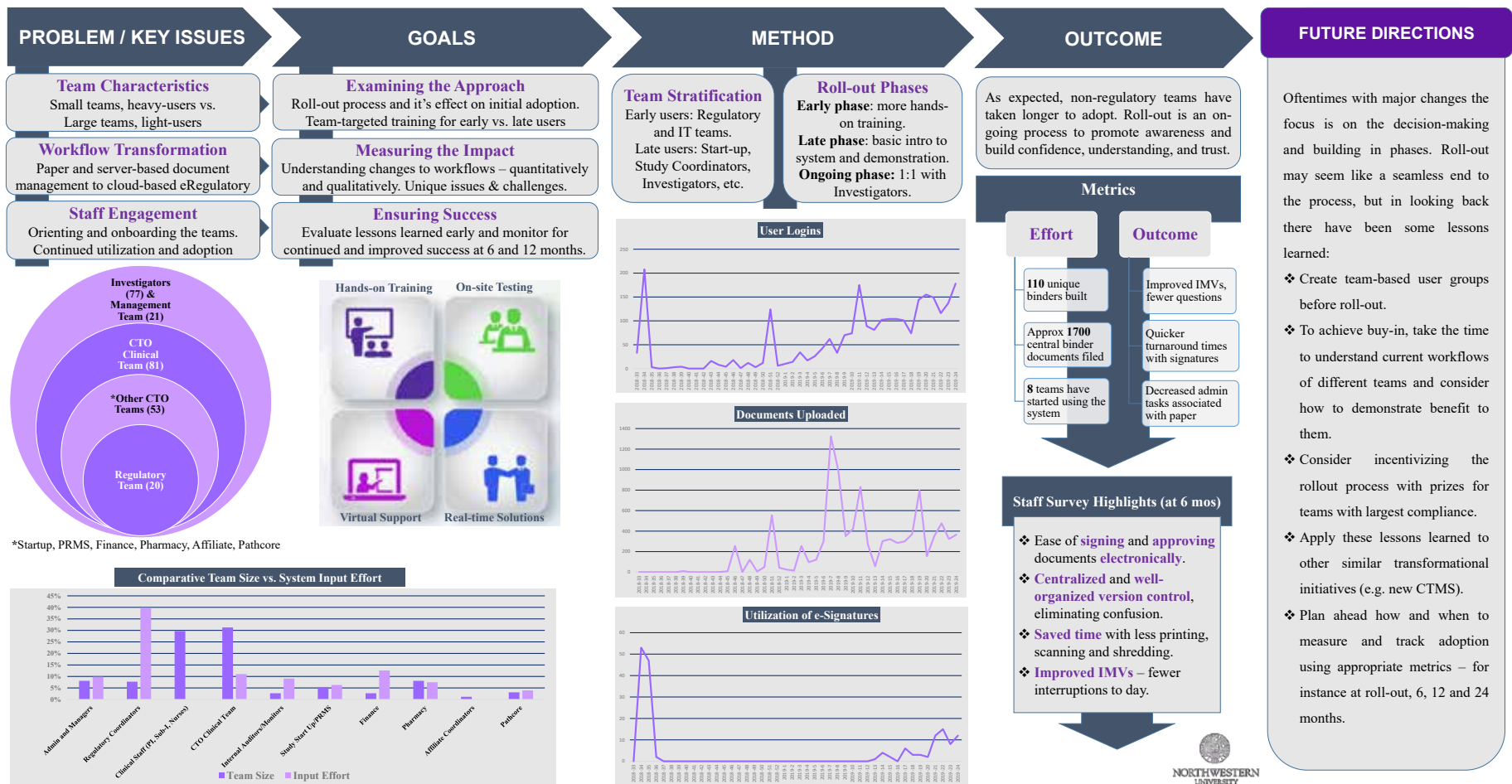
- Heavy focus on regulatory may deter other teams from feeling as invested. Balance pros/cons of having an executive administrative team in charge of the design process as this takes ownership away from teams themselves.
- In order to achieve buy-in from other departments (especially those you do not oversee), take the time to understand their current workflows so you can demonstrate benefit to them.
- Plan for when and how to do roll-out with investigators – not too soon and not too late.
- Consider incentivizing the rollout process with prizes for teams with largest compliance.

GOING LIVE With an e-Regulatory System: Lessons learned in managing the change process during an e-Regulatory rollout at a Comprehensive Cancer Center

A. Drawz¹, K. Akula¹, C. Passaglia¹, M. Hurley²;
Robert H. Lurie Comprehensive Cancer Center of Northwestern University¹; Complion Inc.²



Overview: The Clinical Trials Office of the Robert H. Lurie Comprehensive Cancer Center has recently rolled-out an e-Regulatory system. Applying observations and lessons learned from the initial phase of roll-out may help foster improved adoption in later phases of implementation.



Overcoming the Burden of Paper Regulatory Binders Through eReg and eSignature Implementation

A. Green, M. Brown, K. Linsenmeyer, J. Gonzalez

The Ohio State University Comprehensive Cancer Center, James Cancer Hospital & Solove Research Institute

1. Background

As clinical research costs soar both sponsors and clinical sites are looking to find ways to reduce costs, decrease efforts, and improve compliance. One way to do this is to move to an electronic regulatory binder and electronic regulatory signature process. Industry sponsors have already begun moving to an electronic system but clinical research sites are still lagging behind. This could be due to the daunting task of implementing the system and ensuring 21 CFR Part 11 compliance. It could also be due to the differences in clinical sites, how many different types of electronic regulatory/eSignature systems are currently on the market, and not knowing what system would work best for the individual site.

2. Goals

The goals are to provide the background behind 21 CFR Part 11, costs associated with eRegulatory systems, the benefits and challenges of implementing an eRegulatory system, and lessons learned from a site that has implemented an eReg/eSignature system.

3. Solutions and Methods

Challenges for implementing an eRegulatory/eSignature system include the multiple vendors for an eRegulatory/eSignature system, the costs of a system, the vagueness of 21 CFR Part 11 and the associated guidelines, obtaining buy-in from each of the research team members, not having a implementation already established, and assuring that the system is 21 CFR Part 11 Compliant.

Benefits include improving the workplace environment for team members, decreasing costs to the clinical site, improving compliance, increasing efficiency, increasing productivity, increase availability of the regulatory documents, and improve security of the regulatory documents.

4. Outcomes and Future Directions

As a site that wanted to implement an eRegulatory and eSignature system we initially completed a pilot process for eSignatures to determine the benefit this would have on our site. We chose this pilot because it was our greatest need so that we could increase compliance, increase efficiency and productivity, and decrease duplicative efforts due to lost documents.

We chose to utilize the eSignature system for documents that are not predicate documents and were low risk level documents. Once determining which documents we would utilize the eSignature system for we completed training and validation of the system and implemented the new eSignature system. After completion of the pilot program it was determined that this system improved compliance and improved the work environment of the Regulatory Team as well as decreased costs for the Research Department and decided to move to an entire eRegulatory/eSignature system.

We chose a system that would integrate with our protocol management system because the users were already familiar with the system and because the data input of the protocol management system could feed directly to the eReg system which would further decrease duplicative efforts. Although the system was costly we felt the reduction in cost from decreasing duplicative efforts, filing efforts, and learning the system balanced the cost out. Additionally the system was intuitive and could be built for our individual site needs. After choosing we validated and implemented the system and learned a great deal along the way.

Poster not available.



TRAINING & QUALITY ASSURANCE



The Elephant in the Room – Onboarding of New Staff in an Evolving Research Landscape Plagued by Turnover

D. Farhat, J. Ventimiglia, E. Horvat, L. Casetta, J. Mancini

Barbara Ann Karmanos Cancer Institute, Wayne State University

1. Background

As an NCI-designated Comprehensive Cancer Center, the Karmanos Cancer Institute's Clinical Trials Office (CTO) established its initial orientation program (IOP) in 2007. The curriculum encompassed ten role-specific modules designed to highlight the responsibilities of the Clinical Research Coordinator (CRC). The CTO Education Manager facilitated these modules over the course of 16 weeks. However, like many institutions, the CTO recognized the changing landscape of oncology research due to the increasing complexity of protocols, staff turnover, and institutional expansion- which in our case included the acquisition of 12 statewide cancer centers. In order to support these changes, the CTO staff has grown over 200% in the last 10 years. As such, the need for a more comprehensive and robust orientation program was identified.

2. Goals

1. Update role-specific modules
2. Decrease the length of orientation from 16 to 6 weeks.
3. Provide current staff with professional growth opportunities by serving as subject matter experts (SMEs).

3. Solutions and Methods

Realizing it was no longer feasible for one trainer to adequately onboard new staff, the Education Manager recruited leaders in the CTO, including supervisors and SMEs, to participate in the establishment of an enhanced formal orientation program (EOP) in December of 2016. The EOP is now well established with the following enhancements:

- Orientees complete 16 – 1.5 hour modules over the course of a structured six-week schedule
- Expanded the orientation program to include statewide staff via Web-Ex
- Developed and operationalized role specific competencies
- Re-established a minimum requirement of 80% pass rate on post-module assessments
- Incorporated “hands on” practicums, departmental overviews and opportunities to shadow
- Developed a Post-Orientation Survey, providing feedback and opportunities for continuous improvement
- Implemented quarterly trainer meetings to evaluate and brainstorm areas of possible program expansion and enhancements.

4. Outcomes and Future Directions

One hundred employees have completed the EOP since its debut in 2017. Modules are facilitated by 17 highly trained SMEs, who continuously enhance content to ensure that the most up to date information and practices are disseminated. These sessions occur in an interactive group setting which allows orientees to cultivate professional relationships among staff in various departments. Upon evaluation, supervisors indicate that employees who successfully complete the EOP are more equipped to take on workloads at earlier time points when compared to employees trained through the IOP. Furthermore, the Quality Assurance Team has indicated CRCs display an increased, in-depth understanding of the multifaceted nature of clinical research when providing audit responses.

The evolving landscape of oncology research necessitates robust, comprehensive and accelerated training for new staff. Our EOP provides orientees with the knowledge and skills necessary to take on rigorous workloads in an expedited time frame. While we recognize the benefit of providing our employees with the opportunity to develop greater proficiency in their roles, we also recognize high turnover within the clinical research setting is a problem plaguing many institutions, including our own. Currently, 79% of staff trained through the EOP remain employed at the CTO. This tends to beg the question: Is our accelerated comprehensive training program benefiting our institution, or are we better preparing employees for transition to industry?



The Elephant in the Room – Onboarding of New Staff in an Evolving Research Landscape Plagued by Turnover

Dina Farhat BS, MS; Jaclyn Ventimiglia BS, CCRP; Elizabeth Horvat BA, MEd, CCRP; Lindsay Casetta BSBA, CCRP; Joanne Mancini RN, CCRP



Introduction

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Methods

Realizing it was no longer feasible for one trainer to adequately onboard new staff, the Education Manager recruited leaders in the CTO, including supervisors and SMEs, to participate in the establishment of an enhanced formal orientation program (EOP) in December of 2016. The EOP is now well established with the following enhancements:

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Modules

1. Overview of Orientation
2. Introduction to Clinical Trials
3. The Research Team
4. Human Research Protection & Overview of Regulatory Coordinator Role
5. The Research Protocol & Review of Patient Eligibility (Hands on Practice)
6. Informed Consent
7. Source Documentation and Research Charts
8. Central Data Management (The KCI Network)
9. Oncology 101 / Assessment of a Clinical Trial Patient (Research Nurse)
10. RECIST 1.1 / Tumor Assessments
11. Adverse Events & Deviations
12. CTCAE / Toxicity Assessments
13. OnCore (CTMS)– Protocol Coordinator / Clinical Research Associate Role Overview
14. IND Overview
15. Quality Assurance Overview
16. Overview of Pre and Post Awards

Experiences

- Multi-Disciplinary Team (MDT) Tumor Board Exposure
- Feasibility Review and Operations Committee (FROC) Observation
- Shadow Experience with Research Nurse or Non-Physician Provider
- Bone Marrow Transplant Floor, PK Laboratory, Bio specimen Laboratory, and Pharmacy, Radiation Oncology Center Tours
- Opportunity to Visit Statewide Network Cancer Center(s)

Results

One hundred employees have completed the EOP since its debut in 2017. Modules are facilitated by 17 highly trained SMEs, who continuously enhance content to ensure that the most up to date information and practices are disseminated. These sessions occur in an interactive group setting which allows orientees to cultivate professional relationships among staff in various departments. Upon evaluation, supervisors indicate that employees who successfully complete the EOP are more equipped to take on workloads at earlier time points when compared to employees trained through the IOP. Furthermore, the Quality Assurance Team has indicated CRCs display an increased, in-depth understanding of the multifaceted nature of clinical research when providing audit responses.



Conclusions

The evolving landscape of oncology research necessitates robust, comprehensive and accelerated training for new staff. Our EOP provides orientees with the knowledge and skills necessary to take on rigorous workloads in an expedited time frame. While we recognize the benefit of providing our employees with the opportunity to develop greater proficiency in their roles, we also recognize the elephant in the room – the high turnover within the clinical research setting is a problem plaguing many institutions, including our own. Currently, 79% of staff trained through the EOP remain employed at the CTO. This tends to beg the question: Is our accelerated comprehensive training program benefiting our institution, or are we better preparing employees for transition to industry?



Interactive Web-based Imaging Response Assessment Training Application for Cancer Clinical Trials

T. Urban, E. Ziegler, B. Somarouthu, D. Rukas, M. Leary, B. Beardmore, E. Correa, G. Basinsky, A. Van den Abbeele, G. Harris

Dana-Farber Cancer Institute, Harvard Medical School

1. Background

There are over two dozen imaging assessment criteria used to evaluate tumor response for cancer clinical trials but there is no standardized training available to teach radiologists how to apply these criteria. While image reviewers are often familiar with RECIST, most are not well versed in the other response criteria, which contributes to increased errors and inconsistencies across radiologists.

2. Goals

The interactive, web-based training application will help radiologists:

- Recognize the importance of imaging response criteria in cancer clinical trials
- Categorize metastatic lesions at baseline according to target and non-target definitions
- Determine overall response for follow-up based on targets, non-targets, and new lesions
- Demonstrate response criteria knowledge through interactive image review of baseline and follow-up cases
- Reduce variability across image reviewers and cancer clinical trial sites to better capture tumor response to therapy

3. Solutions and Methods

The training application is made up of three components: 1) lesson slides which explain the rules of each criteria in detail and provide examples of potential areas of confusion; 2) a quiz to test the image reviewer's knowledge of assessment guidelines such as target criteria for baseline and overall response evaluation for follow-up; 3) interactive cases to confirm that the radiologist can appropriately apply these rules during image review.

The training materials will be tailored to each response criteria. The image reviewer will receive a certificate after they 'pass' each response criteria course.

4. Outcomes and Future Directions

The Tumor Imaging Metrics Core (TIMC) at the Dana-Farber/Harvard Cancer Center has implemented a standardized training program which has been shown to increase reliability of image assessments ($r(\text{ICC}) \geq 0.90$) but currently this process is manual and time-consuming for both the trainer and trainee. The web-based platform will give radiologists the opportunity to compare their response criteria knowledge to a 'gold standard,' based on a consensus of a panel of expert imaging reviewers, and allow them to access these training materials at anytime, from anywhere.

As treatment options have evolved and increased in number, response criteria to characterize activity during clinical trials have become progressively more varied and complex. A standardized training platform is needed to ensure response criteria compliant imaging assessments and reduce inconsistencies across cancer centers. The interactive, web-based platform will be made available late 2019 to help radiologists better understand and apply imaging response criteria. In the future, we plan to obtain Continuing Medical Education (CME) credits for each response criteria course.

Interactive Web-based Imaging Response Assessment Training Application for Cancer Clinical Trials

 **PRECISION**
Imaging Metrics

Trinity Urban, MA, PMP; Erik Ziegler, PhD; Bhanusupriya Somarouthu, MD; Daniel Rukas, BS; Matthew Leary, BS; Britney Beardmore, BS; Elizabeth Correa, MA; Gina Basinsky, BS; Annick D. Van den Abbeele, MD; Gordon J. Harris, PhD



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4. Demonstrate response criteria knowledge through interactive review of baseline and follow-up cases
5. Reduce variability across reviewers and clinical trial sites to better capture tumor response to therapy



Figure 1: The dashboard provides easy access to response criteria training courses and related references.

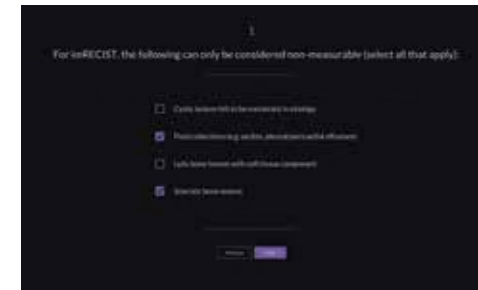


Figure 2: The quiz tests the image reviewers' knowledge of response criteria for both baseline and follow-up to ensure they understand the rules.



Figure 3: The lesson slides educate image reviewers on response criteria guidelines and provide examples for each response type.



Figure 4: Image reviewers identify, measure, and label tumors at baseline and track and categorize response for tumors at follow-up.

Methods

The training application is made up of three components:

1. Lesson slides which explain the rules of each criteria in detail and provide examples of potential areas of confusion
2. A quiz to test the image reviewer's knowledge of assessment guidelines such as target criteria for baseline and overall response evaluation for follow-up
3. Interactive cases to confirm that the radiologist can appropriately apply these rules during image review

The training materials are tailored to each response criteria. The image reviewer will receive a certificate after they 'pass' each response criteria course. Measurements will be compared across reviewers to determine inter-rater reliability for reviewers in each cancer center as well as across participating cancer centers.

Results, Conclusions, and Future Directions

The Tumor Imaging Metrics Core (TIMC) at the Dana-Farber/Harvard Cancer Center has implemented a standardized training program which has been shown to increase reliability of image assessments ($r(\text{ICC}) \geq 0.90$) but currently this process is manual and time-consuming for both the trainer and trainee. The web-based platform will give radiologists the opportunity to compare their response criteria knowledge to a 'gold standard,' based on a consensus of a panel of expert imaging reviewers, and allow them to access these training materials at anytime, from anywhere.

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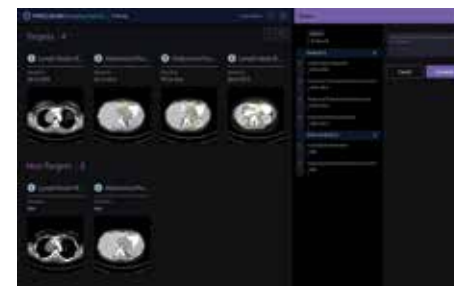


Figure 5: Image reviewers review their measurements and document the time point assessment, as appropriate, for baseline and follow-up.

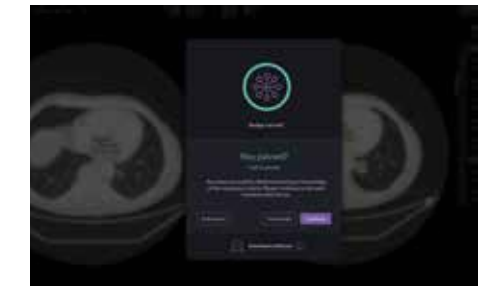


Figure 6: Image reviewers will receive a summary of their performance and will be given a certificate upon successful completion of the training course.

Risk Based Monitoring as a Mechanism to Inform DSMC Practices

T. Negri, D. Otap, M. Kelsen, F. Brogan, L. Blumberg, S. Kelly, J. Wang, M. Galazyn, J. Jurcic
Herbert Irving Comprehensive Cancer Center, Columbia University Irving Medical Center

1. Background

This abstract is a follow-up to the original quality assurance concept presented during the 8th and 9th AACI CRI meetings^{1,2}. Based on the need to increase DSMC oversight, and utilizing FDA guidance for Risk Based Monitoring³, the HICCC DSMC and CPDM Office created study specific data and safety monitoring plans (ssDSMPs) in 2016. Given this process has been in place for 32 months, an evaluation of this process is required in terms of value added to the DSMC Operations Process, and how this RBM approach has improved DSMC reviews. In 2016, there were 21 faculty held INDs and the number has since increased to 34 in 2019. Interventional IITs have grown, and there are currently 54 interventional trials monitored by the HICCC DSMC.

2. Goals

To evaluate added value of ssDSMPs in the context of DSMC Operations (initial and on-going reviews).

3. Solutions and Methods

Once a ssDSMP is submitted to the DSMC for review, this document is sent to the assigned reviewer to inform the initial trial review from a safety perspective. Completion of the key risk indicators (KRIs) associated with the trial will ultimately determine the trial's final risk score (high, moderate or low risk). More importantly, the DSMC reviewer determines if this information accurately reflects the risk level of the criteria based on the completion of the form, and determines the DSMC monitoring frequency for the trial. This DSMC monitoring frequency dictates the timing of submission of DSMC progress reports (referred to as safety reports), as well as the timing of corresponding monitoring summary forms submitted by the assigned Quality Assurance Monitor. Finally, the monitoring activities defined within the ssDSMP are used as a roadmap for the monitoring summary forms which are submitted to the DSMC for on-going review.

4. Outcomes and Future Directions

The HICCC DSMC has approved 33 ssDSMPs with plans using the updated Risk Based Monitoring Guidance created in 2017. Table 1 includes overall DSMC metrics from January 2017 to April 2019. The implementation of ssDSMPs during initial DSMC review has led to more standardized and informed DSMC reviews. The reviews are now based on pre-determined monitoring risk levels, and reporting frequencies as well as greater integration with quality assurance teams within CUIMC. The DSMC reviewers are able to establish clear guidance for QA monitors at the onset of a trial, and make any required recommendations regarding the ssDSMPs. This has led to a downstream effect of improving the quality of the clinical trials as DSMC reviewers are able to assess the study objectives and safety guidelines (e.g. DLTs) before a trial activates. Finally, the corresponding monitoring summary forms (based on the ssDSMPs) allow the assigned QA monitors to communicate any major findings, and confirm that monitoring activities are proceeding as planned. During these continuing reviews, the DSMC has an opportunity to address any concerning findings due to this integration. Future directions will include building a comprehensive library of standardized DSMC trainings in collaboration with CPDM. Compliance to improve compliance and safety monitoring for the Interventional IITs monitored by the HICCC DSMC.

Risk Based Monitoring as a mechanism to inform DSMC practices

Tiffany Negri, ALM, CCRP; Dan Otap, CCRP; Moshe Kelsen, MBA; Frances Brogan, MSN, RN, Lauren Blumberg, MPH, MS; Jennifer Wang, MS, CCRP, Shannon Kelly, Magdalena Galazyn, PhD, Joseph Jurcic, MD

Background

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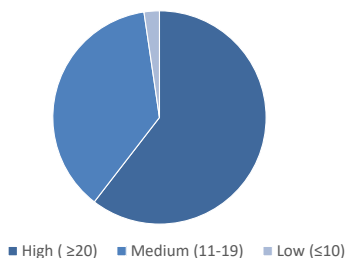
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Solutions and Methods

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Figure 1. Distribution of risk levels as determined by ssDSMP



Results

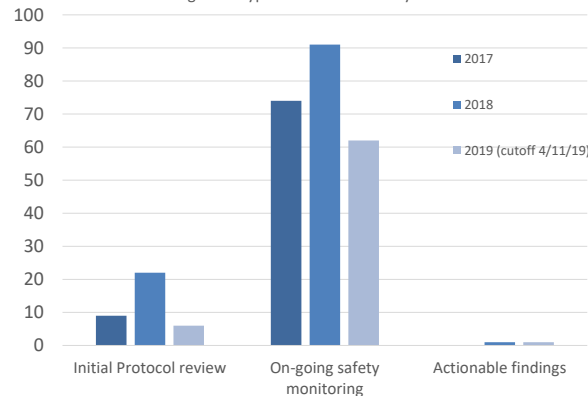
The HICCC DSMC has approved 33 ssDSMPs with plans using the updated Risk Based Monitoring Guidance created in 2017. Figure 2 includes overall DSMC metrics from January 2017 to April 2019.

The implementation of ssDSMPs during initial DSMC review has led to more standardized and informed DSMC reviews. The reviews are now based on pre-determined monitoring risk levels, and reporting frequencies as well as greater integration with quality assurance teams within CUIIMC.

The DSMC reviewers are able to establish clear guidance for QA monitors at the onset of a trial, and make any required recommendations regarding the ssDSMPs. This has led to a downstream effect of improving the quality of the clinical trials as DSMC reviewers are able to assess the study objectives and safety guidelines (e.g. DLTs) before a trial activates.

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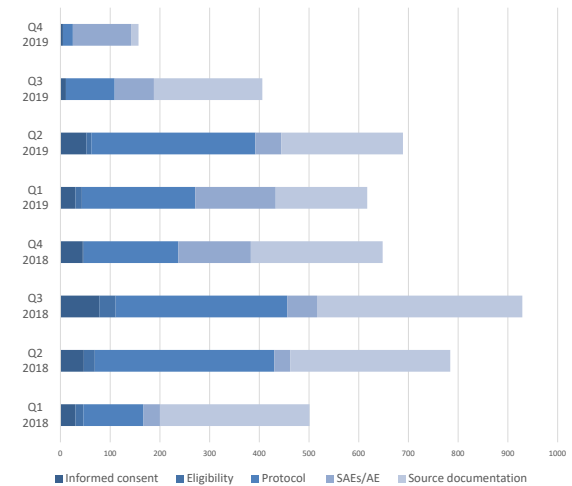
Figure 2. Type of DSMC Review by Year



Future Directions

Future directions will include building a comprehensive library of standardized DSMC trainings in collaboration with CPDM Compliance to improve compliance and safety monitoring for the Interventional IITs monitored by the HICCC DSMC.

Figure 3: Monitoring Findings Over Time (CUIIMC and subsites)



References

- Otap, D, et al. (2016, July). Not the "Ethics Police", a unique approach to internal Quality Assurance (QA) and monitoring procedures. Poster Presented at the Association of American Cancer Institutes, 8th Annual AACI Clinical Research Initiative Meeting, Chicago, Illinois, USA.
- Otap, D, et al. (2017, July). Adapting to Thrive- Risk Based Monitoring of Academic Institutional Investigator Initiated Clinical Trials. Poster Presented at the Association of American Cancer Institutes, 9th Annual AACI Clinical Research Initiative Meeting, Chicago, Illinois, USA.
- FDA Guidance For Industry; Oversight of Clinical Investigations- "A Risk Based Approach To Monitoring, August 2013". <https://www.fda.gov/downloads/Drugs/Guidances/UCM269919.pdf>

Herbert Irving Comprehensive Cancer Center  COLUMBIA

How to Be a Principal Investigator: A Practical Training Program for Investigators

R. Kingsford, D. Pitt, S. Low, L. Weaver, J. Moehle, A. Cohen, T. Werner

Huntsman Cancer Institute, University of Utah

1. Background

Principal investigators complete rigorous medical training and online self-guided training in human subjects protection (HSP) and good clinical practice (GCP). These mandatory trainings focus mainly on the history of HSP and general concepts in GCP. The practical skills required to be a successful investigator are not included in academic training courses.

2. Goals

Our goal was to train new investigators in best practices for conducting clinical research. The planning committee identified six competence domains to inform the content for the training:

- 1) Roles and responsibilities of the investigator
- 2) Federal and international regulations regarding research
- 3) Institutional processes and regulations
- 4) Informed consent, adverse event assessment, and source documentation
- 5) Roles and responsibilities of research staff
- 6) Resources available to investigators in their clinical areas

3. Solutions and Methods

We formed a planning committee of seven people, including experienced principal investigators, research personnel, compliance officers, and research administrators. The committee planned and conducted a half-day seminar entitled “How to be a Principal Investigator.” The initial pilot seminar included junior and senior faculty from 10 internal medicine divisions, pediatrics, and nursing. The planning committee designed pre-, post-, and 3-month surveys to gauge understanding and retention. Self-assessed quantitative cumulative scores showed improvement in understanding that persisted for 3 months. Given the success of the initial intervention, the training is now mandatory for all Department of Medicine investigators. The seminar includes eight lectures, two panel discussions, an interactive case study, and a resource handout. We used the survey again to gauge understanding and garner feedback from the investigators. The planning committee has provided several different sessions of the seminar on different days and different times of the day in order to accommodate schedules.

4. Outcomes and Future Directions

Across the six competence domains, the average cumulative investigator understanding score was 25.95 of a possible 30 following the seminar. Qualitative investigator feedback has been generally positive. Investigators from other departments such as the Department of Surgery for whom the training was not mandated have attended and found the content to be beneficial. Several investigators indicated that they liked the interactive nature of the seminar. We find that interdisciplinary and interdepartmental collaboration on content and identification of speakers continues to generate new ideas for future partnership.

Using feedback generated from the survey, the planning committee will explore format options such as an interactive online training.

The committee is exploring a combined session including trial coordination staff and investigators, based on a suggestion from the surveys. We will continue to evaluate and modify content in response to institutional needs, as well as national and international updates in regulations and institutional needs.



How to Be a Principal Investigator: A Practical Training Program for Investigators

Rachel Kingsford, MS, CCRP; Debbie Pitt, CCRP; Scott Low, MBA, CCRP; Lisa Weaver, CCRP; Jessica Moehle, CCRP; Adam L. Cohen, MD, MS; Theresa L. Werner, MD

Huntsman Cancer Institute at the University of Utah



BACKGROUND

Clinical investigators complete rigorous medical training and are required to complete online, self-guided training in good clinical practice (GCP) and human subjects protection (HSP). These courses do not include the practical skills necessary to be a successful investigator. We formed a committee and created a practical investigator training seminar. After successful completion of the pilot seminar, we have offered the seminar regularly.

METHOD

- The committee identified six competence domains (Figure 1).
- The pilot seminar included junior and senior faculty.
- The seminar is now mandatory for all investigators in the Department of Internal Medicine.
- The seminar is offered regularly on different days of the week and at different times to accommodate schedules.

Figure 1. Core Competencies

1. Roles and responsibilities of the investigator
2. Federal and international regulations
3. Institutional processes and regulations
4. Informed consent, adverse event assessment, and source documentation
5. Roles and responsibilities of research staff
6. Resources available to investigators in clinical areas

Figure 2. Qualitative Feedback Samples

"Very nicely done—thank you! I was afraid it would be painful; it wasn't."

JW, Experienced PI

"Stellar review overall."

WA, Experienced PI

RESULTS

- Self-assessed quantitative scores across the competence domains improved and persisted after three months.
- The average cumulative understanding score for investigators attending the seminar after the pilot was 25.95 of a possible 30.
- Qualitative feedback was generally positive (Figure 2).

CONCLUSIONS

A seminar providing investigator training on practical applications of investigator responsibilities and best practices improved knowledge of investigators across the six competence domains.

FUTURE PLANS

- The committee will explore updated format options such as an interactive online training.
- Based on a suggestion from an investigator, the committee will also explore a combined seminar including coordination staff.
- The committee will update content as needed.

Increasing Minority Oncology REpresentation (MORE) in Clinical Trials

S. Milescu, L. Vaughn, A. Al-Hader, S. Rawl, M. Contreras, K. Miller

Indiana University Melvin and Bren Simon Cancer Center

1. Background

Clinical trials (CTs) are scientifically significant for the safe development and evaluation of new treatments for debilitating diseases like cancer. For this reason, minority representation is essential to decrease ethnic and racial disparities in cancer outcomes. The National Institute of Health (NIH) Revitalization Act of 1993 was implemented to combat issues caused by recruitment barriers, enforcing that women and minorities are proportionately included in all NIH-funded clinical research studies. To date, minorities remain underrepresented while having disproportionately higher rates of chronic diseases (Heller et al, 2014). Clinicaltrials.gov enrollment data showed a decrease in minority accruals between 2003 and 2016 (Duma et al, 2018). As minority populations continue to increase in the United States, their representation in CTs is imperative to decrease disproportionate cancer burdens within minority groups.

Low participation and representation in CTs among minority populations, indicated in local and national data, is caused by provider, system and patient barriers but mediated by awareness and knowledge given that appropriate educational programs set in place for providers and patients moderate the causes. Socioeconomic factors, genetic pre-disposition, lack of access or knowledge of CTs, and historic mistrust in providers, exist prior to the causes.

2. Goals

- 1: Provide awareness of CTs for academic fellows by engaging fellows in recruitment
- 2: Increase the number of minorities recruited and enrolled onto CTs at IUSCC and Eskenazi Health

Objective 1: By end of Q2 (July 2019), current fellows and faculty will be aware of current and upcoming CTs available at IUSCC and Eskenazi Health through use of a clinical trial database

Objective 2: By end of Q3 (Oct 2019), minority accruals onto hematology/oncology CTs will have increased by 5% at IUSCC and Eskenazi Health

3. Solutions and Methods

Increased collaboration and communication will occur between clinical disease oriented teams (DOT), academic fellows and other CT staff at IUSCC and Eskenazi Health starting January 2019. Use of Epic software, creation of a clinical trial database, and staff participation in monthly DOT meetings along with a review of trial portfolios will solidify outcomes. A pre and post evaluation survey will be conducted using Redcap and distributed to fellows March and July 2019 to assess for changes in attitudes, behaviors and awareness of CTs. As new fellows rotate through their academic training, a baseline evaluation will be conducted on month 1 and comparison at the end of month 6 to look for changes in attitudes and awareness as well as accrual increases in minority populations.

4. Outcomes and Future Directions

- Total minority accruals to oncology CTs
- Increases in fellows' awareness of CTs, confidence recruiting, and number of discussions about CTs, RedCap survey results pre and post evaluation

Future

- Re-evaluate curriculum and expectations of all incoming fellows with commitment from IUSCC and Eskenazi Health to increase clinical trial participation.
- Long term future directions are to survey patients about their perceived barriers to clinical trial recruitment and begin establishing new strategies to overcome patient specific



Minority Oncology Representation (MORE)

Sandra Milescu, CPH, BS • LaTrice Vaughn, RN, BSN • Ahmad Al-Hader, MD • Susan M. Rawl, PhD, RN, FAAHB, FAAN • Mario Contreras, MBA, MSN, RN • Kathy D. Miller, MD
Indiana University Simon Cancer Center (IUSCC)

Abstract

Clinical trials are scientifically significant for the safe development and evaluation of new treatments for debilitating diseases like cancer. For this reason, minority representation is essential to decrease ethnic and racial disparities in cancer outcomes. The National Institute of Health (NIH) Revitalization Act of 1993 was implemented to combat issues caused by recruitment barriers, enforcing that women and minorities are proportionately included in all NIH-funded clinical research studies. To date, minorities remain underrepresented while having disproportionately higher rates of chronic diseases (Heller et al., 2014). Clinicaltrials.gov enrollment data showed a decrease in minority accruals between 2003 and 2016 (Duma et al., 2018). As minority populations continue to increase in the United States, their representation in clinical trials is imperative to decrease disproportionate cancer burdens within minority groups (Chen et al., 2014).

Introduction

Low participation and representation in clinical trials among minority populations, indicated in local and national accrual data, is caused by provider, system and patient barriers but mediated by awareness and knowledge given that appropriate educational programs set in place for providers and patients moderate the causes. The socioeconomic factors, genetic pre-disposition, lack of access or knowledge of clinical trials, and historical mistrust in providers, exist prior to the causes. IU Simon Cancer Center (IUSCC) represents the IU Schools of Medicine, Nursing and Public Health, among others, in leading more than 600 active clinical trials for pediatric and adult cancers. Faculty educators train nearly 2000 students, residents and fellows each year. On the IUPUI campus is also Eskenazi Health. In partnering with IU, Eskenazi Health serves as the public hospital division to meet the needs of the underserved and all people of Marion County with facilities both on and off the IUPUI campus. This model of teaching and access to clinical trials allows exposure to clinical trials for the health care provider and for the patients at IUSCC and Eskenazi Health.

Materials & Methods

Increased collaboration and communication will occur between clinical disease oriented teams (DOT), academic fellows and other clinical trial staff at IUSCC and Eskenazi Health starting January 2019. Use of Epic software, creation of a clinical trial interface, staff attendance, participation in monthly tumor boards and DOT meetings, and review of trial portfolios will solidify outcomes. A new interface was developed, located on the Eskenazi Health website, which fellows and community-based faculty are able to access regularly. This ensures they can familiarize themselves with clinical trials open to accrual and refer eligible patients within the health systems network. This interface is in the form of a web based spreadsheet and contains key eligibility criteria to reference prior to an encounter with a patient. Providers using the Epic program messaging system can alert one another of potential clinical trials available for their patient population.

A pre and post evaluation survey was conducted using Redcap and distributed to third year fellows March and July 2019 to assess for changes in attitudes, behaviors and awareness of clinical trials. As new fellows rotate through their academic training, a baseline evaluation will be conducted on month 1 and comparison at the end of month 6 to look for changes in attitudes and awareness as well as accrual increases in minority populations.

Goals and Objectives

Goal 1: Provide awareness of clinical trials for academic fellows by engaging fellows in recruitment

Goal 2: Increase the number of minorities recruited and enrolled onto oncology clinical trials at IUSCC and Eskenazi Health

Objective 1: By end of Q2 (July 2019), all current fellows and faculty will be aware of current and upcoming clinical trials available at IUSCC and Eskenazi Health through the use of a clinical trial database

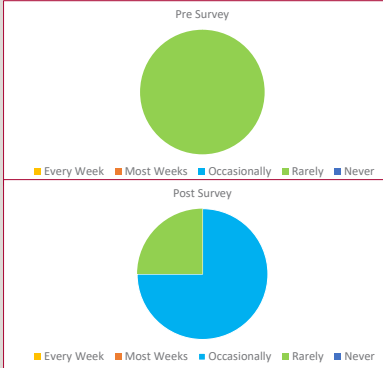
Objective 2: By end of Q3 (Oct 2019), minority accruals onto hematology/oncology clinical trials will have increased by an overall total of 5% at both IUSCC and Eskenazi Health recruitment sites

IUSCC and Eskenazi Health Minority Accruals

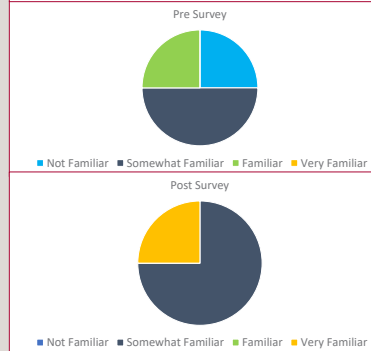
Jan-May 2018	Jan-May 2019
17	21

Results

How often do you attend tumor board meetings at Eskenazi Health?



In the past 3 months, how familiar have you been with the hematology/oncology clinical trials portfolio at Eskenazi Health?



In the past 3 months, how familiar have you been with the hematology/oncology clinical trials portfolio at IUSCC?



Discussion

The MORE project created a model of teaching and access to clinical trials that allowed fellows exposure to clinical trials available to patients at IUSCC and Eskenazi Health. Outcomes were measured by total monthly and annual minority accruals to oncology therapeutic clinical trials and changes in fellows' recruitment behavior as shown through the RedCap survey responses. This data showed increases in fellows' awareness of IUSCC and Eskenazi Health clinical trial portfolios, confidence in recruiting, and number of discussions about clinical trials.

Conclusions

Overall minority accruals onto therapeutic clinical trials increased by over 23%. As the program continues, we may see more significant increases in overall minority accruals.

In the course of 5 months, fellows became more aware of and familiar with the clinical trials available to their patient population. Attendance at clinical research meetings showed an increase in collaboration and communication between academic fellows and the rest of clinical research staff at IUSCC and Eskenazi Health.

Going forward, all new IUSCC and Eskenazi Health academic fellows rotating through their academic training will receive a baseline evaluation (pre-survey) on month 1 of their service. A post survey will be distributed to fellows during the final month of their clinical rotation. A comparison will be made using data from the post survey to look for continued changes in attitudes and awareness. Therapeutic clinical trial accruals at IUSCC and Eskenazi Health will continue to be monitored for increases in minority population accruals.

Our center plans to re-evaluate the academic curriculum and expectations of all incoming fellows with a commitment from IUSCC and Eskenazi Health to increase clinical trial participation.

Future directions are to survey patients about their perceived barriers to clinical trial recruitment and begin establishing new strategies to overcome patient specific barriers to clinical trial recruitment. Focus will be placed on minority patients and location at Eskenazi Health clinic.

The IUSCC will continue to identify other resources and opportunities to increase minority accruals.

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The Case for a Designated Clinical Research Educator

M. Gray, R. Selle, B. Oleson, J. Thomas

Medical College of Wisconsin Cancer Center

1. Background

In a busy clinical trials office with more than 80 staff members, it may be daunting to onboard new staff with the goal of ensuring continued education of current regulations and best practices related to clinical research. This proves particularly challenging given that it is rare that new staff have any previous clinical research experience or a high level of relevant knowledge. Consistency in training (i.e., internal processes and expectations, best practices, etc.) is often also a hurdle. By having designated Clinical Research Educators (CREs), MCW's Cancer Center Clinical Trials Office has been able to provide uniform training across specialties leading to improved adherence to performance expectations and consistent best practices across teams.

2. Goals

The goal of implementing a model with designated CREs was for staff to receive consistent training and messaging. The Cancer Center hoped that staff would feel a sense of support during training, audits, and day-to-day operations.

3. Solutions and Methods

The cancer center CREs provide ongoing education to staff through an onboarding program, which is tailored by position; monthly education seminars; an annual symposium and other specific trainings, as applicable. Methods of teaching include didactic methods, as well as hands-on learning and simulation. The educators also create tools and checklists with the goal of developing uniform intra-department processes. Another unique duty of a cancer center CRE is to assist in distributing and developing learning opportunities that meet continuing education requirements for staff maintaining professional research certifications. This reduces a major burden for staff members (finding applicable courses, obtaining funding/reimbursement, dedicating travel time, etc.), and provides all staff with continued learning opportunities. The CREs also assist staff in preparation for audits.

4. Outcomes and Future Directions

Utilizing dedicated CREs has had a positive impact in the MCW Cancer Center Clinical Trials Office in many areas. For example, during the orientation phase, new staff feel supported by having a main contact and they experience a much smoother and consistent onboarding process when CREs coordinate a majority of the process. This simultaneously decreases the onboarding burden of our experienced staff and reduces variations in training. In addition, audit outcomes have improved significantly as departmental standards and best practices have been developed and enforced. This includes fewer major and minor findings and auditors praising the consistency of documentation practices. The monthly educational opportunities developed by CREs have made it easier for staff to obtain educational credits and maintain their research certifications. Educators also have become resources to our entire department beyond the onboarding process by developing standard operating procedures and guidelines, and providing day-to-day assistance as needed (i.e., troubleshooting, facilitating questions regarding internal processes, required trainings, etc.). The implementation of CREs has proven to be a successful model for the MCW Cancer Center Clinical Trials Office. Other departments have sought out the CREs as resources for their own staff training and education. Our CREs also have collaborated on campus-wide education initiatives. Having designated



The Case for a Designated Clinical Research Educator

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

Purpose

In a busy clinical trials office with more than 80 staff members, it may be daunting to onboard new staff with the goal of ensuring continued education of current regulations and best practices related to clinical research. This proves particularly challenging given that it is rare that new staff have any previous clinical research experience or a high level of relevant knowledge. Consistency in training (i.e., internal processes and expectations, best practices, etc.) is often also a hurdle. By having designated Clinical Research Educators (CREs), MCW's Cancer Center Clinical Trials Office has been able to provide uniform training across specialties leading to improved adherence to performance expectations and consistent best practices across teams.

Methods and Materials

The cancer center CREs provide ongoing education to staff through an onboarding program, which is tailored by position; monthly education seminars; an annual symposium and other specific trainings, as applicable. Methods of teaching include didactic methods, as well as hands-on learning and simulation. The educators also create tools and checklists with the goal of developing uniform intra-department processes. Another unique duty of a cancer center CRE is to assist in distributing and developing learning opportunities that meet continuing education requirements for staff maintaining professional research certifications. This reduces a major burden for staff members (finding applicable courses, obtaining funding/reimbursement, dedicating travel time, etc.), and provides all staff with continued learning opportunities. The CREs also assist staff in preparation for audits and the development of Corrective and Preventative Action Plans.

Results

Utilizing dedicated CREs has had a positive impact in the MCW Cancer Center Clinical Trials Office in many areas. For example, during the orientation phase, new staff feel supported by having a main contact and they experience a much smoother and consistent onboarding process when CREs coordinate a majority of the process. This simultaneously decreases the onboarding burden of our experienced staff and reduces variations in training. In addition, audit outcomes have improved significantly as departmental standards and best practices have been developed and enforced. This includes fewer major and minor findings and auditors praising the consistency of documentation practices. The monthly educational opportunities developed by CREs have made it easier for staff to obtain educational credits and maintain their research certifications. Educators also have become resources to our entire department beyond the onboarding process by developing standard operating procedures and guidelines, and providing day-to-day assistance as needed (i.e., troubleshooting, facilitating questions regarding internal processes, required trainings, etc.).

Conclusions & Discussion

The implementation of CREs has proven to be a successful model for the MCW Cancer Center Clinical Trials Office. Other departments have sought out the CREs as resources for their own staff training and education. Our CREs also have collaborated on campus-wide education initiatives. Having designated educators has promoted a consistent culture of clinical research best practices within the MCW Cancer Center Clinical Trials Office.

Acknowledgements

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

Figure 1: Checklist for new subject screening and enrollment reflecting internal workflows

Figure 2: Competency assessment example for regulatory coordinators/specialists

Figure 3: Answer keys to exercises for data entry, documentation, and eligibility

Onboarding Curriculum

All Staff

- General topics (Weeks 1-2)
- Oncology and clinical trials basics
 - General workflows and ancillary services
 - The flow of a new study (e.g., Confidentiality Disclosure Agreements, Disease Oriented Team, Scientific Review Committee, DSMC, etc.)
 - Training for the Clinical Trial Management System and other applicable software/databases
 - Anatomy of a protocol and source documentation
 - Documentation per GCP, FDA regulations, and internal expectations
 - Review department Standard Operating Procedures and guidelines
 - Preceptor assignment
 - Shadowing opportunities (e.g., Translational Research Unit, Investigational Drug Services (IDS), research lab staff, etc.)

Clinical Research Assistants, Coordinators, and Nurses

- Weeks 2-3
- Electronic Medical Record training including oncology specific workflows
 - IRB reporting
 - Informed consent process
 - Workflows for subject screening, enrollment, and study visits
 - Workflows with ancillary departments (e.g., compliance, imaging, lab, IDS, etc.)

Regulatory Coordinators and Specialists

- Weeks 2-3
- New study submission process including:
 - IRB submission
 - Workflows with ancillary departments (e.g., safety committees, budget and contract team, compliance, etc.)
 - Informed Consent Form preparation
 - Execution of essential documents
 - Guidance in working with sponsors and Clinical Research Organizations
 - IRB submissions of amendments, annual reviews, and reportable events

Competency Evaluations

- 4-6 months into employment
- Review a subject shadow chart or regulatory binder completed by new staff
 - Assess independence and proficiency of workflows and tasks covered during onboarding

Figure 4: Abbreviated onboarding curriculum checklist

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Developing a Standardized Library of Informed Consent Language to Ensure Consistency and Quality Across Clinical Trials at a Large Academic Medical Center

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Memorial Sloan Kettering Cancer Center

1. Background

As the volume of clinical trials at our institution continues to increase, and in view of recent changes to the Common Rule, it has become necessary to develop institutional guidelines for consent writers to ensure consistency, clarity, and quality of informed consent forms across all clinical trials. In January 2018, MSK launched a centralized Protocol Activation Core (PAC) composed of 6 Protocol Activation Managers (PAMs) and 1 Editor. Over the last 15 months, this team (now 10 PAMs and 2 Editors) has written consent forms for all newly-opened clinical trials. Creating this new unit has increased the quality of our consent documents, but it has left primary disease management teams (DMTs) with insufficient resources and training to write or edit consent forms if, for example, a new trial arm is added or a protocol amendment is mandated by the research sponsor. The PAC Editors have created a consent style guide for PAMs and DMTs, and the PAC team is developing a library of IRB-approved frequently used terms and standard descriptions to ensure clarity and consistency as new consent forms are written and older consents are updated and revised.

2. Goals

- Develop PAC Consent Library Excel tool to share with primary DMTs and study teams
- Pilot the PAC Consent Library with 3-5 high-volume DMTs to train the team members and elicit feedback
- Negotiate sponsor-specific language and develop master consent templates and libraries with industry partners
- Roll out PAC Consent Library to all DMTs and track metrics on (a) number of times amendments are returned from the IRB to DMTs for issues with consent language, and (b) time required for PAMs and DMT administrators to write or amend consents

3. Solutions and Methods

We have developed a multi-tab Microsoft Excel tool that is organized according to sections of the consent form (e.g., tests and procedures, risks, costs). The PAC Library includes only language that has been approved by MSK's IRB since the PAC unit was launched in 2018. The consent Library is shared among PAC consent writers and primary DMTs, and updated as needed based on feedback from these groups, and from the IRB and principal investigators (PIs).

4. Outcomes and Future Directions

- Consent writing has been standardized across the institution, according to disease and type of trial
- Time required to develop and revise consents has decreased
- Category: Training & Quality Assurance – Work in Progress
- IRB members and PIs have become familiar with standardized descriptions and language, which has increased the efficiency of consent review (Median time for protocol/consent review by the IRB has decreased, with time-to-IRB approval decreasing from 135 days in 2017 to 80 days in 2018; see Figure.)

The most exciting prospect for the PAC Library is the development of a “smart” eConsent authoring tool that uses keywords to pull language from the Library and insert it into the appropriate section(s) of a consent document as it's being written. As PI interest in MSK's eConsent platform increases, writing and editing consents in the same platform will create a more streamlined and consistent approach to developing informed consent forms.

Standardization and Unification of Deficiency Language in Auditing and Monitoring

M. McGinn, K. Yataghene

Memorial Sloan Kettering Cancer Center

1. Background

Given the ever-expanding diversity and complexity of clinical trials and the regulatory environment, the need for reproducible, consistent, and definitive terminology led the Quality Assurance Unit of Clinical Research Administration at MSK to create a standardized list of detailed descriptions and gradings for observed deficiencies. This list serves as the culmination of our efforts to optimize and centralize findings from both internal MSK Auditing and Monitoring Program reviews and external agency inspections.

2. Goals

We streamlined notation and communication of observed deficiencies with the primary intent of improving efficacy in implementation of corrective and preventive actions. By ensuring that our list efficiently encompassed results from all types of reviews, we also hoped to increase the incisiveness of the metrics generated. Additionally, we aimed to emphasize the document as a practical educational resource, a roadmap of the specific elements of review and citation which will evolve simultaneously with changing regulations.

3. Solutions and Methods

We created our list containing 238 unique deficiencies, specified by 57 subcategories and sorted into 10 general categories – Regulatory Review, Registration, Informed Consent, Eligibility, Evaluation, Treatment/Intervention/Interaction, Toxicity/Adverse Events, Outcome/Response, General Data Quality, and Pharmacy Review. We efficiently described the spectrum of potential observations from auditing and monitoring processes and, critically, linked each with the applicable institutional, federal, and/or ICH guidelines which underpin each entry. We also worked with our institution's research informatics team to update the selectable deficiencies within our in-house electronic records system from the prior iterations to our new list, as well as modernize our mechanisms for obtaining results reports to simplify the process and allow for alignment of auditing and monitoring results.

4. Outcomes and Future Directions

By utilizing a common language for auditing and monitoring activities, communications between operational and quality assurance teams are enriched; implementation of corrective and preventative actions have been expedited and recommended standard actions created; corresponding policies hyperlinked within the list may be easily referenced to guide re-training and generate targeted educational materials; and metrics from audits and monitoring visits have been harmonized to provide a complete, real-time picture of institutional compliance.

While currently considering this project complete, we naturally anticipate additions over time to account for changing regulations and best practices; these changes will have a ripple effect of required accommodation within future QA projects, such as a planned CAPA response library. Finally, we hope to maintain communication with institutions who adopt content relevant to their practice, ultimately promoting collaboration and sharing of lessons learned across cancer treatment centers nationally.

Using Centralized Review of Queries to Improve Data Integrity, a Canadian Clinical Trials Perspective

A. Goyal, E. Strom, S. Duric, S. Pardhan, S. Mulumba, J.M. Veigas, D. Gutierrez, R. Yoganathan, T. Jayasinghe, K. Sabate, M. Kirchmeyer, M. Artemakis, A. Topalovich, L. Baumann

Princess Margaret Cancer Centre, University Health Network

1. Background

The success of a clinical trial is dependent on the integrity of the data entered into an electronic data capture (EDC) system to draw meaningful and accurate conclusions on the intervention. Data integrity is achieved through the generation and resolution of queries. Queries refer to discrepancies in data entered, issued by the sponsor to the site. Over 150 clinical trials are conducted through the Clinical Trials Support Unit (CTSU) at Princess Margaret Cancer Centre (PM) annually. It was recognized that the volume of queries in these trials posed a significant time and cost burden to the CTSU. This led the CTSU to identify potential solutions to prevent common data queries.

2. Goals

The objective is to assess if centralized review of queries by a data coordination unit can result in improved data accuracy and reduce the number of queries by 25% over the next year. Our goal is to achieve this through implementation of standardized tools that will ultimately save time, cost, and resources.

3. Solutions and Methods

A retrospective analysis of thirteen studies from a large cooperative group was performed from October 2017 to October 2018, resulting in analysis of 25,989 total queries. Filters were applied to eliminate system generated (automatic) and cancelled queries, focusing on 6,527 manually generated queries from sponsor data managers. Common categories were coded with sub-categories to determine the prevalence of query types, further prioritizing subsets of data where meaningful changes could be implemented.

4. Outcomes and Future Directions

Four categories were identified as areas for immediate implementation of solutions: Assessments, AE/SAE, TMs, and Concomitant medications. These measures are being implemented within the CTSU:

1. TM: Standardization of TM Worksheet with instructions to customize to protocol specific requirements (i.e. measurement criteria, radiation field, clarification notes)
2. AE/SAE: Creating a reference document of common “other” terms to avoid (i.e. Other: Drowsiness vs. CTCAE: Somnolence)
3. Concomitant Medications: Revising standard operating procedures (SOP) to allow coordinators to input generic vs. trade names for concomitant medications to minimize use of “Other: Specify.”

4. Assessments: Implementing a study visit checklist with protocol specific requirements (i.e. labs) to avoid missed assessments and tests conducted out of window
5. General: Implementing a “Study Summary” tool with process and data entry specifics for each trial, to ease study transfer process between coordinators.

By performing a centralized review of these common queries, the CTSU learned that queries that were once thought to be unique to specific trials were actually found across multiple studies. This project was staff directed and has generated enthusiasm and positive morale within the team. The self-directed education in this project has been a powerful tool leading to improved awareness of data integrity.

The next step is to further implement and evaluate the effectiveness of our tools based on an interim analysis at 6 months. Ongoing feedback within the trials team and sponsor will enable us to apply new solutions to other categories not addressed. Through collaboration with various stakeholders, we hope to expand these findings to research departments across PM and to different sponsors as well.

Using Centralized Review of Queries to Improve Data Integrity, a Canadian Clinical Trials Perspective

Aunshu Goyal, MB BCh BAO; Evan Strom; Suzana Duric, MSc, CCRP; Siddika Pardhan, CCRP; Susan Mulumba, MSc, CCRP; Jyothi Maria Veigas, PhD, CCRP; David Gutierrez; Risho Yoganathan; Thenushi Jayasinghe, CCRP; Kathryn Sabate; Marie Kirchmeyer; Maria Artemakis; Aleksandra Topalovich; Liesa Baumann, CCRP

Background

Queries refer to discrepancies in data entered for clinical trials, issued by sponsor to the site.

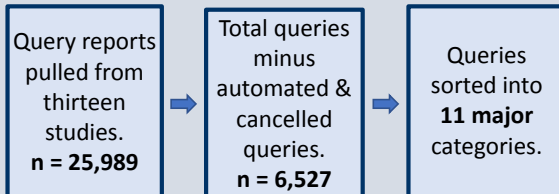
The volume of queries in these trials posed a significant time and cost burden, leading to the identification of potential solutions to prevent common data queries.

Goals

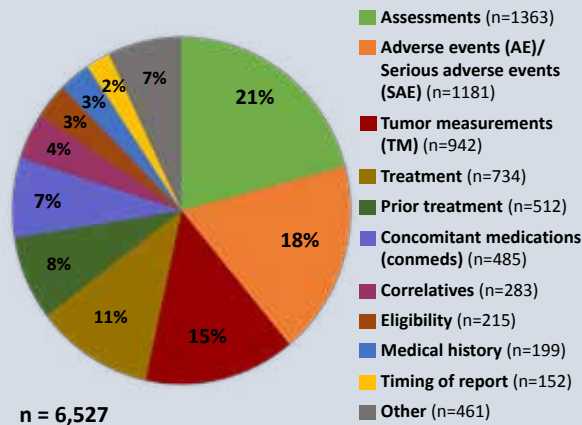
To determine if centralized review of queries can:

- Improve data accuracy
- Reduce the number of queries by 25% over the next year
- Save time, cost, and resources

Methods



Outcome



Category	Query example
Assessments	"Amylase, lipase, TSH are all required to be done at Day 1. Explain why they were missed."
AE/SAE	"To avoid the use of other, please consider using 'somnolence' for this AE term."
TM	"Please confirm whether any lymph nodes are > 15 mm in short axis."
Conmeds	"Please select as 'hydrocortisone valerate' as generic name."

Discussion

Measures being implemented within CTSU:

- **TM worksheet** – customize to protocol specific requirements (i.e. clarification notes)
- **AE/SAE reference document** – list of common "other" terms to avoid
- **Standard operating procedures (SOP) revision for conmeds** – to allow coordinators to input generic vs trade names to minimize use of "Other: Specify"
- **Study visit checklist** – to avoid missed assessments and tests conducted out of window
- **"Study Summary" tool** – data entry specifics for each trial to ease transfer process between coordinators

Lessons learned:

- Noted improvement in data accuracy through increased awareness
- Queries preventable with detailed guidelines and clear communication

Conclusion

Our next steps will entail:

- Performing interim analysis to review if goals achieved
- Collaborating with all study sponsors and implementing tools across all studies
- Sharing our findings with other teams

Deciding How to Decide: Let Your Values Be Your Guide

J. Edwards, C. Knoerle, D. Jenkins, N. Wallace

Siteman Cancer Center

1. Background

Most of our decisions are constrained by “realities” like budgets, time horizons, infrastructure or policies. But what if they weren’t? In the absence of typical limits, how do you decide how to decide?

Our quality assurance audit team confronted this problem in the fall of 2018 as we embarked on extensive revisions of our policies and procedures (P&Ps). With everything on the table, we immediately turned to “experts,” other groups’ P&Ps, feedback from the people we audit, guidance from regulatory bodies, and documented best practices—and we combed through our own data. In so doing, we discovered that while helpful, there was no “one way” to achieve our goals.

2. Goals

1. To develop effective P&Ps as well as standard operating procedures (SOPs) which advance the mission of the Cancer Center in general and the Quality Assurance and Safety Monitoring Committee in particular.
2. To have P&Ps and SOPs which reflect best practices and the current regulatory environment.
3. To improve our stakeholders’ experiences with audits and the auditors.

3. Solutions and Methods

1. Establish team values, a team vision, and mission statement.
2. Clarify how our team works within that vision and mission.
3. Allow our values, vision, and mission to constrain decision-making in the development of our P&Ps and SOPs.

4. Outcomes and Future Directions

First, we have been able to concentrate on selecting policies and procedures that move our vision forward. By filtering ideas through a matrix of “how does this make us a better partner with teams,” or “how does this make us better advocates for patient safety,” we have made better decisions about critical issues like which studies to audit, case selection, and audit frequency.

Second, by developing a cohesive understanding of “who we are” and “what we do” we have been able to make better choices outside of our policies and procedures, including how we provide education and how we communicate.

Finally, our group decision-making has been supported by our values. For instance, one of our values is that we will use available data to understand trends. Because of this value, we have dug deep into our data about audits to understand what we already know about our process and its impact.

We anticipate that we will continue to use our values, vision, and mission as a tool. Having recognized the strength of values-based decision-making to unite our group and serve as a north star for our work, our next steps are to begin promulgating them from our team to constituents with whom we work.

Deciding How to Decide: Let Your Values Be Your Guide

Jennifer Edwards, MSW, MA, CCRP, Daveta Jenkins, MBA, Catie Knoerle, CCRP



ABSTRACT

- Most of our decisions are constrained by “realities” like budgets, time horizons, infrastructure or policies. But what if they weren’t?
- Our quality assurance audit team confronted this problem in the fall of 2018 as we embarked on extensive revisions of our policies and procedures (P&Ps).
- With everything on the table, we immediately turned to “experts,” other groups’ P&Ps, feedback from the people we audit, guidance from regulatory bodies, and documented best practices—and we combed through our own data.
- We discovered that while helpful, there was no “one way” to achieve our goals.

GOALS TO BE ACHIEVED

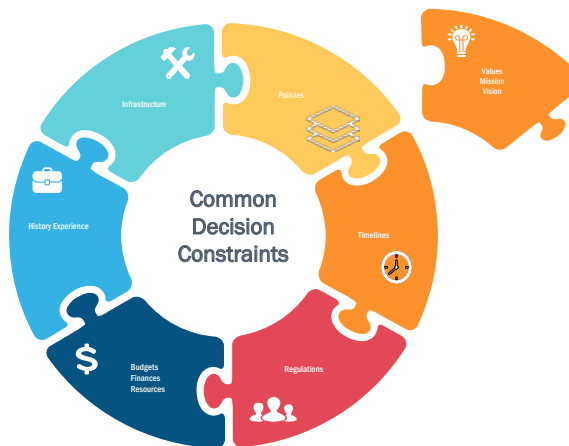
1. To develop effective P&Ps as well as standard operating procedures (SOPs) which advance the mission of the Cancer Center in general and the Quality Assurance and Safety Monitoring Committee in particular.
2. To have P&Ps and SOPs which reflect best practices and the current regulatory environment.
3. To improve our stakeholders’ experiences with audits and the auditors.

QASM’S VISION

An objective source of support to clinical trial teams; providing an opportunity to evaluate and improve operations to ensure reliability of data and protection of participant rights.

METHODS

1. Establish team values, a team vision, and mission statement.
2. Clarify how our team works within that vision and mission.
3. Allow our values, vision, and mission to constrain decision-making in the development of our P&Ps and SOPs.



QASM’S MISSION

To perform systematic and independent examination of trial-related activities and documentation. This examination will assess whether evaluated activities were appropriately conducted according to the study protocol, standard operating procedures (SOPs), federal regulations and good clinical practices (GCPs) and will confirm that data were generated, recorded, analyzed, and accurately reported.

RESULTS

- We have been able to concentrate on selecting policies and procedures that move our vision forward. By filtering ideas through a matrix of “how does this make us a better partner with teams,” or “how does this make us better advocates for patient safety,” we have made better decisions about critical issues like which studies to audit, case selection, and audit frequency.
- We have developed a cohesive understanding of “who we are” and “what we do”. Because of this we have been able to make better choices outside of our policies and procedures, including how we provide education and how we communicate.
- Our group decision-making has been supported by our values, vision and mission.

CONCLUSIONS

- Crafting these common values, vision and mission was time intensive, but we continue to reap the values of our efforts.
- The tool allows us to envision our future, and face challenges head-on.
- Creates a safe space for a market-place of ideas.

NEXT STEPS

- Continue to work on sharing our vision and mission.
- Continue to evaluate how our vision and mission shape our policies and procedures.
- As we implement new policies and procedures, continue to provide ongoing review of their “fit.”

Creating a Positive QA Team Image and Strengthening the Auditor/Research Team Relationship

C. Knoerle, J. Edwards, D. Jenkins, N. Wallace

Siteman Cancer Center

1. Background

The Quality Assurance and Safety Monitoring (QASM) team is responsible for auditing investigator-initiated studies at Siteman Cancer Center. Study teams are often uneasy or even fearful about an upcoming audit. As auditors, it can be discouraging to hear that the audit process is considered burdensome, awkward, or punitive. QASM is taking steps to strengthen the auditor/research team relationship.

2. Goals

In the past several years, our QA team has grown from a team of one to a team of four. As our team grew, we set forth on a path of bolstering a positive image and shifting how auditors and the audit process are viewed.

3. Solutions and Methods

We rolled out 4 new initiatives:

- Weekly team meetings
- With a growing team it became evident that a weekly auditor meeting would be beneficial.
- A QASM team communication plan
- Communication from our team didn't reach all who needed the information. We developed a template that presents new information more clearly.
- An audit working group
- Team discussions about common audit findings and mining audit data revealed teams who excelled at certain aspects of study management and had great processes. We convened an audit working group composed of auditors, team leaders, and managers to connect groups and improve working processes.

- Specific multi-step audit training
- We developed individualized and study-specific audit training for teams to prepare them for what to expect from the audit process.

4. Outcomes and Future Directions

Our weekly team meeting has made it possible for our team to thrive and generate new ideas.

As new information becomes available we are now better equipped to communicate to all study team members due to our communication plan. This greatly improves our ability to level the playing field when everyone receives the same information at the same time.

Our audit working group attendees were interested in learning from each other. This opened the lines of communication, giving us a platform for sharing information and collaboration and allowing teams to discuss common roadblocks.

Our multi-step process for audit education helps team members become comfortable with the process by knowing what to expect.

Our team realized that though each of us brings to the table a wealth of information and opinions, we sometimes disagree. We discussed in detail how we would conduct our meetings, where each team member has a voice and a listening ear. Our team meetings and discussion guidelines have strengthened our team due to our ability to discuss ideas freely and to truly work together.

Our next steps are to create an internal intranet where educational communications can be stored and accessed by our teams, to continue our audit working group not only in an effort for us to collaborate more with our teams but to also provide an opportunity for teams to collaborate with each other, and to assess how our new training plan affects audit findings and teams' connection to the process.

Creating an image of us as a partner and focusing on collaboration with teams can only improve processes. Working together can help us all reach our goals.

Background

The Quality Assurance and Safety Monitoring (QASM) team is responsible for auditing investigator-initiated studies at Siteman Cancer Center. Study teams are often uneasy or even fearful about an upcoming audit.

"My study is being audited next week, I can't wait!" Let's be honest, those words have most certainly never been spoken! Most of us are not excited at the notion of having our study looked at with a magnifying glass, data and case report forms sifted through with a fine-tooth comb, and our hard work critiqued and evaluated.

As auditors, it can be discouraging to hear that the audit process is considered burdensome, awkward, or punitive. QASM is taking steps to strengthen the auditor/research team relationship.

Goals to be Achieved

In the past several years, our QA team has grown from a team of one to a team of four. As our team grew, we set forth on a path of bolstering a positive image and shifting how auditors and the audit process are viewed.

Our goal is to help teams to ensure the rights and welfare of research study patients are protected. We want to be seen as a source of support and knowledge, a partner to the research team.



Methods and Materials

We rolled out 4 new initiatives:

Weekly team meetings

With a growing team it became evident that a weekly auditor meeting would be beneficial. With a team of 1 and even 2, a routine meeting was not necessary. But as the team grew we realized that having a weekly meeting with a set agenda was what we needed to work through issues and questions and help with consistency and keep us on track as a team.

A QASM team communication plan

New information was communicated to teams in a variety of ways but we realized that communications from our team didn't always reach all who needed the information. We concluded that email was the best route for communicating with our teams and developed an email template that is short and simple and highlights to whom the information is most important (i.e. regulatory, clinical coordinator).

An audit working group

Team discussions about common audit findings and mining audit data revealed teams who excelled at certain aspects of study management and had great processes. We convened an audit working group composed of auditors, team leaders, and managers to connect groups and improve working processes. We planned quarterly meetings with this group to discuss our data and ideas for improvement. The group was very interested to see how they compared to each other and to learn from each other. Groups that excelled in a particular area provided insight to the group on processes that were successful.

Specific multi-step audit training

We developed individualized and study-specific audit training for teams to prepare them for what to expect from the audit process. We became aware that in our efforts to improve relationships with teams we should be involved with the education and training leading up to the actual audit of the study. Though our department had always provided a new team member training which touched on audit and audit prep; the training was more of an overview of the process and did not often touch of study specifics. We determined that team members could be more prepared for what to expect from the audit process and how they could be more in tune with what would take place in the weeks leading up to the audit, the audit week(s), and the post-audit processes

Outcomes

- Our weekly team meeting has made it possible for our team to thrive and generate new ideas.
- As new information becomes available we are now better equipped to communicate to all study team members due to our communication plan. This greatly improves our ability to level the playing field when everyone receives the same information at the same time.
- Our audit working group attendees were interested in learning from each other. This opened the lines of communication, giving us a platform for sharing information and collaboration and allowing teams to discuss common roadblocks.
- Our multi-step process for audit education helps team members become comfortable with the process by knowing what to expect.

Lessons Learned and Future Directions

Our team realized that each of us brings to the table a wealth of information and opinions, and we sometimes disagree. We discussed in detail how we would conduct our meetings, where each team member has a voice and a listening ear. Our team meetings and discussion guidelines have strengthened our team due to our ability to discuss ideas freely and to truly work together.

Our next steps are to create an internal intranet where educational communications can be stored and accessed by our teams, to continue our audit working group not only in an effort for us to collaborate more with our teams but to also provide an opportunity for teams to collaborate with each other, and to assess how our new training plan affects audit findings and teams' connection to the process.



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Epic Transitions: How to Prepare Your Staff for Enterprise Wide Change

E. Menne, K. Williams, E. Hawkins

Siteman Cancer Center

1. Background

Our institution implemented a new EMR system, EPIC, in June 2018. Given the scope of the project, the transition involved implementing many new procedures and practices that were developed without input from Oncology Research Management. Information was updated frequently, since many decisions were not finalized until several weeks prior to go-live. The EPIC staff provided system training, but they did not cover any job-specific instruction or speak to the Division's policies and procedures. To complicate things further, our staff consists over 180 members in varying roles requiring different levels and degrees of training and preparation for go-live. In order to maximize staff education, we supplemented the Epic provided training with 4 optional in-person sessions for research coordinators prior to Go-Live, 3 mandatory in-person training sessions hosted after Go-Live, created 25 tip sheets that were stored for quick review, and identified 18 staff as SuperUsers to assist with in person support. Given the unique opportunity presented by the transition, we wanted to learn what tools were most helpful to help guide training sessions surrounding significant change in the future.

2. Goals

Since the time leading up to go-live was hectic, we wanted to hear from our staff on how they experienced the change and transition. Post Epic Go-Live we sought to understand what was helpful and added benefit vs. what was unnecessary or lacking during the transition. By their responses to this large change, we could not only see what learning and communication styles they preferred, but also better understand how they prefer to learn about and implement change for future program developments.

3. Solutions and Methods

We sent a 10 question survey to all staff 3 months post go-live to better understand their experience during go-live and the months leading up to it. We surveyed what was most helpful, their preferred learning style, and what resources they knew were available to them.

4. Outcomes and Future Directions

- Most helpful thing they did to prepare for Epic implementation: 40.8% attend Oncology sponsored training sessions led by the Education and Training Team
- When coordinators were unsure how to navigate something, they found the most helpful resources to be their teammates and the Education and Training Team
- When asked what they wished could have gone differently to help them prepare for go-live, 59.4% requested more job-specific, in-person training.
- When asked how coordinators prefer to receive information, 53.8% of coordinators requested an emailed tip sheet.

Large overall themes throughout the data were that staff appreciated being notified of procedural changes in advance and they found job-specific training provided by our internal Education & Training Team to be the most effective way of communicating information. While staff requested that information be shared via email or work instructions, they realistically are more likely to consult a person than a set of work instructions. This points to the importance of investing effort in job specific in-person education as opposed to relying on tools or tip sheets.

EPIC Transitions: How to Prepare Staff for Enterprise Wide Change

Kristi Williams, Elizabeth Menne, RN, BSN, OCN, Emily Hawkins, MS, CCRP



Background:

Our institution implemented a new EMR system, EPIC, in June 2018. Given the scope of the project, the transition involved implementing many new procedures and practices that were developed without input from Oncology Research Management. Information was updated frequently, since many decisions were not finalized until several weeks prior to Go-Live. The EPIC staff provided system training, but they did not cover any job-specific instruction or speak to the Division's policies and procedures. To complicate things further, our staff consists over 180 members in varying roles requiring different levels and degrees of training and preparation for Go-Live.

In order to maximize staff education, we supplemented the EPIC provided training with 4 mandatory in-person sessions for research coordinators prior to Go-Live, 3 optional in-person training sessions hosted after Go-Live, created 25 tip sheets that were stored for quick review, and identified 18 staff as SuperUsers to assist with in-person support. Given the unique opportunity presented by the transition, we wanted to learn what tools were most helpful to help guide training sessions surrounding significant change in the future.

On a scale of 0-100, how often do you access the following resources?

Ask a teammate	81
Ask the Education & Training Team	81
Ask a supervisor	77
Ask a member of the clinical team	76
Search Outlook mailbox for an email about the topic	74
Ask an EPIC Super User	73
Reference a "cheat sheet" you made for yourself	61
Look for a Tip Sheet within the EPIC Learning Home Screen	54
Look for Tools on the shared drive	54

What was most helpful preparation?

Attend Oncology sponsored training sessions led by the Education and Training Team	40.78%
Using the EPIC "Playground" on your own	15.53%
Attend the EPIC sponsored training sessions	14.56%
Other	9.71%
Work with your team in trainings led by your supervisor	7.77%
Reviewing online EPIC modules in Learn@Work	4.85%
Nothing was helpful	4.85%
Blank response	1.94%

Goals:

- Identify preferred methods of communication surrounding institutional change
- Identify what end users found most helpful in navigating transition
- Identify preferred tools for communication and training
- Assess staff perceptions of change and their preferred style of notification

Methods:

We sent a 10 question survey to all staff 3 months post Go-Live to better understand their experience during Go-Live and the months leading up to it. We surveyed what was most helpful, their preferred learning style, and what resources they knew were available to them.

Participants were asked about their awareness of resources including various staff roles (clinic, education, peer, supervisor), tools developed by the EPIC team, and tools developed by our education program. Questions also explored where staff look for information (email inbox, shared drives, leaning dashboards).

Staff were also asked what resources they used and what resources they would like to have developed for other significant changes in the future.

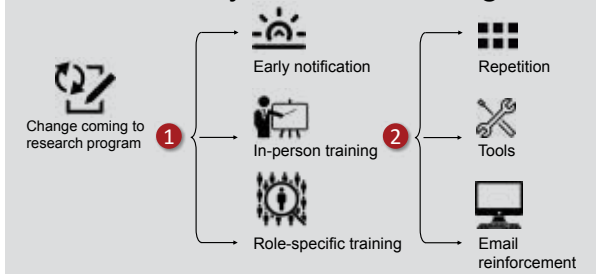
Outcomes:

- Most helpful thing they did to prepare for EPIC implementation:
- 40.8% attend Oncology sponsored training sessions led by the Education and Training Team
 - When coordinators were unsure how to navigate something, they found the most helpful resources to be their teammates and the Education and Training Team
 - When asked what they wished could have gone differently to help them prepare for Go-Live, 59.4% requested more job-specific, in-person training
 - When asked how coordinators prefer to receive information, 53.8% of coordinators requested an emailed tip sheet

Future directions:

Large overall themes throughout the data were that staff appreciated being notified of procedural changes in advance and they found job-specific training provided by our internal Education & Training Team to be the most effective way of communicating information. While staff requested that information be shared via email or work instructions, they realistically are more likely to consult a person than a set of work instructions. This points to the importance of investing effort in job specific in-person education as opposed to relying on tools or tip sheets.

What would you like to see again?



The Critical Need for Consistent Training for Clinical Research Professionals

K. Jelinek, R. Amoah

The Ohio State University Comprehensive Cancer Center, James Cancer Hospital & Solove Research Institute

1. Background

Clinical research training has not kept pace with growth in the field. No formal regulations exist that provide the training requirements for research professionals; therefore, training typically lacks consistency. While some academic institutions have begun offering advanced degrees in clinical research, there is still no universally accepted measure of competency across the profession.

2. Goals

Organizations around the world acknowledge the need for consistent clinical research training and the lack thereof. The Joint Task Force (JTF) on Clinical Trial Competency assembled in 2013 to bring uniformity to clinical research training. The JTF consolidated training input from numerous organizations into the eight competency domains shown in the figure below. Organizations can use these tools to develop specific clinical research training programs. Wider implementation of such programs can help establish consistent professional expectations in clinical research.

3. Solutions and Methods

The Ohio State University Comprehensive Cancer Center (OSUCCC) Clinical Trials Office (CTO) Education Curriculum was written in 2014 to standardize training for all teams and individuals within the CTO. The JTF clinical research competency tool was used to revamp the CTO Education Curriculum and training program to align training content with the eight JTF Competency Domains for the various roles within the CTO. A more robust in-person training program has also been developed to provide CTO staff more detailed consistent training.

Using the revised CTO Education Curriculum as a guide, the following training methods for CTO staff was implemented:

- On-boarding: Separate on-boarding checklists for managers and staff ensure effective integration of new staff;
- Orientation: The CTO New Staff Orientation delivers overviews of internal and external areas and explanations of the relationships of these areas;
- In-person training: Staff attend standard, interactive in-person training regarding topics such as Informed Consent Process, Adverse Event and Deviation Documentation, Serious Adverse Event Reporting, Research Chart Organization, Data Collection, etc.;
- Assignment of a preceptor: Each new employee is assigned a preceptor from their team to provide in-depth training regarding team and protocol items; and
- Continuing Education Opportunities: Individuals with various research expertise present at regular CTO Education webinars. The training team also provides ongoing training for any new or revised CTO processes and procedures.

4. Outcomes and Future Directions

The outcomes of a vigorous training plan provide the following benefits:

- Interactive trainings allow for more engaged learning for staff members;
- Role-specific curricula provide tailored, detailed training for each research role;
- Staff are more comfortable with their position and feel that they can perform their jobs at a higher level;
- Improved audit results;
- Increased overall morale;
- Streamlined training overseen by the Training Team leads to all teams conducting research consistently, alleviating ambiguity regarding policies; and
- All research subjects receive the same appropriate research oversight.

A well-defined training program aligned with the JTF competency tool leads to more competent and satisfied staff which leads to reduced turn-over and better service. It is not enough to provide training about a research topic once in one format; multi-modal training – in-person, hands-on labs, written resources, annual refreshers, and routine reminders – are proving to be more effective in providing continual education for clinical research professionals.

The Critical Need for Consistent Training for Clinical Research Professionals



Kathryn Jelinek, Roselyn Amoah

The Ohio State University Comprehensive Cancer Center, James Cancer Hospital & Solove Research Institute

Clinical Research Training Concerns

- No formal consistent training
- No regulations controlling training
- On-the job training
- Some certification and advanced degree programs available but not consistent
- No universally accepted measure of competency across the profession

Original CTO Education Curriculum

- | | |
|--|--|
| <ul style="list-style-type: none"> • CITI (Biomedical Research), CITI Good Clinical Practice (GCP), HIPAA • Tools Involving Research • IHIS • Components of a Research Protocol • Departments Outside of the CTO • SIV/Study Initiation • OCDC/JARO | <ul style="list-style-type: none"> • Multi-Institution Program • Regulatory Processes • Informed Consent Process • Conduct of a Study • Medication Accountability • Subject Safety • Audits and DSMC • CSRC • Data Management |
|--|--|

Original CTO Education Curriculum Concerns

- Flow of information not always logical
- Some information out of date
- Much of training was delivered through manuals and documents
- Not role specific
- Modules did not always clearly specify the action to be taken
- Possible inconsistencies in training from team to team

The Joint Task Force on Clinical Trial Competency (JTF) Eight Competency Domains



Uses for Eight Competency Domains Framework:

- Developing job requirements
- Assessing job candidates
- Matching employees/contractors with assignments
- **Planning training to support career paths**
- Assessing investigator qualifications
- Designing conference agendas and training programs
- **Choosing training and education events to attend.**

Revised CTO Education Curriculum Using JTF Competency Domains

- | | |
|--|---|
| I. Scientific Concepts and Research Design | <ol style="list-style-type: none"> 1. Components of a Research Protocol 2. Clinical Scientific Review Committee (CSRC) |
| II. Ethical and Participant Safety Considerations | <ol style="list-style-type: none"> 1. CITI (Biomedical Research); CITI Good Clinical Practice (GCP); HIPAA 2. Informed Consent Process 3. Audits and Data Safety Monitoring Committee (DSMC) |
| III. Medicines Development and Regulation | <ol style="list-style-type: none"> 1. Regulatory Processes |
| IV. Clinical Trials Operations (GCPs) | <ol style="list-style-type: none"> 1. SIV/Study Implementation 2. Conduct of a Study 3. Medication Accountability 4. Subject Safety |
| V. Study and Site Management | <ol style="list-style-type: none"> 1. Tools Involving Research 2. IHIS 3. OCDC/JARO |
| VI. Data Management and Informatics | <ol style="list-style-type: none"> 1. Data Management |
| VII. Leadership and Professionalism | <ol style="list-style-type: none"> 1. Leadership and Professionalism |
| VIII. Communication and Teamwork | <ol style="list-style-type: none"> 1. Departments Outside of the CTO 2. Multi-Institution Program |

Implementation of Revised CTO Education Curriculum and Onboarding

- Revised Manager and Employee Onboarding Checklists
- Revised CTO New Staff Orientation
- Revised CTO CRC/CRA Education Curriculum
- Developed RCO Education Curriculum
- Developed In-Person and Online Trainings
- **In Progress:** Revamping of team preceptor program
- **In Development:** Annual refreshers, hands on-labs



Help is on the Way: A CTMS Training Solution at an NCI-Designated Cancer Center

M. Farris, J. de Jong

The University of Kansas Cancer Center

1. Background

The clinical trials management system (CTMS) is designed to securely store and retrieve information on all current and historical research projects conducted at the University of Kansas Cancer Center (KUCC). The CTMS tracks and stores regulatory information, study-related documents, study participant data, and study participant finance calendars. The CTMS is utilized by the KUCC Regulatory, Clinical, and Administrative teams. Additionally, the CTMS is used by other research teams across the University outside of KUCC; therefore, the IT Support group that manages the system provides a very high-level and generalized training for users to gain initial access that is not geared toward the user's KUCC-specific role.

KUCC uses the CTMS more robustly than the other University research groups, thus a need for role-specific training was recognized. The lack of structured, role-specific training created frustration and confusion in users, along with inconsistent and/or erroneous data entry. Additional training was desired as a solution to produce better data quality results as well as increase user confidence in the system. The Clinical Systems Program Manager and CTO Training Manager collaborated to develop a role-specific training program to better equip users to enter data within the CTMS with accuracy and confidence.

2. Goals

1. Collect user feedback via initial survey and focus groups to determine training needs;
2. Define and clarify tasks within the CTMS appropriate to specific user roles, and provide role-specific CTMS Work Instructions for data entry guidance;
3. Align CTMS training initiative with existing onboarding processes;

4. Initiate monthly, hands-on CTMS training sessions led by the Clinical Systems Program Manager;
5. Evaluate users' confidence levels prior to and post CTMS training.

3. Solutions and Methods

1. New employees are provided the onboarding checklist, which provides a link to a CTMS training request link, via REDCap; the training survey is delivered to the Clinical Systems Program Manager for inclusion in the next training session.
2. The IT Support group training was reformatted from in-person to on-demand video format (this is the high-level training which all University users must complete to gain system access).
3. Hands-on, role-specific CTMS training with access to the test environment allows users to enter mock data, gaining proficiency in the behavior and feel of the production environment.
4. CTMS Work Instructions for step-by-step guidance are provided to all employees.
5. Continuing education is provided as needed; for example, break-out sessions offered during monthly staff meetings where current topics and refresher trainings are offered.

4. Outcomes and Future Directions

The CTMS training process was streamlined to ensure all new employees attend role-specific CTMS training. The Clinical Systems Program Manager and Training Manager collaborated to create CTMS training resources available to all employees, and host monthly, in-person CTMS trainings where users have access to the test environment to enter mock data.

These specific outcomes were recognized:

1. Implementation of monthly, in-person CTMS training program has increased new employee, role-specific training rate from less than 10% to 100%.
2. Development of tools and resources, such as the CTMS Work Instructions, has increased data entry quality in trained employees.
3. Increased confidence in CTMS system navigation and data entry reported by users.

BACKGROUND

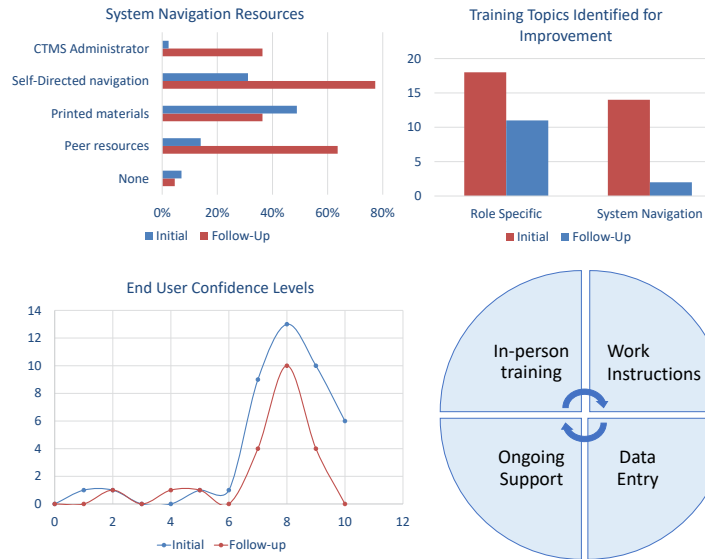
The Cancer Center uses the CTMS more robustly than the other University research groups, thus a need for role-specific training was recognized. The lack of structured, role-specific training created frustration and confusion in users, along with inconsistent &/or erroneous data entry. Additional training was desired as a solution to produce better data quality results.

GOALS

- Collect user feedback to determine training needs.
- Define and clarify tasks within the CTMS appropriate to specific user roles, and provide role-specific CTMS Work Instructions for data entry guidance.
- Initiate monthly, hands-on CTMS training sessions led by the CTMS Administrator.
- Evaluate users' confidence levels prior to and post CTMS training.

METHOD

- An initial survey was provided to gauge CTMS end user perceptions, and evaluate the potential impact of role-specific system training for data entry tasks.
- Focus groups were formed based on end user role to gather feedback on training topics.
- CTMS Work Instructions and monthly, hands-on CTMS training sessions were developed.
- The training initiative was realigned with existing onboarding processes to ensure all new employees would be included in the monthly CTMS training session.



RESULTS & CONCLUSION

- Trained employees show increased utilization of tools and resources for system navigation.
- Although confidence levels decreased slightly, we believe this is due to exposure of the CTMS on a global level during the hands-on training, leading to a more realistic understanding of the system capabilities.
- Implementation of monthly, in-person CTMS training program has increased new employee, role-specific training rate from less than 10% to 100%.
- Continuing education is provided regularly; for example, break out sessions offered during monthly staff meetings where new topics and refresher trainings are offered.

LESSONS LEARNED & FUTURE PLANS

In the future, we intend to continue to improve the training program by utilizing Skype and Web-ex options to increase end user attendance, developing Work Instructions for all new training topics, and restructuring the monthly in-person trainings to incorporate these new topics.

Instructions

Step	Instruction	Illustration
1a	<p>1. Assign a Treatment Arm</p> <p>From the Manage Patient >> Screening/Enrollment page, click the Add New Treatment Arm link.</p>	
1b	<p>The Patient's Treatment Arm window displays.</p> <ul style="list-style-type: none"> • Select the correct Treatment Arm from the drop-down • Enter the Start Date (date the treatment arm is assigned) • Enter your e-signature • Submit the form 	<p>*Treatment field: The drop-down options for this field are based on the treatment arm information listed on the Study >> Setup page, managed by the CTO Finance/Budget group.</p>

Initial Survey Quotes:

"All Velos [CTMS] training was lacking. It was just a basic intro of how to log-in."
 "For a new hire the initial training does not have a lot of impact other than gaining access. More hands on opportunities should be incorporated, maybe through the test environment."

Follow-up Training Quotes:

"I liked that the training was presented through slides, handouts and hands on within the test system. The handouts will be very helpful going forward."
 "The training was easy to follow, and I really appreciated the handouts provided."

Peer-to-Peer Quality Chart Review

A. Skafel, P. Steiding, S. Barajas, A. Ferdinando

UCSF Helen Diller Family Comprehensive Cancer Center

1. Background

Regulatory audits and inspections can happen at any time and the onus is on the study team to always be 'audit ready'. While addressing findings in monitoring reports is an important step in the audit preparation process, deficiencies and subsequent responses are seldom shared outside the study team and rarely inspire organizational quality improvement initiatives. The Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) developed and implemented an internal peer-to-peer chart review process aimed at not only improving data accuracy, but building a culture of quality improvement and higher standards.

2. Goals

The chart review process was designed with the following objectives:

1. Ensure patient safety and quality data;
2. Ensure workflows, policies and regulations are followed;
3. Identify training gaps; and
4. Develop corrective and preventative action plans.

Additionally, the peer-to-peer review process is an opportunity for clinical research staff development.

3. Solutions and Methods

A comprehensive checklist was developed by a working group from each program at the HDFCCC. Each month, clinical research staff in each program review a pre-defined number of study charts, including charts completed by new staff, new studies and a random selection of active patients. All CRCs have at least one chart reviewed per year.

The results of peer-to-peer chart reviews are reviewed in two phases: monthly at program specific internal reviews where individual personnel training gaps and program specific workflows can be identified and addressed; and quarterly at HDFCCC wide reviews where common oversights and omissions are identified and overall process improvement can occur across the entire organization. The two step review of findings ensures communication and immediate action first within the program, then organizational training and workflow gaps are discussed in groups with representation across the entire HDFCCC.

4. Outcomes and Future Directions

In the first 12 months of implementation, 182 charts were reviewed using the comprehensive checklist. The most common findings were documentation of eligibility and timeliness of investigator review. Sponsors have anecdotally commented that study charts are cleaner and staff doing the chart reviews have developed a better understanding of processes, workflows and the purpose of clear and concise documentation.

Clinical research staff buy-in into the process and its objectives was fundamental in the success of the initiative. The focus of the initiative is continuous improvement and education, and not another onerous, ineffective and inefficient process.

As the initiative moves into the second year, efforts are underway to examine the trial portfolio in each program and tailor the chart review based on the external oversight already in place. Additionally, a system for a cross-program review of charts is being developed to ensure high standards are consistent across all programs.

Policy review is a key component of the review process, and while policies have been updated over-time, older trials were following old policies at their inception. The version of the policy at the time of procedure execution, and the implication of changes in the new policy, need to be considered in future chart reviews.

Peer-to-Peer Quality Chart Review

Andrea Skafel¹ MSc CCRP, Paige Steiding¹ CCRP, Sara Barajas¹ CCRP, Alyssa Ferdinando¹ CCRP
¹University of California San Francisco, Helen Diller Family Comprehensive Cancer Center



Background

Regulatory audits and inspections can happen at any time and the onus is on the study team to always be 'audit ready'. While addressing findings in monitoring reports is an important step in the audit preparation process, deficiencies and subsequent responses are seldom shared outside the study team and rarely inspire organizational quality improvement initiatives. The Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) developed and implemented an internal peer-to-peer chart review process aimed at improving data accuracy, and building a culture of quality improvement and high standards.

Methods

A comprehensive checklist (Figure 3) was developed by a working group with representation from each clinical research program at the HDFCCC. Each month, clinical research staff in each program review study charts with a focus on:

- Charts completed by new staff;
- New studies; and,
- Random selection of active patients.

All CRCs have at least one chart reviewed per year.

The results of peer-to-peer chart reviews are reviewed in two phases:

- Monthly within each HDFCCC clinical research program. Programmatic reviews identify individual training gaps and areas for process improvement in program specific workflows.
- Quarterly HDFCCC wide reviews. Center wide reviews identify common oversights and omissions across the organization, and areas for overall process and training improvement.

The two step review of findings ensures communication and immediate action first within the program, then organizational training and workflow gaps are discussed in groups with representation across the entire HDFCCC.

Outcome

In the first 12 months of implementation, 182 charts were reviewed (21% of all therapeutic accruals) using the comprehensive checklist. The number of findings per chart decreased from 2.6 to 2.1 over the year. Sponsors have anecdotally commented that study charts are cleaner, and staff doing the chart reviews have developed a better understanding of processes, workflows and the need for clear and concise documentation.

Policy review is a key component of the review process, and while policies have been updated over time, older trials were following older policy versions when they first started. The version of the policy at the time of procedure execution, and the implication of changes in the revised policy, need to be considered in the review process.

Clinical research staff buy-in into the process and its objectives was fundamental in the success of the initiative.

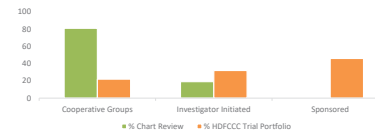
Future Directions

As the initiative moves into the second year, efforts are underway to:

- Examine the trial portfolio in each program and tailor the chart review priorities based on the external oversight already in place.
- Establish a system for a cross-program review of charts to ensure high standards are consistent across all programs.
- Formalize the quarterly review of findings and update policies, guidelines and training based on findings.



Figure 1: Top 10 Observations by Category
 Primary observations found in first year of chart review implementation. The most common findings were documentation of eligibility and timeliness of investigator review.



- Establish a system for a cross-program review of charts to ensure high standards are consistent across all programs.
- Formalize the quarterly review of findings and update policies, guidelines and training based on findings.

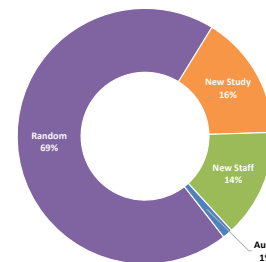


Figure 2: Reason for Chart Review
 Most charts were selected at random and unexpected, 1% were selected as part of sponsor audit preparations.

Figure 3: HDFCCC Chart Review Checklist

Heat Mapping Noncompliance to Better Target the Extent of Corrective and Preventive Action Plans and Training

J.K. Morrison, S. Scott

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

1. Background

In a complex regulatory environment, where the first reaction is always to institute new procedures or office wide trainings, we needed a better way to determine the required scope of proposed corrective and preventative action plans (CAPAs). Often academic centers rely on office-wide CAPAs due to a particular instance of noncompliance getting escalated by a single stakeholder such as a principle investigator or functional group manager. However, many of these single events are not representative of the totality of the office and may not require a change in office-wide practices. Rather these less prevalent instances of noncompliance may simply require a more focused training or subgroup change in process to more easily and accurately address gaps in compliance.

2. Goals

The goal of this experiment was to find a way to better visualize the extent of noncompliance within our Clinical Protocol Office and to determine if this noncompliance was isolated to a single individual, disease group, functional group or management group, or more widespread across the office.

3. Solutions and Methods

Heat mapping can be used to determine the scope of the required CAPAs. Our heat mapping is a graphical representation of events requiring CAPAs. Colors from green to yellow to red represent the numbers of CAPAs an individual, group, or the office has submitted over the last year for a specific a category of noncompliance. Specifically, green represents no CAPAs and yellow and red represent a certain number of CAPAs with red indicating a higher number than yellow.

The categories we have explored include consenting mistakes, dosing errors, missed assessments, privacy breaches, eligibility violations, and individuals receiving prohibited medications.

4. Outcomes and Future Directions

Heat mapping enabled us to determine the extent of noncompliance in order to better target the scope of CAPAs. Not only did we observe that many events were more isolated occurrences of noncompliance that did not rise to the level of requiring office-wide corrective action, we also determined that many of the more talked about events due to stakeholder escalation were not prevalent within the office and thus did not necessarily require office-wide SOPs, trainings or procedure updates. Additionally, we determined certain subgroups were incredibly compliant on issues that plagued the majority of the office. This allowed us to better analyze what those compliant groups may be doing more successfully and what knowledge they may be able to share with other subgroups within the office.

Importantly, we learned that sometimes the more hot topic occurrences of noncompliance may not be the issues that overall are the most prevalent in the office and that by focusing on these hot topic issues we may not improve overall office compliance. Our future directions include better understanding the contributing factors that make some groups more successfully compliant within different categories and to work with those subgroups to spread their knowledge with other subgroups within the office.

Abstract

In a complex regulatory environment, where the first reaction is always to institute new procedures or office-wide trainings, we need a better way to determine the required scope of proposed corrective and preventive action plans (CAPAs). Often academic centers rely on office-wide CAPAs due to a particular instance of noncompliance getting escalated by a single stakeholder such as a Principle Investigator (PI) or functional group manager. However, many of these single events are not representative of the totality of the office and may not require a change in office-wide practices. Rather these less prevalent instances of noncompliance may simply require a more focused training or subgroup change in process to more easily and accurately address gaps in compliance.

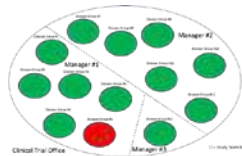
The goal of this experiment was to find a way to better visualize the extent of noncompliance within our Clinical Protocol Office and to determine if this noncompliance was isolated to a single individual, disease group, functional group or management group, or was more widespread across the office.

Introduction

Heat mapping can be used to determine the scope of the required CAPAs. Our heat mapping is a graphical representation of events requiring CAPAs. Color from green to red represent the numbers of CAPAs an individual, group, or the office have submitted over the last year for a specific category of noncompliance. The categories we have explored include consenting mistakes, dosing errors, missed assessment, privacy breaches, eligibility violations, and individuals receiving prohibited medications.

Schematic Representations of different trends that we looked for:

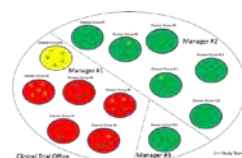
Isolated to an individual:



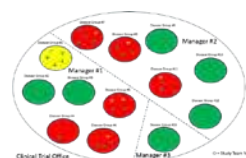
Isolated to a disease group:



Isolated to a particular manager's staff:



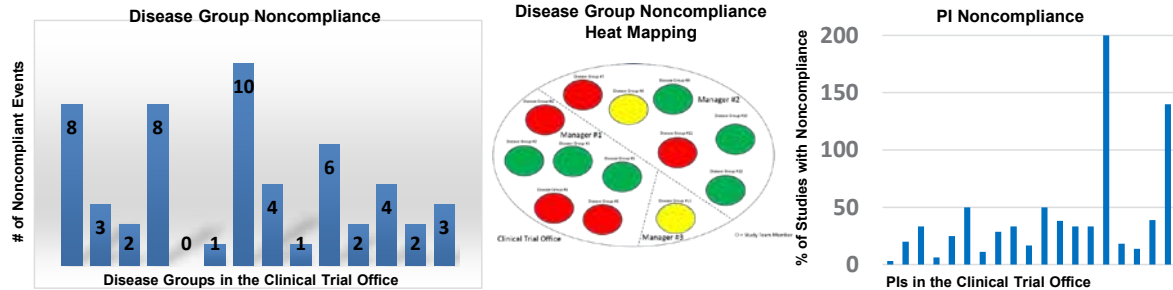
Widespread throughout the office:



J. Kaitlin Morrison, PhD and Shaw Scott, JD

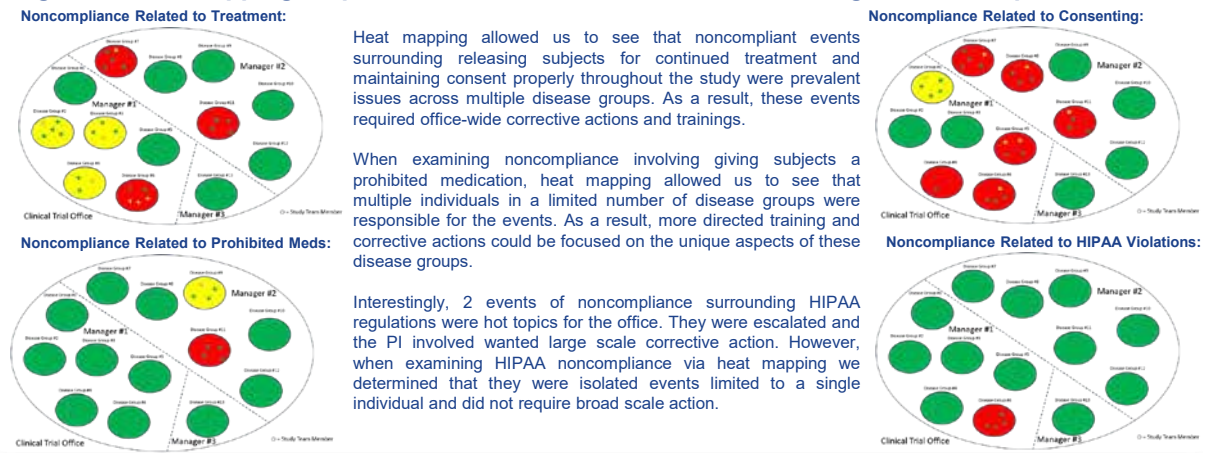
Results

Figure 1: Heat Mapping Helps Disease Group Leader Visualize Noncompliance



Disease group leaders often question how their team is operating in comparison to other teams in the office. By providing them a visual comparison, the disease group leader can better understand where their team may need improvement and where their team is succeeding.

Figure 2: Heat Mapping Helps CTO Leaders Direct CAPAs and Training for Noncompliance



Conclusions

Heat mapping enabled us to determine the extent of noncompliance in order to better target the scope of CAPAs. Not only did we observe that many events were more isolated occurrences of noncompliance that did not rise to the level of requiring office-wide corrective action, we also determined that many of the more talked about events due to stakeholder escalation were not prevalent within the office and thus did not necessarily require office-wide SOPs, trainings or procedure updates. Additionally, we determined certain subgroups were incredibly compliant on issues that plagued the majority of the office. This allowed us to better analyze what those compliant groups may be doing more successfully and what knowledge they may be able to share with other subgroups within the office.

Educating the Next Generation of Clinical Researchers

A. Ivey, L. Pettiford, T. George

University of Florida Health Cancer Center

1. Background

Many healthcare providers, including physicians, advanced practice providers, nurses, and pharmacists, have limited exposure to clinical research during their formal education. These providers often do not understand how to effectively integrate the research process into routine care, and how clinical research can provide additional treatment options for patients. Discussions about the availability of clinical trials and participation in clinical research are sometimes avoided by many providers due to lack of knowledge and the perception that cancer clinical trials are not acceptable treatment options for patients (1). This dilemma can adversely impact clinical trial recruitment, potential outcomes for patients, and moving science forward.

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

2. Goals

The goal of this program is to provide clinical research experience and education to future healthcare providers so that, once they are active clinicians, they have a better understanding of the research process and how clinical research can impact the healthcare and outcomes of oncology patients.

3. Solutions and Methods

The UF Health Cancer Center Clinical Research Office (CRO) implemented a clinical research internship for recent college graduates who are preparing for future careers in healthcare or continued education in health sciences. During the yearlong salaried commitment, interns will have the opportunity to work as Clinical Research Assistants (CRAs), assisting clinical investigators and study teams with the research process while also gaining clinical and oncology exposure. As a CRA, the interns participate in data capture and entry, laboratory procedures, and regulatory affairs related to clinical research. As part of the program, interns also participate in a quality improvement project and analyze the data. Each intern is provided a six-week orientation program developed by CRO leadership and the Education and Training Coordinator. The orientation program consists of all institutional required training in addition to CRO specific modules. These are a combination of both in-person and web-based trainings. Each intern is also assigned a mentor that works closely with them to ensure they have exposure to patients in the clinical setting, interaction with treating providers, and engagement with investigators. Below is a list of the areas covered during the internship:

- Good Clinical Practice and Research Ethics
- Biology and Treatment of Cancer
- Informed Consent
- Study Management and Operations
- Principles of Data Management

4. Outcomes and Future Directions

The program is currently ongoing with the first set of interns working within our adult Solid Tumor and Hematologic Malignancies Divisions of the CRO. A second cohort of interns will be onboarded in May 2019 so as to stagger and overlap intern classes. Informal and formal feedback is being solicited from both the interns as well as the study teams in which they are embedded. William New, an intern in the UFHCC CRO's Hematologic Malignancies Division said, "For someone who wants a permanent future in research, this internship provides a comprehensive experience involving both patient follow-up and data management".

Future directions include opening internship positions within the CRO's IIT Project Management Office and assessing permanent recruitment for interns that would like to continue their career in oncology clinical research.

BACKGROUND

Many healthcare providers, including physicians, advanced practice providers, nurses, and pharmacists, have limited exposure to clinical research during their formal education. These providers often do not understand how to effectively integrate the research process into routine care, and how clinical research can provide additional treatment options for patients. Discussions about the availability of clinical trials and participation in clinical research are sometimes avoided by many providers due to lack of knowledge and the perception that cancer clinical trials are not acceptable treatment options for patients (1). This dilemma can adversely impact clinical trial recruitment, potential outcomes for patients, and moving science forward.

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The UF Health Cancer Center Clinical Research Office (CRO) implemented a clinical research internship for recent college graduates who are preparing for future careers in healthcare or continued education in health sciences. During the yearlong salaried commitment, interns will have the opportunity to work as Clinical Research Assistants (CRAs), assisting clinical investigators and study teams with the research process while also gaining clinical and oncology exposure. As a CRA, the interns participate in data capture and entry, laboratory procedures, and regulatory affairs related to clinical research. As part of the program, interns also participate in a quality improvement project and analyze the data. Each intern is provided a six-week orientation developed by CRO leadership and the Education and Training Coordinator. The orientation program consists of all institutional required training in addition to CRO specific modules. These are a combination of both in-person and web-based trainings. Each intern is also assigned a mentor that works closely with them to ensure they have exposure to patients in the clinical setting, interaction with treating providers, and engagement with investigators. Below is a list of the areas covered during the internship:

- Good Clinical Practice and Research Ethics
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- Study Management and Operations
- Principals of Data Management

OUTCOMES

The program is currently ongoing with the first set of interns working within our adult Solid Tumor and Hematologic Malignancies Divisions of the CRO. A second cohort of interns will be onboarded in May 2019 so as to stagger and overlap intern classes. Informal and formal feedback is being solicited from both the interns as well as the study teams in which they are embedded. William New, an intern in the UFHCC CRO's Hematologic Malignancies Division said, "For someone who wants a permanent future in research, this internship provides a comprehensive experience involving both patient follow-up and data management."

FUTURE DIRECTIONS

Future directions include opening up internship positions within the CRO's IIT Project Management Office and assessing permanent recruitment for interns that would like to continue their career in oncology clinical research.

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Evolving Recruitment Strategies Through the Development of a Research Nurse Residency Program for New Graduates

J. Feliu, D. Cline, B. Showalter

The University of Texas MD Anderson Cancer Center

1. Background

Research is an integral element in the care of patients and the mission of MD Anderson Cancer Center (MDACC). Last year, more than 10,800 patients were enrolled in 1,250 plus active clinical trials across the institution. The clinical research nurse (CRN) plays a pivotal role in managing the trials, including assisting the Principal Investigator in reviewing eligibility criteria, coordinating care, and monitoring the patient to identify any safety concerns and reporting those concerns according to regulations. Recognizing the growing challenge of recruiting and retaining CRNs and its potential to impact the ability to conduct trials, interprofessional leaders worked collaboratively to address this concern and identify evidence based, and innovative solutions. As a result, design and implementation of the Research Nurse Residency (RNR) program for nurses with less than one-year experience, was identified and implemented as one solution.

2. Goals

The goals of the RNR program were to develop an additional means of recruitment of CRNs to reduce the vacancy rate and improve retention of CRNs throughout the institution by providing a strong foundation and orientation program that would enable the institution to foster a robust, experienced CRN workforce.

3. Solutions and Methods

The RNR program for the CRN was developed to be complementary to the institution's existing Clinical Nurse Residency Program as well as with current onboarding CRN practices. The RNR curriculum consists of a four-week orientation followed by monthly residency classes over a twelve-month period. Orientation concentrates on the role of clinical research using a variety of educational methods. In the assigned department, the participant is paired with an experienced CRN for department specific orientation. Monthly residency classes expand on clinical research topics, including simulation exercises, oncology content, transition to practice, and education specific to the MDACC institutional role of a CRN. Support from a dedicated clinical research educator is also provided.

4. Outcomes and Future Directions

The first cohort of four RNR participants started in October 2016. More than 875 applications have been received for the program. Forty residents have started the program with 26 graduates resulting in an increase in the CRN workforce. Five residents have left the institution for varying reasons. Retention rates correlate with those outside of the program. Outcomes will also be measured utilizing the Casey-Fink Graduate Nurse Experience survey including questions based upon recognized Oncology Trials Nurse Competencies. Feedback has been overwhelmingly positive from both residents and research departments, with departments participating in multiple cohorts. An unanticipated benefit of the program has been increased interdepartmental communication and collaborations across the institution resulting in sharing of best practices and other new initiatives.

Preceptors who are engaged and empower the CRN residents to become competent CRNs prove to be essential to success. In addition, a robust department orientation is key to provide the CRNs with a strong foundation of learning the role with the accompanied educator support to provide added opportunities and resources. Currently, the initial four-week orientation is only provided to CRNs in the residency program. Future plans include expanding this intensive orientation to all new CRN hires.



Evolving Recruitment Strategies through the Development of a Research Nurse Residency Program for New Graduates

Jennie Feliu BSN, RN, CCRP; Debbie Cline DNP, RN, CNL, OCN, NEA-BC; Brandi Showalter MS, RN, CCRP

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



Background

Research is an integral element in the care of patients and the mission of MD Anderson Cancer Center (MDACC).



The clinical research nurse (CRN) plays a pivotal role in managing the trials, including assisting the Principal Investigator in:

- Reviewing eligibility criteria
- Coordinating care
- Monitoring the patient for safety concerns
- Reporting concerns according to regulations

Recognizing the growing challenge of recruiting and retaining CRNs and its potential to impact the ability to conduct trials, interprofessional leaders worked collaboratively to address this concern and identify evidence based, and innovative solutions. As a result, design and implementation of the Research Nurse Residency (RNR) program for nurses with less than one-year experience, was identified and implemented as one solution.

Goals

- Develop an additional means of recruitment of CRNs
- Reduce the vacancy rate and improve retention of CRNs throughout the institution
- Provide a strong foundation and orientation program to foster a robust, experienced CRN workforce for the institution

Program Development

The program was developed through a unique collaboration between the Division of Nursing and Clinical Research Administration. A sub team comprised of nursing leaders in both clinical and research areas met weekly to develop the program and curriculum. Progress reports and executive and departmental presentations were effected to gain feedback and promote program buy-in. The RNR program for the CRN was developed to be complementary to the institution's existing Clinical Nurse Residency Program as well as with current onboarding CRN practices.

Methods Implemented

The RNR curriculum consists of a four-week orientation followed by monthly residency classes over a twelve-month period. Orientation concentrates on the role of clinical research using a variety of educational methods. In the assigned department, the participant is paired with an experienced CRN for department specific orientation. Monthly residency classes expand on clinical research topics, including simulation exercises, oncology content, transition to practice, and education specific to the MDACC institutional role of a CRN. Support from a dedicated clinical research educator is also provided.



Outcomes

- The first cohort of four RNR participants started in October 2016.
- More than 875 applications have been received for the program.
- 40 Residents have started the program:
 - 26 completed and graduated from the program
 - 13 currently active in the program
 - 5 left the institution
 - 5 transferred to another position within the institution
 - 31 remain in research roles
- Retention rates correlate with those outside of the program.

Outcomes are measured utilizing the Casey-Fink Graduate Nurse Experience survey with questions related to Oncology Trials Nurse Competencies. Feedback has been overwhelmingly positive from both residents and research departments, with departments participating in multiple cohorts. An unanticipated benefit has been increased interdepartmental communication and collaborations across the institution resulting in sharing of best practices and other new initiatives.



Lessons Learned

Preceptors who are engaged and empower the CRN residents to become competent CRNs prove to be essential to success.

In addition, a robust department orientation is key to provide the CRNs with a strong foundation of learning the role with the accompanied educator support to provide added opportunities and resources.

Future Directions

Currently, the initial four-week orientation is provided to CRNs in the residency program. Future plans include expanding the intensive, expanded orientation to all new CRN hires.

The research nurse residency continues to recruit and hire graduate nurses for up to three cohorts per year.



References

- Casey, K., Fink, R., Krugman, M., & Propst, J. (2004). The graduate nurse experience. *The Journal of Nursing Administration*, 34(6), 303-311.
- Oncology Nursing Society. (2016). Oncology trials nurse competencies. Retrieved from https://www.ons.org/sites/default/files/OCTN_Competencies_FINA_L.PDF.

Winship Clinical Trials Office CRC/CRN and Data Manager Orientation Program

T. Kurilo, J. Presley

Winship Cancer Institute of Emory University

1. Background

Winship Clinical Trials Office (CTO) CRC/CRN and data manager orientation program was originally developed and implemented in December 2010. During years of leading the orientation program, the Quality Management (QM) Team has received extensive feedback from CRC/CRN. While some opinions of the program were positive, many CRC/CRN and data managers expressed stress and frustration due to the lack of practical training and support, and felt unprepared to perform independent research-related activities at the end of the orientation.

In August 2018, QM team revamped the orientation and training program by adopting a multidisciplinary approach, involving team supervisors and mentors, investigators and other experts from different research fields.

We have created a new flow for the orientation program. The new hires start with their team, are greeted by the mentor and receive an orientation binder. During the early weeks they complete mandatory online courses, shadowing their mentor.

After being at Winship CTO for at least three weeks, they attend the 2-day Winship Clinical Trials Orientation Class that provides a comprehensive introduction to clinical research and the job functions of the CRC/CRN and data manager for cancer-related clinical trials. The course is conducted in the classroom setting. Winship clinical trials standard operating procedures, case studies, and research best practices are presented to emphasize how the learning objectives apply directly to the responsibilities of the CRC/CRN and data manager. After completing the class, they return to their team to shadow another team member followed by completing the mentor-guided competency assessment. If found competent, assuming they have completed all mandatory credentialing requirements, the new CRC/CRN or data

manager can start consenting subjects independently. The first subject enrolled in any study by a new CRC/CRN will receive a real-time QA/QC audit until competency is determined.

We provide continuing education to our research staff in the form of educational seminars and training sessions, such as "Critical Updates for Clinical Research," "SOP Made Simple" sessions, "Oncology Educational Sessions," where staff can receive CMEs for attending.

2. Goals

We hope to provide comprehensive support throughout the orientation process, verify competency before CRC/CRN and data managers can perform essential research-related activities independently. We expect to see an increase in job satisfaction and confidence and a decrease in deviations and errors that are due to new CRC/CRN and data managers' lack of basic oncology knowledge, basic clinical trials knowledge, Winship Clinical Trials SOP, and GCP.

3. Solutions and Methods

Methods implemented:

- Orientation binder for the new CRC/CRN and data specialist
- "Winship Clinical Trials 2-day Orientation Class"
- Mentor-guided competencies
- Clinical trials "Post-Orientation Workshop" for New Hires
- "Oncology Educational Sessions" for Clinical Trials Office staff (CME credits available)
- "SOP Made Simple" quarterly sessions
- 1st Chart QM review of each new CRC/CRN

- 1st data entry case review of each new data manager
- Orientation tracker to keep up with progress of each new CRC/CRN and data manager
- Post-Orientation survey (confidential) to get feedback from each new hire

4. Outcomes and Future Directions

Future directions:

- Reference manual for the new Winship Clinical Trials Office Team Supervisors
- Widen the scope for an orientation program to include orientation for Winship Clinical Trials Office regulatory specialists

Clinical Trials Office Winship Clinical Trials Office CRC/CRN and Data Manager Orientation Multidisciplinary Approach

Tatiana Kurilo Jacquis Presley
Quality Management and Education

Aim Statement

Goal: To provide a comprehensive, multidisciplinary value based orientation and training program for clinical research coordinators (CRC), clinical research nurses (CRN) and data managers who are involved in the management of subjects who participate in Winship cancer-related clinical research trials. To ensure subject safety, foster a culture of responsibility, and ensure high quality research in accordance with ethical principles, federal regulations and Institutional policies.

Winship Clinical Trials 2-Day Orientation Training Class

The 2-day CRC/CRN and data manager orientation class provides a comprehensive introduction to clinical research and the job functions of the CRC, CRN and data manager for Winship cancer-related clinical trials. The course is conducted in the classroom setting. Winship clinical trials standard operating procedures, case studies, and research best practices are presented to emphasize how the learning objectives apply directly to the responsibilities of the CRC/CRN and data manager.

Learning Objectives

- Understand the roles and responsibilities of CRC/CRN and data manager
- Define essential processes involved in clinical research, such as informed consent process, eligibility, adverse events capture and reporting, deviations, etc.
- Understand the requirements for source documentation, case report forms, study tools, forms and logs, and SOP
- Discuss regulatory compliance and quality assurance as it relates to CRC/CRN and data manager practices

Who Should Attend

- New CRC/CRN and data managers who have been in Winship CTO for at least four weeks from the date of hire
- Non-CTO CRC/CRN and data managers involved in conduction of Winship cancer-related clinical trials

Tools

- Orientation binder (paper and electronic format)
- PowerPoint presentations, videos
- Webinars
- Case studies and discussion
- Role play

Metrics

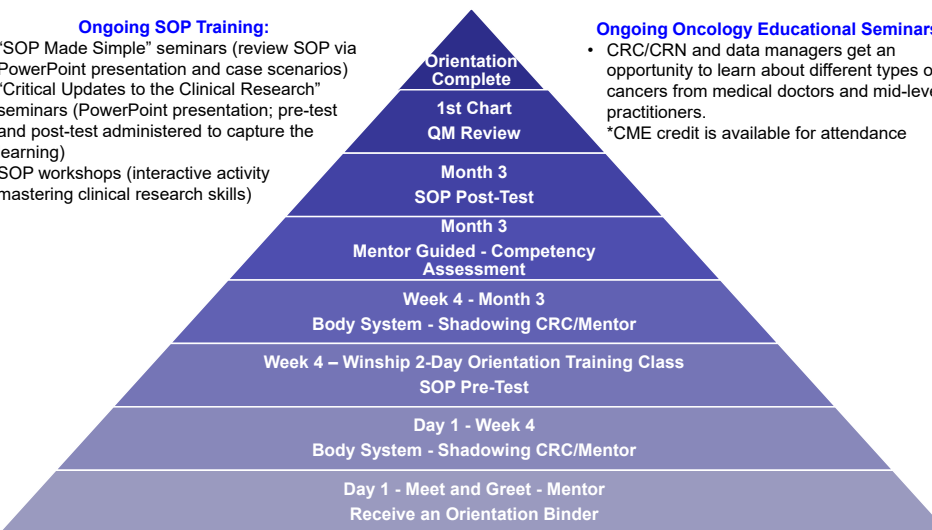
- Core competency skills assessment
- Mentor competency skills assessment
- Skills assessment testing
- Pre- and post-SOP training test
- Deviation prevention rate
- Staff retention

CRC/CRN Orientation Process



- Ongoing SOP Training:**
- "SOP Made Simple" seminars (review SOP via PowerPoint presentation and case scenarios)
 - "Critical Updates to the Clinical Research" seminars (PowerPoint presentation; pre-test and post-test administered to capture the learning)
 - SOP workshops (interactive activity mastering clinical research skills)

- Ongoing Oncology Educational Seminars:**
- CRC/CRN and data managers get an opportunity to learn about different types of cancers from medical doctors and mid-level practitioners.
- *CME credit is available for attendance



Course Outline

Day	Training
Day 1	Welcome to Winship – Training Schedule Overview
Day 1	Orientation Binder Review & Helpful Reminders
Day 1	SOP Review, Credentialing Application Requirements
Day 1	SOP 3.5 Reporting Unanticipated Problems/Adverse Events SOP 4.3 Protocol Deviations
Day 1	IRB/Regulatory Training
Day 1	SOP 2.1 Obtaining Informed Consent for Greater than Minimal Risk SOP 2.2 Obtaining Informed Consent for Minimal Risk Interventional and Non-Interventional Clinical Trials
Day 1	SOP 3.13 Central Subject Registration
Day 1	SOP 3.2 Determining Eligibility for Clinical Trials
Day 1	SOP 4.1 Managing Research Records SOP 4.2 Data Completion Metrics
Day 1	OnCore Training
Day 1	SOP 3.0 Reproductive Status Assessment and Pregnancy Testing
Day 1	ECG Training
Day 2	Welcome/Schedule Overview
Day 2	CTRC Training
Day 2	DSMC Training
Day 2	How to Read and Understand Clinical Trial Protocols
Day 2	SOP 5.2 Opening a Clinical Trial to Accrual Study Activation Checklist
Day 2	SOP 3.4 Preparing a subject for a visit Assembling Lab Kits
Day 2	PIMS Training
Day 2	Research Tubes and Research Lab Policies
Day 2	PowerChart Training
Day 2	Cooperative Group Training
Day 2	SOP 3.8 Screen Falls
Day 2	QM Training - SOP Test



TRIAL RECRUITMENT & DISPARITIES RESEARCH



Trial Recruitment & Disparities Research: How Multicenter Institutional Studies Can Improve Enrollment

A. Bauchle, L. Segó, S. Edwards

Indiana University Melvin and Bren Simon Cancer Center

1. Background

Trial recruitment remains an issue among many sites around the country and world. Frequently, sites are not meeting recruitment expectations set at study start-up by the sponsor or institution. Accrual is slow and/or goals are not met resulting in extra work to open and maintain sites for little return. Institutional studies (investigator-initiated trials or IITs) are often a priority for Cancer Centers, but trial recruitment continues to be a challenge for these trials where the infrastructure available to support the trials is small when compared to a large pharma company with more staff and resources.

2. Goals

- Develop multicenter infrastructure to support engagement and recruitment from outside sites: Outside institutions may include affiliates associated with the institutional hospital system or satellite sites within the institution itself that the PI has oversight of.
- Develop systems and processes to streamline study start-up and maintenance
- Meet realistic accrual goals: Identify potential studies to open at additional sites.
- Systematically increase predictability for accrual when selecting sites
- Make institutional PIs aware of such programs: PIs may not be aware that multicenter programs are available at their institution or an institution they may know colleagues.

3. Solutions and Methods

- Worked with administration and Cancer Center leadership to write job descriptions for new or existing positions to support management of outside sites and developed relationships with hospital partners to engage the research teams.
- Standardized procedures, guidance documents and SOP's were created to streamline multicenter coordination.
- Considered opening trials at a multisite level. This allowed a PI to reach larger geographical areas and therefore have a larger patient population to offer their trial as an option. Sent newsletters as reminders that the trial was still ongoing.
- Created a feasibility checklist for sites to complete that requested accrual numbers for the patient population to support recruitment prior to selecting a site. The feasibility checklist also determined if enough resources were available for site participation.
- Made PIs aware of such programs via email, standing meetings, or teleconferences.

4. Outcomes and Future Directions

Since implementing the strategies outlined above, accrual has increased over the past years for multicenter institutional trials from 2016 to 2018 by 39%. Several trials have met accrual goals since the implementation of these plans in 2016.

While enrollment can be improved with the implementation discussed previously, there is always room for further growth. Streamlined processes and consistent systems should be considered for the best results. New policies and expectations take time to implement before an accrual growth is realized. Be aware the processes are always evolving and plan to adjust and refine current policies and develop new policies as required to meet the demands of an ever-changing oncology world. Have realistic expectations and understand the patient populations as well as the institutions you plan to work with prior to proceeding and including them in the trial. The use of advertising can be developed further with institutional policies considered prior to implementation.



Trial Recruitment & Disparities Research: How multicenter institutional studies can improve enrollment.

Amber Bauchle BS CCRP, Lina Segó BA CCRP, Sara Edwards, MSc, CCRC

Indiana University Melvin and Bren Simon Cancer Center

Problem

Trial recruitment remains an issue among many sites around the country and world. Frequently, sites are not meeting recruitment expectations set at study start-up by the sponsor or institution. Accrual is slow and/or goals are not met resulting in extra work to open and maintain sites for little return. Institutional studies (investigator-initiated trials or IITs) are often a priority for Cancer Centers, but trial recruitment continues to be a challenge for these trials where the infrastructure available to support the trials is small when compared to a large pharma company with more staff and resources.

Goal

Develop multicenter infrastructure to support engagement and recruitment from outside sites: Outside institutions may include affiliates associated with the institutional hospital system or satellite sites within the institution itself that the PI has oversight of.

Method

Worked with administration and Cancer Center leadership to write job descriptions for new or existing positions to support management of outside sites and developed relationships with hospital partners to engage the research teams.

Outcome

Since implementing the strategies outlined above, **accrual has increased over the past years for multicenter institutional trials from 2016 to 2018 by 39%**. Several trials have met accrual goals since the implementation of these plans in 2016.

Develop systems and processes to streamline study start-up and maintenance

Standardized procedures, guidance documents and SOP's were created to streamline multicenter coordination.

Indiana University's Clinical Trial Office currently manages 9 multicenter IITs with 24 active sites.

Meet realistic accrual goals: Identify potential studies to open at additional sites.

Considered opening trials at a multisite level. This allowed a PI to reach larger geographical areas and therefore have a larger patient population to offer their trial as an option. Sent newsletters as reminders that the trial was still ongoing.

Conclusions

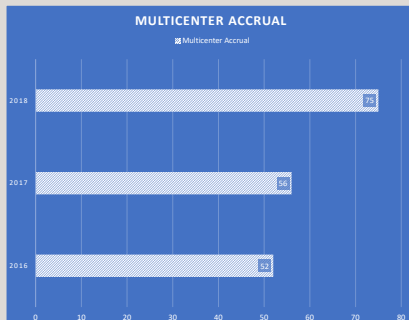
While enrollment can be improved with the implementation discussed previously, there is always room for further growth. Streamlined processes and consistent systems should be considered for the best results. New policies and expectations take time to implement before an accrual growth is realized. Be aware the processes are always evolving and plan to adjust and refine current policies and develop new policies as required to meet the demands of an ever-changing oncology world. Have realistic expectations and understand the patient populations as well as the institutions you plan to work with prior to proceeding and including them in the trial. The use of advertising can be developed further with institutional policies considered prior to implementation.

Systematically increase predictability for accrual when selecting sites

Created a feasibility checklist for sites to complete that requested accrual numbers for the patient population to support recruitment prior to selecting a site. The feasibility checklist also determined if enough resources were available for site participation.

Make institutional PIs aware of such programs: PIs may not be aware that multicenter programs are available at their institution or an institution they may know colleagues.

Made PIs aware of such programs via email, standing meetings, or teleconferences.





MNCCTN: Challenges to Opening a Statewide Network and the Pathway to Success - A Two Year Perspective

M.L. Rahne, R. Leed, C. Stibbe, J. Alkire

Masonic Cancer Center, University of Minnesota

1. Background

People living in rural areas face barriers to high quality cancer care. Additionally, these patients are often diagnosed with more advanced disease and have been shown to have worse outcomes than those living in urban areas.

Often, cancer clinical trials are offered at large, academic institutions in urban areas. For patients willing and able to travel, participation can mean frequent long drives and logistical challenges, but for many, participation is not an option. 42% of Minnesotans live beyond the practical reach of the state's two NCI-designated comprehensive cancer centers; the Masonic Cancer Center, University of Minnesota and Mayo Clinic Cancer Center.

2. Goals

The Minnesota Cancer Clinical Trials Network (MNCCTN) aims to reduce the burden of cancer on all Minnesotans through greater access to cancer clinical trials. MNCCTN allows sites that have not previously offered their patients access to cancer clinical trials the opportunity to do so.

3. Solutions and Methods

Partnering with five of Minnesota's largest healthcare providers, MNCCTN provides funding for infrastructure necessary to conduct cancer clinical trials. This includes research staff (physicians and coordinators), equipment, and capital upgrades. Acting as a research coordinating center, MNCCTN brings forward studies from the Masonic Cancer Center, the Mayo Clinic Cancer Center, and Hormel Institute in which sites can choose to participate.

4. Outcomes and Future Directions

1. MNCCTN has awarded funding to 27 sites to be opened by 2020. To-date, 11 sites have enrolled 137 patients onto 29 unique cancer clinical trials.
2. 79 personnel are actively working on MNCCTN throughout the state. 21 research coordinators have been hired and trained.
3. MNCCTN developed a clinical trial educational video that aired statewide and a broad suite of study-specific and general educational brochures and media materials.
4. Three investigator-initiated studies are open to enrollment at 9 sites.

Working with distinct and competing healthcare organizations requires transparency and consistent communication to establish mutually agreeable procedures and to maintain productive working relationships. MNCCTN places a daily emphasis on continually strengthening and reinforcing the MNCCTN partnership.

MNCCTN works with partners to understand the needs of sites. Staffing and education are two areas of focus.

1. Rural sites can have difficulty hiring and retaining qualified research staff, and once hired, these staff can be pulled in competing directions. MNCCTN works with sites to ensure protected research time and on methods for integrating research into the site's daily operations.

2. MNCCTN offers funding for research staff training and education to assist in maintaining engaged, quality staff. MNCCTN places a strong focus on research education, emphasizing both clinical and regulatory compliance practices and leads educational initiatives for research and clinic staff.

MNCCTN's current priorities focus on standardization and efficiency.

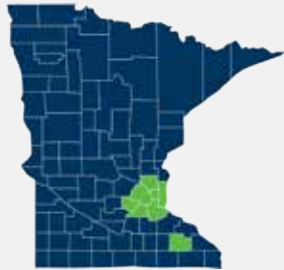
1. Expanding standardized procedures and documents will streamline the start-up process, make reporting more efficient, and ensure quality.
2. Several options exist for IRB review of multi-site studies including local approval, sIRB review at an MNCCTN partner, and a commercial IRB. MNCCTN is piloting each of these methods to evaluate cost, efficiency, and general compliance with the aim of balancing compliance, costs, and time.

Authors: Marie L. Rahne, MBA, Cheryl Stibbe, MA, RN, CCRC, Rana Leed, MPH, Jessica Alkire, BA

Minnesota Cancer Clinical Trials Network,
Masonic Cancer Center, University of Minnesota

Medical Director: Charles Loprinzi, MD
Senior Manager: Marie L. Rahne, MBA

Expanding Access, Removing Barriers

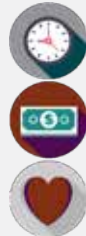


People living in rural areas face barriers to high quality cancer care. Additionally, they are often diagnosed with more advanced disease and have worse outcomes than those living in urban areas.

42% of Minnesotans live in counties (blue) beyond the practical reach of the state's two NCI-designated Comprehensive Cancer Centers (green).

Barriers to participation in the clinical trials offered at these institutions include:

- **Time.** Enrollment requires significant time away from work and family.
- **Cost.** Enrollment incurs many indirect costs to patients such as fuel, lodging, childcare, and meals.
- **Comfort.** A familiar setting, doctors, and being 'at home' reduce the emotional burden on participants and caregivers.



Mission

The Minnesota Cancer Clinical Trials Network (MNCCTN) aims to improve cancer outcomes for all Minnesotans through greater access to cancer clinical trials in prevention and treatment.

Funded by the State of Minnesota, MNCCTN:

- Increases access to cancer clinical trials through a statewide cancer clinical trials network
- Provides statewide access to clinical trials developed at Minnesota academic centers
- Enhances provider and public knowledge of cancer clinical trial activity in Minnesota

<https://www.mncancertrials.umn.edu>

Network Structure and Coverage

- Acting as a research coordinating center, MNCCTN has partnered with five of the state's largest healthcare providers.
- MNCCTN has provided funding for 27 clinical sites to be opened by 2020.

Current Sites



Essentia Health Fairview Health Mayo Clinic Cancer Center Metro-MN Comm. Oncology American Indian Band Sanford Health

Future Sites



MNCCTN focuses on interventional investigator-initiated trials from academic institutions and increasing access to cooperative group trials through our NCI Community Oncology Research Program partners.



15 Sites Enrolling

29 Cancer Clinical Studies

227 Minnesotans Enrolled

Lessons Learned

Partnering with distinct healthcare organizations requires transparency and consistent communication to establish mutually agreeable procedures and to maintain productive working relationships.

Research Staff and Education

Rural sites can have difficulty hiring and retaining qualified research staff, and once hired, these staff can be pulled in competing directions (clinical).

Objectives

- Ensure protected research time.
- Provide methods for integrating research into daily clinical operations.
- Offer funding for training and education to maintain engaged, quality staff.

Results

- ✓ 79 personnel are working on MNCCTN initiatives.
- ✓ 21 research coordinators have been hired and trained.

Standardization and Efficiency

MNCCTN has prioritized the implementation of standardized procedures and documents to better:

- Streamline start-up
- Efficient reporting
- Ensure quality and consistency



- ✓ Network Standard Operating Procedures
- ✓ Quality Assurance Program
- ✓ Study Manual of Procedures
- ✓ Aggregate reporting for pre-screening/screening efforts

MNCCTN is exploring three methods of IRB review for multi-site studies.

1. sIRB review at an Academic Institution
 2. sIRB review by a Commercial IRB
 3. Individual local IRB review
- Pilots projects will evaluate cost, efficiency, and general compliance
 - With the aim of balancing compliance, costs, and time.

Planting a Seed: How Bringing Research to the Community Can Blossom Into Patients Making Informed Health Care Decisions and Participating in Clinical Trials

C. Moss, E. Meisler, K. Hunt, D. Allen, C. Hugney, S. Abraksia

The Cleveland Clinic Cancer Center

1. Background

Minority under-representation in clinical trials is a challenge in research today. According to a study performed by ProPublica, 24 out of the 31 cancer drugs approved in the past three years had less than 5% African American clinical trial participants despite African Americans accounting for 13% of the nation's population and having the highest death rate among cancer patients. South Pointe Hospital, a Cleveland Clinic Regional Hospital, serves an area that is predominately African American. A Community Health Needs Assessment showed compared to other local areas, patients in South Pointe's community have an unfavorable health status, particularly for minority residents. Bringing clinical trials out into the community can provide education on cancer, decrease barriers to care and increase participation in clinical trials.

2. Goals

- Integrate Research and Community Outreach
- Provide education on cancer and clinical trials
- Decrease barriers to care
- Increase enrollment of minorities

3. Solutions and Methods

- Created a Clinical Research Coordinator (CRC) position to work with both Research and Community Outreach at South Pointe Hospital.
- Successfully executed two research studies (prostate, colorectal) within Community Outreach screening events to bring clinical trials into the neighborhood.
- Implemented an education table at community outreach events and created new educational materials for patients.

4. Outcomes and Future Directions

Outcomes

- The CRC has become an integral member of both the Research and Community Outreach Teams. The research education table is considered for every community outreach event allowing the CRC to attend and gain trust from community members. They are able to answer questions about clinical trials and help dispel myths about participating in research studies.
- The CRC also designed new educational materials such as a poster and a video that answer questions about participating in a clinical trial.
- Incorporating a Patient Navigator within the team provides patients an advocate that can assist with scheduling appointments and reducing barriers (i.e., coordinating transportation for those that cannot drive themselves).
- Adding the Research Nurse to community outreach events allows that RN to learn more about the targeted community, positively impacting their practice.
- The Prostate study was our first trial introduced to the community and has been conducted successfully for 3 years. This unique approach of offering education, informed decision making and prostate screening modalities resulted in 48 accruals in 2017 and 54 accruals in 2018. South Pointe has now established a colorectal cancer screening study, which will be conducted during an educational community outreach event. These research trials are being successfully funded by grants that the Medical Director of Oncology at South Point secured.

Lessons/Future

- Conducting research in the community requires a multidisciplinary team.
- Gaining trust from community members provides an opportunity for open communication between the clinic and the community
- Minorities are interested and willing to participate in clinical trials if they have trust in the system, feel valued and are offered appropriate education.
- Through learning more about the community, South Pointe Hospital can open trials that target the most prevalent diagnoses for their patients.
- Increase enrollment to clinical trials by reducing barriers and dispelling myths.
- Standardize this process and expand to other Cleveland Clinic sites.

PLANTING A SEED:

How bringing research to the community can blossom into patients making informed health care decisions and participating in clinical trials

Carol Moss; Eileen Meisler, RN, BSN; Kimberlee Hunt, MS; Debra Allen; Cathy Hugney, RN, CCRP; Samir Abraksia, MD
Cleveland Clinic Taussig Cancer Center, Cleveland, Ohio

Abstract category:
Trial Recruitment &
Disparities Research

Type of project:
Work in progress

Describe the background of the problem:

Minority under-representation in clinical trials is a challenge in research today. According to a study performed by ProPublica, 24 out of the 31 cancer drugs approved in the past three years had less than 5% African American clinical trial participants despite African Americans accounting for 13% of the nation's population and having the highest death rate among cancer patients. South Pointe Hospital, a Cleveland Clinic Regional Hospital, serves an area that is predominately African American. A Community Health Needs Assessment showed compared to other local areas, patients in South Pointe's community have an unfavorable health status, particularly for minority residents. Bringing clinical trials out into the community can provide education on cancer, decrease barriers to care and increase participation in clinical trials.

Provide metrics or goals to be achieved:

- Integrate research and community outreach
- Provide education on cancer and clinical trials
- Decrease barriers to care
- Increase enrollment of minorities

Describe the solutions or methods implemented:

- Created a Clinical Research Coordinator (CRC) position to work with both Research and Community Outreach at SouthPointe Hospital
- Successfully executed two research studies (prostate, colorectal) within Community Outreach screening events to bring clinical trials into the neighborhood
- Implemented an education table at community outreach events and created new educational materials for patients

Describe the outcome or show data representing a change (+ or -):

- The CRC has become an integral member of both the Research and Community Outreach Teams. The research education table is considered for every community outreach event allowing the CRC to attend and gain trust from community members. They are able to answer questions about clinical trials and help dispel myths about participating in research studies.
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Address lessons learned and future directions:

- Conducting research in the community requires a multidisciplinary team.
- Gaining trust from community members provides an opportunity for open communication between the clinic and the community.
- Minorities are interested and willing to participate in clinical trials if they have trust in the system, feel valued and are offered appropriate education.
- Through learning more about the community, South Pointe Hospital can open trials that target the most prevalent diagnoses for their patients.
- Increase enrollment to clinical trials by reducing barriers and dispelling myths.
- Standardize this process and expand to other Cleveland Clinic sites.



C3OD, An Abstraction and Recruitment Tool

D.P. Mudarantakam, J. Thompson, D. Streeter, B. Gajewski, D. Koestler, M. Mayo, R. Jensen
The University of Kansas Cancer Center

1. Background

Clinical trials remain the best avenue to establish the efficacy of newly proposed interventions. However, recruitment, retention, management, and execution of clinical trials have numerous associated challenges that can impact successful completion. From feasibility analysis, to enrollment targets, there are quantifiable barriers to trial recruitment that arise in part from the manual process of screening candidates. Examples include the need to manually review medical records including information from multiple locations, the need to consider complex recruitment criteria for a multiple trials, and overburdened care-providers. Additionally, clinicians expressed the strong need for the patients to be identified BEFORE their date-of-service so they and clinical trial staff can engage them during their appointment. Thus, it is critical to provide more automated solutions to pre-screening that can efficiently facilitate recruitment.

2. Goals

Our goals include improving the efficiency of clinical trial development through delivery of improved feasibility analysis and improved management of clinical trials through automated pre-screening of candidates.

3. Solutions and Methods

Out of the many different modalities that are being employed to address recruitment obstacles, we are attempting to design a technical solution to the prescreening process with both; rate (of recruitment), efficiency, and accuracy as drivers. We have designed a curated database called C3OD, with which we are able to fulfill requests for identifiable and actionable patient data underlying those numbers. In this use-case, we are addressing the arduous prescreening process by reducing the total number of potential study participants with which our coordinators must abstract data by delivering a curated (and drastically reduced list) of potential participants that meet study criteria. Additionally, this list incorporates the extra dimension of future-visit dates-of-service and is being delivered to our coordinator team prior to when the patient is being seen by the physician. This process allows time for additional abstraction of outlier criteria. Moreover, we have automated the generation and delivery of said list on a recurrent basis and delivered via secure means.

4. Outcomes and Future Directions

Below is a table of our first 9 patient extracts. Patients identified by study inclusion/exclusion that have future physician visits vs. the number of total patient charts that would have needed to be extracted without the use of C3OD

Address lessons learned and future directions: During the initial roll-out, we have identified some critical areas-of-opportunity for future developmental efforts. These include hardware and software improvements, data source management and growth, UI development and the need for additional human resources to support and improve C3OD.



C3OD, An Abstraction and Recruitment Tool

Dinesh Pal Mudarantakam¹, Jeffrey Thompson¹, David Streeter¹, Byron Gajewski¹, Devin C. Koestler¹, Matthew S. Mayo¹, Roy Jensen¹



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

INTRODUCTION

Clinical trials remain the best avenue to establish the efficacy of newly proposed interventions. However, recruitment, retention, management, and execution of clinical trials have numerous associated challenges that can impact successful completion. From feasibility analysis, to enrollment targets, there are quantifiable barriers to trial recruitment that arise in part from the manual process of screening candidates. Examples include the need to manually review medical records including information from multiple locations, the need to consider complex recruitment criteria for a multiple trials, and overburdened care-providers. Additionally, clinicians expressed the strong need for the patients to be identified BEFORE their date-of-service so they and clinical trial staff can engage them during their appointment. Thus, it is critical to provide more automated solutions to pre-screening that can efficiently facilitate recruitment.

Goals Our goals include improving the efficiency of clinical trial development through delivery of improved feasibility analysis and improved management of clinical trials through automated pre-screening of candidates.

FUTURE DIRECTIONS

During the initial roll-out, we have identified some critical areas-of-opportunity for future developmental efforts. These include hardware and software improvements, data source management and growth, data transfer and automation, UI development, NLP and improved unstructured data searching capabilities.

KEY VALUE METRICS

- 3** Number of additional trials able to be screened per coordinator
- 263.33** Computational rate of abstraction (charts per second)
- 97.68 %** Reduction in chart screening burden
- 134.9** Hours of screening time saved over 9 extracts (at a very conservative 2 minutes per patient chart review)
- 0** Number of enrolled participants not included in C3OD extracts for C3OD sourced studies

METHODS

Out of the many different modalities that are being employed to address recruitment obstacles, we are attempting to design a technical solution to the prescreening process with both; rate (of recruitment), efficiency, and accuracy as drivers. We have designed a curated database called C3OD, with which we are able to fulfill requests for identifiable and actionable patient data underlying those numbers.

C3OD utilizes a multi-sourced, automated approach to data aggregation. These data are filtered, transformed, and indexed (where appropriate) during data extraction then loaded into a centralized repository on a specified schedule to be utilized as a single harmonized data-source. Data is then deidentified with unique keys for consumption in other use-cases.

In this use-case, we are addressing the arduous prescreening process by reducing the total number of potential study participants with which our coordinators must abstract data by delivering a curated (and drastically reduced list) of potential participants that meet study criteria. Additionally, this list incorporates the extra dimension of future-visit dates-of-service, and is being delivered to our coordinator team prior to when the patient is being seen by the physician. This process allows time for additional abstraction of outlier criteria. Moreover, we have automated the generation and delivery of said list on a recurrent basis and delivered via secure means. This automation has eliminated the administrative time burden of directly interfacing with the tool to run the study extracts.

RESULTS

Below is a table of our first 9 patient extracts. Patients identified by study inclusion/exclusion that have future physician visits vs. the number of total patient charts that would have needed to be abstracted without the use of C3OD.

Extract No.	Total Scheduled	Total Identified	Percent Identified vs total
1	409	16	3.41
2	480	12	2.50
3	424	11	2.59
4	376	8	2.12
5	506	9	1.62
6	451	8	1.77
7	483	11	2.28
8	509	13	2.55
9	402	8	1.99

Total number of extracts	9
Total Scheduled Patients	4182
Total Identified Patients, by Inclusion-exclusion	95
Average Percent Identified vs Total scheduled	2.28
Number of enrolled patients	2
Estimated productivity unit savings	97.68 % per 1 FTE of total chart screening time for C3OD sourced studies
Number of additional trials able to start recruiting a direct result of time savings	3

WHAT THE TEAM IS SAYING

"This is working and helping, a pretty great tool" – **Natalya B.**, Study Coordinator.

"C3OD has provided our research team with the opportunity to maximize potential participant screening; what used to take a coordinator hours of time to screen hundreds or charts, is now a streamlined process based on key eligibility criteria and screening only those who meet this threshold. Therefore, saving us time, maximizing coordinator efforts, and an overall more efficient process of matching patients to clinical trials." - **Jennifer K.**, Associate Professor, Medicine - Clinical Oncology

"The use of C3OD has streamlined our prescreening process, allowing us to distribute resources to clinical locations where we have pre-identified potentially eligible patients. This high-throughput screening allows us to screen more efficiently and effectively." – **Joaquina Baranda**, MD Early Phase Oncology

The Impact of Modifying Eligibility Criteria on Accrual to Cancer Clinical Trials

D.P. Mudarantakam¹, J. Thompson¹, D. Streeter¹, J. Unger², M. Fleury³

¹The University of Kansas Cancer Center; ²Fred Hutchinson Cancer Research Center; ³American Cancer Society Cancer Action Network

1. Background

Recently ASCO, the Friends of Cancer Research, and the USFDA proposed modifications to “default” eligibility criteria often used in oncology clinical trials. These recommendations are meant to ensure criteria are scientifically justified, and if implemented would make trials more representative of the population with cancer. We hypothesized that these changes would also increase the pool of potential trial participants, but the impact of these recommendations on patient enrollment to trials has not been evaluated using comprehensive patient-level eligibility data.

2. Goals

We utilized the Curated Cancer Clinical Outcomes Database (C3OD) database of The University of Kansas Cancer Center as a resource for evaluating the potential magnitude of the ASCO recommendations on trial participation for patients with any solid tumor. The goal was to examine both the marginal (i.e. individual) and joint (i.e. combined) impact of modifying the following selected eligibility criteria: brain metastases, minimum age 12 or older, HIV status, renal function, hepatic function, and prior malignancies. An examination modifying the joint impact is of interest given the fact that criteria are likely correlated. Together these evaluations will provide a benchmark for the impact of adopting these recommendations.

3. Solutions and Methods

The C3OD database provides an opportunity to quantify the potential effect of adopting the recommendations. One major advantage of this unique resource is its capacity to identify modifications to specified eligibility criteria, rather than simply their exclusions or removal. The large size of the data resource enables detailed examination of the influence of modifying selected eligibility criteria across different cancer types and treatments, including immunotherapies and targeted agents.

4. Outcomes and Future Directions

In total, data on n=62,572 adult (age >18 years) patients with any solid tumor malignancy were available. The inclusion of patients with brain metastases was estimated to increase available patients by 68 (0.1%); of patients >12 years by 120 (0.2%); of patients positive for HIV by 159 (0.3%); of patients with renal dysfunction as measured by measured by creatinine clearance from 30-60 mL/min by 138 (0.2%); of patients with hepatic dysfunction (ascites) by 587 (0.9%); and of patients with prior malignancy between 2 to 5 years before most recent cancer diagnosis by 2979 (4.8%) (see Table). The inclusion of patients with any one of these conditions would increase the pool of available patients by up to 6.7%, which would allow up to 5695 (9112) additional patients to participate in trials in the U.S. overall if the trial participation rate is 5% (8%).

The recently recommended expansion of eligibility criteria would have varying impacts on patient eligibility depending on the disease condition. Our estimate of the cumulative impact of expanding all comorbidities combined indicates that several thousand patients would be available for trial participation each year, with accompanying benefits on the speed with which trials are conducted and the accessibility of trial participation as a choice for care for patients with cancer.

Retrospectively apply the ASCO recommended criteria to a set of actual, completed clinical treatment protocols, to identify the impact of trial criteria modification on the speed with which these trials would have been completed.



The Impact of Modifying Eligibility Criteria on Accrual to Cancer Clinical Trials

Jeffrey Thompson¹, David Streeter¹, Dinesh Pal Mudaranthakam¹, Joseph M Unger², Mark Fleury³

1. The University of Kansas Cancer Center, Kansas City, KS, USA, 2. Fred Hutchinson Cancer Research Center 3. American Cancer Society Cancer Action Network, Inc.



Introduction

Recently ASCO, the Friends of Cancer Research, and the USFDA proposed modifications to "default" eligibility criteria often used in oncology clinical trials. These recommendations are meant to ensure criteria are scientifically justified, and if implemented would make trials more representative of the population with cancer. We hypothesized that these changes would also increase the pool of potential trial participants, but the impact of these recommendations on patient enrollment to trials has not been evaluated using comprehensive patient-level eligibility data.

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Future Directions

Retrospectively apply the ASCO recommended criteria to a set of actual, completed clinical treatment protocols, to identify the impact of trial criteria modification on the speed with which these trials would have been completed.

Methods

The C3OD database provides an opportunity to quantify the potential effect of adopting the recommendations. One major advantage of this unique resource is its capacity to identify modifications to specified eligibility criteria, rather than simply their exclusions or removal. The large size of the data resource enables detailed examination of the influence of modifying selected eligibility criteria across different cancer types and treatments, including immunotherapies and targeted agents.

With this approach we identified a population based upon certain criteria, then layered each additional criterion on top of this population to simulate a cohort. We could then "toggle" these criteria as needed (and in specific combinations) to determine increased or decreased pool-size.

We then calculated an overall participation increase by using the US overall trial participation rate of 8%.

C3OD was used exclusively to determine these data which sits on-top of KUMC's EMR as a data source. Each criterion was entered individually and in combinations to determine the subpopulation. Criteria combinations were determined to be erroneous in the calculation of Total Possible Gain in Eligibility due to the fact that if a subject had >1 criteria, then the sum of patients per criterion (Total Possible Gain in Eligibility) would begin to decrease, leading us to skewed results. Due to this we designed the methods to only consider each criterion individually vs. total N of the population.

Results

In total, data on n=62,572 adult (age >18 years) of a total patients with any solid tumor malignancy were available. The inclusion of patients with brain metastases was estimated to increase available patients by 68 (0.1%); of patients >12 years by 120 (0.2%); of patients positive for HIV by 159 (0.3%); of patients with renal dysfunction as measured by creatinine clearance from 30-60 mL/min by 138 (0.2%); of patients with hepatic dysfunction (ascites) by 587 (0.9%); and of patients with prior malignancy between 2 to 5 years before most recent cancer diagnosis by 2979 (4.8%) (see Table). The inclusion of patients with any one of these conditions could increase the pool of available patients by up to 6.7%, which would allow up and additional to 5695 (5%) additional patients to participate in this analysis. Additionally, if the overall trial participation rate in the U.S. is 8%, then that would raise the additional participants to 9112 if the national overall percentage was applied against this cohort.

Criterion	Difference in patients by modifying criterion (n=62572)	Percent increase in eligible pool
Age down to 12 years	120	0.2%
Brain metastases	68	0.1%
HIV/AIDS positive	159	0.3%
Renal dysfunction (creatinine clearance)	138	0.2%
Hepatic dysfunction (ascites)	587	0.9%
Prior malignancies	2979	4.8%

The recently recommended expansion of eligibility criteria would have varying impacts on patient eligibility depending on the disease condition. Our estimate of the cumulative impact of expanding all comorbidities combined indicates that several thousand patients would be available for trial participation each year, with accompanying benefits on the speed with which trials are conducted and the accessibility of trial participation as a choice for care for patients with cancer.

Enhancing Accruals via Automated Performance Monitoring

A. Ivey, T. George, A. Anderson, W.J. Stokes, H. Koranne

University of Florida Health Cancer Center

1. Background

The University of Florida Health Cancer Center (UFHCC) Clinical Research Office (CRO) is a rapidly expanding research unit which oversees a portfolio of approximately 300 actively accruing studies. Prior to 2016, accrual to interventional studies averaged 330 subjects per year with treatment accruals comprising approximately 75% of enrollments. The UFHCC's Disease Site Groups (DSG), which were formalized in 2016, are charged with management of their group's research portfolio and ensuring that activated trials can be successfully accrued. The CRO created the DSG Performance Dashboard to establish DSG level enrollment targets and facilitate transparency and awareness of trial activity.

2. Goals

- Enhance investigator awareness of the available research portfolio
- Enhance investigator awareness of trial progress in meeting enrollment goals
- Provide automation and transparency in metric reporting

3. Solutions and Methods

Leveraging OnCore, the CRO developed a monthly DSG dashboard report that is distributed to leaders of the DSG, CRO and UFHCC. This dashboard provides real-time data and reflects the current DSG research portfolio of studies by type, year to date accrual (with historical trends), and enrollments by study, gender, race and ethnicity. These latter data are critical for DSGs to maintain awareness of enrollment disparities. Monthly enrollment targets are benchmarked for each DSG with accruals displayed in a "stoplight" report with a clear green (>75% monthly enrollment goal met), yellow (between 25-75%) or red (<25%) designations.

These dashboards provide transparency and offer opportunities to monitor performance trends across and between DSGs. Friendly DSG competition has provided measurable results. This report is distributed monthly via email to UFHCC, DSG, and CRO leadership via an automated OnCore report.

4. Outcomes and Future Directions

Overall, since implementation of the DSG Performance Dashboard, interventional treatment enrollments increased 2.6-fold from 2016 to 2018 with enrollments to Cancer Population Science interventional studies increasing by 1.7 fold. DSG leader (n=8) survey results showed that 87.5% review the Dashboard on a monthly basis. In addition, while only 62.5% noted they believed the Dashboard had impact on DSG operations, 87.5% reported that they felt that publication of the Dashboard had contributed to increasing accruals.

Future directions include integrating data regarding underperforming studies and routine review by UFHCC's Community Outreach and Engagement director to better analyze alignment of enrollments with catchment area demographics as well as identifying trials that might benefit from COE resources.

Alison Ivey, RN, MS, OCN, CCRP; Thomas George, MD, FACP; Ashley Anderson, MBA, ACRP-CP; William Stokes, RN, MBA, Harshita Koranne, BE, MS

BACKGROUND

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GOALS

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CONTACT

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(352) 294-8567 • aivey@ufl.edu

SOLUTION & METHODS

Leveraging OnCore, the CRO developed a monthly DSG dashboard report that is electronically distributed to leaders of the DSG, CRO and UFHCC. This dashboard provides real-time data and reflects the current DSG research portfolio of studies by type, year to date accrual (with historical trends), and enrollments by study, gender, race and ethnicity. These latter data are critical for DSGs to maintain awareness of enrollment disparities. **Figure 1**

Monthly enrollment targets are benchmarked for each DSG with accruals displayed in a "stoplight" report with a clear green (>75% to monitor performance trends across and between DSGs. monthly enrollment goal met), yellow (between 25-75%) or red (<25%) designations. **Figure 2**

These dashboards provide transparency and offer opportunities to monitor performance trends across and between DSGs. Friendly DSG competition has provided measurable results. This report is distributed monthly via email to UFHCC, DSG, and CRO leadership via an automated OnCore report.

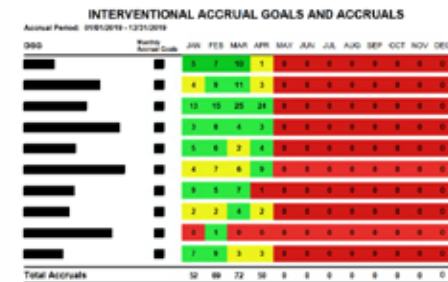


Figure 1. Individual DSG Dashboard

OUTCOMES

Overall, since implementation of the DSG Performance Dashboard, interventional treatment enrollments increased 2.6-fold from 2016 to 2018 with enrollments to Cancer Population Science interventional studies increasing by 1.7 fold. DSG leader (n=8) survey results showed that 87.5% review the Dashboard on a monthly basis. While only 62.5% noted they believed the Dashboard had impact on DSG operations, 87.5% reported that they felt that publication of the Dashboard had contributed to increasing accruals.

Figure 2. DSG Enrollment Stoplight Report



FUTURE DIRECTIONS

Future directions include integrating data regarding underperforming studies and routine review by UFHCC's Community Outreach and Engagement director to better analyze alignment of enrollments with catchment area demographics as well as identifying trials that might benefit from COE resources.



TRIAL START-UP/ CLOSURE



Clinical Trials Office New Study Committee: A Streamlined and Collaborative Approach for Clinical Trial Portfolio Management

K. Krul, S. Bigelow, M. Kelley, L. Lange

Barbara Ann Karmanos Cancer Institute, Wayne State University

1. Background

Cancer centers across the nation face comparable obstacles during the various stages of trial start-up. At the Barbara Ann Karmanos Cancer Institute (KCI), incoming clinical trials were funneled through various paths: physician investigators, finance, and coordinators, inadvertently complicating start-up and affecting protocol activation timelines. The KCI Clinical Trials Office (CTO) identified the need for a centralized mechanism earlier in the activation process in order to manage concerns related to trial prioritization, feasibility, research team communication, multi-disciplinary team (MDT) assignment, trial suitability, and CTO resources.

2. Goals

The goal of the CTO New Study Committee (NSC) is to streamline the process for reviewing incoming clinical trials in order to ensure the trial could be feasibly and appropriately conducted at KCI. With the creation of the CTO NSC, the CTO strived to standardize MDT assignment and workloads, as well as improve communication and centrally manage the trial portfolio.

3. Solutions and Methods

A collaborative committee including the Vice President, Directors, Managers, Supervisors, and expert coordinators is scheduled each week to review incoming studies that are submitted by physician investigators or CTO staff. A centralized email was created and minimum criteria for submission were established, which included: protocol or synopsis, accrual to date, total target accrual, protocol population, and expected KCI participation. Upon receipt of trial feasibility documents or NCI study activation notification, the study is added to the next CTO NSC agenda. The Committee reviews the trial, assigns the appropriate MDT staff and treatment area(s), and considers the trial for Network involvement.

The Committee also provides a recommendation as to whether KCI should proceed with the activation process. The Committee utilizes a Task List from our site's clinical trial management system, OnCore®, to document the Committee's review and recommendation. Following the meeting, the recommendation is communicated to the physician investigator and study team.

4. Outcomes and Future Directions

The CTO NSC held its first meeting on June 21, 2018 and has reviewed 218 studies as of April 15, 2019. Data has been provided in Appendix I CTO NSC Review Summary. Historically, physicians drove the MDT assignment; however, now the CTO NSC directs the path of the protocol, which allows for the CTO to take into account resources, competing trials, and the institution's ability to make a significant contribution to the studies. An unexpected, positive outcome of the Committee was earlier identification of unique trial requirements (i.e., biosafety, interventional radiology, unique testing, etc.) which is subsequently reviewed at our site's Feasibility Review and Operations Committee. This initiative also led to optimization of OnCore® and the ability to track all incoming protocols managed by the KCI CTO.

The CTO NSC highlighted the need for a more robust protocol activation initiative. The KCI CTO is working to establish a more formal tracking mechanism in OnCore®, starting with the receipt of trial feasibility documents or notification of NCI study activation. The CTO NSC has been supported by institutional leadership to be the starting point for tracking incoming studies. In the future, the CTO will analyze CTO NSC data to support process changes in order to drive efficiency.

Clinical Trials Office New Study Committee: A Streamlined and Collaborative Approach for Clinical Trial Portfolio Management

Sarah Bigelow, CCRP¹; Kasha Krul, CCRP¹; Maureen Kelley, MSBMS, CCRP¹; Lisa M. Lange, MSN, ANP-BC, AOCN¹

¹Barbara Ann Karmanos Cancer Institute, Wayne State University

Background

Cancer centers across the nation face comparable obstacles during the various stages of trial start-up. At the Barbara Ann Karmanos Cancer Institute (KCI), incoming clinical trials were funneled through various paths: physician investigators, finance, and coordinators, inadvertently complicating start-up and affecting protocol activation timelines. The KCI Clinical Trials Office (CTO) identified the need for a centralized mechanism earlier in the activation process in order to manage concerns related to trial prioritization, feasibility, research team communication, multi-disciplinary team (MDT) assignment, trial suitability, and CTO resources.

Goals

The goal of the CTO New Study Committee (NSC) is to streamline the process for reviewing incoming clinical trials in order to ensure the trial could be feasibly and appropriately conducted at KCI. With the creation of the CTO NSC, the CTO strived to standardize MDT assignment and workloads, as well as improve communication and centrally manage the trial portfolio.

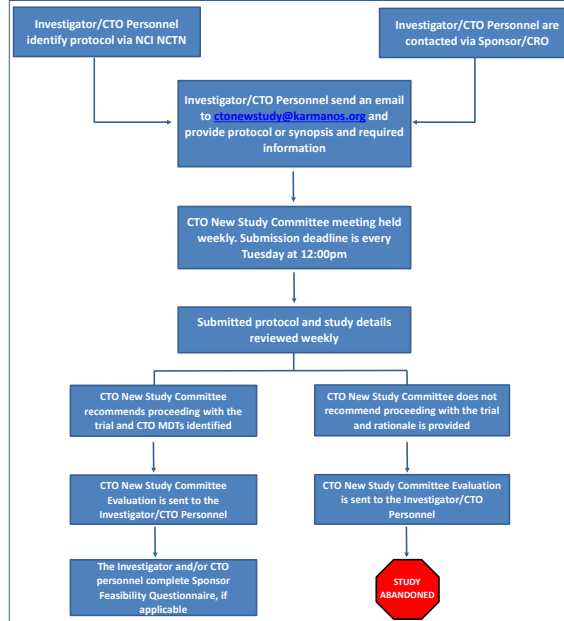
Solutions and Methods

A collaborative committee including the Vice President, Directors, Managers, Supervisors, and expert coordinators is scheduled each week to review incoming studies that are submitted by physician investigators or CTO staff. A centralized email was created and minimum criteria for submission were established, which included: protocol or synopsis, accrual to date, total target accrual, protocol population, and expected KCI participation. Upon receipt of trial feasibility documents or NCI study activation notification, the study is added to the next CTO NSC agenda. The Committee reviews the trial, assigns the appropriate MDT staff and treatment area(s), and considers the trial for Network involvement. The Committee also provides a recommendation as to whether KCI should proceed with the activation process. The Committee utilizes a Task List from our site's clinical trial management system, OnCore®, to document the Committee's review and recommendation. Following the meeting, the recommendation is communicated to the physician investigator and study team.

Appendix I – Clinical Trials Office New Study Committee Review Summary

CTO New Study Committee - Review Summary	2018	2019	TOTAL
Total Number of Protocols Submitted	129	89	218
Total Number of Protocols Committee Recommended Proceed	120	85	205
Total Number of Protocols Committee Recommended Not Proceeding	7	1	8
Total Protocols Withdrawn/Tabled/Pending Re-Review	2	3	5
	100.0%	100.0%	100.0%
Total Number of Protocols that Remained with the Submitting MDT	96	71	167
Total Number of Protocols that Transferred to a Different MDT	24	14	38
	80.0%	83.5%	82%
	20.0%	16.5%	18%

Process Flow for Receipt and Review of CTO Managed Studies

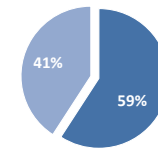


Outcomes and Future Directions

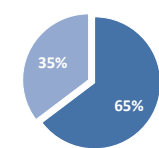
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2018 Study Outcome Summary



2019 Study Outcome Summary (as of April 2019)



The Need for Speed: Piloting a Study Activation Committee

S. Flores, N. Sender, L. Blumberg, L. Segall, S. Mistretta, J. Wang, L. Butaud-Rebbaa, Q.-D. Quiles, T. Negri, M. Kelsen, F. Brogan, D. Otap, N. Rizzo
Herbert Irving Comprehensive Cancer Center, Columbia University Irving Medical Center

1. Background

The adapting landscape, increasing complexity, and personalization of oncology clinical trials implores faster clinical trial activation. Our mission is to deliver novel treatments to acutely ill patients, and in this we cannot delay. Considering the volume of new studies submitted to our IRB, it became increasingly imperative to develop a workflow for tracking pipeline studies centrally and successfully seeing them to IRB approval.

2. Goals

- Decrease study activation timelines.
- Track review of pipeline studies and solve impediments in real time.
- Establish selection criteria for high priority studies to gain accelerated IRB approval.

3. Solutions and Methods

A Time to Activation (TTA) committee, comprised of representatives from Regulatory, Clinical Operations, and Compliance Divisions within our Department formed. The committee began by identifying the “activation” metric. Many factors contribute to a study’s activation. However, the committee implemented tracking the most all-encompassing factor: IRB approval. This was defined as the date of IRB submission through date of initial IRB approval. This key metric incorporates approvals from all required stakeholders: PRMC, Sponsor, FDA, etc. TTA members were assigned disease teams. During weekly meetings, members provided updates for studies in IRB submission pipeline for over 30 days. This identified rate-limiting factors in real-time. These included dates of submission, review committee meetings, correspondence content, and Sponsor/CRO/PI response times. The committee outlined actions to resolve these issues, including, follow up to the study team, addressing difficult correspondence, and, in limited cases, recommendation for withdrawal from IRB review until a more optimal time. A Rapid Activation Initiative (RAI) was born from the TTA committee to have select trials IRB approved in under 60 days, prioritizing studies of important clinical value and the Principal Investigator was a primary intellectual contributor. We met with key stakeholders (IRB, PRMC, Research Teams, and Sponsor/CRO) to gain commitment for review and communicate timelines.

4. Outcomes and Future Directions

The Time to Activation Committee successfully decreased IRB approval timelines. Overall, there was a 24% decrease in average IRB approval from 2018 to 2017 (93 days to 71 days). Industry and Investigator-Initiated Trials showed the most improvement:

- Investigator-Initiated studies decreased 32% (2017: 114 days, 2018: 77 days)
- Industry studies decreased 18% (2017: 96 days, 2018: 79 days)

As a result, our site was the first activated and enrolled the first patient globally for two studies. Six RAI studies were IRB approved in 2018 with an average review of 51 days, showing a 35% decrease compared to similar non-RAI studies. The quickest RAI study was approved in 33 days (58% decrease from non-RAI average). On a recent RAI study, Columbia treated the first patient in the United States.

The National Cancer Institute (NCI) activation goal is 90 days.¹ Our Time to Activation Committee showed successful Proof of Concept that real-time tracking and commitment amongst review committees, study team, and Sponsor/CRO, results in quicker approvals. Since implementation, we have successfully decreased IRB approval timelines, ultimately accelerating patient access to novel therapies.

As we continue our initiative, we hope to review timelines for studies that took longer than average, identify additional metrics for “activation” tracking, and vet the RAI selection process.

The Need for Speed: Piloting a Study Activation Committee

Susie J. Flores, CCRP; Nicole Rizzo, CCRP; Naomi Sender; Lauren Blumberg, MPH, MS; Leslie Segall, MPH; Suzanne Mistretta; Jennifer Wang, MS, CCRP; Laurence Butaud-Rebbaa, CIP; Qiana-Denise Quiles; Tiffany Negri, ALM, CCRP; Moshe Kelsen, MBA; Fran Brogan, MSN, RN, OCN, CCRP; Dan Otap, CCRP

Background

The adapting landscape, growing complexity, and personalization of oncology clinical trials calls for faster clinical trial activation. Our mission is to deliver novel treatments to acutely ill patients, and in this we cannot delay. With the increasing volume of new studies submitted to our IRB, it became imperative to develop a workflow for centrally tracking pipeline studies and successfully seeing them to IRB approval.

Goals

- Decrease study activation timelines.
- Track review of pipeline studies and solve impediments in real time.
- Establish selection criteria for high priority studies to gain accelerated IRB approval.

Methods

A Time to Activation (TTA) committee, comprised of representatives from Regulatory, Clinical Operations, and Compliance Divisions within our Department was formed. The committee began by identifying the “activation” metric. Many factors contribute to a study’s activation time line. The committee implemented tracking the most all-encompassing factor: IRB approval, defined as the date of IRB submission through date of initial IRB approval. This key metric incorporates approvals from all required stakeholders: PRMC, Sponsor, FDA, etc.

TTA committee members were assigned disease teams to track. During weekly meetings, members provided updates for studies in IRB submission pipeline for over 30 days. This allowed for real time identification of rate-limiting factors. These included dates of submission, review committee meetings, correspondence content, and Sponsor/CRO/PI response times. The committee outlined actions to resolve these issues, including: follow up to the study team, addressing difficult correspondence, and, in limited cases, recommendation for withdrawal from IRB review until a more optimal time.

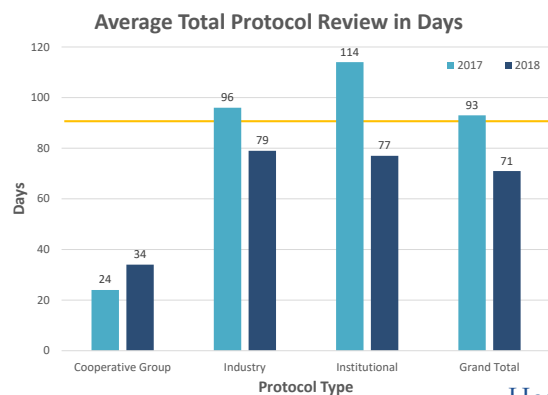
A Rapid Activation Initiative (RAI) was born from the TTA committee to select trials for targeted IRB approval in under 60 days. Studies of important clinical value for which the Principal Investigator was a primary intellectual contributor were prioritized. We met with key stakeholders (IRB, PRMC, Research Teams, and Sponsor/CRO) to discuss timelines and gain commitment for rapid review.

Results

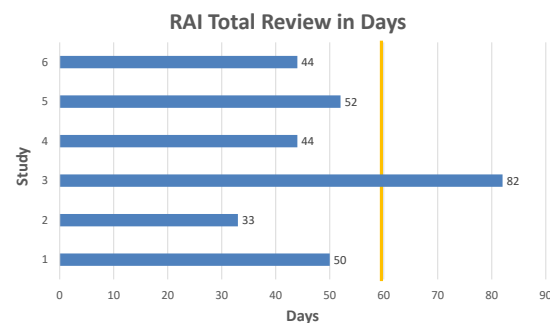
Since implementing the Time to Activation Committee, IRB approval timelines have considerably decreased. Overall, there was a 24% decrease in average IRB approval from 2018 to 2017 (93 days to 71 days). Industry and Investigator-Initiated Trials showed the most improvement :

- Investigator-Initiated studies decreased 32% (2017: 114 days, 2018: 77 days)
- Industry studies decreased 18% (2017: 96 days, 2018: 79 days)

As a result, our site was the first activated and enrolled the first patient globally for two studies.



Six RAI studies were IRB approved in 2018 with an average review of 51 days, showing a 35% decrease compared to similar non-RAI studies. The fastest RAI study approval was 33 days, a 58% decrease from the non-RAI average. On a recent RAI study, Columbia treated the first patient in the United States.



Future Improvements

The National Cancer Institute (NCI) activation goal is 90 days (1). Our Time to Activation Committee showed successful Proof of Concept that real-time tracking and commitment amongst review committees, study team, and Sponsor/CRO, results in quicker approvals. Since implementation, we have successfully decreased IRB approval timelines, thus accelerating patient access to novel therapies. Future TTA initiatives include review of timelines for studies that took longer than average, identifying additional metrics for “activation” tracking, and vetting of the RAI selection process.

Sources:
(1) Abrams, Jeffrey S et al. "Implementation of timeline reforms speeds initiation of National Cancer Institute-sponsored trials." *Journal of the National Cancer Institute* vol. 105,13 (2013): 954-9. doi:10.1093/jnci/djt137

Improving Efficiency and Time Management During the Site Selection Process: A Collaborative Approach

L. Lujan, S. Sharry, J. Moehle, T. Werner, E. Constantz, J. Espinosa, S. Fairbairn, B. Johnson

Huntsman Cancer Institute, University of Utah

1. Background

Prior to site selection, Cancer Centers receive multiple requests for information from sponsors and their contract research organizations (CROs) to assess site feasibility. Confirming a site's feasibility to conduct a clinical trial involves assessments in many areas including site logistics, technical capabilities, accrual potential, activation timelines and administrative infrastructure, and reviews of site-specific standard operating procedures. All of these areas require completion of lengthy questionnaires, gaining access to portals, multiple email conversations, and often times meetings in addition to required pre-site selection visits (PSSV). The requests for information and required questionnaires are extensive, time-consuming, and in many cases, duplicative.

2. Goals

Our goal is to streamline communication during the site selection process to work more efficiently and collaboratively with our sponsors and CROs. Another goal is ensuring accuracy and consistency of information provided during the site selection process. We expect that by creating and maintaining a comprehensive document that provides our sponsors and CROs site-specific information and answers to frequently asked questions we will improve efficiency for all parties. The document will reduce time to confirmation of site selection, as well as the amount of time required during pre-site selection visits.

3. Solutions and Methods

We created a comprehensive new study start-up packet, that we provide to sponsors and CROs as soon as discussions related to site selection commence. The packet includes our site-specific study start-up requirements, activation timelines, technical capabilities, answers to frequently asked questions, and standard operating procedures. This comprehensive document helps our sponsors and CROs assess the feasibility of conducting clinical research at Huntsman Cancer Institute in a more efficient manner.

4. Outcomes and Future Directions

The unsolicited feedback received from sponsors and CROs has been positive. Most state they are able to complete the majority of their site selection reports with the data provided in the start-up packet prior to the PSSV. Now, time spent with the principal investigator and site study staff during the PSSV is spent more productively discussing study-specific recruitment strategies and protocol requirements, as well as addressing questions.

Site selection timelines appear to have improved, especially for our Phase I experimental therapeutics studies, primarily for participation in dose escalation where rapid site selection is necessary.

Reports from our management team, as well as sponsors and CROs, have confirmed that providing the study start-up packet prior to the PSSV improves transparency, communication, and the sponsor-site relationship overall.

We will continue to collect feedback from sponsors and CROs to measure satisfaction.

We will continue to update the new study start-up documents as clinical research requirements and site-specific processes evolve.



Improving Efficiency and Time Management During the Site Selection Process: A Collaborative Approach

Leanne Lujan, BS, CCRP; Brett Johnson, BS, CCRP; Sally Fairbairn, BS, CCRP; Elizabeth Constantz, BS, CCRP; Janna Espinosa, BA, CCRP; Jessica Moehle, BS, CCRP; Theresa L. Werner, MD; Susan Sharry, BS, CCRP

Huntsman Cancer Institute at the University of Utah



BACKGROUND

Cancer centers receive multiple requests for information from sponsors and their contract research organizations (CROs) to assess a site's feasibility to conduct a clinical trial. This involves assessments in many areas:

- Site logistics
- Technical capabilities
- Accrual potential
- Activation timelines
- Administrative infrastructure
- Site-specific standard operating procedures

Gathering information in these areas requires lengthy questionnaires, access to portals, multiple email conversations, and meetings in addition to required pre-site selection visits (PSSVs). The requests for information and required questionnaires are extensive, time-consuming, and in many cases duplicative.

METHOD

- Our goal is to streamline communication during the site selection process to work more efficiently and collaboratively with our sponsors/CROs as well as ensure accuracy and consistency of information provided during the site selection process.
- By creating and maintaining a comprehensive document with site-specific information and answers to frequently asked questions for our sponsors/CROs, we expect to improve efficiencies for all parties by reducing the time it takes to confirm site selection.

RESULTS

We created a comprehensive new study start-up packet to give sponsors/CROs as soon as site selection discussions commence. The packet includes the following:

- Site-specific study start-up requirements
- Activation timelines
- Technical capabilities
- Answers to frequently asked questions

We provide this comprehensive document to our sponsors and CROs to help them assess the feasibility of conducting clinical research at HCI in a more efficient manner.

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New Study Approval Process
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IRB and Regulatory FAQ
Additional Regulatory Considerations
Investigational Pharmacy and Drug Dispensing FAQ
Specimen Processing, Local Lab, and Pathology FAQ
Radiology and Imaging FAQ
Imaging Review, Quantitative Assessment, and Reporting for Clinical Trials
Monitoring, Electronic Data Capture (EDC) and Medical Records FAQ
Infusion FAQ
Site Training FAQ
Appendices: Local Lab Normal Ranges, SOPs, AE Flowchart, IRB Guidance Documents; Templates

Table of Contents for the site-specific study start-up packet.

CONCLUSIONS

- The feedback from sponsors and CROs has been positive. Most state they are able to complete the majority of their site selection reports with the data provided in our site-specific study start-up packet prior to the PSSV.
- Time with the principal investigator and site study staff during the PSSV can now be spent more productively, addressing questions and discussing study-specific recruitment strategies and protocol requirements.
- Site selection timelines appear to have improved, especially in our Phase I experimental therapeutics space, where rapid site selection is necessary, primarily for participation in dose escalation.
- Internal reports from management as well as sponsors and their CROs have confirmed that providing the study start-up packet prior to the PSSV allows for transparency, which improves communication and the sponsor/site relationship overall.

FUTURE PLANS

- Create and implement sponsor/CRO surveys to confirm feedback received to date and measure satisfaction
- Begin discussion with CROs/sponsors regarding creation of databases to capture site-specific study start-up requirements, activation timelines, technical capabilities, and answers to frequently asked questions
- Continue to update the New Study Start-up Documents as clinical research requirements and site specific processes evolve

Interdisciplinary Approach to Research Biopsy Acquisition in Oncology Clinical Trials

K. Schroeder¹, J. Roessler², S. Zindars¹, M. Rau¹, E. Polak², J. Fleischman¹

¹Medical College of Wisconsin Cancer Center; ²Froedtert Hospital

1. Background

While imaging-guided tumor biopsies have been a main-stay for the histologic diagnosis of cancer, fresh tumor research biopsies in clinical trials are a more recent requirement.

Since each clinical trial sponsor has unique guidelines that can vary greatly on the acquisition and processing of these samples, the Froedtert & Medical College of Wisconsin interdisciplinary team, including: Advanced Radiology Procedures (ARP) clinic, Office of Clinical Research and Innovative Care Compliance (OCRICC), Medical College of Wisconsin Tissue Bank, and the Clinical Trials Office (CTO) manager, found that there was no consistent communication plan, and with each biopsy that was being performed there was often last minute planning. This led to frustration among team members, the potential risk for error, and concern for patient safety.

2. Goals

Since communication between departments was pivotal in developing a formal process, the CTO manager met with the interdisciplinary team to understand the capabilities and needs of each department.

It was determined that a single communication guidance document would properly contain the required information for each department, as well as the key information for the specific trial.

3. Solutions and Methods

It was determined that the initial draft of the guidance document is to be created by the CTO manager/staff and reviewed by each department during the planning phase of the trial. Once approved, the document is sent out in the final activation packet from OCRICC to all departments. This approval has to be granted before the trial can be activated at the site.

The template guidance document includes:

1. Naming convention (each trial is named using the OnCore® ID, IRB PRO number, and the OCRICCNnumber)
2. Expected samples needed and the type of biopsy allowed (helps the staff understand what type of biopsy can be ordered based on the contracted budget)
3. Contact and communication information for each department
4. Specific instructions from the trial specific lab manual for the collection and processing

The template guidance document contains 5 steps where staff can add and edit the content to match the specific needs of the trial. However, the template also includes language that must remain present regardless of the type of procedure.

Step 1: DETERMINE IF BIOPSY PROCEDURE WILL BE DONE AS ROUTINE CARE or RESEARCH

Step 2: NAMING CONVENTION FOR RESEARCH BIOPSY

Step 3: NOTIFICATION OF GROUP(S) INVOLVED

Step 4: COMMUNICATE PRIOR TO PROCEDURE DATE, REGARDLESS OF BIOPSY SITE OR GUIDANCE

Step 5: INSTRUCTIONS FOR COLLECTION AND PROCESSING

4. Outcomes and Future Directions

With a single communication tool encompassing the needs of each department created prior to the activation of each trial, the last minute planning of these biopsies no longer occurs. This organization provides a guidance to the staff to appropriately manage these research biopsies and also a tool to educate trial participants on the process.

Challenges that remain include:

1. Investigators requesting routine tissue samples along with research samples during the same procedure.
2. Utilizing the correct naming convention at the time of ordering the biopsy (often done by Investigators)
3. Managing amendments if the biopsy process changes

Interdisciplinary Approach to Research Biopsy Acquisition in Oncology Clinical Trials

Katy Schroeder, BSN, RN, OCN, CCRP; Jarrod Roessler, BS; Stacey Zindars, MS, CCRP; Mary Rau, BS; Elizabeth Polak, BSN, RN, CNOR; Jennifer Fleischman, RN, BBA, CCRP

Significance/Background

While image-guided tumor biopsies have been a mainstay for the histologic diagnosis of cancer, fresh tumor research biopsies in clinical trials are a more recent requirement.

Since each clinical trial sponsor has unique guidelines that can vary greatly on the acquisition and processing of these samples, the Froedtert & Medical College of Wisconsin interdisciplinary team, including: Advanced Radiology Procedures (ARP) clinic, Office of Clinical Research and Innovative Care Compliance (OCRICC), Medical College of Wisconsin Tissue Bank, and the Clinical Trials Office (CTO) RN manager, found that there was no consistent communication plan, and with each biopsy that was being performed there was often last minute planning. This led to frustration among team members, the potential risk for error, and concern for patient safety.

Interdisciplinary Team

CTO RN manager-Manages portfolio of oncology clinical trials; from trial activation to closure

ARP clinic-Manages new referral/consult services for patients who need image-guided procedures in radiology

OCRICC- The link between the investigators and/or their designees and the health system clinical business leaders for research projects using Froedtert resources

Medical College of Wisconsin Tissue Bank- Provides a secure storage facility for research samples as well as the structure to process research related tissue biopsy samples

Intervention

Since communication between departments was pivotal in developing a formal process, the CTO RN manager met with the interdisciplinary team to understand the capabilities and needs of each department.

It was determined that a single communication template would properly contain the required information for each department, as well as the key information for the specific trial. The document includes:

1. Naming convention (each trial is named using the OnCore® ID, IRB PRO number, and the OCRICC number)
2. Expected samples needed and the type of biopsy allowed (helps the staff understand what type of biopsy can be ordered based on the contracted budget)
3. Contact and communication information for each department
4. Specific instructions from the trial specific lab manual for the collection and processing

The initial draft of the guidance document is created by the CTO RN manager/staff and reviewed by each department during the planning phase of the trial. Once approved, the document is sent out in the final activation packet from OCRICC to all departments. This approval has to be granted before the trial can be activated at the site.

Guidance Document Template Example

PI: Smith; UB-16-0578-PANC; PRO 41027; OCRICC 19-0199

Biopsy Collection Plan

Lab Manual version 2.0 3-14-19

Instructions: Rename file to your study folder using OnCore® Protocol No, IRB PRO & OCRICC#. Delete all green instructions, examples and <insert> prompts and replace with purple, study-specific text. Black & red language is template. Delete template language that is not applicable.

Expected Biopsies: Example: This study wants 2 cores fresh frozen and 2 cores paraffin-embedded tissue blocks from intrahepatic lesion, pre and post SBRT (same lesion). Budget allows for ultrasound guided liver biopsies, but based on previous experience, guidance may vary by patient. We will allow for US and CT guidance, but US is preferred. Per PI, patients will not require routine biopsies at the same time as these research biopsies, so all biopsies per protocol will be billed to research.

Please seek permission from manager prior to exploring other biopsy types, as the cost may be prohibitive.

The template contains 5 steps where staff can edit (based on the colored language mentioned above) the content to match the specific needs of the trial.

Step 1: DETERMINE IF BIOPSY PROCEDURE WILL BE DONE AS ROUTINE CARE or RESEARCH

Step 2: NAMING CONVENTION FOR RESEARCH BIOPSY

Step 3: NOTIFICATION OF GROUP(S) INVOLVED

Step 4: COMMUNICATE PRIOR TO PROCEDURE DATE, REGARDLESS OF BIOPSY SITE OR GUIDANCE

Step 5: INSTRUCTIONS FOR COLLECTION AND PROCESSING



For additional information please contact:
Katy Schroeder BSN, RN, OCN, CCRP
Froedtert & Medical College of Wisconsin Cancer Center
kschroeder@mcw.edu
www.mcw.edu/departments/cancer-center

Evaluation and Challenges

With a single communication tool encompassing the needs of each department created prior to the activation of each trial, the last minute planning of these biopsies no longer occurs. This organization provides a guidance to the staff to appropriately manage these research biopsies and also a tool to educate trial participants on the process.

Challenges that remain include:

1. Investigators requesting routine tissue samples along with research samples during the same procedure.
2. Utilizing the correct naming convention at the time of ordering the biopsy (often done by Investigators)
3. Managing amendments if the biopsy process changes

How Does a Master CDA Affect Timelines?

C. Mackay¹, J. King²

¹The University of Kansas Cancer Center; ²Covance, Inc.

1. Background

Having a master confidentiality agreement (mCDA) in place streamlines the ability to share study specific information with a site. Master agreements, in general, decrease time to activation and reduce the time and administrative burden on site research teams. The first step in any study feasibility process for a sponsor or CRO, is to determine if a site is interested and capable of conducting that clinical trial. That process usually starts with establishing a confidentiality agreement between either the site and sponsor or the site and CRO.

Many sites have specific legal language or confidentiality term requirements. A considerable amount of time is spent between the sponsor/CRO and the site's legal team negotiating language for a confidentiality agreement. Since this process is being performed for every study a site takes under consideration, there is a significant amount of time spent on the negotiation of confidentiality agreements by both parties.

2. Goals

- Reduce the administrative burden on the legal teams at the University of Kansas Cancer Center (KUCC) and Covance by establishing a mCDA with addendum.
- Evaluate the acceptance rate by sponsors for using the Covance mCDA.
- Compare the time to confidentiality agreement execution between using the mCDA addendum versus using a sponsor specific CDA.

3. Solutions and Methods

The University of Kansas and Covance negotiated and executed a mCDA, most recently renewed in 2018. When Covance was awarded a study, Covance first presented the mCDA to the sponsor for review. Sponsors either accepted or rejected use of the Covance mCDA prior to study specific information being shared. The mCDA includes a one-page addendum template which required entry of trial specific information for each new study. If the mCDA was accepted by the sponsor, KUCC was sent the mCDA addendum for signature.

4. Outcomes and Future Directions

From July 1, 2018 through April 19, 2019, there were twenty (20) study opportunities which met these evaluation criteria:

- Trial opportunities for which Covance was seeking research site interest and capability.
- Covance discussion with sponsor about mCDA use.
- Trials in which KUCC was interested.
- Trials for which CDAs were executed.

Nearly half of sponsors accepted the mCDA (see figure). Acceptance of the Covance mCDA (9)

- 23 business days on average to fully execute the mCDA addendum
- 67% were executed in 17 business days or less

Use of sponsor CDA (11)

- 30 business days on average to fully execute the sponsor CDAs
- 36% of these CDAs took an average of 55 business days to execute

Sponsor acceptance of the Covance mCDA resulted in achieving a fully executed mCDA addendum 7 business days faster on average than obtaining a sponsor specific CDA.

Using a mCDA template decreases the ever-growing administrative burden on sites and study teams by eliminating the time to negotiate. Quickly executing the CDA allows Covance to quickly engage with a site to initiate the trial start up process.

We will continue to evaluate the acceptance by sponsors of the Covance mCDA and comparing timelines from CDA receipt to execution.



How Does a Master CDA Affect Timelines?



Christine Mackay, PhD, RN¹; Jessica W. King, CCRA²

¹University of Kansas Cancer Center; ²Covance, Inc.

Background

This study feasibility process usually starts with the sponsor (SP) or clinical research organization (CRO) establishing a confidentiality agreement (CDA). A considerable amount of time is spent between the SP/CRO and the site's legal team negotiating language for a CDA for every study a site takes under consideration.

We believe having a master confidentiality agreement (mCDA) in place can streamline the ability for Covance to share study specific information with University of Kansas Cancer Center (KUCC), thereby reducing time and site administrative burden, and ultimately decreasing study start-up time.

Goals

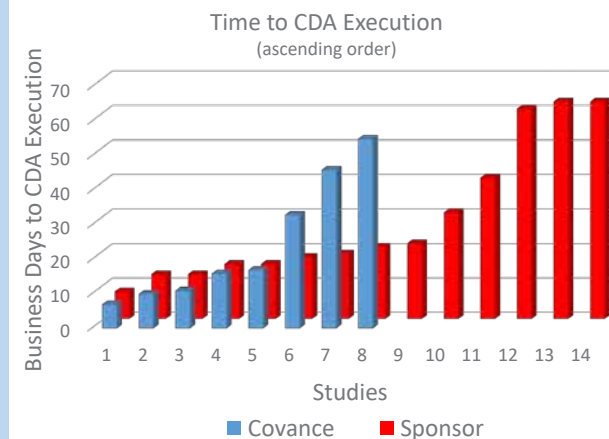
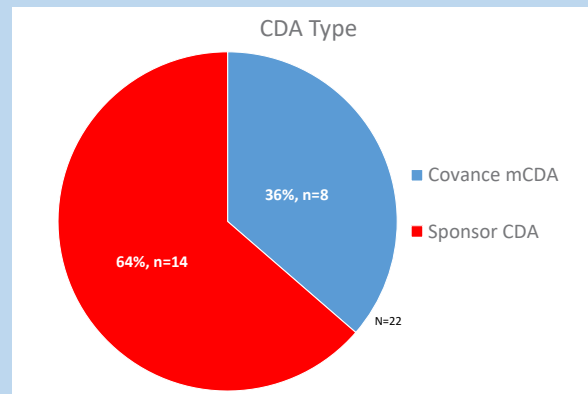
- Reduce the administrative burden on the legal teams at KUCC and Covance by establishing a mCDA.
- Evaluate the acceptance rate by sponsors for using the Covance mCDA.
- Compare the time to confidentiality agreement execution between using the mCDA versus using a sponsor specific CDA.

Methods

KUCC and Covance negotiated and executed a mCDA (renewed in 2018). The mCDA includes a one-page addendum template which requires trial specific information for each new opportunity. From July 1, 2018 through June 23, 2019, there were twenty-two (22) study opportunities meeting these evaluation criteria:

- Covance approached KUCC with new a trial opportunity.
- Covance discussed with SP mCDA use.
- KUCC did not have mCDA with SP.
- Trials in which KUCC expressed interest.
- Trials for which CDAs were executed.

Results



Avg. days to CDA execution: Covance 24, Sponsor 29

Lessons Learned

- With the establishment of a mCDA, Covance was able to initiate trial discussions with KUCC an average of **5 business days faster** than when the mCDA was not used.
- Most (63%) of the mCDA addendums were executed in 17 business days or less.

Of note, one SP required its own CDA, which was a standard template previously used with KUCC. When these studies (n=4) were excluded, the time for SP CDA execution increased to 35 days.

Future Direction

- Continue to capturing the acceptance rate of the Covance mCDA.
- Evaluate how the time to CDA execution may correlate with the time to study activation.
- Consider analyzing the detailed timepoints of non-mCDA negotiations as support for increasing mCDA acceptance

We would like to acknowledge the University of Kansas Medical Center Research Institute staff for their work in negotiating and executing the master CDA .

Contacts: Chris Mackay cmackay@kumc.edu; Jessica King Jessica.king@covance.com

Value of Centralized Pre-study Process

A. Roberts, S. Davidson, N. Streeter, C. Mackay

The University of Kansas Cancer Center

1. Background

Principal Investigators (PIs) and research sites are contacted in multiple ways when Sponsors or Contract Research Organizations (herein referred to collectively as “sponsor”) are seeking sites for participation in a clinical trial. Prospective sites may be excluded from consideration if response to these initial inquiries are delayed or missed, thus decreasing the availability of cutting-edge research to patients. Additionally, when study start up materials are sent to multiple individuals, this causes confusion and further delay. Finally, for studies that do not align with the Cancer Center’s mission, resources may be needlessly spent evaluating these studies.

2. Goals

- Develop a single point of contact for sponsors to facilitate communication about new study opportunities
- Decrease the possibility of a new opportunity being missed
- Streamline the new opportunity process to alleviate the number of emails sent to PIs and study team members

3. Solutions and Methods

A central email address, KUCCNewOps@kumc.edu, for receiving all new study opportunities was established and serves as a single point of contact for sponsors. This email account is managed by the New Opportunities (NewOps) team which acknowledges receipt of the trial opportunity, tracks and stores information about the trial, and records the trial’s eventual outcome.

4. Outcomes and Future Directions

The central email address has been used to collect feasibility and study start up documentation, including final protocols, regulatory documents, study manuals, and contract/budget templates. These items are readily available to the appropriate study team member for access throughout the study start-up phase.

Throughout 2018, there were 476 new trial opportunities managed by the NewOps team. By the end of the year:

87 trials had been reviewed and approved to move forward by the disease groups. Approval to move forward requires discussion of the full protocol by the proposed Principal Investigator and discussion of how the new trial fits into the group’s overall trial portfolio. 119 trials were still in the start-up process (not yet reviewed by the disease groups).

270 trials were not pursued (see graph)

Over half (56.7%, n=270) were not pursued, due to numerous reasons.

Utilizing a single point of contact for managing all study start up from initial contact through site selection further facilitates timely and consistent communication with the sponsor. In addition, this provides a uniform method for internal teams to access the study materials easily throughout the internal approval process.

Cancer Centers should be aware of how potential studies fit into their mission, while PIs and their study teams should consider thoroughly evaluating new study opportunities to ensure successful participation.

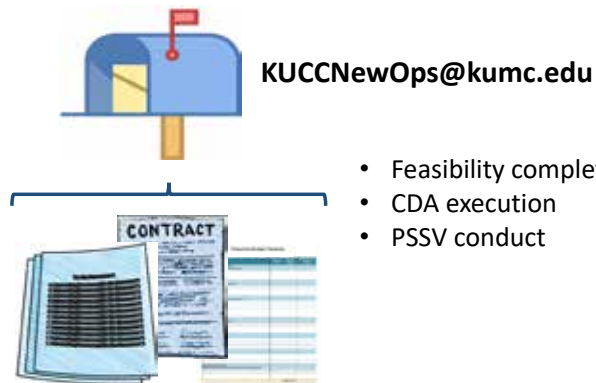
Background

Principal Investigators (PIs) and research sites are contacted in multiple ways when Sponsors or Contract Research Organizations (collectively as “sponsor”) are seeking sites for trial participation. Prospective sites may be excluded from consideration if response to these initial inquiries are delayed or missed. Additionally, when study start up materials are sent to multiple individuals, confusion and further delay may occur. Finally, for studies that do not align with the Cancer Center’s mission, resources may be needlessly spent evaluating these projects. To address these issues we propose a centralized pre-study process.

Goals

- Develop a single point of contact to facilitate communication about new study opportunities
- Streamline the process to alleviate the number of emails sent to PIs and study team members
- Ensure new opportunities match the Cancer Center’s mission Increase efficiencies of site selection process

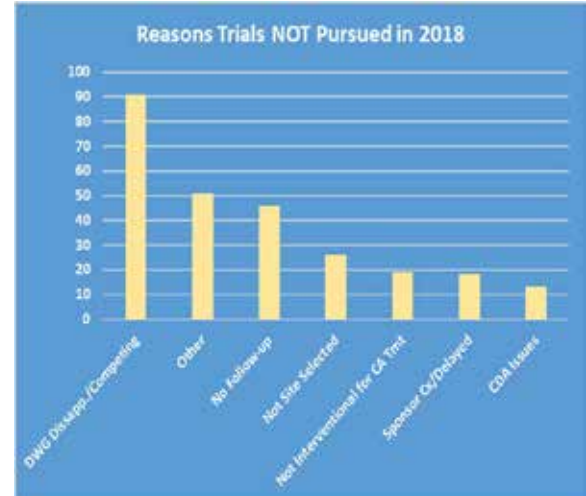
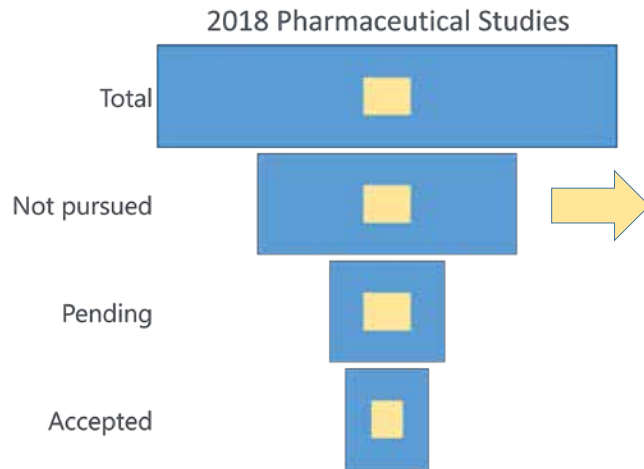
Method



Lessons Learned

Establishing a single point of access for sponsors with new study opportunities has allowed the KUCC NewOps team to facilitate timely and consistent communication focused on operational timelines. Following this process has eliminated the need for disease groups to spend time reviewing trials that do not align with their research interests and trial portfolios. The team will continue capturing these metrics to evaluate how this process relates to overall study activation timelines.

Outcomes



Graphic acknowledgements: VectorStock.com, 123RF.com, Template Lab

Enhancing the Voice of Clinical Research Staff in the Trial Feasibility Process

A. Daniels, A. Anderson, A. Ivey, T. George, L. Pettiford

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. In many cases, trial success is contingent upon performance of a thorough feasibility assessment during the protocol activation process. Underperforming trials occupy significant CRO resources (personnel, financial, material) creating operational barriers and limiting the activation of new trials. At UFHCC, studies not meeting accrual goals (locally defined as 50% of the annual accrual goal) are subject to closure by the Scientific Review and Monitoring Committee (SRMC). Investigators often do not understand the staff investment in activation and study maintenance (estimated as 150 hours for activation alone) and the impact underperforming studies have on staff workload and morale. A review of approximately 300 studies completed between 2007 and 2017 demonstrated that 60% of trials failed to meet at least 25% of their local target accrual, most due to misalignment with available patient populations. To combat this issue, the UFHCC CRO created the Feasibility Group (FG) with membership comprised of CRO personnel to ensure that research staff have a voice in assessing and choosing trials for the center.

2. Goals

- Decrease the number of trials terminated due to low accrual and other logistical barriers
- Establish a forum for formal review of trials at the CRO staff level to provide a voice to the personnel ultimately managing these trials

3. Solutions and Methods

The CRO Feasibility Group was established in late 2017 to provide decision support to Disease Site Groups (DSGs) in determining if trials were feasible in terms of available patient population, logistics and financing. All trials are eligible for FG review at the request of the DSG; however, FG reviews are mandatory for any interventional trial that will be supported with direct dollars or in-kind support by the UFHCC. The FG is composed of CRO leadership with the input of CRO research managers and clinicians who would assume responsibility for the execution of the trial if approved and activated. The FG review includes assessment of tumor registry and clinical records as well as review of prior accrual performance of studies enrolling similar patient populations. Logistical factors involving clinical facilities and staffing, such as prolonged infusions, frequent patient monitoring and multiple blood draws requirements, as well as study funding, are analyzed. FG reviews may lead to the DSG abandoning the trial, modifying enrollment goals, enlisting additional enrollment sites, and/or requesting additional financial support from external sponsors or the UFHCC. The FG review results in non-binding recommendations to DSG leaders and investigators.

4. Outcomes and Future Directions

This innovative forum has allowed clinical and logistical concerns to be voiced by individuals who will be involved in the trial conduct. While concerns with the additional layer of review were voiced, activation timelines have shortened. Attendees are able to openly discuss concerns and prior experiences as part of FG deliberations. Since deployment, the FG has reviewed a total of 77 trials, with a recommendation for 82% of those trials to be feasible.

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. In many cases, trial success is contingent upon performance of a thorough feasibility assessment during the protocol activation process. Underperforming trials occupy significant CRO resources (personnel, financial, material) creating operational barriers and limiting the activation of new trials. At UFHCC, studies not meeting accrual goals (locally defined as 50% of the annual accrual goal) are subject to closure by the Scientific Review and Monitoring Committee (SRMC). Investigators often do not understand the staff investment in activation and study maintenance (estimated as 150 hours for activation alone) and the impact underperforming studies have on staff workload and morale. A review of approximately 300 studies completed between 2007 and 2017 demonstrated that 60% of trials failed to meet at least 25% of their local target accrual, most due to misalignment with available patient populations. To combat this issue, the UFHCC CRO created the Feasibility Group (FG) with membership comprised of CRO personnel to ensure that research staff have a voice in assessing and choosing trials for the center.

GOALS

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- Establish a forum for formal review of trials at the CRO staff level to provide a voice to the personnel ultimately managing these trials.

SOLUTIONS & METHODS

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- Tumor registry and clinical records as well as review of prior accrual performance of studies enrolling similar patient populations;
- Logistical factors involving clinical facilities and staffing, such as prolonged infusions, frequent patient monitoring and multiple blood draws requirements;
- Study funding and Medicare Coverage Analysis

FG reviews may lead to the DSG abandoning the trial, modifying enrollment goals, enlisting additional enrollment sites, and/or requesting additional financial support from external sponsors or the UFHCC. The FG review results in non-binding recommendations to DSG leaders and investigators (**Figure 1**).

OUTCOMES

This innovative forum has allowed clinical and logistical concerns to be voiced by individuals who will be involved in the trial conduct. While concerns with the additional layer of review were voiced, activation timelines have shortened. Attendees are able to openly discuss concerns and prior experiences as part of FG deliberations. Since deployment, the FG has reviewed a total of 77 trials, with a recommendation for 82% of those trials to be feasible.

Figure 1 – Protocol Activation Workflow



CONTACT

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Increasing Activation Transparency With Research Insights Dashboards

E. Rocco, N. Licht, N. O'Dell, R. Arzoumanian, T. Johnson

Yale Cancer Center, Yale School of Medicine

1. Background

In 2016, the Yale School of Medicine and the Yale Cancer Center (YCC) identified clinical trial activation timelines as a strategic improvement opportunity. The intended goal of improving activation timelines is to advance medical care and research, to enhance Yale's position as a competitive Medical School and Comprehensive Cancer Center, and to ultimately improve patient access to clinical trials within the Yale Medicine network. The Protocol Activation Cycle Empowerment (PACE) team is working with Forte to build a tool for displaying study activation progress in real-time for the investigators, disease teams and sub-process owners. Data for each activation sub-process are expected to be entered in real-time into OnCore, Yale's Clinical Trial Management System. These data are then displayed as interactive charts called "Protocol Activation Dashboards" in Research Insights.

2. Goals

The goal of implementing the activation dashboards is to increase the data transparency between the PACE team, sub-process owners, disease teams, study teams, departmental and Cancer Center leadership. Real-time availability of the data provides study team members the opportunity to identify roadblocks and challenging steps within the activation process and address them appropriately to ensure that the protocol activation timeline proceeds on schedule.

3. Solutions and Methods

The PACE project team recently introduced three study activation dashboards. The first dashboard offers a past performance view to assess the time it takes to complete an activation sub-process compared to the target duration. The second dashboard offers a portfolio view to assess how protocols in a disease team's portfolio are progressing towards study activation in comparison to the expected target durations. The third dashboard offers a protocol-specific view to assess how each sub-process is progressing for a selected protocol compared to the target durations.

4. Outcomes and Future Directions

To date, 49 stakeholders have been provided access to the protocol activation dashboards. The PACE team attended several disease team meetings, clinical trial manager meetings and cancer center leadership meetings to orient users to the dashboard system and to demonstrate features and functionality. The disease teams have started to incorporate the dashboards into their weekly protocol review discussions. Yale looks forward to incorporating feedback from the investigators, the research teams, and from leadership to further optimize the current dashboards and create additional dashboards as needed. In the future, the activation task list structure will be rolled out to all departments within the Yale School of Medicine.

- Quick access to information related to the output of your program, teams, department and institution as a whole
- Turnkey, intuitive dashboards deliver meaningful insights, with in-depth analysis of past performance, current state and projected outcomes
- Visualizations to help you make informed, proactive decisions and take your research operations to the next level
- Leverage OnCore data to get a comprehensive view into your research portfolio and ensure your organization is moving in the right direction

Background

In 2016, the Yale School of Medicine and the Yale Cancer Center (YCC) identified clinical trial activation timelines as a strategic improvement opportunity. The intended goal of improving activation timelines is:

- advance medical care and research,
- enhance Yale's position as a competitive Medical School and Comprehensive Cancer Center, and
- ultimately improve patient access to clinical trials within the Yale Medicine network.

The Protocol Activation (PAct) Team worked with Forte to build a tool for displaying study activation progress in real-time for the investigators, disease teams and sub-process owners. Data for each activation sub-process are expected to be entered in real-time into OnCore, Yale's Clinical Trial Management System. These data are then displayed as interactive charts called "Protocol Activation Dashboards" in Research Insights.

Goals

The goal of implementing the activation dashboards is to increase the data transparency between the PAct team, sub-process owners, disease teams, study teams, departmental and Cancer Center leadership. Real-time availability of the data provides study team members the opportunity to:

- provide transparency to where a study is in the activation process
- ensure studies continue to move through the activation process
- identify any roadblocks and challenging steps within the activation process

Methods

The PAct project team introduced three study activation dashboards:

Study Activation: Past Performance
Offers a past performance view to assess the time it takes to complete an activation sub-process compared to the target duration.

Study Activation: Portfolio Task List
Offers a portfolio view to assess how protocols in a disease team's portfolio are progressing towards study activation in comparison to the expected target durations.

Study Activation: Protocol Task Lists
Offers a protocol-specific view to assess how each sub-process is progressing for a selected protocol compared to the target durations.

Outcomes

- To date, 60 stakeholders have been provided access to the protocol activation dashboards.
- The PAct team is integrated into disease team meetings, clinical trial manager meetings and Cancer center leadership meetings
- The disease teams have started to incorporate the dashboards into their weekly protocol review discussions.

Lessons Learned and Future Direction

Yale looks forward to incorporating feedback from the investigators, the research teams, and from leadership to further optimize the current dashboards and create additional dashboards as needed. In the future, the activation task list structure will be rolled out to all departments within the Yale School of Medicine.

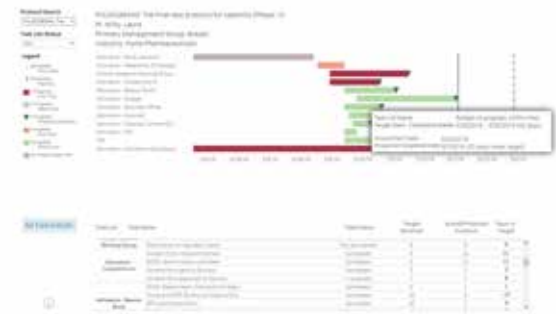
Study Activation : Past Performance*



Study Activation : Portfolio Task Lists*



Study Activation : Protocol Task Lists*



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*Sample Data

Acknowledgment: Yale Center for Clinical Investigation and the Clinical and Translational Science Award Grant Number: UL1 TR001983 from the National Center for Advancing Translational Science (NCATS), a component of the National Institutes of Health (NIH).

Empowering Study Teams to Improve Clinical Trial Activation Timelines

E. Rocco, N. Licht, N. O'Dell, T. Johnson, R. Arzooonian

Yale Cancer Center, Yale School of Medicine

1. Background

In 2016, the Yale School of Medicine and Yale Cancer Center (YCC) identified clinical trial activation timelines as a strategic improvement opportunity. The intended goal of improving activation timelines is to advance medical care and research, to enhance Yale's position as a competitive Medical School and Comprehensive Cancer Center, and to ultimately improve patient access to clinical trials within the Yale Medicine network. An initial activation analysis was conducted which included input from more than 100 stakeholders. The analysis resulted in the identification of 43 areas for improvement and the creation of the Protocol Activation Cycle Empowerment (PACE) project. A pilot of all YCC trials opened since December 2017 have utilized this strategy-driven business process.

2. Goals

The overall goal of the PACE project is to improve timelines so that clinical trial activation occurs within 90 calendar days. The PACE team identified 13 sub-processes that play a key role in activating a new clinical trials and developed OnCore Task Lists for each sub-process. Currently, the PACE team is working with a designated owner for each sub-process to identify the tasks that start and end their sub-process, to identify co-dependencies with other sub-processes, and to review actual and target durations for their sub-process.

In addition to individual sub-process timelines, PACE also monitors the overall time to activation for each protocol from the date that feasibility is complete and from the date of Protocol Review Committee (PRC) submission. The target durations for study activation range from 55 to 130 calendar days, depending on the Institutional Review Board (IRB) of record and the type of contract agreement. Clinical trials that utilize an external, commercial IRB and pre-negotiated Master Agreement language are assigned shorter target durations compared to trials utilizing new contract language.

3. Solutions and Methods

To date, the PACE team has developed and implemented new activation task lists for each sub-process, developed data definitions for each task field, implemented several communication strategies to relay activation metrics to stakeholders, and held meetings with sub-process owners, regulatory managers, and disease-aligned study teams to ensure a bidirectional flow of information. These efforts have resulted in a coordinated approach to study activation with an eye on efficiency and process improvement.

4. Outcomes and Future Directions

There was a notable decrease in activation timelines since the initiation of PACE. Metrics show that between 2017 and 2018 the overall clinical trial activation timelines were decreased by 30 calendar days.

The PACE project is an ongoing endeavor which continues to evolve based on the data trends. As the project matures, the data will more fully demonstrate how implementation of PACE initiatives impacts study activation. PACE is actively working with sub-process owners and disease teams to identify and address additional areas for improvement.

Background

In 2016, the Yale School of Medicine and Yale Cancer Center (YCC) identified clinical trial activation timelines as a strategic improvement opportunity to:

- advance medical care and research,
- enhance Yale's position as a competitive Medical School and Comprehensive Cancer Center, and
- expand patient access to clinical trials within the Yale Medicine network.

An initial activation analysis included input from more than 100 stakeholders, which resulted in the identification of 43 areas for improvement and the creation of an internal Protocol Activation (PAct) Team. A pilot of all YCC trials opened since December 2017 has utilized newly established processes and metric tracking (over 130 protocols to-date).

Goals

- **Empower research teams to improve start-up timelines in order to consistently achieve clinical trial activation within 90 calendar days from Protocol Review Committee (PRC) submission.**
- **Optimize 13 individual activation sub-processes**
 - Establish tasks that start and end each sub-process
 - Identify co-dependencies with other sub-processes
 - Review actual and target durations for each sub-process
- **Decrease overall time to activation (TTA), to achieve current target timelines (Table 1)**

Table 1: Target calendar days from PRC submission to open to accrual

Master Contract Agreement; External IRB	55
Master Contract Agreement; Internal IRB	60
Existing Contract Agreement; External IRB	75
Existing Contract Agreement; Internal IRB	75
New Contract Agreement; External IRB	130
New Contract Agreement; Internal IRB	130
Cooperative Group/NCI; CIRB	55

Methods

Sub-process workflows translated into **OnCore Activation Task Lists (Table 2)**

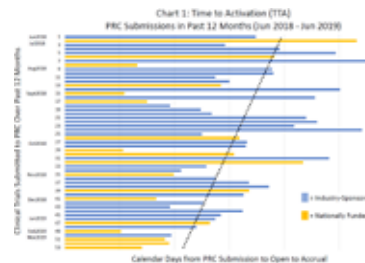
- Track completed tasks and achieved milestones
- Feed into custom protocol activation dashboards

Table 2: OnCore Activation Task Lists [Number of Tasks]

Study Decision [5]	Internal IRB [5]
Feasibility [10]	Internal IRB Contingencies [4]
Consent Form [4]	Internal IRB Deferred [5]
OnCore Build [36]	External IRB [3]
Beacon Build [9]	CIRB [5]
Protocol Review Committee (PRC) [6]	Negotiate Contract (Master/Existing/New) [3]
Radiation Safety Committee [6]	Execute Contract (Master/Existing/New) [3]
Institutional Biosafety Committee [4]	Budget [7]
Human Research Protection Program [3]	Business Office [3]
	Activation [20]

Monitoring of the **overall time to activation (TTA)** for each protocol (Chart 1)

→ Decrease in median TTA seen for trials submitted to PRC June 2018 through June 2019



Outcomes

- Creation of an internal Protocol Activation (PAct) Team
- Implementation of 19+ new activation task lists in OnCore
- Development of data field definitions for over 100 task fields
- Concurrent PRC and HRPP submissions for industry sponsored and authored protocols
- Regular meetings with sub-process owners, regulatory managers, and disease-aligned study teams to ensure a bidirectional flow of information

There has been a notable decrease in activation timelines since the initiation of the YCC Pilot with the PAct Team. Metrics show that between 2017 and 2018, the overall clinical trial activation timelines decreased by 19 calendar days. As of June 2019, the TTA median for protocols submitted to PRC in 2019 is 96 calendar days.

Future Direction

- Continue working with sub-process owners and disease teams to identify and address additional areas for improvement
- Continue attending oncology research team meetings to present metrics and identify bottlenecks for pending trials in real time
- Currently finalizing a number of **additional process improvements**, based on stakeholder feedback:
 - Implementing Centralized Medicare Coverage Analysis
 - Streamlining submission processes to ancillary committees
 - Optimizing treatment plans in Epic Beacon
 - Tracking of IND submissions associated with investigator-initiated trials
 - Expanding access to dashboards and enhance metric reporting

The Protocol Activation (PAct) project is an ongoing endeavor which continues to evolve based on the data trends. As the project matures, the data will more fully demonstrate the impacts on study activation timelines



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