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FOR CANCER PATIENTS



2018 ABSTRACTS AND POSTERS

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10th Annual AACI CRI Meeting

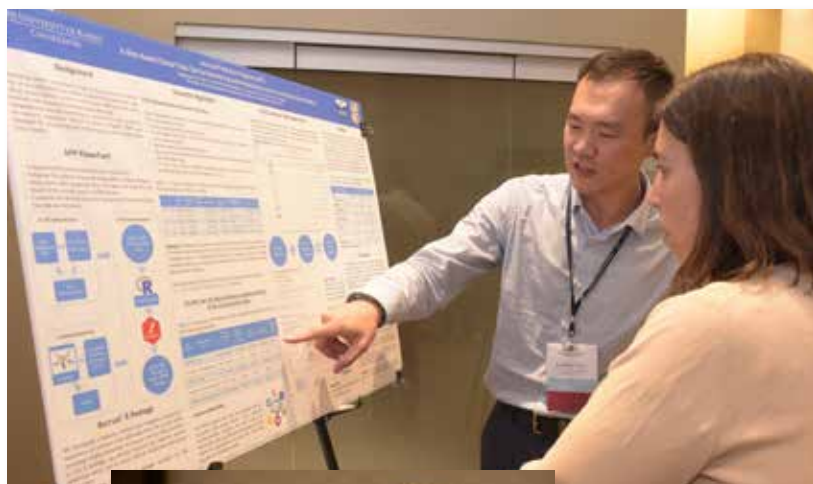


The Association of American Cancer Institutes (AACI) comprises 98 leading cancer centers in North America. AACI's membership roster includes National Cancer Institute (NCI)-designated centers and academic-based cancer research programs that receive NCI support.

Participation in CRI has grown since 2009, from 83 individuals from 47 cancer centers attending the first meeting, to 405 attendees from 75 centers at the 10th annual meeting, held July 11–12 in Chicago. The CRI listserv reaches 650 individuals from 85 AACI cancer centers, fostering daily interaction among clinical trials office colleagues from various institutions.

Recognizing CRI's longevity, consistent growth, and established brand, the program's name was officially changed in late 2018 to **Clinical Research Innovation**. While the name has changed the goals of CRI remain the same.

The abstract presentations and poster session were among the highlights of this year's meeting, providing opportunities for centers to further discuss concepts that are being explored and implemented at cancer centers to solve common operational problems. The AACI CRI Steering Committee thanks everyone who submitted an abstract for review; the concepts demonstrated creative and thoughtful methods being used at cancer centers to address clinical trial process issues.



In 2009, AACI established a network for cancer center clinical research leaders, the AACI Clinical Research Initiative (CRI), to address obstacles to activating and conducting cancer clinical trials. Challenges include the growing complexity of clinical trials, expanding staffing requirements, administrative barriers, rising trial costs, regulatory constraints prolonging trial activation, and lagging patient accrual.

CRI examines and shares best practices that promote the efficient operation of cancer center clinical research facilities and that leverage the ability of AACI cancer centers to advocate for improvement in the national clinical trials enterprise. A steering committee composed of clinical trial administrators and medical directors guide CRI's activities, leading to dissemination of best practice models across the AACI cancer center clinical trials network.



Leveraging Change to Advance Cures for Cancer Patients



THIS YEAR THE CRI STEERING COMMITTEE RECEIVED 68 ABSTRACTS, MORE THAN TWICE AS MANY AS LAST YEAR.

AACI's CRI convened its 10th annual meeting in July in Chicago. The 2018 meeting covered two full days and was attended by more than 400 clinical research office leaders, medical directors, cancer center administrators, and representatives from the NCI and industry.

This year's meeting theme was "Leveraging Change to Advance Cures for Cancer Patients." With more than 10 years of management and consulting experience in a variety of mid-sized, Fortune 500 companies, along with academic experience in program design and innovation, Kimberly S. Scott, PhD, of Northwestern University, delivered a talk on the guiding principles of change. Her presentation was informed by insights from research and cutting-edge practice in facilitating organizational change.

The AACI CRI annual meeting is designed to improve the clinical research process; understand the global impact of conducting clinical research in the United States, Canada, and abroad; discuss trends in clinical trials safety and compliance; and recommend policies to promote staff retention at the cancer centers. To help achieve these goals, the meeting offers many opportunities to share ideas including panel discussions, breakout sessions led by peers, and poster presentations.

This year the CRI steering committee received 68 abstracts—more than twice as many as last year—from 30 AACI cancer centers. Many abstracts reflected collaborations between AACI cancer centers and industry partners as well as AACI sustaining members. Three winning abstracts, as selected by the steering committee, come from authors representing the University of Cincinnati Cancer Institute; Rutgers Cancer Institute of New Jersey; and Sylvester Comprehensive Cancer Center, University of Miami Health System.

Panel discussions delved into CRI objectives such as developing better methods for disseminating information across cancer centers; identifying and addressing clinical research challenges; and measuring progress with conducting trials at the main cancer center and community network practice sites.

One session examined lessons learned by experienced investigators for developing and managing an investigator initiated trial requiring Investigator New Drug (IND) application. The presentation listed common errors made by investigators. Another talk laid out five guidelines for successful IND management.



Panelists for a session on integrating clinical research into clinical care suggested best practices that can ease the burden of conducting cancer clinical research studies. They also discussed trial recruitment procedures, completing trial management tasks during patient visits, documenting trials care in the electronic medical record, and managing safety while providing timely appointments and patient care.



Response Evaluation Criteria in Solid Tumors (RECIST), the standard for providing objective, accurate, and reproducible tumor evaluations to measure a patient's response to cancer treatment, was the focus of another session. Panelists described how cancer centers implement various methods to obtain tumor evaluations for research trials (e.g., imaging software to evaluate radiology digital content, centralized radiology reviewers for providing research patient radiology assessments, integrating a dedicated radiologist into the cancer program). Costs and reimbursement structures and the pros and cons of each method were also examined.



Breakout sessions at the meeting covered four areas of interest: NCI's National Clinical Trials Network; Disaster Preparation at Clinical Trials Offices; Operationalizing Clinical Trials at Satellite Locations; and Anticipating Financial and Therapeutic Toxicities for Patients in Complex Clinical Trials.

2018 AACI CRI Steering Committee Members

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First Place

Building a Strong Foundation: How Leveraging Cross Collaboration Can Improve Standardization and Adoption of an eRegulatory Solution

Trisha Wise-Draper, MD, PhD¹; Justin Osborne¹; Benjamin Quast, MBA, CCRP¹; Emily Werff¹; Michael Hurley, MBA²

¹University of Cincinnati Cancer Institute; ²Complion

Describe the background of the problem:

Adoption of electronic regulatory (eRegulatory) systems offer an opportunity to reduce paper-based processes, improve turn-around times, and streamline access to study documents for Cancer Centers and clinical research groups.

However, in larger institutions, lack of centralization means adoption of eRegulatory systems often occurs at the department level. Furthermore, therapeutic groups organize and manage their documents differently, in the manner most efficient for their respective use. Utilization of disparate systems and inconsistent document naming and organization results in lack standardization across the research enterprise and inefficient internal reviews.

A collaborative implementation approach when defining and implementing regulatory document standards represents an opportunity to ensure buy-in and adoption across the organization to improve compliance, teamwork and transparency.

Provide metrics or goals to be achieved:

- Define Standards: Develop standard regulatory documents and processes to promote consistency across teams conducting clinical trials
- Streamline Adoption: Improve the adoption of an enterprise eRegulatory solution across therapeutic groups by engaging stakeholders in the standards development process to minimize changes between teams and departments
- Improve Access: Improve and control clinical trial stakeholder access to regulatory documentation based on an enterprise wide authorization program.

Describe the solutions or methods implemented:

1. Invited key personnel from centralized clinical trial office to regularly meet through creation of the regulatory template and standards.
2. Leveraged a recommended best practices eRegulatory binder template and document naming conventions developed by Complion based on the experience of working with over ten NCI designated Cancer Centers.
3. Defined a common template and nomenclature ensuring standards were broadly applicable to the rest of the organization.

Describe the outcome or show data representing a change (positive or negative):

- Established standard regulatory binder template, considerations taken for:
 - Varying process differences from department to departments (e.g. safety reports)
 - Identifying best practices used throughout the institution
 - Future needs and possibilities for growth of department and organization
- Identified new processes or SOPs to facilitate sharing of ideas
 - A particular area of focus was the Delegation of Authority (DOA) which was designed to be an institutional DOA instead of individual per study.
- Promoted standardization to ensure consistent use and compliance.
- Improved collaboration by proactively identifying and addressing areas of inconsistency or variance between departments to support of common organizational goals.
- Enhanced compliance as the central office can look at trends and quality metrics across functional areas and therapeutic areas to inform business decisions or process improvements.

Address lessons learned and future directions:

- Roll-out to additional therapeutic teams starting with teams with larger infrastructure and regulatory staff and move to smaller departments as standardization increases
- Larger time commitment on the project team to finalize the standards and processes
- Don't reinvent the wheel - Leveraging best practices can get you 75% of the way there. Successful coordination with other internal stakeholders can get you another 20% with the final 5% of effort being comprised of the remaining outstanding comments and feedback.
- Important to take any standard that was developed outside of your organization and tailor it using the terms familiar to those at your institution.



IN SCIENCE LIVES HOPE.

Building a Strong Foundation: How Leveraging Cross Collaboration Can Improve Standardization & Adoption of an eRegulatory Solution

University of Cincinnati Cancer Institute, UC Health, Complion, Inc. ²

Trisha Wise-Draper¹, Justin Osborne¹, Benjamin Quast¹, Emily Werff¹, Michael Hurley²

OVERVIEW: The University of Cincinnati Cancer Institute (UCCI) collaborated with the UC Health Office of Clinical Research (OCR) to rollout out an eRegulatory system based on an NCI Standard from Complion. The UCCI Cancer Standard was leveraged to create a Non-Cancer Standard and rollout to the University.



20% of final standard was identified through collaboration

Process Tips

- Start with an NCI Standard
- Collaborate with other departments and Institutional Stakeholders
- Partner with a vendor who leverages previous experience to provide a standard from which to build

This process was an investment in time and effort as the knowledge gained through collaboration was invaluable. The ability to deeply explore existing processes uncovered knowledge and enabled the project team to visualize what future outcomes will look like.

2

Second Place

It Takes a Village - Onboarding Clinical Trials Staff at an NCI-Designated Comprehensive Cancer Center

Ginnette Watkins-Keller, MSN, RN, OCN; Tracie K. Saunders, MS, RN, CCRC, OCN; René Kurz, DNP, MSN, FNP-BC

Rutgers Cancer Institute of New Jersey

Describe the background of the problem:

The Office of Human Research Services (OHRS) was established to provide Rutgers Cancer Institute of New Jersey (RCINJ) investigators with centralized resources, information and expertise in clinical research. Training and retention of staff with specialized skills is critical to implementing and maintaining these operations. In 2016, the leadership of OHRS identified the need for improving its onboarding process due to a significant departure of staff for the past several years. In the summer of 2016 a new position, a Clinical Trial Educator was created. The principal responsibilities of this newly created position include the onboarding, training, and development of staff.

Provide metrics or goals to be achieved:

Goal: To improve the retention of OHRS staff by initiating a comprehensive onboarding program.

Describe the solutions or methods implemented:

The OHRS Clinical Trials Educator collaborated with RCINJ Education Assistant Director to develop a comprehensive onboarding program, not only for OHRS but also for RCINJ Clinical Operations. In addition, a formal preceptor program was developed to assist in staff to understand their role in training new orientees. The onboarding program is three months in length and includes:

- Two-day mandatory orientation program for all new staff
 - This is an opportunity for new orientees to begin to develop interprofessional relationships.
- Weekly 2-hour re-cap and education meetings for eight weeks.
 - In-depth educational topics presented
 - Opportunities to meet with educator and other orientees to discuss challenges and opportunities experience throughout the week

- Competency-based Orientation Checklist for each job description
- Pairing of new orientees with preceptors
- Weekly meetings with orientees and preceptors
- Formal 3-month meeting at the end of the onboarding process

Describe the outcome or show data representing a change (positive or negative):

Improvement of retention of OHRS staff has been seen. In 2013 through 2016 the total number of staff lost to attrition was 66. Since the implementation of the new OHRS Onboarding program in October 2016, 34 staff has participated in this program. Of the 34 new staff, 28 continue to be active staff, two were terminated for performance issues that were identified early in the onboarding program, and four left to pursue careers at pharmaceutical companies (this continues to be a challenge we are looking at ways of improving).

Address lessons learned and future directions:

We have learned a few lessons from this experience. First, we continue to experience attrition to the pharmaceutical industry, and we are currently looking at ways to improve this. Second that we are in need of more preceptors that have received training on how to be a preceptor. We will be addressing this by holding future preceptor workshops to meet this need. Finally, creating this program has helped to standardize our onboarding process not only at OHRS, but also throughout RCINJ. Future directions for this program include creating ongoing continuing education for all clinical trial topics for both the clinical trials staff at RCINJ and partner sites throughout New Jersey.

It Takes a Village – Onboarding Clinical Trial Staff at a NCI - designated Comprehensive Cancer Center

Ginnette Watkins-Keller, RN, MSN, OCN; Tracie K Saunders MS, RN, OCN; Renéé Kurz, DNP, FNP-BC, AOCNP



BACKGROUND

In the Office of Human Research Services (OHRS) at Rutgers Cancer Institute of New Jersey (RCINJ), our mission is to conduct state of the art clinical trials. OHRS relies on retaining staff that has a unique knowledge set of clinical trials research and oncology to help fulfil this mission. In 2016, the leadership of OHRS identified the need for improving its onboarding process due to attrition, as well as departmental growth. Exit interviews revealed employees transferred to other positions within Rutgers, felt they received insufficient orientation experience, challenges understanding expectations of the job, and obtained positions in the pharmaceutical industry. The first area that management felt that could have an immediate impact was improving the onboarding experience and training. Before 2016, there had not been a formal orientation program in OHRS. In the summer of 2016 a new position, Clinical Trial Educator was created. One principle responsibility of this newly created position would be the onboarding, training, and development of staff.

GOALS & OBJECTIVES

To improve the retention of OHRS staff by initiating a comprehensive onboarding program.



METHODS

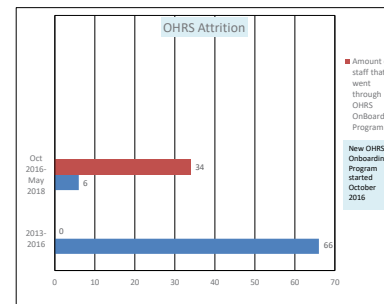
The OHRS Clinical Trials Educator in conjunction with RCINJ Education Assistant Director worked together to develop a comprehensive onboarding program, not only for OHRS but for RCINJ Clinical Operations. In addition, a formal preceptor program was developed to assist staff in understanding their role in training new orientees. Components of the onboarding training program include:

- Two-day mandatory orientation program for all new staff
 - This is an opportunity for new orientees to develop interprofessional relationships.
 - Clinical staff clearly understand the mission and vision of a NCI-designated cancer center
- Weekly 2 hour re-cap and education meetings for eight weeks.
 - In-depth educational topics presented
 - Opportunities to meet with educator and other orientees to discuss challenges and opportunities experienced throughout the week
- Newly hired employees receive a 3 month orientation
- Orientation Checklist developed for every job description
- Pairing of new orientees with preceptors
- Weekly meetings with orientees and preceptors
- Formal 3-month meeting at the end of the onboarding process
- Purchased web-based learning management system
 - Created customized clinical trials training modules
 - Organized modules into job-specific bundle packs.



OUTCOME

Improvement of retention of OHRS staff have been seen. In 2013 through 2016 there have been 66 staff that have left RCINJ for a variety of different reasons. The staff that left during this time did not go through a formal orientation program. Since the implementation of the OHRS Onboarding program in October 2016, 34 staff have participated in this program. Of the 34 new staff, 28 continue to be active staff, two were terminated for performance issues that were identified early in the onboarding program, and four left to pursue careers at pharmaceutical companies.



END OF ORIENTATION SURVEY – PARTICIPANT RESPONSES

“Being able to meet weekly with the educator was very helpful! It gave me an overview of my own goals, that way I knew what I should be learning for that week.”

“Very useful.”

“The feedback from management was encouraging. The checklist was useful in familiarizing myself with the process. My colleagues were great sources for information.”

“This was a great idea, made my orientation process easy.”

“The orientation checklist was very helpful in guiding my goals during my beginning period. Evaluations were beneficial in providing feedback on improvement areas.”

“This is a well developed program.”

DISCUSSION

- Continue to expand to web-based clinical trial education topics for a more comprehensive training experience.
- Working towards providing continuing education credit for all clinical trial education
- All Orientation related documents to be kept in a centralized location on OHRS Intranet Orientation webpage.
- Continue to expand shadowing experiences for all new Orientees
- Continue to offer enduring formal education for OHRS preceptors.
- Development of a Preceptor Checklist and Evaluation Tools
- Looking at ways of improving attrition to pharmaceutical companies
- Continue to develop competency-based orientation checklist for all job description



Orientee and Preceptor

LESSONS LEARNED AND FUTURE DIRECTIONS

We have learned a few lessons from this experience. First, we continue to experience attrition to the pharmaceutical industry, and we are currently looking at ways to improve this. Second that we are in need of more preceptors that have received training on how to be a preceptor. We will be addressing this by holding future preceptor workshops to meet this need. Finally, creating this program has helped to standardize our onboarding process not only at OHRS, but throughout RCINJ. Future directions for this program include creating contact hour education for all clinical trial topics that are taught and to make an adaptation of this program for onboarding clinical trials staff at partner sites.

Winning Abstracts and Posters

3

Third Place

Framework for Strategic Performance Management in an Academic Cancer Center's Research Administration Finance Office

Lauren Gjolaj, RN, BSN, MBA; Avantika Dang, MHA, CSSGB, PMP; Yunie Castillo, MPH; Jorge Contreras, MBA

Sylvester Comprehensive Cancer Center, University of Miami Health System

Describe the background of the problem:

In many institutions faced with rapid growth in clinical trial portfolio, aligning the cost of expansion in infrastructure with collection rates to support growth is challenging. The purpose of this project was to use process improvement tools to create a framework for fiscal sustainability.

Provide metrics or goals to be achieved:

Project goals include:

- Streamline processes to support a focus on billing and collections
- Increase collection rate and financial sustainability for clinical research
- Increase collaboration and transparency between functional units

Describe the solutions or methods implemented:

A Six Sigma Process improvement approach was deployed to evaluate opportunities for improvement. A multidisciplinary taskforce was formed, qualitative and quantitative baseline data was reviewed and a process-mapping exercise was completed. The taskforce completed a root cause analysis to identify process failures, including:

- Lack of technological systems to support decision making
- Rates and revenue not aligned with cost structure
- No standardized internal payment processes causing non value added time spent on internal payment and taking away value added time available to focus on billing and collection processes

Key interventions include:

- Development and implementation of a budget template with rates aligned to cost structure
- Capacity analysis for finance staff and creation of a proactive staffing model
- Implement CTMS finance module to simplify and automate/track invoicing, and allow for reporting capabilities
- Standardize processes for internal payments

Describe the outcome or show data representing a change (positive or negative):

The use of a Six Sigma process improvement approach was effective at meeting initiative goals.

Address lessons learned and future directions:

The team recognizes that using a Six Sigma approach was essential to success in this project and as an organization, as increasing collections allows for further investment in research. Additionally, the team notes that the opportunities addressed were systems and processes to give our team the tools they needed to succeed.

Suggestions for others:

The use of a Six Sigma approach is transferable to other institutions and allows for identification of key process failures that require interventions for optimum performance.

The Sylvester team recommends the following steps to address fiscal sustainability:

1. Form a multidisciplinary taskforce to ensure solution met needs of all stakeholders
2. Obtain quantitative and qualitative data and generate process flow maps to identify baseline performance and process failures. Complete root cause analysis as needed
3. Generate project goals, scope and objectives
4. Use tools such as brainstorming and data analysis to generate interventions that address key process failures
5. Implement interventions
6. Evaluate outcomes
7. Continue to use learning and data to make cyclic improvements

Address lessons learned and future directions:

Process improvement never ends. Sylvester plans to leverage new data gained by implementing CTMS finance system to further streamline processes and ensure fiscal sustainability of clinical research.

Framework for Strategic Performance Management in an Academic Cancer Center's Research Administration Finance Office



Lauren Gjolaj, RN, BSN, MBA, Avi Dang, MHA, CSSGB, PMP, Yunie Castillo, MPH, Jorge Contreras, MBA
Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine

Background

- In many institutions faced with rapid clinical trial portfolio growth, aligning the cost of expansion in infrastructure with collection rates to support growth is challenging.
- The purpose of this project was to use Six Sigma process improvement tools to create a framework for fiscal sustainability.

Goals

Streamline processes to support a focus on billing and collections

Increase collection rate and financial sustainability for clinical research

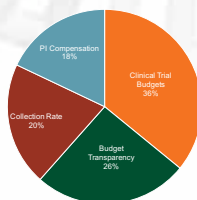
Increase collaboration and transparency between functional units

Methods

A Six Sigma Process improvement approach was deployed to evaluate opportunities for improvement.

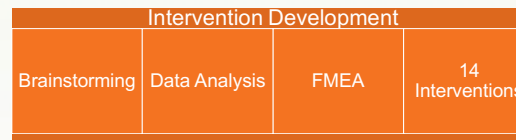


Amalgamation of qualitative data assisted in identifying key themes: Funds Flow Opportunities

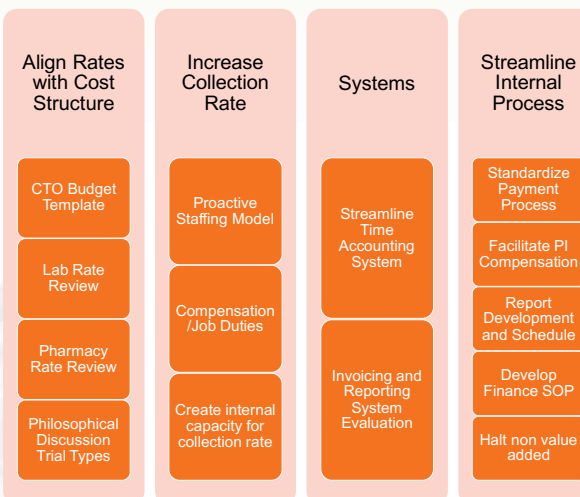


Methods (Cont.)

- After project initiation, process failures were identified including:
- Lack of technological systems to support decision making
 - Rates and revenue not aligned with cost structure
 - No standardized internal payment processes causing non value added time spent on internal payment and taking away value added time available to focus on billing and collection processes



Interventions



Outcomes

Outcomes Achieved	Alignment with Project Goal
Increased collection rates ↑	Financial sustainability
Decreased financial liability associated with research by aligning cost with revenue ↓	Financial sustainability
Decreased and standardized process steps of internal payment ↓	Collaboration and transparency Streamline processes
Increase in value added activity ↑	
Decreased and standardized process steps through planned implementation of a CTMS finance system ↓	Financial sustainability Streamline processes
Streamline existing systems	

Lessons Learned & Future Directions

Lessons Learned	<ul style="list-style-type: none"> Six Sigma approach is transferable to other institutions and allows for identification of key process failures that require interventions for optimum performance. Financial assessment should include thorough review of internal processes for non value added activity Increasing collections allows for further investment in research. Opportunities addressed were systems and processes to give our team the tools they needed to succeed
Future Plans	<ul style="list-style-type: none"> Process improvement never ends. Complete implementation of CTMS Finance Module Leverage new data gained from CTMS finance system to further streamline processes and ensure fiscal sustainability of clinical research.
Suggestions for Others	<ol style="list-style-type: none"> Form a multidisciplinary taskforce to ensure solution met needs of all stakeholders Obtain data and generate process flow maps to identify baseline performance and process failures. Complete root cause analysis as needed Generate project goals, scope and objectives Use tools such as brainstorming and data analysis to generate interventions that address key process failures Implement interventions Evaluate outcomes Continue to use learning and data to make cyclic improvements

Additional Abstracts

(alphabetical order by AACI cancer center)

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Using a Team-Building Strategy to Coordinate Institutional Biosafety Practices

Sarah Bigelow, CCRP; Cathy Galasso, RN, OCN, CCRP; Kasha Krul, CCRP; Barbara Manica, PharmD; Morris Magnan, PhD, RN

Barbara Ann Karmanos Cancer Institute, Wayne State University

Describe the background of the problem:

Karmanos Cancer Institute (KCI), a research intensive National Cancer Institute (NCI) designated Comprehensive Cancer Center (CCC), regularly participates in research to test new cancer therapies. Immunotherapies are now emerging as promising therapeutic options for cancer treatment. As a result, the number of clinical trials involving the use of genetically engineered organisms (e.g., viruses and bacteria) is increasing at an accelerated pace both nationally and internationally. Teaching immune cells to recognize malignant cells as foreign is the primary goal and major challenge in the development of effective cancer immunotherapies. In antigen-specific approaches a tumor-specific antigen is directly targeted. Some therapies incorporate a genetically engineered vector, such as a virus (e.g. Herpes Simplex Virus [HSV]) or bacterium (e.g., Listeria), to allow the antigen to reach its intended target and stimulate an immune response. Genetically engineered vectors used in immunotherapy trials often have some associated level of biohazardous risk. As a result, research involving the use of recombinant DNA (rDNA) or synthetic nucleic acid (SNA) molecules is strictly regulated by National Institutes of Health (NIH) guidelines. At KCI, research protocols are processed, from application to implementation, through our Clinical Trials Office (CTO).

Provide metrics or goals to be achieved:

The CTO has well-established, robust policies, procedures, and practices to expeditiously process clinical trial protocols; however, clinical trials involving the use of genetically engineered organisms and under NIH regulation bring an added degree of complexity that: (1) exceeds the CTO's usual processing procedures, and (2) requires coordination of activities across a number of departments and agencies. Given the potential biohazardous risk to patients, families, clinicians, the public and the environment, there is a need for institutions to establish guidelines, standardize institutional procedures, and coordinate activities to ensure error free storage, transfer, preparation, administration, containment, and disposal of investigational agents containing rDNA or SNA molecules.

Describe the solutions or methods implemented:

The purpose of this process improvement initiative was to identify and develop the structures and coordinate processes across departments and agencies to safely implement clinical trials involving the use of biologic agents containing rDNA or SNA molecules. A cross-functional team-building strategy was used to engage intra- and extramural stakeholders/team members to develop, codify, approve, and implement policies, guidelines and procedures related to the storage, transfer, preparation, administration, containment, and disposal of investigational agents containing rDNA or SNA molecules.

Describe the outcome or show data representing a change (positive or negative):

Results of this process improvement initiative include: (1) improved interdepartmental communication (2) policies, guidelines, and procedures related to storage, transfer, preparation, administration, containment, and disposal of these investigational agents are codified, and (3) team members have an explicit rather than tacit understanding of their roles and responsibilities.

Address lessons learned and future directions:

Team-building under the direction of an identified team leader facilitated interdepartmental communication, reduced interdepartmental conflict, and helped team members clarify, explicate and take responsibility for their distinct roles in the interest of safely implementing clinical trials involving the use of investigational agents containing rDNA or SNA molecules. Moreover, team members at all levels report increased confidence in their ability to fulfill their role responsibilities.

Background and Significance

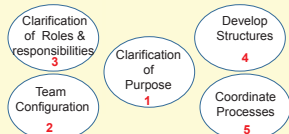
Karmanos Cancer Institute (KCI), a research intensive National Cancer Institute (NCI) designated Comprehensive Cancer Center (CCC), regularly participates in research to test new cancer therapies. Immunotherapies are now emerging as promising therapeutic options for cancer treatment. As a result the number of clinical trials involving the use of genetically engineered organisms (e.g., viruses and bacteria) is increasing at an accelerated pace both nationally and internationally. Teaching immune cells to recognize malignant cells as foreign is the primary goal and major challenge in the development of effective cancer immunotherapies. In antigen-specific approaches a tumor-specific antigen is directly targeted. Some therapies incorporate a genetically engineered vector, such as a virus (e.g. Herpes Simplex Virus [HSV]) or bacterium (e.g., *Listeria*), to allow the antigen to reach its intended target and stimulate an immune response¹. Genetically engineered vectors used in immunotherapy trials often have some associated level of biohazardous risk. As a result, research involving the use of rDNA or sNA molecules is strictly regulated by National Institutes of Health (NIH) guidelines². At KCI, research protocols are processed, from application to implementation, through our Clinical Trials Office (CTO). The CTO has well-established, robust policies, procedures, and practices to expeditiously process clinical trial protocols; however, clinical trials involving the use of genetically engineered organisms and under NIH regulation bring an added degree of complexity that: (1) exceeds the CTO's usual processing procedures, and (2) requires coordination of activities across a number of departments and agencies. Given the potential biohazardous risk to patients, families, clinicians, the public and the environment, there is a need for institutions to establish guidelines, standardize institutional procedures, and coordinate activities to ensure error free storage, transfer, preparation, administration, containment, and disposal of investigational agents containing rDNA or sNA molecules.

Purpose

The purpose of this process improvement initiative was to identify and develop the structures and coordinate processes across departments and agencies to safely implement clinical trials involving the use of biologic agents containing recombinant DNA (rDNA) or synthetic nucleic acid (sNA) molecules.

Methods

A cross-functional team-building strategy was used to engage intra- and extramural stakeholders/team members to develop, codify, approve, and implement policies, guidelines, and procedures related to the storage, transfer, preparation, administration, containment, and disposal of investigational agents containing rDNA or sNA. Five key elements were addressed:



Clarification of Team Purpose

Team building principle: Teams need a compelling and clear direction. Members need to know, and agree on, what they're supposed to be doing together^{3, p.29}.

The purpose of the biosafety team is to establish guidelines, standardize institutional procedures, and coordinate activities to ensure error free storage, transfer, preparation, administration, containment, and disposal of investigational agents containing rDNA or sNA molecules in order to protect patients, families, clinicians, the public and the environment from potential biohazardous risk that might arise from the use of these investigational agents.

Team Configuration

Team building principle: Team members are selected based upon skill and skill potential, not personality. No team succeeds without all the skills needed to meet its purpose and performance goals^{3, p.40}. Complex tasks require input from highly specialized individuals^{3, p.69}.



Clarification of Roles and Responsibilities

Team building principle: On a genuine team, members understand their roles and responsibilities, members do equivalent amounts of real work; all members, the leader included, contribute in concrete ways to the team's collective work-product(s)^{3, p.38}

Biosafety Trained Nurses: The Research Nurse works under the direction of the Principal Investigator to ensure accurate data and adherence to protocol and institutional requirements. Research Nurses are essential to the administration and disposal of biologic study agents.

Environmental Services: Ensure that waste disposal containers meet regulatory requirements and are removed and destroyed/decontaminated by an approved waste management company.

Housekeeping: Ensures terminal cleaning of treatment rooms is carried out effectively using appropriate personal protective equipment and approved cleaning agents.

Investigational Drug Pharmacist: The Investigational Pharmacy ensures proper storage, handling, accountability and preparation of the biologic study agent.

Clinical Trials Office Coordinators: Regulatory coordinators, in collaboration with the Principal Investigator, process the required institutional, Institutional Biosafety Committee, and Institutional Review Board documentation to ensure compliant study activation and management.

Wayne State University Institutional Review Board (IRB): The institutional IRB of record for the Karmanos Cancer Institute and ensures protection of human subjects.

Western Institutional Review Board & Institutional Biosafety Committee: Identify Biosafety risk level. Ensure institutional compliance with NIH guidelines. Approve written standard operating procedures (SOP) for each investigational agent.

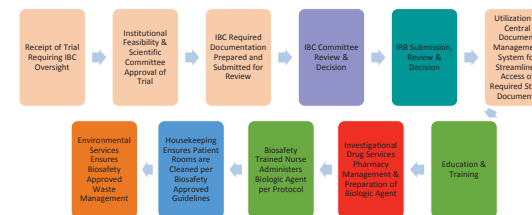
NIH Approved Institutional Representative: Coordinates activities and facilitates team communication

Developed Structures

Team building principle: Effective teams measure and track performance directly by assessing collective work products^{3, p.36}.

- Public posting template developed to notify community of protocol review
- Template developed for writing SOPs for each IBC protocol to address
 - General information about investigational agent
 - Packaging of investigational agent
 - Risk information including 1) routes of exposure, 2) pre-exposure requirements, 3) anticipated effect of exposure, and 4) staff restrictions
 - Storage and handling of investigational agent
 - Required personal protective equipment (PPE) for preparation, administration and spill clean up
 - Administration procedures
 - Receipt, storage, preparation, and transportation requirements
 - Biohazard signs – required information and posting
 - Biohazard waste disposal
 - Disposal of used, thawed, unused vials
 - Disposal of remaining agent after final subject
 - Waste bins, waste storage
 - Disposal of solid waste and large volume of unused study agent
 - Special handling
 - Accidental spills or exposure
 - Training requirements
- Biosafety signage developed and standardized for treatment rooms and pharmacy
- Housekeeping policy developed and implemented
- Procedures for storing and retrieving protocol documents in restricted access network computer established
- Waste disposal signage developed and posted in treatment areas

Coordinated Process



References

1. McMahon, S. Minimizing hazards associated with live-virus immunotherapeutic cancer vaccines. *CJON*. 2016; 20: 602-604.
2. NIH guidelines for research involving recombinant or synthetic nucleic acid molecules (NIH Guidelines). Office of Science Policy Website https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html. Published April 2016.
3. Katzenbach JR, Smith DK, *On Teams*. Boston, MA: Harvard Business School Publishing; 2013.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Advancing Clinical Research Nurse Practice in a Vibrant Clinical Trial Office

Pamela S. Herena, MSN, RN, OCN; Glenna Paguio, MSN, RN, CCRP; Bernadette Pulone, BSN, RN, OCN; Brenda Williams, BSN, RN

City of Hope Comprehensive Cancer Center

Describe the background of the problem:

In 2015 we had approximately 20 clinical research nurses, by 2017 we had approximately 50 clinical research nurses. Due to our growth in clinical trial endorsements, we more than doubled our need for clinical research nurses. We hired many nurses who had no previous research experience. We paired them with a preceptor who had a heavy work load and trained the new nurses quickly so they could unload some of their trials. This created research nurses who learned by fire, and did not have a clear understanding of their role. They could complete the research tasks, however, there was no clinical research nurse foundation to continue to build their role upon. We developed a 3 hour CEU course using the Clinical Research Nursing: Scope and Standards of Practice to build that foundation, and to build the specialty practice of Clinical Research Nursing at City of Hope.

Provide metrics or goals to be achieved:

The purpose of the mandatory 3 hour course was to:

- Engage and educate the nurses about the Professional Clinical Research Nurse role and discuss how it had been designated a Specialty practice by the ANA.
- Increase their knowledge base, and build confidence in their practice to gain their partnership in implementing quality practices.
- Begin to standardize their practice.
The level of research experience varied from nurse to nurse.

Describe the solutions or methods implemented:

We broke down the Clinical Research Nursing: Scope and Standards of Practice book into NIH Domains of Practice, Scope & Standards, Nursing and research ethics. We included a collaborative section so the nurses could discuss the scope and standard together and how their current practices follow the scopes and standards. We included information regarding ethical guidance from The Belmont Report, Nuremberg Code, Declaration of Helsinki, and FDA. We utilized a pre and post five-point Likert scale questionnaire (strongly agree to strongly disagree) to focus on four specific domains that we wanted to measure (see questions in Table 1).

Describe the outcome or show data representing a change (positive or negative):

The responses show an increase in the number of strongly agree and a decrease in the neither and disagree category. An increase in knowledge can be seen in all four domains, which supports our course objectives.

Address lessons learned and future directions:

It is challenging to find experienced research nurses, and with the continued influx of complex clinical trials. We have and continue to make changes to our training and onboarding process, to help us retain our current staff. Implementing the training programs and refresher presentations throughout the year is a necessity; however, it is very time consuming for Managers and Directors. Our future direction will focus on looking at ways to combine the training for all of our Clinical Trials Office roles, and include experience staff in providing some of the refresher presentations.

Advancing Clinical Research Nurse Practice in a Vibrant Clinical Trial Office



Pam S. Herena, MSN, RN, OCN; Glenna Paguio, MSN, RN, CCRP; Bernadette Pulone, BSN, RN, OCN; Brenda. Williams, BSN, RN; Ashley Baker-Lee

Program Background & Overview

In 2015 we had approximately 20 clinical research nurses, by 2017 we had approximately 50 clinical research nurses. Due to our growth in clinical trial endorsements, we more than doubled our need for clinical research nurses. We hired many nurses who had no previous research experience. We paired them with a preceptor who had a heavy work load and trained the new nurses quickly so they could unload some of the clinical trials. This created research nurses who learned by fire, and did not have a clear understanding of their role. They could complete the research tasks, however, there was no clinical research nurse foundation to continue to build their role upon. We developed a 3 hour CEU course using the *Clinical Research Nursing: Scope and Standards of Practice* to build the specialty practice of Clinical Research Nursing at City of Hope.

Purpose

The level of experience varied from nurse to nurse and in order to promote consistency in practice, the purpose of the mandatory 3 hour course was to:

- Engage and educate the nurses about the Professional Clinical Research Nurse role and discuss how it had been designated a Specialty practice by the ANA.
- Increase their knowledge base, and build confidence in their practice to gain their partnership in implementing quality practices.
- Begin to standardize their practice.

Intervention

For the presentation, we broke down the *Clinical Research Nursing: Scope and Standards of Practice* book into NIH Domains of Practice, Scope & Standards, and Nursing Research Ethics. We included a work session so the nurses could discuss the scope and standards with each other and come up with how their current work follows the scope and standards. We included information regarding ethical guidance from The Belmont Report, Nuremberg Code, Declaration of Helsinki, and FDA. We utilized a pre and post five-point Likert scale questionnaire (strongly agree to strongly disagree) to focus on four specific domains that we wanted to measure. These included questions to evaluate the nurses' understanding of the scopes and standards of clinical research nursing, research rules and regulations related to human research, how nursing ethics is applied to the research nurse role, and how comfortable they felt describing their role.



Limitations

As open positions are filled, the number of new Clinical Research Nurse hires become less and less. This is challenging to provide a large enough size for good interaction. This also creates a challenge for the timing of this course. When do new Clinical Research Nurses have enough knowledge to fully understand their role and its impact on their patients?

Discussion

The pre and post Likert scale clearly shows that our Clinical Research Nurses had limited knowledge in the rules & regulations related to human research, as well as limited knowledge of their role. Although we knew there were some challenges with the orientation and training process, this session helped us identify knowledge gaps. Since we did provide CEUs, we also collected an evaluation sheet. This too was valuable, because nurses commented on what topics were most helpful, least helpful, and they provided suggestions to improve the course. Most of the nurses liked the open interactive portion, and learning from other colleagues. The only two improvement suggestions we received were:

- "Make more interactive – include games, questions & answers"
 - Handout slides before starting so they could make notes
- Some of the positive comments we received were:
- "good job" multiple times
 - "should be ongoing"
 - "great help"
 - "very helpful"

Conclusion

Providing support and education with peer interaction can result in increased knowledge for research nurses. Continued expansion of the course will help ensure we are consistently promoting the Clinical Research Nurse Specialty practice as well as providing continued education. With the growth of Oncology clinical trials, hiring inexperienced research nurses will inevitably be part of our continued practice. Additionally, role education seems to build more confident and satisfied research nurses, and this may be evidenced by a decrease in our turn over rate, which was 28% in fiscal year 17 (12 months), compared to the current turnover of just 5% for fiscal year 18 (8 months).

References

- CRN 2010 Domain of Practice Committee 2009. Building the Foundation for Clinical Research Nursing: Domain of Practice for the Specialty of Clinical Research Nursing. 2009. National Institutes of Health Clinical Center, Nursing and Patient Care Services. Available at http://www.cc.nih.gov/nursing/cm/DOP_document.pdf
- International Association of Clinical Research Nurses (IACRN). Scope and Standards of Practice: Clinical Research Nursing Draft. Retrieved April 2016, from <https://www.google.com/search?q=IACRN+scope+and+standards+of+practice&q=IACRN+scop&aq=chrome.0.6959j957j9j9i64.1767j9j7&sourceid=chrome&ie=UTF-8>

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Precision Imaging Metrics: Changing the Way Clinical Trial Imaging Assessment is Managed

Trinity Urban, MA¹; Erik Ziegler, PhD¹; Bhanusupriya Somarouthu, MD¹; Elizabeth Correa, MA¹; Gina Basinsky¹; Danielle Nacamuli²; Cheryl A. Sadow, MD¹; Ryan O'Malley, MD²; Carolyn Wang, MD²; Annick D. Van den Abbeele, MD¹; Gordon J. Harris, PhD¹

¹Dana-Farber Cancer Institute, Harvard Medical School; ²Fred Hutchinson Cancer Research Center

Describe the background of the problem:

Over the past two decades, clinical trials have become increasingly dependent upon image-based surrogate endpoints for evaluation of cancer therapeutics. The growing complexity of image-based response evaluation criteria has made it challenging for radiologists to provide reliable, timely, protocol-compliant measurements.

Provide metrics or goals to be achieved:

Our goal is to improve protocol adherence by eliminating common discrepancies which may impact patient care decisions, as well as to accelerate turnaround of tumor measurements so that radiologists can provide same-day results.

Describe the solutions or methods implemented:

The Tumor Imaging Metrics Core (TIMC) of the Dana-Farber/Harvard Cancer Center has increased the quality and efficiency of imaging assessments by developing a system, branded Precision Imaging Metrics (PIM), which is available to cancer centers as a NCI-shared resource through an academic licensing model. As shown in Figure 1, the system is an integrated (A) cloud-hosted clinical trial imaging assessment and (B) workflow management application, which supports high-level trial analytics, fiscal tracking, and user-auditing capabilities. The system was implemented by the Fred Hutchinson/University of Washington Cancer Consortium in 2014 and is currently in use at seven other NCI-designated cancer centers with three additional centers coming onboard this summer.

Describe the outcome or show data representing a change (positive or negative):

Implementation of the PIM system has been shown to reduce imaging assessment errors from over 25% to nearly 3% at participating cancer centers. Common errors prior to implementing PIM included: 1) follow-up response discrepant with the trial's imaging criteria (29% of errors);

2) missing measurement and/or response data (24% of errors); 3) targets do not meet size criteria at baseline (18% of errors); 4) incorrect response criteria applied (e.g. RECIST 1.1 used instead of irRECIST 1.1; 16% of errors); 5) incorrect baseline used as comparison (8% of errors); and 6) not considering baseline and nadir in response calculations (5% of errors).

Address lessons learned and future directions:

These challenges demonstrate the need for advanced clinical trials imaging informatics tools. Most applications are focused on Clinical Research Organizations and do not fully meet the needs of site reads. The PIM system has been designed and developed specifically for cancer centers and continues to evolve based on the feedback provided by the oncologists, radiologists, and clinical research teams that use PIM.

A future development goal for the application is to add analysis tools to promote advanced visualization and statistical exploration of trial data. In the era of molecularly targeted therapies, the evaluation of treatment efficacy may be impacted by inconsistencies in response patterns, which may not be uncovered until after the trial has been closed. The PIM system will help investigators better visualize a patient's response pattern, create analyses to test their hypotheses, and apply them to all patients enrolled in a trial in real-time. For example, oncologists may wish to evaluate lesions by organ group to identify varying response to treatment throughout the body. These longitudinal data visualization tools will be made available to cancer centers in 2019.



Precision Imaging Metrics: Changing the Way Clinical Trial Imaging Assessment is Managed



Trinity Urban; Erik Ziegler, PhD; Matthew Leary; Bhanusupriya Somarouthu, MD; Elizabeth Correa; Gina Basinsky; Danielle Nacamuli; Cheryl A. Sadow, MD; Ryan O'Malley, MD; Carolyn Wang, MD; Annick D. Van den Abbeele, MD*; Gordon J. Harris, PhD*

*co-senior authors

Introduction

Oncology clinical trials have become increasingly dependent upon image-based surrogate endpoints for determining patient eligibility and treatment efficacy. As therapeutics have evolved and multiplied in number, the response criteria used to characterize therapeutic response have become progressively more varied and complex. The growing intricacies of image-based response evaluation, together with rising expectations for rapid and consistent results reporting, make it difficult for site radiologists to adequately address local and multicenter imaging demands. These challenges demonstrate the need for advanced cancer imaging informatics tools that can help ensure protocol-compliant image evaluation while simultaneously promoting reviewer efficiency.

Need for Clinical Trial Informatics

- Trial requirements are growing in complexity
 - Not just RECIST anymore; over a dozen criteria
 - Modifications to standard criteria are common
- Adequate clinical trial imaging review/reporting tools usually only available to Clinical Research Organizations (CROs)



Precision Imaging Metrics System (PIM)

The system was developed to manage:

- Trial/patient registration & assessment requests
- Demanding requirements for turnaround time
- Protocols review, worklists, and results reporting
- Communication between radiologists & oncologists

Methods

Tumor Imaging Metrics Core

The Tumor Imaging Metrics Core (TIMC) was established in 2004 to address the Dana-Farber/Harvard Cancer Center needs by providing centralized imaging review services for patients enrolled in clinical trials. To support the service, the Precision Imaging Metrics system was developed in-house to promote communication between oncology and radiology teams.

Precision Imaging Metrics System

PIM is comprised of an integrated cloud-hosted imaging analysis application and a workflow and data management system. Our goal is to improve protocol adherence by eliminating common discrepancies, which may impact patient care decisions, as well as to accelerate turnaround of tumor measurements so that radiologists can provide same-day results.

Cancer Center Imaging Core Network

PIM was implemented by the Fred Hutchinson/University of Washington Cancer Consortium in 2014 and is currently in use at seven other NCI-designated cancer centers (Table 1) with three additional centers coming onboard this summer. The system is available as a NCI-shared resource through an academic licensing model.

Cancer Center	Location	Date Active	Trials	Time Points
Dana-Farber/Harvard Cancer Center	Boston, MA	2004	1,974	93,588
Yale Cancer Center	New Haven, CT	2013	608	17,047
Fred Hutch/UW Cancer Consortium	Seattle, WA	2014	627	17,486
Huntsman Cancer Institute	Salt Lake City, UT	2015	288	2,977
Massey Cancer Center	Richmond, VA	2015	69	818
Winship Cancer Institute	Atlanta, GA	2017	316	2,785
Medical College of Wisconsin Cancer Center	Milwaukee, WI	2017	45	252

Precision Imaging Metrics System

1) Cloud-hosted Imaging Analysis Application



2) Workflow and Data Management System



Results

Common Errors (Pre-PIM)

- Follow-up response discrepant with trial's imaging criteria (29% of errors)
- Missing measurements and/or response data (24% of errors)
- Targets do not meet size criteria at baseline (18% of errors)
- Incorrect response criteria applied (e.g. RECIST 1.1 vs. irRECIST; 16% of errors)
- Incorrect baseline used as comparison (8% of errors)
- Not considering baseline and nadir in response calculations (5% of errors)

Error Reduction (Post-PIM)

PIM has shown to reduce imaging assessment errors from over 25% to less than 3% at participating cancer centers.

Lessons Learned

These clinical trial challenges demonstrate the need for advanced imaging informatics tools. Most applications focus on Clinical Research Organizations and do not fully meet the needs of site reads. The PIM system has been designed and developed specifically for cancer centers and continues to evolve based on the feedback provided by the oncologists, radiologists, and clinical research teams that use PIM.

Future Directions

A future development goal for the application is to add analysis tools to promote advanced visualization and statistical exploration of trial data. In the era of molecularly targeted therapies, the evaluation of treatment efficacy may be impacted by inconsistencies in response patterns, which may not be uncovered until after the trial has been closed. PIM will help investigators better visualize a patient's response pattern, create analyses to test their hypotheses, and apply them to all patients enrolled in a trial in real-time. For example, oncologists may wish to evaluate lesions by organ group to identify varying response to treatment throughout the body.

Acknowledgements

This project was supported in part by U24 CA199460 grant from the National Cancer Institute (NCI) Informatics Technology for Cancer Research (ITCR) program.



Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Diamond in the Rough: Realizing the Value of a Clinical Research Business Operations Team

Patricia D. Black, MBA

Fox Chase Cancer Center, Temple Health

Describe the background of the problem:

The business roles and functions of a centralized Office of Clinical Research (OCR) has not always been well understood, within the context of a cancer institute. This is due to its many nuances driven by the requirements within the healthcare environment. In addition, the landscape of the OCR was one populated with many "silos." In 2017, the Office of Clinical Research (OCR) experienced a season of unprecedented turnover across multiple Units. This had the potential to seriously cripple the strategic goals of the institution, patient flow, clinical operations, quality and safety, financial stability, and the efficiency of business operations.

During this time, Business Operations Unit of the OCR, patterned after a shared services model, was largely viewed as the "batting cage," where any issues that did not directly impact patient care were haphazardly "thrown" into the Unit without consideration for resource bandwidth, timelines, nor expertise. As a result, this Unit was overburdened, appeared less engaged, and felt undervalued.

Provide metrics or goals to be achieved:

One of the first goals of the management of the Business Operations Unit was to reduce turnover, strengthen the team through the building of core competencies, increase staff engagement, and implement a structured operational approach to Business Operations partnerships.

Metrics/Graphs:

- Retention: Turnover Rate
- Staff Education and Engagement Survey
- Pre- and Pre-Post Organizational Satisfaction Survey Data

Describe the solutions or methods implemented:

- Cost-Effective Educational Options
- Change Management Training
- Adding Structure & Process: Process Mapping/Process Improvement/Project Management
- Breaking down silos – the bridges of communication and collaboration
- Retention: "Getting to Know You" Retention Events
- Internal: Higher Quality Responsibilities
 - association membership;
 - access to confidential information
- External: Value Added Services:
 - Consultative Financial Management
 - C-level presentations

Describe the outcome or show data representing a change (positive or negative):

Aligning Business Office Operations to Optimize Patient Care:

- Showcasing Talent:
 - Consultative Financial & Data Services
 - Lutathera Story
 - Patient Experience Efficiency (PXE) Process improvement; leveraging automation

Address lessons learned and future directions:

Lessons Learned:

Barriers: Seconds to build; Months to demolish
Patience
Understanding Change
Value your Own Value!
State Your Partnership Requirements and Stick to Them

Future Directions:

The Business Operations Unit is one that is proud of their professional development opportunities and the ability to showcase them when members are sought after for help with challenging assignments which allow for growth.

Through strengthened partnerships we are moving towards optimal cancer clinical research operational efficiency.

DIAMOND IN THE ROUGH: REALIZING THE VALUE OF A CLINICAL RESEARCH BUSINESS OPERATIONS TEAM

Patricia D. Black, MBA, Manager, Business Operations, Office of Clinical Research



Introduction

The Business Operations Division provides a shared services module of support to the Office of Clinical Research (OCR):

- Administration
- Revenue Financial Analysis
- Research Budget Financial Analysis (*eff. May, 2018*)
- Systems & Data
- Project Management
- Patient Financial Counseling
- Patient Navigation & Timekeeping

These roles and functions have lacked clarity and definition, within the context of a cancer institute.

The incoming Manager needed to identify opportunities for improvement and implement change.

Background

In 2017, the Office of Clinical Research was in the following state:

- Unprecedented turnover across multiple Units
- Many new hires in Business Operations Division
- Many "silos" across Departments; limited info sharing and cross-collaborations
- Numerous, un-reviewed requests from clinicians and leadership
- Lack of organized intake process..."batting cage"..."junk drawer"
- Lackluster perceptions of Division
- Team was in "infancy" stage; as Division was relatively new, staff had not worked together for more than six months

This had the potential to seriously cripple the strategic goals of the institution, patient flow, clinical operations, quality and safety, financial stability, and the efficiency of business operations.

Goals

- Strengthen Team Capabilities
- Foster Employee Engagement
- Improve Business Operations Division Perception through Value-Added Services for Stakeholders and Building Bridges Across the Institution

Employee Engagement

- **Leadership in Division Committees:** Organized into Committee "communities" (Systems & Data, Financial Management, Project Management & Administration), Business Operations Teams collaborate across Communities and Departments, on projects and assignments requiring a blend of skills
- **C-Level Presentations:** Some staff have had the opportunity to deliver presentations that drive decision making to C-level leaders
- **Staff Retention Events:** As the overall team has only worked together for approximately one year or less, Team members are offered the opportunity to organize events to foster inclusion in leadership, and host outings that will appeal to diverse groups. This provides a great opportunity to get to know "the person behind the work."

Strengthening Team Core Competencies

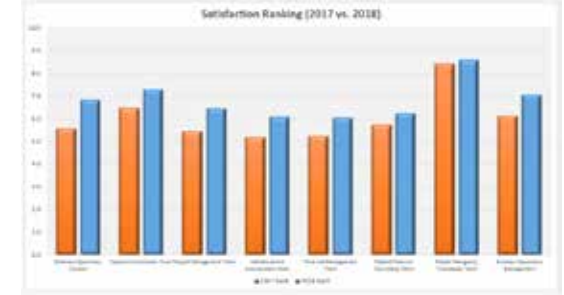
- Nearly 250 hours of training were provided to staff in FY18
- Management has reduced cost barriers by leveraging low/no-cost opportunities offered through Fox Chase/TUHS or free online courses (i.e., *LinkedIn Learning*, webinars, etc.)
- In a survey to measure employee perceptions of employer investments in training 86% of staff felt they had good opportunities to participate in non-required training
- Participation in Change Management Training



Examples of Value-Added Services

- **Lutathera Story:** Clinicians with complex clinical trial involving Radiation, Isolation, Decontamination, Interventional Radiology, Nuclear Medicine, Drug shipped from Italy with short shelf life, utilize **Project Management Team** to map optimal planning for patient flow, patient safety, and compliance.
- **Launch of Financial & Data Consultative Services:** Disease Site Principal Investigators (PI) lacked comprehensive reporting and support in interpreting Disease-Site specific portfolios. **Revenue Financial Analysis** and **Systems & Data Teams** collaborated in financial and data report design and consult with PIs monthly to interpret performance, address concerns, and make recommendations.
- **Project Management Intake System:** To identify Stakeholder needs, ensure appropriate resources were assigned to requests, reduce the number or undocumented requests, and capture metrics on types of services requested, the **Project Management** and **Administration Teams** developed a Project/Report/Task Submission Form.
- **Stipend Reimbursement:** Patient Reimbursements are essential to patients balancing the crushing diagnoses of cancer, along with support for the cost of attending treatment. **The Systems & Data, Patient Financial Counseling, and Project Management Teams** worked across Department lines to link individual Sponsor-provided support to the clinical trials management system allows. This resulted in expedited patient reimbursement, as well as compliance with Sponsor contracts.
- **Kronos Scheduling Efficiency:** **Our Patient Navigators/Timekeepers** support the payroll process for the entire institution. Partnering with the **Project Management Team**, they created efficiencies through process changes and links to *SharePoint*.

Conclusion



- In < 1 year, the Business Operations Division has improved perceptions and provided satisfaction to stakeholders, through improved business processes, service-oriented support, cross-collaborations, improved efficiency and quality.
- We first needed to value our own value and have both leadership and team commitment to working towards improvement and partnerships.
- We have learned that this requires both a keen understanding of change, and corresponding patience.

Stakeholder Satisfaction: FY17 vs. FY18	
Role	FY18 %'s
Business Operations Division	22.5%
Systems Coordinator Team	12.6%
Project Management Team	18.3%
Administrative Coordination Team	16.9%
Financial Management Team	14.9%
Patient Financial Counseling Team	9.2%
Patient Navigator/Timekeeper Team (*)	1.7%
Business Operations Management	15.4%

*Ranking was already at highest among all Units

The Future of the Business Operations

- The Business Operations Division has demonstrated its value to both clinical and leadership stakeholders, as it now sought after for its expertise.
- With our continued approach towards partnerships, leadership, and excellence, there is no doubt that we will continue to be a model for how a strong business foundation can advance the goals of the clinical research environment!

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

The Business of Investigator Sponsored Research

Jeanie Magdalena Gatewood

Fox Chase Cancer Center, Temple Health

Describe the background of the problem:

The Office of Clinical Research (OCR) at Fox Chase Comprehensive Cancer Center (FCCC) is a centralized administrative & operations office that oversees the conduct of oncology clinical research within the Temple University Health System (TUHS). Within the scope of that office rests responsibility for development of investigator-sponsored trials (IST's). Included is standard practice for clinical trial development, monitoring, conduct and management, as well as increasing the number of clinical trials available at TUHS.

As a Comprehensive Cancer Center ISTs are an institutional priority. In 2015 there was 1 Clinical Trial Development Project Manager to assist investigators in writing clinical trial protocols, corresponding with industry collaborators & FDA, and engaging with external trial sites. During the course of a given year at least 5 new protocol concepts would be presented for development by the PM. While growth is always a key strategic aim – little support was available to power the effort. It was identified that basic business principles could be applied to fuel the IST engine. This would include Systems & Technology, Financial Management, Stakeholder Involvement and Strategic Planning

Provide metrics or goals to be achieved:

- Increase the Number of IST's
- Increase the Number of Sub-Sites participating in IST's
- Increase the Accruals to ISTs
- Increase the Funding available to support IST's
- Create, Improve and Enhance the Administrative Data and MetaData pertaining to the IST portfolio
- Create a comprehensive business model for conducting Investigator Sponsored Research within a Comprehensive Cancer Center

Describe the solutions or methods implemented:

1. Design & Launch of a Dedicated Investigator Sponsored Research Unit (ISRU)
2. Application of Basic Business Principles to Support the Technology & Financial Requirements of such a Structure

Describe the outcome or show data representing a change (positive or negative):

- 2015 thru 2018 Staffing Increase with Org Charts & HeadCount/Roles Definition
- 2015 thru 2018 IST Volume Increase with Graphics
- 2015 thru 2018 Sub-Site Capacity Tables
- 2015 thru 2018 Enhanced Technology/Systems Map
- 2015 thru 2018 Financial Data

Address lessons learned and future directions:

Continued development of an Investigator Sponsored Research Unit and infrastructure to enhance support for oncology clinical research available at all FCCC and affiliated sub-sites will benefit from bridging communication with partner divisions. Already inclusive of Contracts, Budgets, IT, Finance – In the next phase we will expand to collaborate and address opportunities with Education, Molecular Therapeutics, Epigenetics and other Translational Disease Research Groups. This will help to meet all the objectives of the model depicted above.

The Business of Investigator Sponsored Research



Jean M Gatewood MBA Vice President Clinical Research



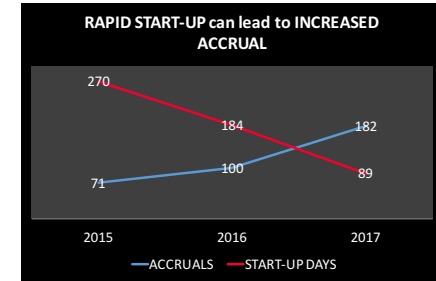
A Cancer Center Designated by the National Cancer Institute

BACKGROUND

The Office of Clinical Research (OCR) at Fox Chase Comprehensive Cancer Center (FCCC) is a centralized administrative & operations office that oversees the conduct of oncology clinical research within the Temple University Health System (TUHS).

As a Comprehensive Cancer Center, Investigator Sponsored Research is an institutional priority. In 2015 there was 1 Protocol Development Project Manager (PDPM) to assist investigators to write clinical trial protocols, correspond with industry collaborators & FDA, and engage with external trial sites.

While growth is always a key strategic aim – little support was available to power the effort. It was identified that basic business principles could be applied to fuel the IST engine. This would include Systems & Technology, Financial Management, Stakeholder Involvement, and Strategic Planning.



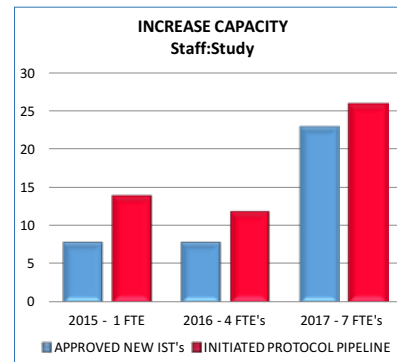
	Institutional Investment		
	2015	2016	2017
Revenue	\$0	\$86,000	\$233,000
Expense	\$68,000	\$242,000	\$409,000
Investment	\$68,000	\$174,000	\$176,000

AIMS

1. Increase the Number of IST's
2. Increase the Accruals to ISTs
3. Reduce IST Start-Up Timelines
4. Create, Improve, and Enhance the Administrative Data and MetaData pertaining to the IST portfolio

OVERALL

Create a comprehensive business model for conducting Investigator Sponsored Research within a Comprehensive Cancer Center



CONCLUSIONS

An Investigator Sponsored Research Unit (ISRU) has been established as a Core Resource for FCCC investigator-sponsored research studies. A Site Selection database has been developed to prospectively support external site selection.

This combination has resulted in overall efficiencies in capacity to initiated, FCCC ISTs, locally and at sub-sites, in rapid fashion – resulting in increased accrual while the science is still of interest & importance.

METHODS

- A) Design & Launch of a Dedicated Investigator Sponsored Research Unit (ISRU)
- B) Application of Basic Business Principles to Support the Technology & Financial Requirements of such a Structure

RESULTS

- Objective 1: a) Number of newly initiated Protocols in the Pipeline has Doubled & b) Number of Newly IRB approved protocols has Tripled
- Objective 2: Number of Annual Accruals has greater than doubled
- Objective 3: Study Start Up has reduced nearly 70%
- Objective 4: SubSite Selection Database in Use

FUTURE DIRECTION

- Enhance ISRU infrastructure support for ISTs at preferred sub-sites.
- Bridge communication with partner divisions - inclusive of Contracts, Budgets, IT, Finance et al
- Expansion to collaborate with Molecular Therapeutics, Epigenetics and other Translational Disease Research Groups.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Building an Investigator-Sponsored Research Unit from Scratch

Michael C. Oldfield, JD, MBA, CCRP

Fox Chase Cancer Center, Temple Health

Describe the background of the problem:

Fragmented processes and little support contributed to the many obstacles FCCC physicians faced moving their Investigator-sponsored trials from concept through development to activation. Without a cohesive research support unit, most protocols took many months, in some cases years, to make it to activation, and many struggled to meet accrual goals or did so over a much longer period of time than anticipated.

Provide metrics or goals to be achieved:

Creating a dedicated unit for Investigator-sponsored research would allow the Investigator one core group with which to work throughout every step of the clinical trial lifecycle. This core unit would combine dedicated individuals for protocol development, FDA regulatory submissions (including CT.gov and CTRP postings), TMF document management (both internally and for participating Sites), and data monitoring and analysis. The program would allow for a fluid process throughout the study lifecycle in order to increase productivity and protocol value while decreasing the concept-to-activation timeline, in order to increase our patient's therapeutic options and the speed with which we can offer these options.

Describe the solutions or methods implemented:

The Investigator-Sponsored Research Unit (ISRU) was created, combining some pieces previously existing in separate departments and then filling the remaining gaps. On the study development end, Stakeholder Meetings were implemented at both the initiation of the development process and prior to submission for review, which has dramatically reduced both the development timeline and the need for protocol amendments during the time of review and immediately following the SIV. On the data oversight side, the ISRU developed a comprehensive monitoring plan in order to ensure that all data collected is complete and accurate for both ongoing oversight (by both the Investigator and the FCCC DSMC) and publication at the study's completion.

Describe the outcome or show data representing a change (positive or negative):

Within two years, the program has improved the writing, conduct, and publishing of Investigator Sponsored clinical trials at the Center. With the creation of a dedicated Unit, the volume of ISTs has increased significantly: the 26 studies initiated in 2017 alone equal the number imitated over the previous two years combined. And despite these volumes the development timeline has shortened significantly (from 178 days in 2015 to 81 days in 2016 to just 55 days in 2017) while IST accrual has increased dramatically (from 71 in 2015 to 100 in 2016 to 182 in 2017).

Address lessons learned and future directions:

Dedicated specialists contributing to each aspect of a clinical trial greatly improves quality and increases output. As the ISRU grows both in size and experience, various opportunities have been identified: the need for a Multisite Research Manager, to assist with coordinating large multisite trials; the need for preferred vendor relationships, in order to reduce some of the costs of the trials external to the ISRU; and the need for a more robust infrastructure, in terms of budgeting and finance, in order to support both the larger multi-institutional Phase II studies currently in the development process as well as the Phase III trials we expect to coordinate in the future.

Building an Investigator-Sponsored Research Unit from Scratch

Michael C. Oldfield, JD MBA CCRP

Director of Regulatory Affairs & Investigator Sponsored Research Unit



The Issues

- Fragmented processes and little support
- Most protocols took many months, in some cases years to activation
- Many studies struggled to meet accrual goals or did so over a much longer period of time than anticipated

The Potential Solution

Creating a dedicated unit for:

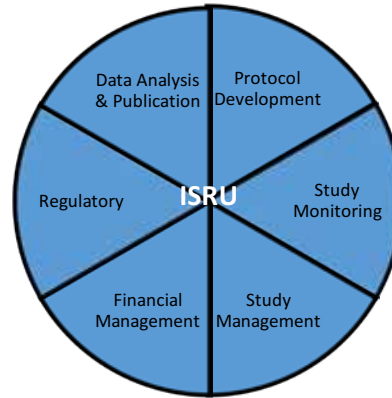
- Protocol development
- FDA regulatory submissions (including CT.gov and CTRP postings, and safety reporting)
- TMF document management (both internally and for participating Sites)
- Data monitoring and analysis
- Financial management (including budgeting)

Creation of the ISRU

A dedicated Investigator-Sponsored Research Unit (ISRU) was created:

- Half of the unit handles all study development, including amendments to the protocol and all FDA-required submissions
- The other half of the unit oversees trial execution, including site monitoring, pharmacovigilance, and data management

What Exactly Does the ISRU Do?



Dedicated specialists contributing to each aspect of a clinical trial greatly improves quality and increases output

Study Development

- Develops the protocol & ICF, including Stakeholder review (Biostatistics, Pharmacy, Lab, Study Team) and Grantor approval, and study submission
- FDA submission and CTRP/CT.gov entry/maintenance
- eCRF and calendar creation and implementation
- Comprehensive database continues to be built, with detailed information on all existing External Sites, to inform future Site selection

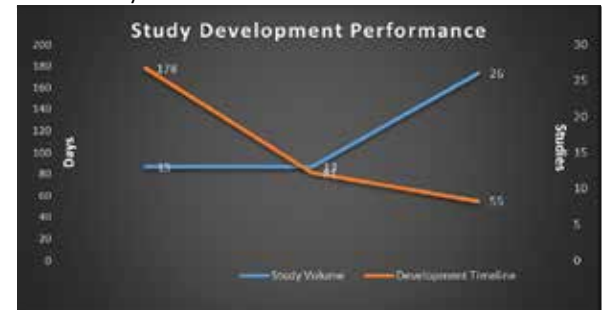
Study Operations

- Conduct of the SIV, patient registration, and monitor visits
- Study start-up, safety reporting coordination, and collection/dissemination of regulatory documents for all Sites
- Maintenance of monitoring plan system tailored to each specific study to facilitate Investigator and DSMC review

Preliminary Outcomes

The volume of ISTs has increased significantly: the number of studies initiated in 2017 alone equal the number initiated over the previous two years combined

Despite these volumes, the development timeline has shortened significantly while IST accrual has increased dramatically



Future Direction

Various opportunities have been identified, including:

- A more robust budgeting and finance infrastructure
- Preferred vendor relationships, in order to reduce costs external to the ISRU

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Collating Data Table 4 for the Cancer Center Support Grant (CCSG) from Clinical Trials Reporting Program (CTRP) Data for Interventional Studies

Raymond Skeps, MS; Linda Mendelson; Dana Johnson Robbins; Marlisa Isom, MS; Kristi Stiffler, MPH

Fred Hutchinson Cancer Research Center

Describe the background of the problem:

Recent changes to the submission process for Data Table 4 interventional trials through CTRP has required tremendous efforts by research institutions. Institutions with a Cancer Center Support Grant are now required to ensure accurate reporting of protocol accruals and data elements associated with these trials in CTRP, as opposed to just managing and assessing their local database.

Provide metrics or goals to be achieved:

The primary goal is to generate an accurate Data Table 4 that is consistent across the local and CTRP databases. A secondary goal is to establish a defined method, and system and communication network across entities responsible for reporting CTRP data, including cancer centers and sponsors, to ease the process for reconciling and adjusting accrual and protocol specific data.

Describe the solutions or methods implemented:

A comparative method was created using Excel Spreadsheet Compare and discrepancies were identified between the FH/UW Cancer Consortium's local data and the CTRP data. All Data Table 4 elements were reviewed, and every discrepancy was evaluated. Outreach to industrial sponsors and other institutions were conducted to make appropriate changes within CTRP if it was warranted. As part of these efforts, a database of site and sponsor contacts was developed. We are currently implementing a web-based solution to allow sites to share data discrepancies and corrections across the institutions.

Describe the outcome or show data representing a change (positive or negative):

Numerous issues were identified within automated CTRP files including: accrual upload errors, inaccurate sponsor registration of study elements, and incongruous organizational structures. All issues identified were fixed within the CTRP data or identified as in progress through the comments field on the submitted Data Table 4. In addition, a database of sponsors and institutional contacts was created and is being expanded to include a web-based site to share data discrepancies and corrections.

Address lessons learned and future directions:

Various lessons were learned from this process and include the need to review automated files regularly for proper assessment of the data, educate engaged sponsors of CCSG definitions, as well as leverage established connections to help identify contacts. Next steps involve the development of the contact database to enable the research community to query as well as reviewing the need of a CTRP task force. Currently the process warrants adjustments with community input through mechanisms such as the contact database and central shared site to streamline data corrections and to maintain accurate CTRP data across all cancer centers.

Generating an Accurate CCSG Data Table 4 from the NCI Clinical Trials Reporting Program



Raymond Skeps, MS¹; Linda Mendelson¹; Dana Johnson Robbins¹; Marlisa Isom, MS¹; Kristi Stiffler, MPH¹
¹ Fred Hutchinson Cancer Research Center

Introduction

Recent changes to the submission process for CCSG Data Table 4 interventional (INT) trials using the Clinical Trial Reporting Program (CTRP) export requires significant efforts by Cancer Centers to ensure an accurate data table. In 2017, the NCI started using CTRP to generate non-competing renewal Data Table 4 for interventional studies. This process is being rolled-out for competing renewals in 2018. A comprehensive data reconciliation process is necessary to align accrual and protocol data across the reporting institution, sponsors and other centers. To ensure the accuracy of the CTRP Data Table 4 for the CCSG competing and non-competing renewal, a comprehensive review, comparison and reconciliation process across reporting entities was necessary.

Timeline of CTRP Updates



Goals

Primary: Generate an accurate CTRP Data Table 4 report by identifying and reconciling protocol and accrual data discrepancies across CTRP, sponsors, other centers, and internal databases.

Secondary: Define a method and communication network across institutions and sponsors for reconciling and adjusting accrual and protocol specific data.

Methods

- Data Table 4 was generated and exported from local database and STRAP
- Spreadsheet Compare was used to compare the two files and identify discrepancies
- Determinations were made using ClinicalTrials.gov and study team data validation and discrepancies were rectified via:
 - Outreach to sponsors to request change to CTRP (industry sponsors, external sites, NCTN Groups)
 - CTR manual changes and accrual batch uploads
- Sponsor contacts were identified through protocols, funding sources, institutional websites, local database, and outreach, and a contact database was created to expedite future outreach efforts

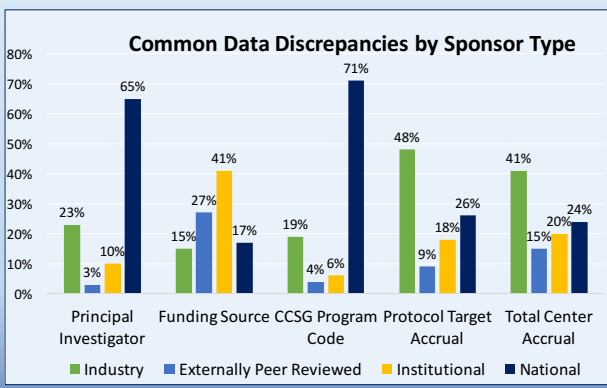
Discussion

The CTRP Data Table 4 report exposed protocol and accrual data discrepancies between institutional databases, CTRP, sponsors and external sites. Several issues were identified that resulted in data discrepancies with the CTRP export, including: accrual upload errors, inaccurate sponsor registration of study elements, and incongruous organizational structures.

Reconciliation of the disproportionately high volume of data discrepancies on industry and NCTN-sponsored trials was the most time and resource-intensive part of the process in part due to difficulties identifying the appropriate external contacts.

Results

- The majority of data discrepancies were identified on industry and NCTN-sponsored trials and required outreach to rectify
- The most common data fields with errors include: PI, Funding Source, CCSG Program Code, Protocol Target Accrual, and Total Center Accrual



Lessons Learned

- Perform ongoing quality control and reconciliation between CTMS and CTRP Data Table 4
- Leverage established sponsor connections to help identify contacts
- Initiate sponsor outreach immediately upon identifying discrepancies with sponsor-managed CTRP data
- Proactively reach out to sponsors regarding CTRP registration if your site is the first trial site
- Improve process and quality control of Funding Source data entered into local CTMS

Future Directions

- Partner with other Cancer Centers to educate sponsors on CCSG data definitions
- Develop a web-based solution to allow sites to share data discrepancies and corrections across Cancer Centers
- Expand database of sponsor's CTRP contacts and share across Cancer Centers



NCI Designated Cancer Center since 1976



Addressing Patient Barriers to Cancer Clinical Trial Enrollment

Joseph M. Unger, PhD¹; Suanna S. Bruinooge, MPH²; Mark E. Fleury, PhD³

¹Fred Hutchinson Cancer Research Center; ²American Society of Clinical Oncology; ³American Cancer Society Cancer Action Network

Describe the background of the problem:

Clinical trials are the key step in advancing potential new cancer treatments from the research setting to the cancer care clinic, and patient participation in trials is crucial to this success. Most patients express a willingness to participate in clinical research, yet only a small fraction ultimately end up enrolling in a cancer clinical trial due to barriers that make participation difficult or even impossible. Consequently, approximately 20% of cancer clinical trials fail due to insufficient patient enrollment. Understanding and addressing these barriers is critical to accelerating progress in cancer research.

Provide metrics or goals to be achieved:

One goal of this work was to comprehensively assemble the evidence describing the spectrum of barriers facing patients interested in enrolling in cancer clinical trials, describing how these barriers relate to each other and how large of a contribution each category made toward overall barriers.

In addition to describing the known barriers, a second goal of this work was to create policy and programmatic recommendations based on the compiled evidence that if implemented, would make meaningful differences in reducing enrollment barriers.

Describe the solutions or methods implemented:

This project resulted in a comprehensive landscape report describing the barriers preventing or inhibiting patient enrollment in therapeutic clinical trials the report is organized by chapters dedicated to patient barriers, provider and institution barriers, and trial-design barriers, including a special focus on disparities in trial enrollment. The project also resulted in 23 consensus recommendations endorsed by over 15 organizations representing patients, research institutions, providers, and research organizations.

Describe the outcome or show data representing a change (positive or negative):

The consensus recommendations along with the report represent a collective commitment to set of specific steps that the clinical cancer research community can take to improve clinical trial enrollment.

Address lessons learned and future directions:

Some of the recommendations echo existing recommendations and reflect activities already underway, and the group of endorsing organizations will examine opportunities to enhance implementation of those existing efforts, while also pursuing implementation of recommendations that are not currently being acted upon.

Addressing Patient Barriers to Cancer Clinical Trial Enrollment

Joseph M. Unger, PhD¹; Suanna S. Bruinooge, MPH²; Mark E. Fleury, PhD³

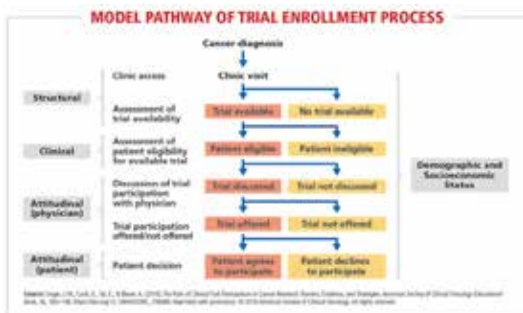
¹Fred Hutchinson Cancer Research Center; ²American Society of Clinical Oncology; ³American Cancer Society Cancer Action Network

Abstract

Clinical trials are the key step in advancing potential new cancer treatments from the research setting to the cancer care clinic, and patient participation in trials is crucial to this success. Most patients express a willingness to participate in clinical research, yet only a small fraction ultimately end up enrolling in a cancer clinical trial due to barriers that make participation difficult or even impossible. Consequently, approximately 20% of cancer clinical trials fail due to insufficient patient enrollment. Understanding and addressing these barriers is critical to accelerating progress in cancer research.

Barriers in Multiple Domains

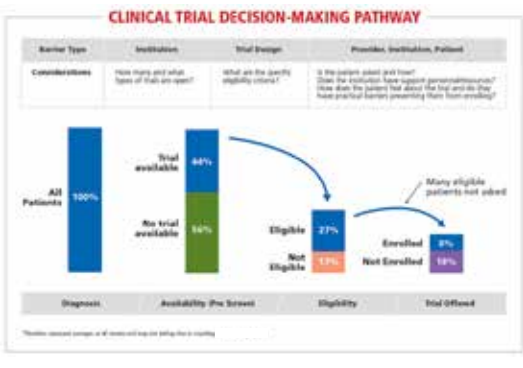
Enrollment in a cancer clinical trial involves a multi-step process and while participation is typically thought of in terms of a patient decision, it is notable that the patient is not presented with the option until the last step, which is only reached if previous barriers have not been encountered



Analyzing studies across a variety of settings suggests that:

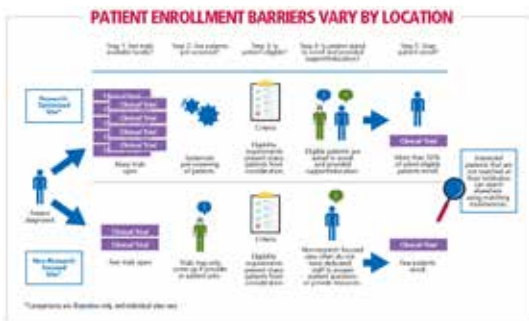
- 56% of patients will not have a local trial available for their cancer
- 17% will be ineligible for a trial due to exclusion criteria
- Many eligible patients will not be asked by their provider to enroll
- Only 27% of cancer patients will have the option to enroll in a local clinical trial

Among patients eligible for an available clinical trial, typically greater than 50% of patients asked will enroll. Patients who decline to participate cite fear of side effects, loss of control, costs, and logistics involved with participating in trials as their primary reasons.



Provider and Institution Barriers

Healthcare providers and institutions have a significant impact on cancer clinical trial enrollment as a result of decisions regarding which and how many trials to open at a site, the quantity and type of research personnel employed, and whether and how they identify and enroll patients in trials. These decisions are heavily dependent upon adequate funding, often supplied from the National Cancer Institute or the pharmaceutical industry, to support necessary research personnel and infrastructure. Typically, high-performing sites manage their trial portfolios to match the patient population they serve, systematically pre-screen their patients for trial eligibility, and collaborate across networks.



CLINICAL TRIAL ENROLLMENT PATTERNS FOR MULTIPLE STUDIES IN THE LITERATURE*

	TRIAL UNAVAILABLE	ELIGIBLE	NOT ENROLLED	ENROLLED
Academic Centers				
Average rate†	41.4%	24.2%	19.5%	14.8%
Community Centers				
Average rate†	52.0%	15.7%	17.9%	6.3%
Combined				
Adjusted rate†	34.2%	17.4%	19.2%	8.9%

* Excerpted from Unger et al. (2012) and Bruinooge et al. (2013).
† Percentages are based on the number of patients who were screened for a clinical trial and were eligible to enroll in a trial.

Trial-Design Barriers

As science propels cancer treatments forward, clinical trials are increasingly designed around very small genetically defined subsets of cancer patients, making finding eligible patients even more difficult. At the same time, eligibility criteria like age, HIV status and the presence of previous cancers are being reexamined to ensure that restrictions are not unnecessarily preventing willing patients from enrolling on trials. Involving patients in the design of clinical trials has also been found to improve their appeal to patients and accrual success.

Patient Barriers

PATIENT-REPORTED REASONS FOR DECLINING TRIALS

STUDY	Rank of Responses			
	1ST	2ND	3RD	4TH
Cancer Patients				
Harrop, (2007) [75]	Fear of side effects: "Top side effects that might come with treatment on a clinical trial"	Control: "I am uncomfortable with being randomly assigned. For example, a 50% loss to a treatment"	Control: "I am receiving a placebo. For me to be a judge of the requirements due to logistical barriers such as transportation."	Logistics: "I would be unable to fulfil the requirements due to logistical barriers such as transportation."
Unger, (2012) [94]	Control: "Barriers treatment and protocol would compromise care"	"Did not want treatment"	Fear of side effects: "Treatment side effects"	"No general barrier"
Lera, (2004) [100]	Control: "Gains for other treatment"	Logistics: "Distance from site"	"Unknown"	Costs: "Insurance barrier"
Kalish, (1999) [111]	"Concern about experimentation"	"Uninformed"	Costs: "Concern about cost" and "Insurance refusal"	Fear of side effects: "Concern about toxicity"
Zafra, (2013) [204] (Monoclonal)	Control: "Feeling uncomfortable with being randomly assigned to a treatment"	Control: "Feeling receiving a placebo"	Fear of side effects: "Feeling side effects that may come with treatment"	Costs: "Believing that health insurance would not cover a clinical trial"
Jovic, (2012) [34]	Control: "Did not like that protocol started treatment"	Fear of side effects: "I am afraid that after treatment, I had too many side effects"	Lack of personal benefit: "Did not want treatment unless it was proven to be better than standard of care"	Logistics: "Did not want to travel to the site"
Public				
CHSRP, (2017) [5] (International)	Fear of side effects: "Side effects scared me"	Logistics: "Too many study visits"	"Medical procedures too invasive"	Control: "Anxiety of receiving placebo and too many medical procedures"
Memorial Sloan-Kettering, (2014) [26]	Fear of side effects: "Anxiety about side effects, not just about safety"	Costs: "Uncertain about insurance coverage, not just about cost"	Logistics: "The location is inconvenient"	Control: "Worried about getting a placebo"
Research America, (2017) [6]	Fear of side effects: "Too risky" & "Multiple surgeries"	"Lack of trust"	Costs: "Little or no insurance reimbursement"	"Lack of access"

Recommendations

Informed by an this analysis, a set of 23 recommendations were developed to address the identified barriers. The recommendations were endorsed by 17 organizations and companies and are organized under the themes of:

- Provider and Institution Barriers
- Patient Barriers
- Trial-Design Barriers
- Disparities

Report and recommendations available at:
www.acscan.org/clinicaltrialbarriers



Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Establishing a Research Nurse Practitioner-Led Clinic for Early Phase Clinical Trials

Edward Bentlyewski, MSN, APN, NP-C, AOCNP®; Eneil de la Peña, MSN, ANP-BC, OCN; Cirah Mira Falkenstern, MSN, RN; Fran Brogan, MSN, RN, OCN, CCRP; Moshe A. Kelsen, MBA; Richard D. Carvajal, MD; Andrew B. Lassman, MD, MS; Gary K. Schwartz, MD

Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center

Describe the background of the problem:

Implementing clinical research is a complex endeavor that requires careful coordination. Nurse practitioners are uniquely positioned to alleviate the logistical challenges associated with caring for patients on early phase clinical trials.

The research related goals of The Cancer Moonshot Initiative include improving clinical research and regulatory efficiency as well as increasing accessibility of clinical trial information for patients. (ASCO, 2017) Oncology providers may struggle to meet this demand as the oncology workforce is aging and retiring at increased rates. Demand for oncology services is expected to increase, with increased population & survivorship, leading to gap in supply and demand of oncology providers. One potential solution is increased utilization of nurse practitioners and physician assistants. (Erikson et al, 2008)

The research setting is subject to the same strains on provider coverage though may be felt more acutely due to the unique associated complexities that have become even more apparent in recent years. Clinical trial complexity is expected to continue to increase (AACI, 2015).

The time spent on attending to details of clinical trial can be a burden for physician investigators. (Unger et al, 2016) Investigators and institutions experience greater workload with early phase trials in comparison to other phases of trials. (Craft et al, 2009) Our institution is establishing a research nurse practitioner-led clinic and leveraging the skills of the research nurse practitioner in order to meet the increased complexities of caring for patients on early phase clinical trials.

Provide metrics or goals to be achieved:

- Positive effect on study enrollment & retention. We will be able to look retrospectively & prospectively number of patients accrued
- Patient satisfaction. We anticipate increased satisfaction. Can be assessed with satisfaction survey results
- NP job satisfaction improvement with respect to sense of autonomy. Will assess with surveys and department retention figures.
- Achieve consensus on description of Research Nurse Practitioner role and scope of practice.

Describe the solutions or methods implemented:

We are implementing & piloting a nurse practitioner-led clinic in the phase 1 setting to help meet the needs of patients enrolled to early phase studies. The Research Nurse Practitioner is a blended role of the Nurse Practitioner and Research Nurse. The Research NP is adaptable and can consent, screen, manage toxicities and follow up patients on clinical trial. The Research NP may also perform procedures and may be listed as an investigator.

Describe the outcome or show data representing a change (positive or negative):

We expect to see improved Nurse practitioner autonomy, job satisfaction & retention.

It is early on in the implementation of the research NP clinic and there is no objective data yet. We anticipate that the Research NP clinic will have a positive effect on retention & enrollment to clinical trials. We plan to describe the scope of the Research Nurse Practitioner role and it's best application in the phase 1 setting. We then hope to apply this model in other disease specific research teams within our institution.

Address lessons learned and future directions:

The blended nature of the research NP role may also be a limitation. There is potential for role ambiguity. The level of engagement and "buy-in" can vary between other providers and investigators.

Nurse practitioner scope of practice may vary between practitioners due to non-uniform certifications, credentialing and collaborative practice agreements.

Establishing a Research Nurse Practitioner-Led Clinic for Early Phase Clinical Trials

Edward Bentlyewski, MSN, APN, NP-C, AOCNP®, Eneil de la Peña, MSN, ANP-BC, OCN, Cirah Mira Falkenstern, MSN, RN, Fran Brogan, MSN, RN, OCN, CCRP, Moshe A. Kelsen, MBA, Richard D. Carvajal, MD, Andrew B. Lassman, MD, MS, Gary K. Schwartz, MD

Columbia University Medical Center Herbert Irving Comprehensive Cancer Center

Background

Implementing clinical research is a complex endeavor that requires careful coordination. Early phase trials often have higher acuity & require more frequent assessments. Nurse practitioners are uniquely positioned to alleviate the logistical challenges associated with caring for patients on early phase clinical trials.

Our institution is implementing & piloting a nurse practitioner-led clinic in the phase 1 setting to help meet the needs of patients enrolled to early phase studies. We are leveraging the skills of the research nurse practitioner in order to meet the increased complexities of caring for patients on early phase clinical trials.

The Research Nurse Practitioner is a blended role that incorporates responsibilities of the Investigator, Coordinator, Research Nurse and oncology nurse practitioner. (See figure 1)

The Research NP is adaptable and can independently manage patient care while on clinical trial. Some of the key functions of the role are:

- Obtain informed consent/ Screening
- Toxicity assessment, grading & management
- Provide study related and standard of care visits as needed
- Refer to specialties for further workup & management as needed
- May perform procedures such as biopsy
- May be listed as investigator at some institutions

FIGURE 1. Research Roles Diagram



Goals

- Positive effect on study enrollment & retention:
- Continued improvement with Patient satisfaction
- NP job satisfaction improvement with respect to sense of autonomy.
- Achieve consensus on description of Research Nurse Practitioner role and scope of practice.

Methods

The research Nurse practitioner will be seeing and independently assessing patients at routine study visits and standard of care visits for toxicity management. Patients who present for day 1 of a cycle or for restaging visit will see an investigator on study.

We plan to:

- Assess retrospective & prospective enrollment & retention data
- Assess patient satisfaction with surveys
- Assess nurse practitioner satisfaction with surveys & interviews
- Meet with investigators weekly to discuss patient care, research NP role/ scope of practice and logistics of clinic operation

Results

We expect to see improved Nurse practitioner autonomy, job satisfaction & retention.

It is early on in the implementation of the research NP clinic and there is no objective data yet. We anticipate that the Research NP clinic will have a positive effect on retention & enrollment to clinical trials. We plan to describe the scope of the Research Nurse practitioner role and its best application in the phase 1 setting. We then hope to apply this model in other disease specific research teams within our institution.

Conclusion

Nurse practitioners provide quality, safe & patient centered care for clinical trial patients.

A research nurse practitioner can balance the patient needs with complex study requirements lead to accurate data, thus enhancing cancer care.

Future improvements

The blended nature of the research NP role may also be a limitation. There is potential for role ambiguity. The level of engagement and “buy-in” can vary between other providers and investigators.

Nurse practitioner scope of practice may vary between practitioners due to non-uniform certifications, credentialing and collaborative practice agreements.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Integrating Centralized Delegation and Training Documentation

Susie Flores; Kathryn Cooper; Leslie Segall, MPH; Makan Fofana; Katherine Lestrade, MAT; Melissa McAvoy; Suzanne Mistretta; Timothy Johnson; Dan Otap, CCRP; Moshe Kelsen, MBA

Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center

Describe the background of the problem:

As evidenced by previously presented AACI CRI abstracts¹, lack of documentation of protocol training and maintenance of Delegation of Authority Logs (DALs) are common non-compliance findings across clinical trials. Ongoing maintenance of traditional training logs and paper DALs requiring signatures from study personnel have proven to be substantial administrative burdens. Logs are particularly challenging for academic centers with large research teams and protocols that undergo numerous amendments.

Provide metrics or goals to be achieved:

- Accurate and timely documentation of study personnel training and delegation of responsibilities
- Decrease regulatory staff time and effort associated with ongoing training documentation and DALs
- Reduction of training and DAL findings identified during monitor visits, audits, and inspections

Describe the solutions or methods implemented:

The Clinical Protocol and Data Management (CPDM) department created a centralized system that simultaneously serves to document institutional/protocol specific trainings as well as document PI delegations of study responsibilities.

The Columbia University's Research Compliance and Administration System (RASCAL) is a proprietary software used to submit research studies to the IRB. Since all key personnel are required per institutional policy to log-in and complete a conflict of interest verification, the department collaborated to enhance this system. The enhancement enables PIs and regulatory staff to electronically notify key personnel of study amendments, requiring staff to log-in and attest within RASCAL, prior to IRB submission. Self-training is documented via time-stamped electronic signatures.

After consulting with authors of similar concepts¹, the CPDM transitioned to a central DAL model, which also utilizes RASCAL. Across all CPDM managed studies, a Master Signature Sheet captures study personnel's name, credentials, signatures, initials, start and stop dates. RASCAL enables study personnel to agree to participate in research studies and for the PI to delegate study responsibilities. These study specific delegations are documented within this system.

Describe the outcome or show data representing a change (positive or negative):

Since its implementation in September 2017, there has been a decrease in training documentation non-compliance findings across monitoring visits and audits.

The central DAL SOP was implemented in April 2018, and it is anticipated that the new model will lessen non-compliance findings. Additionally, a 10% reduction in time/effort associated with regulatory coordinator activities is predicted. Thus, the initiative will permit an increased focus on other vital activities such as study start-up, annual renewals, and final close out projects.

Address lessons learned and future directions:

Collaborations amongst academic research centers, at conferences such as the annual AACI CRI, provide opportunities to develop and implement best practices not otherwise known.

Since the implementation of the updated training SOP, our department has observed a substantial decrease in findings associated with ICH-GCP documentation concerns.

As a quality improvement project within the CPDM, metric analyses for both training and DAL findings will be performed on an ongoing basis. Necessary adjustments will be implemented as continued data is obtained to further optimize systems and structures.

Integrating Centralized Delegation and Training Documentation

Susie J. Flores; Leslie Segall, MPH; Kathryn Cooper; Makan Fofana; Katherine Lestrade, MAT; Melissa McAvoy; Suzanne Mistretta; Timothy Johnson; Dan Otap, CCRP; Moshe Kelsen, MBA

Background

As evidenced by previously presented AACI CRI abstracts¹, lack of documentation of protocol training and maintenance of Delegation of Authority Logs (DALs) are common non-compliance findings across clinical trials. Ongoing maintenance of traditional training logs and paper DALs requiring signatures from study personnel have proven to be substantial administrative burdens. Logs are particularly challenging for academic centers with large research teams and protocols that undergo numerous amendments.

Goals

- Accurate and timely documentation of study personnel training and delegation of responsibilities.
- Decrease regulatory staff time and effort associated with ongoing training documentation and DALs
- Reduction of training and DAL findings identified during monitor visits, audits, and inspections

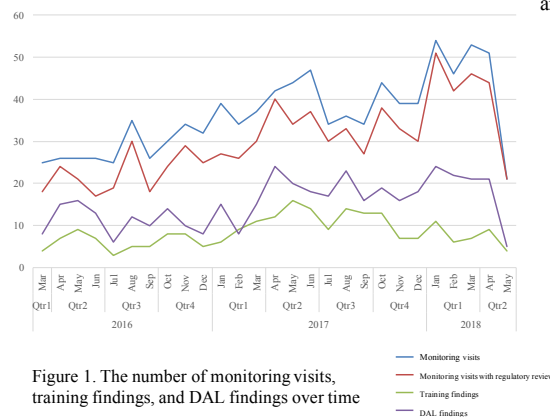


Figure 1. The number of monitoring visits, training findings, and DAL findings over time

Methods

The Clinical Protocol and Data Management (CPDM) department created a centralized system that simultaneously serves to document institutional/protocol specific trainings as well as document PI delegations of study responsibilities.

The Columbia University's Research Compliance and Administration System (RASCAL) is a proprietary software used to submit research studies to the IRB. Since all key personnel are required per institutional policy to log-in and complete a conflict of interest verification, the department collaborated to enhance this system. The enhancement enables PIs and regulatory staff to electronically notify key personnel of study amendments, requiring staff to log-in and attest within RASCAL, prior to IRB submission. Self-training is documented via time-stamped electronic signatures. The new training SOP incorporating this update was implemented at the end of September 2017, replacing the previous SOP dated February 2016.

After consulting with authors of similar concepts, the CPDM transitioned to a central DAL model, which also utilizes RASCAL. Across all CPDM managed studies, a Master Signature Sheet captures study personnel's name, credentials, signatures, initials, start and stop dates. RASCAL enables study personnel to agree to participate in research studies and for the PI to delegate study responsibilities. These study specific delegations are documented within this system.

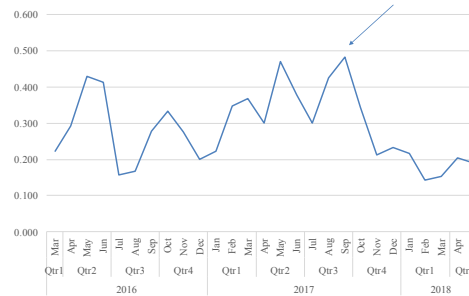


Figure 2. Proportion of training findings over time. The arrow indicates when the new training SOP went into effect.

Results

We reviewed 979 monitoring visit follow-up letters for training and DAL findings between the time period of March 2016 and May 2018 (Figure 1). This review encompassed industry trials across 66 sponsors, and 42 CROs. We limited our analysis to the 814 monitoring visits in which regulatory was examined.

Over the 814 monitoring visits, there were 230 findings associated with protocol specific training of personnel. We also examined the impact of the new CPDM SOP for protocol specific training by looking at the number of findings before and after its implementation in September 2017 (Figure 2). Before the new training SOP went into effect, there were 165 findings across 509 monitoring visits (32.4%). After the new SOP went into effect, there were 64 findings across 305 monitoring visits (21%). This represents a decrease in monitoring visit findings associated with protocol specific training of more than 10%. During the time period examined, there were 415 findings associated with DAL creation and maintenance. The new CPDM SOP regarding DAL creation and maintenance went into effect April 2018, and as such, we do not have enough data to accurately illustrate the impact this SOP has had on our DAL activity.

Conclusion

Since the implementation of the updated training SOP, our department has observed a substantial decrease in findings associated with ICH-GCP documentation concerns.

Future improvements

Collaborations amongst academic research centers, at conferences such as the annual AACI CRI, provide opportunities to develop and implement best practices not otherwise known.

As a quality improvement project within the CPDM, metric analyses for both training and DAL findings will be performed on an ongoing basis. Necessary adjustments will be implemented as continued data is obtained to further optimize systems and structures.



COLUMBIA UNIVERSITY
MEDICAL CENTER

Herbert Irving Comprehensive Cancer Center

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Dedicated Research Nursing Staff Retention and Impact on Clinical Trial Enrollment

Ruby Wu, MSN, RN, AOCNP; Alyssa Macchiaroli, MSN, RN; Frances Brogan, MSN, RN, OCN; Moshe Kelsen, MBA

Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center

Describe the background of the problem:

Clinical research nurses are essential to the successful registration and treatment of clinical trial participants in adherence to Good Clinical Practice (GCP). This subspecialty of oncology registered nurses (RNs) or advanced practice nurses (APNs) are highly trained and represent a small population of nursing professionals. The urgency associated with enrolling subjects on oncology treatment trials and safety monitoring in early phase studies often place demands beyond what a traditional 8 or 10-hour outpatient work schedule can accommodate. Declines in staffing cause significant problems in caring for clinical trial participants.

Provide metrics or goals to be achieved:

At Herbert Irving Comprehensive Cancer Center (HICCC) our goal was to increase the number of clinical research nursing staff and improve retention rates within the department in an effort to support patient participation on clinical trials.

Describe the solutions or methods implemented:

To increase nursing recruitment, retention, and improve patient care HICCC implemented a flexible working arrangement, allowing for RNs and APNs to work three 12 hours shifts during the work week. Nurses are managed through a central research office of the cancer center, and are assigned to cover specific disease groups according to calculated workload which is adjusted to need. Primary nurses are assigned to a disease group to maintain continuity of care, with designated secondary and tertiary coverage. This adaptable coverage fosters an environment that can support the demands of rapidly changing clinical trial portfolios, achieves balanced workloads, and allows patients to enroll on trials expeditiously. A structured template was created for nursing documentation allowing for seamless hand-off between nurses for optimal patient care on trials. This nursing note enables clinical trial data integrity while being flexible enough to accommodate specific disease site and protocol requirements. All nurses are oriented through a structured 8-week program, rotating

through at least 2 disease groups. Nurses are encouraged to attend hematology/oncology grand rounds, tumor boards, and professional conferences. A flexible working arrangement of three 12 hour shifts also grants time for continuing education and several nurses have attained advanced nursing degrees while working full time.

Describe the outcome or show data representing a change (positive or negative):

As HICCC has undergone rapid expansion of our clinical research program, improvements have been made in parallel to increase nursing retention. From 2011 to 2017 the full time nursing staff grew from 7 to 23. During this same period, enrollment on therapeutic clinical trials increased by 45%. In the course of growth, the diversity of the clinical trial portfolio has shifted from primarily cooperative group and non-interventional trials to expanding to include more early phase and immunotherapy trials. Phase I and II trial accruals tripled over a four-year period from 2013 to 2017. The ability to grow the nursing core has been a key contributor to maintaining patient safety, insuring overall compliance, and keeping pace with high volume clinical trial enrollment.

Address lessons learned and future directions:

Clinical research nursing is highly specialized, thus requiring a department that can cultivate their training and optimize their workload. Through the flexible work arrangement research nursing recruitment and retention has increased allowing for growth of experienced research nurses within the department, improved patient care, and ultimately higher patient enrollment in clinical trials. Nursing professionals have supported the growth of the clinical trial program and are necessary for ongoing improvements to interventional trial accrual as HICCC continues to expand.

Dedicated Research Nursing Staff Retention and Impact on Clinical Trial Enrollment

Ruby Wu, MSN, RN AOCNP; Alyssa Macchiaroli, MSN, RN; Frances Brogan, MSN, RN, OCN; Moshe Kelsen, MBA

Background

- Clinical research nurses are essential to the successful registration and treatment of clinical trial participants.
- Urgency associated with enrolling subjects on oncology treatment trials and safety monitoring in early phase studies place demands beyond what a traditional 8 or 10-hour outpatient work schedule can accommodate.
- Declines in staffing cause significant problems in caring for clinical trial participants.

Goals

- At Herbert Irving Comprehensive Cancer Center (HICCC) our goal was to increase the number of clinical research nursing staff and improve retention rates within the department in an effort to support patient participation on clinical trials.

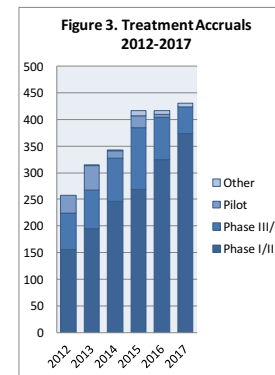
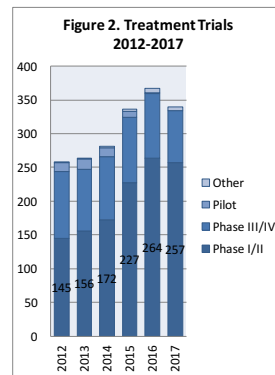
Methods

- HICCC implemented a flexible working arrangement, allowing RNs and APNs to work three 12 hours shifts/week.
- Nurses are managed through a central research office of the cancer center, and assigned to cover specific disease groups according to workloads, adjusted to need.
- Nurses are assigned to a primary disease group to maintain continuity of care, with designated secondary and tertiary coverage.
- A structured template for research specific nursing documentation allows for seamless hand-off between nurses for optimal patient care.
- Research nursing note enables accurate capture of clinical trial data and adapts to different disease site and protocol requirements (Fig. 1.).
- All nurses are oriented through a structured 8-week program, rotating through at least two disease groups.
- Flexible working arrangement grants time for continuing education.

- Phase I and II trial accruals tripled over a four-year period from 2013 to 2017.
- Several nurses have attained advanced nursing degrees while working full time.
- Ability to grow the nursing core helps maintain patient safety, insures overall compliance, and keeps pace with high volume clinical trial enrollment.

Figure 1. Nursing Note Example

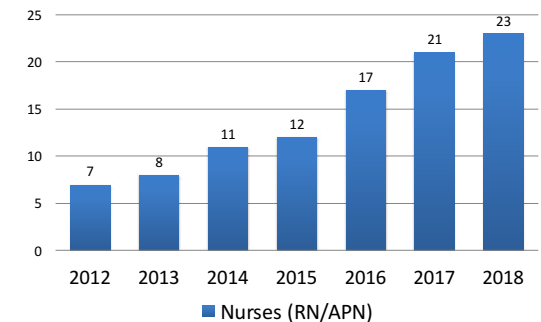
Patient Name: Joan Smith MRN: 1234567 DOB: 01/Jan/1950 Randomization: Arm A; Cohort 2		Date of Visit: 02-Feb-2018 Study ID: ABCDEFG Study Name/IRB#: Randomized Phase III Trial of Medicine A in Metastatic Breast Cancer/ABC123 Study Time Point: Cycle 2, Day 8				
REVIEW OF SYSTEMS AND ADVERSE EVENTS (AE) ASSESSMENT BASED ON CTCAE VERSION 4.0						
Changes among AEs reported since prior assessment?: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No						
SYSTEM	COMMENTS (Normal except as documented below)	AE TERM	GRAD E	START DATE	STOP DATE	ATtribution TO PACT/FAKEL
Constitutional	Intermittent fatigue, relieved by rest	Fatigue	1	3/1/18	Intermittent	Probably related
HENT	Runny, itchy nose related to seasonal allergies; not intervention taken	Allergic rhinitis	1	3/1/18	Ongoing	Pre-existing
Dermatologic	Pruritic, erythematous, flat rash on anterior chest and face occurred 30 minutes post dose on CD1. Today is mild and localized only to upper chest, less than <10% BSA.	Rash Maculo-Papular	2	3/1/18	3/1/18	Definitely related
Cardiovascular		None				
Respiratory		None				
Musculoskeletal	Intermittent left arm pain; known site of bone metastases; difficulty with carrying groceries	Bone pain	2	1/15/18	Intermittent	Pre-existing
Laboratory	See lab report for details	Anemia	2	2/1/18	Ongoing	Pre-existing
CONCOMITANT MEDICATIONS						
Changes among concomitant medications reported since prior assessment?: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No						
Medication Name/Dose/Route/Frequency	Indication	Start Date	Stop Date	Comments		
STANDING MEDICATIONS						
Diphenhydramine 25 mg tab, 2 tabs PO once	Rash maculo-papular	3/1/18	3/1/18			
PRN MEDICATIONS						
Acetaminophen/oxycodone 325/5mg tab; 1 tab PO Q4-6hrs PRN	Bone pain	1/18/18	Ongoing			
NON-PRESCRIPTION / OTC SUPPLEMENTS						
Vitamin D 1000IU tab; 1 tab PO daily	Health Maintenance	5/15/2010	Ongoing			



Results

- As HICCC has undergone rapid expansion of our clinical research program, improvements have been made in parallel to increase nursing retention.
- From 2012 to 2017 the full time nursing staff grew from 7 to 23 (Fig. 4.).
- From 2012 to 2017 enrollment on therapeutic clinical trials increased by 45% (Fig. 3.)
- Trial portfolio shifted from primarily cooperative group/non-interventional trials to more early phase /immunotherapy trials (Fig. 2.).

Figure 4. Growth of Nursing Core 2012-2018



Conclusion

- Central research office can help to train and optimize workload for research nurses
- Flexible work arrangement improves retention and allows for growth of experienced research nurses within the department, improved patient care, and ultimately higher patient enrollment in clinical trials.

Future Improvements

- Nursing professionals have supported the growth of the clinical trial program and are necessary for ongoing improvements to interventional trial accrual as HICCC continues to expand.

Standardizing Selection and Prioritization of Interventional Clinical Trials at Hollings Cancer Center

Kate Anderton, MPH, CCRP; Tricia Bentz, MHA, CCRP

Hollings Cancer Center, Medical University of South Carolina

Describe the background of the problem:

Hollings Cancer Center (HCC) divides diseases areas up into 13 Disease Focus Groups (DFGs) to review clinical trials. These focus groups are tasked with identifying potential studies, facilitating the startup process, and discussing barriers to enrollment. Historical data from CY 2014 and 2015 showed that approximately 28% of the adult therapeutic trials activated did not accrue in the first year. Activating clinical trials requires significant resources of the HCC Clinical Trials Office (CTO), Investigator, Protocol Review Committee (PRC) and other services. HCC assessed that there were major variations in how trials were selected among the DFGs and oftentimes, key information impacting accrual estimates and feasibility were not part of the trial decision-making process.

Provide metrics or goals to be achieved:

Over the last year, the HCC CTO has developed initiatives to help with standardizing study selection and trial prioritization. With the implementation of these initiatives, the HCC CTO hopes to demonstrate the following metrics:

- Decrease time to activation of Interventional trials
- Standardize DFG trial portfolios to show representation of institutional and/or external peer reviewed trials, national trials, and industry-sponsored trials and prioritizing institutional and/or external peer review trials across all DFGs.
- Increase accrual within the first year of study activation.

Describe the solutions or methods implemented:

In March 2018, the following process improvements were implemented in the DFGs at HCC.

Resource Allocation and Feasibility Team Review (RAFT): To assist with the DFG trial selection, improve accrual projection decisions, and decrease study activation timelines, the HCC CTO implemented a RAFT review to formalize a multidisciplinary feasibility review of each interventional trial.

The purpose of this review is to identify operational issues that make a study unfeasible or may delay trial activation. The outcomes of the RAFT review are discussed with the PI and DFG. Outstanding issues for highly complex trials are kept on the agenda at both the disease focus group and the RAFT working group meeting until resolved.

DFG Prioritization Form:

This form requires investigators to identify competing studies and standardize how trials are prioritized across DFGs. RAFT reports are reviewed and feasibility information is considered when the DFG estimates accrual projections. Trials are ranked using standardized Cancer Center criteria and recorded using an impact score that considers the study's sponsorship type and contribution to HCC research programs; the anticipated rate of accrual; potentially overlapping trials; and trial innovation and clinical need. Trials are ranked 1-5 with one being the highest score and this prioritization is then confirmed at the time of the scientific review. The goal is to ensure that the trial prioritization standards set forth by HCC are implemented within the DFGs and DFGs have a standard framework for better management of the DFG portfolio.

Describe the outcome or show data representing a change (positive or negative):

These initiatives were implemented in March 2018, so outcome metrics are unavailable. Preliminary feedback indicates a greater engagement of investigators in the study selection process and improved selection of trials. Fifteen trials have undergone RAFT review where feasibility issues were identified and addressed through involvement of key stakeholders. Effect on the time to activation and accrual within the first year of trial activation is pending.

Standardizing Selection and Prioritization of Interventional Clinical Trials At Hollings Cancer Center

Kate Anderton, MPH, CCRP; Tricia Bentz, MHA, CCRP

BACKGROUND

Hollings Cancer Center (HCC) divides diseases areas up into 13 Disease Focus Groups (DFGs) to review clinical trials. These focus groups are tasked with identifying potential studies, facilitating the startup process, and discussing barriers to enrollment. CY 2014 and 2015 data showed that approximately 28% of the adult therapeutic trials activated did not accrue in the first year. Activating clinical trials requires significant resources of the HCC Clinical Trials Office (CTO), Investigator, Protocol Review Committee (PRC) and other services. HCC assessed that there were major variations in how trials were selected among the DFGs and oftentimes, key information impacting accrual estimates and feasibility were not part of the trial decision-making process

METRICS

- Decrease time to activation of Interventional trials
- Standardize DFG trial portfolios to show representation of institutional and/or external peer reviewed trials, national trials, and industry-sponsored trials and prioritizing institutional and/or external peer review trials across all DFGs.
- Increase accrual within the first year of study activation.

Figure 1. Start Up Process

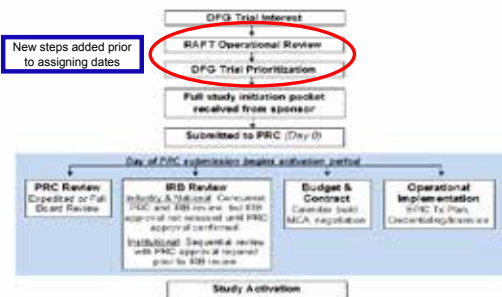


Figure 2 (above). Example of RAFT review outcome

Figure 3 (right). Example of DFG Prioritization Form

Resource Allocation and Feasibility Team Review (RAFT): formalize a multidisciplinary feasibility review of each interventional trial. The purpose of this review is to identify operational issues that make a study unfeasible or may delay trial activation. The outcomes of the RAFT review are discussed with the PI and DFG. Outstanding issues for highly complex trials are kept on the agenda at both the disease focus group and the RAFT working group meeting until resolved.

DFG Prioritization Form: This form requires investigators to identify competing studies and standardize how trials are prioritized across DFGs. RAFT reports are reviewed and feasibility information is considered when the DFG estimates accrual projections. Trials are ranked using standardized Cancer Center criteria and recorded using an impact score that considers the study's sponsorship type and contribution to HCC research programs; the anticipated rate of accrual; potentially overlapping trials; and trial innovation and clinical need. Trials are ranked 1-5 with one being the highest score and this prioritization is then confirmed at the time of the scientific review.

These initiatives were implemented in March 2018, so outcome metrics are unavailable. Preliminary feedback indicates a greater engagement of investigators in the study selection process and improved selection of trials. Fifteen trials have undergone RAFT review where feasibility issues were identified and addressed through involvement of key stakeholders. Effect on the time to activation and accrual within the first year of trial activation is pending.

SOLUTIONS

OUTCOMES

Implementation of Quality Improvement Processes to Reduce Patient Wait Time for an Investigator Initiated Trial (IIT)

Vistea Crawford, CCRP

Hollings Cancer Center, Medical University of South Carolina

Describe the background of the problem:

The timeline for enrollment to a newly opened Investigator Initiated window of opportunity trial became problematic due to delays up to 4.5 hours while attempting to provide same day turnaround. Patients receive the study drug between the diagnostic breast biopsy and planned surgical resection. In some cases, a same day registration was necessary for patients who did not live locally so that an additional trip to the Cancer Center did not create a possible barrier to enrollment. Thus, requiring same day consent, screening, labs, pathology confirmation, eligibility review, patient enrollment, and IP distribution. In a review of the same day enrollment process, the following areas were identified as the main barriers to a more timely process.

- Pathologist confirmation of tissue availability
- Lab result time
- Completion of Physician clinic note with documentation of eligibility criteria and planned surgery date.
- Central eligibility review
- Investigational Drug Services medication preparation and drug dispersal.

Provide metrics or goals to be achieved:

The goal is to decrease patient same day turn around wait time to less than 4 hours.

Describe the solutions or methods implemented:

- Pathologist confirmation of tissue availability
 - Engagement of the pathology department in the pre-screening process helps to ensure that a confirmation of tissue availability can be determined more quickly.
- Lab result time
 - Communication with the care team to have patients sent to the lab immediately after signing informed consent in an effort to have the results in a more timely manner.

- Completion of Physician clinic note with documentation of eligibility criteria and planned surgery date.
 - Guidance was provided to the enrolling investigator on what to address in the clinic note for central eligibility review to avoid timely delays.
- Central eligibility review
 - Source documentation for eligibility review is submitted as soon as it is available as opposed to waiting until all of the documents are available, and the review team has gained access to the EMR to save time on uploading documents.
- Investigational Drug Services medication preparation and drug dispersal.
 - Investigational Drug Services is notified with a "potential patient alert" as soon as a patient has signed consent in an effort to put these patients on their radar. This ensures they are included in the pharmacy workflow, and not an "add on" patient, which may cause a delay in processing the study drug.

Describe the outcome or show data representing a change (positive or negative):

Though we are still in the process of fine-tuning some of the methods implemented. The application of these changes has resulted in a decrease in the time it takes for the same day turn around process. We have observed a reduction in time from 4.5 hours to 3.5 hours.

Address lessons learned and future directions:

In an effort to support clinical trials and ensure that patient satisfaction in the timeliness of appointments is not compromised, we have discovered that taking important measures upfront to communicate a strong plan and engage everyone involved in the process helps to meet these goals. Our aim for the future is to target a timeframe of 3.5 hours or less for the same day turn around process.

Implementation of Quality Improvement Processes to Reduce Patient Wait Time for an Investigator Initiated Trial (IIT)

Vistea Crawford, BA, CCRP

BACKGROUND OF THE PROBLEM	METHODS IMPLEMENTED	PROJECT OUTCOME
<p>The timeline for enrollment to a newly opened Investigator Initiated window of opportunity trial became problematic due to delays up to 4.5 hours while attempting to provide same day turnaround. Patients receive the study drug between the diagnostic breast biopsy and planned surgical resection. In some cases, a same day registration was necessary for patients who did not live locally so that an additional trip to the Cancer Center did not create a possible barrier to enrollment. Thus, requiring same day consent, screening, labs, pathology confirmation, eligibility review, patient enrollment, and IP distribution. In a review of the same day enrollment process, the following areas were identified as the main barriers to a more timely process:</p> <ul style="list-style-type: none"> - Pathologist confirmation of tissue availability - Lab resulting time - Completion of MD clinic note with documentation of eligibility criteria and planned surgery date - Central eligibility review - Investigational Drug Services medication preparation and dispersal 	<ul style="list-style-type: none"> -Pathologist confirmation of tissue availability Engagement of the pathology department in the pre-screening process helps to ensure that confirmation of tissue availability can be determined more quickly. -Lab result time Communication with care team to have patients labs drawn immediately after signing informed consent in an effort to have timelier results -Complete MD clinic note with documentation of eligibility criteria and planned surgery date. Guidance provided to the enrolling investigator on what to address in the clinic note for central eligibility review to avoid timely delays. -Central eligibility review Each source document for eligibility review is submitted as soon as available as opposed to waiting until all of the documents are available, and the review team has gained access to the EMR to save time on uploading documents. -Investigational Drug Services (IDS) medication preparation and dispersal. IDS is notified with a “potential patient alert” when patients sign consent in an effort to put these patients on their radar. This ensures that these patients are included in the pharmacy workflow, and not an “add on” patient, which may cause a delay in processing the study drug. 	<p>In an effort to support clinical trials and ensure that patient satisfaction in the timeliness of scheduled appointments are not compromised, we have discovered that taking important measures upfront to communicate a strong plan and to engage everyone involved in the process helps to meet these goals. Our aim for the future is to target a timeframe of 3.5 hours or less for the same day turnaround process.</p>
<p>PROJECT GOAL</p> <p>Decrease patient same day turn around wait time to less than 4 hours.</p>		<p>LESSONS LEARNED/FUTURE DIRECTIONS</p> <p>Though we are still in the process of fine-tuning some of the methods implemented. The application of these changes have resulted in a decrease in the time it takes for the same day turn around process. We have observed a reduction in time from 4.5 hours to 3.5 hours.</p>



A National Cancer Institute
Designated Cancer Center

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

How to Be a Principal Investigator: Developing and Implementing of a Practical Training Program

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, University of Utah

Describe the background of the problem:

Conduct of clinical trials is highly regulated and complex. Principal investigators complete rigorous medical training and online self-guided training in human subjects protection (HSP) and good clinical practice (GCP). However, these mandatory trainings focus mostly on the history of HSP and general concepts in GCP. The practical skills required to be a successful clinical investigator are not included in academic training courses.

Provide metrics or goals to be achieved:

Our goal was to train new investigators in best practices for conducting clinical research. We measured knowledge of investigator responsibilities and conduct of research in six key domains: 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; and 6) resources available to investigators in their clinical areas. We administered a pre-survey to determine baseline understanding. Participants completed a post-survey immediately following completion of the seminar to determine if knowledge improved and a final survey three months later to assess retention.

Describe the solutions or methods implemented:

A planning committee of seven people, including experienced principal investigators, research personnel, compliance officers, and research administrators defined competency domains and identified content experts for curriculum development. The committee planned an intervention and created surveys to assess outcomes and garner feedback. The intervention consisted of a half-day seminar entitled "How to be a Principal Investigator" where the training was presented. Attendees included both junior and senior faculty and other investigators and staff from ten internal medicine divisions, pediatrics, and nursing. The seminar included eight lectures, two panel discussions, and a resource handout.

Videos of the seminar, slides from all of the lectures, and the resource handout were available after the seminar on the internal website of the Department of Medicine. Continuing medical education (CME) and maintenance of certification (MOC) credits were offered. The planning committee reviewed and analyzed the survey data for pre-, post- and 3-month surveys. ANOVA with pair-wise t-tests with Bonferroni correction were used for comparison.

Describe the outcome or show data representing a change (positive or negative):

Self-assessed quantitative cumulative scores showed improvement in understanding that persisted for three months. P-values were 4.647e-005 for the immediate post-survey compared to the pre-survey and 5.596e-006 for the 3-month survey compared to the pre-survey. No difference was seen between the immediate and 3-month post-surveys. Qualitative feedback from the attendees was positive and provides direction for future iterations of this seminar. At three months, participants indicated they had changed behavior and still used seminar resources.

Address lessons learned and future directions:

A seminar focused on practical applications of investigator responsibilities based on the six competency domains, with collaboration across academic departments, improved and enriched the practical knowledge of clinical investigators. Going forward, this seminar will be offered several times per year; it is now mandatory for Department of Medicine investigators at our institution. Content will be evaluated and modified based on national and international updates in regulations and institutional needs.

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 and the Department of Internal Medicine at the University of Utah

BACKGROUND

Clinical investigators complete rigorous medical training and online, self-guided training in human subjects protection (HSP) and good clinical practice (GCP). These courses do not include the practical skills required to be a successful investigator. To address this gap, we formed a committee to plan an intervention and design a survey to assess understanding.

METHOD

- To meet the need for practical investigator training, we formed a planning committee including two experienced investigators, four experience research coordinators. The committee identified six competency domains for clinical investigators.
- We created a half-day seminar called "How to Be a Principal Investigator." (Figure 1)
- The seminar included eight lectures, two panels, and a resource handout. Lectures focused on teaching skills in documentation, oversight, feasibility, and coordinator management.
- We administered surveys before, immediately after, and 3 months after to measure the efficacy of the intervention.

Figure 1. Seminar Agenda

Presentations, each about 20 minutes, by experienced PIs and research coordinators:

- What I wish I had known when I started
- What are you signing and why?
- Penalties, reporting, and where to go if things go wrong
- Ensuring study success through feasibility and budget review
- Informed consent
- Deviations, adverse events, attributions, clinical significance, expectedness
- Source documentation
- The PI and research coordinator relationship

Panels on regulations and clinical research

Q and A sessions

RESULTS

- Twenty-five junior and senior faculty, other investigators, and staff attended the half-day seminar.
- Self-assessed quantitative cumulative scores showed improvement in understanding that persisted for 3 months.
- Understanding scores in the pre-survey ranged from 7-20 points of a possible 40. Immediate and 3-month post-survey scores ranged from 20-30 points. (Figure 2)
- Qualitative feedback from open-ended questions on the surveys was also positive. (Figure 3)

Figure 2. Understanding Scores

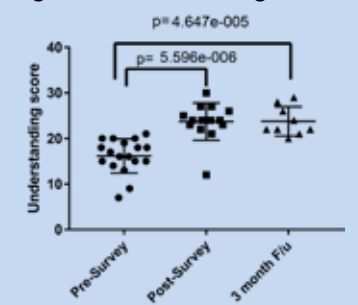


Figure 3. Qualitative Feedback Samples

"This course should be mandatory...it offers so much useful information for the new PI."
BS, Hematology Fellow

"I have used the handout from the talk several times."
AB, Experienced PI

CONCLUSION

A seminar focused on practical applications of investigator responsibilities in identified competency domains improved knowledge of clinical investigators.

FUTURE PLANS

We will offer this seminar several times per year. Participation is now mandatory for Department of Medicine investigators at our institution. We will modify seminar content to reflect national and international regulation changes and institutional needs.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Improving Study Activation Timelines Using a Workflow Management Approach

Erica Love, MA, MPH, CCRP¹; Paul K. Davis, KMP²; Nida Cassim, MPH¹; Stephen Vettorino²

¹Laura and Isaac Perlmutter Cancer Center at NYU Langone; ²Essex Management

Describe the background of the problem:

Decreasing study activation timelines is a perpetual holy grail of research organizations. The Laura and Isaac Perlmutter Cancer Center's (PCC) Clinical Trials Office (CTO) at NYU has implemented a novel approach to reducing time to activation (defined as the time from PRMC submission to the date a study is opened to enrollment) to 100 days or less for interventional treatment trials and 45 days or less for National Cooperative Group trials.

Provide metrics or goals hoped to be achieved with the solutions to address the problem:

Reduce study activation time and increase satisfaction of CTO staff and PCC faculty by:

- Providing real-time visibility into the study activation pipeline;
- Managing work-in-progress via defined targets;
- Reducing variability in study activation processes;
- Optimizing CTO resource allocation based on study prioritization.

Describe the solutions or methods implemented:

The CTO combined a task management system (Jira Core) with a workflow management approach (Kanban) for tracking and managing the tasks required to activate a study. The processes by which studies are activated were documented in use cases, tasks and workflows were modeled within a system (Jira Core), and CTO staff were trained on utilizing workflow management techniques (Kanban). The new approach was launched on Apr 3rd, 2017 and has been in use for all interventional studies since.

Baseline metrics prior to 2017 were established for study activation timelines. Survey data was collected pre- and post-launch of the new approach to capture CTO staff and investigator satisfaction with the study activation process.

Describe the outcome of the solutions implemented or show data representing a change whether positive or negative:

- Decreased time to study activation by 26%. Activation timelines dropped from an average of 140 days prior to implementation to 104 days afterwards;
- Increased overall satisfaction with study activation services provided by the CTO. Staff satisfaction increased by 20% and investigator satisfaction increased by 15%;
- Decreased time CTO staff spend reporting status and shifted focus to monitoring upcoming work and resolving exceptions (e.g., process bottlenecks, stalled tasks, overdue tasks and studies);
- Reduced variability in study activation timelines from a standard deviation of 66 days prior to implementation to 52 days afterwards (21% reduction);
- All tasks and associated workflows are codified in the system thereby enforcing standardization of activation processes;
- Study start up staff workload is now monitored systematically via reports and dashboards.

Show lessons learned, others to involve in the future, changes to the methods to achieve a better outcome:

- Utilizing workflow management techniques (i.e., limiting work-in-progress) to monitor and control the flow of work through the CTO resulted in decreased study activation timelines, reduced variability, better resource management, and greater overall satisfaction with the process;
- Variables outside of the CTO's control (sponsor response time with contract negotiations, response time of internal service providers and investigators) remain barriers to decreasing study activation timelines. Formalized internal escalation processes and more

master contract agreements with industry sponsors are needed to control for these variables;

- Increases in concurrent work-in-progress seem to have a negative impact on study activation timelines; data continues to be collected to further evaluate this correlation and ultimately define appropriate work-in-progress limits;
- Utilization of the NCI's CIRB for National Cooperative Group trials does not seem to have a positive impact on time to study activation. Further evaluation is needed to determine how to decrease time to study activation of these trials below 90 days.

Improving Study Activation Timelines Using a Workflow Management Approach



Erica Love¹, Paul K. Davis², Nida Cassim¹, Stephen Vettorino²
 Laura and Isaac Perlmutter Cancer Center¹, Essex Management²

Laura and Isaac Perlmutter Cancer Center
 Clinical Trials Office

INTRODUCTION

The Laura and Isaac Perlmutter Cancer Center partnered with Essex Management to combine a task management system (JIRA Core) with a workflow management approach (KANBAN) for tracking and managing tasks associated with study activation. With this homegrown system, and an infrastructure using a dedicated study start up unit consisting of 6 senior regulatory specialists, time to activation decreased by 26% (from an average of 140 days pre-pilot to an average of 104 days post pilot), and remains consistent despite intermittent increases in pipeline activity.

METHODS

- Developed study activation workflows for all study sponsorship types;
- Limited work in progress and workflow for staff involved in study activation;
- Dedicated study start up unit consisting of 6 Sr. Regulatory Specialists work only on study activations;
- Concurrent pilot with NYULH IRB to identify areas for improvement both with quality of study submissions and quality of IRB reviews;
- Weekly stand up teleconferences with all relevant parties (Radiology, Investigational Pharmacy, Budgets, Contracts, Study Start Up Staff) to address bottlenecks in real time.

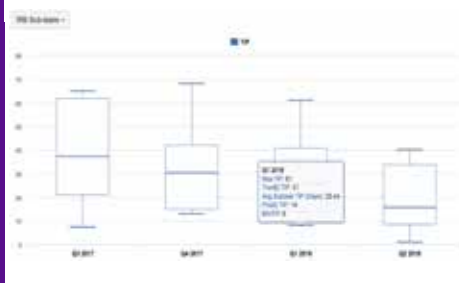
RESULTS

- Decreased time to study activation by 26%. Activation timelines dropped from an average of 140 days prior to implementation to 104 days afterwards;
- Increased overall satisfaction with study activation services provided by the CTO. Staff satisfaction increased by 20% and investigator satisfaction increased by 15%;
- Decreased time CTO staff spend reporting status and shifted focus to monitoring upcoming work and resolving exceptions (e.g., process bottlenecks, stalled tasks, overdue tasks and studies);
- Reduced variability in study activation timelines from a standard deviation of 66 days prior to implementation to 52 days afterwards (21% reduction);
- All tasks and associated workflows are codified in the system thereby enforcing standardization of activation processes;
- Study start up staff workload is now monitored systematically via reports and dashboards.

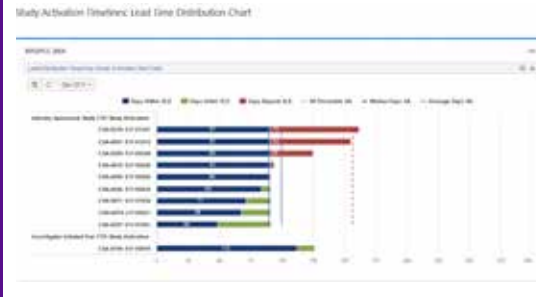
Real Time Metrics on Study Pipeline Activity



Decreased Time to Complete IRB Related Tasks



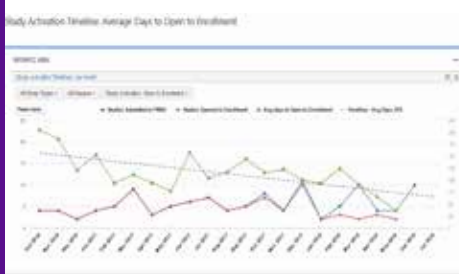
Complete Visibility of Service Level Expectations For Each Study



Real Time Identification of Overdue Studies and Studies Due to Activate

Study Number	Study	Class	Site	Support	Study Comments
10000001	Study 1	Phase 1	Site A	Support A	Study 1 - Phase 1 - Site A - Support A
10000002	Study 2	Phase 2	Site B	Support B	Study 2 - Phase 2 - Site B - Support B
10000003	Study 3	Phase 3	Site C	Support C	Study 3 - Phase 3 - Site C - Support C
10000004	Study 4	Phase 4	Site D	Support D	Study 4 - Phase 4 - Site D - Support D
10000005	Study 5	Phase 5	Site E	Support E	Study 5 - Phase 5 - Site E - Support E

Systematic Reporting of Monthly Time to Activation, # Of Studies Pending Activation, and # Studies Activated



Systematic Reporting on Pipeline Activity by Disease Group



Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Trial Activation Alignment Across Three Geographic Early Phase Cancer Center Locations

Katherine Gano, MS; Jill Burton, CCRP; Andrea Kukla; Linda Sanders, MS; Andrea Tavlarides, PhD

Mayo Clinic Cancer Center

Describe the background of the problem:

Opening early phase cancer clinical trials across a large academic institution can be timely and costly due to the detailed nature of such trials and necessary collaboration by numerous departments across the clinic to operate these trials. Consequently, many trials do not open soon enough to accrue patients at an optimal rate or the trial closes as soon as the study activates. Availability of unique early phase trials attracts new patients to the clinic that may not otherwise have come, leading to higher accrual numbers for the program and better access for patients to new, novel agents. Therefore it is critical to have a system in place that allows for speedy activation of early phase cancer trials.

Provide metrics or goals to be achieved:

- Create a unified enterprise-wide study activation process for early phase cancer clinical trials
- Attract novel cancer agents from pharmaceutical companies to treat patients at all sites by streamlining the activation process and opening trials more quickly.
- Eliminate redundancies across 3 geographic centers

Describe the solutions or methods implemented:

In July 2017, Mayo Clinic created one Early Cancer Therapeutics Program across the 3 geographic clinics, Arizona, Florida and Minnesota. Program consists of an enterprise Program Manager, centralized protocol development, protocol activation (including budgeting), protocol management, and regulatory personnel who will manage studies across all three sites. The Program Manager and program executive committee are responsible for providing functional direction to all Mayo Clinic staff (research and clinical) performing early phase cancer clinical trial specific work to meet activation goals and objectives.

Initial steps taken to map individual site process differences and similarities occurred in summer 2017. Areas identified that could be aligned and performed once instead of 3 times include: pre-site selection visits, site initiation visits, development of source documents, staff training, lab template alignments, and alignment of drug order sets. In addition, with the single model, 1 lead regulatory staff member was assigned to each trial to perform and manage all activation processes and timelines and be a single point of contact for the Industry sponsor (IRB, budget, contract, and regulatory documentation).

Describe the outcome or show data representing a change (positive or negative):

The average time from scientific review to study activation for the Cancer Center in 2017 was 200 days (Data inclusive of all trial types as well as single and multi-Mayo Clinic site trials). Since implementation of the Early Cancer Therapeutics Program in July 2017 the average time from scientific review to study activation for studies activated after July 2017 was 154 days. However if you remove those trials started prior to July 2017 and only report on those started after implementation of the program the average time from scientific review to activation was 112 days, a 44% decrease in activation time from 200 days.

Address lessons learned and future directions:

In addition to the amount of time saved within the unified model, post interviews were conducted in January and February with regulatory and clinical study staff to discuss lessons learned and opportunities for future success. Overall feedback was very positive from staff at all levels. Areas identified for improvement focused more on fine tuning the process versus major modifications.



Trial Activation Alignment Across Three Geographic Early Phase Cancer Center Locations

Katherine Gano, M.S., Jill Burton, CCRP, Andrea Kukla, Linda Sanders, M.S., Andrea Tavlarides, Ph.D.
Mayo Clinic, Arizona, Minnesota and Florida

Background

Opening early phase cancer clinical trials across a large academic institution can be timely and costly due to the detailed nature of such trials and necessary collaboration by numerous departments across the clinic to operate these trials. Consequently, many trials do not open soon enough to accrue patients at an optimal rate or the trial closes as soon as the study activates.

Availability of unique early phase trials attracts new patients to the clinic that may not otherwise have come, leading to higher accrual numbers for the program and better access for patients to new, novel agents. Therefore it is critical to have a system in place that allows for speedy activation of early phase cancer trials.

Objectives

- Create a unified enterprise-wide study activation process for early phase cancer clinical trials
- Attract novel cancer agents from pharmaceutical companies to treat patients at all sites by streamlining the activation process and opening trials more quickly.
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Methods

In July 2017, Mayo Clinic created one Early Cancer Therapeutics Program across the 3 geographic clinics, Arizona, Florida and Minnesota. Program consists of an enterprise Program Manager, centralized protocol development, protocol activation (including budgeting), protocol management, and regulatory personnel who will manage studies across all three sites. The Program Manager and program executive committee are responsible for providing functional direction to all Mayo Clinic staff (research and clinical) performing early phase cancer clinical trial specific work to meet activation goals and objectives.

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Results

The average time from scientific review to study activation for the Cancer Center in 2017 was 200 days (data inclusive of all trial types as well as single and multi-Mayo Clinic site trials). Since implementation of the Early Cancer Therapeutics Program in July 2017 the average time from scientific review to study activation for studies activated after July 2017 was 154 days. However if you remove those trials started prior to July 2017 and only report on those started after implementation of the program the average time from scientific review to activation was 112 days, a 44% decrease in activation time from 200 days (Table 1).

Table 1



Lessons Learned

In addition to the amount of time saved within the unified model, post interviews were conducted in January and February with regulatory and clinical study staff to discuss lessons learned and opportunities for future success. Overall feedback was very positive from staff at all levels. Areas identified for improvement focused more on fine tuning the process versus major modifications. Obviously this is a small sample size to date as well and will look to see continued improvement as the sample size increases.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Tailored Training to Accelerate Study Assessment and Start-up

Andrea Kukla

Mayo Clinic Cancer Center

Describe the background of the problem:

At Mayo Clinic, staff focused on study activation is under the job title of research protocol specialist (RPS). In review of activation timelines for newly hired RPS from 2016 through Q2 of 2017, the average time for study activation was 247 days, far beyond our goal of 120 days. A root cause analysis identified the lack of training as a prominent factor in the delay. While there are several training resources and programs available both within Mayo Clinic and outside for study coordinators, the complexity of the activation process has evolved beyond these resources. In an effort to continuously improve study activation turnaround time, we developed a training program tailored to the RPS staff in activating interventional studies.

Provide metrics or goals to be achieved:

The goal of the training program is to decrease the time to study activation by staff who participated in the training to be as close to target of 120 days as possible. To determine the success of the training program, we assessed the average turnaround time from receipt of study documents from the sponsor to activation, first time quality of study document submission, and a survey completed by trainee's pre and post training assessing their confidence in skills for the following 6 key areas on a four point scale:

1. Study assessment
2. Budget assessment
3. Informed consent form development
4. IRB submission
5. Coverage determination
6. Budget development

Describe the solutions or methods implemented:

A study assessment and start-up (activation) training program was created in addition to the general clinical research training provided through the Center for Clinical and Translational Science (CCaTS). Due to the high priority of the cancer related activations, Cancer Center study start-up team members were selected to pilot the training and provide feedback. The program was designed to offer a consistent introduction and hands on support to study assessment and start-up for staff assigned to complete this process. Participants bring a real, document ready study to work through the activities in class as each topic is introduced. Each day of training consists of overview and concept application.

Describe the outcome or show data representing a change (positive or negative):

Since implementation in fall of 2017, 17 RPS staff has completed the training activating 12 studies. Activation times for the 12 studies activated averaged 132 days, a decrease from the baseline by 46.5%. Additionally, staff confidence level in accomplishing the 6 core areas dramatically increased by 56%.

Address lessons learned and future directions:

The training program has proven to shorten the learning curve due to the consistent training and using the same study through each step of study activation. The program also provides an introduction to research services business units through active training and helped establish relationships and best practices for first time quality. RPS staff has a preceptor to guide them through processes and offer support when needed. As the program continues to grow the goal would be to see shorter timelines approximately 90 days and to provide continued follow-up and training to staff that have went through the program.



Tailored Training to Accelerate Study Assessment and Start-up

Andrea Kukla, William Simmons, M.Ed., Justin Anderson, M.Ed., Laura Hanson, M.S., PMP,
Katie Cornelius, M.P.H, Carley Vrieze, Linda Sanders, M.S.
Mayo Clinic, Rochester, MN

Abstract

Background: At Mayo Clinic, staff focused on study activation have the job title of Research Protocol Specialist (RPS). In review of activation timelines for newly hired RPS from 2016 through Q2 of 2017, the average time for study activation was 247 days, far beyond our goal of 120 days. A root cause analysis identified the lack of training as a prominent factor in the delay. While there are several training resources and programs available both within Mayo Clinic and outside for study coordinators, the complexity of the activation process has evolved beyond these resources. In an effort to continuously improve study activation turnaround time, we developed a training program tailored to the RPS staff in activating interventional studies.

Objective: The goal of the training program is to decrease the time to study activation by staff who participated in the training to be as close to target of 120 days as possible. To determine the success of the training program, we assessed the average turnaround time from receipt of study documents from the sponsor to activation, first time quality of study document submission, and a survey completed by trainee's pre and post training assessing their confidence in skills for the following 6 key areas on a four point scale:

1. Study assessment
2. Budget assessment
3. Informed consent form development
4. IRB submission
5. Medicare Code and Coverage determination
6. Budget development

Methods: A study assessment and start-up (activation) training program was created in addition to the general clinical research training provided through the Center for Clinical and Translational Science (CCaTS). Due to the high priority of the cancer related activations, Cancer Center study start-up team members were selected to pilot the training and provide feedback. The program was designed to offer a consistent introduction and hands on support to study assessment and start-up for staff assigned to complete this process. Participants bring a real, document ready study to work through the activities in class as each topic is introduced. Each day of training consists of overview and concept application.

Results: Since implementation in fall of 2017, 17 RPS staff has completed the training activating 15 studies. Activation times for the 18 studies activated averaged 121 days, a decrease from the baseline by 46%. Additionally, staff confidence level in accomplishing the 6 core areas increased by 56%.

Conclusions: The training program has proven to decrease the learning curve due to the consistent training and using the same study throughout each step of study activation. The program also provides an introduction to research services business units through active training and helped establish relationships and best practices for first time quality. RPS staff has a preceptor to guide them through processes and offer support when needed. As the program continues to grow the goal would be to see shorter timelines approximately 90 days and to provide continued follow-up and training to staff that have went through the program.

Objectives

The objective of this training program is to offer a consistent introduction and hands on support to study assessment and start-up for RPS staff assigned to complete this process. Participants will bring a real, document ready study to work through the activities in class as each topic is introduced.

Ultimately, the goal of training these RPS staff is to achieve an average of full activation within 120 day of document ready status.

Each day of training will consist of a topic overview and concept application. The training program is open to anyone that performs the study assessment and start-up activities. Participating staff need a current new, document ready protocol/amendment available for program participation.

In order to design the training program, the logic model shown in Figure 1 below was created to identify the inputs, activities, outputs, outcomes, and impacts desired from the training program.

Methods

Designing the Training Program:

Content was designed based on the logic model (Figure 1) with instruction from Subject Matter Experts and each Business Unit (Office of Sponsored Projects Administration, Institutional Review Board, Code and Coverage Analysis, and ancillary committees) to allow for consistent and uniform training across the enterprise.

The program is scheduled every 6 weeks, with 6-8 participants per session. Each day of training consists of a lecture on a given topic, an in-class activity with a standard protocol, followed by in class, mentored working time for application of the concepts to their own protocol. There are 10 days (~40 hours) of in-class time. In addition to the schedule class sessions, participants are assigned relevant e-learning modules to prepare for class, relying upon existing instructional training.

The Study Assessment and Start-up training program monitors both the impact on the participant as well as the outcome of the study start-up process in order to draw positive correlations:

1. Surveys of participant confidence:

Pre and post student surveys assess participant's confidence level in study assessment and start-up activities. Surveys are provided to the participant's supervisor for awareness and consideration for continued work unit mentorship.

Surveys assess confidence in their ability to independently perform study start-up activities.

2. Length of start-up process:

The duration of the start-up process is determined based on the length of time from receiving final study documents through the financial account activation (representing completion of the budget, contract, and IRB approval). These metrics are tracked routinely and a comparison was made for studies supported by participants in the training program compared to average.

Results

17 participants have completed the training program since it was fully implemented in Q3 of 2017. Clinical research staff participating in the program have been in their role between 3 months and 3 years.

Participant confidence:

Each of the participants completed the pre- and post-assessment regarding confidence in their ability to complete the activity in the 6 core areas. The participant confidence level in accomplishing these core area activities showed an increased of 56%.

Length of start-up process:

Since implementation of the start up training program, the participants have activated 18 studies. Activation times for these 18 studies supported by trained staff averaged 121 days, a decrease from the baseline by 46%. Moreover, these studies essentially achieved our activation goal of ~120 days from document ready to activation.

Discussion

Efficient and effective study start-up is critical in supporting an academic medical center's research program to: allow opportunity for competitive enrollment, attract studies of greatest interest, and most importantly, to bring new therapies and hope to our patients.

The clinical research staff role in supporting study start up is distinct from the study conduct aspect of coordination, and therefore warrants a specialized training effort to enable success.

Historically, many academic centers have relied on job shadowing & mentorship to provide this type of training.

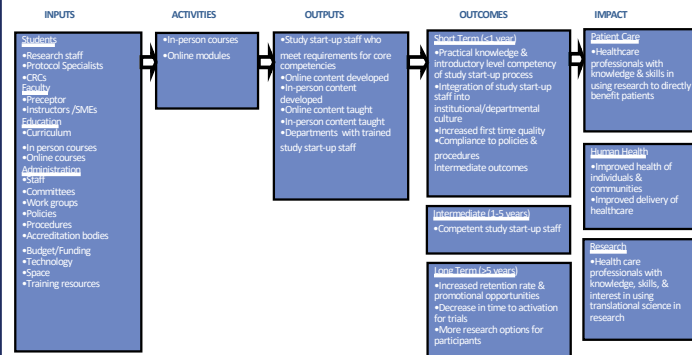
A dedicated training program as well as mentorship is a more effective approach to orienting these staff.

This training program achieved Mayo Clinic's goal of activation in ~120 days.

Acknowledgment

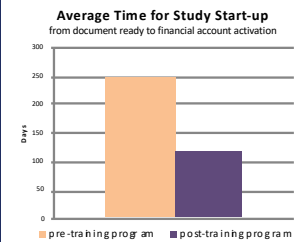
This publication [or project] was supported by Grant Number UL1 TR002377 from the National Center for Advancing Translational Sciences (NCATS). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NIH.

Figure 1: Training Program Logic Model



This logic model represents the inputs impacting the training, activities, desired outcomes, & impacts anticipated.

Figure 2: Schedule



A comparison of the number of days in study start-up for studies supported by RPS who completed the training program compared to average demonstrates that well-trained staff complete study start-up faster.

Conclusion

A dedicated training program improves staff success and efficiency in supporting the study start-up process, justifying the institutional effort commitment to support a specific training program.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Huddle Up! An Interprofessional Effort to Optimize Patient Care

Katy Schroeder, BSN, RN, OCN, CCRP; Judy Ranous, BSN, RN, OCN; Theresa Rudnitzki, MS, RN, AOCNS, ACNS-BC; Rebecca Selle, CCRP

Medical College of Wisconsin Cancer Center

Describe the background of the problem:

The purpose of the Nicholas Family Foundation Translational Research Unit (TRU) is to provide an environment that meets the care needs of patients on Phase 1 and 2 oncology clinical trials and other multifaceted studies in the ambulatory setting. Not only does each protocol have intricate details to follow, which are critical to maintaining the study's integrity and successful execution, but the patients also have their own complex needs. Research staff, nurses, and pharmacists are part of the research team and each has their unique role and responsibilities to ensure optimal care of these patients.

Provide metrics or goals to be achieved:

To communicate the expected plan of care for each patient on study, a daily huddle was developed to constructively discuss patients coming in for treatment the next day. This discussion is interprofessional and includes infusion nurses, clinical research coordinators and research nurses, research laboratory staff, and investigational drug pharmacists. The huddle is led by the lead nurse in the TRU.

Describe the solutions or methods implemented:

The huddle promotes accountability and ownership of the patient care requirements for the next day and allows staff to proactively address outstanding items before the patient arrives in the clinic. A worksheet is completed at the huddle and is used for nursing report the next day.

Items discussed at the huddle include coordination of research care, accuracy of orders/treatment plan, amendments, lab results, disease evaluations, study-related tasks, drug assignments, any outstanding issues, and patient-specific needs.

Describe the outcome or show data representing a change (positive or negative):

A survey was sent out to research coordinators, research nurses, and laboratory staff to evaluate the effectiveness of the daily huddle. Results were very positive. Survey themes indicated the interprofessional discussion is productive, and allows all staff to be on the same page (90% favorable). If there are outstanding issues, they can be proactively addressed before the patient arrives, making for a smoother appointment the next day.

Address lessons learned and future directions:

Challenges that remain include thoroughness and accuracy of the study teams' report on each patient, the follow-up by the study team on outstanding issues, and communication from the lead nurse to the direct care nurse on the day of treatment.

Other suggestions for improvement relate to time of day, location (TRU versus conference room to promote privacy), redundancy (long-term patient with minimal research tasks), flexibility (phone call versus in-person attendance), efficiency (report by each coordinator versus patient scheduled time), complexity (starting with least complex patient to the most complex), patient education (who is accountable?).

Huddle Up!! An Interprofessional Effort to Optimize Patient Care

Katy Schroeder, BSN, RN, OCN, CCRP; Judy Ranous, BSN, RN, OCN; Theresa Rudnitzki, MS, RN, AOCNS, ACNS-BC; Rebecca Selle, BS, CCRP

Significance/Background

The purpose of the Nicholas Family Foundation Translational Research Unit (TRU) is to provide an environment that meets the care needs of patients on Phase 1 and 2 oncology clinical trials and other multifaceted studies in the ambulatory setting.

Not only does each protocol have intricate details to follow, which are critical to maintaining the study's integrity and successful execution, but the patients also have their own complex needs.

Research staff, nurses, and pharmacists are part of the research team and each has their unique role and responsibilities to ensure optimal care of these patients.



Nicholas Family Foundation Translational Research Unit (TRU)

For additional information please contact:
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Froedtert & Medical College of Wisconsin Cancer Center
kschroeder@mcw.edu

Intervention

To communicate the expected plan of care for each patient on study, a daily huddle was developed to constructively discuss patients coming in for treatment the next day.

This discussion is interprofessional and includes infusion nurses, clinical research coordinators and research nurses, research laboratory staff, and investigational drug pharmacists.

The huddle is led by the lead nurse in the TRU.

Items discussed include:

- Coordination of research care
- Accuracy of orders/treatment plan
- Study changes
- Amendments
- Lab results
- Disease evaluations
- Study-related tasks
- Drug assignments
- Any outstanding issues
- Patient-specific needs

The huddle promotes accountability and ownership of the patient care requirements for the next day and allows staff to proactively address outstanding items before the patient arrives in the clinic.

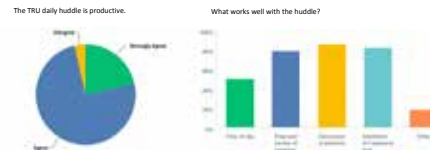
Daily Huddle Flowsheet

Research Coordinator	Huddle Notes	Pre-Huddle Notes	CRC Follow-Up Complete Y/N	Time	Cycle/Day	Study Name	Lab Orders Complete Y/N	Tx Plan Complete Y/N	Acuity	Tx Length
	C1D1 eligibility. CRC to do IVRS and EKG's. Treatment plan to be placed. Has a port and will have peripheral line as well. Was ineligible due to hgb and got 2 units PRBCs- will have labs on Monday.	Schedule appointment? Per CRC urine can be transported in a cooler if the patient has one, otherwise it will be okay to transport normally in the car to TRU.		7:00AM	C1D1	A			6	600
A.B.	IVRS by .CRC Drug A only			8:30 AM	C3 W3	B	Y	Y	2	240
M.T.	IVRS by .CRC Drug A only			8:30 AM	W5 D1	C	Y	N	2	240
J.G.	predose Sees Dr. T. on Weds. PK within 30 min of oral			8:30 AM						
S.Y.	PK's. Bringing Oproz and Dex with her. Snack boat. Predose in lab.	pt. to bring low fat meal, complete C1D15 treatment plan not released, predose in lab		9:00 AM	C1 D22	D	Y	Y	2	540
L.R.	IVRS by CRC. No ekg needed this day.	Add Clinical Research Lab to Lab Orders		9:30 AM	C3 D15	E	Y	Y	3	300
B.K.	IVRS by CRC. No ekg needed this day.	Needs treatment plan, consent current, labs from 2/13? Otherwise needs lab appointment, predose in TRU		9:30 AM	C17 D8	F	N	Y	3	360
L.V.	Res of lab from Tuesday. Treatment has to be placed. IVRS: CRC, randomize on Monday.			10:30AM	C1D1	G				
T.N.	orders signed. Peripheral pokes for PKs. 1 hour infusion and 1 hour of observation.	Predose in TRU, obs decreases to 1 hour Slide date from 12/06/17 to 02/19/2018; Add GGT, CK, Lipid Panel, Amylase, Lipase, PT/INR, PTT/JA Macro and Micro, Osmolality Urine, Creatinine Urine Random, Urea Nitrogen Urine Random, Lytes-Urine Random, Clinical Research Study Lab to Lab Orders; is patient still able to be on study? Predose in lab?		11:00 AM	C1 D15	H	Y	Y	3	240
J.D.	C4D1. CRC put in lab orders. Predose PK in TRU. Orders are signed but need sponsor approval. Remains in CR. GGT is gr. 3. Recovering from sinus surgery. 75mg/kg			12:30 PM	C4 D1	I	N	Y	3	180

Evaluation

A survey was sent out to research coordinators, research nurses, and laboratory staff to evaluate the effectiveness of the daily huddle.

Results were very positive (96%). Survey themes indicated the interprofessional discussion is productive, and allows everyone to be on the same page. If there are outstanding issues, they can be proactively addressed before the patient arrives, making for a smoother appointment.



Next Steps

Challenges that remain include:

- Thoroughness and accuracy of the study teams' report on each patient
- Follow up on outstanding issues
- Communication from the lead nurse to the direct care nurse on the day of administration

Other suggestions for improvement relate to:

- Location (TRU versus conference room to promote privacy)
- Redundancy (long term patient with minimal research tasks)
- Flexibility (phone call versus in-person attendance)
- Efficiency (report by each coordinator versus patient scheduled time)
- Complexity (starting with least complex patient to most)
- Patient education (who is accountable to confirm it is completed?)
- Time of day

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Checking the Eligibility Checklist

Adrian Granobles; Karima Yataghene, MD; Kenasha Johnson; Saray Simo; Collette Houston

Memorial Sloan Kettering Cancer Center

Describe the background of the problem:

Ensuring that the eligibility checklist is used, managed, and executed properly in the process leading to the informed consent is a critical and substantial task. At Memorial Sloan Kettering Cancer Center (MSK) the volume of patients being consented into clinical trials continues to grow annually, so it is important that adequate resources are dedicated to enforce proper eligibility checklist management. The Quality Assurance Unit was assigned to develop, implement and maintain a real-time participant/patient eligibility verification process to ensure that clinical trial registrations are conducted according to regulations. Implementing this new verification lead to piloting a program and discovering ways to improve this important quality assurance process.

Provide metrics or goals to be achieved:

The goals of the eligibility checklist verification review are to ensure that participants are eligible when registered to a protocol, that the eligibility checklist captures the protocol's eligibility criteria accurately, and that related source documentation are being managed appropriately. These goals will ensure that ineligible participants are not enrolled and exposed to unnecessary risk. Actively reviewing every participant registration would require a considerable team to monitor on a daily basis, so MSK is currently reviewing a randomized sample of registered participants. The pilot began in the fourth quarter of 2017 and will run until the second quarter of 2018, after which it will be launched as an official program. With an average of 96 therapeutic weekly registrations, the QA team reviews 10 eligibility checklist verifications per week.

Describe the solutions or methods implemented:

The method is to monitor the clinical trial registrations by focusing on the eligibility checklist and the source documents in the EMR. Monitors are assigned patient registrations, they review the eligibility checklist for accuracy and validate that the documentation used to support each of the protocol's inclusion and exclusion criteria is present in the research record. All findings are recorded in

a master file for easy access and query. Additionally, the review findings are communicated with the research team associated with the participant registration, with the intent to immediately rectify all identified issues and as a continual educational opportunity.

Describe the outcome or show data representing a change (positive or negative):

The pilot phase has shown that there is room for improvement in the areas of managing the eligibility checklist document to completely reflect the inclusion and exclusion criteria, and uploading source documents within a reasonable timeframe into the EMR. These findings have been a learning experience for the research teams and have had an impact on the eligibility process. We are looking forward to collecting more data and comparing results to continually define any major improvements.

Address lessons learned and future directions:

We have learned that we need to streamline the verification process and centralize our efforts; as a result, we began to develop a database to automatically capture the registration data, assign to Monitors, and expand the data management for statistical and query purposes. This process has highlighted the importance of having a robust verification system at any institution conducting clinical trials. Our continuous communication with research staff on issues discovered through the verification process will have an impact on further education, consistency and proper compliance of eligibility practices.



Checking the Eligibility Checklist

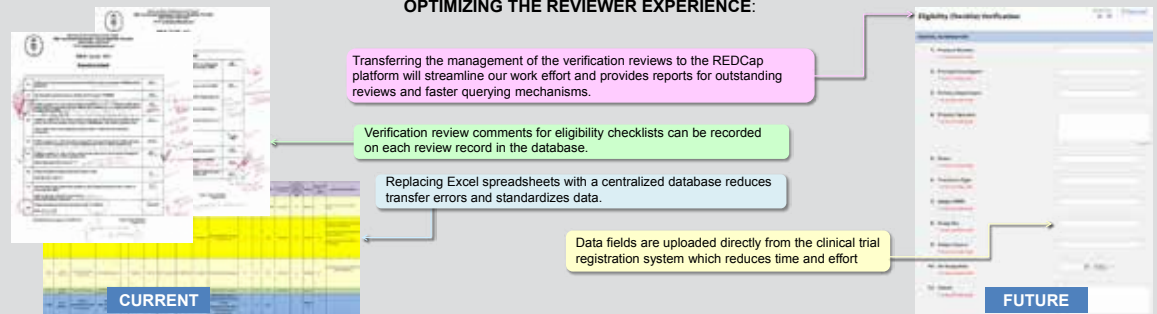
Adrian Granobles; Karima Yataghene, MD; Saray Simo; Collette Houston

BACKGROUND: Ensuring that the eligibility checklist (ECL) is created, used, managed, and executed properly in the process leading to the informed consent is a critical and substantial task. At Memorial Sloan Kettering Cancer Center (MSK) the volume of participants consented into clinical trials continues to grow annually, so it is important that adequate resources are dedicated to enforcing proper eligibility checklist management. The Quality Assurance (QA) Unit was assigned to develop, implement and maintain a real-time participant eligibility verification process to ensure that clinical trial registrations are conducted according to regulations, and to act as an independent review from the study team. Implementing this new verification lead to piloting a program and discovering ways to improve this important quality assurance process.

GOALS:

The goals of the eligibility checklist verification review are to ensure that participants are eligible when registered to a protocol, that the eligibility checklist captures the protocol's eligibility criteria accurately, and that related source documentation is being managed appropriately. Achieving these goals ensures ineligible participants are not enrolled and exposed to unnecessary risk. The Principal Investigator (PI) with the study team are responsible for ensuring that all participants are eligible at the time of enrollment. The ECL verification program acts as an independent second level review. The challenge in achieving these goals is that actively reviewing every participant registration would require a considerable team to monitor on a daily basis, so MSK is currently reviewing a randomized sample of registered participants. The pilot began in the fourth quarter of 2017 and will run until the second quarter of 2018, after which it will be launched as an official program. With an average of 96 therapeutic weekly registrations, the QA Unit reviews 10 eligibility checklists per week.

OPTIMIZING THE REVIEWER EXPERIENCE:



PROCESS:



VERIFICATION OUTCOMES:

The pilot has shown that there is room for improvement in the areas of managing the eligibility checklist document to completely reflect the inclusion and exclusion criteria, and uploading source documents within a reasonable timeframe into the Electronic Medical Record (EMR). These findings have been a learning experience for the study teams and have had an impact on the eligibility process.

ACKNOWLEDGMENTS:

We thank the monitors and staff that assisted with the project: Kulood Kamil, Michelle DeLaRosa, Mimi Chung, Tori Velez, Kris Kaufman, Andrew Zarski, Leigh Gaffney.

CONCLUSIONS:

We have learned that we need to streamline the verification process and centralize our efforts; as a result, we began to develop a database to automatically capture the registration data, assign reviewers, and expand the data management for statistical and query purposes. This process has highlighted the importance of having a robust verification system at any institution conducting clinical trials. Our continuous communication with research staff on issues discovered through the verification process will have an impact on further education, consistency and proper compliance of eligibility practices.

FINDING CATEGORIES, RATINGS, AND ACTIONS

STATUS	FINDINGS	RATING	ACTION
Eligible	Eligible	Acceptable	No response required
Not Evaluable	Eligibility checklist not present in EMR Eligibility checklist template errors Eligibility checklist completed inaccurately Eligibility checklist does not match protocol inclusion/exclusion Informed Consent Form not present in EMR Protocol participant registration procedures not followed Informed consent procedures not followed	Acceptable – Needs Follow up	Findings must be addressed within five business days. An email addressing the findings must be received.
Not Eligible	Ineligible participant or questionable eligibility Wrong consent version used Wrong ECL version used	Unacceptable	Findings must be addressed within three business days. An email with attached Corrective and Preventive Actions (CAPA) plan must be received.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Developing & Implementing Institutional Workflow for Reviewing Scientific Amendments

Xhene Lekperic; Sara Hanley, MSW; Alexia Iasonos, PhD; Krista Napolitano, MA; Ann Rodavitch, MA; Collette Houston; Michael Ayerov; Roy Cambria; Paul Chapman, MD

Memorial Sloan Kettering Cancer Center

Describe the background of the problem:

The NCI's Cancer Center Support Grant (CCSG) requires that participating institutions have a Protocol Review and Monitoring System, which is handled by the Research Council (RC) at Memorial Sloan Kettering (MSK). The frequency and complexity of amendments involving scientific design changes is continually increasing, making it more difficult to complete comprehensive scientific review of amendments with rapid turnaround. Institutional data shows that the number of amendments doubled from 2015 to 2017. Our workflow was revised in early 2017 to ensure appropriate amendments are identified for RC review, enhance scientific review to aid the IRB, and allow RC to critically evaluate the increasing volume of complex amendments.

Provide metrics or goals to be achieved:

- Establish a workflow for scientific review of amendments at RC
- Identify appropriate protocols requiring scientific review
- Use technology to coordinate with MSK's IRB, investigators, and research staff

Describe the solutions or methods implemented:

- Institutional workflow developed with sequential reviews for amendments which includes the PI/study team, RC, and the IRB.
 - RC approval is required prior to IRB submission.
- Utilization of shared Amendment Submission Form (ASF) between IRB and RC, with RC-specific questions to aid identification of amendments requiring scientific review.

- Leverage institutional Protocol Information Management System (PIMS) for reviews
 - Enables electronic submissions and includes expedited and full review options
 - Improves tracking of amendments in the review process
 - Facilitates communication between research staff, RC, and IRB
 - Ability to generate metrics
- Streamlined RC review process
 - Implemented RC reviewer checklist to increase efficiency and focus on design changes
 - Created a PIMS-generated abbreviated ASF for RC reviewers which includes RC-specific questions
 - Limited RC statistical review to external studies only
 - For internal studies involving an MSK biostatistician, RC requires documentation that the statistician has approved the amendment before RC reviews
- Increased communication with IRB
 - Ability for RC to submit amendments to the IRB on behalf of PIs after RC approval
 - Ability for IRB to submit submissions to RC if determined that scientific review is required
 - Shared RC/IRB/study team access to centralized electronic submission tab in PIMS for increased transparency
 - Established criteria for approving dose escalation/expansion trials with limited expansion cohort design information

Describe the outcome or show data representing a change (positive or negative):

- There was a 7-fold increase in RC amendment reviews from 2016 (7) to 2017 (47).
- In 2018 to date, RC has reviewed an average of 7 amendments per month. This is compared to a monthly average of 3.9 amendments per month in 2017 and .5 amendments per month in 2016.
- RC reviews are more efficient and timely because of new expedited review process

Address lessons learned and future directions:

- Lessons learned:
 - MSK must maintain an equilibrium of preserving the integrity of MSK's research portfolio and upholding its commitment to patients while keeping up with industry changes to ensure scientific progress
 - Scientific rigor and transparency must be sustained throughout the protocol's lifecycle
- Future goals:
 - Further streamline RC/IRB workflow and improve ASF
 - Improve metrics and continue data analysis to guide future changes
 - Establish policy to define scientific amendment best practices with criteria to differentiate between an amendment and a new clinical research protocol



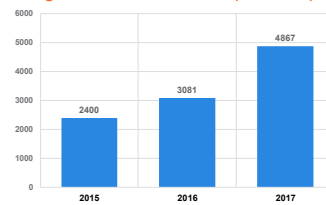
Developing & Implementing Institutional Workflow for Reviewing Scientific Amendments

Xhenete Lekperic, Sara Hanley, MSW, Alexia Iasonos, PhD, Krista Napolitano, MA, Ann Rodavitch, MA, Collette Houston, Roy Cambria, Michael Ayerov, Gary Dranch, Paul Chapman, MD

Background

The NCI's Cancer Center Support Grant (CCSG) requires that participating institutions have a Protocol Review and Monitoring System, which is handled by the Research Council (RC) at Memorial Sloan Kettering (MSK). RC reviews protocols for scientific merit, priority, and progress, and monitors protocols for accrual performance. RC also reviews amendments to Institutional Review Board (IRB) approved protocols that have significant scientific design changes. RC review does not duplicate nor overlap with IRB responsibilities, and the intention is for reviews to be complimentary. The frequency and complexity of amendments involving scientific design changes is continually increasing, making it more difficult to complete comprehensive scientific review of amendments with rapid turnaround. Institutional data shows that the number of amendments doubled from 2015 to 2017 (Figure 1). Our institutional amendment review workflow was revised in early 2017 to ensure appropriate amendments are identified for RC review, to enhance scientific review to aid the IRB, and to allow RC to critically evaluate the increasing volume of complex amendments.

Figure 1: MSK Amendments (2015-2017)



Goals

1. Establish a workflow for scientific review of amendments at RC
2. Identify appropriate protocol amendments requiring scientific review
3. Leverage technology to coordinate with MSK's IRB, investigators, and research staff

Methods

- Developed institutional workflow (Figure 2) with sequential reviews for amendments requiring scientific review
- Implemented utilization of shared Amendment Submission Form (ASF) between IRB and RC, with RC-specific questions to aid identification of amendments requiring scientific review (Figure 3)
- Leveraged a home-grown, multi-tiered web based application called Protocol Information Management System (PIMS) for the review process
 - Enables electronic submissions to committees, including electronic completion of ASF
 - Includes expedited and full review options for RC and IRB
 - Facilitates electronic communication amongst PIs, study teams, RC, and IRB via centralized electronic submission tab in PIMS for increased transparency (Figure 4)
 - Improves tracking of amendments in review process
 - Generates metrics
- Streamlined RC review process
 - Implemented RC reviewer checklist to increase efficiency and focus on design changes (Figure 5)
 - Limited RC statistical review
 - Requires documentation of MSK statistician's involvement before RC review (internal MSK studies only)
- Established criteria for approving dose escalation/expansion trials with limited expansion cohort design information

Figure 2: Institutional Amendment Review Workflow

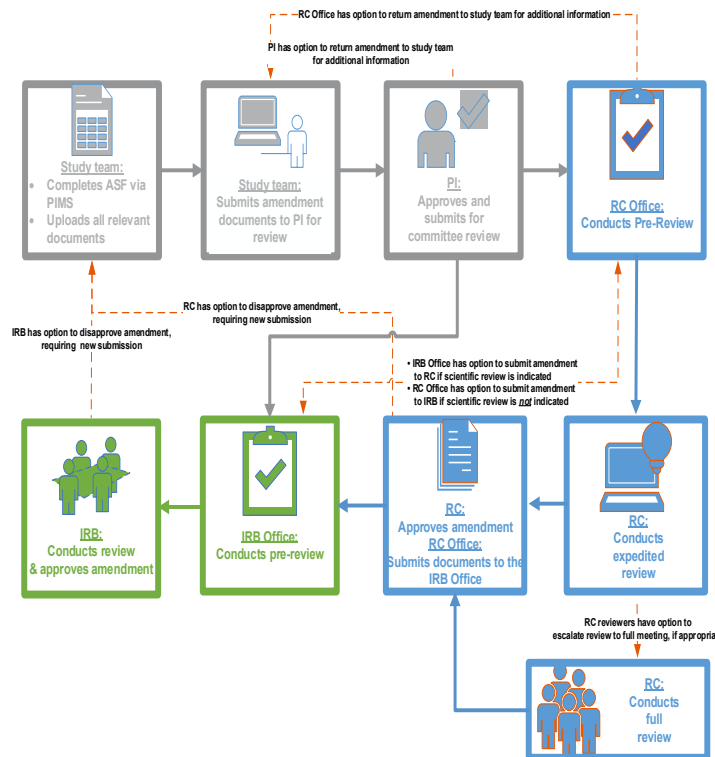


Figure 3: RC-Specific Electronic ASF (Completed by PI)

Figure 4: Protocol Information Management System

Figure 5: RC Review Checklist (Completed by Reviewers)

1. Is there a valid scientific rationale for the design change(s)?
2. Are the changes to the methods/experimental design appropriate and the new trial endpoint(s) scientifically valid?
3. Are the design changes feasible (number of patients, recruitment, competing studies)?
4. Do the design changes comply with RC expansion cohort guidelines (if applicable)?

Outcome

- There was a 7-fold increase in RC amendment reviews from 2016 to 2017 (Figure 6)
- In 2018 to date, RC has reviewed an average of 6.7 amendments per month compared to 3.9 in 2017 and .6 in 2016 (Figure 7)
 - Assuming the same rate, we expect the monthly average to approach 10 protocols in the next year
- RC reviews are efficient and timely because of our expedited electronic review process
 - RC's overall review time from submission to approval is 7.1 calendar days
- Workflow promotes increased communication and coordination between RC and IRB

Figure 6: RC Amendment Reviews

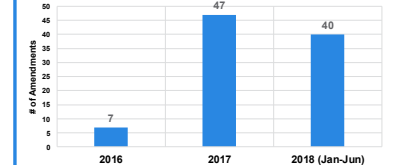
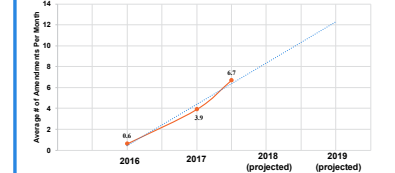


Figure 7: Average Monthly Amendments at RC



Lessons Learned

- MSK must maintain an equilibrium of preserving the integrity of MSK's research portfolio and upholding its commitment to participants while keeping up with industry changes to ensure scientific progress
- Scientific rigor and transparency must be sustained throughout the protocol's lifecycle
- Specialized PRMS review of amendments allows the IRB to focus more on their human subjects protection responsibilities

Future Goals

- Further streamline workflow and improve ASF
- Expand metrics and continue data analysis to guide future changes
- Improve time to approval
- Establish policies to define scientific amendment best practices with criteria to differentiate between when an amendment is acceptable versus when a new clinical research protocol is required

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Developing a Protocol Activation Unit

Ann Rodavitch, MA; Collette Houston; Paul Sabbatini, MD; Eric Cottingham, PhD; Katherine Rolla; Sara Hanley; Roy Cambria

Memorial Sloan Kettering Cancer Center

Describe the background of the problem:

As the number of early-phase protocols continues to increase, the Center needs to activate a greater number of protocols rapidly. Our previous activation model was highly decentralized and utilized significant staffing resources. The PI and Service-based research staff coordinated all aspects of protocol activation. Coordination was limited, both among review committees, and between committees and staff working to activate protocols. This decentralized model resulted in prolonged activation time, and frustrated investigators, review committees, and sponsors. A better model was needed.

Provide metrics or goals to be achieved:

- Decrease Time to IRB approval (TTIA)
 - Defined as days from first department committee review to IRB approval
- Decrease Time to Activation (TTA) to \leq 75 days
 - Defined as days from first department committee review to Open to Accrual

Describe the solutions or methods implemented:

1. In 2016, we established a working group of investigators, staff, and committee members to review activation metrics, identify causes of delays, and interview stakeholders
2. The working group recommended:
 - a. Creating a central unit to coordinate all aspects of the protocol activation process, including writing informed consents
 - b. Centralizing administrative management of all review committees
3. In early 2017, the Center began to develop lean workflows, create job descriptions, and recruit Protocol Activation Managers and Protocol Review Managers for a new Activation Unit

4. Piloting the new Unit began in July 2017, with Services added throughout the year
5. In January 2018, the Unit launched across the entire institution, activating all new non-exempt protocols regardless of department, protocol type, or sponsor
 - a. Activation coordination was transferred from the local study team to a centralized team called the Protocol Activation Core (PAC)
 - b. Administrative management of review committees was shifted from local teams to a central Protocol Review Core (PRC)
 - c. PAC, PRC, and the IRB were connected under one Unit with three distinct teams

Describe the outcome or show data representing a change (positive or negative):

- As of April 2018, the new centralized unit has coordinated more than 240 protocols
- Although it is still early in the implementation of the unit, results to date have been positive:
 - Median days TTIA
 - 2017 Q1-Q3: 139
 - 2017 Q4: 112 (pilot begins)
 - 2018 Q1: 49 (unit launch)
 - Median days TTA
 - 2017 Q1-Q3: 158
 - 2017 Q4: 130
 - 2018 Q1: 100

Address lessons learned and future directions:

- Lessons learned:
 - The three teams function within a cohesive unit to maximize communication and expertise, and implement a lean, coordinated infrastructure and workflow.
 - Holding weekly Monday meetings with all three teams is essential to increase efficiencies, and to foster effective communication and transparency.
 - Leveraging technology and real-time dashboards helps track the daily progress of protocol activation tasks.
 - Centralizing consent writing and building a library of common/approved content have reduced review time at the IRB while improving the quality of consent documents.
- Future goals:
 - Continue to improve workflows and further decrease TTA to achieve goal of \leq 75 days
 - Improve coordination with local research staff
 - Develop criteria to identify protocols that are more likely to encounter challenges during activation, and intervene earlier to prevent or minimize delay



Developing a Protocol Activation Unit

Ann Rodavitch, MA; Collette Houston; Paul Sabbatini, MD;
Eric Cottington, PhD; Katherine Rolla; Sara Hanley, MSW; Roy Cambria

BACKGROUND

As the number of early phase protocols continues to increase, the Center needs to activate protocols rapidly without increasing the overall staffing infrastructure. Our previous activation model was highly decentralized utilizing significant staffing resources. The PI and service-based research staff coordinated all aspects of protocol activation. Coordination was limited, both among review committees, and between committees and staff working to activate protocols. This decentralized model resulted in prolonged activation time and frustrated investigators and external sponsors. A better model was needed.

METHODS

- Established a task force in 2016 to review activation metrics, identify causes of delays, and interview stakeholders
- Working group recommendations
 - A central unit for the protocol activation process, including writing informed consents and administrative management of all review committees
- Developed Unit
- Opened Unit with three distinct teams in 2017:
 - Protocol Activation Core (PAC)
 - Protocol Review Core (PRC)
 - Human Research Protection Program (HRPP)
- Transferred activation coordination from the local study team to PAC in January 2018
- Shifted administrative management of review committees to PRC in January 2018

MISSION AND GOAL

- High quality and efficient protocol activation process
- Improve User Experience
- Decrease Time to IRB approval (TTIA)
- Decrease Time to Activation (TTA) to 75 days

CHANGES

New - Protocol Activation Core

- Centralized coordination
- Protocol Road Map
- Centralized Informed Consent writing and editing
- Consent libraries
- Regular status email to all parties involved
- Coordinated workflows with PRC and IRB

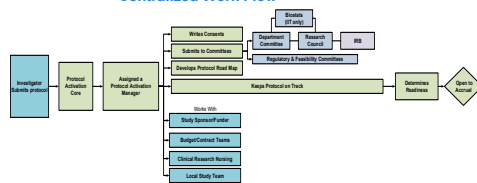
New - Protocol Review Core

- Central committee management
- Streamlined the Protocol Review and Monitoring (PRMS) activation workflow
- One pre-review for all committees
- Parallel submissions and reviews
- Focused scope of each committee
- Eliminated redundant reviews
- Limited consent form review to IRB
- Stricter criteria for performance and data and safety monitoring

Human Research Protection

- Institutional Review Board
- Privacy Board
- Consent Office and non-English Consents
- Genomic Advisory Panel
- IRB of Record

Centralized Work Flow



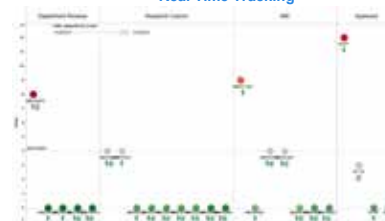
Protocol Road Map



Fully Integrated Electronic Protocol Review System



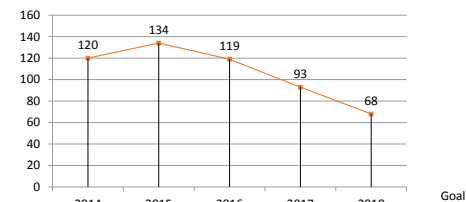
Real Time Tracking



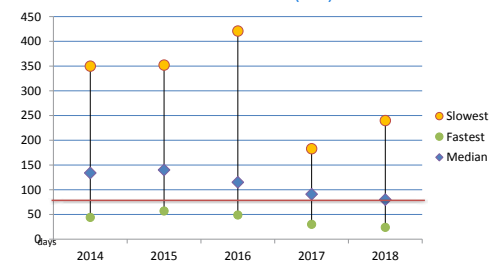
OUTCOMES

- As of April 2018 >240 protocols have been processed
- Significant decreases in both median time to activation and time to IRB approval

Time to IRB Approval (TTIA)



Time to Activation (TTA)



LESSONS LEARNED

- The three teams function within a cohesive unit to maximize communication, expertise, and implement a lean, coordinated infrastructure and workflow
- Holding weekly Monday meetings with all three teams is essential to increase efficiencies, foster effective communication and transparency
- Leveraging technology and real-time dashboards improves transparency
- Centralizing consent writing has reduced review time at the IRB while improving the quality of consent documents
- Decreasing activation time created backlogs in other areas that need to be addressed to further improve the overall system

FUTURE GOALS

- Work with study teams to address backlogs in study readiness to further decrease TTA
- Continue to improve workflows
- Finalize master sponsor consent templates
- Develop criteria to identify protocols that are more likely to encounter challenges during activation, and intervene earlier

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

MSK Cancer Alliance: Accelerating Cancer Care in the Community Setting

Mary Warren¹; Ellen Dornelas²; Eric Muelle³; Deborah Suarez⁴; Peter Yu, MD²; Suresh Nair, MD³; Miguel Villalona, MD⁴; David Pfister, MD¹; Paul Sabbatini, MD¹; Jessica Kennington¹; Collette Houston¹

¹Memorial Sloan Kettering Cancer Center; ²Hartford HealthCare Cancer; ³Lehigh Valley Health Network; ⁴Miami Cancer Institute at Baptist Health South Florida

Describe the background of the problem:

More than eighty percent of cancer care in the United States is delivered by community oncologists. However, cancer advances can take years to be adopted in a community setting and by 2030, the population of cancer patients is expected to increase by 45% to 2.3 million new cases per year.

Therefore, the need for high quality patient care, access to clinical trials, and education of a skilled oncology workforce will grow enormously over the coming years. In order to address this problem MSK established the MSK Cancer Alliance in 2013 with our first member, Hartford HealthCare Cancer (HHC) Institute. Lehigh Valley Health Network (LVHN) joined in 2016 and Miami Cancer Institute at Baptist Health South Florida (MCI) in 2017.

Provide metrics or goals to be achieved:

MSK Cancer Alliance Goals:

- To foster the rapid adoption of the newest standard of care in the community setting
- To expand access to MSK clinical trials and cutting-edge cancer research that raises the standard of care
- To improve the quality of care and outcomes for cancer patients

Describe the solutions or methods implemented:

Methods established to meet our goals:

- A Collaboration Agreement and Cooperative Research Agreement are executed. The Cooperative Research Agreement includes the IRB Reliance language as MSK is the IRB of Record, streamlining the clinical research activation process.
- MSK Disease Management Teams (DMTs) define the Standard of Care (SoCs) by identifying hallmarks of MSK care provided throughout the patient care continuum, from diagnosis to survivor follow-up care and each Alliance Member undergoes SoC assessment.

- Resources and Capabilities documents the operational standards for ten departments as well as clinical research to ensure alignment in faculty training & expertise, accreditation & licensure, infrastructure, practice & process, clinical research, and quality assurance.
- DMTs, Tumor Boards, Conferences and Committees are utilized to promote bi-directional learning and improve the quality of care and outcome for cancer patients.
- Clinical Research DMTs are utilized for trial selection to ensure our Alliance Members have access to clinical trials to meet the needs of their patient population.

Describe the outcome or show data representing a change (positive or negative):

This has been positive a positive change for all parties. There has been an increase in the number of clinical trials, enrollment, and access to genomic sequencing of patient's tumors has been expanded. Our focus on bi-directional learning is at the physician, nursing and clinical research level. We have implemented new work flows to carry out MSK processes and established a clinical research monitoring program.

Address lessons learned and future directions:

We learned we needed to better understand the patient population to ensure appropriate clinical trial selection and our near future directions include the expanding of our clinical trial program to include Phase I research this year.



MSK Cancer Alliance: Accelerating Cancer Care in the Community Setting

Mary Warren (MSK), Ellen Dornelas (HHC), Eric Mueller (LVHN), Deborah Suarez (MCI), Peter Yu, MD (HHC), Suresh Nair, MD (LVHN), Miguel Villalona-Calero, MD (MCI), David Pfister, MD (MSK), Paul Sabbatini, MD (MSK), Jessica Kennington (MSK), Collette Houston (MSK)

Memorial Sloan Kettering Cancer Center (MSK), Hartford HealthCare (HHC), Lehigh Valley Health Network (LVHN), Miami Cancer Center (MCI)

Background

More than eighty percent of cancer care in the United States is delivered by community oncologists. However, cancer advances can take years to be adopted in a community setting and by 2030, the population of cancer patients is expected to increase by 45% to 2.3 million new cases per year. Therefore, the need for high quality patient care, access to clinical trials, and education of a skilled oncology workforce will grow enormously over the coming years. In order to address this problem, MSK established the MSK Cancer Alliance in 2013 with our first member, Hartford HealthCare Cancer (HHC) Institute. Lehigh Valley Health Network (LVHN) joined in 2016 and Miami Cancer Institute at Baptist Health South Florida (MCI) in 2017.

HHC includes six acute care hospitals across central Connecticut with a mission to improve the health and healing of served communities.

LVHN is located in Eastern Pennsylvania, and is composed of seven acute-care hospitals, a children's hospital and community health centers with a mission to comfort and care for the community.

Miami Cancer Institute at Baptist Health South Florida is one of seven hospitals on six different campuses and is the largest faith-based, not for profit healthcare organization in South Florida with a mission to be a symbol of hope, faith and caring.

Where Are we

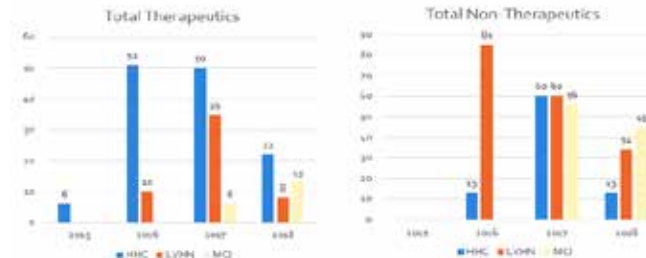


Goals, Methods and Metrics

MSK Cancer Alliance Goals

- To foster the rapid adoption of the newest standard of care in the community setting where 80% of all cancer care is delivered.
- To expand access to MSK clinical trials and cutting-edge cancer research that raises the standard of care.
- To improve the quality of care and outcomes for cancer patients in an accelerated, cost-effective model.

MSK Cancer Alliance Accrual Metrics



2018 Accruals through end of May

MSK Cancer Alliance Methods

- A Cooperative Research Agreement is part of the initial Affiliation Agreement between MSK and an Alliance Member. The Cooperative Research Agreement includes IRB Reliance language making MSK the IRB of Record, streamlining the clinical research activation process.
- MSK Cancer Alliance members adopt and adapt MSK Standards of Care (SoCs) for diseases comprising at least 50% of their patient population.
- Resources and Capabilities Assessments are conducted to ensure alignment in training & expertise, accreditation & licensure, infrastructure, practice & process, clinical research, and quality assurance in 11 departments, including Clinical Research Administration.
- DMTs, Tumor Boards, Conferences and Committees promote bi-directional learning and improve the quality of care and outcome for cancer patients.
- Clinical Research DMTs are utilized for trial selection to provide Alliance members a forum to discuss to clinical trials to meet the needs of their patient population.

Outcomes

Positive Change for All Parties

- There has been an increase in the number of clinical trials, enrollment, and access to genomic sequencing of patient's tumors has been expanded.
- Our focus on bi-directional learning is at the physician, nursing and clinical research level.
- We have implemented new work flows to carry out MSK processes and established a clinical research monitoring program.



Future Plans

Lessons Learned and Future Directions

- We learned we needed to better understand the patient population to ensure appropriate clinical trial selection.
- Our near future directions include the expanding of our clinical trial program to include Phase I research this year.
- Possible program expansion.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Digitizing Cancer Clinical Trial Management: A Single Site Experience with Implementing 21 CFR Part 11 Compliant Digital Signatures in a Regulatory Environment

Therica Miller, MBA, CCRP; Jenny Lester, MPH, CCRP; Brett Ouimette; BJ Rimel, MD

Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center

Describe the background of the problem:

Cancer clinical trials are challenging to conduct. Federal and Local regulations have become increasingly complex and the rapid acceleration of technology and science, namely precision medicine, further confounds the already inefficient and costly management of clinical trials. The burden is magnified within academic medical centers (AMCs) who maintain large trial portfolios across multiple disease areas and local, national and international network sites. The traditional paper-based research documentation process is cumbersome, wrought with errors and unreliable. The lack of quality control further exacerbates the administrative burden. This coupled with the depletion of available funding for clinical trial offices and diminishing skilled labor force necessitates palpable and lasting advancements.

Provide metrics or goals to be achieved:

To improve document transactions in clinical research, a pilot study, comparing digital document distribution and signature to paper routing and wet ink signature, was designed. The goal was to identify a sophisticated method for the management of essential documents that: reduced the administrative burden, accelerated completion timelines, improved quality of records and would easily harmonize with an electronic document management system. The pilot study measured:

- Total document completion time
- Number of errors per document
- Number of hours (hrs) for document preparation
- Signature routing time (days)
- End user satisfaction

Describe the solutions or methods implemented:

The pilot study was conducted in two phases: project planning and pilot execution.

First Phase: A digital signature vendor was selected. The system and securities were validated, 21CFRpart11 compliance was verified and a letter of certification was filed with the Food and Drug Administration (FDA). A post assessment survey was developed; access roles were configured and staff training was performed.

Second Phase: Disease research groups (DRGs) were assigned to paper (control) or digital. Essential documents were routed and signed according to the assigned method (Table 1). Data was entered in real time on a standard collection tool for six months.

Describe the outcome or show data representing a change (positive or negative):

A total of 156 documents were routed for digital signatures and 109 on paper.

The Wilcoxon Rank-Sum Test was used to compare completion time for the digital verses traditional paper groups. Digital documents were completed significant (5.2 days compared to 6.4 days, $p=0.03$) and took significantly less staff effort to complete (8.0 hrs compared to 10.9 hrs, $p= <0.001$). In addition, a post satisfaction assessment of those using the digital method showed that 80% found the system Very Easy to Use, 92.3% thought it was More Efficient, and 88.5% preferred the digital method of signing. Survey responses were not impacted by experience level or technological skill.

Address lessons learned and future directions:

Use of digital signatures resulted in notable decrease in document completion time and a marked decrease in regulatory burden as represented by staff hours. Further cost and time savings and information liquidity can be realized through integration of digital signatures and electronic document management.

Digitizing Cancer Clinical Trial Management: A single site experience with implementing 21 CFR part 11 compliant digital signatures in a regulatory environment

Therica Miller MBA, CCRP¹; Jenny Lester MPH, CCRP²; BJ Rimel, MD²
¹AOC Oncology, ²Cedars-Sinai Medical Center,

Introduction

Cancer clinical trials are challenging to conduct. Federal and Local regulations have become increasingly complex and the rapid acceleration of technology and science, namely precision medicine, further confounds the already inefficient and costly management of clinical trials. The burden is magnified within academic medical centers (AMCs) who maintain large trial portfolios across multiple disease areas and local, national and international network sites. The traditional paper-based research documentation process is cumbersome, wrought with errors and unreliable. The lack of quality control further exacerbates the administrative burden. This coupled with the depletion of available funding for clinical trial offices and diminishing skilled labor force necessitates palpable and lasting advancements.

Methods and Materials

To improve document transactions in clinical research, a pilot study, comparing digital document distribution and signature to paper routing and wet ink signature, was designed. The goal was to identify a sophisticated method for the management of essential documents that: reduced the administrative burden, accelerated completion timelines, improved quality of records and would easily harmonize with an electronic document management system.

The pilot study measured:

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Second Phase: Disease research groups (DRGs) were assigned to paper (control) or digital. Essential documents were routed and signed according to the assigned method (Table 1). Data was entered in real time on a standard collection tool for six months.

Results

A total of 156 documents were routed for digital signatures and 109 on paper.

The Wilcoxon Rank-Sum Test was used to compare completion time for the digital versus traditional paper groups. Digital documents were completed **significantly faster** (5.2 days compared to 6.4 days, $p=0.03$) and took **significantly less staff effort** to complete (8.0 hrs compared to 10.9 hrs, $p<0.001$). In addition, a post satisfaction assessment of those using the digital method showed that 80% found the system Very Easy to Use, **92.3% thought it was More Efficient**, and 88.5% preferred the digital method of signing. Survey responses were not impacted by experience level or technological skill.

Table 1. Summary of Results

	Digital (n=156)		Paper (n=109)	
Number of signatures on document				
1 signature	138	88.5%	99	90.8%
2 or more signatures	18	11.5%	10	9.2%
Types of Documents				
CV	2	1.3%	1	0.9%
Delegation of Authority	15	9.6%	12	11.0%
FDA Form 1572	10	6.4%	17	15.6%
Financial Disclosure Forms	55	35.3%	43	39.4%
IB Signature Page	16	10.3%	11	10.1%
Note to File	2	1.3%	3	2.8%
Protocol Signature Page	12	7.7%	14	12.8%
Training Log	38	24.4%	6	5.5%
Satellite clinic signatures required				
Yes	5	3.2%	22	20.2%
No	151	96.8%	81	74.3%
Not Reported	0	0.0%	6	5.5%
Revisions				
None	134	85.9%	77	70.6%
1	11	7.1%	3	2.8%
>1	0	0.0%	0	0.0%
Not Reported	11	7.1%	29	26.6%

Discussion & Limitations

Limitations

The single most limitation of this project was that it was conducted in a very focused space at a single institution. Regulatory attrition rates required greater oversight and re-training of the regulatory team and loss of that continuum created some data compliance issues that resulted in significant clean up. Implementation also required minor modification of business practices to best leverage the benefits of the technology. For example, our DOA template log was modified to single page to accommodate signature stamp block.

While we expected there to be enhanced productivity when multiple campuses were engaged the data from the pilot does not support that assumption. This may be attributed to the fact that we are still integrating our satellite clinics and network sites into our research program therefore the volumes are much lower and these numbers may not be representative of the potential gains.

Discussion

Despite these limitations, when comparing the error rate between the paper and digital group we found **greater quality with digital signatures**. What this tells us is there was also less time/effort required to update documents, re-route or make corrections for missed signatures, incorrect date formats or other common errors.

We analyzed time to completion across all document types and while statically different, these data are reported from the standard data collection tool which captured time to completion using the measurement of "days" rather than "hours". This was necessary because there was no way to track or document hours for the control arm, as well all know paper documents are often left on an investigator's desk or with their assistant. We know however from the auto generated digital time stamps within the DocuSign system that **most documents were signed in less than 2 hours**.

Conclusions

Use of digital signatures resulted in notable acceleration in document processing time and a marked decrease in regulatory burden as represented by staff hours. Further cost and time savings and information liquidity can be realized through integration of digital signatures and electronic document management.

Contact

Jenny Lester MPH, CCRP
 Samuel Oschin Comprehensive Cancer Institute
 Cedars-Sinai Medical Center
 Email: jenny.lester@cshs.org

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Improving SRC Submission Quality and Reducing Time for SRC Approval

Amanda Balaban, MS, CCRP

Siteman Cancer Center

Describe the background of the problem:

The Scientific Review Committee (SRC)'s findings, also called contingencies, often result in delays during submission and start-up process for new studies. These delays can result in unfavorable determinations by external sponsors (decisions against opening our site) but they are especially detrimental to investigator-initiated studies (IITs), in that delays can lead to loss of funding, loss of interest on the part of participating sub-sites, and loss of accruals to competing studies. Furthermore, the review of contingency responses puts an extra burden on the SRC's reviewers.

Provide metrics or goals to be achieved:

Our goal is to increase the quality of initial SRC submissions, measured by the number of SRC contingencies overall. We will accomplish this reduction in SRC contingencies by identifying trends in contingencies given and then communicating results with the SCC Protocol Development team, SCC Biostats Core and individual principal investigators.

Describe the solutions or methods implemented:

We identified the eleven most common areas of review (listed below) and created an SRC Issues Tracking spreadsheet whereby each contingency could be logged and categorized:

- Background/ Rationale
- Objectives
- Competing Studies
- Eligibility and Enrollment
- Treatment Plan/ Duration
- Pharmacy (procurement, formulation, administration)
- Dose Modifications

- Supportive Care/ Con Meds
- Response Assessment
- Statistical Considerations
- Data Forms/ CRFs

Following each SRC meeting, each study and its corresponding findings are entered in the tracking spreadsheet.

Describe the outcome or show data representing a change (positive or negative):

Review of the IIT submissions from 2017 (n = 53) showed that the most contingencies were given for the following categories:

- Statistical Considerations (n=25)
- Treatment Plan/ Duration (n = 20)
- Data Forms/ CRFs (n = 18)

Collecting this data in real time has allowed the SRC to strategize with the Protocol Development team, Biostats Core and Education Coordinator to improve investigator-initiated study submissions by flagging areas that can often benefit from extra attention during the development process.

For example, by identifying statistical concerns as the most likely contingency, we were able to review the data with the Biostats Core and determine the main area(s) of concern. Upon discussion, it was determined that the biggest concern was the reviewer's perception of missing information from the protocol. Once the scope of statistical SRC review was more clearly defined, this area of contingency decreased by 25%.

Address lessons learned and future directions:

Moving forward, we will assess the PRMC contingencies against future internal QA audit findings to assess any significant correlation between contingencies at the time of initial PRMC review and contingencies at the time of QA audit.

We will also include this data for IITs and industry studies in the internal PI Dashboard report, which includes information regarding accrual progress, inclusion of minorities, and internal audit findings. By sharing the most common SRC review contingencies with each PI and/ or department, we hope to provide a valuable summary of the issues identified, and assist in identifying the resources needed to avoid these contingencies in the future. By assessing this data on an investigator and/ or department level, we are able to identify trends which may warrant follow up from our internal education coordinator.

Finally, we intend to use this data to assess the SRC submission forms and process and identify areas for improvement.



Improving SRC submission quality and reducing time for SRC approval

Amanda Balaban, MS, CCRP
Siteman Cancer Center

Background

The Scientific Review Committee (SRC)'s findings, also called contingencies, often result in delays during submission and start-up process for new studies. These delays can result in unfavorable determinations by external sponsors (decisions against opening our site) but they are especially detrimental to investigator-initiated studies (IITs), in that delays can lead to loss of funding, loss of interest on the part of participating sub-sites, and loss of accruals to competing studies. Furthermore, the review of contingency responses puts an extra burden on the SRC's reviewers.

Goal

Our goal is to increase the quality of initial SRC submissions, measured by the number of SRC contingencies overall. We will accomplish this reduction in SRC contingencies by identifying trends in contingencies given and then communicating results with the SCC Protocol Development team, SCC Biostatistics Core and individual principal investigators.

Methods

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Following each SRC meeting, each study and its corresponding findings are entered in the tracking spreadsheet.

Outcome

Review of the IIT submissions from 2017 (n = 53) showed that the most contingencies were given for the following categories:

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Collecting this data in real time has allowed the SRC to strategize with the Protocol Development team, Biostatistics Core and Education Coordinator to improve investigator-initiated study submissions by flagging areas that can often benefit from extra attention during the development process.

For example, by identifying statistical concerns as the most likely contingency, we were able to review the data with the Biostatistics Core and determine the main area(s) of concern. Upon discussion, it was determined that the biggest concern was the reviewer's perception of missing information from the protocol. Once the scope of statistical SRC review was more clearly defined, this area of contingency decreased by 25%.

Future Directions

- Assess the PRMC contingencies against future internal QA audit findings to assess any significant correlation between contingencies at the time of initial PRMC review and contingencies at the time of QA audit
- Include this data for IITs and industry studies in the internal PI Dashboard report to identify trends
- Assess the SRC submission forms and process and identify areas for improvement

Issues Tracking Spreadsheet



Issues are tallied after each SRC meeting for analysis

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

An Audit Tool for the Delegation Log That Will Fix Your FDA Audit Woes

Melissa R. Haley

Siteman Cancer Center

Describe the background of the problem:

The FDA has shown increased attention in the Delegation of Authority logs (DOAs), in particular, protocol-specific training of delegates related to their designated tasks. We have noted this trend over the past few years through an analysis of the publicly available FDA inspection observations and, as well as our own experiences during inspections.

The DOA must demonstrate that protocol-specific training qualifies delegates for study-specific tasks. As protocols become more complicated and increasingly span multiple tumor types, tracking this protocol-specific training is a larger challenge across multiple disease groups.

A robust quality assurance program should ensure that the DOA is properly created, especially with respect to protocol specific training. Whether an external auditors or an internal QA program, a system should direct a reviewer to this documentation. Even more fundamentally, there is no systematic way to train regulatory personnel on how to complete a DOA, either as part of an initial training or as a corrective action.

Provide metrics or goals to be achieved:

During multiple audits the recurring trend emphasized the importance of documenting training. We also saw an increase in noncompliance for improper delegation. Preliminary audits showed that there were discrepancies between the study team and the training that was documented.

Describe the solutions or methods implemented:

Using feedback from recent FDA inspections we developed a tool to track DOA changes. These changes could come from a protocol modification requiring training or study team updates. There may be many such changes during the life of a study.

The tool is very simple: the study team members are listed on the left hand column, and the amendments are listed on the top row. Once a team member received training, the date is entered into that column. In this way it is easy to visualize compliance or missing training.

Describe the outcome or show data representing a change (positive or negative):

Our expectation is that this will reduce the number of DOA-related findings in three ways: First, the ease of use in navigating site files makes review easy for the auditor. Second, using this tool internally identifies gaps quickly for correction. Finally, a systematic tool can better identify systematic errors, prompting process updates.

As you can see from the data below, in April we have a 15% decrease (between January and April) in errors simply by identifying the gaps and educating the regulatory staff on fixing errors before study activation.

- January 14 audits - 31 errors (40%)
- February – no audits complete
- March 13 audits - 35 errors (37%)
- April 4 audits - 13 errors (25%)

Address lessons learned and future directions:

We continue to find new ways to use this system beyond the original intent. Because it contains this information in a single place it is useful for communicating:

1. Protocol modifications
2. Training type/date
3. Pending regulatory documents

An Audit Tool for the Delegation Log That Will Fix Your FDA Audit Woes

Division of Oncology



Washington University Division of Oncology
Melissa R. Haley, Regulatory Supervisor, Brett Ramsey, Manager, Clinical Trials

Background

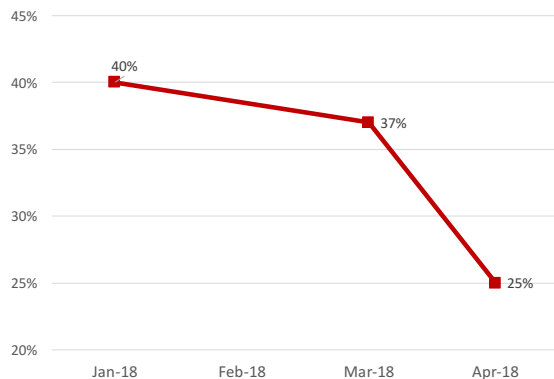
Regulatory agencies such as the FDA have shown increased attention in the Delegation of Authority logs (DOAs) in particular **protocol-specific training of delegates** related to their designated tasks. We have noted this trend over the past few years through an analysis of the publicly available FDA inspection observations, as well as our own experiences during inspections.

The DOA must demonstrate that protocol-specific training qualifies delegates for study-specific tasks. As protocols become more complicated and increasingly span multiple tumor types, tracking this protocol-specific training is a larger challenge across multiple research teams.

A robust quality assurance program should ensure that the DOA properly captures protocol-specific training. Whether for an external auditors or internal QA programs, **a system should direct a reviewer to the documentation that demonstrates that an individual is qualified.**

Such a system also provides **a framework to train regulatory personnel on how to complete a DOA**, either as part of an initial training or as a corrective action.

DOA Error Rate, Internal QA Auditing



IRB tracking document for FDA Auditor					
IRB approvals	Date	Reason for modification	Consent changes Y or N	Reconsent required?	Notes:
Initial Approval	2/27/2018	N/A	N/A	N/A	
	3/6/2018	Open to accrual			
Modification	3/20/2018	Study team update & admin ICF changes (Update to protocol title and page numbering)	Y	N	we will not re-consent patients because this does not change the risk/benefit ratio

Goals

The recurring trend across inspections emphasized the importance of **documenting protocol-specific training**. We also saw an increase in noncompliance for improper delegation. Preliminary audits showed discrepancies between the list of delegates the training documentation. Our goal **increase compliance, adjust processes in our practice and training, and to assist auditors** easily get past the regulatory part of the audit.

Methods

Using feedback from recent FDA inspections we developed a tool to track DOA changes. These changes could come from a **protocol modification requiring training or updates to the study team**. There may be many such changes during the life of a study.

The tool is very simple: the study team members are listed on the left hand column, and protocol modifications are listed on the top row. Once a team member received training, the date is entered into that column. This creates an **easy way to visualize compliance or missing training**.

Outcomes

This has reduced the number of DOA-related findings in the following ways:

1. It is **easy** for external inspectors to navigate files
2. Internally, gaps can be **quickly identified & corrected**
3. Any **systematic errors are revealed**, prompting intervention such as process updates or education/training

Our data shows between January 2018 and April 2018 **a 15% decrease in errors** simply by identifying the gaps and educating the regulatory staff on fixing errors before study activation.

Future Uses

We continue to find new ways to use this system. Because this information is in a single place it is useful for communicating:

- Protocol modification type and
- Training type/date
- Pending/missing regulatory documents

Regulatory document to cross check study team/DOA/Regulatory documents					
			Initial approval	Open to Accrual	ICF admin changes & Study team update
On 1572?	FDI in File	DOA member	2/27/2018	3/6/2018	3/20/2018
X	X	PI	N/A	SIV	3.20.2018-update
		Study Coordinator-Backup	N/A	SIV	N/A
X	X	Sub-Investigator	N/A	2.28.2018-team	N/A
		Study Coordinator-Backup	N/A	3.6.2018	N/A
		Study Coordinator-Backup	N/A	2.28.2018-team training	N/A
		Study Coordinator-Backup	N/A	3.6.2018	N/A
removed	N/A	Sub-Investigator	N/A	n/a	n/a
X	X	Sub-Investigator	N/A	3.15.2018	N/A
X	X	Sub-Investigator	N/A	3.9.2018	N/A
		Study Coordinator-Backup	N/A	3.15.2018	N/A
		Study Coordinator-Backup	N/A	3.9.2018	N/A
		Study Coordinator-Backup	N/A	SIV	N/A

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

A Policy on Policies: Why Policy Management Shouldn't End at Creation

Emily Harms, MA, CCRP; Elizabeth Menne, RN, OCN; Brett Ramsey, MBA, CCRP

Siteman Cancer Center

Describe the background of the problem:

A robust set of policies ensures program-wide compliance and consistency with regulatory and institutional guidelines during the conduct of research. Washington University Division of Oncology Clinical Research Program has been operating without a formal system for policy creation, review, and approval. No single party is currently responsible for creating and maintaining policies, and in many cases, policies are drafted and implemented without consulting the individuals affected by them. Furthermore, many policies are created in response to a single issue and then applied globally. This disconnect contributed to inconsistent format and policies have been saved independently, in multiple locations. Outdated or obsolete policies have continued to be referenced due to a lack of a formal archiving method.

This lack of consistency and oversight has led to a poor understanding of Division policies and practices, both internally and externally, making policy comprehension and compliance more challenging.

Provide metrics or goals to be achieved:

In addition to clearly defining the scope, audience and ownership of Division policies, we set out to:

- Review policies that have not been reviewed within the last three years
- Reduce the number of redundant or obsolete policies
- Remove internal work instructions from policies
- Develop a user-friendly archiving system
- Convert policies to a single format

Describe the solutions or methods implemented:

First, we formed a committee of Division leaders, including representatives from each of our clinical, data, regulatory and education groups. While keeping oversight with Division leadership, we designed a process in which the

executors of a policy are involved in its creation, hoping to empower staff to share ideas and feel included.

Next, we created a policy on policy management, describing the workflow for policy creation, the frequency of reviews, and the committee's scope of work.

Then, the committee organized current policies by compiling these independent documents into a single manual. We determined which policies serve an essential function, which are not within the scope of the committee, and which require updates.

Describe the outcome or show data representing a change (positive or negative):

To date, the committee has accomplished the following:

- Eliminated 9 policies that were no longer necessary; introduced, edited and approved 4 new policies; combined the remaining 30 policies into a single manual
- Standardized 5 formats into a single, consistent policy template
- Decreased policies older than three years from 71% to 33%, projecting 0% requiring update by July 2018

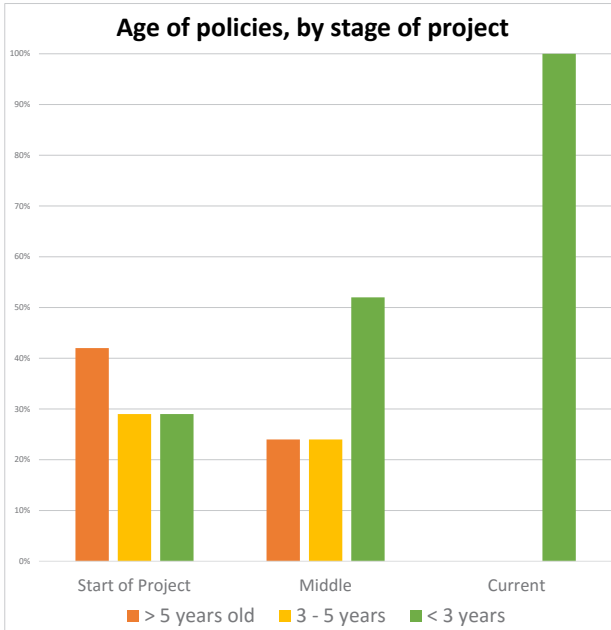
Address lessons learned and future directions:

We were surprised how often a policy was stored with study-specific materials or was distributed from a personal computer. This punctuated the importance of maintaining the policies as a manual in a central location.

We also found that, while involving multiple parties in the process is a democratic approach to completing this project, it is not efficient. At times, issues became controverted and gridlocked. We intend to combat these problems with strong committee leadership and clear rules regulating the practices of the committee.

A Policy on Policies: Why Policy Management Shouldn't End at Creation

Emily Harms, MA, CCRP, Elizabeth Menne, RN, OCN, Brett Ramsey, MBA, CCRP



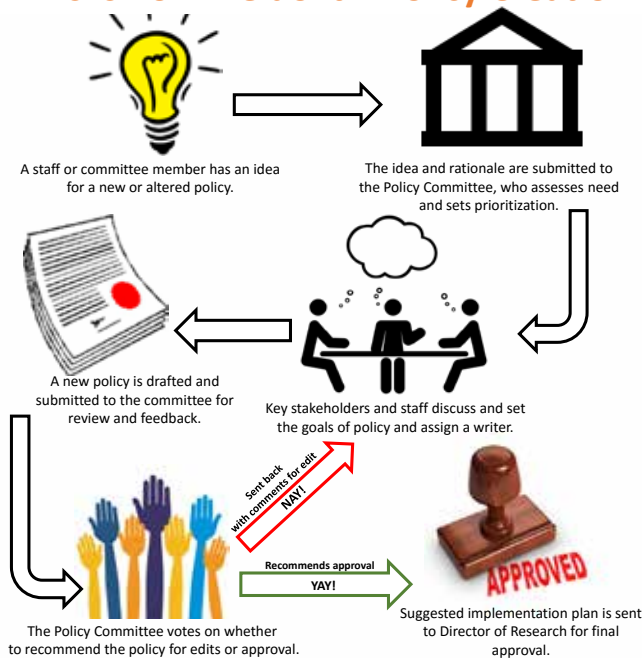
Problems with old system

- **No central ownership** of policy creation and maintenance
- Policies created **in response to specific events** without input from those carrying out the policy
- **Inconsistent** policy format
- Policies housed in **multiple locations**
- Lack of awareness of current policies, leading to **poor understanding and compliance**
- No mechanism for updating or archiving **outdated or obsolete policies**

First steps to solving the problem

- ☑ **STEP 1: Assemble a committee**
 - Gather experienced leaders representing division stakeholders
- ☑ **STEP 2: Create a "Policy on Policies"**
 - Define the scope of work and goals of the committee
 - Outline the methods for policy creation and updates
- ☑ **STEP 3: Inventory and clean-up**
 - Identify high-impact, low-effort policies to tackle first
 - Prioritize future policy updates according to need
 - Move individual policies to one centralized storage location

"This is how we do it": Policy Creation



Outcomes

- Reduced policies > 3 years old from **71% to 0%**
- Eliminated policies that are obsolete (n= 15)
 - Division policies quoting IRB policies were eliminated
 - Policies describing practices that are no longer relevant were archived
- Introduced, edited and approved **6 new policies in 3 months**, proving the new method for policy creation to be very efficient
- **Standardized policy format** from five distinguishable formats into a single policy template, consistent across all policies
- Pulled individual policies from numerous storage locations and moved policies to **one centralized location**
- Combined 19 policies into **one user-friendly manual** – *Now available for distribution to monitors and sponsors*



Looking ahead

More policy changes are coming

- Effects of the Final Rule
- Increase in use of single central IRBs
- Rollout of our new EMR system, EPIC
- Updates in institutional practices (e.g. delegation of authority)



Our staff are our best assets

- We will create an electronic "suggestions box" to encourage staff to share their feedback and to spur thoughtful policy discussions.

Communication and appropriate implementation of new policies are essential

- We are working in tandem with the Education & Training and QA teams to create work instructions for staff

We must continue to anticipate challenges

- Not all of our study teams operate the same. We are determining how to handle team-specific practices that cannot be applied globally.

Development of a Principal Investigator-Specific Audit Results Dashboard

Nicole Kensinger

Siteman Cancer Center

Describe the background of the problem:

Principal investigator (PI) involvement in the management of a study is arguably the most important factor in determining that study's success. PIs are expected to oversee all aspects of their studies; however, PIs have a wide range of responsibilities and may struggle with routine study monitoring. This challenge is magnified by the complexity and sheer length of audit reports. The serious errors that require prompt intervention can be lost amongst the "white noise" of minor findings. A long audit report with a full accounting of even minor errors may be mistakenly construed as failure, leading to discouragement and frustration with the audit process. Additionally, the contents of an audit report rarely engage PIs throughout the year, but systemic issues raised during an audit require continuous corrective action. The audit team at Siteman Cancer Center created a tool that addresses the obstacles related to robust study monitoring faced by PIs.

Provide metrics or goals to be achieved:

1. Create a visual which displays institutional audit metrics for PIs' studies compared to their department and the overall center.

Describe the solutions or methods implemented:

1. For all audits, 12 pre-determined components were assessed.
2. Each component was scored a 0 (no error), 1 (minor errors), 2 (major errors), or 3 (severe errors) on a rubric.
3. A database of all the rubric data was generated.
4. The frequency of major and severe errors for each PI (figure 1) was tabulated.
5. A scale for audit expectations was set and PI results were color coded accordingly.
6. The dashboard will be piloted April 2018 by sending all PIs their personalized dashboard via a link in email.

Describe the outcome or show data representing a change (positive or negative):

The PI dashboard summarizes audit findings more efficiently than any other platform available; however, the effectiveness is unknown at this time. During the pilot, we will use google data analytics and survey tools to assess the utility of the dashboard to PIs.

To date, the audit team has utilized the PI dashboard to inform our own processes in the following ways:

1. We have identified the most common and serious errors that occur during the lifetime of a study
2. We have identified the departments and PIs who would most benefit from intervention/training
3. We have identified the departments and PIs who are meeting or exceeding our expectations.

Address lessons learned and future directions:

Future directions are as follows:

- Iterative versions: We will continuously update the dashboard based on PI feedback and results from data analytics.
- Mentorship: We will pair successful PIs with Junior PIs by using the dashboard as a platform for mentorship.
- Intervention assessment: We will evaluate audit findings pre and post interventions put into place to see if there is a positive or negative correlation.
- Prevention: We will investigate severe errors and perform a root cause analysis, allowing us to develop targeted interventions to prevent future errors.

The Problem

Principal investigator (PI) involvement in the management of a study is arguably the most important factor in determining that study's success. PIs are expected to oversee all aspects of their studies; however, PIs have a wide range of responsibilities and may struggle with routine study monitoring.

This challenge is magnified by the complexity and sheer length of audit reports. The serious errors that require prompt intervention can be lost amongst the "white noise" of minor findings. A long audit report with a full accounting of even minor errors may be mistakenly construed as failure, leading to discouragement and frustration with the audit process.

Additionally, the contents of an audit report rarely engage PIs throughout the year, but systemic issues raised during an audit require continuous corrective action.

The audit team at Siteman Cancer Center created a tool that addresses the obstacles related to robust study monitoring faced by PIs.

Goals

1. Create a visual which displays institutional audit metrics for PIs' studies compared to their department and the overall center.
2. Identify audit trends across the cancer center, management groups and PIs.
3. Identify the most common and severe errors.

Contact:

Nicole Kensinger MPH, CCRP
Siteman Cancer Center
Phone: 314-362-0524
Email: nkensin@wustl.edu

Solutions and Methods

1. For all audits (n= 497), 22 pre-determined components were assessed.
2. Each component was scored a 0 (no issues were identified), 1 (minor issues were identified for a few patients), 2 (there is a pattern of errors for the majority of patients), 3 (errors identified that would affect the validity of the study). Errors that would impact patient safety were also explicitly noted.
3. A database of all the rubric data was generated.
4. Each component was re-grouped into role-associated categories.
5. The frequency of studies identified with level 2 or level 3 errors, from 2011-2017 in each role-associated category, was generated for each department and management group across the cancer center (figures 2a and 2b).
6. Individual study PI Dashboards (figure 1) were sent to teams post-audit to summarize results. The same dashboard will be sent 6 weeks prior to an audit to remind teams which area(s) of the audit need(s) improvement.

PI Dashboard Example



Figure 1: Study results are color-coded according to the audit dashboard key. The dashboard is sent to PIs pre and post-audit.

Trends Report Example

Figure 2a: Percent of studies across the cancer center found to have level 2 or level 3 clinic errors* from 2011-2017.

Key:
Level 2
Errors
Level 3
Errors

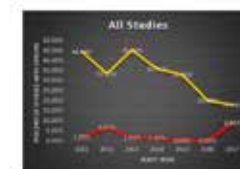


Figure 2b: Percent of studies within a specific management group found to have level 2 or level 3 clinic errors* from 2011 to 2017.

Key:
Level 2
Errors
Level 3
Errors



*The components evaluated within the category of clinic errors includes eligibility, informed consent, completion of protocol required procedures and available source documentation.

Future Directions

1. Collaborate with the education department to disseminate findings.
2. Identify the risk factor(s) associated with underperforming studies (i.e. high accruing studies, junior PIs, studies with an IND, phase I studies).
3. Facilitate collaborations between experienced teams and un-experienced teams.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Real-World Research Training for Junior Investigators

Bethany Rensink, CCRP

Siteman Cancer Center

Describe the background of the problem:

Recent trends across research institutions display a heavy reliance on junior investigators rather than senior faculty to conduct research. While providing an abundance of regulatory education, research institutions frequently lack real-world training. Without this training, junior investigators do not have the experience to differentiate between clinical and research decisions, or to apply the rules of research in a practical manner. This leads to research errors and poor research quality, which can affect the welfare of participants.

Provide metrics or goals to be achieved:

Our goal is to provide all junior investigators (those holding the position of assistant professor and below) engaged in clinical research with practical real-world training, distinct from formal regulatory education such as GCP, in order to improve research quality, prevent errors, and protect participants.

Describe the solutions or methods implemented:

We developed a PI-focused curriculum framed by the commitments on the FDA's Statement of Investigator (Form 1572), deliberately avoiding the formal tone of regulatory and GCP training. The training is led by senior faculty within each department with a wealth of knowledge to share. All junior investigators engaged in clinical research will be required by their departments to complete this training.

The following principles make our curriculum distinctive from other resources at our institution:

Practical

At the end of each section is a summary slide presenting the consequences of failing to apply the information in research practice. The summary is designed to stand out and highlight the main point. (Attached).

Experiential

Many training resources are online or presented by a trainer rather than someone with real-world experience. When presented by senior faculty within the junior investigators' own department, realistic examples and appropriate insight can relate directly to their research.

Adaptable

The framework of this curriculum is universally applicable, created in a way that is easily adapted to fit each department's unique culture and needs.

Realistic

We acknowledge all investigators have time constraints due to research and clinical duties, therefore we designed this as an hour-long training.

Describe the outcome or show data representing a change (positive or negative):

Since 2015, nearly 1600 participants have been enrolled to interventional trials at our site by junior investigators. Each year, the number of junior investigators enrolling participants increases.

This demonstrates a growing population of investigators who will benefit from a training program developed specifically for them along with the potential to make an extraordinary impact in the conduct of research at our center.

We successfully piloted this program with four Radiation Oncology junior investigators. Given the positive feedback we have received, it is now being expanded into other departments. The flexibility and adaptability of the program make this feasible.

Address lessons learned and future directions:

Moving forward, we will include the departments of Surgery and Medical Oncology in this training program to reach all applicable junior investigators.

We see value in reaching a broader audience. Our next step is to develop a web-based version of this training to post in our institution's learning portal. With this available, senior investigators can access a refresher at their convenience.

Real-World Research Training for Junior Investigators

Bethany Rensink, CCRP, Siteman Cancer Center

Background of the problem:

Recent trends across research institutions display a heavy reliance on junior investigators rather than senior faculty to conduct research. While providing an abundance of regulatory education, research institutions frequently lack adequate real-world training. Without this training, junior investigators do not have the experience to differentiate between clinical and research decisions, or to apply the rules of research in a practical manner. This leads to research errors and poor research quality, which can affect the rights and welfare of participants.

Goals to be achieved:

Our goal is to provide all junior investigators (those holding the position of assistant professor and below) engaged in clinical research with practical real-world training, distinct from formal regulatory education such as GCP, in order to improve research quality, prevent errors, and protect participants

Methods implemented:

We developed a PI-focused curriculum framed by the commitments on the FDA's Statement of Investigator (Form 1572), deliberately avoiding the formal tone of regulatory and GCP training. The training is led by senior faculty within each department with a wealth of knowledge to share. All junior investigators engaged in clinical research will be required by their departments to complete this training.

Distinctive principles:

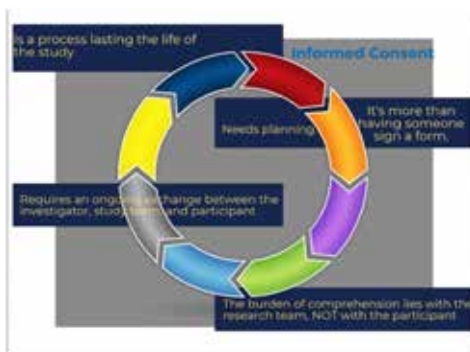
Practical

At the end of each section is a summary slide presenting the consequences of failing to apply the information in research practice, designed to highlight the main point.



Experiential

Many training resources are online or presented by a trainer rather than someone with real-world experience. When presented by senior faculty within the junior investigators' own department, realistic examples and appropriate insight can relate directly to their research.



Adaptable

The framework of this curriculum is universally applicable, created in a way that is easily adapted to fit each department's unique culture and needs.



Realistic

We acknowledge all investigators have time constraints due to research and clinical duties, therefore we designed this as an hour-long training. This hour includes time for discussion and questions in addition to the presentation of study material.



Data representing a change:

Since 2015, nearly 1600 participants have been enrolled to interventional trials at our site by junior investigators. Each year, the number of junior investigators enrolling participants increases.

This demonstrates a growing population of investigators who will benefit from a training program developed specifically for them along with the potential to make an extraordinary impact in the conduct of research at our center.

We successfully piloted this program with four Radiation Oncology junior investigators. Given the positive feedback we have received, it is now being expanded into other departments. The flexibility and adaptability of the program make this feasible.

Future Directions:

Moving forward, we will include the departments of Surgery and Medical Oncology in this training program to reach all applicable junior investigators.

Since the pilot, we have developed a video-based version of this training which will be posted in our institution's learning portal. With this available, senior investigators can access a refresher at their convenience, and faculty presenters can use the videos within their lecture as desired.

A curriculum guide to further support senior faculty is in development and will include a glossary of common terms, discussion points, and frequently asked questions.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Using Rapid Cycle Improvement to Design a Scalable Appointment Scheduling System for Complex Oncology Clinical Trials at an Academic Cancer Center

Avantika Dang, MHA, CSSGB, PMP; Lauren N. Gjolaj, MBA, BSN, RN

Sylvester Comprehensive Cancer Center, University of Miami Health System

Describe the background of the problem:

Timely appointment scheduling for clinical trial patients is critical for ensuring proper care coordination, timeliness of care, protocol adherence, and sufficient time to obtain insurance prior authorizations. At matrixed cancer centers, scheduling appointments for clinical trial patients is complex, involves multiple processes, functional units, and inputs. Leadership noted an increase in appointments scheduled < 2 weeks before the appointment date (reduction in lead time), which often causes increased protocol deviations and appointment cancellations due to insufficient time to obtain insurance authorizations.

Provide metrics or goals to be achieved:

Goals included:

- Optimizing the efficiency of research schedulers' workflows.
- Designing a scalable research scheduling team to meet the growing demands of an Academic Cancer Center with increasing clinical trial accruals in a proactive way.

Describe the solutions or methods implemented:

Plan Do Study Act (PDSA) rapid cycle improvement methodology was deployed:

- Plan – Conducted one-on-one Voice of the Customer interviews.
- Do – Process mapped baseline workflows and analyzed billing data.
- Study – Calculated cycle time (actual time required to complete a process), takt time (time in which a process needs to be completed to meet customer demand), and conducted a capacity analysis. An average cycle and takt time of 5.3 and 4.3 minutes, respectively was calculated for scheduling an appointment. Understanding that a 20% increase in efficiency was required to achieve the pace needed to meet customer demand (i.e. make cycle time equal takt time), interventions to improve efficiency were developed.

- Act – Implemented interventions to increase efficiency and reduce non-value added (NVA) activities (figure 1).

Describe the outcome or show data representing a change (positive or negative):

Outcomes include:

- 33% reduction in the process steps in the schedulers' workflow.
- Reduction of NVA activities:
 - Decreased modes and volume of ad-hoc communication.
 - Integrated previously siloed sub-processes to create one multi-disciplinary process.
 - Improved management and prioritization of workload and data collection to facilitate proactive staffing.
- Increased appointment lead time to 1 month in advance of appointment date

Address lessons learned and future directions:

The team learned that quantifying workload and capacity creates a shared understanding of the problem and helps create scalable staffing frameworks.

Suggestions for others include:

1. Ensure a multidisciplinary process improvement team to bridge gaps between functional units.
2. Create process maps to ensure a shared understanding of complex processes.
3. Evaluate existing processes critically and assess whether each process step adds value. Do not accept NVA activities because they are the status quo.
4. Discuss end-user requirements and how eliminating NVA activities is beneficial in resource-constrained environments.

5. Use data to quantify staff workload and capacity (including takt and cycle time) to determine capacity, increased efficiency required to meet existing demand, and to develop proactive staffing models.

Project methodology and tools are transferrable and can be used to evaluate existing processes, identify process failures, and remove NVA work at other Cancer Centers. The framework of calculating takt time, cycle time, and conducting a capacity analysis could be applied to assess efficiency and staffing needs and create scalable staffing models for other areas (pharmacy, nursing, etc.) within Cancer Centers that coordinate care for patients on complex clinical trials.

Future directions include building scheduling requests within the EMR chemotherapy protocols.

Using Rapid Cycle Improvement to Design a Scalable Appointment Scheduling System for Complex Oncology Clinical Trials at an Academic Cancer Center



Avantika Dang, MHA, CSSGB, PMP; Lauren N. Gjolaj, MBA, BSN, RN
Sylvester Comprehensive Cancer Center (Sylvester) at the University of Miami Miller School of Medicine

Background

- Timely appointment scheduling for clinical trial patients is critical for ensuring:
 - Proper care coordination
 - Timeliness of care
 - Protocol adherence
 - Sufficient time to obtain insurance prior authorizations
- Scheduling appointments for clinical trial patients is complex, involves multiple processes, functional units, and inputs.
- Leadership noted an increase in appointments scheduled < 2 weeks before the appointment date (reduction in lead time), which often causes increased protocol deviations and appointment cancellations due to insufficient time to obtain insurance authorizations.
- Scope of project
 - From the time an appointment is requested for a research patient to the time billing is routed to insurance or the sponsor for the study.

Goals

- Optimize the efficiency of research schedulers' workflows.
- Design a scalable research scheduling team to meet the growing demands of an Academic Cancer Center with increasing clinical trial accruals in a proactive way.

Methods

Plan Do Study Act (PDSA) rapid cycle improvement methodology was deployed:

- Conduct Voice of the Customer (VOC) interviews to understand processes and potential process failures or inefficiencies



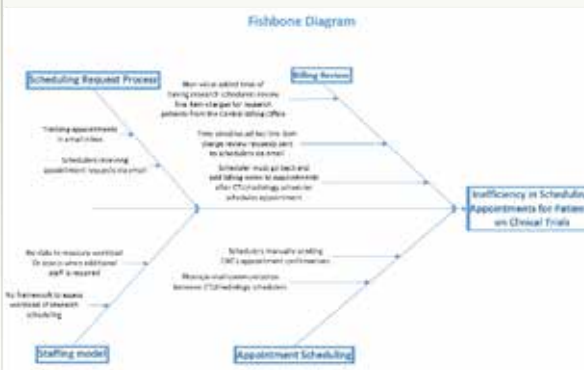
- Develop process map of baseline workflow
- Analyze billing data to quantify defects

- Implement interventions to increase efficiency
- Develop process map of post-intervention workflow
- Track and calculate post-intervention metrics

- Track and calculate baseline metrics
- Use a fishbone diagram to identify process failures
- Develop interventions to address inefficiencies

Methods (Cont.)

A fishbone diagram was used to identify the root causes of inefficiencies:



Solutions Implemented

Interventions were implemented in three areas to improve efficiency:

- Billing**
 - Halted non-value added (NVA) billing activities.
 - Deployed EMR work queues to ease the tracking and prioritization of billing requests (vs. e-mail).
 - Deployed EMR work queues to allow billing notes and communication between departments within the EMR (vs. e-mail).
- Scheduling**
 - Built appointment request form into EMR to allow coordinators to request and view the status in one system vs. one by one via e-mail
 - Deployed interdepartmental EMR work queues to reduce phone and email communication required to discuss requests.
- Staffing**
 - Created a framework for conducting capacity analyses
 - Created a scalable framework for proactive staffing

Outcome

- 33% reduction in the process steps in the schedulers' workflow.
- 11% reduction in the cycle time for scheduling an appointment.
- Reduction of non-value added activities (NVA) activities.
- Increased scheduling lead time to 1 month in advance of appointment date.

Process Metrics	Baseline Assessment (October 2017)	Post-Intervention Assessment (May 2018)	Change From Baseline to Post-Intervention
Total # of Appointments Request Received Weekly	926	1000	↑ 8%
Total # of Appointments Scheduled Weekly	731	763	↑ 4%
Total Time Spent Scheduling Appointments Weekly (Hours)	65	60	↓ -8%
Cycle Time Per Appointment (Minutes)	5.3	4.7	↓ -11%
Takt Time Per Appointment (Minutes)	4.3	3.6	↓ -16%
Cycle Time Reduction Required to Meet Takt Time	20%	24%	↑ 19%
Additional Time Required to Meet Scheduling Requests (Hours)	17	19	↑ 7%

Lessons Learned & Future Directions

Lessons learned:

- Quantifying workload and capacity creates a shared understanding of the problem and to create scalable staffing frameworks.
- A multidisciplinary process improvement team helps bridge gaps between functional units.
- Creating process maps ensures a shared understanding of complex processes.
- Evaluating existing processes critically and assessing whether existing activities add value is vital to identify non-value added (NVA) activities.
- Discussing end-user requirements and how eliminating NVA activities is beneficial in resource-constrained environments helps facilitate change from the status quo.
- Using data to quantify staff workload and capacity (including takt and cycle time) helps determine capacity, increased efficiency required to meet existing demand, and to develop proactive staffing models.

Project methodology and tools are transferrable and can be used to assess efficiency and create scalable staffing models for other areas in Cancer Centers (pharmacy, nursing, etc.). Future directions include building scheduling requests within the EMR chemotherapy protocols.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Utilizing Voice of the Customer in Clinical Research to Drive Plan Do Study Act (PDSA) Process Improvement Projects at an Academic Cancer Center

Avantika Dang, MHA, CSSGB, PMP; Lauren Gjolaj, MBA, BSN, RN

Sylvester Comprehensive Cancer Center, University of Miami Health System

Describe the background of the problem:

Clinical trial operations at cancer centers involve complex processes with many inputs from various teams. Frequently, stakeholders experience process issues and provide feedback but lack the tools to translate qualitative feedback into action. Not acting on feedback provided by staff can lead to frustration and low employee morale.

Provide metrics or goals to be achieved:

Project goals included using the Plan Do Study Act (PDSA) methodology to:

1. Quantify qualitative feedback to validate the problem, prioritize efforts, and create urgency around process improvements
2. Generate interventions addressing process failures and feedback
3. Create and complete action plans to implement interventions
4. Increase communication among functional units and with stakeholders

Describe the solutions or methods implemented:

The following steps and tools were implemented using the PDSA methodology to achieve project goals:

- Plan: Qualitative feedback was obtained from 40+ stakeholders via one-on-one Voice of the Customer (VOC) interviews.
- Do: Data was quantified by categorizing key themes, summing the frequency the topic arose in VOC interviews, and creating a pareto diagram to illustrate that focusing on the top 2 VOC themes would address 50% of feedback received (figure 1).
- Study: Using a cause-and-effect diagram, process failures (root causes of issues) relating to key themes were identified.

- Act:
 - Through a Failure Modes and Effects Analysis (FMEA), each process failure was rated 1-5 indicating impact and alignment with 3 project goals and multiplied to generate an indexed score. A higher score signified a higher priority process failure.
 - Interventions were brainstormed to address process failures and 19 high impact interventions were selected.
 - Work streams and action plans were developed to facilitate implementation and track progress.

Describe the outcome or show data representing a change (positive or negative):

Six months post-initiation the project is 85% complete. Out of 19 interventions developed:

- 11 have been 100% implemented.
- 8 are in progress, all of which are >60% complete and are long-term projects.

Project outcomes are significant because it provides an effective and transferrable framework that can translate qualitative feedback on clinical research processes into actionable interventions to drive improvements.

Address lessons learned and future directions:

The team learned the value of using real-world data to drive decision-making in validating that a problem exists, creating consensus for agreement on opportunities for improvement, facilitating transparency, and avoiding the “squeakiest wheel gets the oil” phenomenon.

Suggestions for others include:

- Planning
 - Form multi-disciplinary teams to ensure solutions developed meet the needs of all impacted.
 - Use data to drive project selection and conduct an FMEA to drive project prioritization.

- Use data and cause-and-effect diagrams to identify true process failures. Frequently feedback is about symptoms of a problem, not the problem itself.

- Implementation
 - Tackle “low hanging fruit” or easy wins to gain stakeholder buy-in and build project momentum.
 - Focus on smaller tangible milestones to ensure progress for interventions that are large or long-term.
 - Deploy project management such as meeting action plans to ensure progress and accountability.
 - Communicate with stakeholders frequently and through different channels to ensure engagement.

Process improvement is continuous and the team looks forward to completing interventions in progress and reassessing stakeholder feedback to identify further Process Improvement opportunities.

Utilizing Voice of the Customer in Clinical Research to Drive Plan Do Study Act (PDSA) Process Improvement

Avantika Dang, MHA, CSSGB, PMP; Lauren N. Gjolaj, MBA, BSN, RN
Sylvester Comprehensive Cancer Center (Sylvester) at the University of Miami Miller School of Medicine



Background

- Sylvester's catchment area serves >6 Million people, which is greater than 1/3 of Florida's population
- Sylvester has a main campus location in downtown Miami and 5 satellite locations throughout South Florida
- Sylvester Comprehensive Cancer Center is the only academic cancer center in South Florida
- Sylvester's clinical trial accruals have increased by 150% between 2013 – 2017 with a notable increase in Phase I or early stage clinical trials.
- Due to rapid growth in clinical trial accruals, SCCC Administration embarked on a process improvement project to identify opportunities for improvement in our clinical trial operations which involves complex processes with many inputs from various teams. Project selection aligned with our mission of reducing the human burden of cancer through research and the delivery of the highest quality cancer care.

Goals

Goals included using the Plan Do Study Act (PDSA) methodology to:

Quantify qualitative feedback to validate the problem, prioritize efforts, and create urgency around process improvements

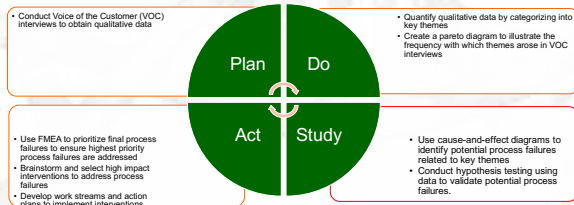
Generate interventions addressing process failures and feedback

Create and complete action plans to implement interventions

Increase communication among functional units and with stakeholders

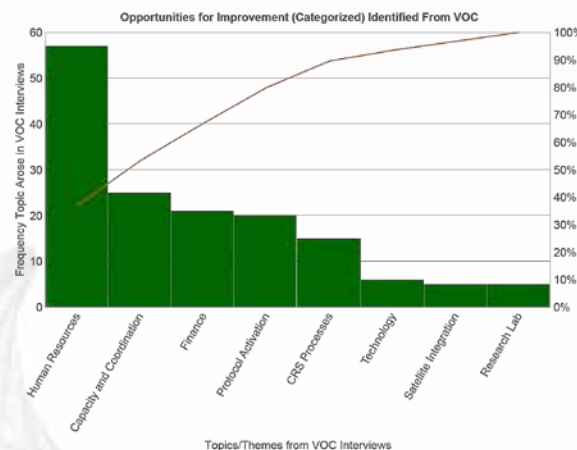
Methods

Plan Do Study Act (PDSA) methodology was deployed to achieve project goals:



Methods (Cont.)

- Plan:** Qualitative feedback was obtained from 40+ stakeholders via one-on-one Voice of the Customer (VOC) interviews.
- Do:** Data was quantified by categorizing key themes, summing the frequency the topic arose in VOC interviews, and creating a pareto diagram to illustrate that focusing on the top 2 VOC themes would address 50% of feedback received.
- Study:** Using a cause-and-effect diagram, potential process failures relating to key themes from VOC were identified. Hypothesis testing was conducted using data to validate hypotheses of potential process failures.
- Act:**
 - Through a Failure Modes and Effects Analysis (FMEA), process failures were rated 1-5 indicating impact and alignment with 3 project goals.
 - Interventions were brainstormed to address process failures and 19 high impact interventions were selected.
 - Work streams and action plans were developed to facilitate implementation and track progress.
- Qualitative feedback was obtained from 40+ stakeholders via one-on-one Voice of the Customer (VOC) interviews.
- Data was quantified by categorizing key themes, summing the frequency the topic arose in VOC interviews, and creating a pareto diagram to illustrate that focusing on the top 2 VOC themes would address 50% of feedback received.



Implementation

To facilitate implementation, four key work streams were developed:

- Human Resources
 - Capacity and coordination of care
 - Finance
 - "Just Do It" Projects (projects requiring completion due to strategic importance).
- Key stakeholders for each work stream were identified and engaged to participate in a higher level task force to provide status updates. Operational process owners were engaged in smaller work groups that met more frequently to implement interventions.
 - Project management including meeting agendas, post-meeting action plans, and following up until action items were completed were critical to project success.
 - Formal stakeholder communications were sent out via e-mail every 2 months to update stakeholders at all levels on project progress.

Outcomes

Six months post-initiation the project is 85% complete. Out of 19 interventions developed:

- 16 have been 100% implemented.
- 3 are in progress and greater than 75% complete, all of which are long-term projects.

Project outcomes are significant because it provides an effective and transferrable framework that can translate qualitative feedback on clinical research processes into actionable interventions to drive improvements.

Lessons Learned & Future Directions

The team learned the value of using real-world data to drive decision-making in validating that a problem exists, creating consensus for agreement on opportunities for improvement, facilitating transparency, and avoiding the "squeakiest wheel gets the oil" phenomenon. Other lessons learned include:

- Planning**
 - Form multi-disciplinary teams to ensure solutions developed meet the needs of all impacted.
 - Use data to drive project selection and conduct an FMEA to drive project prioritization.
 - Use data and cause-and-effect diagrams to identify true process failures. Frequently feedback is about symptoms of a problem, not the problem itself.
- Implementation**
 - Tackle "low hanging fruit" or easy wins to gain stakeholder buy-in and build project momentum.
 - Focus on smaller tangible milestones to ensure progress for interventions that are large or long-term.
 - Deploy project management such as meeting action plans to ensure progress and accountability.
 - Communicate with stakeholders frequently and through different channels to ensure engagement.

The team looks forward to completing interventions in progress and reassessing stakeholder feedback to identify further Process Improvement opportunities.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Opportunities & Challenges in Growing an Early Phase (Phase 1) Research Infrastructure

Yvonne Dinh, CCRP; Kristen Englund, CCRP; Jaime Merchan, MD, MMSc

Sylvester Comprehensive Cancer Center, University of Miami Health System

Describe the background of the problem:

The growth of a high-functioning, multidisciplinary Phase 1 program is an important strategy for many cancer centers. In 2014, Sylvester's Phase 1 program had low accruals, high protocol activation times, limited dedicated staff, and operational challenges due to a lack of streamlined processes.

Provide metrics/goals to be achieved:

A baseline assessment (BA) to gather data from the Phase I program was conducted in 2014 and identified 24 accruals, an average of 315 days to activation, and 2 dedicated personnel. Based on this BA, program goals included:

1. Achieve 20% annual increase in accruals
2. Reduce protocol activation time by 50%
3. Balance workload of each clinical research coordinator (CRC) to carry \leq 12 patients

Describe the solutions/methods implemented:

Solutions implemented include:

2015: Changed leadership and brought under the direction of the Clinical Trial Office; added additional CRCs and introduced data entry role to align with increased volume

2016: Created project manager position dedicated to study activation and nurse practitioner (NP) to optimize patient care; expanded laboratory space to conduct complex procedures; introduced study-specific flowcharts to minimize deviations

2017: Opened dedicated Infusion Unit with 16 chairs for research patients; created research Radiology Clinic; implemented EMR access; added an additional NP and triage nurse

2018: Created a dedicated Phase 1 clinic; implemented electronic chemotherapy ordering system and electronic regulatory system

Continuous Process Improvement:

Actively collaborate with other departments involved in the study and patient care (e.g. Nursing, Pharmacy and Laboratory) to discuss operational challenges and collaboratively develop solutions.

Describe the outcome/show data representing changes:

1. 329% increase in accruals from 2014-2017 (100+ accruals in 2017)
2. 43% decrease in protocol activation times
3. 100% compliance with internal benchmark of workload per CRC < 12 patients

Address lessons learned and future directions:

Optimization in operational and organizational structure plus interdepartmental collaboration are keys to achieving success. The team realized the importance of regularly collaborating with key stakeholders to enhance operational processes, as it reduced institutional barriers to growing a Phase I program and allowed the team to scale the program quickly.

Recommendations:

1. Increasing accruals:
 - "Baby Steps": set monthly accrual goals
 - Create slot availability dashboard for quick portfolio overview
 - Create internal app with embedded link to Clinicaltrials.gov for instant access to eligibility criteria
2. Scaling and growing a Phase I program:
 - Utilize workload tool to assess volume and staff workload distribution
 - Retain high-performing personnel through internal promotions and recognitions

- Increase staffing in other departments to align with accruals
- Employ staffing agency to nationally source highly specialized talent to perform complex procedures for a finder's fee or short-term contract to permanent conversion
- Cultivate relationships with pharmaceutical counterparts by shortening activation times

3. Reducing activation times:

- Prioritize studies in the start-up process
- Initiate chemo order development at IRB submission
- Align volume with staffing capacity for processing contracts/budgets
- Engage physicians up-front in the budget creation process

Future Directions:

- Add eligibility coordinator
- Add dedicated personnel to process budgets
- Increase program visibility through external advertising and institutional website
- Partner with academic and NCI-affiliated centers for referrals

Opportunities & Challenges in Growing an Early Phase (Phase 1) Research Infrastructure

Yvonne Dinh, CCRP; Kristen Englund, CCRP; Jaime Merchan, MD, MMScl
Sylvester Comprehensive Cancer Center (Sylvester) at the University of Miami Miller School of Medicine



Background

The growth of a high-functioning, multidisciplinary Phase 1 program is an important strategy for many cancer centers. In 2014, Sylvester's Phase 1 program had low accruals, high protocol activation times, limited dedicated staff, and operational challenges due to a lack of streamlined processes.

Goals

- 1) Achieve 20% annual increase in accruals
- 2) Reduce protocol activation time by 50%
- 3) Balance workload of each clinical research coordinator (CRC) to carry ≤ 12 patients

Methodology

A baseline assessment (BA) to gather data from the Phase I program was conducted in 2014 and identified 24 accruals, an average of 315 days to activation for 6 studies, and 2 dedicated personnel.

Solution Implemented

2015:

- Changed leadership and brought under the direction of the Clinical Trial Office
- Added additional CRCs and introduced data entry role to align with increased volume

2016:

- Created project manager position dedicated to study activation and nurse practitioner (NP) to optimize patient care
- Expanded laboratory space to conduct complex procedures
- Introduced study-specific flowcharts to minimize deviations

2017:

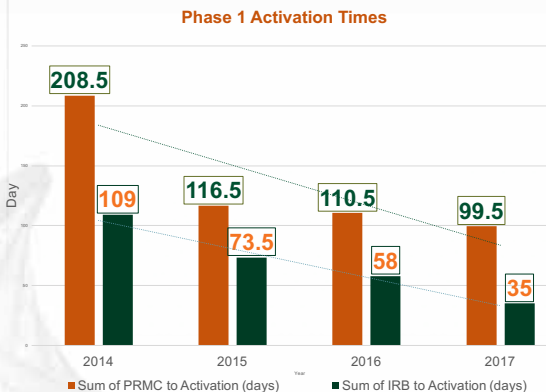
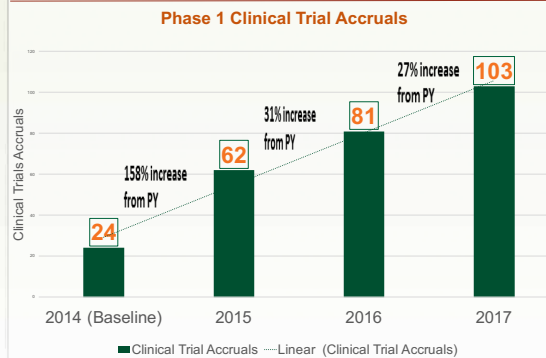
- Opened dedicated Infusion Unit with 16 chairs for research patients; created research Radiology Clinic
- Implemented EMR access
- Added an additional NP and triage nurse

2018:

- Created a dedicated Phase 1 clinic
- Implemented electronic chemotherapy ordering system and electronic regulatory system

Outcome

- 1) **329%** increase in accruals from 2014-2017 (100+ accruals in 2017)
- 2) **43%** decrease in protocol activation times
- 3) **100%** compliance with internal benchmark of workload per CRC < 12 patients



Lessons learned

Optimization in operational and organizational structure plus interdepartmental collaboration are keys to achieving success. The team realized the importance of regularly collaborating with key stakeholders to enhance operational processes, as it reduced institutional barriers to growing a Phase I program and allowed the team to scale the program quickly.

Recommendations:

- 1) **Increasing accruals:**
 - "Baby Steps": set monthly accrual goals
 - Create slot availability dashboard for quick portfolio overview
 - Create internal app with embedded link to Clinicaltrials.gov for instant access to eligibility criteria
- 2) **Scaling and growing a Phase I program:**
 - Utilize workload tool to assess volume and staff workload distribution
 - Retain high-performing personnel through internal promotions and recognitions
 - Increase staffing in other departments to align with accruals
 - Employ staffing agency to nationally source highly specialized talent to perform complex procedures for a finder's fee or short-term contract to permanent conversion
 - Reduce activation times improves relationships with sponsors and enhances opportunities for being awarded additional studies
- 3) **Reducing activation times:**
 - Prioritize studies in the start-up process
 - Initiate chemo order development at IRB submission
 - Align volume with staffing capacity for processing contracts/budgets
 - Engage physicians up-front in the budget creation process

Continuous Process Improvement:

Actively collaborate with other departments involved in the study and patient care (e.g. Nursing, Pharmacy and Laboratory) to discuss operational challenges and collaboratively develop solutions.

Future Directions

- Add eligibility coordinator
- Add dedicated personnel to process budgets
- Increase program visibility through external advertising and institutional website
- Partner with academic and NCI-affiliated centers for referrals

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Implementation of a Molecular Tumor Board as a Decision Support Tool Leverages Genomic Testing to Increase Clinical Trial Accrual and Identification of Precision Oncology Therapy

Bat-ami K. Gordon; Jared A. Cotta, MPH; Sarah Simko; Jonathan C. Trent, MD, PhD

Sylvester Comprehensive Cancer Center, University of Miami Health System

Describe the background of the problem:

Results of advanced molecular tests, especially Next Generation Sequencing (NGS), are increasingly used as determinants of eligibility for clinical trials. Many cancer centers order NGS testing from 3rd party laboratories that recommend trials and therapies related to the identified alterations. Physicians rely on these recommendations when they cannot access decision support tools that combine clinical and molecular data. Recommendations from external laboratories are limited by factors which cannot be accounted for by molecular results alone, which can minimize clinical trial opportunities for late stage cancer patients.

Provide metrics or goals to be achieved:

Goal	Metrics
Provide clinically relevant recommendations to patients based on molecular results	<ul style="list-style-type: none"> Percent of patients that pursue MTB recommendations Frequency that a pursued recommendation was identified by the MTB but not the external laboratory
Increase clinical trial accrual among the population of patients who have undergone NGS testing	<ul style="list-style-type: none"> Quantity of patients who pursue molecular driven clinical trials at Sylvester

Describe the solutions or methods implemented:

Sylvester implemented the MTB in March 2016. The MTB consists of clinical oncology, hematology, pathology, radiology, and molecular biology specialists. The MTB process is as follows:

1. Refractory and late stage patients with prior NGS results are referred to the MTB by their treating physician.

- There was no specified timeline for this testing, MTB reviews could be requested at any point after results were returned.
2. The MTB reviews the case and yields a 1–2 page report that includes relevant therapy options.
 - This review accounts for molecular and clinical data, including the patient's previous lines of therapy, performance, and geographic restrictions. Studies that meet patient needs are included on the MTB report along with on/off label therapy guidance.
 - These reports are separate from the original NGS result and the recommendations made by the test vendor.
 3. A Redcap database is utilized to track these recommendations.

Describe the outcome or show data representing a change (positive or negative):

A retrospective analysis of the 255 patients that were reviewed between March 2016 and March 2018 was completed to determine whether they pursued MTB recommendations:

- 25% of reviewed patients pursued recommendations
 - 44 consented to clinical trials
 - 16 received targeted therapy
- 63% of the trials pursued were identified by the MTB, but were not included on the original NGS report.

The identification of additional relevant trials allowed this patient population to accrue to clinical trials at higher rate than the Sylvester institutional rate (17% compared to 11%, $p=0.001$). These outcomes illustrate that the MTB can bridge knowledge gaps between physicians that practice within site disease groups and molecular based tumor type agnostic clinical trials.

Address lessons learned and future directions:

Lessons Learned:

- Vendors of NGS tests promote recommendations based on their findings, but the reports are not adapted to patient access limitations, individual patient characteristics and treatment history. Often, relevant clinical trials for a patient lie outside of the recommendations that appear on NGS results from 3rd party laboratories.

Future Directions:

- Implement reflexive MTB reviews of NGS test results for patients in the late-stage/ refractory setting
- Create collaborative MTBs between academic and community practices to expand the impact precision medicine.

Implementation of a Molecular Tumor Board leverages genomic testing to increase clinical trial accrual and identification of precision oncology therapy



Authors: Bat-ami Gordon, Jared Cotta, MPH; Sarah Simko, Charles Vogel, MD; Chukwuemeka Ikpeazu, MD, PhD, MBA, FACP; Carmen Calfa, MD; Brian Slomovitz, MD; Jonathan Trent, MD, PhD
 Institutions: Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine

Background

Results of advanced molecular tests, especially Next Generation Sequencing (NGS), are increasingly used as determinants of eligibility for clinical trials. Many cancer centers order NGS testing from 3rd party laboratories that recommend trials and therapies related to the identified alterations. Physicians rely on these recommendations when they cannot access decision support tools that combine clinical and molecular data. Recommendations from external laboratories are limited by factors which cannot be accounted for by molecular results alone.

To address this issue, Sylvester implemented a Molecular Tumor Board (MTB). The Sylvester MTB has 2 primary goals:

1. Provide clinical recommendations to patients, based on their molecular testing results.
2. Increase clinical trial accrual among the population of patients who have undergone NGS testing.

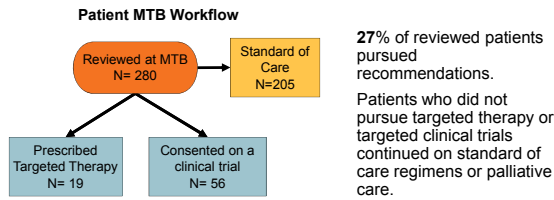
Methods

Sylvester implemented the MTB in March 2016 as a means of decision support for cases with molecular test results. The MTB consists of clinical oncology, hematology, pathology, radiology, and molecular biology specialists. The MTB process is as follows:

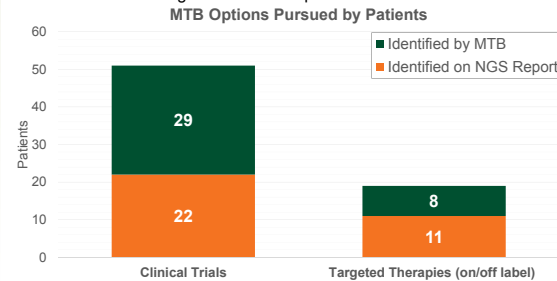
1. Physician refers patient case to MTB
2. Patient case is reviewed at the MTB
 - Refractory and late stage patients with prior NGS results are referred to the MTB by their treating physician.
 - This review accounts for molecular and clinical data:
 - Patient's mutations and biomarkers
 - Patient's previous lines of therapy
 - Patient performance and comorbidities
 - Geographic and financial restrictions
3. A 1-2 page report is provided back to the physician. This report includes:
 - Relevant clinical trials, including the site location and the contact information provided by clinicaltrials.gov
 - Targeted therapies that are applicable with on/off label guidance

A retrospective analysis of the 280 patients that were reviewed between March 2016 and April 2018 was completed to determine whether they pursued MTB recommendations and whether or not the pursued therapy was also identified on the NGS report.

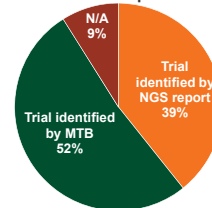
Results



The patients who pursued an MTB recommended course of care were analyzed to understand where the MTB provided recommendations that were not included on the original NGS test report.



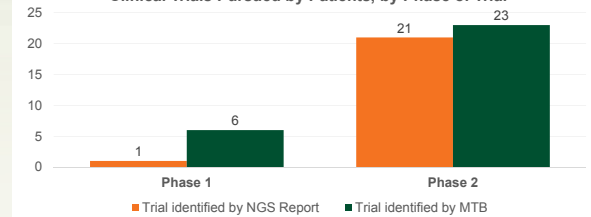
Frequency of a clinical trial appearing on NGS report



61% of the trials pursued were identified by the MTB, but were not included on the original NGS report. Those trials listed as N/A are those that are not a direct match from a biomarker to a trial, i.e. the Cetuximab arm of TAPUR which is matched by the lack of alterations in KRAS, BRAF, and NRAS.

The identification of additional relevant trials allowed this patient population to accrue to clinical trials at a higher rate than the Sylvester institutional rate (20% compared to 11%, $p < 0.0001$).

Clinical Trials Pursued by Patients, by Phase of Trial



These patients mostly enrolled onto Phase II trials, and the pursued clinical trial could have been identified with the NGS report 47% of the time. The pursued Phase I trials were infrequently listed on the NGS test reports. Among phase I trials, only one was identified on the NGS report.

Discussion

Vendors of NGS tests promote recommendations based on their findings, but the reports are not adapted to patient access limitations, individual patient characteristics and treatment history. Often, relevant clinical trials for a patient lie outside of the recommendations that appear on NGS results from 3rd party laboratories.

The MTB serves as a mechanism to create more clinically relevant targeted therapy options for each individual patient. This effort allows Sylvester to accrue these patients to targeted clinical trials at a higher rate than the population in the health system. Matching patients to clinical trials algorithmically becomes particularly challenging with trials looking for not only positively identified molecular alterations, but also patients whose profile is lacking particular alterations. Manual review can account for these different situations.

When analyzed by phase of the trial, the proportion of Phase II trials identified via the NGS test reports and MTB was nearly 50%. But, in patients who pursued Phase I trials, only 1 of 7 patients had been identified by the NGS test result. Phase I trials are particularly challenging trials, and many patients who would be candidates for these trials (late stage, refractory) are undergoing NGS testing. The MTB largely benefits institutions with robust Phase I programs, where most of the trials are not likely to be included on NGS test results.

While the benefit of a manual review is clear for participation in clinical trials, the same does not hold true for Targeted Therapies. Whether they are used in the on or off label setting, most NGS test results are able to direct patients to a matched targeted therapy. 58% of patients who pursued targeted therapy options were directed to those therapies on their NGS test result.

These outcomes illustrate the MTB can bridge knowledge gaps between physicians that practice within site disease groups and molecular based tumor type agnostic clinical trials.

Future directions for this work includes:

- The implementation of reflexive MTB reviews of NGS test results for patients in the late-stage/ refractory setting
- The creation of collaborative MTBs between academic and community practices to expand the impact of precision medicine.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Optimizing the Regulatory Department Infrastructure Within the Clinical Trials Office at an Academic Cancer Center

Andrew Nilson; Rosa Hsieh, MS, CCRP, RAC

Sylvester Comprehensive Cancer Center, University of Miami Health System

Describe the background of the problem:

To strengthen an impending CCSG application and accommodate a growing research portfolio, the Cancer Center (CC) sought to maximize efficiency by centralizing regulatory operations in the research enterprise. A baseline assessment of the existing regulatory operations identified that three offices needed realignment under the Regulatory Department (regulatory) organizational structure, the trial distribution method based off site disease group (SDG) contributed to high workload by disproportionately assigning trials to regulatory staff, and a flat reporting structure affects timely resolution of issues, regulatory oversight, and professional growth opportunities.

Provide metrics or goals hope to be achieved with the solutions to address the problem:

In the new Regulatory structure, the goals are to:

1. Operations
 - a. Improve the regulatory service line
 - b. Decrease trial activation times
 - c. Change the trial distribution method
2. Quality Measures
 - a. Effectively manage regulatory compliance workload
 - b. Develop subject matter experts (SME)
3. Employee Growth
 - a. Establish a succession plan and career growth opportunities

Describe the solutions or methods implemented:

The Regulatory implemented the following methods and solutions:

1. Operations
 - a. Realigned the protocol development, study activation, and IND offices.
 - b. Tracked activation metrics.

- c. Completed a workload analysis on the SDG trial distribution method.
2. Quality Measures
 - a. Developed an Analytic Operations system that allows reallocation of workload.
 - b. Redefined the job duties of regulatory staff and developed specialized unit.
3. Employee Growth
 - a. Developed career growth opportunities and succession planning.

Describe the outcome or show data representing a change (positive or negative):

The following are the outcomes to the methods and solutions.

1. Operations
 - a. Integrated the new service lines, thus improving transparency and communication among the previous independent groups.
 - b. Improved study activation metrics from CY2016 to CY2017 (median days):
 - i. New trial submissions: 78 to 90
 - ii. PRMC Submission to Activation: 214 to 186.
 - iii. PRMC Approval to IRB Submission: 28 to 4.
 - c. Changed the trial distribution method from SDG based to the NCI's definition of sponsor group.
2. Quality Measures
 - a. Effectively developed a workload operation system to support timely resolution of issues and completion of tasks. This provides Sr. Regulatory Analysts the opportunity to distribute work evenly among the Regulatory Analysts within a unit.
 - b. Developed six regulatory units based on NCI sponsor groups through introduction of specialized teams thus creating SME's.
 - c. Removed Sr. Regulatory Analysts from traditional regulatory activities into a quality assigned position to improve oversight and compliance within each assigned unit.

3. Employee Growth
 - a. Created growth ladder and opportunity for staff to advance into a leadership role. This helps to establish a succession plan.

Address lessons learned and future directions:

Engaging CC leadership and regulatory staff in the planning phase was instrumental to a successful implementation, and providing staff to cross train within the different units is fundamental to their continued development and growth. Management will also need to identify new opportunities to improve the services lines and identify any overlap in regulatory functions to minimize redundancy and improve efficiency.

Optimizing the Regulatory Department Infrastructure Within the Clinical Trials Office at an Academic Cancer Center

Andrew Nilson, BHA, and Rosa Hsieh, MS, CCRP, RAC
Sylvester Comprehensive Cancer Center (Sylvester) at the University of Miami Miller School of Medicine



Current State

To strengthen an impending CCSG application and accommodate a growing research portfolio, Sylvester sought to maximize efficiency in its regulatory operations by conducting a baseline assessment of the Clinical Trials Office (CTO) Regulatory Affairs Division (Regulatory) using quantitative methods for quality improvement. The results identified the following:

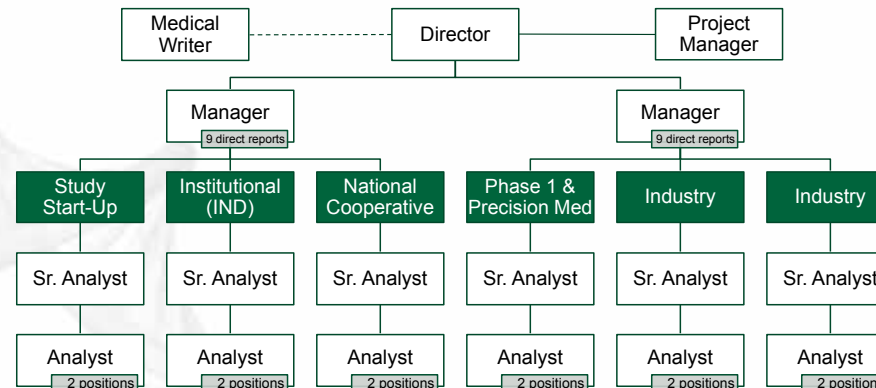
- Three offices – Investigational New Drug (IND), Protocol Development (PDO), Study Start-up (SSU) – performing regulatory related activities independent of CTO Regulatory and each other, contributed to duplication of efforts and poor communication and transparency.
- One Regulatory Analyst (Analyst) assigned to manage multiple disease groups is unsuitable for cross-coverage and causes instability in the event of a resignation, termination, or periods of extended leave (e.g., sick or maternity leave).
- The Analysts' portfolios encompass various types of studies, but they are not properly trained nor have the knowledge base to appropriately manage the complex sponsor groups and study types they were assigned to (e.g. NCTN, Phase I).
- No formal process or efficient method to track the regulatory activities of the Analysts.
- Uneven workload distribution among the Analysts due to sponsor group, study type and protocol complexity.
- Bottom-heavy organization model with limited succession planning, managerial oversight, professional growth, and employee enrichment.

Regulatory Proposed Concept

Derived from the baseline assessment, proposed changes were categorized into three areas of focus – Operations, Quality, and Professional Development. A proposal to realign the CTO Regulatory operations would add strong and sustainable performance by centralizing regulatory service lines and by creating position layers to promote succession planning and minimize staff attrition. Additionally, this proposal would drive performance and establish quality improvement measures by allowing for increased oversight and streamlined processes.

Areas	Goal	Methodology
Operations	Add new service lines	Realign IND, PDO, & SSU offices within Regulatory
	Improve activation time	Centralize study start-up tasks to Regulatory service line
	Distribute workload	Adjust workload by the number of tasks and not studies
	Improve oversight	Create management and senior level positions
Quality	Implement task tracking	Develop an analytic system to track regulatory activities
	Identify quality measures	Implement quality reviews prior to closing tasks
	Develop subject experts	Assign teams by sponsor group or study type
Professional Development	Establish mentorship	Assign Sr. Analysts to teams for mentorship opportunities
	Create employee growth	Add job levels for professional growth and enrichment

Proposed Regulatory Restructure



Future State

The SSU was transitioned in January 2017. The **percent decrease** represented in the activation milestones (calculated by median calendar days) below demonstrates efficiency and value in the added service line post realignment of the SSU office.

- 72% PRMC approval to IRB submission
- 38% IRB submission to IRB approval
- 37% PRMC submission to IRB approval
- 21% PRMC submission to activation

In July 2017 the IND office transitioned under the Institutional sponsor group to improve the quality of all sponsor-investigator initiated studies. The realignment of all three offices was complete in March 2018, with the transfer of the PDO. Unifying the new service lines brought transparency and collaboration among the Regulatory teams.

Under the new organization model, a team of 3 analysts are assigned a sponsor group or study type, which will help develop subject experts, improve regulatory compliance and provide appropriate cross-coverage support.

A centralized task tracking system able to generate reports was developed in May 2018, to monitor Analyst workloads and improve oversight of regulatory activities.

A Gantt Chart was developed in June 2018 to monitor the restructure implementation plan with a project completion date of Q3 CY2018. The current model has 20 staff reporting into the Director, but the proposed model will add management and Senior Analyst layers to better support the new infrastructure. This will provide professional growth opportunities, minimize attrition rates, and enrich the professional lives of the employees.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Implementing a Tracking System for Clinical Research

Rizalia Rivera-Cvijovic; Geoffrey DeGennaro; Andrew Nilson; Helen Peck, RN, MA, OCN, CCRP

Sylvester Comprehensive Cancer Center, University of Miami Health System

Describe the background of the problem:

Managing and maintaining study team credentials, and the ability to capture protocol specific material (deviations, amendments, coordinator workload, activation timelines etc.), are important aspects in clinical trials. Issues can develop when these requirements and milestones are not completed in a timely manner. These issues can stem from constraints on protocol lifecycles, mismanagement of study team member credentials, and multiple categories of deviations (including expired credentials and untimely re-consents). In some cases improper staffing can cause patient services to falter. The current systems and processes in place would not allow clinical personnel to record the day to day duties needed to conduct an efficient study.

Provide Metrics or goals to be achieved:

- Address staffing issues
- Reduce the number of deviations caused by invalid or expired study team credentials
- Improve activation time for research studies
- Provide a transparent process for both the study team and leadership
- Provide dashboards and reporting to assess our accruals and protocol activity. Ensure study team and leadership is well informed using automated notifications
- Aid Regulatory with providing an automated Deviations Log

Describe the solutions or methods implemented:

The Clinical Trials Tracking System (CTTS) was developed by the IT team and allowed for study team personnel and leadership to view important information related to clinical trials. The tool combines data from multiple systems including CITI, the Florida Department of Health, and the Cancer Center's Clinical Trials Management System (CTMS). Study team members are now notified when their credentials are expiring which helps avoid study deviations. A feature was also built to help users track what patients have been re-consented and what deviations may have occurred while conducting the study. A Workload module was generated which helped leadership determine if a Site Disease Group needed more staff. Reports and dashboard now provide a one stop shop for all clinical trial related needs.

Describe the outcome or show data representing a change (Positive or negative)

- Up to date credentials
- Centralized system for deviations and ICF amendments
- Reporting is now available on tracking a protocol, accruals, number of re-consents pending, workload as well as what deviations were captured

Address lessons learned and future directions:

Research is constantly evolving along with workload and the need for quick and accurate data is becoming more and more important. The goal is to provide tools and improve system processes that will ultimately complete a task in less time so that more time is given to patient service.

Implementation Lessons:

- Gather all final requirements before development begins
- Ensure all parties are included with the process so that everyone is on the same page

Future Direction:

- Implement a module for each key committee that integrates with each other. These modules include:
 - QA Training Module to ensure all staff are properly trained and within a timely manner
 - Auditing and Monitoring results and reporting
- Implement a CTO Dashboard to help with daily duties and team productivity
- Ultimately deliver a tool that answers all the needs of the Clinical Trials Office (CTO)

Implementing a Tracking System for Clinical Research

Rizalia Rivera-Cvijovic, BA; Geoffrey DeGennaro, BS; Barbara A Vance, Ph.D, CRA; Helen Peck, RN, MA, OCN, CCRP
Sylvester Comprehensive Cancer Center (Sylvester) at the University of Miami Miller School of Medicine



Background

Managing and maintaining study team credentials, and the ability to capture protocol specific material (deviations, amendments, coordinator workload, activation timelines etc.), are important aspects in clinical trials. Issues can develop when these requirements and milestones are not completed in a timely manner. These issues can stem from constraints on protocol lifecycles, mismanagement of study team member credentials, and multiple categories of deviations (including expired credentials and untimely re-consents). In some cases improper staffing can cause patient services to falter. The current systems and processes in place would not allow clinical personnel to record deviations correctly and consistently, and there was no tool for them to identify which patients needed to be re-consented and on what version of the ICF.

Goals

- Define workload calculations to determine if more staff is needed
- Reduce the number of deviations caused by invalid or expired study team credentials
- Provide accurate meaningful reporting
- Improve activation time for research studies
- Identify bottlenecks in the clinical trials' activation process
- Provide a transparent process for both the study team and leadership to view any information regarding a study, including study team credentials, workload, deviations and ICF amendments
- Provide dashboards to assess our accruals and protocol activity. This includes a view to see our top five accruing studies/physicians, as well as the bottom five
- Ensure study team and leadership is well informed using automated notifications
- Aid Regulatory in submitting Continuing Reports with our automated Deviations Log
- Provide a one stop shop for all clinical trial related needs

Solutions Implemented

The Clinical Trials Tracking System (CTTS) was developed by the IT team and allowed for study team personnel and leadership to view important information related to clinical trials. The tool combines data from multiple systems including CITI, the Florida Department of Health, and the Cancer Center's Clinical Trials Management System (CTMS). Study team members are now notified when their credentials are expiring which helps avoid study deviations. Study team members can also see if they have studies still pending that have exceeded the allotted time. A feature was also built to help users track what patients have been re-consented and what deviations may have occurred while conducting the study. A Workload module was generated which helped leadership determine if a Site Disease Group needed more staff. Reports and dashboard now provide a one stop shop for all clinical trial related needs.

Credentials

Name	Study Team Role	CRM Certifications	CF	Medical License (If Applicable)															
De Lima Lopez Jr Gilbert	Study Sub-Investigator	<table border="1"> <thead> <tr> <th>CRM Certification</th> <th>Completion Date</th> <th>Expiration Date</th> </tr> </thead> <tbody> <tr> <td>Group 1: Biomedical Researchers</td> <td>09/24/2018</td> <td>09/24/2018</td> </tr> <tr> <td>GCP for Investigators and Staff</td> <td>Incomplete</td> <td>Completed</td> </tr> <tr> <td>Good Clinical Practice and ICH (GCP)</td> <td>09/24/2018</td> <td>09/24/2018</td> </tr> <tr> <td>Conflict of Interest</td> <td>09/28/2020</td> <td>09/28/2020</td> </tr> </tbody> </table>	CRM Certification	Completion Date	Expiration Date	Group 1: Biomedical Researchers	09/24/2018	09/24/2018	GCP for Investigators and Staff	Incomplete	Completed	Good Clinical Practice and ICH (GCP)	09/24/2018	09/24/2018	Conflict of Interest	09/28/2020	09/28/2020	01/23/2020	01/31/2018
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Conflict of Interest	09/18/2020	09/18/2020																	

Protocol Milestone



ICF Amendment/Re-Consent

IRB Modification Number	Amendment Type	Date Regulatory Submitted	Date PI Submitted	Date of IRB Approval	ICF Language	ICF Status	Patients Impacted/Reconsented or Resolved
W000007434	Spanish Translation	06/23/2015	06/23/2015	06/23/2015	Spanish	✓	8/8
W000009400	Procedures	10/16/2015	10/16/2015	10/30/2015	Spanish	✓	8/8
W000008230	Watermark Error	07/31/2015	07/31/2015	08/05/2015	English	✓	0/0
W0000016868	Typographical/Administrative Corrections	03/16/2017	03/28/2017	03/28/2017	Spanish	✓	0/0

Outcome

- All clinical trials entered in our CTMS are tracked in CTTS
- Clinical Trials Credentials office can now ensure credentials are all up to date
- Deviations are now captured in a centralized system
- Study team can keep track of patients that require ICF amendments resulting in less deviations
- Reporting is now available on tracking a protocol, accruals, number of re-consents pending, workload as well as what deviations were captured

Lesson learned

Research is constantly evolving along with workload and the need for quick and accurate data is becoming more and more important. The goal is to provide tools and improve system processes that will ultimately complete a task in less time so that more time is given to patient service.

Implementation Lessons:

- Gather all final requirements before development begins
- Ensure all parties are included with the process so that everyone is on the same page
- Constant training and accountability
- Assign additional FTE because of the scope of the application

Continuous Process Improvement:

Continuous collaborating with UM IT to integrate other applications

Future Directions

- Implement a module for each key committee that integrates with the protocol tracking section. This will make the process more transparent by incorporating data entry in their everyday activity
- Implement a CRS Dashboard that allows study team members and leadership to see their daily duties in one screen improving accuracy of data and organization Ultimately deliver a tool that answers all the needs of the Clinical Trials Office (CTO)
- Implement a New Employing Training checklist to ensure that all staff were properly train
- Implement a module to track the monitoring and audit reports
- Implement Regulatory Workload
- More IRB integration to avoid redundancy

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Implementing a CCSG Dashboard

Rizalia Rivera-Cvijovic; Rania Saghira, MS; Geoffrey DeGennaro

Sylvester Comprehensive Cancer Center, University of Miami Health System

Describe the background of the problem:

The University of Miami's Sylvester Cancer Center is currently in preparation for applying to the NIH to become an NCI designated cancer center. The Cancer Center Support Grant (CCSG) is awarded to qualified institutions and will foster a deeper, more efficient, and effective interaction between all the facets the cancer center is comprised of. CCSG is geared at assisting cancer centers develop their resources used primarily for research in various cancers, and to facilitate better collaboration across these resources and the centers respective cancer programs. This increase in efficiency will lead to better and more effective treatment of cancer patients within the community. There are different metrics used to measure a cancer center's eligibility for the CCSG submission. Based on preliminary metrics, the cancer center had identified multiple areas that needed improvement. However, the inability to continuously track and measure performance based on these metrics had made it difficult for program leaders to identify areas for improvement and evaluate performance.

Provide metrics or goals hoped to be achieved with the solutions to address the problem:

Ensure that leadership and all the parties involved can monitor key performance metrics across the different research programs via a dashboard that:

- Is easily accessible
- Provides real time data based on up to date CCSG guidelines
- Clearly identifies problem areas, supports the implementation of strategies, and provides means to measure performance at various levels
- Improve performance

Describe the solutions or methods implemented:

- The first step was to identify the different metrics that should be tracked for CCSG application submission. Second, the data needed to track these metrics. Third, make the necessary changes in our existing systems to track or collect any additional data required to measure performance.
- Developed an online application (CCSG Dashboard) that will allow program leaders to track their performance. The CCSG Dashboard is divided into different sections. The start page will provide an overview of overall metrics. Program leaders can drill down into their sections and get a better picture of how they are currently performing and projections of future performance as far as funding is concerned.
- This tool allowed program leaders to identify key areas for improvement and implement different strategies to address these problems.
- The CCSG dashboard also served as a tool to measure the efficacy of the strategies implemented.

Show lessons learned, others to involve in the future, changes to the methods to achieve a better outcome:

A thorough understanding of the CCSG guidelines and engaging leadership in the implementation process was crucial in developing a successful tool that improved performance across all research programs.

Implementation Lessons:

- Gather all completed user requirements before development begins
- Add more flexible features to allow users to explore data
- Ensure all business users are involved with the process from the beginning

Implementing a CCSG Dashboard

Rizalia Rivera-Cvijovic, BA; Rania Saghira, BS, MS; Geoffrey DeGennaro, BS; Barbara A Vance, Ph.D, CRA
Sylvester Comprehensive Cancer Center (Sylvester) at the University of Miami Miller School of Medicine



Background

The University of Miami's Sylvester Cancer Center is currently in preparation for applying to the NIH to become an NCI designated cancer center. The Cancer Center Support Grant (CCSG) is awarded to qualified institutions and will foster a deeper, more efficient, and effective interaction between all the facets the cancer center is comprised of. CCSG is geared at assisting cancer centers develop their resources used primarily for research in various cancers, and to facilitate better collaboration across these resources and the centers respective cancer programs. This increase in efficiency will lead to better and more effective treatment of cancer patients within the community. There are different metrics used to measure a cancer center's eligibility for the CCSG submission. Based on preliminary metrics, the cancer center had identified multiple areas that needed improvement. However, the inability to continuously track and measure performance based on these metrics had made it difficult for program leaders to identify areas for improvement and evaluate performance.

Goals

Ensure that leadership and all the parties involved can monitor key performance metrics across the different research programs via a dashboard that:

- Is easily accessible
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Solutions Implemented

The first step was to identify the different metrics that should be tracked for CCSG application submission. Second, the data needed to track these metrics. Third, make the necessary changes in our existing systems to track or collect any additional data required to measure performance.

Developed an online application (CCSG Dashboard) that will allow program leaders to track their performance. The CCSG Dashboard is divided into different sections. The start page will provide an overview of overall metrics. Program leaders can drill down into their sections and get a better picture of how they are currently performing and projections of future performance as far as funding is concerned.

This tool allowed program leaders to identify key areas for improvement and implement different strategies to address these problems.

The CCSG dashboard also served as a tool to measure the efficacy of the strategies implemented.

DT4 Interventional TX Protocols (Active in CY):

Sponsor Group	CY 2013	CY 2014	CY 2015	CY 2016	CY 2017
Institutional - SCCC	22 (14.47%)	21 (12.88%)	19 (11.60%)	22 (11.22%)	16 (7.00%)
Institutional - Non SCCC	13 (8.55%)	12 (7.30%)	12 (7.50%)	10 (5.10%)	12 (5.31%)
Externally Peer-Reviewed	7 (4.61%)	8 (4.91%)	9 (3.75%)	6 (3.09%)	7 (3.10%)
Institutional - SCCC/Non SCCC Externally Peer-Reviewed (30% Goal)	42 (27.63%)	41 (25.15%)	37 (23.13%)	38 (19.38%)	35 (15.49%)
National Cooperative Group	66 (43.42%)	64 (39.20%)	59 (36.88%)	54 (27.55%)	65 (29.70%)
Industrial	44 (28.95%)	58 (35.50%)	64 (40.00%)	104 (53.06%)	126 (55.75%)
Grand Total	152	163	160	190	226

Sponsor Group	CY 2013	CY 2014	CY 2015	CY 2016	CY 2017
Institutional - SCCC	26 (26.54%)	38 (14.80%)	47 (19.20%)	57 (24.79%)	54 (13.31%)
Institutional - Non SCCC	3 (4.39%)	14 (6.28%)	0 (0.00%)	3 (3.34%)	11 (5.41%)
Externally Peer-Reviewed	11 (16.84%)	11 (13.30%)	11 (19.30%)	11 (13.47%)	11 (11.09%)
Institutional - SCCC/Non SCCC Externally Peer-Reviewed (20% Goal)	40 (38.00%)	79 (34.88%)	104 (34.24%)	100 (28.80%)	101 (28.42%)
National Cooperative Group	35 (18.37%)	38 (15.11%)	61 (21.23%)	71 (17.45%)	116 (23.34%)
Industrial	42 (21.52%)	83 (18.88%)	122 (12.91%)	162 (19.40%)	200 (10.24%)
Grand Total	158	225	227	401	487

PRMC Trials Summary

3-Year Summary of Number of Trials			
Source of Support	CY 2015	CY 2016	CY 2017
Institutional - SCCC	26	30	40
Institutional - Non SCCC	10	9	11
Externally Peer-Reviewed	5	7	7
National Cooperative Group	15	25	15
Industrial	69	76	62
Grand Total	125	147	135

Outcome

- Protocols and Accruals can be displayed by Interventional Type, Sponsor Group, Phase, Pediatrics, IIT and Precision Medicine in a given time summary and detail information
- DT4 reports are available overall and by research program
- DT3 report
- Tumor Registry Cases and Treatment accruals comparison
- PRMC and DSMC Team
- PRMC Reviewed Trials
- Demographic and Patient Population
- Accruals by Race and Ethnicity
- Exportable to Excel

Lesson learned

- A thorough understanding of the CCSG guidelines and engaging leadership in the implementation process was crucial in developing a successful tool that improved performance across all research programs
- Gather all completed user requirements before development begins
- Add more flexible features to allow users to explore data
- Ensure all business users are involved with the process from the beginning
- Flexible software design to support changing data requirements.

Future Directions

- Flexibility or Customized time frame
- Graphs/Charts
- DSMC Tables
- Collaborations
- Optimize the speed

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Implementing an Electronic Protocol Review System for the PRMC and DSMC

Simonnette Thompson, MPH, CIP, CCRP; Geoffrey DeGennaro; Matthew Santiago; Rizalia Rivera-Cvijovic; Helen Peck, RN, MA, OCN, CCRP; Jonathan Trent, MD, PhD
Sylvester Comprehensive Cancer Center, University of Miami Health System

Describe the background of the problem:

While efficiency and transparency are important in the Protocol Review and Monitoring Committee (PRMC) submission and review process, Sylvester was using a clinical trial management system (CTMS) that reduced its ability to adequately track submission processes or monitor review times. Since the CTMS version at Sylvester has no "Committees" module, study teams were required to complete submissions on paper and submit them via email to the PRMC Manager. The PRMC Manager had to indicate when the submission was received, reviewed, and processed via an excel spreadsheet, the tracking system (a homegrown system to track protocol activation) as well as in the CTMS. The multiple tracking systems were not beneficial in that study teams were unable to verify if their studies were accepted and adequately track the progress until a final determination was made. Further, PRMC metrics were difficult to track, concise reports were unavailable and the data often unreliable.

Provide metrics or goals to be achieved:

- Create a transparent PRMC review system
- Decrease PRMC review times
- Reduce redundancies by capturing key performance indicators (KPIs) (time from submission to assigned review, time from assignment to determination and time from determination to letter dissemination) in real-time and evaluating process performance based on those KPIs
- Increase efficiency of the PRMC
- Provide reliable metrics

Describe the solutions or methods implemented:

The Protocol Electronic System (PES) was developed and designed to capture all PRMC submissions and KPIs in a single platform. PES houses all milestones (date of initial submission to date of dissemination of determination

letter) while maintaining an audit trail of each activity. PES was developed to harmonize with existing homegrown systems and reduce multiple entries to decrease errors and discrepancies. Additionally, PES has a similar interface and functionality as IRB-7, a system that staff and researchers are familiar with, and thereby reduces training requirements.

Describe the outcome or show data representing a change (positive or negative):

- All cancer-related studies are submitted via PES since implementation on 10/30/17
- Study teams have the ability to track submissions and progress in real time
- PES is accessible on any electronic device which facilitates and improves review times
- Decreased review times from an average of 22 days (3rd quarter 2017) to 10 days (1st quarter 2018) or 15 to 5 median days. Fourth quarter data was not compared to remove implementation bias.

Address lessons learned and future directions:

Since implementation, the PRMC has received fewer calls from researchers about the progress of their submissions; however, calls regarding the submission process have increased. These calls have started to decrease as more researchers become familiar with the system and as additional trainings are provided.

Implementation lessons:

- Allow time after implementation/launch to address system and submission issues.
- Use various dissemination strategies to share information about the system with the research community and end users.
- Utilize department administrators to engage study teams and facilitate participation

Future Direction:

- Implement electronic PRMC reviews with checklists for exempt, expedited, and full committee as well as primary, secondary and biostatistician reviews, voting and determination dissemination.
- Implement an accrual and scientific monitoring review module.
- Implement a DSMC Module utilizing a campaign encouraging buy-in.

Implementing an Electronic Protocol Review System for the PRMC and DSMC

Simmy Thompson, MPH, CIP, CCRP; Geoffrey DeGennaro, BS; Matthew Santiago, BS; Rizalia Rivera Cvijovic, BA; Helen Peck, RN, MA, OCN, CCRP; Jonathan Trent, MD, Ph.D
Sylvester Comprehensive Cancer Center (Sylvester) at the University of Miami Miller School of Medicine

Background

Efficiency and transparency are important in the Protocol Review and Monitoring Committee (PRMC) submission and review process; however, the clinical trial management system (CTMS) used by Sylvester reduced our ability to adequately track submission processes or monitor review times. Submission to the PRMC meant study teams were required to complete submissions on paper and email them to the PRMC Manager. The PRMC Manager had to indicate when the submission was received, reviewed, and processed via an excel spreadsheet, a tracking system (a homegrown system to track protocol activation) as well as in CTMS. The multiple tracking systems resulted in study teams unable to track submissions or verify when studies were accepted by the PRMC and PRMC metrics were difficult to track. Concise reports were unavailable and the data was often unreliable. This study describes the move from paper to an electronic system.

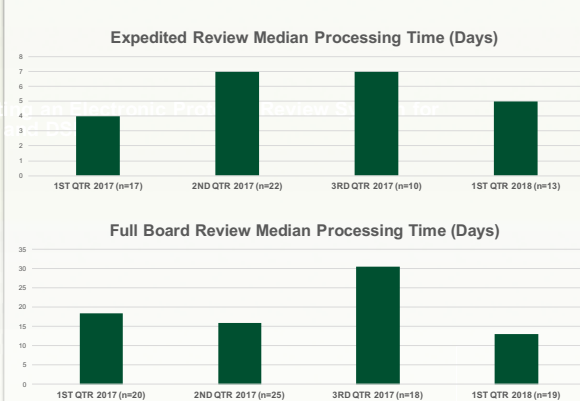
Objectives

- Create a transparent PRMC review system
- Decrease PRMC review times
- Reduce redundancies by capturing key performance indicators (KPIs) (time from submission to assigned review, time from assignment to determination and time from determination to letter dissemination) in real-time and evaluating process performance based on those KPIs
- Increase efficiency of the PRMC
- Provide reliable metrics

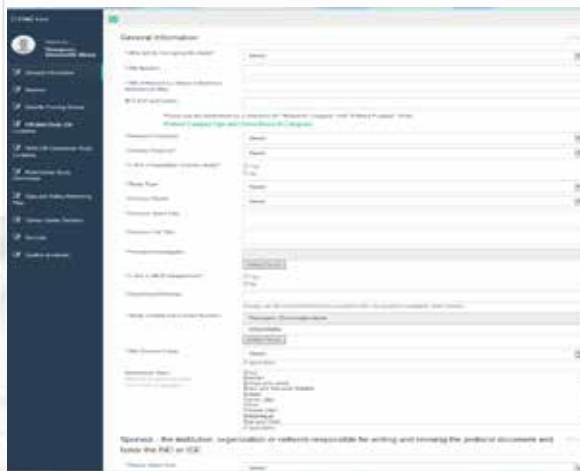
Methodology

- Design an electronic system for all PRMC submissions that:
- Houses all milestones (date of initial submission, date of SDG approval/disapproval, date of PRMC assignment to a meeting or expedited review, date a determination was made, date letter was disseminated)
 - Captures all key performance indicators
 - Captures all study related communications regarding the study
 - Maintain an audit trail for each activity
 - Harmonize with other homegrown systems to reduce the duplication of data being entered and reducing errors

Data



PRMC Submission Form



Results

- All cancer-related studies are submitted via Protocol Electronic System (PES) since implementation on 10/30/17
- 4th quarter data was not compared to remove implementation bias.
- Study teams have the ability to track submissions and progress in real time
- PES is accessible on any electronic device which facilitates and improves review times
- 40% reduction in median review times for Expedited Review (3Q2017, med=7 days; n=10 studies to 1Q2018, med=5 days; n=13 studies)
- 57.4% reduction in median review times for Full Board Review (3Q2017, med=30.5 days; n=18 studies to 1Q2018, med=13 days; n=19 studies)
- Despite an increase in studies, decreased review times from an average of 22 days (3Q2017) to 10 days (1Q2018) or in terms of median from 15 to 5 days.

Lessons Learned

- Allow time for multiple trainings
- Allow time after implementation/launch to address system and submission issues
- Provide all research personnel access to the system upon release to allow teams to get acquainted with the new system
- Use various dissemination strategies to share information about the system with the research community and end users
- Utilize department administrators to engage study team and facilitate participation

Future Directions

- Since the abstract –
- Implementation of electronic PRMC reviews with checklists for exempt, expedited, and full committee as well as primary, secondary and biostatistician reviews, voting and determination dissemination was completed
- Pending work –
- Implement amendment submissions
 - Implement an accrual and scientific review monitoring module in 2018
 - Implement a DSMC Module

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Investigator Initiated Trial Steering Committee

Christine Mackay, RN, CCRP; Stephen Williamson, MD; Scott Weir, PharmD, PhD; Andrew Godwin, PhD; Hobs Apell; Carolyn Foster, MSLIS; Kevin Schorno, MBA

The University of Kansas Cancer Center

Describe the background of the problem:

To achieve Comprehensive Cancer Center status from the NCI, institutions must develop and support Investigator Initiated Trials.

Provide metrics or goals to be achieved:

- Increase the number of high quality Investigator Initiated Trials (IITs) opened at KUCC.
- Develop and rollout an IIT development “boot camp” to all new and junior Investigators.
- Shorten the review cycle time for IITs by proactively reviewing and providing feedback to the Investigator through participation in the boot camp and subsequent summary reports.

Describe the solutions or methods implemented:

In January 2016, the Investigator Initiated Trial Steering Committee (IITSC) was launched with the purpose of mentoring and educating basic and clinical investigators in developing their own clinical trial protocols and provides an interactive venue for researchers to present concepts arising from laboratory and bedside discoveries to clinical researchers. Representatives with critical, multidisciplinary expertise spanning the spectrum of clinical trial development and implementation provide instant feedback and further discussion.

Describe the outcome or show data representing a change (positive or negative):

Feedback received from participants has been positive and several protocols have begun enrollment. See figure below.

Address lessons learned and future directions:

- Continue the acceleration of scientific discovery of novel therapeutics through the conduct of investigator-initiated clinical trials.
- Invite Program co-leaders to attend when a concept aligning with their program is presented in order to increase and broaden Program influence and knowledge of the clinical trial enterprise.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

LEARN-INFORM-RECRUIT: Increasing the Offer of Urological Cancer Trials

Christine Mackay, RN, CCRP^{1,2}; Ariel Shifter²; Mugur Geana, MD, PhD^{1,2}; Shellie Ellis, MA, PhD^{1,2}

¹The University of Kansas Cancer Center; ²University of Kansas Medical Center, Department of Health Policy and Management

Describe the background of the problem:

Most interventions to increase awareness and the offer of clinical trials target oncologists, yet urologists diagnose and treat up to 20% of cancers before an oncologist is consulted. Through our formative research, we identified that urologists and their practice staff recognized the benefits of offering clinical trial opportunities to their patients but faced certain barriers in incorporating these opportunities into their practices (poster data presented at AACI-CRI in 2017). In addition:

- Practices perceive screening and education to be burdensome and lack knowledge, capacity, skills, educational materials, and accurate understanding of patients' motivations to join trials.
- Trial naïve practices misunderstand their role in following patients on trial and need structured communication about their patients' trial activities.
- Urologists prefer face-to-face interactions to learn about trials and cited the influence of state/regional professional societies.

Provide metrics or goals to be achieved:

To address the above barriers, we aimed to:

- Develop and prepare materials to assist urology practice personnel in speaking with patients about clinical trials.
- Conduct sessions designed to educate urology practice personnel about offering clinical trials to their patients, followed by a survey to evaluate the developed materials.
- Understand how to support urologists and staff in communicating with patients about treatment options and decisions, including clinical trials.

Describe the solutions or methods implemented:

The educational sessions included facts about clinical trials, how patients feel about clinical trials, and information about how and why to speak with patients about participating in clinical trials. The sample materials presented during the sessions were personalized per site (i.e.-site logo, urologist name, etc.) and included examples like:

For urologists:

- A snapshot of available trials in the community
- Quarterly newsletters
- Clinical trial referral prescription pads
- Enrollment feedback
- Networking

For patients:

- Videos about the specific trials available, with information about what it means to be a part of a clinical trial.
- Brochures about participating in clinical trials
- Trial specific brochures

For practices:

- Meet the Investigators lunches
- Co-management chart notes
- Website to house the materials

After participating in the educational session, urologists were asked to complete a survey using a five-point scale regarding the utility of the educational session and materials. We also inquired about how being able to offer clinical trials relates to their practice priorities.

Describe the outcome or show data representing a change (positive or negative):

Presentations were made at three state urology society meetings, with a total of 32 participants completing the survey. Most (75%) respondents reported currently offer clinical trials to their patients and the average overall approval of the materials was high (4.6/5). Matching the right patient to the right treatment was the most common reason for offering clinical trials.

Address lessons learned and future directions:

We are confident the tools we developed can assist urologists in discussing possible trial participation with their patients. We hope to expand the availability of these tools to more urology clinics in the near future with the ultimate goal of increasing enrollment to urological clinical trials.

Learn-Inform-Recruit

Increasing the Offer of Urological Cancer Trials



Christine Mackay RN, PhD^{1,2}; Ariel Shifter²; Mugur Geana, MD, PhD^{1,2}; Shellie Ellis, MA, PhD^{1,2}

Background

Through our formative research (presented at AACI-CRI 2017):

Urologists and their practice staff:

- **Recognize the benefits** of offering clinical trials
- **Face certain barriers** in offering clinical trials
- **Lack knowledge**, capacity, skills about, and educational materials for discussing clinical trials
- Trial naïve practices **misunderstand their role**
- Urologists **prefer face-to-face interactions** to learn about trials and cited the influence of state/regional professional societies.

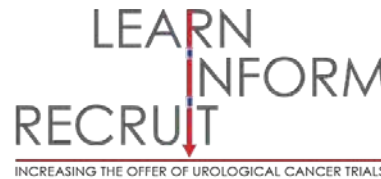
Goals

- **Develop and prepare materials** to assist urology practice personnel in speaking about clinical trials.
- **Educate** urology practice personnel about offering clinical trials to their patients.
- **Evaluate** the developed materials.
- **Understand how to support urologists** and staff in communicating with patients about treatment options and decisions, including clinical trials.

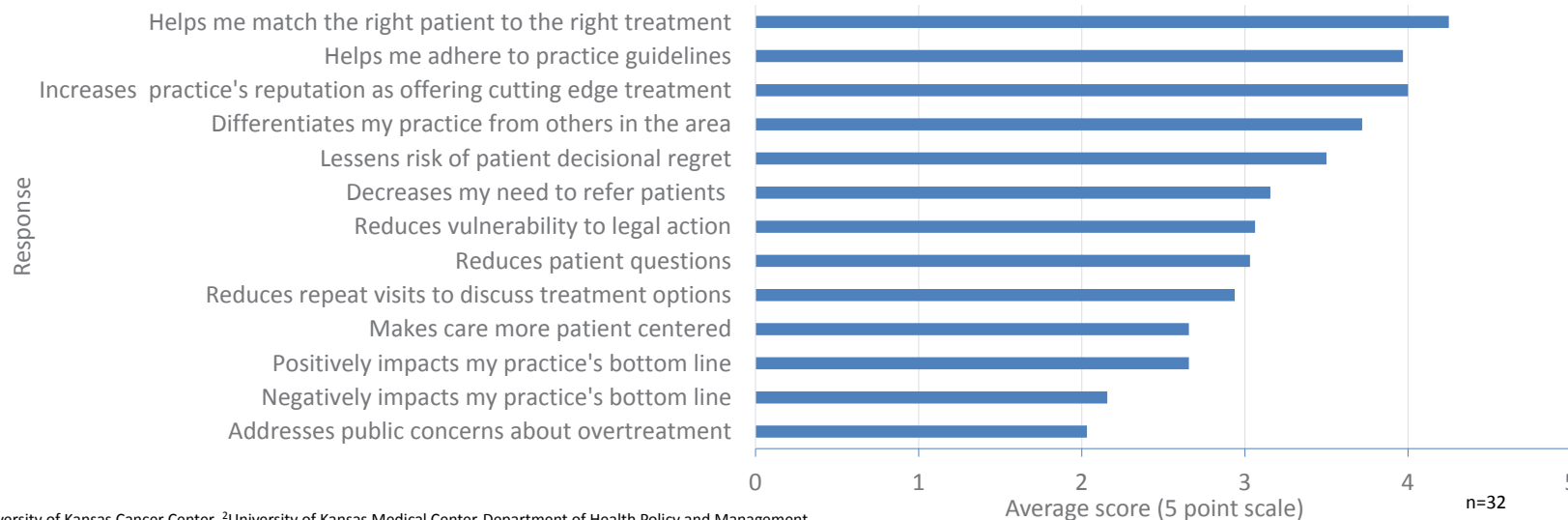
Methods

- Conduct educational sessions
 - Clinical trial facts
 - Patients' feelings about clinical trials
 - Personalized site materials
- Conduct survey of attendees regarding
 - utility of session
 - materials presented
 - how trials relate to practice priorities

Data was collected during 3 State Urological Society Meetings, in Louisiana, Kansas, Oklahoma.



Offering Clinical Trials...



Next Steps

- Expand availability of tools to other urology clinics.
- Increase the enrollment to urological clinical trials.

¹University of Kansas Cancer Center ²University of Kansas Medical Center-Department of Health Policy and Management

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

A Curated Cancer Clinical Outcomes Data Base (C3OD) for Accelerating Patient Recruitment in Cancer Clinical Trials

Dinesh Pal Mudarantkham, MS¹; Jeffrey Thompson¹; Jinxiang Hu¹; Dong Pei¹; Shanthan Reddy Chintala¹; Michele Park¹; Brooke L. Fridley²; Byron Gajewski¹; Devin C. Koestler¹; Matthew S. Mayo¹

¹The University of Kansas Cancer Center; ²Department of Biostatistics and Bioinformatics, Moffitt Cancer Center

Describe the background of the problem:

Data used to determine patient eligibility for cancer clinical trials often come from disparate sources that are typically maintained by different groups within an institution, use differing technologies, and are stored in different formats. Collecting data and resolving inconsistencies across sources increase the time it takes to screen eligible patients, potentially delaying study completion.

Describe the solutions or methods implemented:

C3OD merges data from the electronic medical record (EMR), tumor registry, bio-specimen and data registry, and allows querying through a single unified platform. By centralizing access and maintaining appropriate controls, C3OD allows researchers to more rapidly obtain detailed information about each patient in order to accelerate eligibility screening. C3OD is an implementation of the Velos Spring software platform.

Describe the outcome or show data representing a change (positive or negative):

In order to assess the reliability of C3OD, a blinded informatician used the IE criteria from the seven selected clinical trials to query in C3OD, resulting in a list of eligible patients' MRN. Table 1 contains the results of our assessment. Across all seven studies considered here, C3OD successfully retrieved the MRN of patients who were actually recruited and enrolled in each study, with most retrieval rates over 80%. Upon further examination, we discovered that for cases in which C3OD did not retrieve the MRN of a recruited patient (studies NCT01611090 and NCT00491816), the PI had granted an eligibility waiver for those enrolled that did not meet all IE criteria.

Address lessons learned and future directions:

Based on our experience, most of the eligibility criteria for cancer clinical trials are contained in electronic sources. However, some information is stored under different systems, including: pathology software, lab software, etc., which are silo systems and not part of the EMR. In addition, at times, the data is in free-text format, which is not readily amenable for analytics. A major challenge faced by recruiters at KUCC involves the identification of patients with a certain tumor subtype; for example, breast cancer hormone receptor status. This information is typically contained in pathology reports in free-text format. In order to curate the data, KUCC has decided to have nurse abstractors manually retrieve this information from patient records in order to streamline and structure the information in a more user-friendly format (Class III variables in Figure 1B). In addition to augmenting C3OD to incorporate Class III variables, we are also in the process of developing a natural language processing algorithm that parses free-text in pathology reports (Class II variables, Figure 1B). Including Class II and III variables extends the coverage of IE criteria, and in doing so, decreases the need for manual validation.



Curated Cancer Clinical Outcomes Database (C³OD)

Dinesh Pal Mudaranthakam¹, Jeffrey Thompson¹, Jinxiang Hu¹, Dong Pei¹, Shanthan Reddy Chintala¹, David Streeter¹, Michele Park¹, Brooke L. Fridley², Byron Gajewski¹, Devin C. Koestler¹, Matthew S. Mayo¹



1. The University of Kansas Cancer Center, Kansas City, KS, USA, 2. Department of Bioinformatics, Moffitt Cancer Center, Tampa, FL, USA

Introduction

A major challenge of cancer clinical studies is finding enough subjects that match inclusion and exclusion (IE) criteria. IE criteria represents detailed descriptions of characteristics that subjects must meet to participate in a clinical trial. Determining eligibility of potential subjects involves gathering data across multiple sources. Although most of the information might be contained in a patient's electronic medical record (EMR), incomplete data-sets and/or prolonged collection efforts are barriers to successfully determining eligibility. For cancer clinical trials, EMR data alone is insufficient to screen patients. This inefficiency increases study duration and cost,^{3,4} and can lead to early termination of a trial.⁵

Eligibility screening is mostly done manually⁶⁻⁸. It is tedious, time consuming, and can be a financial burden on an institution⁹. Furthermore, a lot of data related to IE criteria is in disparate sources and in order to identify eligible subjects, one often needs to review EMR data from other departments, with their respective software. Any inconsistencies slows the recruiting process. Software that enables querying across multiple sources could speed up the process.

To automate and improve patient screening for clinical trials conducted at the University of Kansas Cancer Center (KUCC), we developed the Curated Cancer Clinical Outcomes Database (C³OD). Electronically stored subject information, such as demographics, patient history, and diagnosis are curated directly from the data source and entered in C³OD.

Future Directions

Most eligibility criteria for cancer clinical trials are stored electronically. However, some information is stored under different systems, e.g. pathology software, lab software, etc., which are not part of the EMR. Additionally, most data are in free-text format, which are not readily amenable for analytics. KUCC has decided to have nurse abstractors manually retrieve this information from patient records in order to streamline and structure it in a more user-friendly format (Class III variables in Figure 1B). In addition to augmenting C³OD to include Class III variables, we are in the process of developing natural language processing algorithms to parse free-text in pathology reports (Class II variables, Figure 1B). Including Class II and III variables extends the coverage of IE criteria, and in doing so, decreases the need for manual validation.

Methods

Five Use Cases

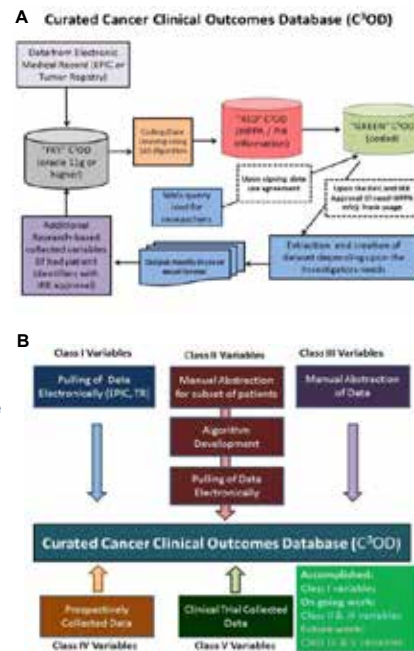
- Pre-screening
- Projection
- Retrospective Studies
- Linking to Bio specimens
- Aid preventative health studies

Implementation:

C³OD merges data from the EMR, tumor registry, bio-specimen and data registry, and allows querying through a single unified platform. By centralizing access and maintaining appropriate controls, C³OD allows researchers to more rapidly obtain detailed information about each patient in order to accelerate eligibility screening. C³OD is an implementation of the Velos Spring software platform.

Data Sources

The C³OD database is populated with data that are extracted from the tumor registry with 'NAACCR 16C', and EMR, as represented in Figure 1A. The tumor registry is typically 6 to 8 months behind as the abstraction and diagnosis confirmation is a time consuming and laborious process. Raw data from these sources are curated, which makes it easy for researchers to execute the query using the user interface. The tumor registry contains information on tumor anatomic site, histology and other disease characteristics, whereas the EMR system contains information on patient demographics, family history, diagnosis and comorbidities. Based on the curation level and source, data was classified into five different class variables (Figure 1B) with most of the core variables being consistent across different diseases. As a first step, C³OD was populated with Class I variables.



Results

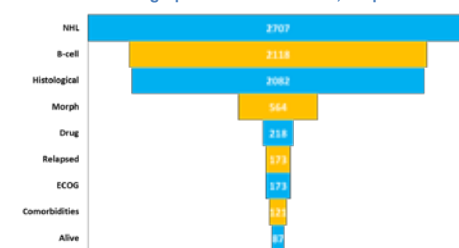
To assess the reliability of C³OD, a blinded informatician used IE criteria from seven clinical trials to query in C³OD, resulting in a list of eligible patients' Medical record number (MRN). Table 1 contains the results of our assessment. Across all seven studies considered here, C³OD successfully retrieved the MRN of subjects who were actually recruited and enrolled in each study, with most retrieval rates over 80%. For cases in which C³OD did not retrieve the MRN of a recruited patient (studies NCT01611090 and NCT00491816), the PI had granted an eligibility waiver for those enrolled that did not meet all IE criteria.

Trial	Number Identified by C ³ OD that were screened	Number Identified by C ³ OD that were enrolled	Actual Number enrolled	Percentage identified by C ³ OD among those actually enrolled
NCT00433511	19	15	15	100%
NCT02595320	42	36	36	100%
NCT00491816	39	26	32*	81%
NCT02136134	3	3	3	100%
NCT01974440	5	3	3	100%
NCT01779791	14	4	4	100%
NCT01611090	8	4	5*	80%

* Eligibility Waiver granted - Patient statistics were outside of IE criteria.

NCTXXXXX40 I/E FUNNEL

Demographics I/E Criteria = 85,309 patients



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Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Accrual Prediction Program (APP): A Web Based Clinical Trials Tool for Monitoring and Predicting Accrual for Early Phase Cancer Studies

Junhao Liu, MS¹; Jo Wick, PhD¹; Dinesh Pal Mudaranthakam, MS¹; Yu Jiang, PhD²; Matthew Mayo, PhD¹; Byron Gajewski, PhD¹

¹The University of Kansas Cancer Center; ²School of Public Health, University of Memphis

Describe the background of the problem:

Subject recruitment for clinical research is always challenging. Slow patient accrual leads to delay in research, which may increase the costs of study, decrease statistical power and even trial discontinuation. Understanding patterns of patient accrual is critical in clinical trials and researchers need reliable tools to manage the accrual rate for their studies.

Provide metrics or goals to be achieved:

Currently, the Clinical Trials Office (CTO) administers 128 clinical trials which are conducted at the University of Kansas Cancer Center (KUCC). One important responsibility of CTO is to monitor and predict patient accrual. The most essential purpose is the prediction on time frame for recruiting a certain number of subjects, to meet the trial recruitment goal, leading to a probability the trial will be late.

Describe the solutions or methods implemented:

The Accrual Prediction Program (APP), a comprehensive and accurate web-based tool, was developed to provide accrual prediction for each trial. APP will contribute significantly to the cancer research in terms of the daily accrual prediction for early phase cancer trials. The APP applies a Bayesian accrual prediction model and was calculated based on protocol information and trial enrollment data. This model provides reliable prediction on time frame for which the study will be completed to achieve the sample size goal. The prediction generates a point estimate and its 95% posterior prediction interval, by using an integration of the "accrual" R package and enrollment information entered into eResearch powered by Velos.

Describe the outcome or show data representing a change (positive or negative):

The KUCC Accrual Application website was designed and implemented via APP and was released in 2016.

Address lessons learned and future directions:

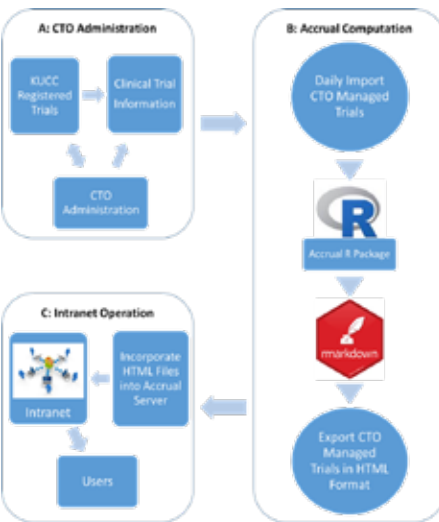
The KUCC Accrual Application makes accessing and summarizing clinical accrual information easier than before, which is convenient and friendly for researchers to obtain clinical trial information and accrual time frame prediction. By reproducing APP, other cancer center researchers are able to monitor and predict patient accrual easily and conveniently for early phase cancer clinical trials.

Background

Monitoring subject recruitment is key to the success of a clinical trial. At an institutional level, delays in identifying studies with high risk of accrual failure can lead to too many inefficient and costly trials with little chances of meeting study objectives. Comprehensive accrual monitoring is necessary to the success of the research enterprise. Accrual Prediction Program (APP) was developed for Monitoring and Predicting Accrual for Early Phase Cancer Studies.

APP Flowchart

- **A** shows the CTO administration of each clinical trial.
- **B** displays the process of accrual computation using R software, which starts with importing daily CTO data and ends with an export of the accrual report in HTML format.
- **C** presents the Intranet operation by incorporating all the HTML files into accrual server.



'Accrual' R Package

We developed a Bayesian method that integrates researcher's experience on previous trials with data from the current study, providing reliable prediction on accrual rate for clinical studies. In this R package, we present functions for Bayesian accrual prediction which can be easily used by statistician and clinical researchers.

'Accrual' version 1.3 is an R package available on the Comprehensive R Archive Network (CRAN).
<https://CRAN.R-project.org/package=accrual>

Scientific Highlights

CTO Administration of Clinical Trial Data.

Table 1 displays an example of the trial-specific data entered into CRIS by the CTO. The variables include:

- n , the target sample size for the trial;
- T , the target completion time (in units defined by *Study Unit*) to achieve the sample size goal;
- m , the current observed sample size;
- t_m , a system-calculated time to date defined as the time elapsed since the trial activation date.
- P , from the study's principal investigator that represents his or her confidence that the trial will complete on time.

Table 1: A typical example of the protocol and enrollment data for clinical trials entered into CRIS by the CTO.

n	T	Study Unit	Activation Date	Enrolled Subjects (n)	Sponsor ID*	Study Number	Disease Working Group	Title*	PI*
12	24	months	01/10/2017	5	ABCD 1234	STUDY 001	Lung	Title: AAAAA AAA	AAA
25	36	months	11/25/2015	19	KUMC 1234	STUDY 002	Leukemia/Myeloid	Title: BBBBB BBB	BBB
30	36	months	07/17/2015	28	KUMC 1001	STUDY 003	Breast	Title: CCCCC CCC	CCC
5	12	months	12/05/2017	3	ABCD 1001	STUDY 004	Lymphoma/Myeloma	Title: DDDDD DDD	DDD
5	18	months	04/03/2018	4	ABCD 1002	STUDY 005	Lymphoma/Myeloma	Title: EEEEE EEE	EEE

Example: Suppose a lung cancer study that planned to recruit 12 subjects in 24 months was activated on 01/10/2017. The principal investigator was 50% confidence prior to initiating the study that it would achieve this target enrollment within the targeted enrollment period. On 05/10/2018, the study had enrolled 5 subjects.

The information required for running the accrual prediction is given by: $n = 12, T = 24, P = 0.5, m = 5, t_m = 16 \text{ months}$.

The APP uses this data to make an updated prediction of the trial completion date.

Table 2: Trial accrual information and the probability of being late. (All trial information was blinded).

Study Number	Disease Working Group	PI	Expected Completion Date (T)	Prediction Completion Date (T_{pred}) Median	95% CI Lower Bound	95% CI Upper Bound	Probability of being Late (P_{late})
STUDY 001	Lung	AAA	01/10/2019	12/01/2019	12/17/2018	04/08/2022	96.28%
STUDY 002	Leukemia/Myeloid	BBB	11/25/2018	02/25/2019	09/09/2018	01/27/2020	81.70%
STUDY 003	Breast	CCC	07/17/2018	08/04/2018	06/11/2018	01/07/2019	68.07%
STUDY 004	Lymphoma/Myeloma	DDD	12/05/2018	09/28/2018	06/17/2018	12/18/2019	30.59%
STUDY 005	Lymphoma/Myeloma	EEE	10/03/2019	01/03/2019	07/13/2018	01/21/2021	14.47%

Intranet Operation.

All HTML reports are then incorporated into an accessible web server under a local, restricted communications network. The end result is an interactive and user-friendly web-based tool that allows for exploration of active trial information and accrual prediction results.

KUCC Accrual Web Application

Currently, 128 registered clinical trials are active and ongoing at the KUCC. The APP platform is used by the CTO and investigators to monitor updated enrollment information and combine it with current protocol information to predict accrual for all active trials.

Figure 1 (Below). A screenshot of the KUCC APP web application.

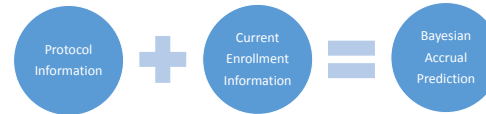
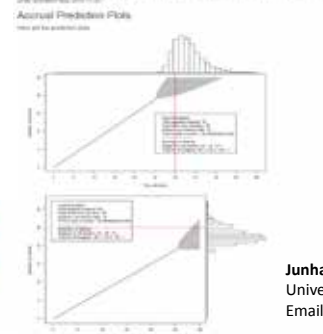


Figure 2 (left). Example of the accrual prediction and posterior predictive distribution plots for one clinical trial.



Selecting a specific Study Number, for example, STUDY0002268 will open a new page displaying the results and interpretation.



Contact

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Results

The CTO uses this information to summarize and report on the accrual progress of all trials across various indicators (e.g., by principal investigator or disease working group). Table 3 presents a summary of the risk for accrual failure across disease working groups in order by the average level of risk for trials within the working group. Of note are the brain and sarcoma/melanoma groups, whose risk is lowest among all disease working groups. Conversely, the multiple early phase clinical trials (EPCT) group has the largest risk.

Table 3: The distribution of the probability of being late across disease working group ordered by mean.

Disease Working Group	Count	Mean(P_{late})	SD(P_{late})
Brain	4	56.37%	0.4060
Sarcoma/Melanoma	6	57.16%	0.3948
Multiple	19	57.85%	0.1083
Leukemia/Myeloid	24	63.52%	0.3378
Breast	13	64.20%	0.3747
Lymphoma/Myeloma	12	69.12%	0.2609
Lung	11	69.33%	0.2585
Gynecology	5	70.71%	0.2302
GI	9	70.85%	0.2627
GU	10	79.78%	0.2767
Head and Neck	2	86.01%	0.1399
Multiple Early Phase Clinical Trials (EPCT)	4	90.53%	0.1577

Conclusion

First released in 2016, the APP web application summarizes enrollment information for active studies categorized by various trial attributes. The APP supports real-time evidence-based decision making for strategic resource allocation and study management of over 120 ongoing clinical trials at KUCC.

The KUCC APP makes accessing comprehensive accrual information manageable at an institutional level. Cancer centers or even entire institutions can reproduce the APP to achieve real-time comprehensive monitoring and prediction of subject accrual to aid investigators and administrators in the design, conduct, and management of clinical trials.

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- [1] Liu J, Jiang Y, Gajewski BJ, et al. accrual: Bayesian Accrual Prediction. R package version 1.3. 2017.
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- [3] Jiang Y, Simon S, Mayo MS, Gajewski BJ. Modeling and validating Bayesian accrual models on clinical data and simulations using adaptive priors. *Stat Med.* 2015;34:613-629.

Funding. This research was supported by the National Cancer Institute Cancer Center Support Grant P30 CA168524 and used BISR core.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Logistical and Financial Challenges Involved in Opening the National Cancer Institute's Molecular Analysis for Therapy Choice (NCI-MATCH) Trial in Hawai'i's Minority/Underserved NCI Community Oncology Research Program (M/U NCORP)

Kate Bryant-Greenwood, JD, CCRP¹; Erin Fukaya, MS¹; Rebecca Ohta, RN²; Jennifer Kimbell, PhD²; Jeffrey Berenberg, MD¹; Paul Morris, MD²; Darlena Chadwick, RN, MBA²

¹University of Hawai'i Cancer Center, University of Hawai'i at Mānoa; ²The Queen's Medical Center

Describe the background of the problem:

When opening the MATCH trial, a federally funded precision medicine trial, multiple logistical and financial challenges were encountered within Hawaii's M/U NCORP composed of community hospitals, associated private practices, and the University of Hawaii Cancer Center (UHCC). UHCC has neither its own hospital nor outpatient facility and therefore collaborates with a network of hospitals as part of the Hawaii Cancer Consortium to enroll patients to cancer clinical trials such as MATCH. The Queen's Medical Center (QMC) is a community hospital partner within the Hawaii M/U NCORP and one of three hospital members of the Hawaii Cancer Consortium. QMC is the largest private hospital in Hawaii and contracts with private physician groups to provide pathology and radiology services to patients. Implementing the MATCH trial within such an environment provided important lessons that will affect the opening of future trials within the Hawaii Cancer Consortium.

Provide metrics or goals to be achieved:

- Create an efficient inter- and intra-organizational process to obtain fresh biopsy specimens for patients enrolled to the MATCH trial initial screening step
- Guarantee MATCH trial research billing accuracy and compliance while simultaneously working within a \$3,000 budget cap for each research biopsy

Describe the solutions or methods implemented:

- Provide multiple in-service, educational sessions at departmental meetings to coordinate between UHCC, QMC, and private physician groups
- Create tools such as a trial-specific pathology memo and imaging packet to communicate effectively between departments and private physician groups
- Educate the billing arms of the two key private physician groups—Pathology and Interventional Radiology—to ensure accurate research billing

Describe the outcome or show data representing a change (positive or negative):

The Queen's Medical Center (QMC) conducted 90% of the total MATCH trial-driven biopsies in Hawaii. An after action review found common themes and barriers within QMC to trial implementation. The review also identified effective actions that were taken to ensure successful trial conduct.

The following most critical barriers to MATCH trial conduct were: 1. Unfamiliarity with research, particularly in ancillary departments (radiology and pathology); and 2. Establishing research billing practices as well as reimbursement rates consistent with a restricted trial budget (\$3,000/case). The analysis identified the following key actions that assisted in successfully conducting the first large-scale precision medicine trial at QMC: 1. Active engagement of key clinical personnel, physician champions/groups, and hospital administration; 2. Design and implementation of tools to integrate trial requirements into standard clinical processes; 3. Educating private ancillary departments on protocol and research billing requirements. These actions resulted in UHCC's Hawaii M/U NCORP being in the top percentile per population nationwide for MATCH screening step enrollment.

Address lessons learned and future directions:

Complex trials such as MATCH require the building and testing of new clinical and administrative processes which take dedicated time and collaboration. These barriers and solutions should be considered by our network when opting into future biopsy-driven trials. The lessons learned may also contribute to the development and implementation of future NCTN trials across the NCORP network.



Financial and Logistical Lessons Learned from Opening the National Cancer Institute's MATCH Trial

Kate Bryant-Greenwood, JD¹, Erin Fukaya, MS¹, Jennifer Kimbell, PhD², Rebecca Ohta, RN²

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²The Queen's Medical Center, 1301 Punchbowl Street, Honolulu, Hawaii 96813



UNIVERSITY OF HAWAII
CANCER CENTER

Introduction and Context

NCI-MATCH

NCI-Molecular Analysis for Therapy Choice

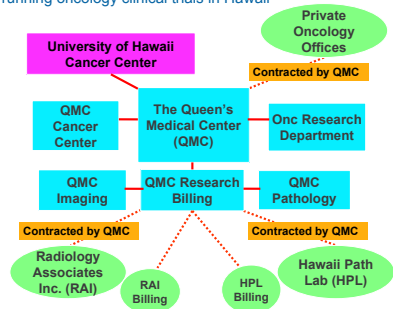
A precision medicine trial that seeks to determine whether treating cancers according to their molecular abnormalities will show evidence of effectiveness

- Study targets adults 18+ years of age with advanced solid tumors, lymphomas, and myelomas that are no longer/never responding to standard therapy and have begun to grow
- Patient tumor is analyzed to determine whether they contain gene abnormalities for which a targeted drug exists
- Treatment is assigned based on gene abnormalities, if any. There are 24 possible treatment arms!



Trial Landscape

- National:**
- Coordinated by the ECOG-ACRIN Cancer Research Group
 - Developed as a collaboration between NCI, ECOG-ACRIN, and three other Research Bases: Alliance, NRG Oncology, and SWOG
 - Pharmaceutical companies also collaborated on NCI-MATCH
 - Part of President Barack Obama's Precision Medicine Initiative
- Local:**
- The Hawaii Cancer Consortium partnership is essential to running oncology clinical trials in Hawaii

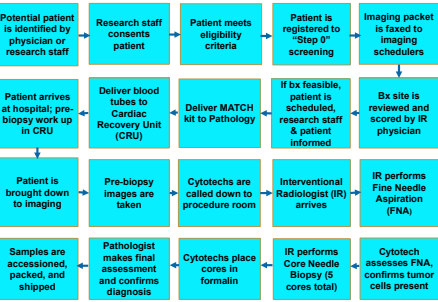


Trial Landscape (cont.)

Administrative Hub	Clinical Site Activities
<ul style="list-style-type: none"> Regulatory <ul style="list-style-type: none"> Tracks 278 cooperative group, industry, and investigator initiated protocols in all stages (from pre-opened to closed) Data Management <ul style="list-style-type: none"> 14 staff members, 1.5 FTE dedicated solely to data entry Specimen Processing & Shipping 	<ul style="list-style-type: none"> Inpatient/Outpatient Oncology Services <ul style="list-style-type: none"> ~2,465 analytic cases annually Oncology Research Department <ul style="list-style-type: none"> 4 Clinical Research RN's, 1 Research Associate, 1 Data Specialist, 2 Study Coordinators (2016)

Workflow and Logistics

Some of the steps involved in the MATCH workflow



Based on the biopsy process, we identified which departments/organizations would be contacted to request support

QMC Departmental Players	External Organizational Players
<ul style="list-style-type: none"> Oncology Research Pathology Imaging Research Billing Revenue Integrity 	<ul style="list-style-type: none"> UH Cancer Center Hawaii Pathologists' Laboratory (HPL) Radiology Associates Inc. (RAI)

Workflow and Logistics (cont.)

We identified key personnel and physician champions within each department

- Provided in-service, educational sessions, and presentations to discuss clinical coordination (e.g., department meetings, tumor boards)
- Provided protocol binders and soft-copies of specific procedural sections to all departments

We created tools to communicate efficiently and effectively with each department

- Imaging packet was created and sent to QMC imaging scheduling department
 - Packet consisted of: Queen's Imaging Form; Imaging Scheduling Memo; Research Registration Form
- Pathology memo sent to QMC Pathology to notify cytotechs/pathologists of biopsy
- There were multiple edits to the pathology memo



MATCH Funding

PROTOCOL EAY131: Molecular Analysis for Therapy Choice (MATCH)

Funding Source and Study Component	Mandatory/Request or Event/Optional	NCTN Funding Amount per Patient (a) Standard/LAPS	NCORP Funding \$ per Patient (b) Startup
Federal (Special) Biospecimen- Biopsy Tissue for Molecular Profiling (Step 0)	Mandatory	\$3000	\$3000

Key Question: Will \$3000 be enough funding to cover entire biopsy cost?

- We started by:**
- Contacting QMC Research Billing Office
 - We were tasked with identifying CPT codes involved in image guided biopsies
 - Started with interventional radiology procedures
 - Different bx sites have unique codes (e.g. breast image guided bx vs. liver image guided bx)
 - BUT what happens to the sample once it is taken out of the patient?
 - Track down pathology-specific CPT codes
 - Pathology portion uses different codes for specific bx sites/tissue

Research Billing

Our efforts to ensure billing accuracy upfront

- Educated the billing arms of the two key private physician groups—Pathology and Interventional Radiology
 - Identified and contacted key billing personnel within both private groups
- QMC Research Business Office created a detailed price list of all possible research biopsy-related charges

Despite our best planning efforts, MATCH related bills were not always accurate

- Private physician groups billing issues**
- Bills were sent to Insurers and UHCC and patients
 - This had to be caught and corrected
 - Why did this happen?
 - QMC has a research billing process in place (patient is flagged, bill is "scrubbed") BUT for the private entities (HPL & RAI) research billing is relatively new
- The Queen's Medical Center's technical billing issues**
- Consolidated QMC technical invoices were sent to UH Cancer Center for each patient biopsy
 - QMC's technical portions were incorrect despite patient flagging and bill scrubbing
 - QMC pathology charges are automatically produced via a chargemaster (institutional charges) and are allowed to bill off of the OPPS fee schedule for the majority of lab tests
 - Charging non-Medicare rate on federally funded trials is unallowable (NIH Grants Policy Statement Section 19.4.1 Computing Research Patient Care Costs)

Additional lessons learned about research billing from the MATCH study

- Do not assume that all clinical care activities in a trial are billable to insurance
- Medicare/Medicaid billing is subject to OIG oversight
 - Incorrect bills put institution at compliance risk and potentially subject to significant fines
- Incorrect bills upset patients, erodes trust
 - Example: Some of our patients incorrectly received insurance co-pay bills
- Billing is an integral part of clinical trial administration
- Billing for services not rendered is unallowable
- Billing insurers for services that the sponsor (e.g., NCI) is paying for is unallowable

Key Concepts and Takeaways

- Identify and establish relationships with key logistical/administrative personnel
- Building and testing new processes (both clinical and administrative) takes time and collaboration
- Do not assume in-depth understanding of clinical research (physicians, staff, administrators)
- Ask questions and solicit feedback
- Have the key players meet together—face to face time

Factors that Impact Oncology Clinical Trial Activation Times at University of Illinois Cancer Center

Mary A. Otoo, MPH; Michelle Uriostigue Preza; Margaret Gavor, MPH; Darlene Kitterman, MBA; Oana C. Danciu, MD

University of Illinois Cancer Center

Describe the background of the problem:

The time from conception to the initiation of clinical trials has been described as costly and time-consuming because of administrative processes (Martinez, D. A. et al). Protracted clinical trials activation time is costly to research sponsors, decreases site patient enrollment, decreases effective resource utilization and affects evidenced-based medical practice. Long clinical trial activation times may be associated with a variety of factors.

Provide metrics or goals to be achieved:

The objective of this research is to identify and assess factors that impact clinical trials activation times at the University of Illinois Cancer Center Clinical Trials Office.

Describe the solutions or methods implemented:

A protocol search for University of Illinois Clinical Trials Office managed studies was generated in OnCore. The search was limited to trials that were activated from January 1st, 2016 through March 26, 2018. Time to activation as defined by the NIH Cancer Center Support Grants guidelines is the time of protocol submission to the Protocol Review Committee (PRC) to the time the study was opened to accrual. Studies which were approved by the PRC in 2016 but attained Open to Accrual status in 2017 were counted as part of 2016 studies. Time to activation differences between 2016 and 2017 studies was assessed by Investigator Initiated studies (IIT), Sponsor Type, Institutional Review Board (IRB) Review Type, and Study Type.

Describe the outcome or show data representing a change (positive or negative):

A sample of 25 studies (Calendar Year 2016, 12; Calendar Year 2017, 13) was identified. The average activation time was 206.8 days for calendar year 2016 and 94.9 days for calendar year 2017. Results indicate that the activation time generally decreased in 2017 across all factors analyzed. The average time to activation for interventional

studies decreased in 2017 but remained similar for non-interventional studies. Notably, average activation time was longer for non -IIT and Industry studies for both years.

Address lessons learned and future directions:

Clinical trial activation times at the University of Illinois Cancer Center Clinical Trials Office decreased by 54% from 2016 to 2017. The mix of study Sponsor Type, IRB Review Type or Study Type between the two years was similar, and the decrease between the years appears to be independent of these variables. Therefore, it can be inferred that the decrease in activation time was due to interventions made to the process between the two years. These interventions included increase in staff, reorganization in staff duties including moving all activation oversight activities to a new start-up coordinator position, and process changes implemented to increase efficiency. These results should take into consideration that 35% of studies submitted to the PRC in 2017 will roll over into 2018 for activation, and are therefore not included in the 2017 sample. The data will be reanalyzed at a later time to capture the activation time for all studies started in 2017. In addition, activation time will continue to be tracked to see the effects of additional process changes.

An Analysis of Factors Associated with Oncology Clinical Trial Activation at University of Illinois Cancer Center Oncology Clinical Trials Office

Mary A. Otoo, MPH, Michelle Uristigüe Preza, BS, Margaret Gavor, MBCHB, MPH, Darlene Kitterman, MBA, Oana C. Danciu, MD



UNIVERSITY OF ILLINOIS
CANCER CENTER
Bench to Community

Background

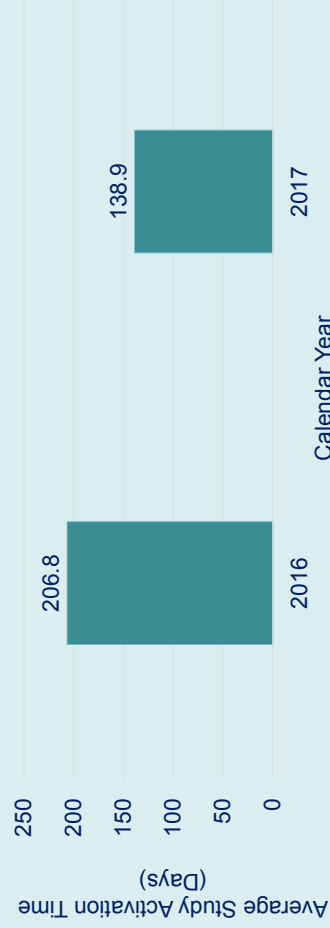
- Protracted clinical trial activation times are inefficient and costly
- Costly to the institution and research sponsors
- Decreases site patient enrollment
- Affects timely evidenced-based medical practice
- Decreases effective resource utilization
- The objective of this study is to identify and assess factors that impact clinical trials activation periods at the University of Illinois Cancer Center Clinical Trials Office (UICCCCTO).

Methods

- UICC CTO managed studies activated between January 1st, 2016 through June 20, 2018 were identified in the UICC Clinical Trials Management System (CTMS)
- Time to activation was defined as the time of protocol submission to the Protocol Review Committee (PRC) to the time the study was opened to accrual
- Studies were counted in the year that they were submitted to the PRC
- Time to activation differences between 2016 and 2017 was assessed by IIT, Sponsor Type, Institutional Review Board (IRB) Review Type and Study Type
- A sample of 28 studies (Calendar Year 2016, 12; Calendar Year 2017, 16) was identified

Results

Average Clinical Study Activation Time by Calendar Year



Average Oncology Clinical Trials Activation Time (Days)

	Calendar Year 2016 (n=12)		Calendar Year 2017 (n=16)	
Average Activation Time (Days)	N (%)	Average Activation Time	N (%)	Average Activation Time
Investigator Initiated Trials (IIT)				
Yes	5(41.7)	164.6	4(25.0)	142.5
No	7(58.3)	236.9	12(10.3)	137.8
Sponsor Type				
National	3(25.0)	226.0	9(56.3)	124.0
Institutional	5(41.7)	164.6	3(18.8)	169.7
Industry	4(33.3)	245.0	4(25.0)	149.5
IRB Review Type				
Full	6(50)	181.2	6(37.5)	241.7
Expedited	6(50)	232.3	10(62.5)	62.6
Study Type				
Treatment (Interventional)	8(66.7)	245.8	11(68.8)	131.5
Non-Treatment	4(33.3)	128.8	5(31.3)	155.2

Conclusions

- Clinical trial activation time at the UICCCCTO decreased 32.8% from 2016 to 2017
- Decreases were seen across most categories analyzed
- Decrease in activation time may be due to:
 - Increase in staff
 - Reorganization of staff duties
 - Process changes implemented to increase efficiency
- These results should take into consideration that 11% of studies submitted to the PRC in 2017 have not been activated and are therefore not included in the 2017 sample.
- Data will be reanalyzed at a later time to capture the activation time for all studies started in 2017

References

- Martinez, D. A., Tsaiatsanis, A., Yalcin, A., Zayas-Castro, J. L., & Djulibegovic, B. (2016). Activating clinical trials: a process improvement approach. *Trials*, 17(1). doi:10.1186/s13063-016-1227-2

Acknowledgements

- Thanks to :
 - Darlene Kitterman, MBA - CTO Director
 - Oana C. Danciu, MD - CTO Medical Director
 - Margaret Gavor, MPH - Start-Up Specialist
 - Michelle Uristigüe Preza, BS - PRC Manager

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Solving the Problem of Study Abandonment: Effectiveness and Analysis Outcomes of Administrative Pre-Review Committee

Jill Kessler, MS, CCRP; Jennifer Richards, MS, CCRP

University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center

Describe the background of the problem:

A number of protocols at UMGCCC each year are not opened to enrollment due to study abandonment. Study abandonment is defined as a protocol being prepared by our research team and reviewed by faculty members, but does not open to accrual. Reasons for study abandonment range from insufficient financial support to lack of clinical resources. In an effort to prevent hours spent preparing a protocol that may not come to fruition; UMGCCC initiated the Administrative Pre-Review Committee (APC) to address this problem and decrease the number of abandoned studies. The focus of the APC is to identify any complex procedures, special equipment required and/or involvement of other departments to conduct research specific procedures. Cancer Center Support Grant (CCSG) guidelines for the research strategy of the Protocol Review and Monitoring System (PRMS) requires a process be in place to prioritize the activations of cancer clinical trial protocols at an institution with respect to site feasibility. The APC complements the review of the PRMS committee.

Provide metrics or goals to be achieved:

- Avoid unnecessary reviews by regulatory staff and faculty members when funding is not available or there are competing trials.
- Decrease the frequency of study abandonment with the implementation of the APC when compared to the previous year.
- Conduct cost analysis to evaluate time spent on abandoned protocols.

Describe the solutions or methods implemented:

- Establishment of the APC to review all new protocols opened at UMGCCC.
- A preventative approach to decrease study abandonment by including as members – CRO Director, Contracts and Budget Director, Associate Director

of Administration, Quality Assurance Manager, CRC coordinator, Solid tumor and Hematology Managers. Protocols are reviewed by all members of the committee with focus on different elements of the administrative process.

- Issues regarding feasibility, ability to accrue, execute and finance a protocol are discussed during meetings.
- Committee concerns are sent to the PI and a decision is made how to move forward.

Describe the outcome or show data representing a change (positive or negative):

Through use of the APC not only have we reduced the number of abandoned protocols, we have also decreased time spent preparing these submissions. The decrease in time allows for focus on other tasks as well as reduction in lost funds related to abandoned protocols.

Address lessons learned and future directions:

Administrative review is an important step that was previously missing from the protocol review and management system (PRMS) at UMGCCC. Investigators and study teams have clinical understanding but lack the staffing, logistical and budgeting knowledge to accurately review a new protocol. Involving those individuals who are involved with the administrative side of conducting clinical trials has provided a layer of knowledge that was previously unused.

Recommendations for implementation would be to involve subject matter experts, such as disease specific study coordinators and research nurses to ensure that the nuances of each protocol are appropriately discussed. Including the center's budget manager will also be advantageous as this individual will have the knowledge and expertise to review draft budgets and provide feedback to the committee regarding the financial feasibility of the protocol. Having a focused group with the appropriate subject matter experts

Solving the problem of study abandonment: Effectiveness and Analysis outcomes of Administrative Pre-Review

Jill Kessler MS, CCRP & Jennifer Richards MS, CCRP

Background

A number of protocols at UMGCCC each year are not opened to enrollment due to study abandonment. Study abandonment is defined as a protocol being prepared by our research team and reviewed by faculty members, but does not open to accrual. Reasons for study abandonment range from insufficient financial support to lack of clinical resources.

In an effort to prevent hours spent preparing a protocol that may not come to fruition; UMGCCC initiated the Administrative Pre-Review Committee (APC) to address this problem and decrease the number of abandoned studies. The focus of the APC is to identify any complex procedures, special equipment required and/or involvement of other departments to conduct research specific procedures.

Cancer Center Support Grant (CCSG) guidelines for the research strategy of the Protocol Review and Monitoring System (PRMS) requires a process be in place to prioritize the activations of cancer clinical trial protocols at an institution with respect to site feasibility. The APC complements the review of the PRMS committee. Cancer Center Support Grant (CCSG) guidelines for the research strategy of the Protocol Review and Monitoring System (PRMS) requires a process be in place to prioritize the activations of cancer clinical trial protocols at an institution with respect to site feasibility. The APC complements the review of the PRMS committee.

Goals

- To avoid unnecessary reviews by regulatory staff and faculty members when funding is not available or there are competing trials that may prevent enrollment.
- To decrease the number of abandoned protocols when compared to previous year with the implementation of the APC.
- Cost analysis will be conducted to evaluate time spent on abandoned protocols.

Methods

- Establishment of the APC to review all new protocols to be opened at UMGCCC.
- A preventative approach was taken to decreasing study abandonment by initiating a committee that included – CRO Director, Contracts and Budget Director, Associate Director of Administration, Quality Assurance Manager, CRC coordinator, Solid tumor and Hematology Managers. Protocols are reviewed by all members of the committee; each member focuses on different elements of the administrative process and protocol.
- Issues regarding feasibility, ability to accrue, execute and finance a protocol are discussed during meetings.
- Committee concerns are sent to the PI and how best to move forward with said trial is determined.

Results

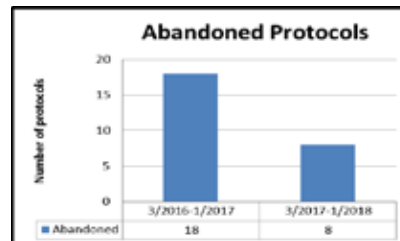


Figure 1: The total number of abandoned protocols prior to and after implementation of the Pre-administrative review committee. Abandoned protocols decreased from 18 (3/2016-1/2017) to 8* (3/2017-1/2018).

*Of the 8 that were abandoned 5 were voted 'no' at Administrative Pre-review.



Figure 2: The cost analysis of abandoned protocols per year. Per the costs of our staff and faculty – each abandoned protocol costs the Cancer Center \$4,319. The 18 abandoned protocols from figure 1 total \$77,759; the 8 abandoned protocols from figure 1 total \$34,559.

Conclusion

Administrative review is an important step that was previously missing from the PRMS strategy at UMGCCC. Investigators and study teams have clinical understanding but lack the staffing, logistical and budgeting knowledge to accurately review a new protocol. Involving those individuals who are involved with the administrative side of conducting clinical trials has provided a layer of knowledge that was previously unused.

Through use of the APC not only have we reduced the number of abandoned protocols, we have also decreased time spent on preparing these submissions. The decrease in time allows for focus on other tasks as well as reduction in lost funds related to abandoned protocols.

Future Directions

The implementation of the Administrative Pre-review Committee can be utilized across cancer centers by taking a similar approach. Developing a committee with the expertise and ability to carefully examine administrative/financial aspects of the protocol that are not discussed during scientific review is the most important part of this process. At UMGCCC, we plan to continue this committee and grow its expertise so issues can be identified more expeditiously.

Recommendations for implementation would be to involve subject matter experts, such as disease specific study coordinators and research nurses to ensure that the nuances of each protocol are appropriately discussed. Including the center's budget manager will also be advantageous as this individual will have the knowledge and expertise to review draft budgets and provide feedback to the committee regarding the financial feasibility of the protocol. Having a focused group with the appropriate subject matter experts will help make this a committee a success at any institution.



Improving Clinical Trial Activation Using Lean Six Sigma Methodology

Amelia Schmidt, MHA, CCRP; Theresa Cummings, RN, MS, CCRP; Jennifer Richards, MS, CIP, CCRP

University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center

Describe the background of the problem:

Clinical trial activation at an Academic Institution involves a multitude of stakeholders that include but are not limited to the hospital, the University, and the financial departments of both. Lean Six Sigma (LSS) methodology accelerates business transformation by creating a culture of continuous, measurable improvement that eliminates non value-added activities and improves quality and responsiveness for patients and customers. The experience at the University of Maryland Greenebaum Comprehensive Cancer Center revealed that delays and barriers throughout the trial activation process lead to considerable time loss in activating our site and opening a study to accrual. This has led to lower patient accrual, termination as a participating site and wasteful use of resources. In a series of root cause analyses conducted at UMGCCC by a LSS green belt, we determined the following were the most significant and impactful contributors to delayed trail activation: lack of Scientific Review Committee (SRC) meetings; delay in calendar creation in our online Clinical Trial Management System (CTMS); Sponsor un- responsiveness leading to a delay in IRB submission; and delayed completion of the Medicare Coverage Analysis and finalization of budgets and contracts.

Provide metrics or goals to be achieved:

- Improve efficiency of trial activation
- Reduce median activation time by 40%
- Protocol assigned/reviewed by SRC within 4 weeks of site approval
- Lower calendar creation time in the CTMS to < 8 days

Describe the solutions or methods implemented:

- Implemented a 3rd SRC meeting per month and added more members and reviewers to the committee. Added a regulatory resource and dedicated CRC coordinator to accommodate this.

- Improved Calendar creation process in the CTMS system by revising the work flow to improve, define, and minimize steps and time involved in the process.
- Education of all CRO staff of the revised study activation timeline.
- Accessed and communicated the obstructions that were found using LSS Methodology. These findings were communicated to Hospital and University management that are overseeing Medicare Coverage Analysis and Budget and Contract negotiation.

Describe the outcome or show data representing a change (positive or negative):

Implementing a third SRC meeting:

- Eliminated the immediate backlog of new clinical trial reviews
- Allowed more time for re-reviews and emergency use protocols while still providing time slots for full reviews.

Lessons learned and suggestion for others:

This work demonstrates that LSS Methodology can be applied to operational issues in clinical research, including clinical trial activation. Ensuring the research team within a designated cancer center includes a staff with LSS experience/certification ensures the resources and knowledge exist to apply the methodology effectively. Sharing results with key stakeholders outside of the research office is critical to allow visibility to the outcome of the problems identified. Future directions for GCCC include performing a quarterly review of randomly selected trials. This allows UMGCCC leadership to perform risk analysis and mitigation, establish/modify goals and review results for further revision of process documentation as needed.

Improving Clinical Trial Activation Using Lean Six Sigma Methodology

Amelia Schmidt, MHA, CCRP; Theresa Cummings, RN, MS, CCRP; Jennifer Richards, MS, CCRP

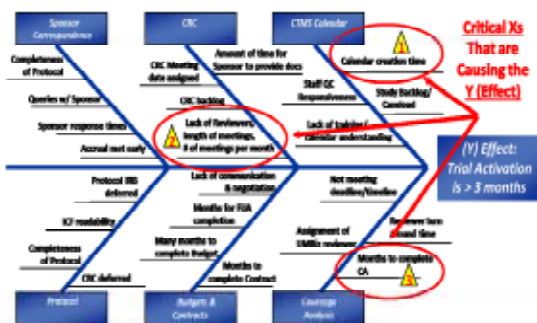
Background

Clinical trial activation at an Academic Institution involves a multitude of stakeholders that include but are not limited to the hospital, the University, and the financial departments of both. Lean Six Sigma (LSS) methodology accelerates business transformation by creating a culture of continuous, measurable improvement that eliminates non value-added activities and improves quality and responsiveness for patients and customers.

The experience at the University of Maryland Greenebaum Comprehensive Cancer Center revealed that delays and barriers throughout the trial activation process lead to considerable time loss in activating our site and opening a study to accrual. This has led to lower patient accrual, termination as a participating site and wasteful use of resources.

In a series of root cause analyses conducted at UMGCCC by a LSS green belt, we determined the following were the most significant and impactful contributors to delayed trial activation: lack of Scientific Review Committee (SRC) meetings; delay in calendar creation in our online Clinical Trial Management System (CTMS); Sponsor un-responsiveness leading to a delay in IRB submission; and delayed completion of the Coverage Analysis and finalization of budgets and contracts.

Figure 1: Fishbone Diagram identifying main causative factors



Goals

- To improve efficiency of trial activation
- To reduce median activation time by 40%
- Protocol assigned and reviewed by SRC within 4 weeks of site approval
- Lower calendar creation time in the CTMS to less than 8 days

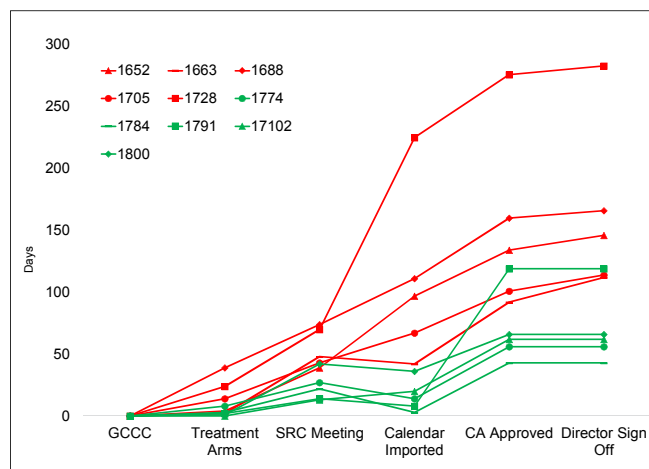
Methods

- Implemented a 3rd SRC meeting per month and added more members and reviewers to the committee. Added a regulatory resource and dedicated CRC coordinator to accommodate this.
- Improved Calendar creation process in the CTMS system by revising the work flow to improve, define, and minimize steps and time involved in the process.
- Education of all CRO staff of the revised study activation timeline.
- Assessed and communicated the obstructions that were found using LSS Methodology. These findings were communicated to Hospital and University management that are overseeing Coverage Analysis and Budget and Contract negotiation.

Results

	Before implementing LSS:		After implementing LSS :	
	Mean	Median	Mean	Median
SRC Review	57.2	54	23.6	22
CTMS Calendar	84.4	97	16.2	14
CA Approval	124.8	118	69.2	62
IRB Submission	150	152	69.2	62

Figure 2: Timeline of study activation when comparing protocols



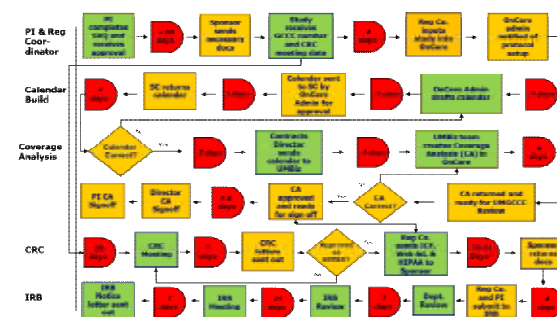
Conclusion

Using Lean Six Sigma Methodology and the DMAIC process, we defined, measured, analyzed, improved, and continue to control underlying causes, waste, and barriers. In doing this, we identified and implemented two process improvement initiatives to improve study activation timelines and were able to improve the speed, quality, and cost of study start up. In addition, we established two new methods of communication and training of staff to increase transparency and "buy-in" to Six Sigma methodology across the team.

Implementation of a third SRC meeting eliminated the immediate backlog of new clinical trial reviews and allowed more time for the possibilities of re-reviews and emergency use protocols while still providing time slots for full reviews.

Through 10 Root Cause Analyses, UMGCCC built process maps, conducted baseline statistics, performed measures of central tendencies, and created pareto charts. In doing this, a significant difference was seen in the trial activation timeline.

Figure 3: "To Be" Process Map



Future Directions

This work demonstrates that LSS Methodology can be applied to operational issues in clinical research, including clinical trial activation. Ensuring the research team within a designated cancer center includes a staff with LSS experience/certification ensures the resources and knowledge exist to apply the methodology effectively. Sharing results with key stakeholders outside of the research office is critical to allow visibility to the outcome of the problems identified. Future directions for GCCC include performing a quarterly review of randomly selected trials. This allows UMGCCC leadership to perform risk analysis and mitigation, establish/modify goals and review results for further revision of process documentation as needed.

Using Data to Determine a Workload Model for Regulatory Staff

Daniela Bashllari, MHA; Mathew Innes, MBA, CCRP

University of Michigan Rogel Cancer Center

Describe the background of the problem:

The University of Michigan Rogel Cancer Center Oncology Clinical Trials Support Unit (OCTSU) splits the study coordinator role between clinical, data management, and regulatory responsibilities. A web-based effort tracking tool, RETA, was developed in 2006 to capture time contributed towards clinical trials logged by staff. In 2016, the Regulatory team was split into a start-up team, handling initial submission and approval, and a maintenance team, which handled the regulatory responsibilities from activation to termination. Fair workload distribution was natural on the startup team as regulatory coordinators rotated new trials and thus workload allocation, in general, was based on number of new studies in progress. The workload of the maintenance team was distributed by therapeutic program, and equality was harder to determine based on just number of studies as study activity due to complexity could vary vastly. A need to objectively determine effort spent by maintenance regulatory coordinators on clinical trials was apparent. A workload model that could be developed using data from RETA for Regulatory coordinators would allow for better staffing decisions and provide a basis for allocating work appropriately amongst the team.

Provide metrics or goals to be achieved:

- Develop a workload tool for regulatory coordinators to successfully manage and distribute staff based on study activity and effort
- Determine the amount of time spent on different regulatory responsibilities based on types of trials

Describe the solutions or methods implemented:

With 10 years of effort data, we first examined the top tasks of staff. While there was some variation over the years, the top nine tasks remained consistent. Second, we looked for tasks which had easily measurable outcomes. We focused on various submission types to the IRB: Amendments (AME), SAEs, ORIOs and Scheduled

Continuing Renewals (SCR). Together these tasks represented 40% of the staff effort. Seeking at least 50% representation, we pulled in another 10% effort associated with investigator regulatory documents (CVs, Licenses, etc.) and the additional metric of co-Investigators per study into the model. To calculate the score, we took the metrics listed above with the average hours per item by sponsor type and phase. With this model, we aim for an expected score of 70 hours for the average regulatory coordinator.

Describe the outcome or show data representing a change (positive or negative):

A workload model for regulatory coordinators was developed that can be grouped either by program or by individual staff. Through this model the allocation of work can be more evenly distributed among staff depending on the type of studies (industry, institutional, etc...) that each program is managing rather than by program alone or number of studies. The expected score of 70 hours for the average regulatory coordinator could be used as a basis to determine if work needed to be shifted should the score increase or decrease over an average of 3 to 6 months.

Address lessons learned and future directions:

Through analyzing data in RETA we learned that regulatory coordinators spend an average of 11 hours on amendments for phase I industry trials. Given that industry trials are constantly amending, this needs to be considered in terms of the types of trials each staff has and how much time they are spending keeping them updated. Another lesson was that regulatory documents were accounting for 10% of the effort with increasing time spent when a study had large numbers of co-investigators. On industry studies, completing regulatory documents was amounting to approximately an hour of time spent per investigator on the study.

Using Data to Determine a Workload Model for Regulatory Staff

Daniela Bashllari, MHA; Mathew H. Innes, BSE, MBA
University of Michigan Rogel Cancer Center

Introduction

The University of Michigan Rogel Cancer Center Oncology Clinical Trials Support Unit (OCTSU) splits the study coordinator role between clinical, data management, and regulatory responsibilities. A web-based Research Effort Tracking Application (RETA), was developed in 2006 to capture staff effort contributing towards clinical trials. Utilizing RETA, a workload distribution tool was developed for data management based on a complexity model that took into account several items including active patients, follow-up patients, number of studies per staff member, and the status of those studies. Previously, studies were assigned to regulatory staff in alignment with his/her assigned disease program. A new workload model for regulatory coordinators was developed using data from RETA which allows for better staffing decisions and provide a more fair-minded baseline for appropriately allocating work amongst the team.

Background

The struggle to equitably allocate work in a clinical trials office is at the forefront of operations. In 2016, the Regulatory team was split into a start-up team, handling initial submission and approval, and a maintenance team, which handled the regulatory responsibilities from activation to termination. Fair workload distribution was natural on the startup team as regulatory coordinators rotated new trials and thus workload allocation, in general, was based on number of new studies in progress. The workload of the maintenance team was distributed by disease program, and equality was harder to determine based on just number of studies as study activity due to complexity could vary vastly. A need to objectively determine effort spent by maintenance regulatory coordinators on clinical trials was apparent.

Contact

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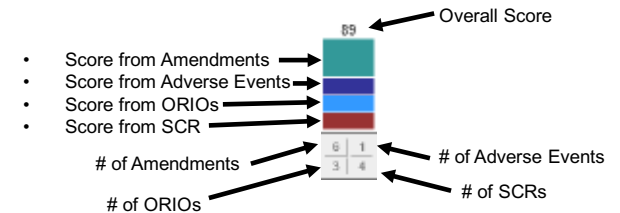
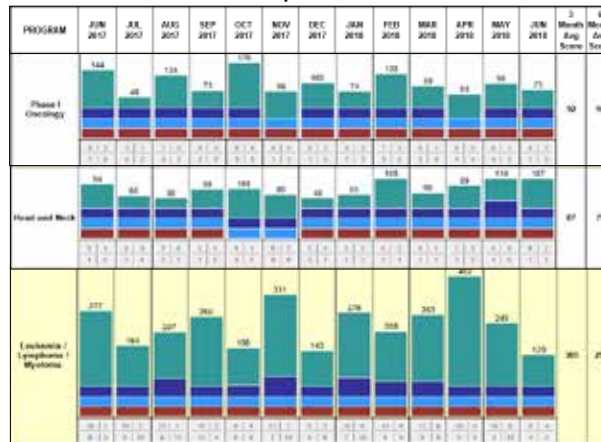
Goals

- Develop a workload tool for regulatory coordinators to successfully manage and distribute staff based on study activity and effort considering trial complexity
- Determine the amount of time spent on different regulatory responsibilities based on types of trials

Results

- 40% of recorded staff effort was logged in as submissions of Amendments, Adverse Events, ORIOs and SCRs
- Regulatory documents were accounting for 10% of the effort with increasing time spent when a study had large numbers of co-investigators.
- On industry studies, completing regulatory documents was amounting to approximately an hour of time spent per investigator on the study.
- Regulatory coordinators spend an average of 11 hours on amendments for phase I industry trials.
- An SCR for an Institutional-Industry Study was on average 67% longer to complete than an SCR for an Industry study.

University of Michigan Rogel Cancer Center
Dashboard Report as of 06/27/2018



Methods

With 10 years of effort data, we first examined the top tasks of staff. While there was some variation over the years, the top nine tasks remained consistent. Second, we looked for tasks which had easily measurable outcomes, so initially focused on various submission types to the IRB: Amendments, SAEs, ORIOs and Scheduled Continuing Renewals which represented 40% of the staff effort. Our assumption is the complexity and effort for "top 50%" of tasks is highly correlated to the "bottom 50%" of smaller tasks. Thus in seeking at least 50% representation, we pulled in another 10% effort associated with investigator regulatory documents (CVs, Licenses, etc.) and the additional metric of co-Investigators per study into the model. To calculate the score, we took the metrics listed above with the average hours per item by sponsor type and phase. With this model, we aimed for an expected score of 70 hours for the average regulatory coordinator. This score represents 50% of monthly effort of a full-time employee after paid-time off:
 $50\% \text{ effort} * (2080 \text{ hours} / 12 \text{ months}) * 80\% \text{ non-PTO} = 69.3$

Conclusions

A workload model for regulatory coordinators was developed that can be grouped either by program or by individual staff. Through this model the allocation of work can be more evenly distributed among staff depending on the type of studies (industry, institutional, etc...) that each program is managing rather than by program alone or number of studies. The expected score of 70 hours for the average regulatory coordinator could be used as a basis to determine if work needed to be shifted should the score increase or decrease over an average of 3 to 6 months.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Multi-Site IITs: Managing Stakeholder Requirements and Balancing Industry Expectations with Academic Realities

Kathleen Granlund, CCRP; Ryan Drzewicki, CCRP; Tracy Wojciechowski, CCRP

University of Michigan Rogel Cancer Center

Describe the background of the problem:

Investigator Initiated Trials (IIT) scope is beginning to evolve causing academic coordinating centers to adapt how they manage these studies. The increased scientific complexity, in conjunction with additional correlative objectives, requires an increase in regulatory oversight. In addition, pharmaceutical companies are wanting to use the results from IITs to supplement their regulatory submissions. This can result in potential gaps, muddled roles and responsibilities, workload increases and a varying multitude of stakeholders. This often can lead to communication breakdowns, responsibility confusion and duplication of effort which can lead to increased institutional risk. Can an academic multi-site project management and monitoring team successfully function as the clinical and data coordinating center; balancing industry expectations with academic realities? Can everyone get what they need?

Provide metrics or goals to be achieved:

The overall goal of the academic coordinating center is to effectively meet stakeholders needs by promoting successful collaboration between the physician and study team, pharmaceutical companies and Contract Research Organizations (CRO). Our role as the academic coordinating center is to manage the overall study conduct to ensure that it is executed with high standards, and is in compliance with the protocol, its time line and with all federal, state and local regulatory obligations while being cognizant of industry expectations, budget, workload, internal processes and institutional risk.

Describe the solutions or methods implemented:

- Discussed stakeholder's expectations including expectations and deliverables.
- Established a roles and responsibilities matrix.

- Leveraged each stakeholder's expertise (i.e. coordinating center retained clinical oversight as oncology specialists).
- Increased communication between all stakeholders and developed additional documentation and process plans.

Describe the outcome or show data representing a change (positive or negative):

Stakeholder feedback has been positive and indicates expectations and needs are being met; especially in regards to the oncology expertise provided by the academic coordinating center; which often is a gap unable to be provided by the CRO. The academic coordinating center, in collaboration with institutional parties, continues to adjust policies and procedures to further facilitate the evolving multi-site studies and mitigate institutional risk.

Address lessons learned and future directions:

- Academic coordinating centers should be involved in CRO selection and scope discussions.
- Use a database that can efficiently transmit data to the stakeholders and/or FDA; reducing programming workload. This could potentially be a database that is housed outside the academic institution.
- Identify areas that could cause workload strain at the coordinating center and consider delegating those tasks to the CRO as they may have less resource constraints.
 - Examples could include: study manual creation, correlative sample/lab kit management, conference call coordination, safety database
- Establish the expectation that the academic coordinating center is the lead for the IIT. The project manager is established as the main point of contact.

- Encourage the pharmaceutical company to identify and avoid overlaps in services between the CRO and the academic coordinating center. Asking the CRO to provide only services to fill the gaps to avoid confusion and potentially inflated budget.
- Be cognizant of potential workload increase required for the academic coordinating center to communicate institutional and/or oncology specific processes that may differ from the CRO and pharmaceutical company standard.

Multi-Site IITs: Managing Stakeholder Requirements and Balancing Industry Expectations with Academic Realities

Authors: Kathleen Granlund, Ryan Drzewicki, Tracy Wojciechowski



Background

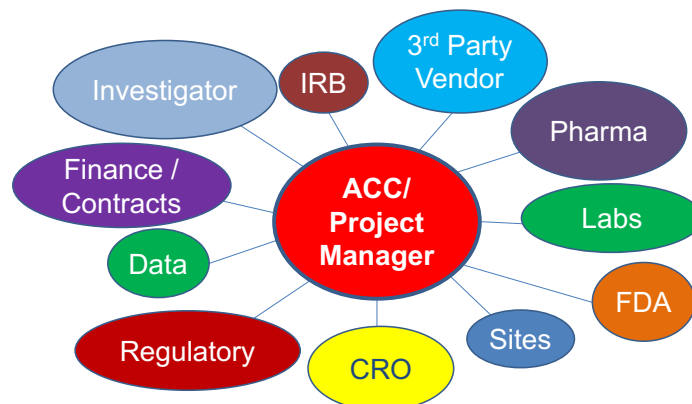
- Evolving Investigator Initiated Trials (IIT)
 - Increase in scientific complexity and correlative objectives.
 - Use of data/results to supplement pharmaceutical FDA regulatory submissions.
- Academic Coordinating Center (ACC) must adapt:
 - Avoid communication breakdown, responsibility confusion and duplication of effort.
 - Balance industry expectations while providing exceptional regulatory oversight and reducing institutional risk.

ACC Goals

1. To effectively manage IIT study conduct through high standards and collaboration between all stakeholders.
2. To provide oversight for protocol and regulatory compliance.
3. To efficiently coordinate stakeholders' varying timelines for successful study completion.
4. To provide leadership, guidance, and act as the central hub for all stakeholders.

Methods

- Discussed stakeholder's needs including expectations and deliverables.
- Established a Roles & Responsibilities matrix specific to the evolving IIT and ACC landscape (Figure 1.0).
- Increased communication between all stakeholders and developed additional documentation and process plans.
- Leveraged each stakeholder's expertise (i.e. coordinating center retained clinical oversight as oncology specialists).



Stakeholder Roles and Responsibility Matrix

R = Responsible; A= Accountable; C= Consult; I= Informed

Task Title	Pharma Company	EDC Vendor/ CRO	ACC
Start Up Tasks/ Study Initiation / Study Closeout			
Study Planning/Develop Project Plan	C	C	R/A
Study close out activities	C	C	R/A
Regulatory / Safety			
Creation and Review of Informed Consent	C	N/A	R/A
Safety management plan	C	R	R/A
Monitoring			
Develop Monitoring Plan	C	C	R/A
Routine Monitoring Visits	I	C	R/A
Site Management			
Central File Setup and Maintenance (TMF)	C/I	C	R/A
Annual IRB Renewals	I	I	R/A
Project Management			
CTMS Input and Support	C	R/A	C
Project Status Reports	I	C	R/A
Medical Monitor			
Physician Review of Eligibility	I	I	R/A
Data Management			
Data Management Plan	C	R/A	C
Data Reconciliation	I	C	R/A
Statistical Analysis			
Statistical Analysis Plan (SAP)	C	R/A	R
SAP Table, Listing, Figure (TLF) Shells	C	R/A	C
Site Audits			
Investigator Site Audits	R/A	C	C
Data Archiving			
Trial Master File Archiving or Transfer to Sponsor	I	C	R/A

Figure 1.0: Snapshot of Roles and Responsibilities Matrix

Future Direction

Addressing Lessons Learned and Practice Solutions:

- Establish a Roles & Responsibility matrix that clearly identifies the ACC Project Manager as the IIT lead.
- Encourage the pharmaceutical company to identify and avoid overlaps in services between the CRO and the academic coordinating center.
 - ACC's should be involved in CRO selection and scope discussions to avoid confusion and inflated budget.
- Use a commercial, compliant database to house and transmit data to stakeholders and/or FDA reducing programming workload.
 - Tip: Database management could be outsourced to a CRO with defined ACC access privileges.
- Identify areas that increase workload and resources at the ACC and consider outsourcing to a CRO as they may have less resource constraints.
 - Examples include: study manual creation, correlative sample/lab kit management, conference call coordination, safety database, and more.
- Be cognizant of potential workload increase required to communicate institutional and/or oncology specific processes variations that may differ from the CRO and/or pharmaceutical company.
- Use the AACI Listserv to utilize colleagues experience and knowledge.

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On TRAC at the Rogel Cancer Center: Centralized Trial Imaging Metrics System

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Describe the background of the problem:

Objective radiographic assessment is crucial for accurately evaluating therapeutic efficacy and patient outcomes in oncology clinical trials. Imaging assessment workflow can be complex, vary with institution and often burden the medical oncologists, untrained in radiology and response criteria, which can lead to high inter-observer variability and investigator bias. Additionally, delayed and potentially error-prone tumor measurements can lead to missed contractual data entry deadlines and increase data/regulatory burden.

Provide metrics or goals to be achieved:

Several goals were identified, including decreased burden on oncologists, provision of radiologist remuneration and superior data quality. A self-sustaining business model was required by the University of Michigan Rogel Cancer Center. Moreover, a leaner workflow with reproducible, timely data to decrease regulatory and data coordinator burden, and meet contractual data entry deadlines to re-establish sponsor trust was needed by the oncology-clinical trials support unit (O-CTSU).

Describe the solutions or methods implemented:

In 2016, we established a tumor response assessment core (TRAC) along with a proprietary web platform in collaboration with the Cancer Center Informatics team. The software supports a novel image-analyst workflow through order requests, work list management, longitudinal records with annotated images, automated graphs (waterfall and spider plots) and user notifications. The application supports multiple customizable response criteria, investigator e-signature and a complete audit log (per CFR part 11). User access is role-based with lightweight directory access protocol (LDAP) authentication controlled through the University identity management services.

Describe the outcome or show data representing a change (positive or negative):

To evaluate TRAC efficacy, we compared tumor assessments of 47 consecutive subjects from 10 lung cancer clinical trials (2005-15) with median age 60 (range, 29-78) done by medical oncologists to those by TRAC and a board-certified radiologist. A linear-weighted kappa test for concordance was fair for TRAC versus oncologists (0.35; 95% CI, 0.20-0.64), good for TRAC versus radiologist (0.71; 95% CI, 0.46-0.85) and fair for oncologists versus radiologist (0.33; 95% CI, 0.12-0.55) for overall response analysis. Additionally, number of observed agreements were 31 (66%), 37 (78.7%) and 28 (59.6%) between the comparison groups, respectively.

TRAC has witnessed 300% growth since 2016 with over 130 clinical trials (pharmaceutical, NIH, NCTN investigator-initiated (IITs)) and 900 scan timepoints (55 per month on average). TRAC has fostered additional sponsor negotiation with annual revenue over \$120,000 to permit business sustainability and radiologist remuneration. Furthermore, in Q3 2017 the Cancer Center decided to cover the cost of imaging assessment for all NCTN and IITs. An O-CTSU lean workflow assessment showed that tumor metrics average turnaround time reduced from 33 to 3 days. Investigator e-signature has eliminated need for wet signatures on paper source documents. Furthermore, an internal survey (n=14) showed research coordinators save an average of 2 (range, 1-5) hours a week due to TRAC.

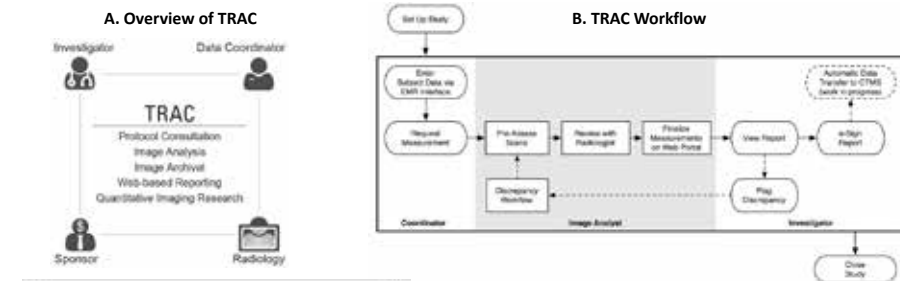
Address lessons learned and future directions:

TRAC has enabled leaner operation for the O-CTSU by providing standardized, timely tumor measurements with e-signature capability. Engagement of radiologists through additional remuneration and academic credit on IITs is crucial. Improved budget negotiation has led to a self-sustaining business model. We are in midst of developing a marketable software as a service model for other cancer centers. Additionally, we are evaluating expansion of services into small animal tumor metrics and pediatric oncology.

INTRODUCTION

- Objective radiographic assessment is crucial for accurately evaluating therapeutic efficacy and patient outcomes in oncology clinical trials.
- Imaging assessment by medical oncologists or measurements transcribed from subjective clinical radiology report¹ may introduce high inter-observer variability,² and experimenter bias due to patient-provider relation as well as knowledge of the treatment-arm and clinical course.³
- The Rogel Cancer Center Oncology Clinical Trial Support Unit (O-CTSU) were unable to meet the real-time data entry contractual deadlines with trial sponsors and embarked on a LEAN exercise to determine the root cause(s).
- The **Tumor Response Assessment Core (TRAC)** was established at the Rogel Cancer Center to provide standardized, objective, unbiased, near-real-time quantitative imaging assessment and consultative services for clinical trials.
- Herein, we discuss (a) our experience in establishing the core as well as highlight the workflow and novel web-based platform, (b) results of the O-CTSU lean exercise, and (c) response concordance between medical oncologists, an independent radiologist and TRAC for clinical trial patients to assess the potential benefit of using an imaging core.

TUMOR RESPONSE ASSESSMENT CORE (TRAC)



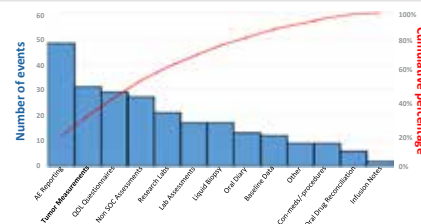
C. Number of radiographic scans analyzed (bars) and revenue (line) per month since April 2016

- Auditable web platform with role-based access
- Lightweight directory access protocol (LDAP) authentication
- Result reporting with measurement data and annotated images within 72 business hours
- Automated graphs per trial (waterfall and spider plots)
- HIPAA-compliant software with FDA Title 21 CFR Part 11 compliant e-signature option for investigators
- Self-sustaining business model
- Support to 145 clinical trials (11 cooperative group, 113 sponsored, 21 investigator-initiated)

O-CTSU LEAN EXERCISE

- O-CTSU study coordinators (data managers) performed a two-week data collection exercise recording type of data not available within the contractual timeframe.
- O-CTSU lean workflow assessment showed average data turnaround reduced from 33 to **3 days**

D. Missing data elements within the contractual deadline: O-CTSU lean exercise

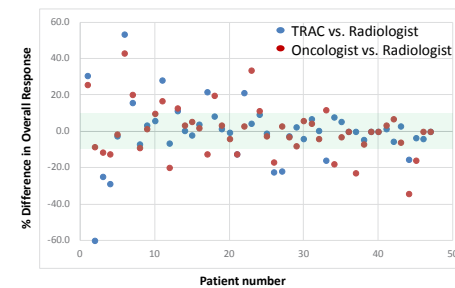


RESPONSE CONCORDANCE B/W ONCOLOGISTS, RADIOLOGISTS & TRAC

- A total of 47 consecutive lung cancer patients enrolled on clinical trials at the Rogel Cancer Center from 2005-2015 were enlisted on this study.
- Baseline and follow-up tumor measurements on CT scans were conducted according to trial-specific response criteria.
- Target lesions were compared to retrospective tumor measurements completed by medical oncologists to those done prospectively by TRAC and a board-certified radiologist in a blinded manner.
- Linear-weighted Kappa test was used to assess concordance in the per-patient analysis.

Patients (N=47)		
Age	Median (range), years	60 (29-78)
Gender	Male	22
	Female	25
Type of lung cancer	Bronchogenic	4
	Small cell	8
	Non-small cell	31
Type of response criteria	RECIST v1.0	25
	RECIST v1.1	17
	iRRC	5
Clinical Trials (N=10)		
Number of trials based on type of response criteria	RECIST v1.0	3
	RECIST v1.1	6
	iRRC	1

iRRC = immune-related response criteria, RECIST = response evaluation criteria in solid tumors



E. Variance in overall response between TRAC vs. Radiologist (blue) and Oncologist vs. Radiologist (red)

Per Patient Analysis (N=47)			
Response Assessment*	Imaging Core	Medical Oncologists	Radiologist
CR	0	0	0
PR	15	17	13
SD	25	26	25
PD	2	3	4
No target lesions identified on baseline scan**	5	1	5
Response Comparison	Imaging Core vs Radiologist	Imaging Core vs Medical Oncologists	Medical Oncologists vs Radiologist
Linear-weighted Kappa value	0.65 (95% CI, 0.46 to 0.85)	0.42 (95% CI, 0.20-0.64)	0.34 (95% CI, 0.12 to 0.55)
Kappa scale	Substantial	Moderate	Fair
Observed Agreements, N (%)	37 (78.72)	31 (65.96)	28 (59.57)

CI=confidence interval, CR=complete response, PD=progressive disease, PR=partial response, SD=stable disease

*Per specific criteria (outlined in Table 1)

**Patients included here with no target lesion on baseline since patients were enrolled on trials by oncologist.

CONCLUSIONS

- Medical oncologists burdened with the task of image analysis and response assessment may introduce variability.
- The LEAN exercise demonstrated that solid tumor response assessments were not available 17% of the time to meet the contractual timeframe. Using TRAC, response assessments are now available within 72 hours of order-entry/scan completion.
- TRAC has a 'substantial' concordance with radiologists. Medical oncologists have only 'fair' and 'moderate' concordance with radiologists or an imaging core.
- Institutional imaging cores, such as TRAC, offer to bridge the gap by providing unbiased and reproducible measurements for clinical trials and reduce data turnaround time for clinical trial staff to enable leaner workflow.
- TRAC has fostered additional trial sponsor negotiation for financial sustainability

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Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Improving Start-Up Times in Oncology Clinical Trials at an NCI-Designated Comprehensive Cancer Center (NCORP site): An ASCO Quality Improvement Project

Zoneddy Dayao, MD¹; Leslie Byatt, CCRC²; Kaylee Deutsch, MHA, CCRP²

¹University of New Mexico Comprehensive Cancer Center; ²New Mexico Cancer Care Alliance

Describe the background of the problem:

With the increasing complexity of clinical trial management and activation, the University of New Mexico Comprehensive Cancer Center (UNMCCC) and the New Mexico Cancer Care Alliance (NMCCA) are seeing increased delays in opening a trial. These delays can adversely affect patient care. Currently, the average time from clinical working group (CWG) review to trial opening is 33 weeks. Creating strategies to shorten the timeline where the longest delays occur will expedite patient access to novel therapies.

Provide metrics or goals to be achieved:

The goals of this project are to identify where delays occur in this process and create effective strategies to shorten time to trial initiation without creating excessive burden to staff and financial resources.

The primary aims are:

1. To define the average time a protocol stays within each timeline for clinical trial initiation
2. To identify the timeline where an intervention will make the most impact in shortening start-up time
3. Implement an intervention, beginning February 2018, with the goal of decreasing this time by 50% by December 31, 2018

Describe the solutions or methods implemented:

1. This study analyzed 81 clinical trials opened in 2017 which included industry, investigator initiated and NCTN trials. Average time a protocol spends in each timeline are as follows:
 - Clinical Working Group Review (4.4 weeks)
 - Protocol Review and Monitoring Committee (PRMC) Approval (4 weeks)

- IRB Submission (7.7 weeks)
- IRB Approval (4.09 weeks)
- Open Active (12.65 week)

This showed that the longest timeline is IRB approved to open active at 12 weeks and identified this as the focus of intervention.

2. Focus Group Approach

Two focus group meetings with involved staff were organized. The goals were to identify recurring barriers and formulate solutions.

3. Interventions were identified.

- There was agreement amongst the focus group that the time to complete activation tasks could not be shortened due to staffing resources. However, shifting these tasks forward in our activation timeline is estimated to decrease the time by at least 50%.
- A sponsor survey was created to allow UNMCCC to identify logistical concerns earlier.
- Regulatory coordinators were provided an email template to request systems access early. Site initiation visits are being scheduled at IRB submission.

Describe the outcome or show data representing a change (positive or negative):

Our data shows that our interventions have had a strong positive impact on our timelines (Figure 1). Our intervention data tracks all studies that have been submitted to the IRB after January 1, 2018. Baseline data tracks studies that were submitted prior to this date.

Address lessons learned and future directions:

Since implementation in quarter 1 of 2018, we have seen an improvement in our study timeline. We will be tracking and analyzing data by trial category (pharmaceutical/cooperative group/ investigator initiated) to determine if these strategies are effective across trials with varying startup complexities.

The methods we used for data collection proved to be a positive exercise for all involved and can be used for future quality improvement projects within the institution.



Improving Start-Up Times in Oncology Clinical Trials at an NCI Designated Comprehensive Cancer Center (NCORP site) An ASCO Quality Improvement Project

Leslie Byatt, CCRC; Kaylee Deutsch, MHA, CCRP ; Zoneddy Dayao, MD
University of New Mexico Comprehensive Cancer Center and the New Mexico Cancer Care Alliance



Abstract

Delays in opening clinical trials adversely affect patient care. New Mexico Cancer Care Alliance's (NMCCA) / University of New Mexico Comprehensive Cancer Center (UNMCCC) average time from clinical working group (CWG) review to trial opening is 33 weeks. Shortening this time will expedite patient access to novel therapies.

Goal: Identify where delays occur in the process and create strategies to shorten the time of trial activation without creating excessive burden to staff and financial resources.

Primary aims:

1. To define the average time a protocol stays within each timeline for clinical trial initiation
2. To identify the timeline where an intervention will make the most impact in shortening start-up time
3. Through an ASCO driven project, create an intervention with the goal of decreasing this time by 50% by December 31, 2018

Methods and Materials

1. Data Gathering

This study analyzed 81 clinical trials opened in 2017 which included industry, investigator initiated and NCTN trials. Data on the average time a trial spent in the following timelines were collected and a Pareto chart was generated (Figure 1):

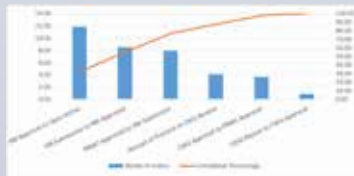
- Clinical Working Group Review
- Protocol Review and Monitoring Committee (PRMC) Approval
- IRB Submission
- IRB Pending
- IRB Approved
- Open Active

2. Focus Group Approach

After identifying the timeline accounting for the longest delay, a focus group of staff directly involved in this process was organized. Two meetings were conducted.

First meeting: Identify barriers. A blinded approach to data collection was used.

Second meeting: Interactive discussion. The top 3 barriers were identified and strategies were formulated, in the context of staff limitations.



Results

Data from 2017 showed that the time between IRB approval and a study becoming open active was 12.67 weeks. As outlined in Figure 1, this represents 38% of the total time (33 weeks) for trial initiation. The data allowed us to identify the timeline that would be the focus of intervention.

The focus group identified the delays encountered from IRB approval to open active as represented in Figure 2.

Among these, the 3 lengthiest processes identified were:

- Scheduling and Completion of Site Initiation Visits
- Completion of Site Budgets
- Access to study portals, EDC, IWRS

There was agreement amongst all the group members that the time to complete these tasks could not be shortened due to staffing resources. However, strategically shifting these tasks by working in parallel with earlier timelines is estimated to decrease the time by at least 50% (6 weeks).

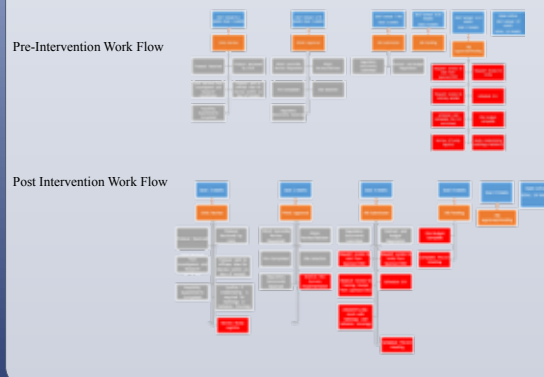
On closer analysis of the average length of these processes, it was also determined that the NMCCA's arbitrarily set goal of reducing this timeline to 2 weeks is likely not achievable and 6 weeks is a more realistic goal.

Process Interventions

To effectively implement the shift in the new workflow, beginning February 2018, strict deadlines for the 3 priority processes will be established for each new trial submitted to IRB.

Process interventions include:

1. New study feasibility questionnaires will be given to sponsors to identify barriers earlier.
2. Template emails have been drafted for the regulatory coordinators to communicate more efficiently at the time of PRMC approval.
3. A template for timeline reporting to the clinical working groups has been created and mandatory deadlines will be established and tracked.



Results

Detailed analysis of 2017 data of newly opened trials at NMCCA/ UNMCCC showed that protocols spent the longest amount of time from IRB approval to open active. The identification of this delay is the critical first step in developing strategies to shorten time to trial initiation at our institution.

The focus group identified the most significant causes of delay. It was determined that shifting the tasks to run in parallel with earlier timelines will allow for the same amount of time for task completion without increasing the stress on the clinical trials staff. It is anticipated that this strategy will reduce the amount of time from IRB approval to open active from 12 weeks to 6 weeks.

Our data shows that our interventions have had a strong positive impact on our timelines. Our intervention data tracks all studies that have been submitted to the IRB after January 1, 2018. Of the 8 studies submitted and IRB approved after our intervention was put into place, 6 met our goal timeframe of 6 weeks to activation after IRB approval.

Of the two studies that did not meet our new goal of 6 weeks, one was delayed due to difficulty scheduling the site initiation visit with the sponsor. The other was delayed due to delays in scheduling the SIV and the completion of the site budget.



Conclusions and Next Steps

It's important to note that we currently do not have enough data-points to make a conclusion about the process's success. However, based off of the data we have collected, our interventions look very promising. We have made a significant difference in our process timeline and will achieve stability of the process with more data collection.

We plan to continue to track our startup time data and gather results in December 2018.

This process was a constructive exercise creating a positive team experience that encouraged collaborative problem solving.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Analysis of Barriers to Clinical Trial Accrual in an Academic Center: The Results of Identifying Clinical Trial Gaps

Jacklyn Nemunaitis, MD; Teresa Stewart, MS; Zoneddy Dayao, MD

University of New Mexico Comprehensive Cancer Center

Describe the background of the problem:

NCI designated centers struggle to meet the 10% accrual benchmark, even with common malignancies such as breast cancer. Despite an average of 20 breast clinical trials open, UNMCC's accrual to breast trials has only averaged 11% annually.

In 2016, we sought to identify which factors were the true barriers to accrual and results were presented at AACI. Detailed analysis of the breast clinical working group data (BCWG) showed that contrary to perceptions, the main barrier was not ineffective screening by clinical trials staff, ineligibility or patients' unwillingness to participate. The results showed that the extensive clinical trial menu, in fact, did not appropriately match our patient population, which primarily comprised of early stage disease.

The results of this individualized assessment provided insights that resulted in a change of policy and trial prioritization within the BCWG.

Provide metrics or goals to be achieved with the solution to address the problem:

The goal was to improve the 11% annual breast clinical trial accrual rate.

Describe the solutions or methods implemented:

This major trial gap was extensively discussed at the BCWG resulting in a major shift in trial prioritization that included early stage hormone receptor positive (HR+), Her2-disease.

Investigator initiated trials addressing this major gap were developed and funded.

Symptom control therapeutic trials addressing common side effects of hormonal treatment were opened. High accruing trials such as ALTERNATE, PALLAS, SWOG 1207 are ongoing.

Describe the outcome of the solutions implemented or show data representing a change whether positive or negative.

In 2016, analysis of the group for which no trials were available showed that the largest trial gap was in HR+ Her2—early stage breast cancer.

With trial prioritization for this population, annual clinical trial accruals have significantly improved. As of December 2017, Data Table 3 showed that 70 out of 353 (19%) new breast cancer patients were enrolled. Out of these, 28% (20 out of 70) were in trials that included early stage HR+, Her2-disease. This represents an increase in accruals from 11% to 19% (see figure).

Breast cancer trials that include HR+, Her2 -, lymph node negative disease now comprise 30% of the clinical trials menu (9 out of 29) .

Address lessons learned and future directions:

Several published barriers and long held perceptions were assumed to impact clinical trial accruals in our institution. In 2016, a root cause analysis was done to identify specific UNMCCC breast cancer accrual barriers. This showed surprising results. Contrary to prior assumptions, the main barrier was not suboptimal screening or ineligibility. Rather, the extensive clinical trial menu primarily targeting advanced disease did not match our patient population. Despite being a major referral center in a largely rural state, the majority of patients did not have advanced disease, as previously assumed. The largest fraction of patients had early stage HR+, Her2 – disease, for which trials were lacking.

A shift in strategy involving trial prioritization has resulted in a significant increase in accrual from 10% to 19%. Trials for this population now comprise 30% of the trial menu.

In summary, it was recognized that published barriers to clinical trial accrual may not necessarily hold true in a specific institution and disease specific root cause analysis can facilitate development of tailored solutions.

Data Table 3 Analysis of a NCI Comprehensive Cancer Center: Results of Identifying Clinical Trial Gaps

Jacklyn Nemunaitis, MD, Teresa Stewart, MS, Zoneddy Dayao, MD • University of New Mexico Comprehensive Cancer Center, Albuquerque, NM, USA



Most of the NCI designated centers struggle to meet the 10% accrual benchmark, even with common malignancies such as breast cancer for which many trials are available.

Published barriers include patient, physician, site and trial-related factors. The goal of this retrospective study is to objectively identify UNM Cancer Center's barriers to breast cancer trial accrual, debunk or affirm perceptions and create targeted solutions. These insights resulted in a change of policy and trial prioritization within the breast working group.



Materials & Methods

- All breast cancer cases from our 2014 Data Table 3 (DT3) were retrospectively reviewed and reasons for non-accrual were categorized as follows:
 - Trial specific: no trial available, or trial available but patient ineligible
 - Patient specific (trial available, patient declined)
 - Patient not screened.
 - Other reasons.
- The identified trial gap resulted in a major shift in trial prioritization that included HR+, Her2- disease.
- Symptom control therapeutic trials were opened.

Results

Out of 145 Cases

- 99.5% met the criteria for NCI-defined registered patient.
- 11% were enrolled in trials.
- Despite 21 therapeutic trials open, no trials were available for 66%.
- For 11%, trials were available, but patients were ineligible.
- 4% declined participation.
- 3% were not screened.

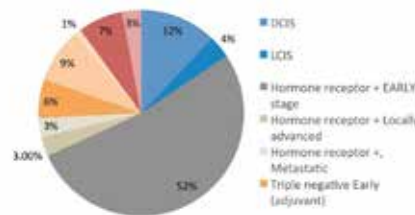
In the No Trial Available Group

- 16 % Stage 0 (DCIS 12%, LCIS 4%)
- 52% Stage I/II node negative ER+, Her2-.
- 16% triple negative.
- 10% Her2neu +.
- 6% had locally advanced or metastatic ER+Her2-

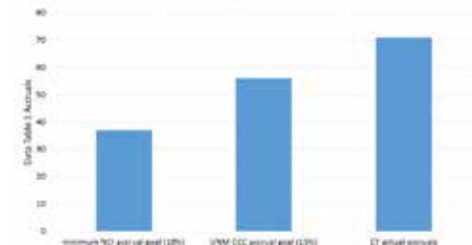
DT3 Breast Cancer : 145



No Trial Available : 96



DT3 Accruals in 2017



Accruals after analysis

- 19% of patients were enrolled in clinical trials (compared with 11% previously).
- 30% of breast cancer trials include early stage HR+, Her2- disease, node negative disease.

Conclusions

- Published barriers do not always reflect an institution's own accrual obstacles.
- This analysis improves the understanding of UNM Cancer Center's true accrual barriers.
- Specific root cause analysis can facilitate development of tailored solutions resulting in significantly improved clinical trial accrual.
- This single center experience may also reflect a trend across institutions. If so, this may provide insight to the NCI regarding the root causes of low accruals and be utilized in prioritizing future study concepts.

Discussion

- Previously, it was perceived that UNM Cancer Center, a major referral center, has a large patient population with advanced disease. This study showed that the majority of patients in fact have early stage, HR+, Her2- cancer.
- It was perceived that the extensive trial menu, with 22 trials currently open, matched the patient population. However, a major trial gap was identified for early stage node negative ER+Her2neu negative disease.
- With trial prioritization for this population within the clinical working group, annual clinical trial accruals have significantly improved from 11% to 19% in 2017.
- Breast cancer trials that include HR+, Her2-, lymph node negative disease now comprise 30% of the clinical trials menu.
- Institution-specific root cause analysis of barriers to clinical trial accrual allowed for tailored solutions that improved clinical trial accrual.

Correspondence: jnemunaitis@salud.unm.edu

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Research and Hospital Integration

Stefanie Belanger, CCRP; Stephanie Ladd, CCRP; Megan Fasold, RN, BSN, PCCN

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

Describe the background of the problem:

The UNC LCCC CPO must facilitate high-quality research within a hospital system containing separate missions, priorities, and organizational structures. Though all recognize the importance of research, integrating with the hospital's care team causes role confusion, strained relationships, taxed nursing staff, perceived silos, and impaired patient experience.

Leadership from UNC Health Care (Hospital) and the CPO (University) collaborated to ensure continuity of care, improve patient safety, improve employee morale and preserve data integrity. Ultimately, the goal was achieving an "our patient" approach.

Provide metrics or goals to be achieved:

Achieve "our patient" mentality via:

- Defining roles and responsibilities
- Enhancing communication
- Leveraging EMR (Epic) capabilities
- Improving protocol compliance

Describe the solutions or methods implemented:

Representatives across roles from the CPO and Hospital jointly examined tasks performed by staff, identifying duplication or gaps in responsibilities. Seeking to standardize roles, a comprehensive grid was created to delineate tasks associated with patients on clinical trials and identify staff responsible; this was presented at staff meetings and disseminated amongst departments.

Communication improved around transitioning care coordination from Coordinator to Hospital staff. Hospital staff began attending research meetings for their disease teams, facilitating real-time awareness of patient status. CPO attends monthly meetings with Infusion leadership, aiding in process improvement and shared goals.

Epic was optimized to facilitate communication via:

- Care Team: upon consent, Coordinators list themselves as Care Team members identifying them as the primary contact for patient. At end of treatment, the Coordinator removes themselves, signaling the Nurse Navigator is once again the primary contact.
- Research Encounter: Coordinators transitioned documenting their progress notes within the provider's encounter to within a "Research Encounter." This facilitates sharing pertinent research information.
- Handoff Tools: A smart-text was created to aid in hand off of research patients back to routine care team. Another smart-text was created to communicate study-specific follow up schedules to ensure appointments are not rescheduled/cancelled. Both tools are Telephone Encounters, allowing for routing to the Nurse Navigator's in-basket.

Infusion staff utilized paper flowsheets to handwrite source documentation. These are now integrated within the treatment plan encouraging real-time documentation, reducing the number of places information is documented, and reducing transcription errors/discrepancies.

Describe the outcome or show data representing a change (positive or negative):

Clear delineation of roles and responsibilities have benefited staff, streamlined patient care, and minimized effort duplication. Communication has increased between CPO and Hospital staff, improving patient experience and employee morale.

Epic optimization and compliance monitoring continues. Coordinators are alerted prior to scheduled appointments changing. Communication through collaboration is better received by Hospital.

Real-time electronic documentation and appropriate hand offs improved protocol compliance. Deviations and patterns are monitored and discussed regularly.

Address lessons learned and future directions:

Changing culture takes time, leadership buy-in, and a common mission. At UNC, the importance of an "our patient" approach and conducting high-quality research is at our mission's core. We continue strengthening relationships between University and Hospital staff and are committed to closing gaps. Standardizing a cross-training regimen of GCP and Hospital policy for all staff may further benefit the quality of research documentation and patient safety. Sharing in success and co-owning failure are key to growing a healthy relationship between two institutions and achieving our full potential.

Research and Hospital Integration

Stefanie Belanger, BA, CCRP, Stephanie Ladd, BS, CCRP, Megan Fasold, RN, BSN, PCCN

Background

The UNC LCCC CPO must facilitate high-quality research within a hospital system containing separate missions, priorities, and organizational structures. Though all recognize the importance of research, integrating with the hospital's care team causes role confusion, strained relationships, taxed nursing staff, perceived silos, and impaired patient experience.

Goals

Achieve "our patient" mentality via:

- Defining roles and responsibilities
- Enhancing communication
- Leveraging EMR (Epic) capabilities
- Improving protocol compliance

Methods

- Hospital staff began attending research meetings for their disease teams, facilitating real-time awareness of patient status.
- CPO attends monthly meetings with Infusion leadership, aiding in process improvement and shared goals.
- Seeking to standardize roles, representatives from the CPO and Hospital created a comprehensive grid was created to delineate tasks associated with patients on clinical trials and identify staff responsible.
- Epic was optimized to facilitate communication via the following methods:

Care Team

PCPI	Name	Type	Role	Research Coordinator
	Glene McQueenie MD	General		
	Stefanie Belanger	Research Coordinator		

Upon consent, Coordinators list themselves as Care Team members identifying them as the primary contact for patient. At end of treatment, the Coordinator removes themselves, signaling the Nurse Navigator is once again the primary contact.

Research Encounter

Coordinators transitioned documenting their progress notes within the provider's encounter to within a "Research Encounter." This facilitates sharing pertinent research information.

Handoff Tools

A smart-text was created to aid in hand off of research patients back to routine care team. Another smart-text was created to communicate study-specific follow up schedules to ensure appointments are not rescheduled/cancelled. Both tools are Telephone Encounters, allowing for routing to the Nurse Navigator's in-basket.

Electronic Flowsheets

Infusion staff utilized paper flowsheets to handwrite source documentation. These are now integrated within the treatment plan encouraging real-time documentation, reducing the number of places information is documented, and reducing transcription errors/discrepancies.

Outcomes

- Clear delineation of roles and responsibilities have benefited staff, streamlined patient care, and minimized effort duplication. Communication has increased between CPO and Hospital staff, improving patient experience and employee morale.
- Epic optimization and compliance monitoring continues. Coordinators are alerted prior to scheduled appointments changing. Communication through collaboration is better received by Hospital.
- Real-time electronic documentation and appropriate hand offs improved protocol compliance. Deviations and patterns are monitored and discussed regularly.

Conclusions

Changing culture takes time, leadership buy-in, and a common mission. At UNC, the importance of an "our patient" approach and conducting high-quality research is at our mission's core. We continue strengthening relationships between University and Hospital staff and are committed to closing gaps. Standardizing a cross-training regimen of GCP and Hospital policy for all staff may further benefit the quality of research documentation and patient safety. Sharing in success and co-owning failure are key to growing a healthy relationship between two institutions and achieving our full potential.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Objective Data Tracking Tool, A Year In Review

Stephanie Ladd, CCRP; Stefanie Belanger, CCRP; Matthew Jansen, MS

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

Describe the background of the problem:

The Clinical Protocol Office (CPO) implemented a data tracking tool in March 2017 to manage data backlog, proactively allocate resources, minimize surprises during audits and monitoring visits, and preserve employee morale. This tool is maintained by each coordinator on a per trial and per patient level. One year post-implementation we sought to determine the utility and end-user compliance of this tool.

Provide metrics or goals hoped to be achieved:

- Review feasibility, compliance, and utility
- Review trends in data backlog (positive or negative)
- Determine if resources were allocated appropriately
- Review feedback from Investigators

Describe the solutions or methods implemented:

Each coordinator was issued a data tool, which aggregated data backlog metrics in coordinator, disease team and CPO level reports. Information was formally disseminated to investigators biannually rather than monthly as originally intended. Staff and manager reviewed individual tool together monthly and discussed utility, compliance and feasibility of maintenance. Workload was reviewed objectively via this tool in combination with OPAL. Assignments of new trials, those requiring coverage, and those transitioned to new staff were aided by these metrics.

Describe the outcome or show data representing change (positive or negative):

Resources were appropriately allocated to upcoming trials and trials in need of additional support. Staff appreciated a tool to facilitate hand off when inheriting or transferring studies between coordinators. Prioritization of work was easier. Trials without regular monitoring (National Group and IITs) saw a decrease in data backlog.

The tool aided in reconciliation between Sponsor-provided delinquency reports and site knowledge of backlog. This helped to dispel any inaccurate perceptions of workload from both the coordinator and investigator perspectives. The CPO and disease team level summary reports were key in monitoring staff compliance and displayed the most useful information for Investigators.

While objectives were largely met, we received feedback from staff that tracking information in an additional place seemed frivolous/duplicative and many admitted to not updating in real time. Optimally, the site's CTMS would capture this information, however it doesn't perform this function at this time. Many failed to proactively track backlog and instead updated when data was complete. This, along with untimely updates, resulted in no change in data reporting and/or skewed reports. Excel based tools require a large amount of manual maintenance, especially as new tools are created and must be linked for functionality to be maintained. Updates to overall summary reports are manual and not automated.

Address lessons learned and future directions:

We discovered that both OPAL and the data tool were good indicators of current workload, but the same correlation between time and effort tracking within our CTMS could not be made. This may have been due to user bias, untimely entry into the various systems, and inconsistent use. The data tool supplements OPAL in capturing workload associated with off study patients that may still be generating data and queries. It may be worth collaborating with CTMS vendors in the future to combine systems and consolidate efforts. Alternatively, we may want to explore automating some of the manual processes required for the data tool to function via advanced coding, such as macros or Python.

Objective Data Tracking Tool, A Year in Review

Stephanie Ladd, BS, CCRP, Stefanie Belanger, BA, CCRP, Matthew Jansen, BA, MS

Background

The Clinical Protocol Office (CPO) implemented a data tracking tool in March 2017 to manage data backlog, proactively allocate resources, minimize surprises during audits and monitoring visits, and preserve employee morale. This tool is maintained by each coordinator on a per trial and per patient level. One year post-implementation we sought to determine the utility and end-user compliance of this tool.

Metrics

- Review feasibility, compliance, and utility
- Review trends in data backlog (positive or negative)
- Determine if resources were allocated appropriately
- Review feedback from Investigators

Methods

Each coordinator was issued a data tool, which aggregated data backlog metrics in coordinator, disease team and CPO level reports. Information was formally disseminated to investigators biannually rather than monthly as originally intended. Staff and manager reviewed individual tool together monthly and discussed utility, compliance and feasibility of maintenance. Workload was reviewed objectively via this tool in combination with OPAL. Assignments of new trials, those requiring coverage, and those transitioned to new staff were aided by these metrics.



Outcomes

- Resources were appropriately allocated to current and pending studies
- Contributed to facilitation of study transfer between staff
- Prioritization of work was easier.
- Trials without regular monitoring (National Group and IITs) saw a decrease in data backlog.
- Data delinquency reports were easily reconciled, dispelling inaccurate perceptions of workload
- Tracking information in an additional place seemed frivolous/duplicative
- Staff struggled to update in real time and proactively. Tool does not work if updated only when data is complete.
- Excel based tools require a large amount of manual maintenance, creating and linking new tools for functionality to be maintained.
- Ideally, the functions of this tool would be available in a site's CTMS

Conclusions

Both OPAL and the data tool were good indicators of current workload, but the same correlation between effort tracking data within our CTMS could not be made. The data tool supplements OPAL in capturing workload for off study patients that still generate data and queries. It may be worth collaborating with CTMS vendors in the future to combine systems and consolidate efforts versus exploring automating the data tool functionality via advanced coding.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Shared Investment to Build a Strong, Streamlined, and Accessible RECIST Foundation for Clinical Research

Alex Arbuckle

University of Wisconsin Carbone Cancer Center

Describe the background of the problem:

Previous tumor response assessment services at the University of Wisconsin Carbone Cancer Center (UWCCC) were hampered by a disjointed user experience. Radiologists were identifying target lesions in the clinical picture archiving and communication system (PACS) and then having a medical physicist use a repurposed, in-house program that had difficulty adjusting base RECIST criteria to the specific requirements of the study. Previous iterations did not successfully marry the expertise within both UWCCC and UW radiology. The service was inflexible, cumbersome, did not align with research aspirations, and was cost prohibitive. This resulted in oncologists performing the assessments themselves, detracting their focus from other areas of study.

Provide metrics or goals to be achieved:

The UWCCC and UW Department of Radiology recognized the importance and value of combining their expertise to offer local investigators an effective response evaluation tool with the hopes of increasing cancer research in a grass roots manner. Offering a tumor response service is a great benefit to attract top oncologists, industry partners, and radiologists to the University of Wisconsin and further develop clinical research opportunities.

To accomplish this, the response evaluation tool needed a lower entry cost, improved flexibility for starting and stopping Investigator Initiated Trials (IITs) based on PI needs, and improved reporting system. Current oncology research heavily leans into the investigation of immune therapies; it is important that the tumor response assessments be able to expand RECIST offerings to include immune related variants.

Metrics

1. Decreased start-up and assessment costs
2. Faster assessment completion time
3. Number of studies using the service

Describe the solutions or methods implemented:

The UWCCC and UW Department of Radiology invested in a centralized assessment system, Mint Lesion by Mint Medical, in November 2017 after sampling a number of response assessment programs by the radiologists. UWCCC and UW Department of Radiology chose Mint Lesion over other programs because of its polish and performance. Their investment in this system subsidizes the service cost for IITs and allows radiologists to do all assessments in the single system with multiple response criteria per study including RECIST 1.1 and its variants. Radiologists can pull images into Mint Lesion from PACS. From Mint Lesion, radiologists perform the assessment with a respective report. In addition, having the radiologists being able to interact with all facets of the system service cut out excessive intermediaries. The result is a system that aligns with both oncology and radiology research aspirations, is cost effective, is quick for assessment completion, and is flexible enough to allow for quick start-up and navigation of IITs.

Describe the outcome or show data representing a change (positive or negative):

Data is shown on the poster in the metrics section on the graph, "Response Assessment Request Received to Time of Completion."

Address lessons learned and future directions:

Any implementation of software requires a ramp up phase for radiologists after software installation. Our radiologists used this time to familiarize themselves with the new digital workspace and train new fellows who will be performing assessments in the future. As the response assessment

Shared Investment to Build a Strong, Streamlined, and Accessible RECIST Foundation in Clinical Research

Alex Arbuckle, University of Wisconsin Carbone Cancer Center

Mission

The Clinical Research Imaging Core (CRIC) is dedicated to serving as the University of Wisconsin Carbone Cancer Center's (UWCCC) nexus to the UW Department of Radiology Medical Imaging Research Support (MIRS) to support the effective and efficient use of imaging-based outcomes in cancer research and tumor response assessments.

Personnel

Faculty Lead: Steve Cho, MD

- Associate Professor of Radiology
- Director of the UWCCC Clinical Research Imaging Core
- Co-Director, UW Radiology MIRS

Core Manager: Alex Arbuckle, BS

- BS, Neuroscience with training in brain imaging
- Manages and coordinates UWCCC Research Imaging Services

Service Implementation

Previous tumor response assessment services at UWCCC were hampered by a disjointed user experience. The service was inflexible, cumbersome, did not align with research aspirations, and was cost prohibitive. Previous iterations did not successfully marry the expertise within both UWCCC and UW Department of Radiology MIRS. This resulted in oncologists performing the assessments themselves, detracting their focus from other areas of study.

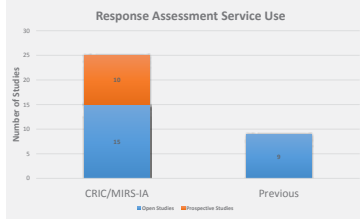
To offer local investigators an effective response evaluation tool the response evaluation tool needed a lower entry cost, improved flexibility for starting and stopping Investigator Initiated Trials (IITs) based on PI needs, faster assessment completion, and improved reporting system. A successful system would be marked by the following: Increased number of assessments, a wider and more varied investigator user base across the UWCCC Disease Oriented Teams (DOTs), and faster assessment completion.

Given the needs of the UWCCC and the expertise of UW Department of Radiology MIRS-Image Analysis (MIRS-IA) there was a joint review of different assessment systems and infrastructure. Ultimately, the Dana-Farber Model was decided upon because of its reputation and efficacy.

The UWCCC and UW Department of Radiology MIRS-IA invested in a centralized tumor response assessment system, Mint Lesion by Mint Medical, in November 2017. UWCCC and UW Department of Radiology chose Mint Lesion over other programs because of its polish, performance, and ease of integration with the Dana-Farber assessment model. In addition to the investment in this system, the UWCCC and the UW Department of Radiology MIRS subsidized the service cost for IITs.

With the system investment and implementation, radiologists and imaging technicians can now do all assessments in the Mint Lesion suite, and are able to support multiple response criteria, including RECIST 1.1 and its variants. Radiologists are able to pull images into the suite from clinical Picture Archiving and Communications System (PACS) for assessment and respective report completion.

To date, the implementation of the centralized assessment system and reliance of local imaging expertise has improved cost effectiveness, continually improved assessment time to completion, and has allowed for quick start-up and navigation of IITs.



Tumor Response Assessment Service

Protocol Review

- The CRIC is made aware of prospective studies via the UWCCC Collaborator Sign-off
- At the time of request for Collaborator Sign-off, the CRIC reviews the protocol for the following: study calendar, applicable imaging, assessment criteria specifications, and desired service use
- Protocol assessment criteria are reviewed for any deviations from RECIST1.1, irRECIST, irRC, etc. It is common that protocols will have variations on established criteria that need to be reflected in assessments

Study Start-up & Activation

- After service use is verified, the study team, CRIC, and MIRS-IA develops the budget for study assessments, including possible subsidization of cost
- CRIC provides the protocol and assessment criteria specifications to MIRS-IA technicians
- To match protocol specifications, the study's assessment criteria are then entered into Mint Lesion assessment suite by Image Analysis technicians
- The standard operating procedure for response assessments is provided to UWCCC study team by the CRIC

Tumor Response Assessment

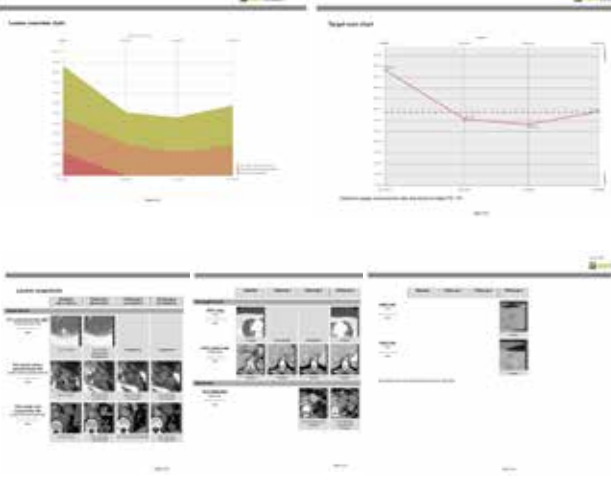
- Study coordinators notify CRIC and MIRS-IA of assessment need via an intake request form
- Assessment request, intake form, clinical report and protocol will be triaged to the radiologist assigned for that day
- Once triaged, technicians pull the images into the Mint Lesion Suite from clinical PACS
- Response Assessment is performed in Mint and the report is generated, reviewed, and sent to the study team with an explanation of next steps needed

Sample Tumor Assessment Report Time Point Summary Table



Lesion Name	Response	Follow-up 1	Follow-up 2
1.01 Lung nodule	Stable	Stable	Stable
1.02 Lung nodule	Stable	Stable	Stable
1.03 Lung nodule	Stable	Stable	Stable
1.04 Lung nodule	Stable	Stable	Stable
1.05 Lung nodule	Stable	Stable	Stable
1.06 Lung nodule	Stable	Stable	Stable
1.07 Lung nodule	Stable	Stable	Stable
1.08 Lung nodule	Stable	Stable	Stable
1.09 Lung nodule	Stable	Stable	Stable
1.10 Lung nodule	Stable	Stable	Stable
1.11 Lung nodule	Stable	Stable	Stable
1.12 Lung nodule	Stable	Stable	Stable
1.13 Lung nodule	Stable	Stable	Stable
1.14 Lung nodule	Stable	Stable	Stable
1.15 Lung nodule	Stable	Stable	Stable
1.16 Lung nodule	Stable	Stable	Stable
1.17 Lung nodule	Stable	Stable	Stable
1.18 Lung nodule	Stable	Stable	Stable
1.19 Lung nodule	Stable	Stable	Stable
1.20 Lung nodule	Stable	Stable	Stable

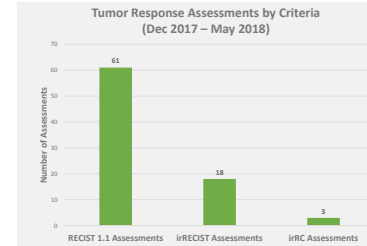
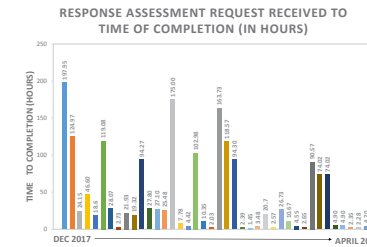
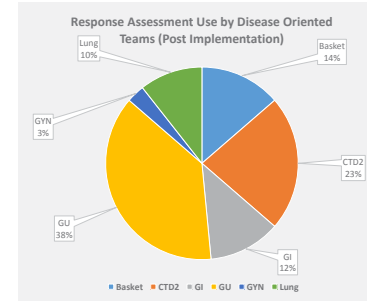
Lesion Overview and Target Sum Charts
Lesion Tracking



Metrics

Results

- Service expanded from 5 unique users in 2 programs to 12 unique users across 6 programs in the first 9 months of the CRIC and MIRS-IA service
- The new service has improved on time to assessment completion, with the current average being 1 business day from time of the request received to assessment and report completion, halving the previous 2 business day average
- 82 tumor response assessments have been completed and reported since service inception in December 2017 through May 2018, including the newly offered irRECIST criteria



Work In Progress

Tumor Response Assessment

- Expand radiologist assessment reading pool in July 2018 by including trained UW Department of Radiology Abdominal Fellows
- Implement Lugano and Cheson criteria for lymphoma studies
- Include trained Nuclear Medicine physicians in the assessment reading pool
- Integration of tumor assessment requests into hospital Electronic Medical Record (EMR) ordering system to streamline study team access
- Increase the number of licenses for Mint Lesion access

Tracking Biospecimen Collection Deviations to Improve Clinical Trial Outcomes

Jamye O'Neal; Heather Barnes; Kimberly Dahlman, PhD

Vanderbilt-Ingram Cancer Center

Describe the background of the problem:

Biospecimen collection deviations are detrimental to clinical trial outcomes and operations; they may result in spurious data, are costly, time-consuming, and may be inconvenient to patients. As a result, it is necessary to systematically track these deviations in order to identify when, and to what extent, they are occurring. The clinical trials management system used by the Vanderbilt-Ingram Cancer Center (VICC) is the Online Collaborative Research Environment (OnCore) system. The majority of VICC clinical trial biospecimens are collected and processed by the Clinical Trials Processing Core (CTPC). Biospecimen deviations are uploaded by CTPC into OnCore as scanned hardcopy paper forms and email missives. As a result, extraction of these data for comprehensive analyses was not easily accessible across all cancer groups at the VICC.

Provide metrics or goals to be achieved:

The objective of our project was to create a better system for tracking and extracting deviated biospecimens data and then, using this information, answer the following questions: 1) Were deviations occurring? 2) How prevalent were they? 3) What kind of deviations were they? 4) At what level did they occur? 5) And, if necessary, what action steps are needed to reduce deviations?

Describe the solutions or methods implemented:

Using the REDCap reporting tool, we built and launched a biospecimen collection deviations tracking database that included 17 cancer groups (i.e., disease teams) and their respective studies across 22 different Vanderbilt University Medical Center clinic locations. Data from 494 REDCap records collected from February 2016 through January 2018 were analyzed.

Describe the outcome or show data representing a change (positive or negative):

During this two year timeframe, across 17 different cancer groups and a total of 166 studies, 24,763 parent samples were slated for collection. The data revealed that 4.6% (n = 1,130) of all parent samples were deviated, with a range of 2.1% (n = 5) to 20% (n = 3) across cancer groups with open studies. The number of deviations reported per clinic ranged from zero to 131 across 22 clinics. We found that the most common reasons for biospecimen collection deviations were: (1) untimely sample processing (23.8%; n = 132), (2) missed sample collections within clinics (17.3%; n = 96), and (3) inadequate notification of specimen collection scheduling by research teams (11.7%; n = 65), (Figure).

Address lessons learned and future directions:

For the first time, we have a comprehensive overview of total biospecimen collections and deviations within the CTPC at the VICC. We are currently refining and better automating our collection and analysis methods in order to utilize these data to provide indicators of process improvement. Additionally, we are performing a cost analysis to determine what resources are being lost due to deviations. Based on these cost analysis data, we are planning education and training opportunities that will help reduce deviation frequency. These initiatives will improve the quality and standards of the clinical trials enterprise, as well as to help deliver better patient care at the VICC.



Tracking biospecimen collection deviations to improve clinical trial outcomes

Jamyé O'Neal^{1,3}, Heather Barnes², Kimberly Dahlman¹

¹ Innovative Translational Research Shared Resource, ² Clinical Trials Processing Core; Vanderbilt-Ingram Cancer Center, Vanderbilt University Medical Center
³ Biomedical Research and Educational Training; Vanderbilt University
 Nashville, TN



ABSTRACT

Biospecimen collection deviations are detrimental to clinical trial outcomes and operations; they may result in spurious data and are costly, time-consuming, and may be inconvenient to patients. As a result, it is necessary to systematically track these deviations in order to identify when, and to what extent, they are occurring. We worked with the Clinical Trials Processing Core (CTPC) management team and Vanderbilt-Ingram Cancer Center (VICC) executives to create a more efficient and streamlined method for recording these collection deviations. Using the REDCap reporting tool, we built and launched a deviations database covering 17 cancer groups and their respective studies across 22 different VUMC clinic locations. Data from 494 records collected from February 1, 2016 through January 31, 2018 indicate that 4.6% of all parent samples were deviated and that there is considerable variability in collection deviations between cancer groups and clinic locations. Common reasons for biospecimen collection deviations recorded were: (1) untimely sample processing, (2) missed sample collections within clinics, and (3) inadequate notification of specimen collection scheduling by research teams. **For the first time, the VICC has a comprehensive overview of total biospecimen collections and deviations within the CTPC.** These data will inform process improvements to optimize biospecimen collections, resulting in greater utility of precious patient samples and resources.

BACKGROUND & OBJECTIVES

The clinical trials management system used by the VICC is the Online Collaborative Research Environment (OnCore) system. The majority of VICC clinical trial biospecimens are collected and processed by the CTPC. Biospecimen deviations are uploaded by CTPC into OnCore as scanned hardcopy paper forms and email missives. As a result, extraction of these data for comprehensive analyses was not easily accessible across all cancer groups at the VICC. The objective of our project was to create a better system for tracking and extracting deviated biospecimens data and then, using this information, answer the following questions: 1) Were deviations occurring? 2) How prevalent were they? 3) What kind of deviations were they? 4) At what level did they occur? 5) and, Is further action needed to reduce deviations?

METHODS

The database launched on October 1, 2016 with CTPC team members as the primary end users logging deviations in real-time. Deviations entered into both the REDCap and OnCore reporting systems from February 1, 2016 to January 31, 2018 were exported and analyzed.

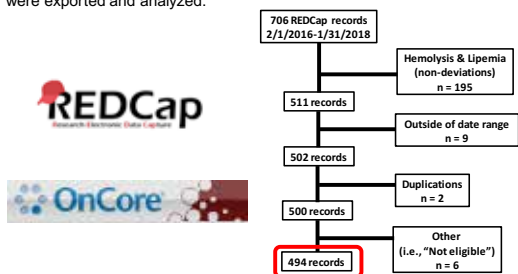


Figure 1. 494 REDCap records were analyzed. Out of 706 records reported in REDCap, 494 records were selected for analysis and were cross-referenced with data collected in the OnCore database. The resulting 494 records were used to calculate the deviation frequencies and interrogate the reason(s) for biospecimen collection deviations.

RESULTS

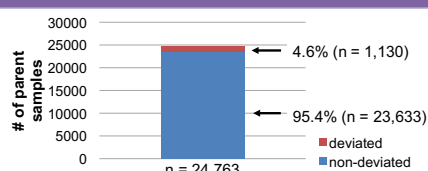


Figure 2. 4.6% of parent samples were deviated. Analysis of data from both REDCap and OnCore reporting systems indicated that 1,130 parent samples were deviated or missed out of 24,763 total samples slated for collection by the CTPC.

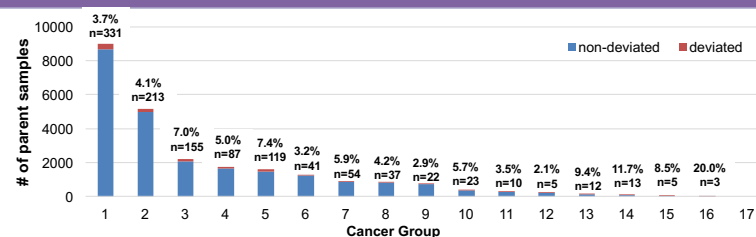


Figure 3. Deviation frequency varies among cancer groups. Analysis of data from both REDCap and OnCore reporting systems indicated variability in number of deviations among cancer groups. All cancer groups are de-identified.

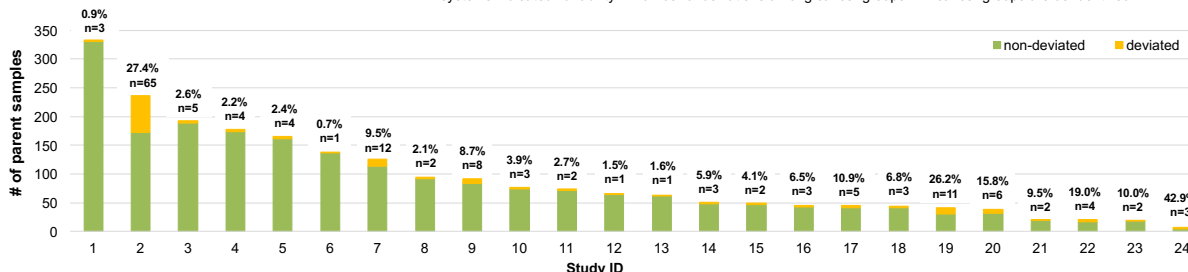
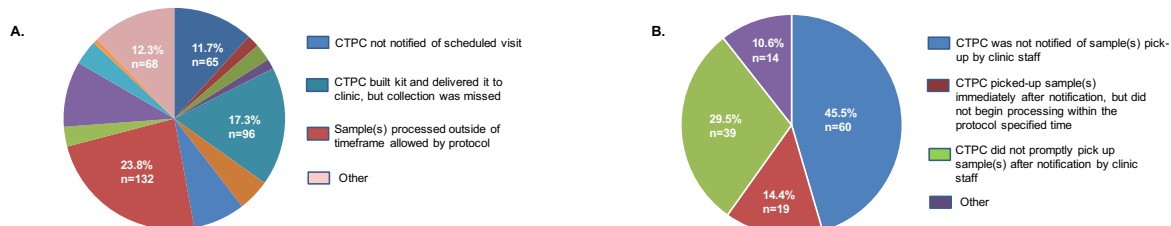


Figure 4. High accrual AND high deviation frequency may point to areas for intervention. Analysis of data from both REDCap and OnCore reporting systems indicated that some studies which had high accrual and incurred a high deviation frequency required closer investigation. Study ID indicates de-identified clinical trial studies from one of the de-identified cancer groups from Figure 3.



Figures 5 A and B. Reasons for biospecimen collection deviations. A. Analysis of data from the REDCap reporting system indicated that samples processed outside of the timeframe allowed by the protocol was the highest reported deviation. B. Follow-up reporting indicated that lack of notification was the largest contributor to sample processing issues.

CONCLUSIONS & FUTURE DIRECTIONS

For the first time, the VICC has a comprehensive overview of the total biospecimen collections and deviations within the CTPC. Less than 5% of all parent samples were deviated or missed and deviation frequency varied among cancer groups, studies within those groups, and clinic locations. Timely sample processing and missed collections were the most common reasons for biospecimen deviations. Future directions include:

- Refine and automate collection and analysis methods
- Create a dashboard for data delivery
- Analyze institutional cost of deviations

ACKNOWLEDGEMENTS

We would like to thank the members of the CTPC, VICC Team Leaders, VICC Executive Committee, VICC Research Informatics Core, and Masters of Laboratory Investigation (MLI) committee (Lisa Gaynes, CCRP, Douglas Johnson, MD, Christine Lovly, MD/PhD, and Ray Mernaugh, PhD) for their invaluable feedback. We would also like to thank the Vanderbilt University School of Medicine Biomedical Research and Educational Training program for its support.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Implementing an EPIC Based Standardized Communication Process Specific to Clinical Trials

Jamie Littleton, RN, BSN, CCRC

Wilmot Cancer Institute, University of Rochester Medical Center

Describe the background of the problem:

A lack of a consistent communication method related to clinical trial requirements and study visit scheduling was identified as a system failure causing treatment delays, missed appointments, missed research data points, and protocol deviations resulting in increasing staff and patient frustration. In order to enhance and strengthen the communication and scheduling processes, a standardized tool and process was developed utilizing the EPIC Research Tab.

Provide metrics or goals to be achieved:

To create a reliable source of clinical trial related information on each individual participant that is accessible to all appropriate clinical and study staff resulting in a streamlined and effective process. A standardized EMR research communication tool was implemented providing a solid mechanism of communication for all study specific information from the clinical trial staff to the care providers.

Describe the solutions or methods implemented:

The Research Tab and processes were implemented using a team approach led by research nursing that included research coordinators, clinic nurses, infusion nurses, and scheduling staff. Initial efforts focused on select disease groups and then rolled out to others as set processes were established. Multiple education and training sessions were conducted over a 5-month period prior to implementation which helped educate staff on the importance of the Research Tab. After implementation, continuous reviews and reporting sessions were conducted in an effort to provide feedback and further fine-tune processes. The nursing staff, coordinators, and Research Nurse collaborated with the aim of achieving the accuracy and completeness goal of 100%.

Describe the outcome or show data representing a change (positive or negative):

Measurement of metrics began 3 months after go-live for each scheduled CT patient visit and included: the percentage of updated research tabs; study calendars in the standardized format; and study visit type used.

Within 5 months of go-live overall compliance was at 98% for research tabs; 52% for study calendars; and 30% for study visit type. At 8 months compliance increased to 100%, 91% and 59%; respectively.

Address lessons learned and future directions:

Research Tab usage improved communication between coordinators and staff across the outpatient, inpatient and Infusion Center settings decreasing the number of missed appointments, missed data points, delays in treatment or research data collection, and increased patient and staff satisfaction. Continuous education and training is critical to the success of a system change like this. Future research should include identifying gaps or risks to the system at various points due to the complex communication processes.

Implementing an EPIC Based Standardized Communication Process Specific to Clinical Trials

Jamie Littleton, RN, BSN, CCRC

BACKGROUND

A lack of a consistent method for communication related to clinical trial (CT) requirements and study visit scheduling was identified as a system failure causing treatment delays, missed appointments and research data points, and staff and patient frustration. To strengthen the communication and scheduling processes, a standardized tool and process was developed utilizing the Research Tab.

PROJECT OBJECTIVES

To create a reliable source of CT related information on individual participants that is accessible to appropriate staff resulting in a streamlined and effective process.

IMPLEMENTATION

- Multiple education sessions conducted over a 5-month period prior to implementation.
- **Study coordinators** – Standardized format for research tab information
- **Clinic Nurses** - Standardized format and information for monthly visit calendar
- **Schedulers** – Schedule with study code and link encounter
- **Infusion Nurses** – Reference the research tab for every study patient encounter



METHODS

- The ISHAPED patient handoff model was modified for oncology clinical trial handoffs.
- The tool was embedded in the EPIC EMR using the research tab.
- The process of communicating CT visit details was then streamlined as outlined below.

THE ISHAPED MODEL
for standardized patient centered handoff using the EMR
TAILORED TO THE ONCOLOGY CLINICAL TRIALS POPULATION

INTRODUCE
The study information including the study drug, dosing, observations, dosing intervals, and patient past status identified.

STORY
The patient's current diagnosis and subdiagnoses relevant to the current clinical trial.

HISTORY
All prior study visit details included to allow for a review of past visits and assessments.

ASSESSMENT
Physical/functional exam, assessment, lab, and functional identified.

PLAN
Study day specific protocol, including study drug administration instructions, just dose PCA, blood work, and QMG measurements.

ERROR PREVENTION
Potential safety issues specific to the patient including study drug deviations from standard of care, known reactions and precautions.

DIALOGUE
The patient is included in a patient-specific handoff of all relevant information to the next team.

CLINICAL TRIAL INFORMATION MANAGEMENT
Utilizing the Research Tab

Study Coordinator
Processes the Research Tab into a color-coded list of necessary specific to each study protocol.
The detailed information is entered into the Research Tab, specific to the trial visit, ensuring the information flows from the template to the research tab.

Clinic Nursing Team
Transfer the details of activities from the research tab into a study calendar, including monthly calendar pages, the appointment study visit.
Further breakdown from the information included in the Research Tab into patient-specific visit information.

Scheduler
Utilizes the data entered to the study calendar to assign specific dates and schedule patient visit using the CTY study code.
This is also used to link appointment to a study and trigger study visit.

Infusion Nursing Team
Reference the research tab for study information at the research tab to determine study, medication, order ID and clarify required study requirements.
Resolves all of the study visit details with any questions.

Patient
Is contacted on an after-visit summary to provide information on the study visit, including any study visit at the end of the visit and any other information.

OUTCOMES

<ul style="list-style-type: none"> • Research Tab: 73% • Study Calendars: 13% • Study visit type: 15% 	<ul style="list-style-type: none"> • Research Tab: 100% • Study Calendars: 91% • Study Visit Type: 59%
2 Months	8 Months

- Improved communication between coordinators and staff in the outpatient and Infusion Center along with the inpatient units
- Increased patient and staff satisfaction
- Less confusion related to CT visit requirements
- Streamlined communication process
- Increased interest in CT's among staff

CONCLUSIONS/IMPLICATIONS

The implementation of a standardized communication tool and process within the EPIC EMR has provided a consistent method of communicating critical CT information to the entire team.

The improved communication process facilitated the development and implementation of a dedicated clinical trial infusion pod which has further streamlined patient care.

ACKNOWLEDGEMENTS

The entire WCI CTO and nursing teams.

Additional Abstracts and Posters (alphabetical order by AACI cancer center):

Effects of Profession Directed Research Order Generation on Clinical Trial Measures

Carrie Belmore, RN, BSN, OCN; Colleen Lewis, MSN, ANP-BC, AOCNP; Cathy Sharp, RN, MN, OCN, CCRP; Jennifer Schreiber, RN, BSN, OCN; Tina Williams, RN, BSN, OCN; Monica Goodman, RN, BSN, OCN

Winship Cancer Institute of Emory University

Describe the background of the problem:

Accurate care delivery and data collection is a clinical trial imperative. Specifically, phase one oncology clinical trials require extensive vital sign monitoring, electrocardiograms, blood sampling and detailed treatment guidelines. Research protocols provide schedules of events and drug administration details that need to be translated into a functional order set for nurses. Research order creation is a critical part of clinical trial implementation and requires multidisciplinary collaboration.

Provide metrics or goals to be achieved:

A systematic, multidisciplinary approach in the form of a research order committee was created and within this committee, nurses led a process change and are now essential to the development and creation of research orders, ensuring accurate patient care and quality data collection. Prior to the initiation of the Research Order Committee in January 2014, pharmacists were responsible for all aspects of research order creation. Often, order creation was delayed due to pharmacist workload, preventing timely study enrollment for potential patients. The Research Order Committee was designed to enhance collaboration, improve the efficiency of the order creation process, and has been implemented and utilized with great success.

Describe the solutions or methods implemented:

Following the establishment of the committee, clinical trials infusion nurses began creating the tables that outline patient care tasks and data collection time points as specified in research protocols. Nurses collaborate with pharmacists, coordinators and principle investigators to effectively translate all aspects of required care. A nurse representative attends each meeting ensuring consistent nurse input on each order set reviewed. In 2016, to further refine the order creation process and increase efficiency, the research order was split into two working documents:

pharmacy order and nursing considerations. This substantially improved formatting and provided additional space for pertinent nursing care guidelines.

Describe the outcome or show data representing a change (positive or negative):

With the new process in place, the time from Scientific Review Committee approval and committee notification to first draft creation decreased by 18 days (54%) and total time required for order completion and approval decreased by 52 days (55%) by 2017.

Address lessons learned and future directions:

Integrative and collaborative patient care is essential in clinical research but a challenge many large institutions struggle with in practice. Oncology research infusion nurses have played an integral role in protocol order development, strengthening the multidisciplinary approach to clinical trials conduct. This new process of developing and managing all research nursing considerations documents has greatly improved quality and efficiency, ensuring trials open faster allowing patients more timely access to clinical trials.



EFFECTS OF PROFESSION DIRECTED RESEARCH ORDER GENERATION ON CLINICAL TRIAL MEASURES

CARRIE BELMORE, RN, BSN, OCN, COLLEEN LEWIS, MSN, ANP-BC, AOCNP, CATHY SHARP, RN, MN, OCN, CCRP, JENNIFER SCHREIBER, RN, BSN, OCN, TINA WILLIAMS, RN, BSN, OCN, MONICA GOODMAN, RN, BSN, OCN
WINSHIP CANCER INSTITUTE OF EMORY UNIVERSITY, ATLANTA, GA

Summary

Objectives: Accurate care delivery and data collection is a clinical trial imperative. Specifically, phase one oncology clinical trials require extensive vital sign monitoring, electrocardiograms, blood sampling and detailed treatment guidelines. Research protocols provide schedules of events and drug administration details that need to be translated into a functional order set for nurses. Research order creation is a critical part of clinical trial implementation and requires multidisciplinary collaboration. A systematic, multidisciplinary approach, in the form of a research order committee was created and within this committee, nurses led a process change and are now essential to the development and creation of research orders, ensuring accurate patient care and quality data collection. Prior to the initiation of the Research Order Committee in January 2014, Pharmacists were responsible for all aspects of research order creation. Often, order creation was delayed due to pharmacist workload, preventing timely study enrollment for potential patients. The Research Order Committee was designed to enhance collaboration, improve the efficiency of the order creation process, and has been implemented and utilized with great success.

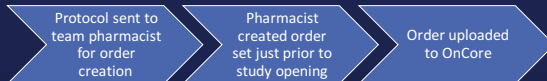
Methods: Following the establishment of the committee, clinical trials infusion nurses began creating the tables that outline patient care tasks and data collection time points as specified in research protocols. Nurses collaborate with pharmacists, coordinators and principle investigators to effectively translate all aspects of required care. A nurse representative attends each meeting ensuring consistent nurse input on each order set reviewed. In 2016, to further refine the order creation process and increase efficiency, the research order was split into two working documents: pharmacy order and nursing considerations. This substantially improved formatting and provided additional space for pertinent nursing care guidelines.

Results: With the new process in place, the time from Scientific Review Committee approval and committee notification to first draft creation decreased by 18 days (54%) and total time required for order completion and approval decreased by 52 days (55%) by 2017. Integrative and collaborative patient care is essential in clinical research but a challenge many large institutions struggle with in practice.

Conclusion: Oncology research infusion nurses have played an integral role in protocol order development, strengthening the multidisciplinary approach to clinical trials conduct. This new process of developing and managing all research nursing consideration documents has greatly improved quality and efficiency, ensuring trials open faster allowing patients more timely access to clinical trials.

Process Prior to Committee Creation

Scientific Review Committee approves protocol



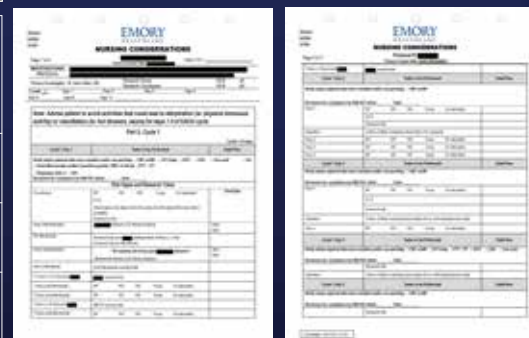
Research Order Committee Process



Results

Average Time from Notification for Order Creation to Final Upload to OnCore	
2013	7 months
2014	4-5 months
2015	4 months
2016	4 months
2017	2 months

Example of Nursing Considerations Document



Conclusions

- Creation of separate pharmacy order and nursing considerations documents allows for improved formatting and inclusion of pertinent patient education, drug administration and protocol guidelines
- Developing the position of the committee nurse lead improved communication, consistency and productivity
- Effective and efficient order creation improves timely study enrollment

Opportunities for Continued Growth:

- PI response rate for approval
- Editing process after first draft creation
- Follow-up and execution of edits due to protocol amendments
- Dedicated time for RN staff to work on orders

Average Number of Days for Order Approval Process 2016-2017

Year	# of Studies	Days from Notification to first draft submission date	Days from committee notification to first draft reviewed in committee or out of committee	Days from committee notification to send to PI	Days from CTIC notification to OnCore upload
2016	41	39	85	62	116
2017	31	21	26	23	64

Additional Abstracts

(alphabetical order by AACI cancer center, no posters available)

Additional Abstracts (alphabetical order by AACI cancer center):

Implementing and Adapting a Protocol Acuity Rating Scale (PARS) for Evaluating Workloads and Employee Effort at an NCI-Designated Cancer Center

Meghan Wakefield, BSN, RN; Nicholas Van Kuren, MS; Daniel Vernau, MS, CCRP; Dawn Poller

Sidney Kimmel Cancer Center at Jefferson Health

Describe the background of the problem:

Determining clinical trial complexity in terms of coordination and management using objective data is a longstanding issue in oncology clinical trial research operations. As a trial manager, grading the level of trial acuity prior to its activation is one struggle; the dual coordination of managing the complexity of the trial and the coordinator during the life of the trial is another. This industry is familiar with the evaluation of clinical trials for feasibility, efficiency, resource planning and trial selection. But, what if we merged the clinical trial assessment score with employee effort to see whether the data generated highlights a protocol issue or an employee issue, or potentially both? So far, oncology clinical trials management has not identified a tool that can provide data that compares trial acuity to employee effort.

Provide metrics or goals to be achieved:

- Develop an analysis tool to compare and evaluate staff self-reported effort against the scores generated from the algorithm.
- Create an algorithm for evaluating and scoring workloads of clinical research staff across protocols and disease teams.
- Automate reporting through enterprise dashboard tools that allow insight into staff self-reported effort and the scoring system metrics.
- Utilize these reports as project management tools to allocate existing staff resources and evaluate future staffing needs based on pipeline.
- Determine the meaningfulness of the PARs score.

Describe the solutions or methods implemented:

Adapted and augmented with permission from Christina Talley, MS, RAC, CCRP, CCRC, a new scoring model based upon the Protocol Acuity Rating Scale (PARS) was created, specifically tailored for oncology clinical trials research. The tool evaluates workload complexity at a trial level based on the following criteria: Phase, complexity of treatment, participant setting, data requirements, monitoring oversight, encounter procedure, lab samples, encounter frequency, study duration, screening effort, and patient activity. We customized the scoring criteria to reflect nuances that arise within oncology research. This pilot included approximately 60 trials across three disease groups, three project managers (PM) and 12 clinical and data coordinators. Automated monthly reports are distributed to the PMs for review of PARs scores and coordinator effort. Scores were adjusted at least monthly to provide real time assessment based on variable protocol changes.

Describe the outcome or show data representing a change (positive or negative):

This customized PARS score forecasts not only trial complexity for workload distribution but includes employee effort data to illustrate correlations between protocol scores and effort. It is a project management tool to analyze trial acuity, as well as potential retraining needs including but not limited to: time management, good clinical practices, and protocol specific training. Using the PARS scores allows project managers to have conversations with coordinators to create equitable distribution of work, high quality data and performance, and staff satisfaction. It also allows fact driven discussions related to protocol portfolio planning and hiring needs with principal investigators, cancer center leadership and administrators.

Address lessons learned and future directions:

With the current project in pilot status and released to a limited number of groups, one challenge is aligning PARS score definitions across disease groups and coordinator skill level. The PARS score definition, or meaning, requires some level of analysis from the project managers to derive meaning in comparing the score with effort. We hope that after several months of utilizing the reports, the scores will become intuitive to use as a project management tool for the disease group managers.

Additional Abstracts (alphabetical order by AACI cancer center):

Improving Timelines When Days Matter: Enhancements to Compassionate Use Submissions

Melissa R. Haley; Brett Ramsey, MBA, CCRP

Siteman Cancer Center

Describe the background of the problem:

When cancer patients are out of standard options for treatment and a drug not yet approved by the FDA is made available by the manufacturer, the FDA allows this treatment through its expanded access program. This so-called “compassionate use” process, while not actually research, requires a submission to the FDA and IRB. This process is similar to research studies, therefore, submissions frequently falls to research staff to complete at our institution.

However, uncommon and unfamiliar, this process can become complex, especially as different manufacturers have different requirements for their programs. Moreover, patients requiring this treatment are often critically ill, consequently any delays caused by mishandling documents, redundant efforts, or incomplete information can become a matter of life and death.

Provide metrics or goals to be achieved:

Over the past five years, 68 requests were made, with 42% of them (n=29) resulting in successful treatment of a patient. Although difficult to compare across different drugs, prior process requests took nearly a week to compile all information required for submission. Adding complication, these issues the lack dedicated staff or delegated responsibility. Furthermore, without an overview of needs for the entire process, parts of requests happened sequentially instead of simultaneously. Before this process was implemented, the average turnaround time was 40 days, with a median of 31 days.

The goal is to make the submission process and the responsibilities thereof more transparent, creating a more efficient course and reducing the timeline from initial request to treatment.

Describe the solutions or methods implemented:

Increased collaboration between groups led to a number of individuals being designated for these submissions,

which allowed a direct flow as staff grew accustomed to the process. A flowchart was created so that those involved knew the entire workflow requirements. Clinical staff were assigned with compiling patients’ history. CRAs were responsible for collecting any other aspects of the request: lab flowsheets, MD’s CVs and licenses, dosing information, signed paperwork, and eliminating PHI. Once the request was submitted to the sponsor, CRAs coordinated with Regulatory, Contracts, Pharmacy, and Orders teams as needed. Combining the flowchart with universal instructions streamlined and clarified the process, proving vital for the expedition of care for patients in exigent circumstances.

Much of this process improvement, division of labor, and information collection has been facilitated using a submission tool. Using the FDA guidance Individual Patient Expanded Access Applications: Form FDA 3926, a document was created to capture all information needed for FDA and IRB approvals (see attached).

Describe the outcome or show data representing a change (positive or negative):

When utilizing the tool we have an average IRB and FDA approval within two days of submission. This has translated directly into patient benefit as we were able to obtain drug and administer within 21 days of the initial notification from physicians.

Address lessons learned and future directions:

Prior to utilizing this document, we were trading many emails to gather information from several different sources (study coordinators, nurses, and treating physicians). This tool allows the regulatory coordinator to create the submission documents for the FDA and IRB submissions in less than an hour.

Developing a Multi-Institutional Program for Investigator-Initiated Trials

Kati Kremer, CCRP; Brett Ramsey, MBA, CCRP; Erin Kelleher

Siteman Cancer Center

Describe the background of the problem:

With the single IRB mandate coming into effect in 2020, the need for a centralized program to manage the SOPs, communication and collaboration for multi-institutional investigator-initiated trials is critical. Our Department of Medical Oncology has 19 actively enrolling investigator-initiated therapeutic trials designated as multi-center, 16 of which have 1 to 15 secondary sites. Each PI independently runs their trial within the respective disease site teams. This has produced an inconsistent program as each team has varying definitions of the roles and expectations for all involved collaborators. The cancer center supports limited auditing of these trials, conducted remotely on 10% of patients 1-2 times per year. Even these limited audits have shown the complexity of oversight of multi-center trials: maintaining regulatory paperwork, effective and regular communication and ensuring accurate data to name a few.

Provide metrics or goals to be achieved:

The department has formally decided to centralize and develop an infrastructure to maintain proper oversight of the multi-center program at both its current and future state. We will:

1. Consolidate the 10 existing, informal policies amongst each PI into a single, formal SOP to establish consistency and to provide a framework for oversight support.
2. Clarify and define roles to leverage resources and set expectations for all centers.
3. Establish a risk-based quality assurance program built to perform a minimum of 10% source data verification on strategic data points which contribute to high protocol, data integrity and patient safety.
4. Provide consistent communication and an education system to maintain effective relationships with all 38 collaborating centers.

Describe the solutions or methods implemented:

To inform the development of the multi-center program, we have conducted a baseline assessment of the 16 trials which encompass 10 PIs and 38 partnering institutions. Through 12 interviews with the disease teams the following non-inclusive solutions were repeatedly proposed and directly align with our objectives:

- Standardize all aspects of a multi-center trial through a single SOP and training program.
- Promote clear communication through a monthly meeting for all coordinating center site staff and maintain a central, web-based platform for collaborating centers.
- Define roles and expectations, adding a project manager for each trial as appropriate.
- Develop source document and data entry guidelines, timelines and delinquent data escalation algorithms to eliminate recurring data issues with participating centers and promote real-time monitoring.

Describe the outcome or show data representing a change (positive or negative):

By recruiting CRCs during the baseline interviews, we have aggregated ideas across the program, generated support and gathered data to establish the size of the problem, which is larger in scale and requires more PI engagement than anticipated. The scale of the issue is driving the creation of a risk-based algorithm for directing resources.

Address lessons learned and future directions:

Engaging and obtaining the support from the CRCs and PIs in the development of this program remains critical. Appropriate oversight will be trial dependent. We will redefine our scope and direct our resources to the top 3 trials that are in the greatest need of this program. After assessment of vulnerabilities, a study-specific, risk-based oversight plan will be developed and executed with the PI.

Additional Abstracts (alphabetical order by AACI cancer center):

An Evaluation of Protocol Availability to Increase Minority Participation on Clinical Trials

Jessica Thein

Siteman Cancer Center

Describe the background of the problem:

The paucity of minority participation in clinical trials is a highly pervasive issue that introduces two critical issues: scientific rigor and equity. We conducted a needs assessment to determine if protocol availability contributes to disparate rates of clinical trial participation. Using the results of the assessment, we implemented steps to address gaps in the protocols available at SCC. We noted a particular challenge of minority accrual in our gynecology (GYN) protocols. Therefore, we piloted this analysis within our GYN oncology department.

Provide metrics or goals hoped to be achieved with the solutions to address the problem:

An increase in the total number of minority patients enrolled on our GYN protocols.

Describe the solutions or methods implemented:

We conducted the needs assessment in three distinct phases:

1. We identified key eligibility criteria of all protocol open to enrollment during a three-month study period. Criteria included disease site and histology, stage, presence of brain metastases, treatment history, and commonly excluded comorbidities.
2. We conducted a chart review of patients diagnosed with a GYN cancer requiring treatment to extract information specific to the criteria noted above.
3. We then identified the patients seen in our clinic that did not have a protocol available to them.

Based on the results of the assessment, we opened additional trials that would address the needs of these patients.

Describe the outcome of the solutions implemented or show data representing a change whether positive or negative:

During the evaluation period,

- 20 interventional therapeutic protocols were open to enrollment
- 189 minority patients and a random sample of 189 non-minority were included in this analysis
- Of these, 100 patients (54 minority and 46 non-minority) had a confirmed GYN diagnosis requiring treatment.
- Through a multistep analysis, we realized that we could increase overall accrual, and particularly minority accrual, by opening uterine trials.
- Two uterine trials were opened in late 2016 and early 2017.
- A recent assessment of minority accrual to GYN protocols showed that minority accrual in 2017 was 3 times higher than in 2016. The percent of minority patients enrolled increased from 9% in 2016 to 23% in 2017.

Show lessons learned, others to involve in the future, changes to the methods to achieve a better outcome:

This process proved to be effective at identifying gaps in our protocols portfolio. We were able to determine and implement specific protocols that would provide the largest benefit for racial and ethnic minorities seen at our center. One limitation is that we did not review charts for patients seen by all of our GYN oncologists. Future studies will be conducted using electronic health record that will allow a comprehensive assessment of the alignment between the center's protocol portfolio and the needs of its patients.

Improving FDA Audit and Monitor Visit Outcomes by Aggregating Knowledge, Experience, and Common Findings

Sarah Uffman; Brett Ramsey, MBA, CCRP

Siteman Cancer Center

Describe the background of the problem:

The Division of Medical Oncology has 438 actively accruing clinical trials spread amongst 13 disease teams. Disease teams work independently without a formal system for sharing information among teams, particularly with audit and monitoring findings. For “Phase 1” of this project, we tackled the following issues:

1. Preparation for FDA inspections relies on an individual’s expertise and a checklist. For example, each of our last three FDA inspections were coordinated by a different person. An audit prep plan and best practices document brought consistency and guidance to this process.
2. Audit and monitor findings have been traditionally compartmentalized to each disease team and have failed to take advantage of our group’s scale, potentially shrouding systemic problems. For instance, we averaged approximately 40 monitor visits per week in the first quarter of 2018 with the outcomes of those visits filed separately. A system for aggregating information from these monitoring letters allow us to identify issues early and proactively improve processes.

Provide metrics or goals to be achieved:

1. A consistent process for FDA audits, including:
 - 1.1. Audit prep and identifying team member roles
 - 1.2. A checklist for preparing for the audit
 - 1.3. Methods for organizing the materials for review
 - 1.4. Post-audit communications & information sharing
2. Identify and categorize common findings in monitoring letters and internal and external audits
 - 2.1. Use findings to determine if the errors occurred on an individual or process level, and respond accordingly

Describe the solutions or methods implemented:

We discussed with teams their process to prepare for an FDA audit and drafted a plan that covers:

1. Who should be directly involved with the audit
2. Assigning responsibilities:
 - 2.1. Preparing materials to be reviewed
 - 2.2. Reviewing patient documents for completeness and organization
 - 2.3. Who should be present for the audit vs. who should be “on call”
 - 2.4. Coordinating audit response
3. Helpful hints/best practices

We review past findings to prepare for future audits by compiling observations from internal and external audits and monitoring letters. Findings are placed into categories which we use to identify common findings and track trends. This information is shared with division leadership to determine what, if any, action should be taken.

Describe the outcome or show data representing a change (positive or negative):

The outcomes we anticipate:

1. A consistent and efficient division-wide audit process
2. Improved management of studies with fewer audit findings
3. Improved coordinator/monitor communications

Address lessons learned and future directions:

1. Many processes are driven by Principal Investigator
 - 1.1. Must strike a balance between allowing/encouraging involvement and asking PI to leave their own methods behind
2. Difficult to require consistency between teams due to difference in treatment type, diseases
3. Challenge to change process, especially when the stakes are high

Future directions include:

1. Development of best practices for preparing for sponsor audits
2. Look more closely at specific study types and/or sponsors with repeat/continual findings
3. Identify areas with high risk to compliance issues
4. Development of a formal method for communicating noncompliance issues

Additional Abstracts (alphabetical order by AACI cancer center):

Reducing Protocol Activation Times Through Centralization of Study Start-Up Tasks

Rosa Hsieh, MS, RAC, CCRP; Andrew Nilson

Sylvester Comprehensive Cancer Center, University of Miami Health System

Describe the Background of the Problem:

Timely protocol activation is critical for maintaining a positive relationship and reputation with Sponsors, as well as high site desirability for coveted sponsored trials. Furthermore, activation metrics are highly scrutinized by the NCI in grant applications, with a gold standard of 90 days. Unfortunately, many academic medical centers suffer from activation times significantly higher than the expectations of the Sponsors and NCI.

Provide Metrics or Goals to be Achieved:

The primary goal is to reduce overall protocol activation times by achieving the following:

1. Reduce PRMC1, IRB2, IBC3, chemotherapy order set, and budget/contract turnaround times
2. Streamline processes to allow for concurrent study start-up activities
3. Maintain consistency and increase quality of regulatory submissions and budgets/contracts

Describe the Solutions or Methods Implemented:

A multi-prong approach was taken:

1. Centralization of regulatory-related tasks with two dedicated Study Start-up Analysts to reduce turnaround times and uphold quality submissions and initial regulatory documents
2. Centralize all cancer-related studies to one IRB Board and dedicate two IRB Analysts to reduce submission times and allow for consistency in reviewer/board/analyst expectations
3. Commencement of chemo order set development immediately after PRMC approval, and requirement that Sponsors participate in a virtual "pharmacy SIV" to clarify any questions early-on in the start-up process

4. Centralize budget development and negotiations with two dedicated Budget Analysts and one dedicated Contract Analyst to optimize budget development and contract negotiations

Protocol activation milestones were established (e.g., 30 days from IRB submission to approval), and a homegrown tracking system developed to capture the dates. The system tracks all relevant start-up dates and provides automated alert to stakeholder when a milestone approaches or exceeds the deadline. Furthermore, auto-generated weekly reports identify upcoming and/or past due milestone dates.

Describe the Outcome or Show Data Representing a Change (Positive or Negative):

Study Start-Up Activity	Change
PRMC	Decrease in turnaround time
IRB	Decrease in turnaround time
IBC	Decrease in turnaround time
Chemo Orders	Not enough data
Budget	No significant improvement
Contract	Decrease in turnaround time

Address Lessons Learned and Future Directions:

Lessons Learned –

1. For successful reduction of overall protocol activation time, the realistic capacity of all relevant parties needs to be accounted for ("capacity alignment"). Must lower the rate of new protocol submissions to that of the limiting factor and/or provide additional resources to that limiting entity. At our institution, the limiting factor was budget negotiations, and we implemented both approaches to achieve a reasonable rate of submissions that would allow for better activation metrics while also maintaining a robust portfolio to serve our patient population and enough studies for fiscal sustainability.
2. While centralized tracking of protocol activation sub-process milestones is useful, a dashboard that allows for filtering and sorting of all studies by type is key to maximizing a system's use. The system should allow aggregate and real-time reporting of metrics, identification of current study status, and a field to capture the primary reason for delay will help to easily discern where the most problematic issues are.

Future Plans – The goal is to increase the rate of new protocol submissions while maintaining quality and acceptable activation metrics and not requiring additional headcount.

Regulatory Document Access: Assessing Value Among Study Stakeholders

Andrew Nilson¹; Rosa Hsieh, MS, RAC, CCRP¹; Helen Peck, RN, MA, OCN, CCRP¹; Michael Hurley, MBA²

¹Sylvester Comprehensive Cancer Center, University of Miami Health System; ²Complion

Describe the background of the problem:

Clinical research studies involve collaboration amongst several study stakeholders, each of which need access to documentation and information to perform their study-related tasks. Like most institutions, the Sylvester Comprehensive Cancer Center (SCCC) utilized a hybrid system, consisting of paper binders and shared network drives, to manage regulatory documents. This approach to document management creates redundancy when an individual or department independently saves a duplicate copy locally, consequently increasing the risk of accessing an outdated or incorrect version. Further inefficiencies and compliance issues occur with obtaining wet-ink signatures on key regulatory documents, as this time-intensive process allows for less control and visibility over the status or location of documents sent for signature, particularly between satellite sites. Hybrid document systems and wet signature processes result in ineffective collaboration between departments.

Provide metrics or goals to be achieved:

The goal of this project is to assess how a centralized approach for accessing regulatory documents brings value to different departments and other study stakeholders. To do this, we will:

1. Identify all study stakeholders, and illustrate how collaboration influences the conduct of research.
2. Survey study stakeholders regarding their ability to have direct access regulatory documents to:
 - a. Quantify the frequency of regulatory document access
 - b. Quantify and rank the value received from regulatory document access
 - c. Identify areas of concern from regulatory document access
 - d. Identify areas of risk from not having access to regulatory documentation
3. Correlate data with clinical departments, experience and workload

Describe the solutions or methods implemented:

SCCC implemented an enterprise-wide electronic regulatory (eRegulatory) system to manage electronic documents and signatures. Leadership identified stakeholders that routinely collaborate with the regulatory department, or require regulatory information to fulfill their responsibilities, and granted direct access to the eRegulatory system. Specific permissions determine who can view, download or export documents. Granular levels of document control enable stakeholders to independently, quickly search and retrieve current and correct records, while precluding access to those that are inactive, archived or confidential.

Describe the outcome or show data representing a change (positive or negative):

Quantitative data will demonstrate areas of value as perceived by each study stakeholder, including:

- Increased efficiency when retrieving regulatory information
- Improved collaboration and reduced redundancy
- Enhanced transparency and oversight over research activities
- Reduced risk of accessing the incorrect version of a document
- Real-time ability to identify who has been trained and delegated
- Streamlined execution of electronic signatures and approvals

Address lessons learned and future directions:

Assigning a dedicated Project Manager to oversee the implementation of an eRegulatory system will help to develop a robust change management plan and ensure the organization meets project deadlines and milestones. Dedicate a significant amount of time (several months) to the system's configuration and separate the implementation process into phases: (1). Creation of electronic study binders, (2). Migration of all documents, (3). Migration of data sources and user group access, and (4). Quality review and functionality test.

Additional Abstracts (alphabetical order by AACI cancer center):

Addressing the Unpredictable: Disaster Planning for a Large Academic Clinical Trials Office

Helen Peck, RN, MA, OCN, CCRP

Sylvester Comprehensive Cancer Center, University of Miami Health System

Describe the background of the problem:

Preparedness planning for severe weather emergencies is multifaceted, requiring communication and collaboration across institutional departments. For most anticipated weather events such as hurricanes, emergency procedures are well established and initiated in advance. However, extensive post-event procedures are rarely included in 'preparedness' planning, necessitating 'just in time' dynamic decision-making and management. This abstract describes pre-event operating policies for disaster planning and discusses unpredictable post-event challenges, to provide a new focus on preparedness, using operational complications and questions presenting after Hurricane Irma.

Provide metrics or goals hoped to be achieved:

- Facilitate communication with all stakeholders
- Reschedule all protocol patient appointments
- Documentation of the event for future reference
- Protection of data and equipment
- Safety of all staff

Describe the solutions or methods implemented:

- Frequent and detailed communication with clinical trials office (CTO) personnel, Sponsors, Principal Investigators, Chemotherapy Treatment Unit (CTU) staff, Investigational Pharmacy staff and patients
- Centralized information detailing upcoming protocol patient schedules
- Contact details for all CTO personnel updated and distributed
- CTO telephone communication tree established
- Distribution of supplies to protect office equipment

- CTO disaster line activated
- Information posted on Sylvester CTO Facebook page
- Remote access to protocol documents and patient information

Three days prior to closure of the medical campus, daily telephone conferences were initiated between CTO Management, (CTU) charge nurse and Investigational Pharmacy Director. The goal of the teleconferences was to assess capacity, prioritize and reschedule patient treatment visits pre and post campus closure.

Describe the outcome or show data representing a change (positive or negative):

The disaster planning was efficient and successful. All patients were rescheduled, communication with Sponsors, patients and Principal Investigators was effective. CTO staff were dismissed Wednesday September 6th 2017. A skeleton team coordinated patient appointments on Thursday morning. Medical campus was closed on Thursday September 7th. Over the ensuing days, all incoming questions were triaged through the CTO dedicated disaster line; the CTO telephone tree was effective and despite a variety of complicated evacuations, the CTO Management team maintained close contact.

Returning to work post event presented the following challenges:

- Return travel to Miami for evacuated staff was impeded with closure of local airports, flight cancellations and high demand for seats
- Return travel by road was hindered by gas shortage, fallen trees and flooding, and imposed night-time curfews
- Areas of Miami were closed to resident return (Miami Beach) due to downed power lines

- Staff experienced damage to their personal homes, cars and widespread neighborhood power and water outages, and lacked viable public transport networks
- Patients experienced the same problems as staff
- Schools were closed creating childcare problems

Problems related to protocol deviations, documentation of the event and confirmation of Investigational product storage and availability were also identified. In addition, HR concerns related to management of CTO staff availability and compensation presented unanticipated procedural questions.

Address lessons learned and future directions:

Careful and detailed planning was initiated to prepare for the imminent hurricane. However, limited plans were made for return to operations after the event. In conclusion, preparing for an impending weather-related or natural disaster with developed SOPs and well-documented work instructions is a necessity, however it is equally important to pay attention to processes required for normalizing clinical and business operations in the immediate aftermath.

Overcoming Regulatory Staffing Challenges

Melissa Field, CCRP

The University of Kansas Cancer Center

Describe the background of the problem:

Career growth and employee job satisfaction can be challenging for an academic-based Clinical Trials Office (CTO), especially during periods of exponential growth. Regulatory department directors can face:

- Limited budget to offer competitive salaries.
- Competitive research job markets.
- The ongoing need for process improvement.
- Inadequate training materials.
- Overburdened regulatory staff.

Provide metrics or goals to be achieved:

Two core goals were identified to simultaneously address the challenges:

- The first goal was to re-organize the staff's roles and responsibilities.
- The second goal focused on standardizing processes across the department.

Describe the solutions or methods implemented:

The first goal began in 2013 with the regulatory department re-organization. The department director re-aligned the team as either start-up specialists or maintenance coordinators. Next, each staff member was assigned to focus on either Industry trials, NCTN trials, or Investigator Initiated Trials. This specialized structure allowed personnel to become proficient in addressing the nuances of a specific type of trial design and provided growth opportunities. This re-organization transformed the global responsibility matrix (all study types and phases being assigned to each regulatory coordinator) to a more defined and focused structure. In 2015, the structure further expanded with the additional tier of an aligned manager within each study type category.

The second goal began in 2015 with a focus on staff instructions and training needs. The department managers created official sets of internal departmental checklists, which clearly defined and standardized processes across the department. These checklists were easy to follow, and visually appealing with the use of divided steps and flowcharts. They were also inclusive enough to provide necessary steps for each task.

Describe the outcome or show data representing a change (positive or negative):

Focusing on the two core goals allowed the department to more easily address other issues. In addition, these solutions paved the way for future efficiency endeavors.

Address lessons learned and future directions:

When a CTO grows rapidly, organizational standards for task completion is key. Additional considerations CTO management should consider when contemplating similar actions include:

- Staff are not always comfortable with change. Therefore, keeping communication open and providing encouragement can assist with implementation strategies.
- This is not a fast effort. Expect delays.

Issues Supported with Core Goals	Goal #1 - Specialized Department Structure	Goal #2 - Concise Task Instructions
Staffing <i>Limited budgets, Competitive job markets, and unchallenged or unsatisfied staff.</i>	<ul style="list-style-type: none"> • Promoted internal job growth • Attractive to external candidates with research experience 	<ul style="list-style-type: none"> • Provided dept. consistency • Provided option to hire administrative employees and train them into research.
Efficiency & Training Expectations <i>Continual process improvements, Inadequate training materials, and Inundated regulatory staff.</i>	<ul style="list-style-type: none"> • Provided feedback needed by empowering each group to focus on their own improvement needs. • Provided more management support when implementing other major improvements 	<ul style="list-style-type: none"> • Mandated managers to revise instructions when changes occurred, which allowed more time to reflect on the benefit. • Required in-person training sessions for changes (instead of email distribution of information). • Allowed more discussion and granular views to eliminate extra effort. • Better identified staff who may need more training.

Additional Abstracts (alphabetical order by AACI cancer center):

Clinical Trials Office Change Management in a Diverse Network Landscape

Kate Bryant-Greenwood, JD, CCRP

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

Describe the background of the problem:

Implementing process improvements and change management within a Clinical Trials Office poses a heightened challenge within the context of the University of Hawaii Cancer Center's network environment. The University of Hawaii Cancer Center (UHCC) does not have a University hospital or ambulatory care facility. All clinical research is conducted at community sites with community and UHCC-affiliated physician investigators. These community sites are affiliated with UHCC through the Hawaii Cancer Consortium/network. Data management, regulatory activities, contracting, and quality assurance are centralized at UHCC and require coordination across the larger network. To implement successful initiatives such as Clinical Research Associate (CRA) productivity mapping and CRA re-assignment, multiple variables must be considered and the diverse oncology landscape offers an additional layer of challenge.

Provide metrics or goals to be achieved:

1. Identify and recreate successful existing partnerships at community clinic sites between Consortium research nursing staff (non-UHCC CTO employees) and UHCC CRA's
2. Utilize OnCore (Forte Systems, Madison, WI) to effectively map CRA effort in screening and enrolling patients on trials
3. Initiate a system of scoring all trials in terms of complexity in order to establish standardized CRA performance metrics
4. Evaluate each CRA based upon an additional Consortium/network score, effectively rating the complexity of a CRA's work environment (i.e. Single UHCC CRA assigned to a private office vs 2 UHCC CRA's assigned to a private office vs Single UHCC CRA partnered with a non-UHCC research staff)

Describe the solutions or methods implemented:

Although goals 1-4 above are in an early phase of implementation, several items have been completed as prerequisites prior to implementing changes within the UHCC CTO: 1) Creation of an assignment map for all CRA's covering current clinic locations; 2) Creation of an OnCore team consisting of the OnCore Coordinator, Manager, Medical Director, and two lead CRA's to guide the use of OnCore for effort mapping; and 3) Engaging UHCC human resources to map current UHCC CRA positions with regard to level, compensation, and salary history.

Describe the outcome or show data representing a change (positive or negative):

With the abovementioned efforts made thus far, the foundations have been laid to drive a cultural shift towards that of increased accountability, effort tracking, and an overall results-oriented program. The CTO leadership team has identified the necessity for building a purposeful change and transition plan while ensuring consistent messaging throughout the process. Part of the change plan includes sharing parts of the CTO organizational change efforts with UHCC's Consortium/network partners in order to foster relationships between institutions and to increase transparency.

Address lessons learned and future directions:

With the beginnings of UHCC CTO organizational change in place, the CTO leadership will communicate strategies with the entire team, engage lead CRA's in the decision-making process, and ensure that everyone has an opportunity to play a part in the transition process.



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