AACI CRI

Association of American Cancer Institutes
CLINICAL RESEARCH INITIATIVE

9TH ANNUAL MEETING

MOVING SCIENCE FORWARD

2017 ABSTRACTS AND POSTERS

Table of Contents

9th Annual AACI CRI Meeting Abstract Overview 1

9th Annual AACI CRI Meeting Summary 2

CRI Steering Committee 3

2017 Winning Abstracts and Posters

First Place
Ensuring PEAK Training and Compliance in Cancer Clinical Trials
Richa Upadhyay, MD; Lediona Ardolli, MA; Rosemarie Gagliardi, MPH, cEdD; Donna Berizzi, RN, MSN, OCN; Matthew Galsky, MD; Chari Ajai, MD
The Tisch Cancer Institute at the Mount Sinai Health System
Abstract 4
Poster 5

Second Place
Improving Reproducibility of Quantitative Imaging Endpoints
Daniel C. Sullivan, MD[1]; Michael Boss, PhD[2]; Thomas L. Chenevert, PhD[3]; Edward F. Jackson, PhD[4]; Alexander Guimaraes, MD, PhD[5]
[1]Duke Cancer Institute, Duke University Medical Center; [2]National Institute of Standards and Technology; [3]University of Michigan Comprehensive Cancer Center; [4]University of Wisconsin School of Medicine & Public Health and Carbone Cancer Center; [5]Knight Cancer Institute, Oregon Health & Science University
Abstract 6
Poster 7

Third Place
Improving Protocol Activation Times via Automation and Centralization
Helen Peck, RN, MA, OCN, CCRP[1]; Joanne Mancini, RN, CCRP[2]; Cathy Galasso, RN, OCN, CCRP[2]
[1]Sylvester Comprehensive Cancer Center, University of Miami Health System; [2]Barbara Ann Karmanos Cancer Institute, Wayne State University
Abstract 8
Poster 9

Submitted Abstracts (alphabetical order by cancer center):

Adapting to Thrive—Risk Based Monitoring of Academic Institutional Investigator Initiated Clinical Trials
Daniel Otap, CCRP; Fran Brogan, MSN, RN; Moshe Kelsen, MBA; Lauren Blumberg; Jennifer Wang, MS; Tiffany Negri, CCRP; Shannon Kelly; Tasha Isles Smith, MA, MPH; Stephen Emerson, MD, PhD; Andrew Lassman, MD, MS; Joseph Jurcic, MD
Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center 10

"If You Build It, They Will Come." — Creation of a Dedicated Oncology Clinical Research Infusion Center
Frances Brogan, MSN, RN; Fawzia Ibrahim; Ryan Shelton; Caryn O'Mullane, RN, MSN, MBA; Moshe Kelsen, MBA; Andrew B. Lassman, MD, MS; Stephen Emerson, MD, PhD; Gary Schwartz, MD; Richard Carvajal, MD
Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center 11

Development of a Streamlined Process to Collect Fresh Biopsy Specimens to Send Out for Clinical Trial Screening
Joni Harris, MS, CCRP
Hollings Cancer Center, Medical University of South Carolina 12

Converting to Electronic Regulatory Binders and the Great Scan
Curt Hampton, MBA, MS; Jessica Moehle, CCRP; Lindsey Byrd, CCRP
Huntsman Cancer Institute, University of Utah 13

Integrating a Clinical Research Nurse Program at an Academic Cancer Hospital
Kristin Maloney, RN, BSN, OCN
Huntsman Cancer Institute, University of Utah 14

Promoting Comprehensive Site Policies and Limiting Industry Overreach
Lindsey Byrd, CCRP; Jessica Moehle, CCRP
Huntsman Cancer Institute, University of Utah 15

All submitted abstracts and posters are available at **http://www.aaci-cancer.org/cri_meeting/2017_abstracts.asp**

Using the Epic EMR for Research Documentation
Rachel Kingsford, MS, CCRP; Jessica Moehle, CCRP; Leanne Lujan, CCRP; Lindsay Carpenter, MSW, CCRC; Sally Fairbairn, CCRP; Susan Sharry, CCRP; Karthik Sonty, CCRP; Theresa L. Werner, MD
Huntsman Cancer Institute, University of Utah 16

Improving Study Activation Timelines: Establishing Flow
Erica Love, MA, MPH, CCRP[1]; Paul K. Davis, KMP[2]; Nida Cassim, MPH[1]; Anna Pavlick, DO, MBA[1]
[1]Laura and Isaac Perlmutter Cancer Center at NYU Langone; [2]Essex Management 17

Development of a Complexity Assessment for Clinical Trials
Alexa Richie, DHSc; Jennifer Lineburg; Andrea Tavlarides, PhD; Dale Gamble, MHSc; Susan Rogers; Carol Griffin
Mayo Clinic Cancer Center 18

Improving Research Lab Sample Tracking and Cost Recovery by Implementing a Web-based System
Wes Rood; Megan Koceja; Brenda Brito; Betty Oleson, BSN, RN, CCRP; Rebecca Selle, CCRP; James Thomas, MD, PhD
Medical College of Wisconsin Cancer Center 19

Not All Tumors Are Created Equal: Evaluating the Impact of an Interdisciplinary Molecular Tumor Board
Allison Martin, PharmD; Ben George, MD; Elizabeth Weil, PharmD, BCOP; Angela Urmanski, PharmD, BCOP; Katrina Schroeder, RN, OCN, CCRP; Kayla Mendenhall, CPhT; Mindy Waggoner, PharmD, BCOP; Carolyn Oxencis, PharmD, BCPS, BCOP
Medical College of Wisconsin Cancer Center 20

They Talked the Talk…But Can They Walk the Walk? Implementing a Written Test During Candidate Interviews for Clinical Research Coordinators and Assistants
Rebecca Selle, CCRP; James Thomas, MD, PhD; Betty Oleson, BSN, RN, CCRP
Medical College of Wisconsin Cancer Center 21

Best Practices to Achieve a Successful FDA Inspection
Susan Puleio, CCRP; Veronica Tomaselli
Memorial Sloan Kettering Cancer Center 22

The Research Council: Developing & Implementing Institutional Policy for Clinical Research Portfolio Management
Sara Hanley, MSW; Xhenete Lekperic; David Spriggs, MD; Ann Rodavitch, MA
Memorial Sloan Kettering Cancer Center 23

Clinical Research Office Monthly Lecture Series
Cindy Wynne-Jones, RN, CCRC; Erin Williams, MBA
Simmons Comprehensive Cancer Center, UT Southwestern Medical Center 24

Coordinators Asked, We Answered: The New Clinic Coordinator Education & Training Program
Emily Hawkins, CCRP; Elizabeth Menne, RN; Maria Westfall, CCRP
Siteman Cancer Center 25

Improving Protocol Activation Times via Automation and Centralization
Helen Peck, RN, MA, OCN, CCRP; Andrew Nilson, BHA; Simmy Thompson, MPH, CIP, CCRP; Rizalia Rivera Cvijovic; Michael A. Samuels, MD; Jonathan Trent, MD, PhD
Sylvester Comprehensive Cancer Center, University of Miami Health System 26

Minimizing Information Redundancy Across the Institution and Improving Quality with Regulatory Document Management
Andrew Nilson[1]; Rosa Hsieh[1]; Cristina Ferrazzano Yaussy, MPH, CCRP[2]; Tom Battle[2]
[1]Sylvester Comprehensive Cancer Center, University of Miami Health System; [2]Complion, Inc. 27

Resource Allocation Review — 2 Year Analysis of Protocols Open to Enrollment at Least 1 Year
Rosemarie Gagliardi, MPH, cEdD; Ariel Hosey; Lediona Ardolli, MA; Catherine Raimond; Richa Upadhyay, MD; Paula Klein, MD; Ajai Chari, MD; Matthew Galsky, MD
The Tisch Cancer Institute at the Mount Sinai Health System 28

Data Reporting: A Simple Tool for Analysis and Forecasting Success
Andrea Skafel, MSc, CCRP; Wade Berry, CCRP; Mallory Kock, CCRP; Thomas Cunningham, PhD, CCRP
UCSF Helen Diller Family Comprehensive Cancer Center, University of California San Francisco 29

Objective Data Tracking Tool
Stefanie Belanger, CCRP; Stephanie Ladd, CCRP; Matthew Jansen, MS
UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill 30

Modeling AACI to Create a Problem Solving Culture within the University of Chicago Comprehensive Cancer Center
Lauren Wall, MS; Amanda Spratt
University of Chicago Medicine Comprehensive Cancer Center 31

Survey of Protocol Review and Monitoring Systems in U.S. Cancer Centers
Deborah H. McCollister, RN, BSN; Carrye Cost, MD; Ian Riley; Stephen Leong, MD
University of Colorado Cancer Center 32

First Impressions: Centralizing the CDA Process
Christine Mackay, RN, MSA, CCRP; Morgan Smotherman; Kathy Schleeter; Donna Palatas, JD; Claire Sabin Koenig, JD; Tiffany Pothapragada, PhD; Peter Griffith, JD
The University of Kansas Cancer Center 33

Learn-Inform-Recruit: Increasing the Offer of Urologic Cancer Trials in Community Practice
Christine Mackay, RN, MSA, CCRP; Andrew Zganjar, MD; Laurie Petty, PhDc; Mugur Geana, MD, PhD; Jessie Gills, MD; Tomas L. Griebling, MPH, MD; Brantley Thrasher, MD; Shellie Ellis, MA, PhD
The University of Kansas Cancer Center 34

Assessing Patients for Clinical Trials: An Evaluation of Radiation Oncologists at an NCI Designated Cancer Center
Mindi TenNapel, MBA, PhD; Christine Mackay, RN, MSA, CCRP
The University of Kansas Cancer Center 35

Streamlining Research Billing with Informatics Tools and Consensus Building
Umit Topaloglu, PhD; Terra Colvin, MS; Megan Brown; Jennifer Black; Jennifer Newsome; Stacey Lewis; Kim Sweat; Jennette Cossey; Selvin Ohene; Brooke Everhart; Robin Harrelson; Meredith Hiatt; Teresa Sells; Brian Strittmatter; Garland Kitts; Lynn Kennedy; Boris Pasche, MD, PhD; Stefan Grant, MD, JD, MBA
Wake Forest Baptist Comprehensive Cancer Center 36

Document Management Beyond Regulatory. Breaking Down Silos and Cultivating Effective Collaboration
Amy MK Rovitelli, MS, CHRC[1]; Tina Marie Bowdish, MS, CRCP, CHRC[1]; Tom Battle[2]; Cristina Ferrazzano Yaussy, MPH, CCRP[2]
[1]Wilmot Cancer Institute, University of Rochester Medical Center; [2]Complion, Inc. 37

Mastering the Delegation of Authority Log: A Centralized Approach to Maintaining Site Regulatory Documents
Stephanie Speaker, CCRP; Brittany Walker, CCRP
Yale Cancer Center, Yale School of Medicine 38

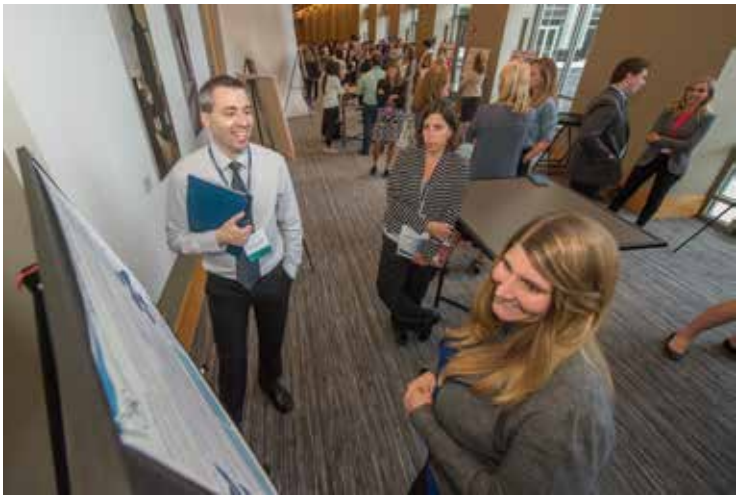
Realizing Rapid Review: Expanding the Use of a Clinical Trials Management System to Streamline the Protocol Review and Monitoring System
LaToya Howard, CCRP; Stephanie Speaker, CCRP; Alyssa Gateman, MPH, CCRP
Yale Cancer Center, Yale School of Medicine 39

9th Annual AACI CRI Meeting Abstract Overview

The Association of American Cancer Institutes (AACI) comprises 97 leading cancer centers in North America. AACI's membership roster includes National Cancer Institute-designated centers and academic-based cancer research programs that receive NCI support.

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. Examples of the 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 guides CRI's activities, leading to dissemination of best practice models across the AACI cancer center clinical trials network.

In January 2017, the AACI CRI Steering Committee issued a call for abstracts to AACI cancer centers for presentation at the 9th Annual AACI CRI Meeting, held July 12–13 in Chicago. The purpose of the abstracts is to inform the AACI CRI meeting audience about clinical trial operational problems and solutions implemented at the cancer centers to address them. The AACI CRI annual meeting is attended by clinical trials operations leaders and medical directors who convene to discuss common challenges. The AACI CRI Steering Committee received a record 33 abstracts and selected three for presentation at the meeting. All abstract authors were invited to submit posters for display at the meeting.



The abstract presentations and poster session were among the highlights of this year's meeting and provided opportunities for centers to further discuss concepts that are being explored and implemented at the cancer centers. The AACI CRI Steering Committee would like to thank everyone who submitted an abstract for review; the concepts demonstrated creative and thoughtful methods that are being employed at the cancer centers to address clinical trial process issues.

9th Annual AACI CRI Meeting Summary

Trial Management, Networks, Staff Retention Spark Interest at CRI Meeting

The Association of American Cancer Institutes' (AACI) Clinical Research Initiative (CRI) convened its ninth annual meeting in July in Chicago. The 2017 meeting covered two full days and was attended by more than 325 clinical research office leaders, medical directors, cancer center administrators, representatives from the NCI and industry.

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 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.

The meeting commenced with an inspiring keynote talk entitled, "Supporting Patients through Clinical Trials and Beyond," by Anna C. Beck, MD, who shared her unique perspective as both a cancer survivor and cancer physician. Dr. Beck described how her personal struggle with cancer has altered her views about her career path and how she is supporting cancer patients throughout their disease trajectory. She also discussed the impact her experience has had on her research and clinical leadership at Huntsman Cancer Institute.

Immediately following Dr. Beck's talk, a panel discussion tackled the challenges and solutions involved in managing clinical trials at affiliate sites. Presenters from three AACI academic cancer centers identified reasons for using affiliate trial sites, the criteria for selecting these sites, and the importance of building relationships, evaluating a site's readiness for trial participation and ways to monitor trial compliance and facilitate rapid data collection.

In a session focused on developing investigator-initiated trials (IIT), panelists explored challenges such as using multiple electronic data capture systems, bridging financial gaps when pilot or donor funding is limited, and navigating complex industry and clinical research organizational structures for junior faculty seeking to develop and conduct IITs.

Another topic of interest was staff recruitment and retention. Panelists from three AACI cancer centers presented insights into how their institutions have addressed staffing challenges, including using surveys to gauge employee satisfaction, analyzing workload metrics data, and assessing various staffing models.

Addressing recent revisions to NCI's Cancer Center Support Grant (CCSG) guidelines and P30 grant renewals, the panel included representatives from the National Cancer Institute (NCI) and two AACI cancer centers who had recently submitted their CCSG applications.

All submitted abstracts and posters are available at **http://www.aaci-cancer.org/cri_meeting/2017_abstracts.asp**

A representative from NCI also talked about steps being taken to use information from its Clinical Trials Reporting Program to complete "data table 4," part of the submission requirements for P30 grant renewals.

Another panel session focused on obstacles to developing centralized coverage analysis for multi-site clinical trials, including payers' interpretation of the rules for trial coverage, which can make developing an accurate trial billing grid and trial budget more complex. Best practices for developing a trial billing grid from the trial coverage analysis include utilizing electronic medical records, clinical trials billing applications and trial consent form language to enhance the work flow required for ensuring compliance and accurate billing.

Lastly, a panel discussion looked at how centers are minimizing non-value added activities, e.g., trial site initiation visits, serious adverse event reporting of nonreportable events required by trials sponsors, and the use of multiple sponsor portals for retrieving trial documents.

Meeting attendees also participated in a poster session featuring 29 posters, and abstract winners from three cancer centers presented their work on innovative approaches to regulatory operations, review of a new workload assessment tool, and how utilizing data from past trials can lead to realistic study budgets. A list of abstract winners and abstract titles, along with all submitted abstracts, are available at the CRI section of AACI's website.

This year's meeting breakout sessions topics included:

- A Deeper Dive into Managing Community and Affiliate Trials Sites
- Enhancing the Relationship between Medical Directors and CTO Administrative Directors
- Operationalizing Complex Clinical Trials Designs
- Research Center and Industry Staff Turnover and its Impact on Quality Data Capture
- The Burden of FDA Inspections

2017 AACI CRI Steering Committee Members

Paul J. Martin, MD – Chair
Fred Hutchinson Cancer Research Center

Carrie Lee, MD, MPH – Chair-Elect
UNC Lineberger Comprehensive Cancer Center
University of North Carolina at Chapel Hill

Elizabeth Anderson, MPH, BSN
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Barbara Duffy Stewart, MPH
Association of American Cancer Institutes

Stephen Williamson, MD
The University of Kansas Cancer Center

1

FIRST PLACE

Ensuring PEAK Training and Compliance in Cancer Clinical Trials

Richa Upadhyay, MD; Lediona Ardolli, MA; Rosemarie Gagliardi, MPH, cEdD; Donna Berizzi, RN, MSN, OCN; Matthew Galsky, MD; Chari Ajai, MD

The Tisch Cancer Institute at the Mount Sinai Health System

Describe the background of the problem:

A large proportion of oncology clinical trials require intravenous infusions of study drugs. A comprehensive understanding of the appropriate administration of such therapies, potential adverse events, and study procedures is critical to minimizing protocol deviations and optimizing patient safety. However, infusion units are typically staffed by nurses that simultaneously care for patients receiving study drugs and standard of care therapies and that "sit" outside of the institutional research organizational structure complicating the delivery and documentation of appropriate training and education. Such protocol-specific education was historically provided at a single in-service meeting at the time of protocol activation with the expectation that slides would be reviewed by infusion nurses unable to attend. However, we conducted an internal audit revealing that a percentage of study infusions were administered by a nurse who had not been adequately trained. The lack of training was attributed to employee turnover, increase in clinic volume, time between in-service and first patient enrolled and study amendments.

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

- Ensure infusion nurses are trained on clinical trials prior to infusing drug by providing educational modules that:
  - Are easily accessible from any workstation and at point of care
  - Are available in a web-based format on a platform already utilized by nurses for other training requirements
  - Can be updated with new information arising from study amendments
  - Allow for tracking of completion of training
- Reduce deviations

Describe the solutions or methods implemented:

- Research compliance provided training on regulatory requirements and good clinical practices for the infusion nursing staff
- Alerts are received by nursing leadership when new research patients enroll allowing scheduling with appropriately trained staff
- Paper systems for RN training was replaced by online modules. Using the existing web based Portal for Education and Advancement of Knowledge (PEAK), a system used to access trainings across the institution by all employees eliminated the need to access a new system. Q/A worked with institutional IT to develop a category specific for Oncology Research. PEAK contains SIV material, study specific fast fact sheet and allows for verification of individual RN training. Training modules are searchable by PI, sponsor, disease or other key works and there are audit capabilities to track completion.
- All research chemotherapy orders in Beacon/ EPIC have a hard stop nursing communication on days of treatment "CONFIRM you have received TRAINING for this clinical trial. If not, please notify the Nursing Leadership."

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

Nursing leadership identified a group of infusion nurses to be lead infusion nurses for clinical trials.
Two new nursing positions were created to be the nursing navigators to liaise with the research staff.
Infusion RNs are required to complete CITI Training /ONS research training and a research overview session has been incorporated into the RN Oncology Orientation for new staff. The Beacon stop went live and to prevent infusion nurses from administrating research drug until trained.

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

Engaging nursing leadership and IT was essential in changing the culture and enhancing educational requirements for infusion nurses. Regular audits of training compliance will be done to assess if the online module leads to more compliance and fewer deviations.

Mount Sinai

Ensuring PEAK Training and Compliance in Cancer Clinical Trials

Tisch Cancer Institute

Richa Upadhyay, MD, Lediona Ardolli, MA , Rosemarie Gagliardi, MPH, cEdD, Donna Berizzi, RN, MSN, OCN, Matthew Galsky, MD and Ajai Chari, MD

Background

A large proportion of oncology clinical trials require intravenous infusions of investigational drugs. A comprehensive understanding of the appropriate administration of such therapies, potential adverse events, and study specific procedures is critical to minimizing protocol deviations and optimizing patient safety.

Infusion units are typically staffed by nurses that simultaneously care for patients receiving investigational drugs and routine therapies . The infusion nurses "sit" outside of the research organizational structure complicating the delivery and documentation of appropriate training and education. Such protocol-specific education was historically provided at a single in-service meeting at the time of protocol activation with the expectation that slides would be reviewed by infusion nurses unable to attend.

An internal audit revealed that a percentage of investigational drug were infused by a nurse who had not been adequately trained. Lack of training was attributed to employee turnover, increase in clinic volume, time between in-service and first patient enrolled and protocol amendments.

Goals

Goals to be achieved with solutions to the problem were:

❖Ensure infusion nurses are trained on clinical trials prior to infusing investigational drug by providing educational modules that:

- Are easily accessible from any workstation and at point of care
- Are available in a web-based format on a platform already utilized by nurses for other training requirements
- Can quickly be updated with new information arising from study amendments
- Allow for tracking and monitoring of completion of training

❖Reduce protocol deviations

❖Assure patient safety

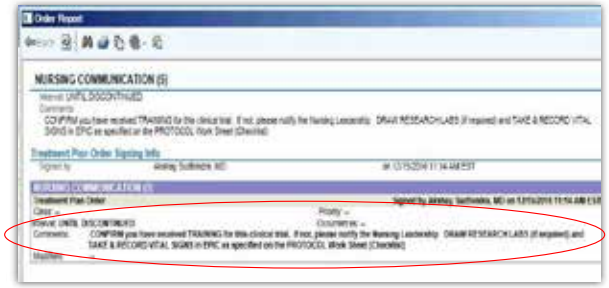


Figure 1. Nursing communication alert

Solutions

❖Research Compliance provided training on Regulatory Requirements and Good Clinical Practices for the infusion nursing staff

❖ Alerts are received by Nursing leadership when new research patients enroll allowing scheduling with appropriately trained staff

❖Paper systems for nurse training was replaced by online module: **Portal for Education and Advancement of Knowledge (PEAK)-** an existing web based system used to access trainings across the institution by all employees eliminated the need to access a new system.

- CCTO and QAP worked with hospital IT to develop a category specific for Oncology Research (Figure 2).
- PEAK contains SIV material, study specific fast fact sheet and allows for verification of individual nurse training.
- Training modules are searchable by PI, sponsor, disease or other key works and there are audit capabilities to track completion (Figure 3).

❖All research chemotherapy orders in Beacon/ EPIC EMR have a hard stop nursing communication on days of treatment to allow confirmation of training as well as at as a reminder during cases where the nurse missed the protocol specific training.

- The Beacon hard stop includes the following statement → "CONFIRM you have received TRAINING for this clinical trial. If not, please notify the Nursing Leadership." (Figure 1)

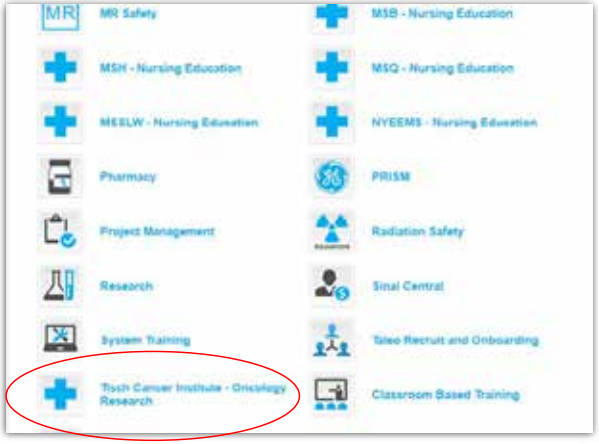


Figure 2. PEAK - Tisch Cancer Institute -oncology research specific training

Outcome

❖Nursing leadership identified a group of infusion nurses to be lead infusion nurses for clinical trials.

❖Two new nursing positions were created to be the navigators to liaise with the research staff and infusion nurses.

❖Infusion nurses are required to complete CITI Training /ONS research training and a research overview session has been incorporated into the Oncology Orientation for new nursing staff.

❖The Beacon stop went live and to prevent infusion nurses from administrating investigational drug until trained.

Conclusions

Engaging nursing leadership and IT was essential in changing the culture and enhancing educational requirements for infusion nurses.

Regular audits of training compliance will be done to assess if the online module leads to more compliance and fewer protocol deviations.

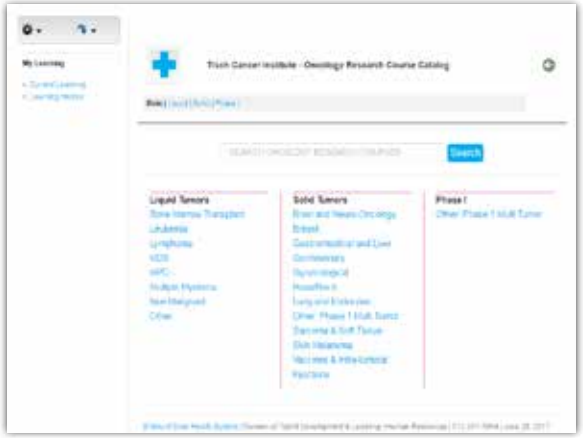


Figure 3. PEAK – Course catalog selections

2

SECOND PLACE

Improving Reproducibility of Quantitative Imaging Endpoints

Daniel C. Sullivan, MD[1]; Michael Boss, PhD[2]; Thomas L. Chenevert, PhD[3]; Edward F. Jackson, PhD[4]; Alexander Guimaraes, MD, PhD[5]

[1]Duke Cancer Institute, Duke University Medical Center; [2]National Institute of Standards and Technology; [3]University of Michigan Comprehensive Cancer Center; [4]University of Wisconsin School of Medicine & Public Health and Carbone Cancer Center; [5]Knight Cancer Institute, Oregon Health & Science University

Describe the background of the problem:

Quantitative imaging biomarkers (QIBs) from CT, MR or PET play an essential role as endpoints in oncology trials. However, differences in technical performance (e.g., scanner hardware, image analysis software, image acquisition logistics) lead to considerable variability in QIB outputs. Rigorous attention to standardizing the technical performance parameters for QIB measurements can mitigate this variability. The Quantitative Imaging Biomarkers Alliance (QIBA) was created to address this problem and improve the reproducibility of QIBs. QIBA adapted standard terminology and methods traditionally used to describe and validate in vitro laboratory assays, and applied them to QIBs. QIBA develops standards documents called Profiles that specify the quantitative reproducibility achievable by following the Profile requirements. Implementation of the QIBA Profile for diffusion-weighted magnetic resonance imaging (DW-MR) in a multi-site setting is described here as an example.

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

The apparent diffusion coefficient (ADC) map from DW-MR is a QIB of recent interest for cancer treatment monitoring. In tumor, increased cellularity leads to a decrease in tissue water mobility, providing a contrast mechanism between pathologic and healthy tissues. During effective treatment, cellularity decreases as pathologic tissue dies; water mobility increases. Thus, one can determine the efficacy of treatment by monitoring changes in ADC. We postulated that use of the QIBA ADC Profile and its associated standardized test object ("phantom") would decrease bias and improve reproducibility of ADC measurements across sites, vendors, and field strengths.

Describe the solutions or methods implemented:

The QIBA DW-MR Profile and phantom were implemented at four European sites participating in an IMI-QuICConCePT/EORTC trial, and eight sites in US/Canada. Details and specifications of the phantom, using concentrations of polyvinylpyrrolidone (PVP) in aqueous solution to generate physiologically-relevant ADC values, are available online (http://qibawiki.rsna.org/images/c/c6/QIBA_Phantom_Preparation-Instructions.pdf), as are all QIBA Profiles and deliverables (http://www.rsna.org/QIBA/).

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

Results from 10 sites, 3 vendor platforms, and 2 MR field-strengths indicate the QIBA Profile and phantom provide a high degree of reproducibility across a wide range of ADC values (Figure 1). ADCs ranged from 0.12 (50% PVP by mass) to 1.1 x 10^{-3} mm^2/s (water) at 0 °C, with repeatability coefficients (RCs) of 1.7% or less for water vials across sites. RCs were below 6% for all but the lowest ADC components of the phantom at 0 °C.

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

This work demonstrates utility of QIBA Profiles and phantoms for QC purposes in multicenter, multivendor studies. Physical phantoms, detailed procedures, and established performance benchmarks are essential to minimize technical variance. In addition to the DW-MR Profile tested here, QIBA has developed analogous Profiles for CT volumetry and for FDG-PET SUV quantification. These latter two Profiles were endorsed by the Cancer Moonshot Initiative (https://medium.com/cancer-moonshot/standards-for-quantitative-imaging-biomarkers-to-advance-research-and-outcomes-in-the-cancer-6e4e4ebf4e75). QIBA's stable, well-characterized tools allow for understanding sources of bias and variability and for providing a robust QC and site qualification platform for QIB acquisitions. Importantly, QIBA standards provide a confidence level for concluding whether an apparent change in an imaging measurement is due to a biologic change or technical variation. Widespread implementation of QIBA Profiles for image acquisition in oncology drug trials will lead to valid, reliable, reproducible QIB data indicative of treatment response.

Improving Reproducibility of Quantitative Imaging Endpoints

Daniel C. Sullivan[1], MD; Michael Boss[2], PhD; Thomas L. Chenevert[3], PhD; Edward F. Jackson[4], PhD; Alexander Guimaraes[5], MD, PhD
[1]Duke University Medical Center; [2]National Institutes of Standards and Technology-Boulder; [3]University of Michigan Comprehensive Cancer Center;
[4]University of Wisconsin School of Medicine & Public Health and Carbone Cancer Center; [5]Knight Cancer Institute/Oregon Health & Sciences University

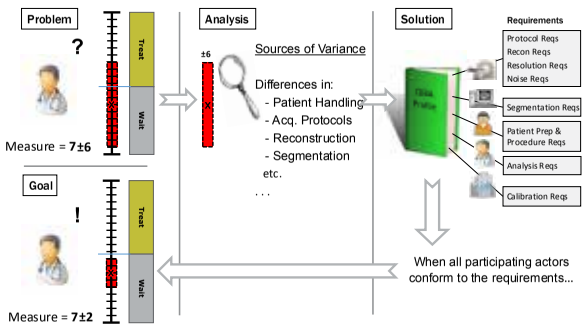
Background

Quantitative imaging biomarkers (QIBs) from CT, MR and PET play an essential role as endpoints in oncology trials. However, differences in technical performance (e.g., scanner hardware, image acquisition parameters, image analysis software and options) lead to considerable variability in QIB outputs. Rigorous attention to standardizing the technical performance parameters for QIB measurements can mitigate this variability. The Quantitative Imaging Biomarkers Alliance (QIBA®) was created to address this problem and improve the reproducibility of QIBs. QIBA adapted standard terminology and methods traditionally used to describe and validate *in vitro* laboratory assays, and applied them to QIBs. QIBA develops standards documents called Profiles that specify the quantitative reproducibility achievable by following the Profile requirements. Implementation of the QIBA Profile for diffusion-weighted magnetic resonance imaging (DW-MR) in a multi-site setting is described here as an example.

QIBA Mission & Process

QIBA's mission is to improve the value and practicality of quantitative imaging biomarkers by reducing variability across devices, clinical sites, and time. QIBA focuses on establishing the Technical Performance of imaging assays, not Clinical Performance. The initiative engages multiple stakeholders from academia, industry and government.

QIBA – Industrializing Imaging Biomarkers



QIBA analyzes sources of bias and variance in the generation of quantitative imaging biomarkers.

A QIBA **Profile** then places requirements on staff and equipment intended to eliminate or compensate for such sources, or at least quantify their impact to establish confidence intervals for the QIB measurement. A QIBA Profile provides a clinical context-specific **Claim**, which tells the user what levels of bias and precision can be achieved by adhering to the Profile requirements.

QIBA Profile Claims Relevant to Oncology

CT Tumor Volumetry :
A true change in tumor volume occurred with 95% confidence if the measured change is > 24% / 29% / 39%, respectively, for tumors with initial diameters of 50-100 / 35-49 / 10-34 mm.

FDG-PET/CT for Tumor Evaluation :
Tumor glycolytic activity (SUVmax) measurements have a within-subject coefficient of variation of 10-12%. A measured increase in SUVmax of 39% or more, or a decrease of -28% or more, indicates that a true change has occurred with 95% confidence.

DWI-MRI for Tumor Tissue Characterization :
A measured change in the ADC of a liver lesion of 26% or larger indicates that a true change has occurred with 95% confidence.

DCE-MRI for Tumor Response :
Microvascular property parameters (K^{trans} & $IAUGC_{BN}$) have a within-subject coefficient of variation of 20% from 1.5T DCE-MRI measurements using low molecular weight extracellular gadolinium-based contrast agents.

CT Small Nodule Volumetry (Screening):
A measured **change in nodule volume** of X% indicates that a true change in nodule volume has occurred if X > (2.77 x CV x 100) with 95% confidence. (CV is the coefficient of variation)

Goal of DW-MR Phantom Reproducibility Study

The apparent diffusion coefficient (ADC) map from DW-MR is a QIB of recent interest for cancer treatment monitoring. In tumor, increased cellularity leads to a decrease in tissue water mobility, providing a contrast mechanism between pathologic and healthy tissues. During effective treatment, cellularity decreases and water mobility increases as pathologic tissue dies. Thus, one can determine the efficacy of treatment by monitoring changes in ADC. We postulated that use of the QIBA ADC Profile and its associated standardized test object ("phantom") would decrease bias and improve reproducibility of ADC measurements across sites, vendors, and field strengths.

Methods and Materials for DW-MR Study

The QIBA DW-MR Profile and phantom were implemented at four European sites participating in an IMI-QuICConCePT/EORTC trial, and eight sites in US/Canada. Details and specifications of the phantom, using concentrations of polyvinylpyrrolidone (PVP) in aqueous solution to generate physiologically-relevant ADC values, are available online (http://qibawiki.rsna.org/images/c/c6/QIBA_Phantom_Preparation-Instructions.pdf), as are all QIBA Profiles and deliverables (http://www.rsna.org/QIBA/).

Figure 1: Final production version of the ADC phantom. A clear polycarbonate shell provides waterproofness, strength, and transparency to easily assess ice-water levels and the presence of air bubbles. Silicone susceptibility-matching plugs covering the equatorial fasteners mitigate image artifacts, facilitating image analysis.

Results from DW-MR Reproducibility Study

Results from 10 sites, 3 vendor platforms, and 2 MR field-strengths indicate use of the QIBA Profile and phantom results in a high degree of reproducibility across a wide range of ADC values (Figure 2). ADCs ranged from 0.12 (50% PVP by mass) to 1.1 x 10^{-3} mm²/s (water) at 0 °C, with repeatability coefficients (RCs) of 1.7% or less for water vials across sites. RCs were below 6% for all but the lowest ADC components of the phantom at 0 °C.

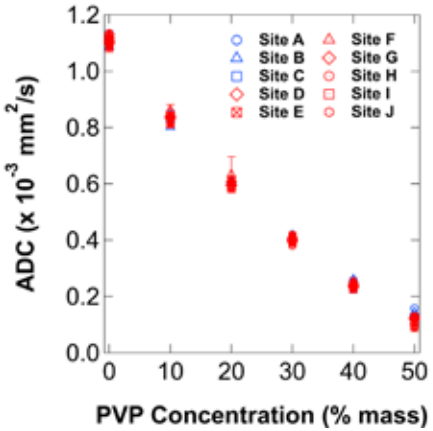


Figure 2: Reproducibility of DW-MR ADC values achieved by use of the PVP phantom at 0 °C across 10 sites and various times. The tight superimposition of values from all 10 sites, and small error bars, indicate the high level of reproducibility that can be achieved using the QIBA Profile and phantom at diverse sites in different countries. Red data points are from ADC values measured using b=0 and b=500 s/mm², while blue data points were measured with b=0 and b=900 s/mm². Sites were from the IMI-QuICConCePT/EORTC trial and U.S./Canadian sites. The 10 sites were: NIST-Boulder; University of Michigan; University of Wisconsin; University of Pennsylvania; Massachusetts General Hospital; AIM Medical Imaging, Vancouver; Memorial Sloan Kettering Cancer Center; The Institute of Cancer Research, UK; University of Manchester, UK; and INSERM, France.

Conclusions

This work demonstrates the utility of QIBA Profiles and phantoms for QC purposes in multicenter, multivendor studies. Physical phantoms, detailed procedures, and established performance benchmarks are essential to minimize technical variance. Two QIBA Profiles were endorsed by the Cancer Moonshot Initiative (https://medium.com/cancer-moonshot/standards-for-quantitative-imaging-biomarkers-to-advance-research-and-outcomes-in-the-cancer-6e4e4ebf4e75). QIBA's stable, well-characterized tools allow for understanding sources of bias and variability and for providing a robust QC and site qualification platform for QIB acquisitions. Importantly, QIBA standards provide a confidence level for concluding whether an apparent change in an imaging measurement is due to a biologic change or technical variation. Widespread implementation of QIBA Profiles for image acquisition in oncology drug trials will lead to valid, reliable, reproducible QIB data indicative of treatment response.

Contact

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2. Boss,M, Chenevert,T, Jackson,E, Attariwala,R, Shukla-Dave,A, Amaro,E, Shiroishi,M, Wu,O, Malyarenko,D, Kirsch,J, Multicenter Study of Reproducibility of Wide Range of ADC at 0 °C. Radiological Society of North America 2015 Scientific Assembly and Annual Meeting, November 29 - December 4, 2015, Chicago IL

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3

THIRD PLACE

Improving Protocol Activation Times via Automation and Centralization

Helen Peck, RN, MA, OCN, CCRP[1]; Joanne Mancini, RN, CCRP[2]; Cathy Galasso, RN, OCN, CCRP[2]

[1]Sylvester Comprehensive Cancer Center, University of Miami Health System; [2]Barbara Ann Karmanos Cancer Institute, Wayne State University

Describe the background of the problem:

Efficient and timely protocol activation is one of the greatest opportunities for process improvement at Sylvester Comprehensive Cancer Center (SCCC) in preparation for the cancer center support grant (CCSG) submission. Protocol activation timelines are beyond the NCI goal of 90 days with no formal process for tracking metrics or identifying roadblocks. This study describes methodologies implemented to provide real time protocol tracking with the goal of decreasing activation times.

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

1. Improve protocol activation time to a median of less than 120 days
2. Automated notification when a trial exceeds predefined time period during any step towards activation
3. Root cause analysis of protocol activation delays

Describe the solutions or methods implemented:

1. The Clinical Trials Activation Analyst (CTAA) was hired in July 2016.
2. Milestone tracking implemented in September 2016.
3. Feasibility Review Committee initiated September 2016.
4. Study Start-Up team (providing specialized expertise in PRMC and IRB submission) was established in December 2016.
5. A web-based tracking tool was developed in conjunction with Informatics; automatic alerts are generated when a protocol exceeds the allotted milestone timeframe. Tracking tool data input from January 1st 2017.
6. Protocol activation metrics analyzed every 2 weeks by Clinical Research Leadership, activation delays identified and corrective action plans implemented.

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

Although the project is in early phase implementation a positive trend in median protocol activation times are indicated:

CY2016 Q4: (21 protocols) Pre protocol activation tracking: 206 calendar days (median)
CY2017 Q1 (22 protocols): 164 calendar days (median)
CY2017 Q2: To be reported at meeting

The FRC review allows all stakeholders to participate in new protocol evaluation prior to PRMC review, ensuring that operational challenges are identified and addressed prior to IRB approval or SIV. This has eliminated the delays due to issues previously identified after IRB approval (usually at the SIV) which have delayed protocol activation. The CTAA position has been instrumental in detecting specific and actual delays, some of these not previously identified. The automated tracking tool e-mail alerts identify in real time, the actual (rather than perceived) etiology of delays in activation and thus individual trial delays are addressed rapidly and systematic improvement processes can be implemented expeditiously. Close frequent review of metrics by clinical research leadership has ensured protocol activation problems consistently receive priority attention.

Show lessons learned, others to involve in the future, changes to the methods to achieve a better outcome:
The protocol activation tracking tool project incorporated several initiatives, new hires, new processes and involved multiple departments and stakeholders. The project was implemented over several months with various delays and challenges including a hiring freeze and partnership department personnel being re-assigned other priorities related to the CCSG submission. Implementation of the individual initiatives might have been more efficient if individuals and departments had received more preparation and education prior to project initiation. Appointing a project leader to manage the entire plan would have been strategic.

Implementing a Research Nurse Model for the Clinical Trials Office

Helen Peck, RN, MA, OCN, CCRP[1]; Joanne Mancini, RN, CCRP[2]; Cathy Galasso, RN, OCN, CCRP[2]
[1]Sylvester Comprehensive Cancer Center, Miami FL, [2]Karmanos Cancer Institute, Detroit MI.

Introduction

Investigators and protocol patients lacked clinically-trained research support staff at Karmanos Cancer Institute. Formal coordination between the Clinical Trials Office (CTO) and clinic staff resulted in suboptimal patient service and the potential for protocol deviations. Time constraints and unavoidable clinical interruptions limited the interactions between the Investigator and the Clinical Research Coordinator (CRC). These limitations were exacerbated by the physical separation between the CTO, CRC and clinic areas which further increased inefficiencies. For example, the CRC waiting for a protocol patient in the clinic, or waiting on the Investigator or vice versa; which inconvenienced the patient and the investigator. Also, patients lacked a clinically-qualified point of contact for protocol questions and/or symptom management. Critically, Investigators lacked consistent, accessible clinical trial resources during clinic which discouraged enrollment.

Background

One of the first initiatives of the new Director of the Clinical Trials Office (CTO) in 2007 was the adoption of a Research Nurse model, having recognized the procedural inefficiencies of the existing clinical model. Implementation of a Research Nurse model had the potential impact for supporting research patients, increasing accrual, collecting accurate data, assessing toxicities, teaching and symptom management. With support from Senior leadership and HR the Research Nurse role was implemented, and over a period of 10 years the Karmanos CTO Research Nurse team was built. Initially, 1 Research Nurse on main campus and 1 Research Nurse at the satellite site was appointed. Currently, there are 12 Research Nurses at the main campus and 10 Research Nurses at the community sites.

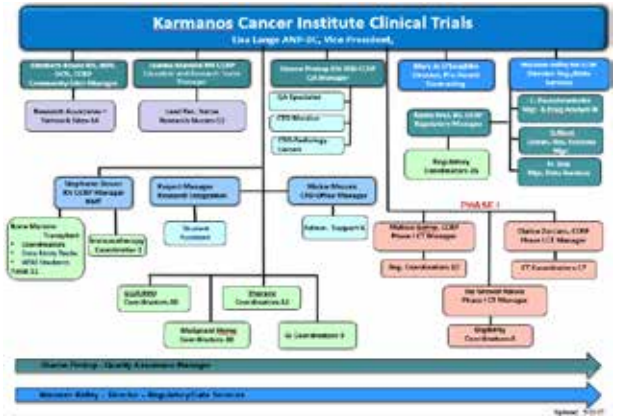
Outcomes

The CTO Research Nurse Team evolved over time. The outcomes are qualitative and descriptive, as no formal baseline metrics were established. However, trends and changes in clinical practice indicate that the Research Nurse model is highly effective, enhancing patient quality of care and improving Investigator engagement in research. Treatment protocol accrual saw a marked increase of 17% from 751 in 2007 when the Research Nurse role was introduced, to 879 in 2009. The CTO functioned more efficiently with improving NCI scores in 2010 (outstanding merit) and again in 2015 (outstanding to exceptional merit). The introduction of the CTO Research Nurse has significantly improved communication and integration of the CTO (research) with the hospital (clinical) which streamlines care, improves processes and enhances team work. FDA audit results in a MDT without a Research Nurse showed multiple missed lab tests and protocol deviations, while an FDA audit in a MDT *with* a Research Nurse resulted in 'no action required'. The corrective action plan for an FDA audit with multiple findings and a 483 was the implementation of the Research Nurse role.

Conclusions

Research Nurses with oncology experience were the most successful in the Research Nurse model. Inclusion of the clinical team in hiring Research Nurses proved beneficial. Establishing operational boundaries early in the process ensured that the research related care only, was coordinated by the Research Nurses. This model can only be successful with excellent teamwork, and communication between CTO Research Nurses, CRCs and clinical staff. Initial Physician hesitancy and skepticism was rapidly overcome once the benefits of the Research Nurse model were demonstrated by significant support in clinic, quality patient support, enhanced enrollment, and improved efficiencies.

Organizational chart



Research Nurses

Research Nurse

PRIMARY GOALS:
- Enhance coordination of care and support for clinical trial patients
- Improve Clinical Research Coordinator (CRC) efficiency
- Increase accrual and data quality
- Improve Investigator engagement in clinical research activity

SECONDARY GOALS:
- Reduce protocol deviations
- Improve liaison between clinic and CTO for the reporting of toxicities and adverse events
- Accessible research support in clinic for Investigators and staff
- Key resource in determining dose and/or treatment modifications
- Pre-Screening all patients for clinical trial match
- Assist in the consenting/re-consenting of the research patient
- Assist in patient education

TEAM ENHANCEMENTS OVER TIME:
- A CTO Research Nurse Supervisor
- Expanded team of 12 disease site specific positions
- Designated office space within proximity of clinics
- Adoption of MacBook Air for mobile record keeping
- Wider implementation of Research Nurse model across the McLaren Health Care network sites statewide (Michigan)

Accomplishments

- Identified dedicated area in the infusion center for research patients
- Streamlined research lab processes which significantly decreased missed labs and minimized protocol deviations
- Developed Screening Nursing Instruction Sheet (NIS) and treatment/follow-up NIS to facilitate protocol specific communication and documentation between CRC's and Research Nurses
- Created a Research Nurse "float" position for coverage purposes
- Primary research patient advocate resulting in improved protocol compliance
- Research Nurse role is regarded by Cancer Center leadership as critical to the success of the clinical trials program
- Development of a Research Nurse workload assessment metric based on protocol complexity and number of patients in treatment
- Community network sites conduct research using the Research Nurse/Central Data Management (CDM) model
- Partnered with Michigan Chapter of the International Association of Clinical Research Nurses
- The Research Nurse model is currently being adopted in the Behavioral and Phase 1 research teams
- 8 out of 12 Research Nurses have earned the Certified Clinical Research Professionals Certificate (CCRP)
- Career ladder for Research Nurses in development

Adapting to Thrive—Risk Based Monitoring of Academic Institutional Investigator Initiated Clinical Trials

Daniel Otap, CCRP; Fran Brogan, MSN, RN; Moshe Kelsen, MBA; Lauren Blumberg; Jennifer Wang, MS; Tiffany Negri, CCRP; Shannon Kelly; Tasha Isles Smith, MA, MPH; Stephen Emerson, MD, PhD; Andrew Lassman, MD, MS; Joseph Jurcic, MD

Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center

Describe the background of the problem:

In late 2016, the HICCC Data Safety Monitoring Committee (DSMC) and Clinical Protocol & Data Management (CPDM) Office initiated study specific monitoring plan procedures utilizing FDA guidance on Risk Based Monitoring activitites.1 The historical practice of monitoring 100% of subject charts, data, and regulatory/pharmacy provided valuable insight but was unsustainable given limited resources and increasing investigator-initiated trial (IIT)/investigational new drug (IND) activities over the past 4 years.

For example, the total number of faculty-held INDs increased from 5 in 2012 to 21 in 2016. The portfolio of multi-center IITs also expanded (2 trials/6 sub-sites in 2012 to 15 trials/33 sub-sites in 2016). Over 300 monitoring visits would have been required if all subjects were reviewed, an impractical and inefficient approach to quality monitoring activities.

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

The intended goal was to increase DSMC oversight through study-specific monitoring plans that would provide clear directives and expectations for monitors and study teams. These outlined expectations and critical data points would enable more effective use of monitoring resources.

Describe the solutions or methods implemented:

Monitors worked with PIs and trial biostatistician's to develop monitoring plans. This process documents the protocol's "Initial Risk Assessment", via Key Risk Indicator (KRI) methodology.2 Baseline Monitoring Expectations (e.g., frequency of remote vs. on-site visits and data compliance checks) were prospectively determined based off the trial's risk score. Identification of Critical Data Points (CDPs) were selected to indicate CRF data that would require 100% SDV at all times. The process involves the study PI, study statistician, study team leadership. The proposed plan is then submitted to the DSMC in parallel with ongoing Protocol Review and Monitoring Committee (PRMC) and IRB submissions. The plan must be approved by the DSMC directly prior to study activation (Fig. 1).

Monitoring Summary Forms were also created to provide DSMC reviewers with high level summaries of the trial monitoring activity at the time of the trial's formally scheduled DSMC review.

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

To date, a total of 16 monitoring plans associated with IIT have been approved by the DSMC. The plans have enabled remote monitoring of data entry compliance which aids decisions for on-site visits. The updated methodology assists the DSMC in its determination of trial risk levels by quantifying risk level assessments. Additionally it assists monitors in rapidly identifying safety/compliance concerns.

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

By approaching trial monitoring with a more specialized assessment methodology, actionable insights to address delinquencies in trial management can be identified in an efficient manner. Embedding monitoring plan proposals directly into the DSMC's review process has increased the DSMC's oversight capabilities.

The monitoring core will further adapt report structures to accelerate dissemination timelines. The DSMC and the core will begin to systematically track compliance findings in aggregate across all trials. This will potentially provide insight into education and training needs for clinical research professionals at HICCC. Additionally, further integration of the Compliance Core into the Multi-Center Core is poised to enhance centralized regulatory, data and QA monitoring activities across the sub-site portfolio.

References:

1. FDA Guidance For Industry; Oversight of Clinical Investigations- "A Risk Based Approach To Monitoring, August 2013"1.

"If You Build It, They Will Come." — Creation of a Dedicated Oncology Clinical Research Infusion Center

Frances Brogan, MSN, RN; Fawzia Ibrahim; Ryan Shelton; Caryn O'Mullane, RN, MSN, MBA; Moshe Kelsen, MBA; Andrew B. Lassman, MD, MS; Stephen Emerson, MD, PhD; Gary Schwartz, MD; Richard Carvajal, MD

Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center

Describe the background of the problem:

Conducting high-intensity early phase oncologic clinical trials within a large, complex, matrix clinical research enterprise is challenging. In particular, infusion center operations pose significant risks as infusion centers not accustomed to research may not be prepared for the rigor required by phase 1 or first in human studies, such as frequent pharmacokinetic blood draws, EKGs, and other safety assessments and procedures.

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

- Create a dedicated Research Infusion unit for a matrix Cancer Center with a specific focus on early phase clinical trials
- Develop a team of dedicated Research Infusion Nurses who are centrally trained in clinical trial operations
- Build adjacent processing laboratory and freezers to ensure efficient and compliance sample processing for clinical trials
- Improve clinical trial patient satisfaction, study compliance, and efficient use of resources

Describe the solutions or methods implemented:

In June 2015, the Adult Research Infusion Center (ARIC) was built to support the Herbert Irving Comprehensive Cancer Center (HICCC) at Columbia University Medical Center (CUMC). The primary focus of the unit was to serve our expanding Phase I portfolio as well as increased volume across other clinical trials. The ARIC is a dedicated research infusion unit consisting of 7 chairs and 1 bed that is in a separate location from the main infusion center, adjacent to the Phase I clinic. It is staffed by a rotation of 5 dedicated Research Infusion Nurses and a Medical Technician. Additionally, new research sample processing and freezer rooms were constructed next to the ARIC to allow for more efficient and compliant processing of research samples.

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

The number of new protocols within the HICCC which utilize the ARIC has increased from 90 in 2015 to 132 in 2017. The number of research subjects increased from an average of 3 to 12 per day during the same period. PK sampling is performed by the Infusion Nurses and samples are then processed by a dedicated specimen coordinator. The creation of the ARIC has increased collaboration between the research team and the infusion nurses. New Standard Operating Procedures (SOPs) were developed and implemented. Weekly educational sessions and protocol specific in-services have been created to address learning needs of the ARIC staff.

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

A multi-disciplinary management team was formed after the first year of operations. It is comprised of multiple stakeholders from both CUMC and New York-Presbyterian Hospital and includes representation from the HICCC clinical trial unit, Research Pharmacy, Infusion Center Management and Medical Directors, Phase I Principal Investigators, and the ARIC Staff. The group was tasked with reviewing operational issues within the unit and developing systematic solutions as needed. These include review of protocol violations, patient-wait times, scheduling/chair utilization and overall patient experience. Additional patient satisfaction surveys and analysis of data that has been collected regarding wait time are currently being analyzed. As the unit moves into its third year of operations, continued work is needed to build upon the existing library of Standard Operating Procedures and workflows with the ARIC team.

Development of a Streamlined Process to Collect Fresh Biopsy Specimens to Send Out for Clinical Trial Screening

Joni Harris, MS, CCRP

Hollings Cancer Center, Medical University of South Carolina

Describe the background of the problem:

When the NCI MATCH trial was in approval process at Hollings Cancer Center, it was apparent that this clinical trial was a much more complex design than most of the other studies open at the institution. For the initial screening step, most subjects do not have sufficient archival tissue for submission, and require a fresh biopsy. This biopsy requires coordination between the Clinical Trials Office (CTO), Medical Oncology, Cytopathology, and Radiology. Such a process had not previously been established for any other study, so the CTO needed to develop a new Standard Operating Procedure for trials requiring fresh biopsies.

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

- Establish connections with representatives from the respective interdisciplinary departments
- Streamline the biopsy process for all parties involved, including study coordinators
- Develop a system to confirm low risk sites to biopsy and schedule procedures
- Work with cytopathology to confirm the cellularity of specimens and collecting samples

Describe the solutions or methods implemented:

Once a potential subject is identified, the treating investigator contacts one of the Division Directors from Radiology to identify the lesion that is safest to access via percutaneous biopsy and presumed to be of high cellularity. Next, the study coordinator contacts Interventional Radiology (IR) to request an appointment for the patient to be evaluated for a biopsy of the chosen lesion, typically on the same day informed consent is signed to avoid inconveniencing the patient. Once the IR attending physician evaluates the patient, a biopsy is scheduled approximately one week out. This allows ample time for source documentation to be submitted to the CTO's Internal Auditors for eligibility confirmation, as well as registration in CTSU OPEN and receipt of the biopsy kit.

On the day of the biopsy, the study coordinator brings the kit to the IR procedure area. The team alerts Cytopathology that their services are needed to determine cellularity of the samples. Once Cytopathology confirms that the specimens will be sufficient, the attending physician collects the cores and places them in formalin, then passes the container to the coordinator to send off to the study sponsor.

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

Through trial and error and lots of communication, all disciplines involved in the biopsy process have collaborated to develop an effective and streamlined approach to obtain fresh tissue to send off for testing prior to enrollment on a clinical trial. The practice also encourages physicians from departments across campus to be engaged in the care of clinical trial patients, which helps promote MUSC's goal of advancing new knowledge and scientific discoveries.

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

The MATCH trial demonstrated the need for an established process for collecting fresh tissue from study patients. Representatives from across the institution met prior to the activation of the study to develop a plan. An initial blueprint was set, but after the first few biopsies, it was apparent that modifications were required. Over the past year, the process has been tweaked several times. Implementing this strategy for future clinical trials requiring biopsies may result in further changes, but for now, it appears to be the best operational strategy for our institution.

Converting to Electronic Regulatory Binders and the Great Scan

Curt Hampton, MBA, MS; Jessica Moehle, CCRP; Lindsey Byrd, CCRP

Huntsman Cancer Institute, University of Utah

Describe the background of the problem:

Regulatory binders often occupy multiple 3-ring binders that contain many pages of paper and take up a significant physical space. That space is used for many years before the file can be destroyed. Binder locations need to be tracked in order to be retrieved when the protocol is monitored and replaced after monitoring has finished. The binders of hundreds of protocols take up a significant space, use a large amount of paper, and must be physically tracked. The Huntsman Cancer Institute created an electronic binder system to address these issues.

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

Goals:

- Reduce physical space used
- Reduce paper usage and cost
- Standardize binder structure
- Enable convenient monitor access
- Convert physical binders to electronic format

Describe the solutions or methods implemented:

Electronic binder site:

- A SharePoint site was created for regulatory files
- Folder templates were created for different protocol types to standardize the organization
- Files are saved to the site rather than printed
- Wet-ink signature documents are stored in a paper folder
- SOPs are followed for creating new protocols

Site monitors:

- Monitors have login accounts to view only the protocol they are monitoring
- Access is available while off-site during the visit
- Access is automatically disabled at the end of the week
- SOPs are followed for creating accounts and enabling access

The Great Scan:

- After using the site for new protocols, older binders were scanned and added to the site, and the binder was archived

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

224 protocols have electronic regulatory binders on the site. Thirty-three were scanned from existing binders, and 191 are only electronic. Electronic monitoring happens for these protocols. Monitors copy files to their laptop instead of printing or photocopying. These electronic binders will save 50 feet of shelf space.

After a year, we started scanning existing binders. Using metrics from the first binder, we estimated 2-3 hours per binder for scanning. "The Great Scan" project scanned existing binders. Regulatory Coordinators recorded scanning data as they went. 33 of 186 identified binders have been scanned with these results:

- Hours of work: 42.3 hours (avg 1.3 / binder)
- Size of scanned files: 7.4 Gbyte (avg 225 Mbyte / binder)
- Shelf space saved: 7.3 feet (avg 2.7 inches / binder)
  Based on average binder size, the binders that started completely electronically will save 515.7 inches of shelf space (42.9 feet).

Although we have not seen a decrease in paper usage, after one year there hasn't been an increase even though there have been 191 new protocols. Paper order frequency has stayed consistent.

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

Lessons learned:

- Scanner paper jams and repairs slowed the process
- Communicate to monitors to bring their laptop

Future changes include:

- Investigating external scanning services
- Implementation of a 21 CFR Part 11 compliant system for additional security and electronic signatures
- Converting the Delegation of Authority log and training logs to electronically signed files

Integrating a Clinical Research Nurse Program at an Academic Cancer Hospital

Kristin Maloney, RN, BSN, OCN

Huntsman Cancer Institute, University of Utah

Describe the background of the problem:

Clinical Research Nurses (CRNs) support best patient care and safe, high quality clinical research and should be considered an essential component of the research team. In the NCI-designated Comprehensive Cancer Center, clinical trials have increased in number and complexity, especially in Phase 1 trials with over 85 active trials across all disease sites. Patients with advanced cancers require specialized care and have complex medical needs. Deviation rates are higher among unlicensed research staff (ULS) versus nurses across deviation types. No program was in place to support CRNs and no strategy had been developed for utilization of CRNs. The CRN role was not delineated from ULS roles. CRNs had no standard job title or description. CRNs did not have clear oversight and or comprehensive training to ensure competency.

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

Plan and implement a CRN program:

- Require minimum qualifications for CRNs, design training and competency checklists, and create a professional development plan.
- Define and customize role of CRN to fit institutional needs; differentiate scope of practice from ULS; and educate department on role of the CRN.
- Create a CRN leadership position to improve collaboration with ULS and investigators, provide clinical mentoring for department, advocate for CRN program, and thus improve quality and safety of research.

Describe the solutions or methods implemented:

We designed a plan which encourages oncology nursing/research certification, sets leadership and behavioral standards, and requires CRN-specific training and competencies.

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

Leadership reports CRNs demonstrate higher quality care, safer research conduct and compliance, and clearer communication with clinical team. Investigators have requested CRNs for their complex precision medicine and immunotherapy trials.

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

In the culture of an institution that did not previously have an established CRN Program, we have demonstrated the unique contributions of CRNs and how they strengthen a program predominantly staffed by ULS. We have increased the number of CRNs in our department with leadership support. Now that the program is established, we recommend further work on role delineation.

Promoting Comprehensive Site Policies and Limiting Industry Overreach

Lindsey Byrd, CCRP; Jessica Moehle, CCRP

Huntsman Cancer Institute, University of Utah

Describe the background of the problem:

Clinical trial support within the oncology research environment is a challenging enterprise given the highly complex nature of the research and ever expanding trial portfolios. Accuracy, consistency, and efficiency cannot be sacrificed despite these pressures. Resource constraints common in academic institutions present additional hurdles particularly when industry demands become infeasible and disproportionate.

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

- Reduce time, effort, and monetary expenditure on inefficient processes
- Promote compliance to local and national guidance while maintaining effective workflow
- Enlist the support of cancer centers nationally to enforce practicable standardized policies
- Foster successful working relationships with industry affiliates

Describe the solutions or methods implemented:

Development of regulation-compliant policies fostering efficiency and quality is imperative in the clinical research realm. We've developed the following policies in response to industry requirements, each have become widely accepted by our industry counterparts.

External Adverse Event Report Policy

In February 2016 we implemented a policy precluding review of individual External Adverse Event reports. We place responsibility for unanticipated problem criteria assessment onto sponsors and agree only to acknowledge actionable communications confirming these criteria are met. Unanticipated problems, being inherently unexpected, will result in study amendments and communications to patients. Local PI review of collective safety data is possible as a separate functionality.

Push-back on Document Portals

We refrain from use of sponsor's document management systems ("portals") due to a number of logistical issues they present:

- Significant training burden for all study staff
- Technical problems precluding access
- Coverage concerns for inaccessible staff when notifications are automated
- Investigator signoff requirements impractical

Amendment Training Policy

Study team members are responsible for training on amended documents as they pertain to specific roles. This training is confirmed as correspondence of newly released versions and documentation of attendance to research team meetings where pertinent study changes are reviewed. Sponsor-generated training documents or logs are not completed by the site. Sponsors can coordinate and document training efforts at on-site monitoring visits.

Electronic Regulatory Files

E-regulatory files are housed within Microsoft Sharepoint with the local IRB submission system considered document source. Site files are accessible for site monitoring and access restrictions address concerns over proprietary content. Additionally, this allows for centralization of documents that span trials preventing duplicative filing efforts.

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

Implementation of these policies affords our site the ability to run more trials of greater complexity, allows flexibility in resource expenditure, and results in greater accuracy and productivity.

- Prohibiting sponsor document management systems has reduced training burden (averages 15 – 60 minutes per person per study) and has simplified communications overall.
- Implementation of E-regulatory files has reduced filing time by 300%, reduced space usage by approximately 175 feet, and has streamlined site monitoring and the staff effort therein.
- Staff effort reduction by 2 FTE's

The table below illustrates an increase in number of trials managed but a decrease in FTE's responsible for these functions. Staff turnover has reduced substantially since 2014 which may demonstrate greater job satisfaction rather than greater work stress as the numbers might otherwise suggest.

Year	Number of Regulatory FTE's	Number of Active Trials Maintained by Regulatory Staff	Number of Local IRB Submissions
2015	11.5	348	838
2016	9.5	389	1084
YTD	9.5	435	TBD

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

- Industry sponsors are flexible in response to site policies furthering cohesion and ultimately advancing cancer research.
- Institutions can successfully defend policies on an individual basis but centralizing these efforts will yield larger-scale improvements.
- Further coordinate efforts adopting broader policies and include more cancer centers in their development.

Using the Epic EMR for Research Documentation

Rachel Kingsford, MS, CCRP; Jessica Moehle, CCRP; Leanne Lujan, CCRP; Lindsay Carpenter, MSW, CCRC; Sally Fairbairn, CCRP; Susan Sharry, CCRP; Karthik Sonty, CCRP; Theresa L. Werner, MD

Huntsman Cancer Institute, University of Utah

Describe the background of the problem:

Accurate and timely documentation of data points, especially investigator assessment of the clinical significance of labs and adverse events, are of paramount importance for clinical research. Maintaining compliance with Good Clinical Practice (GCP) documentation guidelines is essential for data validity and demonstration of adequate principal investigator oversight. The availability of research documentation via the electronic medical record (EMR) to providers is critical for patient safety and continuity of care.

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

The Huntsman Cancer Institute (HCI) Clinical Trials Office (CTO) has successfully implemented a process to create research documentation in the EMR Epic. These were our goals:

- Contemporaneous research documentation
- A 21 CFR Part 11-compliant system with audit trails and valid electronic signatures
- Demonstration of PI oversight through investigator completion of notes, with attestation and signature

Describe the solutions or methods implemented:

HCI CTO Leadership reviewed the resources available in Epic and created SmartPhrase research note templates. HCI investigators also provided input. Leadership then developed a Standard Operating Procedure (SOP) outlining the process and expectations. Epic allows us to leave placeholders (denoted by three asterisks) so investigators can enter required information efficiently. Three key elements of the research note are a visit summary, adverse event table, and documentation of laboratory review. The visit summary documents study procedures; it can also refer to an original source document located in the patient's research chart. Research coordinators enter all necessary data points for adverse events (CTCAE event term, grade, start date, stop date) in a table (see Figure 1); investigators assign attributions.

Figure 1. Sample Adverse Event Table

We import local labs into the note (including date and time) and add a placeholder for investigators to assign clinical significance.

Event	Start Date	Stop Date	Grade	Attribution Drug A	Attribution Drug B	Attribution Drug C	Comment	Action	SAE
Flank Plan	12/7/16	12/9/16	1	1	1	1	Patient reports intermittent right sided flank/kidney pain after first infustion of chemotherapy, Patient states that the pain was intermittent for two days and has not come back		N
Anorexia	12/9/16		1	3	3	1	Patient reports noted absence of appetite but states still knowing he needs to eat. Verbalized along with wife that he is still eating normal meals and snacks		N

CTCAE Version 4.03 Attribution Key: 1: Unrelated 2: Unlikely 3: Possible 4: Probable 5: Definite

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

Our policy of completing research documentation in the EMR has been well received by our investigators. HCI CTO's Medical Director, Dr. Theresa Werner said, "Our research note is easily accessible through the EMR so we can sign off the note at any time which allows much more timely completion of data entry. It also allows us to easily view all the AEs and clinically significant labs in one place. We save so much paper and stay much more organized this way." Sponsor representatives have been receptive to research documentation being captured in this way as it is organized, accessible, and contemporaneous. One industry monitor commented, "I find Epic and the cumulative collection of AEs and labs in the grid form especially useful when monitoring."

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

In order to be successful with this policy, our coordination staff and investigators have had to undergo rigorous training regarding GCP documentation practices and Epic features, including use of the placeholder (***). There have been limitations in the EMR we have had to work around such as amending documents after they are signed, which have been addressed with amendment of our SOP.

Improving Study Activation Timelines: Establishing Flow

Erica Love, MA, MPH, CCRP[1]; Paul K. Davis, KMP[2]; Nida Cassim, MPH[1]; Anna Pavlick, DO, MBA[1]

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

Describe the background of the problem:

Along with increasing participation in cancer clinical trials, decreasing study activation timelines is a perpetual holy grail of clinical trial operations organizations. The Laura and Isaac Perlmutter Cancer Center (PCC) has launched a pilot program to drive down time to activation (defined as the date of PRMC submission to the date a study opened to enrollment) to 100 days or less, and 45 days or less for cooperative group studies.

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

- Increase visibility into the study activation pipeline;
- Create a continuous and sustainable flow of studies through the Clinical Trial Operations (CTO) pipeline by limiting Work-in-Progress (WIP);
- Establish a consistent activation time of 100 days or less, and 45 days or less for cooperative group trials;
- Establish real time metrics on time to activation both overall and by sponsorship type and clinical research category;
- Real time alerts to CTO leadership on bottlenecks negatively impacting time to activation.

Describe the solutions or methods implemented:

The PCC combined a Workflow Management system and approach (Kanban) for tracking and managing the various tasks required to activate a study. Over a 13-week period, the processes by which interventional treatment trials are activated, by sponsorship type, (Industry, Institutional, National, Externally Peer-Reviewed) were documented in Use Cases, the tasks and workflows were modeled within a system, and CTO staff were trained on the new approach for managing the study activation process. The pilot was launched on Apr. 3rd, 2017.

Initial baseline metrics were established for current study activation timelines (~140 days) which will serve as the baseline comparison at the end of the 5-month pilot period. Additionally, survey data on attitudes toward study activation services provided by the CTO were collected from both CTO staff and external customers (Principal Investigators) to assess the quality and effectiveness of the study activation service provided by CTO. Post pilot surveys will be collected for comparison at the end of the pilot period.

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

The pilot launched on Apr. 3rd, 2017 and is only just beginning to collect data for evaluation. It is expected that there will be a period of time when studies that are currently in the activation pipeline will need to complete the activation process before a clean set of data is available for comparison. However, preliminary subjective results are already being observed including:

- Real-time access to study activation status;
- Increased collaboration internally within the CTO and externally with institutional service providers;
- Identification of bottlenecks in the process resulting in potential process enhancements;
- Establishment of Service Level Expectations (SLEs) at both the task and study level resulting in a more disciplined approach to managing and monitoring the completion of work;
- ~ 50% decrease in time spent in weekly pipeline meetings.

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

To date there has been a limited amount of information to assess lessons learned or potential changes to the methods employed to initiate the pilot. However, expanding the pilot to include other institutional service providers and Principal Investigators is already being planned. Lastly, consideration is being given to possibly expanding the use of the system and process for non-interventional trials.

Development of a Complexity Assessment for Clinical Trials

Alexa Richie, DHSc; Jennifer Lineburg; Andrea Tavlarides, PhD; Dale Gamble, MHSc; Susan Rogers; Carol Griffin

Mayo Clinic Cancer Center

Describe the background of the problem:

Knowing the capacity of a research coordinator is difficult to determine since the complexity of each protocol varies from trial to trial. If a uniform way to determine complexity could be developed, it would ensure adequate staffing levels and establish the capacity of each staff member.

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

The goal of this project was to develop a scoring mechanism that would assess the complexity of clinical trials in a uniform and validated manner.

Describe the solutions or methods implemented:

The NCI Complexity Assessment tool was used as a benchmark. It was adapted to fit the scope of this project and assess complexity of ongoing clinical trials. We created 21 unique elements, each with a range of 0-3 points for a total possible score of 63. The elements of the complexity tool relate to study design, team engagement, target accrual, consenting processes, study length, monitoring elements, billing requirements, and ancillary studies. To accommodate the fluctuating needs or varying effort throughout the life-cycle of a clinical trial, a multiple step-down scoring process was developed. The initial score is considered the trial's overall complexity and assumes the study is active and enrolling patients. The first step down occurs when studies close to enrollment, but still follow active patients by zeroing out elements that relate to screening/enrollment. The second step down is when the study closes to enrollment, and all patients have either completed treatment or are in long-term follow-up. To validate the tool, leadership scored all active studies in 2016 (n=~430). When studies were grouped by disease type, there were natural breaks in the scoring that could be used to delineate a high, moderate or low complexity trial. Scores of 53+ were considered highly complex, 46-52 were moderate and below 45 were low complexity studies. The scoring process allowed for leadership to define, based upon the score of all studies within a portfolio, what the maximum score would be for that team. Once natural breaks in the scoring determined the grouping of studies based on complexity, we took the tool a step further to determine how a complexity score could be used to assess the capacity of a clinical research coordinator.

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

A standard complexity tool was developed and validated to score clinical trials in the Cancer Clinical Research Office. Through the original and step-down score processes, we formulated a scalable way to assess the complexity of any clinical trial, non-interventional trial or minimal risk study in a uniform way that accounted for the various stages of the trial. Through this process, we achieved three goals: the ability to assess the working capacity of individual coordinators, assessment of the working capacity of teams, and the development of a predictive staffing model based upon trials currently open and in-development to accommodate incoming workload.

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

The multi-departmental strategy used to build this tool provided insight into how various aspects of trial conduction affect workloads. This provides an additional avenue for development of budgets during protocol development. Given this project's success, we are now validating the scoring process in non-cancer clinical trials.

Improving Research Lab Sample Tracking and Cost Recovery by Implementing a Web-based System

Wes Rood; Megan Koceja; Brenda Brito; Betty Oleson, BSN, RN, CCRP; Rebecca Selle, CCRP; James Thomas, MD, PhD

Medical College of Wisconsin Cancer Center

Describe the background of the problem:

Since its inception, the Medical College of Wisconsin Cancer Center Clinical Trials Office (CCCTO) has managed clinical research specimen processing and shipment. In July 2013, it hired a dedicated laboratory research assistant to manage clinical study samples. At that time, the team tracked this work on an Excel spreadsheet, categorizing samples into three processing levels. Each had a different degree of complexity. After formal evaluation, it was clear that the operation could be improved and made less cumbersome. In addition, the financial team suspected that the costs recovered during the sponsor-invoicing process were not entirely accurate.

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

The CCCTO financial and laboratory teams sought to improve and streamline clinical sample tracking. They wanted to enhance the laboratory staff's data entry system by making it more efficient. In addition, they needed to improve the finance team's data extraction process and to increase sponsor-billing accuracy.

Describe the solutions or methods implemented:

The teams collaborated with the Medical College of Wisconsin Clinical & Translational Science Institute in fall 2016 to design a simple web-based system for tracking study samples. In moving away from the spreadsheet system, the group was able to ensure secured data storage, simultaneous access to the information by multiple users and real-time creation of billing reports, based on the time spent processing the samples. The website stores information pertaining to clinical trial sponsors and their associated protocols, patients enrolled to a trial, research samples collected, and the processing time for each sample type.

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

After implementing the laboratory website in January 2017, the CCCTO made the decision to retroactively enter samples beginning in fiscal year 2017. Three months of duplicate data were analyzed (Table 1). Staff effort and invoices for those three months were evaluated. After analyzing both methods, we could demonstrate that the website had improved our cost recovery by an average of 24.9%. Anecdotal descriptions from the CCCTO laboratory staff indicate a more streamlined and efficient process. The system also allows users to run valuable reports to provide source documentation for sponsors; this was previously a manual process, using Excel.

Table 1: Analysis of duplicate data collected from spreadsheet tracking vs. CCCTO Laboratory Website:

	July 2016	August 2016	September 2016	3-month Average
% increase in lab staff invoiceable hours	+49.1%	+31.8%	+9.6%	+28.1%
% increase in dollars invoiced for effort	+39.2%	+31.6%	+8.0%	+24.9%

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

The CCCTO concluded that having centralized laboratory staff working with a web-based system has increased efficiency of real-time sample entry. Although this platform has only been in place for less than six months, it has had a significant, positive impact on sponsor-billing accuracy. Because the CCCTO has a strong working relationship with the CTSI, changes and enhancements can be requested with a simple email.

Not All Tumors Are Created Equal: Evaluating the Impact of an Interdisciplinary Molecular Tumor Board

Allison Martin, PharmD; Ben George, MD; Elizabeth Weil, PharmD, BCOP; Angela Urmanski, PharmD, BCOP; Katrina Schroeder, RN, OCN, CCRP; Kayla Mendenhall, CPhT; Mindy Waggoner, PharmD, BCOP; Carolyn Oxencis, PharmD, BCPS, BCOP

Medical College of Wisconsin Cancer Center

Describe the background of the problem:

Precision medicine is increasingly important in the care of patients with advanced cancer who have limited therapeutic options. Utilizing genomic profiling, practitioners can determine if genetic aberrations match with targeted pharmacotherapy, generating opportunities for treatment with approved standard of care (SOC) agents, clinical trials, and off-label use of therapies FDA approved for other disease states. The interpretation of somatic mutational profiling data for therapeutic use is complex; not all genomic alterations identified are clinically significant. Alterations must be prioritized in terms of their contributory role as 'driver' alterations, type of alterations, and context of the alterations. A Molecular Tumor Board (MTB) consisting of oncologists, molecular pathologists, bioinformaticians, and pharmacists is crucial to formulating a treatment plan appropriately utilizing genomic information.

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

At Froedtert & Medical College of Wisconsin Cancer Center, a MTB was established in March 2016 to identify therapeutic options based on genomic alterations for patients who failed SOC treatment options.

Describe the solutions or methods implemented:

Limited data exists regarding clinical outcomes associated with MTBs. The primary goal of this project is to collect and analyze demographic, clinical, pathologic, molecular, and treatment information for cases presented at MTB. Analysis of the proportion of actionable genomic alterations identified in presented cases, as well as rate of drug procurement, overall response rates in cases where the medication is procured, and clinical outcomes will be completed. Pharmacy interventions and time spent by pharmacists, prior authorization team members, and the MTB study coordinator will be quantified.

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

Data collection is ongoing. From March 2016-March 2017, 47 patients were reviewed at the MTB. Seventy-nine percent of patients had 3 or more genomic alterations, the majority of patients (90%) had 2 or fewer actionable genomic targets, and 30% of patients evaluated had no actionable genomic targets. The primary MTB treatment recommendation was off-label therapy (60%), followed by SOC treatment (26%), and clinical trial enrollment (11%).

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

Utilizing MTBs, patients have interdisciplinary review of novel therapeutic options based on genomic alterations. Off – label use of anticancer agents has been recommended in the majority of patients presented at MTB. Clinical outcomes will continue to be assessed to evaluate the impact of pharmacist involvement in the MTB and determine the efficacy of genomic-based recommendations.

They Talked the Talk…But Can They Walk the Walk? Implementing a Written Test During Candidate Interviews for Clinical Research Coordinators and Assistants

Rebecca Selle, CCRP; James Thomas, MD, PhD; Betty Oleson, BSN, RN, CCRP

Medical College of Wisconsin Cancer Center

Describe the background of the problem:

Hiring outstanding clinical research staff can pose a challenge in that few formal, in-depth clinical research training programs exist in the United States. Thus, it is difficult to determine an individual's true qualifications, because of the lack of standardized, prerequisite courses or exams. An interviewer cannot quantitatively conclude if a job applicant has the requisite skills to address the actual challenges of the job. It has been noted by managers in the Clinical Trials Office at the Medical College of Wisconsin Cancer Center (CCCTO) that candidate often overstate and misrepresent their qualifications in interviews.

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

CCCTO leadership determined that it is essential that job candidates have the actual skills and knowledge they claim to possess in interviews. Management wanted to create a tool to measure quantitatively a potential hire's strengths and weaknesses in the following areas: computer skills, attention to detail, problem-solving ability, math expertise, writing proficiency and the ability to work under pressure.

Describe the solutions or methods implemented:

The CCCTO education and quality assurance manager developed a written test with five questions. The leaders determined that this would be administered following all face-to-face interviews. At that time, the education and quality assurance manager would brief the individual regarding the test. Then, the candidate would have 35 minutes to complete the test at a computer station. Questions range from open-ended queries about qualifications (e.g., "why do you feel you would be a good fit for this position?") to more specific, practical clinical research scenario-type questions, including math calculations. [Actual questions will be shared on the poster.] In this way, the leadership staff would have a tangible metric that captures a potential hire's true abilities. This would augment the information gathered in the interview.

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

Leadership arrived at an evaluation criteria, based on the applicant's level. An individual applying for a higher-level position is expected to perform perfectly or near perfectly on the written test. Someone applying for an entry-level position is given more leniency. In these cases, managers are looking for qualities in a candidate that indicate strong potential. This written test has proven invaluable in assessing interviewees. It has made the hiring process easier and more successful.

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

The written test provides candidates with the opportunity to prove the claims they make in interviews. In addition, it allows more reserved individuals, who may not interview well, to excel. Overall, the written test has enhanced the CCCTO interview process. In the near future, the CCCTO will devise a written test for regulatory staff.

Best Practices to Achieve a Successful FDA Inspection

Susan Puleio, CCRP; Veronica Tomaselli

Memorial Sloan Kettering Cancer Center

Describe the background of the problem:

U.S. Food and Drug Administration (FDA) inspections of clinical trials, conducted under the Bioresearch Monitoring Program, focus on ensuring human subjects' protection, reliable and accurate data, and compliance to applicable regulations. FDA inspections can be pre-announced or unannounced. Therefore, it is vital research study teams are prepared and inspection-ready at all times.

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

In preparing for an FDA inspection, it is essential for research study teams to understand what an FDA inspection involves, such as reviewing internal operations and critical data points of the clinical trial, understanding FDA regulations, Good Clinical Practices (GCP) and institutional policies, as well as providing the FDA with organized documentation of clinical trial materials, to name a few.

Describe the solutions or methods implemented:

Based on the proceedings and findings from previous FDA inspections, the Memorial Sloan Kettering Cancer Center (MSK) Clinical Research Administration Quality Assurance Program (CRA QA) has identified several processes that can result in a successful FDA inspection. Measures can be taken at various stages of the clinical trials' life (i.e., at the start of the clinical trial, within the first few months of opening to accrual, and throughout the clinical trial) and from when the announcement of an FDA inspection is received to ensure the research study team is prepared and inspection-ready.

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

Through the implementation of an inspection readiness program, including recommendations/best practices and preventative measures, deficiencies are avoided and the likelihood of receiving a Form FDA 483 (Inspectional Observations) or a warning letter is reduced.

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

Active oversight throughout the life of the clinical trial is crucial to recognizing and resolving issues early-on, thereby avoiding systematic and systemic deficiencies and increasing the likelihood of a successful FDA inspection.

The Research Council: Developing & Implementing Institutional Policy for Clinical Research Portfolio Management

Sara Hanley, MSW; Xhenete Lekperic; David Spriggs, MD; Ann Rodavitch, MA

Memorial Sloan Kettering Cancer Center

Describe the background of the problem:

As an NCI-designated Cancer Center, the Cancer Center Support Grant (CCSG) requires that MSK have a Protocol Review and Monitoring System (PRMS) for the institution. At MSK, the Research Council (RC) serves as the PRMS. It is critical for the RC to monitor accrual to our vast clinical research portfolio. Ensuring timely completion of clinical research impacts scientific progress, appropriate resource allocation, and publication rates.

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

- To develop and implement an SOP for accrual monitoring and to define underperforming clinical research protocols.
- To decrease the amount of clinical research protocols requiring a corrective action plan to 10%, and to increase the percentage of underperforming protocols closed or amended within 1 year of initiating a corrective action plan.

Describe the solution or methods implemented:

RC was charged with monitoring accrual performance of MSK's clinical research portfolio in 2013. An SOP was published in 2016 to define the performance monitoring process at our institution. This SOP outlines accrual expectations, documents structure to reviews and determinations, and provides guidance regarding expected interventions to improve accrual rates. The SOP defines an underperforming protocol as one that has an estimated accrual time greater than 5 years (7 years for rare diseases, NCTN/NCI Cooperative Group) and establishes rules for determining exceptions.

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

As a result of the SOP, we have established a streamlined, collaborative, and effective workflow. Biannual reports are generated to identify underperforming protocols which are sent to Department Chairs and Program Managers. PIs must respond with a corrective action plan, using a structured response template. Modification to accrual goals, recruitment strategy and/or eligibility must be considered based on internal data showing >95% of protocols identified as underperforming fail to meet accrual expectations in the absence of a structural protocol amendment. The RC provides a structured review, determination of the action plan, and opportunity to appeal, if applicable.

In our most recent monitoring review, we reviewed 740 protocols of which 11% were considered underperforming and required corrective action plans. Of the underperforming protocols, 20% were closed as a result of our monitoring efforts. SOP-mandated action plans were implemented as structural amendments which led to stronger, more successful trials. The SOP has been used to support RC's decision to close protocols for poor performance and serves as a resource for investigators who are contemplating whether or not a particular protocol is scientifically futile. Compared to 2013, our program closed 58% more underperforming protocols in 2016.

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

Lessons Learned:

- Standardized and collaborative process leads to transparent and unbiased policy.
- Structured review process is a necessary and vital component of the SOP and an appeal process is helpful in identifying exceptions.
- Integrating timely completion of clinical trials as a metric leads to higher productivity of research portfolios.

Future Goals:

- Electronic submissions via our institution's Protocol Management Information System to increase efficiency.
- Continued data analysis to guide future policy and further identify protocols at risk for poor performance in the protocol development and review process.
- Accrual review coordination among institutional committees, for example, DSMC and IRB continuing reviews.

Clinical Research Office Monthly Lecture Series

Cindy Wynne-Jones, RN, CCRC; Erin Williams, MBA

Simmons Comprehensive Cancer Center, UT Southwestern Medical Center

Describe the background of the problem:

A few years ago, we received feedback via an institutional employee engagement survey that teams desired additional training. One challenge has been how to insert a variety of topics into an appropriate environment which is easily accessible. We chose to find an opportunity which would be less structured and available outside of mandatory staff meetings.

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

Initially we did not set a target for attendance; however we were hopeful that many from the office would find the topics relevant and started with an introduction to Oncology lecture (Oncology 101) given by one of our physician faculty. The goal was to provide a monthly educational forum that would provide relevant information to all CRO staff members.

Describe the solutions or methods implemented:

CRO monthly Lecture Series was developed to provide a variety of speakers and topics applicable to all staff (RN, Clinical Research Coordinators, Data Entry Specialists, Regulatory, Financial and Administrative personnel). We have had a variety of speakers from Chaplain Services, Human Resources, Pharmaceutical companies, and Disease Oriented Team Leader Physicians. We provide lunch for staff and run the lecture on an available Friday approximately once a month from 11:30-12:30pm. Pizza is provided at a cost of approximately $150.00. Pharmaceutical companies provide lunch for us when they have a presentation (only unbranded presentations are allowed). Continuing education credits are not provided. Staff can join the meeting via Skype if they are unable to attend in person, or are at another facility. Meetings are recorded and saved along with any handouts in a shared folder that can be reviewed at a later date.

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

Fiscal Year	CRO Staff Numbers	Number of Lectures	Average Attendance	% Attendance
2016 (Year 1)	84	9	37	44%
2017 (Year 2)	88	7	32	37%

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

Overall we would like to improve attendance for the lecture series by setting a goal of 50% attendance. We often get good comments regarding the presentations however implementation of a more formal survey requesting suggestions may improve attendance. We may also consider allowing a lecture series attendance replace one mandatory staff meeting per quarter.

Coordinators Asked, We Answered: The New Clinic Coordinator Education & Training Program

Emily Hawkins, CCRP; Elizabeth Menne, RN; Maria Westfall, CCRP

Siteman Cancer Center

Describe the background of the problem:

Our Division has grown rapidly over the last 10 years. Currently we have 120 coordinators and 13 separate disease teams as compared to 35 coordinators in 2008. Plagued by high turnover, little standardized practices between disease groups, and a rapidly evolving clinical research landscape; our training strategy has not kept up with the demand of the growing program. Prior to this year and the implementation of our new Education and Training Team, our Division had broad clinical research education but no formal on-the-job training in place for new coordinators.

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

Our goal in developing this program was to create a comprehensive training for the clinic coordinator. We want our coordinators to receive a consistent training based on our division's best practices, policies and procedures. With proper education, we also hope to improve the quality of all coordinators' work by eliminating confusion and potential errors. Our goal is to equip all coordinators with knowledge and skills, so they are both confident and satisfied in their important role in clinical research.

Describe the solutions or methods implemented:

Given the diversity in practices between disease teams, it was essential to implement a solution that was adequately broad yet specific enough on team practices to result in well-trained new employees. Our solution was to utilize a collaborative approach, relying on joint training responsibilities between the Education and Training Team, Disease Team Supervisor/Lead, and the New Coordinator.

After 9 months of developing our training materials and extensively vetting them through a working group of managers and experienced coordinators, we implemented the New Clinic Coordinator Education and Training Program on January 1, 2017. Our program utilizes a dynamic, 5 week, intensive structure that is one-on-one and tailored to the individual coordinator's protocols. Each day, for about 3-4 hours, the new coordinator learns and practices job-specific topics and skills with a trainer. Upon completion of each training session, the new coordinator works with their disease team to apply the newly learned topics and skills.

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

To date, we have sent three clinic coordinators through our full program. Although it is too early to have data to provide a direct correlation between our program and improved retention and quality, we have received positive feedback from new coordinators, their supervisors, and managers. At the completion of training, each coordinator has taken "proficiency assessments" which are designed to evaluate comprehension of the program and the coordinator's ability to apply knowledge learned to real life examples. All three coordinators have surpassed our expectations on the proficiency assessments.

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

Our next challenge is creating a similar program for data coordinators. We will revise current applicable training materials and create data-specific materials. Additionally, in an effort to reach more coordinators, we now require all coordinators hired within two years to attend our training sessions.

Improving Protocol Activation Times via Automation and Centralization

Helen Peck, RN, MA, OCN, CCRP; Andrew Nilson, BHA; Simmy Thompson, MPH, CIP, CCRP; Rizalia Rivera Cvijovic; Michael A. Samuels, MD; Jonathan Trent, MD, PhD

Sylvester Comprehensive Cancer Center, University of Miami Health System

Describe the background of the problem:

Efficient and timely protocol activation is one of the greatest opportunities for process improvement at Sylvester Comprehensive Cancer Center (SCCC) in preparation for the cancer center support grant (CCSG) submission. Protocol activation timelines are beyond the NCI goal of 90 days with no formal process for tracking metrics or identifying roadblocks. This study describes methodologies implemented to provide real time protocol tracking with the goal of decreasing activation times.

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

1. Improve protocol activation time to a median of less than 120 days
2. Automated notification when a trial exceeds predefined time period during any step towards activation
3. Root cause analysis of protocol activation delays

Describe the solutions or methods implemented:

1. The Clinical Trials Activation Analyst (CTAA) was hired in July 2016.
2. Milestone tracking implemented in September 2016.
3. Feasibility Review Committee initiated September 2016.
4. Study Start-Up team (providing specialized expertise in PRMC and IRB submission) was established in December 2016.
5. A web-based tracking tool was developed in conjunction with Informatics; automatic alerts are generated when a protocol exceeds the allotted milestone timeframe. Tracking tool data input from January 1st 2017.
6. Protocol activation metrics analyzed every 2 weeks by Clinical Research Leadership, activation delays identified and corrective action plans implemented.

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

Although the project is in early phase implementation a positive trend in median protocol activation times are indicated:

CY2016 Q4: (21 protocols) Pre protocol activation tracking: 206 calendar days (median)
CY2017 Q1 (22 protocols): 164 calendar days (median)
CY2017 Q2: To be reported at meeting

The FRC review allows all stakeholders to participate in new protocol evaluation prior to PRMC review, ensuring that operational challenges are identified and addressed prior to IRB approval or SIV. This has eliminated the delays due to issues previously identified after IRB approval (usually at the SIV) which have delayed protocol activation. The CTAA position has been instrumental in detecting specific and actual delays, some of these not previously identified. The automated tracking tool e-mail alerts identify in real time, the actual (rather than perceived) etiology of delays in activation and thus individual trial delays are addressed rapidly and systematic improvement processes can be implemented expeditiously. Close frequent review of metrics by clinical research leadership has ensured protocol activation problems consistently receive priority attention.

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

The protocol activation tracking tool project incorporated several initiatives, new hires, new processes and involved multiple departments and stakeholders. The project was implemented over several months with various delays and challenges including a hiring freeze and partnership department personnel being re-assigned other priorities related to the CCSG submission. Implementation of the individual initiatives might have been more efficient if individuals and departments had received more preparation and education prior to project initiation. Appointing a project leader to manage the entire plan would have been strategic.

Minimizing Information Redundancy Across the Institution and Improving Quality with Regulatory Document Management

Andrew Nilson[1]; Rosa Hsieh[1]; Cristina Ferrazzano Yaussy, MPH, CCRP[2]; Tom Battle[2]

[1]Sylvester Comprehensive Cancer Center, University of Miami Health System; [2]Complion, Inc.

Describe the background of the problem:

Cancer centers collaborate with many institutional departments, each of which may have their own needs and requirements for managing clinical research documentation. Routinely, regulatory and trial documents are stored in separate systems across departments; however, current methods of controlling access and file sharing of documents result in document redundancy.

Duplication of research related documents decreases staff efficiency, increases material costs, and increases the potential risk of non-compliance caused by poor document control and integrity. Risk of accessing outdated or incorrect versions of a document, in addition to departments working in silos are all contributing factors to poor document management and demonstrates the need to develop a centralized document storage process. Centralization provides institutions the opportunity to reduce redundant storage of research related documents.

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

The goal of this project is to prevent compliance issues by proactively addressing the challenges identified with document management and redundancy. To do this, we will:

1. Quantify how a centralized, document storage workflow process between institutional departments reduces document redundancy.
   a. Office of Research Administration (ORA), Research Pharmacy, Research Laboratory, SCCC Study Start-up Division, Investigational New Drug (IND) Office, and Clinical Research Services (CRS), including the Regulatory, Data Management, and Clinical Coordinating Departments.
2. Identify the same type of documents utilized by multiple institutional departments to improve staff efficiency and decrease redundancy.
3. Demonstrate the correlation between research compliance and document redundancy.
4. Describe how a centralized model improves research transparency on an institutional level and prevents departments from working in silos.

Describe the solutions or methods implemented:

The solutions used include purchasing a centralized document management system, implementation an integrated process or workflow, development of institutional standard operating procedures (SOP) and processes, and establishment of document access controls across institutional departments.

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

Monitoring and auditing reports (internal and external) were evaluated pre- and post CAPA implementation (2013-2014 and 2015-2016 respectively). Compiled data used from previous corrective actions plans will represent the baseline data set, and compared with subsequent follow-up data to determine effectiveness.

The anticipated outcome will represent a reduction in document redundancy as outlined in methods and solutions and supported by data analysis, with an estimate at reduction in material / archiving and staff costs.

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

The lessons learned and future considerations include:

1. Support from senior leadership.
2. Develop a working group that consists of a member from each of institutional group to provide insight on the challenges their department encounters.
3. Embrace the culture change that occurs when introducing a new process.
4. Identify the roles and access level between the different groups.
5. Collaboration and communication. Let this be organic so all parties have a stake in the project and will embrace this solution by becoming a vehicle of the change and not the roadblock.

Resource Allocation Review — 2 Year Analysis of Protocols Open to Enrollment at Least 1 Year

Rosemarie Gagliardi, MPH, cEdD; Ariel Hosey; Lediona Ardolli, MA; Catherine Raimond; Richa Upadhyay, MD; Paula Klein, MD; Ajai Chari, MD; Matthew Galsky, MD

The Tisch Cancer Institute at the Mount Sinai Health System

Describe the background of the problem:

In the past, clinical trial budgets were prepared based solely on information provided by individual investigators with no formal experience in negotiating clinical trial budgets. This resulted in numerous studies being under budgeted and under resourced to support the research. It also caused significant delays in the approval and activation process and created an increased regulatory workload.

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

In October 2012, the Tisch Cancer Institute's (TCI's) Cancer Clinical Trials Office (CCTO) finance team implemented a pre-PRMC Resource Allocation Evaluation (RAE) review. The purpose of Resource Allocation Evaluation is to facilitate the implementation of clinical trials that utilize the resources of the TCI clinic space and CCTO. RAE is an objective, transparent evaluation that scores and weights a clinical trial based on three categories: institutional priority, investigator's metrics, and overall budget.

Describe the solutions or methods implemented:

Protocols are first reviewed by a Disease Focus Group (DFG) and given a priority score based on scientific merit, patient availability, and adherence to the TCI's programmatic goals. Once the DFG prioritizes and scores the study, the investigator can proceed with requesting CCTO resources for the direct conduct of the trial (eg: Clinical Research Nurses and/or Coordinators). For the RAE review, the proposed budget is assessed for projected funding and a score is assigned for the anticipated level of funding. Objective scores are also assigned for proposed subject accrual, PI's accrual history, competing studies, study complexity, and length of study. Scores are weighted and the protocol is given an overall RAE score and reviewed by the CCTO Leadership at its weekly management meeting as to not delay the processes.

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

Cancer Clinical Trials RAE reviewed (between 2013 to 2015) that were activated prior to January 2016:
Preliminary Review of Data:

Overview	Total Portfolio	Comments
Number of Trials Activated with 12 months of enrollment data	107 trials	Includes all Disease Oriented Programs managed by CCTO
• Targeted Annual Accruals as per Investigator on DFG/RAE forms	912 patients	Average of 8.5 pts accruals per trial
• Actual Annual Accruals @ 12 mos post activation	462 patients (50%)	Average of 4.3 pts accruals per trial
• Trials met > 50% targeted accruals @ 12 mos	45/107 trials (42%)	Contributed 347/462 (75%) of accruals
- Trials met 100% targeted accruals @ 12 mos	21/45 trials (20%)	Includes 4 Rare Disease Trials with 2 accruals
Trials Defined as Rare Disease	14/107 trials (13%)	Expect to enroll < 3 patients per trial
Trials Terminated < 12 mos	34/107 trials (31%)	Terminated by PI or Sponsor see summary below
Trials with No Enrollments @12 mos	18/107 trials (17%)	11 of those 18 trials were terminated < 12 mos

Terminated Trials < 12 months (34 trials):
- 5 trials: PI decided to terminate because of no/low accruals

Sponsor Decisions (29 trials):
- 18 trials: Study met overall accrual goal
- 8 trials: Sponsor did not move forward (safety; efficacy; low enrollments)
- 2 trials: Drug received FDA approved – study was terminated
- 1 trial: "other" reasons- PI left institution

Also of interest, 85 /107 (80%) trials had at least 1 protocol amendment within 12 months of activation.

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

Engaging RAE review early in the process by experienced CCTO staff improves accuracy of budgeting, addresses study logistics, reduces study time to activation, and improves the overall economics of clinical research. We will be further analyzing the data above to identify opportunities to better recognize the potential patterns for the trials that under accrued.

Data Reporting: A Simple Tool for Analysis and Forecasting Success

Andrea Skafel, MSc, CCRP; Wade Berry, CCRP; Mallory Kock, CCRP; Thomas Cunningham, PhD, CCRP

UCSF Helen Diller Family Comprehensive Cancer Center, University of California San Francisco

Describe the background of the problem:

Study data is collected and captured across a variety of mediums in the clinical research environment. Each study uses a different electronic data capture (EDC) system and provides reports summarizing data and quality metrics (including data entry completion rates) to the research team.

At the Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) we conduct 467 active trials from 136 different sponsors. The studies are conducted by 132 individual research staff, in 13 different programs across 3 campuses.

Historically the clinical research coordinators (CRCs) reported on their data completion metrics to program leadership, and all reports were reviewed, but as the research portfolio at the HDFCCC grew, it was inefficient to review all sponsor reports to identify data deficiencies.

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

To develop a tool for CRCs to use to capture all data tasks (e.g. data entry for study visits, queries, etc.) for all studies within a program. The tool will aim to:

1) Assess workload and staffing requirements within a program;
2) Track data completion over time to identify any potential workload issues in real time and adjust staffing or program priorities;
3) Provide data entry metrics and goals to all CRCs to ensure high performance; and,
4) Ensure data entry timelines are met as per contractual obligations;

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

We developed a simple spreadsheet and a series of reports to capture all data tasks in a study. The spreadsheets also includes the type of event (e.g. study visit, query, etc.) and timeline to completion. The reports developed highlight: data entry completion rates by CRC and by study; and data entry timelines by type of event. The spreadsheet was implemented in all programs in late 2016/early 2017.

As a result of implementing the spreadsheet:

- Programs with a backlog in data entry were identified and allowed efforts to focus clean-up and preventative action.
  - In the last 9 months, one program went from 14% data completion to 78% by implementing various strategies including program leadership engagement, additional staff and revised program priorities.
  - In the same time period, overall completion across the HDFCCC rose from 78% to 87% completion.
- Documented the average days to complete a study visit and queries: 9.4 days and 5.9 days respectively.
- Senior leadership at the HDFCCC is engaged and actively promotes data standards.
- Lead CRCs in each program evaluate workload of CRCs each month and adjust workload assignments based on report.

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

The data tracking tool captures data entry tasks for all studies at the HDFCCC. It has proved to be the most effective way to combine all reports in a single place to fully assess the workload requirements in a program.

Objective Data Tracking Tool

Stefanie Belanger, CCRP; Stephanie Ladd, 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) maintains hundreds of trials, each with their own data entry systems. Gaining access to each system requires lengthy training. It is not possible for managers to complete this for each trial under their purview and to then regularly examine each. This makes it challenging for managers to know the status of all data at a glance. Trials with regular monitoring provide a constant reminder of deadlines. Trials without regular monitoring are often perceived to be lower priority and therefore fall behind.

Data backlogs negatively impact the morale of those that inherit it, leading to staff dissatisfaction, which then contributes to employee turnover. We needed a way to identify backlogs early to proactively allocate resources, thereby avoiding surprises during auditing and monitoring and preserving employee morale.

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

- To make transparent the state of data entry across all trials
- To help coordinators prioritize data entry
- To maintain compliance with deadlines
- To assist in resource allocation
- To provide additional oversight for PIs

Describe the solutions or methods implemented:

An Excel-based data tracker was created per coordinator; it captures each trial they are responsible for, and tracks:

- Trial: protocol, sponsor type, disease team
- Subject: ID number and status (i.e. screening, on treatment, in follow up)
- Cycles: number completed (by patient) vs. number entered (data)
- Queries: number outstanding

Their metrics feed into a summary page showing the total number of cycles, percent of data, and number of queries outstanding. These individual trackers feed into a summary tool displaying data status and trends at the disease team and CPO level.

Implementation of this tool was key in its success. Presenting its usefulness on multiple levels and focusing on the benefits to the individual using it was the crucial message conveyed. The tool supports our office's goal of maintaining a culture of transparency and safety. Staff were given three months to populate their tools; this could not be rushed, as it was a critical step in uncovering backlogs to address and track.

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

Staff update their tools regularly and see benefit in tracking this information centrally. Tools are discussed in weekly disease group meetings and individually with managers. Aggregated data is sent to disease group lead investigators monthly to provide them with additional oversight, and helps them assess new accrual bandwidth.

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

Design and implementation of the tracker proved to be a lengthy process because of the number of factors involved and the need for a thoughtful rollout to staff. Because of the large number of coordinators, future upgrades may benefit from advanced coding, such as macros or Python.

The CPO uses modified OPAL (Ontario Protocol Assessment Level) scores to assess workload; we plan to compare OPAL and data trends to assess any correlation between the two and to validate our tools. The CPO is implementing a new effort tracking system; this data collected will also be assessed for correlation between data tracking and OPAL. A full assessment of the success of the data tracker, along with the above comparisons, will be done in approximately one year.

Modeling AACI to Create a Problem Solving Culture within the University of Chicago Comprehensive Cancer Center

Lauren Wall, MS; Amanda Spratt

University of Chicago Medicine Comprehensive Cancer Center

Describe the background of the problem:

Conducting safe, efficient, and successful oncology clinical trials is essential in order to meet our cancer center's mission statement. Cancer trials have become increasingly complex. For example in FY16, 50% of new studies required research tissue collection, 72% research blood, and 55% other samples, compared to 30%, 57%, and 34% in FY13. In addition, other measures of complexity (such as screening length, data queries, and data entry timelines) have increased over time.

Historically solutions to research problems were tackled in an isolated fashion and problems would recur across studies and programs. This siloed approach is inefficient and often leads to redundant work. We must be able to operationalize solutions in a holistic fashion in order to maintain compliance and follow best practices.

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

Our overall goal was to empower research staff across all programs to work together to develop better processes/system improvements and share best practices in order to better operationalize increasingly complex studies. We believe that better team work, increased communication, and information sharing will improve our research operations which will ultimately allow us to run more efficient trials and lead to more effective cancer treatments for our patients.

Describe the solutions or methods implemented:

Staff were encouraged to identify barriers to running clinical research, brainstorm potential solutions, pilot their solutions and track results. This process ultimately culminated in a Research Operations Challenge (ROC), wherein staff were asked to highlight the problem and outcomes utilizing the AACI operational initiative format. Participation was voluntary and participants were allowed to work alone or as a team. A diverse group of reviewers, including senior and junior level faculty, were identified to review and score the abstracts.

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

Involvement in the ROC has grown exponentially in terms of number and type of participants and abstracts (Figure 1). Abstracts resulting in a positive change increased from 50% in FY15 to 92% in FY17. Positive changes including developing a guide to assist staff in navigating our EMR, improvements in data entry and sample collection at satellite sites, and multiple improvements to research sample collections. Abstracts have also highlighted areas of need for future process improvements, e.g. restructuring our trial prioritization, improving protocol activation timelines, and costs associated with low enrolling trials.

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

Implementing the ROC within our Cancer Center has been invaluable. We strongly suggest other cancer centers to implement a similar challenge at their institution using the tools provided to us by AACI. It is a great way for research staff to get involved and become a part of the solution instead of just focusing on the problem. Research staff are more willing and prepared to identify barriers to effective trial implementation and to brainstorm and own potential solutions. Because participants tracked metrics, both positive and negative, best practices have been implemented based on a data driven approach. We are hopeful that the annual ROC will continue to grow both within and outside of our Cancer Center. Lastly, our goal is to secure funding so that our annual winners can attend the AACI annual CRI meeting.

Survey of Protocol Review and Monitoring Systems in U.S. Cancer Centers

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University of Colorado Cancer Center

Describe the background of the problem:

A Protocol Review and Monitoring System (PRMS) is required for all National Cancer Institute (NCI)-designated Cancer Centers. NCI grant funding through the Cancer Center Support Grant (CCSG) provides significant financial support to these centers. With this support comes the expectation that an internal mechanism for scientific peer-review of cancer clinical trials performed at the institution is adequate. This entity is the PRMS which evaluates protocols for scientific merit, feasibility and scientific progress of active studies.

While the NCI requirements for PRMS exist, interpreting and actuating them is an individualistic endeavor. A disapproved PRMS has major repercussions to the center, most evident is losing the ability to allocate CCSG funds for clinical research purposes. The PRMS survey was developed to discover the various ways that PRMS' at other institutions operate, and to potentially improve upon the current processes at UCCC.

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

UCCC plans to leverage key findings from this survey to implement solutions for running a successful PRMS.

Describe the solutions or methods implemented:

Three listservs were used in this evaluation:

1. list@Ccaf.org – a cancer center administrator's forum
2. CRIListserv@aaci-cancer.org – Association of American Cancer Institutes Clinical Research Initiative
3. ctoadmins@onsemble.net – Forte listserv for members who use the clinical trial management system OnCore

This anonymous survey was created in SurveyMonkey® and sent to the listservs on 10/28/16. The survey closed on 11/21/16. 68 respondents from U.S. Cancer Centers completed the 28-question survey. Respondents had the option to provide their name and institution.

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

Examples of survey questions include: How many reviewers attend a full board Scientific Review Committee meeting; how many constitute a quorum; professional background of reviewers; whether reviewers are paid; methods for determining low accrual; prioritization of studies, and feasibility determination.

Survey results indicate that Cancer Center PRMS' are operationalized in a variety of ways.

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

Lessons learned include:

1) Landscape of PRMS over 68 institutions, as well as the range and median of selected questions.
2) Areas where UCCC PRMS can improve upon its own processes.

Based on the survey findings, UCCC PRMS has begun implementing changes to improve its PRMS workflow. Areas of change include restructuring the system to facilitate an efficient and integrated operation, increasing scientific review quorum size and revamping the prioritization scoring method of protocols. We anticipate these changes will result in a more effective and highly functioning PRMS that will allow us to maintain an NCI approval rating in the PRMS category.

Several limitations of the survey include the following: 1) some questions in the survey could have been interpreted in more than one way; 2) many valuable comments from respondents were provided but are difficult to quantify; 3) the survey is non-scientific and not validated; and 4) although 50 of the 68 sites provided their institution name, due to the anonymous nature of the survey, it is unknown if responses are from personnel with adequate knowledge of PRMS.

Future plans include re-surveying this same group to improve upon the limitations above.

First Impressions: Centralizing the CDA Process

Christine Mackay, RN, MSA, CCRP; Morgan Smotherman; Kathy Schleeter; Donna Palatas, JD; Claire Sabin Koenig, JD; Tiffany Pothapragada, PhD; Peter Griffith, JD

The University of Kansas Cancer Center

Describe the background of the problem:

Industry sponsors require an executed Confidentiality Disclosure Agreement (CDA) to begin the clinical trial site feasibility process. As a prospective research site interacts with the Sponsor or Contract Research Organization (herein referred to collectively as "sponsor"), first impressions are made of a site's administrative quality. During subsequent feasibility encounters, sponsors expect similar or improved interaction, quality and speed from the research site.

Sponsors transmit CDAs to sites using a variety of mechanisms and routes. Without a centralized CDA review process to respond effectively to those variations in CDA receipt, confusion, duplication, and invalid documentation may result. In response, a sponsor may be discouraged from working with the site on the current and/or future studies.

Provide metrics or goals with solutions to address the problem:

- Develop a central repository to receive and track new study opportunities
- Develop a standardized process to receive, track and execute CDAs
- Evaluate time from CDA submission to execution to identify efficiencies to be duplicated and obstacles to be avoided
- Compare CDA execution timelines with study start up timelines

Describe the solutions or methods implemented:

In January 2015, the legal team developed, pilot tested, and launched an application in RedCap for recording and tracking CDA requests. Once the data pertaining to the CDA (i.e. Sponsor and CRO names, contact information, proposed investigator, etc.) are entered, and the CDA template is uploaded, an email is generated and sent to a central email account (RI-CDA@kumc.edu) alerting the legal team of a new request. Data was extracted from RedCap and contained important dates, as well as key information related to executing the CDA. Simultaneously, the Clinical Trials Office created a central email account (KUCCNewOps@kumc.edu) for receipt of all new study opportunities. Tracking of new study opportunities was recorded in a spreadsheet and was used in conjunction with the RedCap data to track all pre-study activities.

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

In 2016, the average turn-around times (TAT) in business days (excluding holidays):

1.3 days - from receipt of a CDA request to return of initial review with comments to sponsor
4.5 days - from delivery of CDA to investigator to return of signed document from investigator
15.3 days - total time from CDA request to a fully executed document
(Note: 1 day = same day.)

Preliminary findings suggest that neither the sponsor or trial phase seemed to impact TATs.

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

In collaborating with our site's legal team to centralize the CDA process, we are now tracking key early study start-up milestones and it appears there is a positive correlation since the average TATs are relatively short. This data can be used as a benchmark to analyze ongoing and future study start up timelines.

With the ongoing evaluation of the 2015 data, we hope to elaborate further on the impact of efficient CDA execution with overall study start up timelines.

Learn-Inform-Recruit: Increasing the Offer of Urologic Cancer Trials in Community Practice

Christine Mackay, RN, MSA, CCRP; Andrew Zganjar, MD; Laurie Petty, PhDc; Mugur Geana, MD, PhD; Jessie Gills, MD; Tomas L. Griebling, MPH, MD; Brantley Thrasher, MD; Shellie Ellis, MA, PhD

The University of Kansas Cancer Center

Describe the background of the problem:

The National Cancer Moonshot Initiative expects to accelerate cancer research, which requires adequate and timely enrollment to clinical trials. Trial accrual has been a challenge for decades; one reason is that few physicians offer their patients the opportunity to participate in trials. 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 typically consulted.

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

- Identify relevant factors influencing the offering of clinical trials within urology practices
- Assess barriers to effective communication about participation in urological cancer clinical trials
- Develop interventions to inform and engage urologists to promote the offer of trials

Describe the solutions or methods implemented:

We recruited and interviewed 7 urologists, 11 staff members, and 5 stakeholders from both solo and group practices in Kansas communities with open urological cancer trials. Local cancer center stakeholders were included to provide context regarding referral relationships and challenges. Interviews were transcribed and initially coded by the research team to identify Strengths, Weaknesses, Opportunities and Threats of offering clinical trials to urology patients.

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

Participants perceived eligibility screening and patient education to be burdensome. Lack of knowledge, scarce educational materials, and providers' misperceptions of patients' willingness to participate in a trial were identified as barriers. Urologists prefer face-to-face interactions to learn about trials, and cited the influence of state/regional professional societies in shaping practice patterns. Some urologists described strong referral relationships with fellowship-trained urological oncologists at tertiary care centers and weaker relationships with local oncologists. Both surgeons and staff considered trials to be appropriate for patients with few treatment options, and were pleased to learn that some trials are designed for earlier treatment stages.

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

Community urology practices had limited experience and awareness of currently available trials, but appear willing to participate in initiatives to increase clinical trial participation. Targeted communication strategies may be effective in increasing awareness of available trials, but should address barriers as identified. Urologists may be receptive to learning about clinical trials through programs endorsed by state or regional professional societies. Simple, practice-branded tools regarding available trials could support urologists' need for patient education and capitalize on the value community urologists perceive in offering trials. Standardized communications from trial sponsors may dispel misperceptions and facilitate care coordination following enrollment. Strategies to strengthen community urology-oncology interaction are needed to increase/sustain the offer of clinical trials, and should enlist academic urologists to promote local interaction.

Assessing Patients for Clinical Trials: An Evaluation of Radiation Oncologists at an NCI Designated Cancer Center

Mindi TenNapel, MBA, PhD; Christine Mackay, RN, MSA, CCRP

The University of Kansas Cancer Center

Describe the background of the problem:

Despite the increased awareness of the importance of clinical trials, very few adult patients receiving radiation therapy are actually enrolled. Numerous studies of the reasons for low accrual have been reported, and most identify the physician as being critical to successful participation. Various agencies require clinical trial enrollment in order to maintain or gain accreditation.

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

- Evaluate patterns of patient clinical trial assessment by radiation oncologists
- Identify facilitators and barriers to conducting and documenting the assessment

Describe the solutions or methods implemented:

Patients being seen by a radiation oncologist are assessed at the time of consultation to determine possible trial eligibility. This assessment is documented in the electronic health record, EPIC. In late 2014, the fields to capture this assessment were initially added to better enable cancer center providers to document the outcome. The response fields were further refined in early 2015, with the first reports containing this data available in April 2015. Another modification to the response fields was made in August 2016, to comply with Commission on Cancer requirements (see table of responses below). The clinical trial management system is linked to EPIC, thus allowing identification of trial patients in the reports.

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

There were 2,397 radiation oncologist patient assessments from April 2015 to December 2016 that were reviewed, which included over 20 malignant disease categories per ICD10 codes. The majority of patients (96%, n=2309), presenting for radiation therapy were either not eligible for trial participation or there was not an open available trial. Of the patients who were enrolled (3%, n=74), most were female and married. Only 14 patients (0.6%) declined study participation when asked. The patient's type of insurance was not significantly related to whether a patient was enrolled (data not shown). The difference in enrollment of patients at the academic center versus the community sites was statistically significant (p=0.03).

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

Evaluation of these responses supports the often cited adult clinical trial participation rate of 3-5%. We found that trials were not available for most patients, thus bringing awareness to the need for additional or more inclusive trials. The fact that few patients declined participation can be used to encourage other providers to have the discussion about possible trial participation early in the treatment options conversation.

Further analysis of the specific reasons patients did not meet trial eligibility may provide rationale for developing investigator driven trials. A qualitative study of the providers experience in making and documenting this assessment may offer additional information for designing targeted interventions that may ultimately increase trial participation.

Current Trial Assessment Responses in EPIC

1	Enrolled in treatment clinical trial
2	Screening for treatment clinical trial
3	Not eligible for treatment clinical trial
4	No treatment clinical trial available
5	Declined clinical trial

Streamlining Research Billing with Informatics Tools and Consensus Building

Umit Topaloglu, PhD; Terra Colvin, MS; Megan Brown; Jennifer Black; Jennifer Newsome; Stacey Lewis; Kim Sweat; Jennette Cossey; Selvin Ohene; Brooke Everhart; Robin Harrelson; Meredith Hiatt; Teresa Sells; Brian Strittmatter; Garland Kitts; Lynn Kennedy; Boris Pasche, MD, PhD; Stefan Grant, MD, JD, MBA

Wake Forest Baptist Comprehensive Cancer Center

Describe the background of the problem:

Clinical Research (CR) is vital to catalyze innovative methods and technologies for biomedical advancements and better patient care. Yet, financing clinical trials is a major challenge for sponsors as well as Academic Centers. Between 2008 and 2013, the clinical trial activation costs for study sites increased to $50,000 per trial[1] a steady increase of 88%.[2] With the Memorandum of 2000, CMS allows charges made for routine patient care and/or complications associated with a clinical trial. Given the strict regulations[3] and process' complexity[4] in a clinical setting, despite the financial incentives, proper charging for trials creates many administrative and legal burden.[5]

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

1. Eliminating inefficiencies by removing duplicate efforts through process improvements with the help of research informatics tools reduce the afore mentioned burden on study sites.
2. Establish a framework in which independent groups have open communication channels and mechanisms to reduce time to activation for trials.
3. With utilization of accurate and complete treatment plans, minimize any potential study deviations.
4. Properly bill the study procedures to correct payer to avoid any legal and administrative issues.

Describe the solutions or methods implemented:

As depicted in figure 1, first, we obtained the orderable procedure mapping to the chargeable procedures from Epic (WFBCCC's Electronic Medical Record). Second, the study team (regulatory, research nurses) and research pharmacy meet to develop the calendar in OnCore (WFBCCC's Clinical Research Management System). The orderable procedures are used in the study calendar build (and the treatment plan) as well as during routine clinical care. Third, the study team develop the study budget with the corresponding chargeable procedures with Current Procedural Terminology (CPT), and Epic's Procedure Master File (EAP) codes in coordination with the Office of Clinical Research (OCR). Fourth, upon completion of Medicare Coverage Analysis (MCA) and the budget approval, the Beacon Team builds the Epic treatment plan by accessing the OnCore Calendar where all the procedures (chemo, labs, imaging etc.) are entered with correct visit schedule and Epic order codes. Fifth, The OnCore budget with mapped chargeable procedures is pushed electronically to Epic (via CRPC interface). Sixth, the billing protocol is generated from the pushed billing template and the developed treatment plan. Finally, as the study procedures are ordered from the treatment plan at the clinics, generated charges from the orders in Epic are already mapped to the billing protocol (with some exceptions) per the mapping file and are accurately allocated to the correct work queues.

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

The pilot of a second study is underway with consensus of the workflow is in place and generates excitement among groups.

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

Since the typical study lifecycle (i.e. study initiation, conduct, and closing/billing) is usually managed by different groups, working meetings on new workflow have been fruitful as all parties realized the expectations and challenges faced by others. Such understanding has gradually built mutual trust, which is an indispensable requirement for the new workflow's success. With the addition of interoperable systems, we are able eliminate majority of duplicated efforts.

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Document Management Beyond Regulatory. Breaking Down Silos and Cultivating Effective Collaboration

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Describe the background of the problem:

Cancer centers have established specialized teams to handle large, complex clinical trials in efficient and consistent manners. Prompt access to trial related information is critical to all clinical trial stakeholders, enabling timely decisions and ensure patient safety.

Traditionally, at the Wilmot Cancer Institute (WCI), regulatory, finance, clinical, and pharmacy teams maintained separate shared drives, or information silos, to control access and maintain organization. This resulted in redundant duplication and increased time and material costs when information needed to be disseminated across departments.

Based on regulations and institutional requirements, the authoritative copy may reside within shared drives, paper binders, or another system. Even with eRegulatory and other paperless solutions, keeping separate shared drives for the convenience of each team resulted in duplication, decreased staff efficiency, and increased risk of non-compliance.

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

WCI is driving performance by implementing a centralized document management system. By ensuring the right person can see the right document at the right time, clinical trials offices can eliminate information silos, shared drives, and seamlessly collaborate between teams and locations.

The goal is to improve access to information, reduce redundancy, and establish a single document system where all stakeholders, including regulatory, finance, research staff, pharmacists, and non-research clinical staff, have controlled access to a single source of the truth. Demonstrating improved access by stakeholders, confidence of accurate trial information, and a decrease in staff time, material, and archiving costs is anticipated.

Describe the solutions or methods implemented:

In the initial attempt to reduce redundancy, a web-based eRegulatory solution was implemented. Linking to the electronic health record enabled pharmacy, clinical and non-research clinical staff to access regulatory documents including manuals, investigator brochures and protocols. This greatly improved access and collaboration across teams; however, the ability to restrict access to specific documents and configure the system to meet the needs of other stakeholders was limited. Thus, some documents needed to be duplicated in a separate location within the eRegulatory system.

WCI then implemented a configurable centralized document management system across all stakeholders. This provided the flexibility to control, organize and view information in a way that is relevant for each independent user. Furthermore, all teams can work within the same system and share documents across teams, without duplication.
Time, material costs and collaboration was evaluated before and after the system was implemented.

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

Key anticipated and unanticipated outcomes were observed. An initial overall reduction in redundancy, staff time and material costs by all stakeholders resulted. Additional levels of reduction in redundancy, time and costs savings are anticipated after implementation of the configurable centralized document management system.

Unexpectedly, an overall shared sense of engagement and responsibility across the WCI was observed. All stakeholders centrally shared up-to-date trial documentation, demonstrating a sense of ownership. Having the right information readily accessible ceased "crisis mode" operations. Redundant requests and complaints to regulatory have ended. Operational silos have been demolished. Overall, a greater sense of unity and engagement exist.

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

Lessons learned:

1. Identify stakeholder needs throughout implementation
2. Establish timeline to onboard team members
3. Engagement and process ownership can be achieved via collaboration

Mastering the Delegation of Authority Log: A Centralized Approach to Maintaining Site Regulatory Documents

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Describe the background of the problem:

The Master Delegation of Authority (DoA) Log was implemented at the Yale Cancer Center (YCC) to increase compliance, reduce administrative burden, and improve accuracy of data recorded on the DoA. Prior to implementing a Master DoA, regulatory designees were obtaining duplicate signatures and initials from faculty and staff who support our clinical trials, inadvertently not obtaining signatures and initials from staff prior to departure from the YCC, and inconsistently recording tasks and duties. The Master DoA ensures staff are appropriately listed, and signatures and initials are obtained contemporaneous with start dates for a given role.

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

- To ensure staff are appropriately delegated prior to participation
- To reduce compliance issues identified during routine monitoring visits, internal and external audits, and inspections
- To decrease the amount of time spent collecting signatures from study staff on study-specific logs

Describe the solutions or methods implemented:

Two templates were created: one to maintain a master signature and initial log for all staff supporting clinical trials at YCC and another to assign personnel to specific studies, record their delegated role, duties, dates of participation, and obtain PI delegation. Standard roles, duties, start and stop dates were defined. We partnered with our Business Office, Human Resources, and collaborating departments to confirm employment start dates. We updated our standard operating procedure (SOP) and trained key stakeholders in the revised procedure. We dedicated time to complete existing study-specific DoAs such that the new procedure could be implemented on all studies concurrent with the effective date of the SOP.

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

Since the implementation of the Master DoA in February 2017, we participated in routine monitoring visits and internal audits. We noted a reduction in issues identified during monitoring visits that relate to the DoA. We have yet to receive results from internal audits. External monitors have responded favorably to the new procedure and recognize the positive impact it will have on compliance.

The reconciliation of existing study-specific DoAs uncovered gaps in study-specific training as study staff start dates are defined as the latter date of IRB approval (where appropriate) and training. As a result, we are reviewing our process for collecting and documenting training.

Inconsistent entries in our Clinical Trials Management System (OnCore) compared to the hard copy DoA were identified. To address this, we partnered with Yale's OnCore team to customize a report from the system for the DoA to ensure consistency. OnCore now serves as the electronic DoA for all team members to access and review in real time.

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

By engaging the entire Regulatory Affairs department in planning and implementation, we efficiently closed out existing study-specific DoAs. This effort was critical to ensure concurrent implementation of the new procedure across all studies and avoid operating under two procedures. We identified systemic trends related to omitted or inconsistent data on the DoA that the Master DoA has resolved. Examples include duplicate entries, inconsistent delegation of tasks and roles, and missing signatures and initials. Devoting common work time each week to reconciliation ensured all were working towards a common goal and fostered teamwork.

Realizing Rapid Review: Expanding the Use of a Clinical Trials Management System to Streamline the Protocol Review and Monitoring System

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Describe the background of the problem:

The administratively burdensome and fragmented Protocol Review Committee (PRC) submission and review process necessitated simplification. The capabilities of our Clinical Trials Management System (CTMS), OnCore, was underutilized and sought to be leveraged to facilitate a more efficient and transparent review process. This major process change, impacting multiple stakeholders, needed to be expeditiously and efficiently implemented while maintaining the ongoing PRC review throughput.

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

- Develop a procedural framework to implement systematic changes
- Reduce PRC submission and review timelines
- Increase the quality of submissions and reviews
- Lessen administrative burden

Describe the solutions or methods implemented:

Prior to implementation, a procedural framework was developed to:

- Identify key stakeholders and working group members
- Conduct needs assessment and systems evaluation
- Engage key stakeholders and communicate revisions at appropriate intervals
- Document revised process
- Train all end-users

A working group with representatives from the Clinical Trials Office, Office of Quality Assurance and Training, and CTMS support was formed. This collaborative team fostered a strategic implementation through weekly in-person meetings. PRC processes were updated for use within the electronic Protocol Review & Monitoring System (ePRMS) of OnCore and documented. Key stakeholders were engaged to ensure process buy-in from leadership. All process changes were communicated and end-users, including regulatory coordinators, PRC coordinators, and PRC reviewers, were trained by their respective group experts. Following implementation, each group continued to evaluate and refine the system.

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

- The ePRMS system was successfully implemented in 2.5 months.
- PRC submission preparation time decreased by approximately 60%, specifically by significantly limiting the amount of double-entry and eliminating extraction of duplicate information provided in the protocol.
- PRC coordinators observed improvement in submission quality, evidenced by decrease in submission queries.
- PRC submission to approval cycle time decreased by 43%.
- Increased PRC faculty member familiarity and utilization of the CTMS.
- Increased PRC member engagement, demonstrated by greater compliance in submission of completed reviewer forms.
- Reduced administrative tasks, specifically:
  - ePRMS automatic notifications and query functionality eliminated use of Outlook and decreased manual correspondence by 4 e-mails per submission.
  - ePRMS served a document management function, thus use of SharePoint was eliminated.

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

- The strategic and collaborative approach was essential for a timely and successful implementation. The method used allowed for quick decision making during implementation, as key areas were engaged at all times.
- PRC processes required adaptation due to system limitations.
  - Adobe LiveCycle forms were created to supplement ePRMS submission due to inability to customize existing fields in system.
- Training and providing continued support for end-users is pivotal.
- In future implementations, engaging ITS in the planning stages could be considered to better assist end-users that are not technologically savvy.
- CTMS support throughout the implementation was instrumental for system evaluation and troubleshooting.
- The implementation method was successfully replicated for an overhaul of our accrual monitoring process.

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