



Association of American Cancer Institutes
CLINICAL RESEARCH INITIATIVE



8th Annual Meeting
**ACHIEVING OPERATIONAL
EXCELLENCE**

2016 Abstracts and Posters

Table of Contents

AACI CRI Overview	4
8th Annual AACI CRI Meeting Abstract Overview	5
2016 Winning Abstracts and Posters	
First Place	
The Clinical Trial Management Tool: An Innovative Approach to Regulatory Operations	
Abby Statler, MPH, MA, CCRP; Curtis Brinkman; Dennis Urbanek; Laura Bailey, MBA	
<i>Cleveland Clinic Taussig Cancer Institute, The Cleveland Clinic Foundation</i>	
Abstract.....	6
Poster	7
Second Place	
CRANIUM (Clinical Research Assessment Metrics) Workload Assessment Model for an NCI-Designated Comprehensive Cancer Center	
Sally Fairbairn, CCRP; Lindsay Carpenter, MSW, CCRC; Jessica Moehle, CCRP; Leanne Lujan, CCRP; Kelli Thorne, MPH, CCRP; Emily Ostrander, CCRP; Rachel Kingsford, MS, CCRP; Kenneth M. Boucher, PhD; Curt Hampton, MS, MBA	
<i>Huntsman Cancer Institute, University of Utah</i>	
Abstract.....	8
Poster	9
Third Place	
Using Data to Determine Study Budgets for Clinical Trials Office Staff	
Matt Innes, MBA; Kate Harper, MBA, CCRP	
<i>University of Michigan Comprehensive Cancer Center</i>	
Abstract.....	10
Poster	11
Submitted Abstracts (alphabetical order by cancer center):	
Bridging the Gap – Utilizing Web-Based Applications in Clinical Trials	
Jacqueline Shoukry, MBS, CCRC; Katelyn Thompson, CCRP	
<i>Fox Chase Cancer Center, Temple Health</i>	
Establishing Standard Processes to Document Tumor Response in Clinical Trial Patients Using Protocol-Defined Criteria.....	
Rajendra Kumar; Katelyn Thompson, CCRP	
<i>Fox Chase Cancer Center, Temple Health</i>	
Implementing a Functional Work Group Model to Increase Employee Satisfaction and Reduce Turnover	
Dana Keiser, RN, MSN; John O'Neill	
<i>Fox Chase Cancer Center, Temple Health</i>	
Research Patient Financial Counselor – Removing Insurance Barriers from Clinical Trial Enrollment	
Erika Greenidge, MPH	
<i>Fox Chase Cancer Center, Temple Health</i>	
Shortening the Time in Regulatory from Industry Protocol Receipt to Study Activation.....	
Tracy A. Kradzinski	
<i>Fox Chase Cancer Center, Temple Health</i>	
The Investigator Sponsored Research Unit at FCCC.....	
Stephanie Rosati	
<i>Fox Chase Cancer Center, Temple Health</i>	
Implementation of a Recharge Model to Improve the Management of Clinical Trial Expenses.....	
Moshe Kelsen, MBA; Ryan Lichtcsien, MA; Francis Brogan, MSN, RN; Nataliya Samodov, MBA; Daniel Otap, CCRP; Stephen Emerson, MD, PhD; Andrew B. Lassman, MD, MS	
<i>Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center</i>	

Not the ‘Ethics Police’, a Unique Approach to Internal Quality Assurance (QA) and Monitoring Procedures	19
Daniel Otap, CCRP; Moshe Kelsen, MBA; Tiffany Negri, CCRP; Marianne Reyna, CCRC; Josephine G. Jorge; Francis Brogan, MSN, RN; Stephen Emerson, MD, PhD; Andrew B. Lassman, MD, MS <i>Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center</i>	
The Clinical Protocol & Data Management (CPDM) Central Registration Office For Eligibility Confirmation: Advancements in Process Improvement	20
Daniel Otap, CCRP; Moshe Kelsen, MBA; Tiffany Negri, CCRP; Marianne Reyna, CCRC; Josephine G. Jorge; Shannon Kelly; Francis Brogan, MSN, RN; Christina Corpuz; Ryan Shelton; Stephen Emerson, MD, PhD; Andrew B. Lassman, MD, MS <i>Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center</i>	
Creation of a Comprehensive Beacon Treatment Plan to Enhance Functionality Along with Treatment and Billing Compliance	21
Lorraine Harris, RN, BSN, CCRP, OCN; Terri L. Matson, CCRP; John Kelly <i>Hollings Cancer Center, Medical University of South Carolina</i>	
Finding a Cost-Effective, Efficient and User-Friendly Data Capture System for Investigator-Initiated Trials	22
Kate Anderton, MPH, CCRP; Tricia Adrales Bentz, MHA, CCRP <i>Hollings Cancer Center, Medical University of South Carolina</i>	
Utilization of Microsoft SharePoint to Improve Clinical Trial Interdepartmental Communications and Document Management	23
Tricia Adrales Bentz, MHA, CCRP; Terri L. Matson, CCRP <i>Hollings Cancer Center, Medical University of South Carolina</i>	
Development of a Comprehensive Training Program – Building on the Eight Competency Domains for the Clinical Research Professional	24
Rachel Kingsford, MS, CCRP; Emily Ostrander, CCRP; Sally Fairbairn, CCRP <i>Huntsman Cancer Institute, University of Utah</i>	
External IND Safety Report Processing Policy – Reducing Site Workload and Cost with New FDA Compliant SOP	25
Lindsey Byrd, CCRP, MD ¹ ; Barbara (BJ) Broome, CCRP ² ; Jamie White, CCRP ¹ <i>¹Huntsman Cancer Institute, University of Utah; ²Vanderbilt-Ingram Cancer Center</i>	
Fast Fact Sheets for Infusion Nursing Management of Infused Investigational Drugs	26
Rachel Kingsford, MS, CCRP; Joy Lombardi, RN, BSN, OCN <i>Huntsman Cancer Institute, University of Utah</i>	
Streamlining the Participant Reimbursement Process	27
Anita Bowler, CCRP; Marlyn Galindo; Tiffaney Rasmussen; Tracy Jensen; Holly Bateman; Glenda Peck <i>Huntsman Cancer Institute, University of Utah</i>	
Framing Clinical Research and the Importance of Trial Participation: Patient and Physician Perspective	28
Jaclyn Regan, MBA ¹ ; Christine Hickey ¹ ; Chris Targett ² ; Shoko Masuda ³ ; Paul Sabbatini, MD ¹ <i>¹Memorial Sloan Kettering Cancer Center; ²Milward Brown Analytics; ³HKSM Consulting LLC</i>	
Lessons Learned from an EMA/FDA Inspection	29
Tim Barz; Theresa Gold <i>Memorial Sloan Kettering Cancer Center</i>	
MSKCC eTrials: Creating a Digitized Patient Data Ecosystem for Industry-Sponsored Clinical Trials, and Creation of the MyMSK Medication Support App	30
Michael Buckley ¹ ; Milena Silverman ¹ ; Dawn Caron ¹ ; Ophelia Chiu ¹ ; Kai-Hsiung Lin ¹ ; Jennifer White ¹ ; Mary Mitchell ¹ ; John Yee ¹ ; Aaron Wen ¹ ; Stu Gardos ¹ ; Jonathan Wills ¹ ; Jaclyn Regan ¹ ; Janet Murdock ² ; Rajesh Modi ² ; Vinay Sunkari ² ; Ann Dilworth ³ ; Sharon Hanlon ³ ; Mari Clovis ³ ; Collette Houston ¹ ; Paul Sabbatini, MD ¹ <i>¹Memorial Sloan Kettering Cancer Center; ²Novartis; ³Bristol-Myers Squibb</i>	
Resource Allocation Review – An Objective, Transparent Evaluation Performed by CCTO, A One Year Follow Up Analysis	31
Rosemarie Gagliardi, MPH, cEdD; Alyssa Ryan, MBA; Richa Upadhyay, MD <i>Mount Sinai Health System Tisch Cancer Institute</i>	

Using EPIC Electronic Health Record System to Assist with Screening Patients for Cancer Clinical Trials, Results from a Pilot Study in the MPD Program	32
Jill Kleczko, MPA; Ronald Hoffman, MD; Rosemarie Gagliardi, MPH, cEdD <i>Mount Sinai Health System Tisch Cancer Institute</i>	
A Priority Educational Program at Princess Margaret Cancer Centre	33
Pamela Degendorfer, MA, CCRP; Susanna Sellmann; Julie Gundry; Alex Kerr; Leslie Williams; Jasmine Grant <i>Princess Margaret Cancer Centre, University Health Network</i>	
Mobile Electronic Solution for Clinical Research Source Documentation	34
Heather Cole; Alex Kerr; Julie Gundry; Calven Eggert; Aaron DiNardo; Susanna Sellmann; Pamela Degendorfer, MA, CCRP <i>Princess Margaret Cancer Centre, University Health Network</i>	
Quality Assurance Metrics in Clinical Trial Conduct	35
Jennifer Li; Susanna Sellmann; Lindsay Philip; Cristina Guglielmi; Pamela Degendorfer, MA, CCRP; Amit Oza <i>Princess Margaret Cancer Centre, University Health Network</i>	
Automated Hospitalization/Death Notification System	36
Nick Fisher, MBA; Dave Mulvihill <i>Siteman Cancer Center</i>	
Minority Participation in Clinical Trials: A Multifaceted Approach to Increase Enrollment	37
Jessica Thein, MPH, MSW; Nick Fisher, MBA; Amanda DeMoss, MS, CCRP <i>Siteman Cancer Center</i>	
Focus on Improving Quality: Develop, Pilot and Revamp a QA Program	38
Melanie Hines, MPH; Suzanne Friedrich, CCRC; Prudhvi Mandala, MS, CCRP; MaryAnne McNulty; Miriam Bischoff, MS, MBA <i>Stanford Cancer Institute</i>	
Molecular Profiling for Eligibility to Complex Clinical Trials – Improving Operational Efficiencies to Expedite Enrollment	39
Lauren Wall, MS; Laura Hoffman, MA; Kelly O'Connor <i>The University of Chicago Medicine Comprehensive Cancer Center</i>	
Data Table 3 Analysis of a NCI Comprehensive Cancer Center: Identifying Specific Accrual Barriers in Breast Oncology Team	40
Zoneddy Dayao, MD; Teresa Stewart, MS; Olivier Rixe, MD, PhD <i>University of New Mexico Comprehensive Cancer Center</i>	
The Value of Multidisciplinary Approach to the Creation of Research Orders	41
Neera Jagirdar, MS; Cathy Sharp, RN, MN, OCN <i>Winship Cancer Institute of Emory University</i>	
AACI CRI Steering Committee Members	42

AACI Clinical Research Initiative Overview

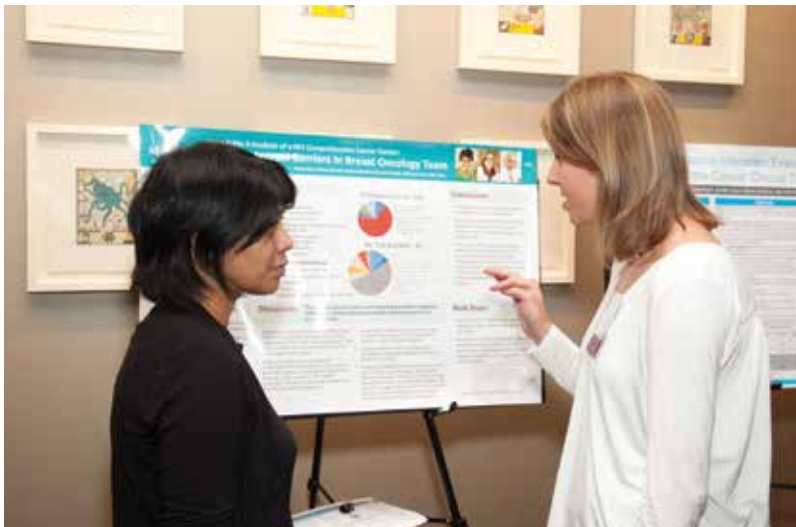
The Association of American Cancer Institutes (AACI) comprises 95 leading cancer centers in North America. AACI's membership roster includes National Cancer Institute-designated centers and academic-based cancer research programs that receive NCI support.

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 trials 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 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 disseminations of best practice models across the AACI cancer center clinical trials network.

8th Annual AACI CRI Meeting Abstracts



In January 2016, the AACI CRI Steering Committee issued a call for abstracts to AACI cancer centers for presentation at the 8th Annual AACI CRI Meeting, held July 20-21 in Chicago, IL. 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. 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 from 14 cancer centers 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 their review; the concepts demonstrated creative and thoughtful methods being employed at the cancer centers to address clinical trial process issues.



FIRST PLACE

The Clinical Trial Management Tool: An Innovative Approach to Regulatory Operations

Abby Statler, MPH, MA, CCRP; Curtis Brinkman; Dennis Urbanek; Laura Bailey, MBA

Cleveland Clinic Taussig Cancer Institute, The Cleveland Clinic Foundation

Describe the background of the problem:

The Clinical Trial Management Tool (CTMT) was developed to address an institute-wide issue related to the decentralization of regulatory resources. Prior to CTMT, Coordinators were required to visit various websites, shared document sites, and electronic files to complete regulatory tasks. This electronic management system provides Coordinators with a central location for all regulatory resources, effectively eliminating the need to reference multiple sources for a single regulatory operation.

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

- To centralize the location of regulatory resources
- To obtain an average value rating (CTMT) of 85 (0-100 scale)
- To decrease the average percentage of coordinators who perceived they spent additional time performing regulatory tasks by 10%

Describe the solutions or methods implemented:

The federal, institutional, and sponsor requirements for all clinical trials were identified and organized into three categories: start-up, maintenance, and termination. Over 150 customized process flows were created, each providing resources for the regulatory requirements related to the scientific review committee, Institutional Review Board, Food and Drug Administration, and data safety review committee. Additionally, CTMT incorporates sponsor communication / application templates, checklists, and guidance documents.

To assess the utility of CTMT, surveys were sent out prior to (2014) and after (2015 and 2016) the launch of the system. These surveys focused on gathering data relevant to the number of resources used to complete 11 distinct regulatory tasks, overall resource satisfaction, and perceived productivity. Number of hours charged to research studies was also compared before and after the implementation of CTMT. Results are reported as means +/- standard deviations.

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

Since its launch, CTMT has been viewed 5,179 times with 92% of Coordinators reporting they use the tool either all the time or sometimes, and 88% reporting CTMT has improved their regulatory skills. The average value of tool, as reported by the Coordinators, is 89.1 (+/- 15.9). The value of the tool was even more pronounced in the subgroup of new Coordinators: 94.6 (+/- 8.8), all of whom indicated CTMT is an essential training resource.

The resource utilization surveys indicated after CTMT was launched, the average percentage of Coordinators who felt they were spending additional time on regulatory tasks decreased: 24% (+/- 9.2) vs. 9.5% (+/- 3.85). This perceived reduction in time spent was supported by the actual time Coordinators tracked to research studies: after CTMT was launched the institute saw an 8% reduction in the number of hours charged to regulatory functions.

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

There were several lessons learned during the development of CTMT. Most importantly, the project revealed systemic operational inconsistencies between disease groups. Although this discovery highlighted the discrete nature of the institute's departments, it allowed the institute to unify regulatory operations, borrowing best practices from across groups to create process flows that effectively guide coherent institute-wide regulatory operations.

CTMT now serves as the institute's primary point of reference for all regulatory operations. Coordinators across several departments have effectively adopted the use of this tool into their regular workflow. Additionally, the early success of CTMT indicates that it could be a solution for other institutes within the Cleveland Clinic health system.



The Clinical Trial Management Tool: An Innovative Approach to Regulatory Operations

Abby Statler, MPH, MA, CCRP, Curtis Brinkman, BS, AAS, Dennis Urbanek, BA, Laura Bailey, MBA
Case Comprehensive Cancer Center, Cleveland Clinic Cancer Institute



BACKGROUND

The Clinical Trial Management Tool (CTMT) was developed to address an institute-wide issue related to the decentralization of regulatory resources. Prior to CTMT, Coordinators were required to visit various websites, shared document sites, and electronic files to complete regulatory tasks. This electronic management system provides Coordinators with a central location for all regulatory resources, effectively eliminating the need to reference multiple sources for a single regulatory operation.

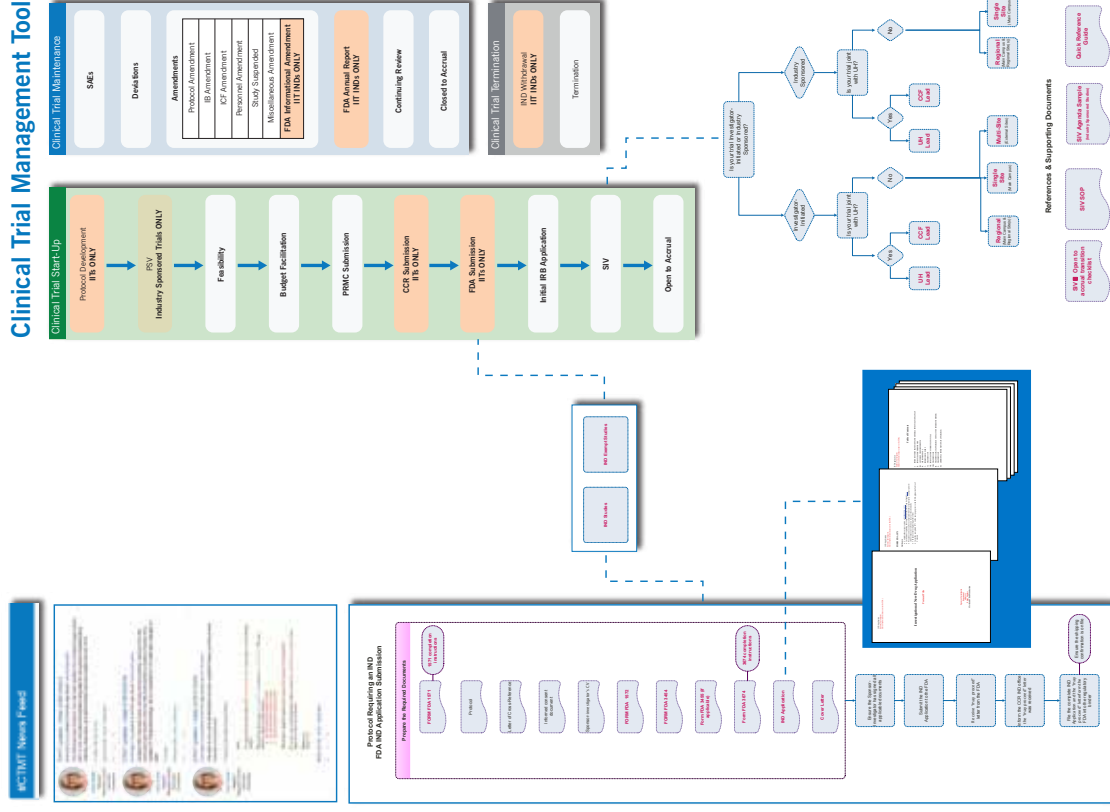
METRICS

- To centralize the location of regulatory resources
- To obtain an average value rating (CTMT) of 85 (0-100 scale)
- To decrease the average percentage of coordinators who perceived they spent additional time performing regulatory tasks by 10%

METHODS

The federal, institutional, and sponsor requirements for all clinical trials were identified and organized into three categories: start-up, maintenance, and termination. Over 150 customized process flows were created, each providing resources for the regulatory requirements related to the scientific review committee, Institutional Review Board, Food and Drug Administration, and data safety review committee. Additionally, CTMT incorporates sponsor communication / application templates, checklists, and guidance documents.

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OUTCOMES

Since its launch, CTMT has been viewed 5,179 times with 92% of Coordinators reporting they use the tool either all the time or sometimes, and 88% reporting CTMT has improved their regulatory skills. The average value of tool, as reported by the Coordinators, is 89.1 (+/- 15.9). The value of the tool was even more pronounced in the subgroup of new Coordinators: 94.6 (+/- 8.8), all of whom indicated CTMT is an essential training resource.

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CONCLUSIONS

There were several lessons learned during the development of CTMT. Most importantly, the project revealed systemic operational inconsistencies between disease groups. Although this discovery highlighted the discrete nature of the institute's departments, it allowed the institute to unify regulatory operations, borrowing best practices from across groups to create process flows that effectively guide coherent institute-wide regulatory operations.

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2

SECOND PLACE**CRANIUM (Clinical Research Assessment Metrics) Workload Assessment Model for an NCI-Designated Comprehensive Cancer Center**

Sally Fairbairn, CCRP; Lindsay Carpenter, MSW, CCRC; Jessica Moehle, CCRP; Leanne Lujan, CCRP; Kelli Thorne, MPH, CCRP; Emily Ostrander, CCRP; Rachel Kingsford, MS, CCRP; Kenneth M. Boucher, PhD; Curt Hampton, MS, MBA

Huntsman Cancer Institute, University of Utah

Describe the background of the problem:

For workload tracking and trial load distribution in academic cancer centers, no standard tool exists. This type of tool is necessary to assist in determining individual workload. Assigning staff to new protocols is often done on a subjective basis. Clinical Research Coordinators (CRCs) and Data Coordinators (RDCs) at the Huntsman Cancer Institute Clinical Trials Office (HCI CTO) are separate staff roles, with various factors contributing to their workload. An automated, objective, and validated tool to compare staff workload within the department is essential to assigning and balancing the workload among staff members.

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

- Create separate, role-specific tools for objectively quantifying the workload of CRCs and RDCs
- Utilize automated reporting within the Clinical Trial Management System (CTMS)
- Validate the scoring system through statistical analysis
- Provide staff workload comparisons
- Provide feedback to staff about their workload and how they compare to the workload of their peers
- Distribute workload among staff more equitably

Describe the solutions or methods implemented:

Two workload scoring models were created. Both utilize staff assignment and subject calendar information from the CTMS. The CRC model includes protocol complexity, number of subjects enrolled, number of consents signed, number of visits, and subject status. The RDC model includes protocol complexity and the likelihood of form queries by approximating the number of data forms a patient has, i.e., patients further on a trial are more likely to have CRF queries.

The models were applied to 300 protocols for 75 staff members and 13 disease groups. Workload reports can be run from the CTMS at the touch of a button. The reports are run over a thirty day period.

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

The models were analyzed in comparison to self-reported time. The Pearson correlation coefficient of the CRC model is $p = 0.89$ and explains 79.21% of the variance. The Pearson correlation coefficient of the RDC model is $p = 0.747$ and explains 55.8% of the variance.

We compare the workload scores of the staff members and track them over time in order to balance their assignments and can compare the disease groups on a per capita basis.

The chart below demonstrates how workload can be tracked over time. It shows how a combination of protocol reassignments and natural workflow changes have brought some scores down and how other scores have gone up over time. The grouping of the chart lines suggests a CRC workload target.

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

Based on our experience, we suggest the following:

- For the model to work most accurately the CTMS must be accurate
- Models must be role specific
- Can be amended to incorporate different job functions
 - i.e. remote monitoring and pre-screening
- Keep the model simple, logical, and easy to explain

For the future, we're working on a refined protocol complexity scoring system based on an NCI standard and adding pre-screening activity to the CRC model. This same tool may also be modified in the future to assist in predicting workload of future clinical trials and the capacity of a team and/or individual to absorb a new project.

CRANIUM (Clinical Research Assessment Metrics) Workload Assessment Model for an NCI-Designated Comprehensive Cancer Center

Sally Fairbairn, BSc, CCRP; Lindsay Carpenter, MSW, CCRP; Jessica Moehle, BS, CCRP; Leanne Lujan, BS, CCRP; Kelli Thorne, MPH, CCRP; Lyna Saffell, MS, CCRP; Emily Ostrander, CCRP; Rachel Kingstord, MS, CCRP; Kenneth M. Boucher, PhD; Curt Hampton, MS, MBA
Huntsman Cancer Institute, University of Utah, Salt Lake City

BACKGROUND

No standardized tool exists for Clinical Research Coordinators (CRC) or Research Data Coordinators (RDC). CRANIUM is an automated, objective, and validated tool to assess, compare, and assign staff workload.

GOALS

- Create role-specific tools
- Utilize automated reporting within the Clinical Trial Management System (CTMS) software (OnCore)
- Compare with other objective and subjective workload analysis
- Validate the scoring system through statistical analysis
- Provide staff workload comparisons
- Distribute workload among staff more equitably

METHOD

- Two workload scoring models were created. Both utilize staff assignment and subject calendar information from the CTMS.
- The CRC model includes protocol complexity, number of subjects enrolled, number of consents, number of visits, and subject status.
 - The RDC model includes protocol complexity, estimated form queries, and subject status.

LESSONS AND SUGGESTIONS

Based on our experience, we suggest the following:

- The CTMS must be accurate for the model to work optimally
- Models must be role-specific
- Reports must be automated
- The model can be amended to incorporate different job functions (i.e., remote monitoring and pre-screening)

FUTURE EFFORTS

- Create a refined protocol complexity scoring system
- Add pre-screening activity to the CRC model
- Predict and manage workload for current and future personnel management
- Define threshold for trial capacity

RESULTS

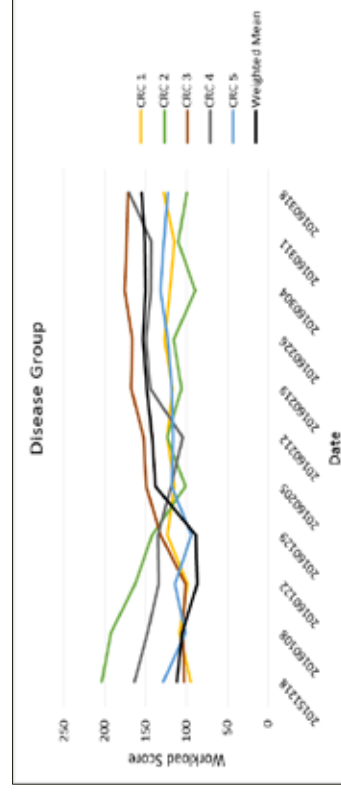
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TOOL USE

Staff workload scores are calculated, compared, and tracked weekly to balance assignments as well as compare individuals and groups.

The chart below demonstrates how workload can be tracked over time. It shows how a combination of protocol reassignments and natural workflow changes have adjusted workload scores. The chart reflects actual CRC workload distribution over six months.



3

THIRD PLACE

Using Data to Determine Study Budgets for Clinical Trials Office Staff**Matt Innes, MBA; Kate Harper, MBA, CCRP***University of Michigan Comprehensive Cancer Center*

The University of Michigan Cancer Center Clinical Trials Office (CTO) began a time and effort tracking system for their staff in 2006. The tracking tool, named RETA, certifies effort and helps identify workload of staff, enabling managers to distribute projects fairly. In 2014, the CTO began using the data collected from time and effort tracking to develop effort estimates for staff, which are used to determine the study budget for clinical trials.

RETA has allowed the CTO to more accurately determine the traditional fixed costs for start-up, amendments, and annual renewals. The traditional per-patient fee is not just a variable cost, but a combination of fixed costs (meetings, conference calls, monitoring visits) and variable costs (data entry, adverse event reporting). Effort tracking has allowed the CTO to separate out the fixed costs (maintenance fees) and variable costs (patient visit fees) from the per-patient budget. This has driven the CTO to create an effort estimate template model that more accurately reflects the true cost of the study. An appropriate study budget that covers the cost of staff effort is developed from the effort estimate. Using data to support CTO costs results in less push back from the industry sponsors during budget negotiation.

The new model has improved alignment between revenue and expenses. Revenue earned for all fixed cost items (start-up, amendments, annual renewals, and annual maintenance) was \$189,000 in Fiscal Year 2014; \$418,754 in Fiscal Year 2015; and is projected to hit \$922,420 for Fiscal Year 2016. This has also decreased the Cancer Center subsidy of the department from 38% to 29% in the last year.

The department conducts an audit at the end of each study to be sure the costs charged for staff effort are in line with the hours the staff logged to the study within the time and effort tracking system. This ensures the CTO charges fairly for the effort expended on clinical trials.

Bridging the Gap – Utilizing Web-Based Applications in Clinical Trials

Jacqueline Shoukry, MBS, CCRC; Katelyn Thompson, CCRP

Fox Chase Cancer Center, Temple Health

Describe the background of the problem:

Having accurate, real time study and accrual information is crucial for the success of clinical trials. Given that, the following problems were identified:

- 1) There was limited access and availability to study information for both patients and physicians. Patients calling the institution were directed to ClinicalTrials.gov. Over time, ClinicalTrials.gov became the main source of information for both physicians and patients to review trials. Additionally, outside recruiting physicians had limited access to information on open and accruing studies at the institution. Overall, this may have resulted in loss of accruals over time.
- 2) Accrual information was acquired by running manual accrual reports. These reports were then distributed, via email, to physicians and staff within the institution. This was done on a monthly basis and was not inclusive of all accrual data up to that point, but rather the previous month's numbers. Without access to accurate study status information, tracking the progress of studies and troubleshooting accrual drops proved difficult.

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

In order to solve these problems, multiple institutional departments combined their efforts to use OnCore, a clinical trial management system, to bridge this knowledge gap. This was accomplished by a complete redesign of the Fox Chase website, coupled with the creation of an accruals dashboard.

Describe the solutions or methods implemented:

The redesigned FoxChase.org provides patients and physicians with much more user-friendly study information. During the launch process, study descriptions and key eligibility information were configured to be extracted from OnCore directly to the website. The website now gives patients access to searchable study information that can be reviewed prior to their arrival at Fox Chase.

FoxChase.org's launch coincided with the release of the accruals dashboard, which allows physicians and staff within the institution to easily access accrual data. With all accrual information being housed centrally in OnCore, the transition from manual data pulls to automated daily dashboard updates has allowed for real-time review by all physicians.

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

During patient visits, physicians have begun utilizing the new FoxChase.org for snapshot reviews of studies with both patients and their families. Additionally, the website's new search function allows patients to search by keywords, disease site, and/or investigator. These searchable items can also be pulled into reports and sent to local physicians to boost recruitment to active trials.

The launch of the dashboard also sparked an increased focus on subject accrual. This was made possible by the consistent tracking, review, and comparison of accruals from month to month and between investigator, disease site teams, and locations.

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

With the launch of any new web-based applications, there must be constant review and revision for improvement upon the original design. Within the website, the need for sub-disease site identification has become important. This will allow patients to search for studies that are more specific to their needs (i.e. 1st line, neo-adjuvant, etc.). Similarly, within the dashboard, the ability to capture staff effort for all clinical trial patients is required. This can be done by including screen fail data into the dashboard. The website and dashboard will continue to be enhanced as new feedback is received.

Establishing Standard Processes to Document Tumor Response in Clinical Trial Patients Using Protocol-Defined Criteria

Rajendra Kumar; Katelyn Thompson, CCRP

Fox Chase Cancer Center, Temple Health

Describe the background of the problem:

Tracking tumor response is a crucial component of oncology trials. With multiple response criteria in use, and report information varying from scan to scan, identifying measurable disease and calculating changes in tumor burden can be difficult. Additionally, lack of communication between clinical trial and radiology staff can cause reporting delays when scan results are inconclusive.

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

Solving these problems required clinical trial staff to meet two distinct goals. First, create a common document to track tumor response, as well as eliminate ambiguity stemming from analysis of individual scan reports. Second, open a pathway of communication between clinical trial and radiology staff to ensure efficient completion of this document and timely resolution of scan-related questions.

Describe the solutions or methods implemented:

To address the first challenge, Tumor Identification and Measurement Forms (TIMFs) were developed to track tumor response, with unique templates for each set of measurement guidelines. At baseline, a patient's measurable and non-measurable disease is recorded on the TIMF, along with each lesion's size, status, and image number. Space is also provided to record the baseline sum of lesions, as well as calculate thresholds for partial response and progressive disease. At follow-up time points, updated measurements are added for each lesion, and overall response is recorded. New lesions can also be documented. Each set of measurements is signed and dated by the radiologist who reviewed the scan, allowing the TIMF to serve as source documentation. The final product is a single document containing the results of every scan a patient underwent while on study.

With the TIMFs in place, clinical trial and radiology staff met to establish a process for completing the forms. TIMFs are now distributed to radiologists prior to patients' scans, and are completed alongside report dictation. If questions arise, radiologists are briefed via email. When required, TIMFs are returned to the radiology department for review and correction. Additionally, a weekly meeting with clinical trial staff and radiologists has been established to facilitate communication between the two groups and address any outstanding issues.

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

The implementation of TIMFs has been largely successful. The forms have increased adherence to protocol-defined response criteria by providing a thorough, easy-to-read summary of patients' tumor response. Their layout also allows clinical trial staff to identify issues quickly, since inconsistencies from scan-to-scan are readily apparent on the forms. This, combined with the newly established rapport between clinical trial and radiology staff, allows most issues to be resolved within one business day, helping to ensure adherence to protocol reporting guidelines.

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

This project demonstrated the importance of strong communication, both within and between institutional departments. Suggestions from staff were invaluable when creating and implementing TIMFs, and continue to facilitate refinements. In recent months, feedback from new employees identified a need for additional training on tumor identification and measurement, which has since been implemented in staff orientation. A Frequently Asked Questions guide was also created to address questions related to tumor response, and will continue to be updated as new questions arise.

Implementing a Functional Work Group Model to Increase Employee Satisfaction and Reduce Turnover

Dana Keiser, RN, MSN; John O'Neill

Fox Chase Cancer Center, Temple Health

Describe the background of the problem:

High employee turnover resulting from low employee satisfaction has long been detrimental to the overall productivity of Clinical Trial Operations (CTO) at our site. Previously, our CTO was structured in a vertical 1 model that promoted the separation of Investigators and Study Staff and established discrete roles with isolated functions. Prior research in other job fields demonstrates that perceived group support, task interdependence, and participation in decision making are positively related to increased job satisfaction, which in turn will reduce the intent to quit. Additionally, implementation of effective standardized workflows has been shown to increase productivity and contribute to overall employee satisfaction. Collectively, this research suggests that fostering a work environment centered on collaboration and founded on efficient workflows will result in higher overall employee satisfaction and subsequent reduction in turnover.

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

To apply this concept, we developed the model of Functional Work Groups (FWGs) that breaks the established vertical hierarchical model and adopts a modified quality circle design. The goals for this concept are to: (1) increase employee satisfaction to help retain staff, (2) improve collaboration between Investigators and Study Staff, and (3) increase productivity to expand trial activations.

Describe the solutions or methods implemented:

We piloted the FWG model over the past year with our genitourinary disease site team which includes the following personnel: Physicians, Advanced Practice Clinicians, Clinical Research Nurses (CRN), Clinical Research Coordinators (CRC), and Clinical Research Associates (CRA). Personnel are assigned roles on the various trials run within the disease site to comprise smaller quality circles referred to as a Study Team (ST). This is done via a metric based workflow that encourages employee input and attempts to minimize overload while maximizing productivity. Once assigned, all members of the ST: Principle Investigator (PI), Sub-Investigators (SIs), CRN/CRC, CRA, and supporting staff; conduct the research in an interdependent fashion relying on intense collaboration by the CRN/CRC and CRA and frequent communication with the PI and SIs. All STs within the disease site then meet biweekly with additional supporting staff to form a FWG that discusses all trials, upcoming trials, and potential trials that the FWG is considering participating in.

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

This process allows for holistic review of CTO within the disease site and development of specific and effective workflows. Preliminary data is being collected to measure the overall employee satisfaction of the FWG model that will be used as a gauge of process efficacy. Comparisons of employee turnover, study activation times, and deviation rates will also be used as objective measures of process efficacy.

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

Implementing this model across several disease sites at our Center will allow us to increase our sample size and power our analysis. While the quality circle model is potentially effective at increasing employee satisfaction, it is necessary to maintain a management structure that can handle administrative tasks and retain a reporting structure.

Research Patient Financial Counselor - Removing Insurance Barriers from Clinical Trial Enrollment

Erika Greenidge, MPH

Fox Chase Cancer Center, Temple Health

Describe the background of the problem:

Cancer patients can experience a number of barriers to clinical trial enrollment including: lack of awareness about clinical trials, experimental fears, concerns about costs and health-insurance constraints. The Patient Protection and Affordable Care Act (ACA) of 2010 requires that most health insurance plans cover routine patient care costs in approved clinical trials. Despite this law, coverage denials continue to be a concern for researchers, treating physicians and patients. Insurance barriers can potentially hold up treatment, reduce the usefulness of the research results, and negatively impact clinical trial enrollment and subject retention.

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

In an effort to streamline insurance coverage approvals, our Institution's Office of Clinical Research created a staff position of Research Patient Financial Counselor. The goal of the Financial Counselor position is to improve the process for obtaining and documenting health insurance coverage for clinical trial participation.

Describe the solutions or methods implemented:

The Financial Counselor's primary responsibilities are to: 1) educate the patient about their insurance benefit prior to any study procedures taking place, 2) work with insurance programs to ensure patient care costs or standard procedures are covered, 3) provide proper documentation so that treatment is covered, and 4) obtain any precertifications to prevent delays in treatment. The Financial Counselor also tracks changes in the patient's insurance coverage and continuously reevaluates financial resources while the subject is on study.

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

The Patient Financial Counselor has been successful in obtaining insurance approvals during clinical trial enrollment, potentially reducing the number of patients experiencing treatment delays during trial participation. The addition of a dedicated staff member responsible for research subject's financial issues is a viable solution to implementing the ACA clinical trial mandate while removing some of the administrative barriers and delays patients and investigators face during clinical trial enrollment.

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

The current process requires that the patient review the informed consent with the study team and agree to participate in the trial prior to the Financial Counselor confirming approval with insurance providers. One possible change to the current process is to alter the timing so that insurance discussions occur during the consent process.

Shortening the Time in Regulatory from Industry Protocol Receipt to Study Activation

Tracy A. Kradzinski

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Describe the background of the problem:

Prior to implementation of our new processes and procedures, the length of time to protocol activation was unacceptable, due in part to fractured, non-streamlined processes and an inefficient tracking system for new studies being submitted to FCCC's scientific committee and applicable IRB.

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

Our timelines from initial contact by an Industry Sponsor to study activation have already decreased significantly. Our goal is to shorten this timeline to 90 days, initially, and eventually to as little as 60 days.

Describe the solutions or methods implemented:

The first tier that we have put in place is the creation of a "Day 0 Sheet" and corresponding process, which elicits the type of information from both the sponsor and Investigator that can often hold up the submission, such as: potential use of a central IRB for the study, or alternatively permission to use an External IRB for the study; the sponsor contacts for regulatory, contracts and budgets; and any sub-Investigators or ancillary staff, if different from the standard for the disease site/indication. This process also includes the requirement that the sponsor provide all materials needed for study activation, including all study documents (protocol, IB, etc.); all required regulatory templates; the contract and budget; any study manuals; and any required study-specific training requirements. All "key players" at the Institution are included in this process, including (in addition to those already mentioned) the Investigational Pharmacy, our Protocol Support Lab (responsible for all research sample collection, processing, and shipping), and scientific committee and IRB representatives. Only once these items are completed/provided is the study entered into our OnCore system, to be scheduled for the scientific review.

Our second tier involves the submission of studies to External IRBs (WIRB and Quorum in particular), as either a central site or single study site, depending on the sponsor and study in question.

The third tier implemented is our weekly "Activation Meeting," which brings together the same stakeholders as are included at Day 0, to determine where each study is in the pipeline and what exactly is needed to move each study towards activation. For each study any/all next steps are identified and assigned.

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

Thus far the timelines have shortened significantly. Based on our current numbers, submission-to-approval timelines for WIRB and Quorum have been approximately 20 and 30 days, respectively, which has drastically reduced our total submission timelines for Industry studies. And through the Activation meeting process, the "queue" of studies awaiting activation in mid-2015 has been entirely cleared, and the volume has remained consistent since (meaning for nearly every study added, one has been removed, i.e. activated to accrual). Though there is still work to do to consistently achieve and maintain a 90 day (or less) timeline from receipt to activation, we anticipate achieving a 90-day mean within the next six months.

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

Some related initiatives include: preparing the consent document for IRB submission, and sending to the sponsor for review and approval, while the scientific review is occurring, so as to be IRB submission-ready; completing all required regulatory documents at the same time; and assisting the other parties involved to ensure that they are as ready as possible (i.e. training, etc.).

The Investigator Sponsored Research Unit at FCCC

Stephanie Rosati

Fox Chase Cancer Center, Temple Health

Describe the background of the problem:

Fragmented processes and little support contributed to the many obstacles FCCC physicians faced moving their Investigator Sponsored trials from concept through development to activation. Without a cohesive research support unit, most protocols took many months, in some cases years, to make it to activation. This severely impacted research timelines and withheld potential therapies from FCCC patients.

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

Building a foundation for Investigator Sponsored research activities will encourage innovative research and contribute to the Center's investigator initiated research focus, as a NCI-designated comprehensive cancer center. The program will allow for a fluid process that will increase productivity and protocol value while decreasing the concept-to-activation timeline, which will increase our patient's therapeutic options and the speed with which we can offer these options.

Describe the solutions or methods implemented:

The newly developed Investigator Sponsored Research Unit is now comprised of six employees who are readily available to support the physicians with any step of the clinical trial process; prior to this, the unit was split between two other departments, creating inefficiencies. This core unit combines dedicated individuals for protocol development and writing, FDA regulatory submissions (including CT.gov and CTRP postings, in addition to IND and IDE requirements) and document management (both internally and for participating Sites), and data monitoring and analysis. Processes implemented within the Unit date include: 1) stakeholder meetings consisting of all departments with any responsibility within the protocol to facilitate the development process; 2) efficient study hand-off for regulatory submission to FDA and IRB for review and approval; 3) focused external site start up; 4) weekly status updates to keep all involved departments accountable; and 5) more frequent and thorough monitoring visits at all accruing sites, including remote monitoring when necessary and feasible.

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

Within five months, the program has improved the writing, conduct, and publishing of Investigator Sponsored clinical trials at the Center. With the creation of a dedicated Unit, we have: 1) increased the number of investigator-sponsored trials; 2) reduced the timeline from study concept to activation; 3) increased the potential for accruals through internal and external site management; 4) forged a productive and supportive relationship between physicians and the Office of Clinical Research; and 5) improved the quality and value of our data to be published, through more effective data management.

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

Dedicated specialists contributing to each aspect of a clinical trial greatly improves quality and increases output. However, the need for a dedicated Manager to oversee the Unit is still needed. This will allow for identification of issues across the Unit areas, and will further improve efficiencies. This Manager is also needed to provide a single point of contact for our physicians, which would allow for better communication between the physicians, Study Teams, and the Unit.

Implementation of a Recharge Model to Improve the Management of Clinical Trial Expenses

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Describe the background of the problem:

Accounting for clinical trial revenue and expenses across a large, complex, matrix clinical research enterprise is challenging. Investigators and Sponsors expect transparency. Personnel have traditionally been budgeted on grants based on time and effort, but this is difficult to adjust when trial activity fluctuates. Therefore, an activity based financial model may more accurately account for the true cost of conducting clinical research.

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

- Create a per-trial accounting structure to improve transparency surrounding clinical trial expenses
- Monitor study teams workload in a more systematic and efficient manner
- Develop a projection tool for prospective trials and provide break-even analysis used in budget negotiations

Describe the solutions or methods implemented:

The Clinical Protocol and Data Management office at the HICCC established a “recharge model” in 2015. All trial-specific expenses are directly applied to the appropriate trial account. Non-personnel charges (such as research procedure fees) are reconciled on a monthly basis to ensure appropriate allocation to the trial accounts. For personnel expenses, the CPDM initiated 4 separate service center licenses for each of the main “cores” within the office – Regulatory, Compliance, Coordinator, and Nursing. These recharge rates allow for specific dollar amounts to be charged to trial accounts based on activities performed rather than time and effort so that fluctuations in work-load and volume are accounted for without manual adjustments to direct salary support.

The Regulatory and Compliance models were constructed using prior year activities (protocol modification submissions, monitoring visits, etc). The Coordinator and Nursing models are derived from a work-unit calculation utilizing a published oncology work-load assessment tool (Ontario Protocol Assessment Level, OPAL¹) which generates a complexity score and workload formula for each trial, leading to a specific charge for trial related activities. In addition, Principal Investigator (PI) salary distributions from industry funded clinical trials are also applied using the same process with a set amount applied per accrual based on the trial’s OPAL score.

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

Expenses are more closely tracked on a per trial basis. Workload is also more closely monitored as data is generated on a bi-weekly basis as part of the “recharge model” billing structure. Lastly, the establishment of an expense structure has enhanced the accuracy of future budget planning allowing for the ability to project out costs based on an individual trial’s complexity, accrual rates and overall lifecycle timeline.

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

Under the newly established “recharge model”, the CPDM increased transparency related to clinical trial finances through the development of disease program specific Profit & Loss statements. Continued efforts to share these reports with PIs and Department Administrators will enable better communication and strategic decision making surround clinical trial operations.

Reference:

¹Smuck B, et al: Ontario Protocol Assessment Level: Clinical Trial Complexity Rating Tool for Workload Planning in Oncology Clinical Trials JOP 10.1200, 2010

Not the 'Ethics Police', a Unique Approach to Internal Quality Assurance (QA) and Monitoring Procedures

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Describe the background of the problem:

Investigator Initiated Trials (IITs) are academically vital but also entail the highest level of risk to the institution and investigator if non-compliance is identified. HICCC investigators have increased activity as lead investigators and/or Sponsor Investigators on both single institution and multi-center IITs. These advancements were identified by Clinical Protocol & Protocol Data management (CPDM) Office management as an opportunity for optimizing internal trial monitoring activities.

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

- Provide real time monitoring findings to the DSMC review process with an internal monitoring team viewed as an extension of the study teams.
- Strengthen human subject protection and trial execution quality.

Describe the solutions or methods implemented:

The CPDM Compliance Core was created in 2012 to monitor all interventional investigator initiated trials. The Core was deliberately embedded within the same department as study teams to enhance communication and reduce negative perceptions; however, it is a separate and distinct Core so no direct conflict exists. This enables objective and effective monitoring across all IITs. The members of the Core are also non-voting members of the Data & Safety Monitoring Committee (DSMC) to improve information flow.

The Core performed monitoring visits on 100% of subject charts for adherence to the protocols, source data verification, regulatory items (such as delegation of authority logs), and research pharmacy reviews.

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

Since its recent inception, the Core has conducted over 150 monitoring visits encompassing over 400 study participants across over 40 trials. Findings from visits led to protocol amendments, training opportunities, and increased compliance.

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

Compliance Core monitoring activities have contributed towards department improvement initiatives and strengthened CPDM IIT execution and compliance. Findings of monitoring visits also informed CPDM leadership of opportunities within the department for increased standardization such as source document and study tool templates.

However, monitoring of 100% of subjects accrued to 100% of trials became unsustainable. Therefore, a more efficient risk-based monitoring approach is being implemented: Key Risk Indicators (KRI) methodology will determine Initial Risk Assessment, Critical Data Points and Baseline Monitoring Expectations plans prior to the initiation of any trial activity. This process will involve the study PI, statistician, CPDM leadership, and formal endorsement by the DSMC. Finally, the creation of Monitoring Plan Activity Summary Forms will provide DSMC reviewers with a synopsis of major findings for each trial, enabling the DSMC to expeditiously address actionable findings.

The Clinical Protocol & Data Management (CPDM) Central Registration Office For Eligibility Confirmation: Advancements in Process Improvement

Daniel Otap, CCRP; Moshe Kelsen, MBA; Tiffany Negri, CCRP; Marianne Reyna, CCRC; Josephine G. Jorge; Shannon Kelly; Francis Brogan, MSN, RN; Christina Corpuz; Ryan Shelton; Stephen Emerson, MD, PhD; Andrew B. Lassman, MD, MS

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Describe the background of the problem:

Many procedures in a health care setting require a "Time Out" with 2-step verification before continuing. Examples include pre-biopsy patient identification, body part, and laterality. We hypothesized that applying a Time Out 2-step verification of trial eligibility, a "Central Registration" would prevent violations of inclusion/exclusion criteria and improve source documentation and avoid major deficiencies on audits and inspections by regulatory authorities.

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

- Prevent violations of inclusion/exclusion criteria
- Enhance informed consent documentation and overall source documentation practices
- Timely accrual entry into the institutional Clinical Trial Management System (CTMS)

Describe the solutions or methods implemented:

In 2012 the CPDM established the Central Registration Office for eligibility confirmation as a quality enhancement division. 100% of all interventional accruals are reviewed via this process. Initial registration reviews serve as real time monitoring of informed consent processes and of source documentation adequacy.

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

Since inception, the Core reviewed over 1,600 submissions of source documentation packets for potential trial subjects through the Time Out process. This prevented accrual of 13 ineligible subjects, enhanced documentation of the informed consent process in 113 cases, and clarified source documentation to support eligibility for 61 potential subjects. In addition, accrual data was entered in more quickly into CTMS, decreasing the average time from 27.5 days pre-Central Registration to 5.27 days in Q1 2016, resulting in simpler reporting of accrual data to the NCI accrual.

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

The CPDM Central Registration process for eligibility confirmation is a vital part of the research infrastructure, and will continue to be utilized. Areas for refinement include defining the medical items requiring detailed source documentation and those that do not.

Having the unit embedded into the same organizational structure as the rest of the research department enhances the speed in which clarifications and potential issues can be resolved. This removes any bottlenecks or delays in treatment-start associated with inter-departmental clarifications. Yet, the Central Registration Office is still part of a separate core within the department, so no direct conflict exists.

Re-assessments will continue to ensure process enhancements are addressed as needed.

Creation of a Comprehensive Beacon Treatment Plan to Enhance Functionality Along with Treatment and Billing Compliance

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Hollings Cancer Center, Medical University of South Carolina

Describe the background of the problem:

With the launch of Epic and Beacon, the challenge of timely and comprehensive research treatment plans quickly presented as a major barrier. The treatment plans were falling short of truly reflecting the research protocols which resulted in varying levels of departure from study compliance. The institutional billing process also became faster, which generated the need for a process to ensure research billing accuracy.

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

Training was implemented, including a timeline metric with submission deadlines, for the creation and review of study-specific roadmaps. Next, we set the goal that 100% of our studies would have a validated study-specific treatment plan within 50 days of the IRB submission deadline or by their activation date, whichever came first. In regards to the roadmap development, our goals were to minimize development time, aid budget creation, minimize treatment plan errors, and develop a submission process inclusive of the constant influx of amendments. Lastly, we sought a 25% decrease in deviations while increasing patient safety.

Describe the solutions or methods implemented:

The Beacon Build Team was staffed by two Pharm D's and an oncology nurse. Next, a Clinical Trials Office (CTO) oncology nurse was placed over the roadmap creation and submission process, the validations, and the monitoring for version control. A roadmap template was developed to incorporate the study treatment and the entire study specific schedule of events. A submission process was then developed utilizing three internal programs. The first, Rapid, is a .NET website study start-up tracking tool. Rapid has a group of checkpoints and corresponding sub-checkpoints that are applied to a study during the build process. Once a task is started, a checkpoint is entered and the time to completion can be tracked. The second is the Clinical Data Center (CDC) which is a .NET Windows forms application that builds custom reports from data in our CTMS and in Rapid. We set priorities that are automatically generated by Rapid checkpoint entries to monitor the progression of the submission process within the CDC. Microsoft's web-based collaboration environment, SharePoint, stores the Beacon roadmaps and the routing form that is used for routing them to the various research team disciplines for review and comments/additions. The application allows for sorting, filtering, and exporting data. Once submitted and built, the research team meets to validate the plan prior to pushing it into production.

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

Since the initiation of the build process January, 2015, we have come within reach of our goal timeline (as depicted in figure). Also, of note is a 34% reduction in deviations, and <5% of our active trials do not have a validated treatment plan. The most recent CTO billing compliance audit yielded 98% accuracy which is a direct result of this roadmap process. Roadmap development has also improved budget content.

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

Initially, physician and pharmacy engagement was difficult due to limited resources; however, it quickly became apparent that each treatment plan validation saved countless hours of back-end modifications. As such, validations have become a priority for each study team. Roadmap content has proven challenging and has required significant training for less experienced Coordinators.

Finding a Cost-Effective, Efficient and User-Friendly Data Capture System for Investigator-Initiated Trials

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Describe the background of the problem:

Investigator initial trials (IITs) can be minimally funded making it difficult to justify significant resources for the development of a unique data capture system. With the advent of electronic data capture systems, the Sponsor-Investigator Support Unit (SIS Unit) at HCC searched for a cost-effective mechanism to collect data from multiple centers that could be easily exported for data analysis and also allow for quality checks throughout the course of the study. The system would need to be user friendly from a set up standpoint and data entry standpoint.

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

By transitioning from hard copy case report forms (CRFs) to an electronic data capture system, we hope to see higher quality, more complete data, decreased time to case report form completion and query resolution, and decreased time to publication after the study is completed.

Describe the solutions or methods implemented:

Through MUSC's Clinical and Translational Science Award, the HCC's SIS Unit is able to utilize at no-cost the REDCap data capture system developed by Vanderbilt University. Once a protocol is finalized, the SIS Unit Coordinator reviews the schedule of assessments and endpoints to draft the data dictionary and eCRFs for the study database. The coordinator then sends the data dictionary to the Sponsor-Investigator and statistician to ensure all relevant data fields are included in the dataset and coded in a manner that can be used for data analysis. Once data is entered, the SIS Unit Coordinator reviews the data for completion and accuracy and issues queries through the system. A library of forms for collecting common oncology data such as adverse events and RECIST was created.

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

The implementation of REDCap has led to less lag time in data entry and query responses. The dataset can be easily exported from the system leading to more efficient and higher quality safety reporting to applicable regulatory agencies. Time monitoring data and conducting quality checks has also reduced. Additionally, per user feedback, standardization of data forms and instructions has improved user satisfaction and overall data quality. By establishing a form library in REDCap, creating new eCRF systems for future studies is less resource intensive.

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

Ensuring the dataset at the end of the trial is acceptable and complete requires all parties involved to provide feedback and input on the design of the database and is essential for successful data capture.

Involvement of the statistician was essential and we learned that establishing common naming conventions and data validations improved output and saved time. REDCap has a number of features that we hope to employ in future studies to help automate data quality measures. As studies become more complicated and regulatory oversight more intense, having this data entry system in place will help ensure the work produced is accurate, usable and replicable.

Utilization of Microsoft SharePoint to Improve Clinical Trial Interdepartmental Communications and Document Management

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Describe the background of the problem:

As the HCC Clinical Trials Office (CTO) increased staffing and occupied multiple locations both on and off campus, the ability to efficiently conduct common business operations and manage shared documents became a hardship. The CTO utilized a shared network that became unmanageable. This shared network lacked enforceable permission rules and did not provide audit trails. Conducting business functions such as employee leave requests, employee training tracking, and processing of reportable events was resource intensive. Employees conducted these operations utilizing hard copy paper and distributed materials across campus by a paid courier, or multiple scanned documents were distributed via email. To improve efficiencies, ensure standardized tracking, and decrease time and expense, an electronic solution was needed.

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

By adopting an electronic solution, we hope to reduce time and effort of employees. We needed a solution that would allow managers to access and track submissions within a centralized system. By limiting the use of paper, our office could save money on supplies, courier time, and archival costs. Additionally, we hoped to increase employee satisfaction and better utilize the talents of our employees for higher functions.

Describe the solutions or methods implemented:

We utilized our University's Microsoft SharePoint software to establish a CTO SharePoint site to serve as an operational hub. The SharePoint site includes libraries for study document, staff and facility credentialing certificates, and employee training resources. Forms libraries were also established to support reportable events submission (internal and external safety reports and reportable deviations), faculty and staff onboarding, new protocol processing, patient eligibility review, and other common business functions such as leave requests. SharePoint is supported by 0.5 FTE computer programmer who completed advanced SharePoint training. The system has been in use for over one year.

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

Over the past year, over 21 clinical trial management procedures have been modified to incorporate SharePoint as an operating platform. Employee rounding and focus groups have revealed positive feedback and use of SharePoint has become common place. Managers are now able to sort and query SharePoint operating forms to analyze work units completed versus having employees enter specific time and effort reports. For document management, naming conventions have been enforced and permissions based documents are posted. Employees state that documents are more easily accessible than through the traditional network drives. As the volume of external SAE reports and other hard copy documents reduced, courier time and effort of couriers reduced by half.

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

Rolling out operational changes always requires extensive and ongoing training. The use of small group meetings to gain ongoing feedback was helpful to ensure consistent adoption of the new procedures and identify issues early. Having a computer programmer available to assess problems and implement revisions and including a quality assurance manager to verify procedures were occurring as expected were critical success factors. Overall, the incorporation of SharePoint has helped build efficiency and quality within the CTO. Future steps may involve testing how SharePoint may interact with other information management systems.

Development of a Comprehensive Training Program — Building on the Eight Competency Domains for the Clinical Research Professional

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Describe the background of the problem:

Oncology clinical research is highly regulated and specialized and the backgrounds of clinical research professionals is varied. Due to the complex nature of trial work and staff turnover experienced in the industry, a comprehensive training program is a necessity. The Joint Task Force for Clinical Trial Competency identified eight competency domains for the clinical research professional. The Huntsman Cancer Institute Clinical Trials Office has developed a training plan with the eight competency domains as the foundation.

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

Onboarding new research staff needs to be done quickly and completely. Using the eight competency domains identified by the Joint Task Force as a foundation, a broad training program was developed. Self-paced online training modules, in-person classes, and job shadowing to reinforce the competency domains and institutional policies has been developed.

Describe the solutions or methods implemented:

An online, self-guided general training program was developed to build training material to meet the competency objectives set forth by the Joint Task Force. The training modules contain a mix of presentations, discussions, readings and resources, assignments, and quizzes. The online learning management system (Canvas) additionally serves as an online repository for training certifications such as HIPAA, GCP, etc. When renewals are due, staff are able to upload new certificates into the online system where they can be easily downloaded when needed. In addition to the online training, in-person training classes on selected topics provide an opportunity for collaboration and mentorship for existing staff to work with new staff. This has led to the development of several best practices. Content developed for these in-person classes is stored in the online training system for quick reference. Institutional policies and standard operating procedures are woven into the training presentations with real-life examples. The final component of the training program is job shadowing. New staff are paired with a mentor on their team who will provide real-time training opportunities. New staff are given the opportunity to shadow during the initial onboarding period in order to see how the training topics are implemented on the job. After the initial period of shadowing, the new staff members are then shadowed by their mentor as they start to take on job responsibilities. Additional training is provided for role-specific functions.

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

Employees who started before the training process was fully implemented have indicated that they would have greatly benefited from full participation. New coordinators are able to begin managing full trial and patient loads in four weeks compared to the six weeks it was taking with prior iterations of the training program. Locating training certification for HIPAA and GCP as required by sponsors has been much easier with the online system.

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

The training program is constantly being reevaluated and growing based on feedback from new and existing staff, but the institution of the multifaceted program starting with the foundation of the eight competency domains has improved coordinator satisfaction with the onboarding process and served as a catalyst for improved productivity quickly. As the ACRP (Association of Clinical Research Professionals) has taken over development and implementation of the competencies, we plan to consult them as our training program moves forward.

External IND Safety Report Processing Policy – Reducing Site Workload and Cost with New FDA Compliant SOP

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¹Huntsman Cancer Institute, University of Utah; ²Vanderbilt-Ingram Cancer Center

Describe the background of the problem:

In clinical research pharmaceutical companies observe and analyze safety data collected from patient experience with study drugs. Per regulation companies provide individual safety reports to sites when events are unexpected and potentially related to the study drug. This method of distribution creates an overwhelming workload for investigators and support staff costing centers time, effort, and money and in many cases impeding other crucial clinical research efforts.

Given the site personnel's limited overall knowledge of the study drug's safety profile, site investigators and staff are unable to confirm with certainty which events are related. It is the sponsor's responsibility to determine this. Correspondence indicating the event is potentially related is not usable by the site. Additionally, local IRB's will not accept an external safety report as complete information arguing that if an event is related and unexpected it should alter the conduct of the trial, prompt an amendment to the associated documents, and require patients be immediately informed of the increased risk.

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

Variations in interpretation of regulations in combination with changing perceptions and demands in the field have caused safety report processing to be widely discussed amongst research centers. Over time the internal policies at both HCI and VICC have been modified to reduce site impact while remaining compliant. Further, we hope to work with other cancer centers in this purpose and ultimately improve the way sponsor's process safety information and provide updates to sites. To date, our centers have implemented successful SOP's outlining policies that protect our institutions from undue burden.

Describe the solutions or methods implemented:

While both VICC and HCI recognize that under the Federal Drug Administration (FDA) regulations, pharmaceutical sponsors are required to distribute these individual safety letters, both VICC and HCI have implemented policies based on the FDA final rule issue September 29, 2010, FDA Guidance for Industry and Investigators issue December 2012 and OHRP guidance that not only would they refrain from processing IND safety reports they'd ask that sponsors refrain from sending IND safety letters that do not meet strict criteria for reporting.

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

VICC has had significant success in negotiating their policy with sponsors and the decrease in time processing these reports has increased efficiency of research staff. The successful implementation of this policy at HCI has allowed HCI to go from employing 2 FTE's committed only to reviewing external safety reports to employing no personnel for this purpose.

Both centers have been successful in increasing efficiency within their regulatory support staff while remaining compliant with federal and local regulation. There has been no evidence that this change has impacted the knowledge of the safety profile of investigational drugs among the investigator or impacted patient care negatively.

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

The SOP's that VICC and HCI have implemented adhere strictly to regulations but have drastically reduced the amount of time, effort, and monetary cost expended on review of external IND safety reports.

In the instances of sponsor resistance to the policies, there has been success in negotiating additional fees for requirements of maintaining external safety reports without increase workload on research staff.

Fast Fact Sheets for Infusion Nursing Management of Infused Investigational Drugs

Rachel Kingsford, MS, CCRP; Joy Lombardi, RN, BSN, OCN

Huntsman Cancer Institute, University of Utah

Describe the background of the problem:

Infusion is a common method of delivery for oncology medications, both approved and investigational. Urgent management adverse infusion reactions is a skill that Infusion nurses use daily but management of reaction to study drugs may differ from standard of care. Compliance with research protocol parameters is essential for data quality. In research centers without dedicated areas for research patients, the oncology nurse must be able to manage these potential reactions for study patients to ensure adequate patient safety in addition to avoidance of protocol deviations. Infusion room nurses who care for patients receiving standard-of-care therapies in addition to study patients are not always familiar with research protocols.

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

Implementation of Fast Fact Sheets accompanying research patients has improved collaboration between research and nursing staff in the main infusion room and elsewhere within the facility that research patients are cared for. Providing research training and resources to nursing staff has integrated research with standard of care creating an environment where research is routine. The availability of a Fast Fact Sheet has increased the nurses' confidence in caring for research patients and improved relationships between nursing staff and research staff.

Describe the solutions or methods implemented:

To allow Huntsman Cancer Institute infusion room nurses to provide quality care to patients and maintain protocol integrity, the research coordinators began creating Fast Fact Sheets. A template was developed in cooperation with nursing staff for the Fast Fact Sheet including contact information for principal investigator and coordinator, information about the study drug(s), and information from the protocol regarding potential for reaction and how those reactions should be managed to remain compliant with the protocol. The clinical research coordinator in cooperation with their manager creates the Fast Fact Sheet which will accompany the patient on the first day of their treatment and remain available for the duration of trial treatment. In addition to providing support to nursing staff in caring for trial patients, creation of the Fast Fact Sheet also serves as a training exercise for the coordinator to identify pertinent information from the protocol and truly become an expert on all aspects. Version control is present on each of the documents and they are revised with amendments as necessary.

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

Implementing the Fast Fact Sheet policy has created a positive change in four main ways:

- Having the information at hand provides security for nursing staff caring for patients on treatments they may not be as familiar with. This leads to increased patient safety.
- The availability of the protocol information in a user-friendly and readable format ensures protocol compliance.
- Creation of the Fast Fact Sheet at the outset of a trial is a good exercise for coordinators to be able to identify the salient points of a protocol in order to communicate them to nursing staff.
- The new process has improved collaboration between nursing personnel and research personnel.

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

Collaboration with research staff and nursing staff to develop this policy and the template has been a positive experience. We will continue to evaluate the template and are open to feedback from research and nursing staff as we continue.

Streamlining the Participant Reimbursement Process

Anita Bowler, CCRP; Marlyn Galindo; Tiffaney Rasmussen; Tracy Jensen; Holly Bateman; Glenda Peck
Huntsman Cancer Institute, University of Utah

Describe the background of the problem:

Participant visit reimbursements were being missed after visits and the reimbursement process was time-consuming. The responsibility of ensuring that payments were issued was with the Clinical Research Coordinator (CRC). Since participant reimbursement is an Accounting process, the responsibility was transferred to the Finance team within the Clinical Trials Office (CTO) to manage the whole process.

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

- Eliminate the need for a CRC to notify the Finance team to issue a payment once a participant visit has occurred, unless to provide receipts for hotels and meals
- Identify eligible participants and track reimbursement visits within the CTMS
- Consolidate the Check Request form and study-specific reimbursement documentation for mileage, stipend, hotel, and meals into one Participant reimbursement form
- Reduce the amount of time and paper it takes to generate a participant reimbursement
- Increase reimbursement accuracy

Describe the solutions or methods implemented:

We implemented the following new process:

Once a participant signs consent, the CRC confirms their eligibility for reimbursement. If eligible, a Form W9 is completed and emailed to the Patient Billing Specialist (PBS). When the consent is entered into the CTMS, the PBS is automatically emailed, confirms participant eligibility, and updates the participants console with a reimbursement flag.

A report of occurred visits and flagged participants is generated weekly from the CTMS and is used to issue reimbursements. The PBS completes the Participant Reimbursement Form for the study and saves it to a network drive to be used while the participant is on study. This consolidated form includes the study-specific reimbursement information, eliminating the need to look it up, eliminates the need for all participant information to be retyped, and includes mileage verification. The only supporting documentation that is needed is if we are reimbursing hotels or meals.

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

Prior to implementation, reimbursements took 10 minutes each to process compared to 5 minutes now. We process 40 reimbursements, providing us three extra hours a week. Each reimbursement included three sheets of paper (Check request form, Mileage reimbursement log, mileage verification report). We now only use one, reducing our paper expense by 2/3 and photocopying expense by 2/3. The stipend reimbursement form no longer has to be taken back to the CRC for the next participant visit for the participant to sign.

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

- The University Accounts Payable Department (UAPD) was hesitant to change the reimbursement forms because there was nothing "attached" for documentation. We met with them several times to demonstrate the improved form.
- Under the new process, we have been reviewing each participant's payment history to ensure that all payments owed have been paid. We have found payments that were missed.
- During the change, we identified these additional changes:
 - UAPD eliminated the participant signature requirement eliminating the form to be passed back and forth between CRC and PBS.
 - Mileage verification could be included on the form instead of a separate document.
- We trained the CRCs on the new process at a staff meeting. In retrospect, additional separate training would have helped adoption.

Framing Clinical Research and the Importance of Trial Participation: Patient and Physician Perspective

Jaclyn Regan, MBA¹; Christine Hickey¹; Chris Targett²; Shoko Masuda³; Paul Sabbatini, MD¹

¹Memorial Sloan Kettering Cancer Center; ²Milward Brown Analytics; ³HKSM Consulting LLC

Describe the background of the problem:

Clinical trials are the foundation for bringing innovative therapies into the clinic to improve outcomes for patients with cancer. Unfortunately, only 2.5-3% of adult cancer patients nationwide participate in a cancer clinical trial. At Memorial Sloan Kettering Cancer Center (MSK) approximately 30% of patients participate in a clinical trial as part of their care continuum.

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

MSK conducted a national survey of consumers and physicians to determine how the public perceives clinical trials and to understand how physicians discuss trials with their patients. 65% of consumers surveyed felt that clinical trials are an important aspect of medicine but only about one third stated they were likely to enroll.

MSK hopes to leverage key findings from this survey to start a dialogue to drive familiarity with clinical trials and their potential benefits. The overall goal would be to 1) increase the number of patients who enroll on a clinical trial throughout their cancer care and to 2) provide physicians with patient-friendly education materials as they are the key drivers for education when patients are considering clinical trial enrollment.

Describe the solutions or methods implemented:

MSK is in the process of developing an internal campaign to address perceived barriers to clinical research by highlighting 5 key areas:

- 1) Patients enrolled on a clinical trial receive the newest drug or therapy before they are available elsewhere
- 2) There is typically no increase in a participants out-of-pocket costs for treatments being studied in a clinical trial
- 3) Patients enrolled benefit from close collaboration among doctors and scientists and oversight of a compassionate and highly experienced staff
- 4) Clinical trials rarely utilize placebos and they are only offered when appropriate for the treatment context of an individual patient, and use is fully discussed with the patient at the time of enrollment.
- 5) Care related to clinical trial enrollment can be provided at many of our Regional and Alliance facilities.

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

After reading a general and brief statement providing more information about clinical trials the positive impressions among consumers increased to 60% (from 40%) and the likelihood to enroll in a research study increased to 44% (from 35%). These results elucidated that by sharing basic information and improving the education of patients and their care providers regarding clinical trials it is possible to potentially transform how clinical trials are perceived as part of cancer care. By improving methods for communicating the benefits of clinical trials and demystifying the perceived barriers, the percentage of people with a positive impression of clinical trials can be increased.

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

The survey raises a major call to action towards a national conversation about clinical trials. Participation in cancer clinical trials is becoming ever more important in light of the National Cancer Moonshot Initiative to accelerate cancer research if we are to action new discoveries.

The survey supports the notion that the key element to enhance patient participation is education. Revolutionizing perceptions of cancer clinical trials amongst consumers and physicians will positively impact the pace of progress towards providing improved outcomes for patients.

Lessons Learned from an EMA/FDA Inspection

Tim Barz; Theresa Gold

Memorial Sloan Kettering Cancer Center

Describe the background of the problem:

The evolution of successful cancer clinical trials leads to new drugs getting approval for standard use from regulatory agencies in the United States and around the Globe. In order for new drugs to be approved, regulatory agencies conduct inspections at high enrollment sites to verify and validate the data provided by the industrial sponsor. A successful inspection is critical for the data to be accepted and for the drug to be approved. Thorough preparation at the study team and Institutional level is vital to ensuring a successful inspection.

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

MSK has firsthand experience in preparing for regulatory agency inspections both from the Food and Drug Administration (FDA) and European Medicines Agency (EMA). The preparation for these inspections should go well beyond reviewing for protocol and regulatory compliance and data accuracy. The Sarcoma Medical Oncology Service has recent experience in this space as a result of a joint EMA and FDA inspection and would like to share the lessons learned throughout these experiences, in order to guide and assist other cancer centers in preparing for agency inspections.

Describe the solutions or methods implemented:

Inspection Preparation Methods:

- Frequent meetings with Principal Investigator
- Identification of study components likely to be reviewed during the inspection
- Creation of tools and trackers to aid in preparation activities
- Collaboration with Departmental and Institutional quality assurance (QA) groups
- Coordination with outside departments relevant to the study
- Escalation of issues to Departmental and Institutional leadership
- Identification of Standard Operating Procedures relevant to the study
- Distribution of pre-audit findings to Cancer Center leadership
- Collaborative working relationship with Industrial Sponsor
- Familiarization with inspection methods, scope of inspection and enforcement actions that can be taken by the inspecting regulatory agency

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

When preparing for, and during the Inspection, the Sarcoma team identified areas for possible improvement:

At the study level:

- Re-examine study specific processes to identify deficiencies
- Focus on overall trends in data collection and reporting
- Meet frequently to prioritize/reprioritize pre-audit tasks
- Establish timelines for completion of corrective and preventative action plans
- Facilitate collaboration and communication between study team, Clinical Research Organization (CRO), Sponsor and Institution

At the Institutional level:

- Administrative aspect of inspection preparation should be delegated, allowing the study team focus on identifying and resolving issues with the trial
- Escalate concerns immediately to Institutional leadership to ensure prompt resolution of issues
- Make all hospital standard procedures and practices available for evaluation by inspectors immediately
- Distribute guidelines for conduct during an inspection to relevant departments outside of the study team
- Strong communication at all levels

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

Communication between the study team, CRO, and sponsor is crucial in order to identify and resolve study issues before and during the inspection. It is imperative to clearly define roles within the inspected institution, as this promotes efficiency and eliminates ambiguity when fielding questions raised by the inspection team. Finally, collaboration between all parties is essential for the successful implementation of new practices and process improvement initiatives that are required in response to the inspection findings.

MSKCC eTrials: Creating a Digitized Patient Data Ecosystem for Industry-Sponsored Clinical Trials, and Creation of the MyMSK Medication Support App

Michael Buckley¹; Milena Silverman¹; Dawn Caron¹; Ophelia Chiu¹; Kai-Hsiung Lin¹; Jennifer White¹; Mary Mitchell¹; John Yee¹; Aaron Wen¹; Stu Gardos¹; Jonathan Wills¹; Jaclyn Regan¹; Janet Murdock²; Rajesh Modi²; Vinay Sunkari²; Ann Dilworth³; Sharon Hanlon³; Mari Clovis³; Collette Houston¹; Paul Sabbatini, MD¹

¹Memorial Sloan Kettering Cancer Center; ²Novartis; ³Bristol-Myers Squibb

Background of the problem and solutions implemented:

At last year's meeting we reported that the standard clinical trial contains 352 data eCRF pages per patient per visit, and 107 (30%) can be removed using our four distinct eTrials modules. eTrials was created and launched in 2014 to address the following shortcomings: manual data entry into industry-sponsored clinical trial EDC systems is inefficient, can introduce errors into the dataset from transcription processes, and consumes valuable site and sponsor time and effort (T/E) to reconcile and resolve non-conformant data. We have now partnered with pharma (Novartis, Bristol-Myers Squibb, etc.) to scale the program into a digitized platform for the direct clinical trial data transfer from MSK source systems to these sponsor's EDCs.

Since last year's meeting, we created the MyMSK Medication Support App to solve the bottleneck in workflows for our existing paper based pill diary process. The App focuses on compliance and reliable tracking of oral protocol medication for complex poly-pharmacy clinical trial patients. This digital intervention will allow both patients and staff to: increase protocol compliance, offer real-time intervention and actionable touch points for patients and clinical staff between onsite visits, and digitize this data set for future direct transfers.

Results:

2015 eTrials Program data security enhancements allowed the creation of a scaling web-based eMonitoring system that is now made available to sponsors and CRO monitors/auditors for EMR source document verification via their own devices. We were previously limited in scaling the program by deploying an MSK laptop for each new eMonitor. eMonitoring is our most productive eTrials module with 78% (179/229) of all active industry-sponsored trials. We have increased from 30 monitors and 90 trials in 2015, to 79 monitors and 179 trials in 2016 (163%, 99% increase, respectively).

We began the patient-centered design, including initial prototyping of the new MyMSK Medication Support App in 2015 to present. This tool will be an extension of the existing MyMSK App, and seeks to improve patient participation and experience on clinical trials by supporting patients and research staff to better manage and increase compliance on clinical trials with: logging meds, adhering to fasting schedules, receiving updates from the clinical team, and visit preparation/reconciliation. The MyMSK Meds App will make data gathering more convenient, increase patient compliance, and reduce administrative overhead.

Recommendations:

Directly parsing data decreased sponsor query rates by 50% compared to manual entry methods in a limited sample. eMonitoring returns 7 seats per week to MSK staff, and allows MSK to reclaim 3 hours of staff T/E that was otherwise required for onsite face-to-face visits. Because major pharma has committed to the MSK eTrials Program, and this technology is available for all sites, we would like to alert the wider clinical research community to its benefits including cost savings. We will also share our best practices with other centers that may be considering the creation of a clinical research App, and share lessons learned as we move into the App coding/development/integration phase.

Resource Allocation Review- An Objective, Transparent Evaluation Performed by CCTO, A One Year Follow Up Analysis

Rosemarie Gagliardi, MPH, cEdD; Alyssa Ryan, MBA; Richa Upadhyay, MD

Mount Sinai Health System Tisch Cancer Institute

Describe the background of the problem:

In the past, clinical trials budgets were prepared based solely on information provided by individual investigators with no formal business experience in negotiating clinical trial budgets. This resulted in numerous studies being under budgeted and under resourced to support the research. It also causes significant delays in 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:

Implemented in October 2012, the Tisch Cancer Institute's (TCI's) Cancer Clinical Trials Office (CCTO) finance team performs a pre-PRMC Resource Allocation Evaluation (RAE) review. 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 the accuracy of 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 the 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:

Between January 2014 to December 2015, one hundred ten (110) clinical trials requesting CCTO resources were reviewed. 67 studies (61%) were approved at initial RAE while 43 studies (39%) were deferred back to either the PI/ DFG or TCI's Clinical Population Research Committee (CPRC). 21 of 43 deferred studies (49%) went back to the PI for clarification in which 16 were re-reviewed and approved at RAE while 5 were withdrawn by the PI. 22 of 43 deferred studies (51%) were sent to the CPRC in which 17 were approved to receive additional resources and 5 studies were withdrawn by the investigator. A total of 10 clinical trials (9%) did not continue to PRMC after RAE review. Furthermore, as a result of RAE we continue to see a 30% increase in negotiated budgets compared to before RAE because of unseen costs related to complicated study procedures that were not originally reimbursed. We also identified and addressed logistical issues that required special consideration early in the RAE process which facilitated study 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 have begun reviewing the progress of studies that have been open for at least one year (n = 42) and found that 24% of trials have met targeted annual accruals while 57% have met at least ½ of the targeted annual accruals. We will be analyzing this information to identify opportunities to better recognize the potential barriers for the 19% of trials that under accrued such as molecular sub-sets.

Using EPIC Electronic Health Record System to Assist with Screening Patients for Cancer Clinical Trials, Results from a Pilot Study in the MPD Program

Jill Kleczko, MPA; Ronald Hoffman, MD; Rosemarie Gagliardi, MPH, cEdD

Mount Sinai Health System Tisch Cancer Institute

Describe the background of the problem:

The Myeloproliferative Disorders (MPD) Research Program is a specialized program in the Tisch Cancer Institute that sees specific blood cancer patient populations. The program relies on standard patient recruitment methods for cancer clinical trials – clinicaltrials.gov website, newsletter announcements, and circulating lists of trials to referring physicians. A goal of the Cancer Clinical Trials Office (CCTO) is to continuously improve upon screening and recruitment methods for clinical trials to increase enrollment. The CCTO chose the MPD Program to pilot the use of the EPIC as an automated recruitment tool. The aim was to achieve a higher level of enrollment to clinical trials through this method. The data in this report has been updated to include results from 2015, combined with those from the 2014 pilot.

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

Goals that were achieved:

- Pilot the EPIC Medical Record system to assist in identifying potentially eligible subjects
- Use an automated process to flag potential patients eligible for trials and to alert faculty of active trials
- Increase cancer clinical trial enrollment

Describe the solutions or methods implemented:

- A comprehensive team was assembled for this pilot including: CCTO Leadership, MPD Research staff, Investigators, EPIC personnel, IRB personnel
- Approval was granted by groups for this pilot: IRB, TCI, EPIC Research Committee
- Four investigator initiated MPD Clinical trials were identified for the pilot
- Eligibility criteria was mapped into EPIC so that an automatic alert would initiate when a potential patient who met that criteria was identified: lab values, ICD-9 codes, co-morbidities, providers who see this patient population
- EPIC was configured – alert was created (Image #1), a systematic behind the scenes inbox for MPD staff was created to see patients who triggered the alert, what criteria triggered the alert, and note from that visit
- MPD Program staff created a pre-screening log to track patients who were triggered by the alert and review them in more detail to see if they were eligible for trials

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

From 2014-15, the MPD Program enrolled 57 patients onto therapeutic clinical trials.

The EPIC pilot accounted for 23% of these new subjects (13 enrollments).

- The EPIC Pilot project “go-live” date was 1/24/14 - 12/31/15
- Outcome:
 - 283 unique patients were identified for the 4 MPD trials
 - 194 “pre-screen failures” - did not meet other eligibility criteria
 - 89 identified as potential candidates (31%)
 - 24 patients already enrolled in a trial
 - 65 added to MPD “pre-screening” log
 - 48 patients did not continue on to screen*
 - 13 patients successfully enrolled (20%)
 - 4 patients are currently in screening

*Patient declined participation or patient was not appropriate candidate (i.e. non-compliance concurrent illness, too far to travel, investigator’s discretion).

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

Institutional collaboration is critical to implement changes in clinical trials. In this pilot, EPIC personnel, IRB personnel, MPD Research staff, and Investigators were involved in the efforts. During the onset of the pilot, EPIC was critical in adjusting Medical Record settings and helping resolve technical issues. This pilot has been extended to other disease groups within CCTO to augment clinical trial accrual in TCI.

A Priority Educational Program at Princess Margaret Cancer Centre

Pamela Degendorfer, MA, CCRP; Susanna Sellmann; Julie Gundry; Alex Kerr; Leslie Williams; Jasmine Grant

Princess Margaret Cancer Centre, University Health Network

Describe the background of the problem:

The clinical research environment is consistently evolving with new methodology, complexity and regulatory stringency. With this evolution, the need for a well-educated clinical research team is critical. There are approximately 300 clinical research staff at Princess Margaret and 100 Principal investigators. Ensuring research teams are well trained and educated is critical. The Cancer Clinical Research Unit (CCRU) is a support department within the Princess Margaret Cancer Program. The CCRU provides a dedicated Educational Specialist and an Advanced Practice Nurse Educator to implement, and facilitate clinical research education across the program. Operationally, it is a challenge for two staff to support the growing number of clinical research staff, and the increasing variety of training topics in a timely and effective manner.

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

The CCRU Education team currently offers 50 unique education sessions with an average of 25 sessions per month. Starting in 2010, 8415 attendees have attended 802 CCRU in-person sessions. Since 2015, 174 sessions have been attended by 25 Canadian sites. Sessions are available in-class, online through eLearning, and through WebEX teleconference.

For 2016, CCRU Education aims to increase volume by 20% in both attendance and number of sessions. This translates into a goal of 305 in-class sessions to serve approximately 2668 participants. CCRU Education currently provides 3 online courses, and aims to increase that number to 8 online courses by the end of 2016. In addition, CCRU aims to increase support and clarity around the clinical research education expectations for new and current staff, as well as the number of education sessions.

Describe the solutions or methods implemented:

In collaboration with the Princess Margaret Nurse Educators, CCRU has implemented an "Orientation Pathway" for new clinical research staff. This pathway provides clear guidance on mandatory research training activities, as well as role and task-specific training activities.

In 2016, CCRU has modified course content to include more workshop-style courses, providing scenario-based learning models. The CCRU uses a blend of online, in-class, and case-based learning sessions to promote critical thinking and stimulate vibrant group discussion. Interactive sessions, paired with evaluation and follow-up ensure learning needs are met.

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

Since implementing the interactive training sessions, and the clinical research staff Orientation Pathways, the CCRU Quality Assurance department has seen a reduction of insufficient documentation findings. To measure this, the total number of Quality Assurance Review (QAR) findings on insufficient and/or incomplete documentation of the consent process was averaged and compared in 2014 and 2015 and a 25% decrease was noted.

In addition, clinical research staff feedback is regularly collected through an online survey. Quarterly, survey comments are reviewed by the CCRU Quality-Education committee for training quality improvement.

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

Positive feedback from clinical research staff, and a reduction of QAR findings has encouraged CCRU Education to continue creating workshop-based training sessions that are interactive, timely and effective. Efforts will continue to include stakeholders and subject matter experts in the development of new course offerings, as well as creating more eLearning course content.

Mobile Electronic Solution for Clinical Research Source Documentation

Heather Cole; Alex Kerr; Julie Gundry; Calven Eggert; Aaron DiNardo; Susanna Sellmann; Pamela Degendorfer, MA, CCRP

Princess Margaret Cancer Centre, University Health Network

Describe the background of the problem:

As trial complexity increases, there is a growing need to facilitate rapid communication of trial data among the research and clinical care teams. Timeliness of investigator review and high quality data are critical to clinical trial documentation. At Princess Margaret (PM) trials are managed by a team: Investigators, clinical research nurse coordinator (CRNC) for the patient visits and source documentation, study coordinator for the regulatory and data requirements, and correlative staff. Due to program size, staff are in multiple physical locations. Historically PM used standardized paper research charts; however the physical layout of our teams yielded challenges, as only a single team member could utilize the chart at any one time, increasing complexity of achieving data locks, and Investigator review.

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

The goal of the project was to facilitate the workflow of multi-person teams, to enable our Investigators to review/sign off events electronically, and to develop a system to track and review source documentation.

Describe the solutions or methods implemented:

PM developed an electronic application, eSource, which is integrated into the electronic patient record (EPR), allows source documentation into the EPR from a tablet at the point of care, allows for electronic review and approval by Investigators, and enables review of source documentation practices.

Focus groups were held to evaluate application and device needs. Device needs were: usability, compatibility with EPR, and encryption. Application needs were templates for: the informed consent process, clinical notes, vital signs, baseline symptoms, adverse events, and concomitant medications. The project started with a 4 month pilot with 10 CRNCs, and implementation was completed in August 2014 to all our CRNCs.

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

eSource currently supports over 70 CRNCs and PM has trained almost 200 Investigators/Fellows on the application. Historically, Investigators were required to review and sign off events within a cycle (~28 days), and there was no capability to determine the total number of events that occurred across trials. In 2015 PM recorded 13,946 adverse events, across 1072 trial patients. The time to review by Investigators was 7.6 days (average). 79% of all adverse events reported were CTCAE grade 1-2. eSource has also enabled systemic reviews of documentation quality, such as reviewing our CRNC practices with completing adverse event attributions, which has driven education and process change.

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

Point of care electronic documentation was a significant practice change for our CRNCs and Investigators, and change management strategies were required to assist with the adoption of the application, including education about incorporating technology into patient care, and focus groups to identify additional improvements to the IT interface, which are in progress. We are currently assessing new templates to better meet the needs of the research teams. We are also in the process of understanding and exploring the potential for the data in the system, such as systemic reviews of adverse event data by drug class. eSource has been fully implemented for over a year, and following the change management initiatives, the CRNCs have embraced the application, along with the other team members.

Quality Assurance Metrics in Clinical Trial Conduct

Jennifer Li; Susanna Sellmann; Lindsay Philip; Cristina Guglielmi; Pamela Degendorfer, MA, CCRP; Amit Oza

Princess Margaret Cancer Centre, University Health Network

Describe the background of the problem:

Quality assurance (QA) in clinical trials is a safeguard against non-compliance, which impacts patient safety and data integrity. On an institutional level, compiling quality findings provides insight to gaps within existing processes, protocol compliance, and educational content.

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

A QA metrics methodology has been implemented, which is streamlined with the ICH-GCP, and institutional Standard Operating Procedures (SOPs) and policies.

Describe the solutions or methods implemented:

Individual findings are assigned an alphanumeric code, based on severity and category, and a reference for each Quality Assurance Review (QAR). Annual data is tracked for all QAR findings. Different data sets are created to allow for analysis of quality gaps and quality changes over time. Results are used in the creation or revision of educational content, SOPs, and to drive process improvement.

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

To date, a total of 1608 QAR observations between 2014 and mid-2015 have been coded and tracked across 22 studies. Areas of quality gaps, such as most-cited categories (e.g. 27% in Source Documentation and 13% in Regulatory) and references (e.g. 30% on SOPs and 14% on guidelines), are communicated to the Quality and Education team regularly and incorporated into training content. This has also prompted the development of new SOPs, processes, and research tools, after which QA metrics continues to be used to monitor program wide quality improvement. For example, following the implementation of Electronic Source Documentation, the proportion of findings on delays in Adverse Event sign off has seen a decline. For individual QARs, a personalized trends summary is provided to the study team with an overview of the quality of the study conduct. The report displays the distribution of findings across different categories and severity levels. Lastly, quality metrics has increased the efficiency of tracking and reporting program wide QA activity.

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

The regular analysis of quality metrics has proven to be a pivotal step in the Quality Management Cycle. It presents a quick snap shot of the quality of individual research studies under review. When implemented on an institutional scale, it offers valuable feedback on the current SOPs, processes, and training content.

Automated Hospitalization/Death Notification System

Nick Fisher, MBA; Dave Mulvihill

Siteman Cancer Center

Describe the background of the problem:

Research teams struggle to monitor hospitalizations and deaths of research patients. This information is essential, but often difficult to attain. Study teams must know about hospitalizations to ensure that the protocol is properly executed during the hospitalization. They must also report many hospitalizations and deaths to sponsors and IRBs. Delayed notifications can lead to protocol noncompliance and violations which can be harmful to patients.

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

The goal of the process is to reduce the risk of harmful protocol violations by automatically informing research teams when patients are admitted, discharged or transferred, allowing staff to take necessary steps to ensure protocol compliance. Additionally, the process will streamline event reporting to sponsors and IRBs (by ensuring that the team is immediately aware of the events) and eliminate late reporting of deaths to the IRB, by notifying them immediately upon each research participant death in the hospital system.

Describe the solutions or methods implemented:

Hospitals within the BJC network use a common enterprise master patient index (eMPI) to match patients between facilities. The OnCore CTMS is used to track patients enrolled on clinical studies and patients are linked by using the eMPI. An electronic list of all admissions, discharges, transfers or expirations (ADT) is provided by the hospital which is imported via an open source extract, transform, load (ETL) tool. Since OnCore contains a comprehensive list of active study participants we can further implement the ETL to perform accurate, automated matching which provides an intersection of the two datasets. Thus, a list of patients that had an ADT event and are active on a clinical study is output. From the protocol details available in OnCore we can further electronically extract detailed contact information about the principal investigator, clinical coordinators and others that are approved to receive study notifications. Details concerning these study participants are then electronically distributed to only those authorized to receive them. In the case of an expiration, the IRB is included on the notification.

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

With this system active, study teams are promptly notified of all research participant admissions and deaths within the vast hospital network. This directly results in a decreased chance of dangerous protocol violations and late event reporting. In the case of deaths, it eliminates late IRB reporting entirely, by including them on the notification.

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

Research teams can effectively utilize electronic EMRs and CTMSs to notify essential personnel of key safety events. This process can lead to an improvement in patient safety, protocol compliance, and event reporting. The framework of our process can be replicated at other centers, regardless of the specific electronic systems utilized.

Future plans include:

- Expansion of process to include automated reporting of deaths to industry sponsors utilizing sponsor contact info stored in CTMS
- Expansion of process to include automated reporting of admissions to both IRB and sponsors utilizing "cause of admission" data available within the hospital system
- Expansion of process to include inpatient nursing leaders in the initial admission notifications, based on the inpatient floor of the patient's admission and pre-loaded contact information for nursing leadership on each inpatient floor

Minority Participation in Clinical Trials: A Multifaceted Approach to Increase Enrollment

Jessica Thein, MPH, MSW; Nick Fisher, MBA; Amanda DeMoss, MS, CCRP

Siteman Cancer Center

Describe the background of the problem:

Public Law 103 mandates adequate representation of minorities in NCI-funded clinical trials (CTs); however enforcement of the law proves to be difficult. Beyond the legal obligation, lack of inclusion of minorities in clinical research poses two primary issues: one of scientific inquiry and the other of equity. Thus, the responsibility of providing equitable care falls to the medical community. Care provided in a CT setting results in better clinical outcomes and may expose a patient to a novel agent, but African Americans (AA) and other minorities are not proportionally enrolled to CTs. Consequently, AAs are not receiving cutting edge treatments to the same degree as Caucasians. This is clearly exemplified in the case of triple negative breast cancer (TNBC), widely considered to be the most aggressive subtype with the poorest prognosis. A contributory factor to the paucity of scientific knowledge regarding TNBC treatment is the lack of inclusion of AA women in breast cancer CTs. Enrollment to these trials skews heavily towards Caucasian women with conspicuous underrepresentation of AA women (despite respective TNBC prevalence rates of 10% and 25%). This is the result of a complex array of barriers that Ford et al. conceptualized through three principle domains: Awareness, Acceptance, and Opportunity. Using this framework, Siteman Cancer Center (SCC) surveyed 250 patients to evaluate barriers and attitudes towards CT participation.

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

Our goal is to use existing literature and insights gained from SCC patient responses to develop a comprehensive program that will address barriers to participation, thereby increasing minority enrollment to CTs at rates that mirror SCC's catchment area.

Describe the solutions or methods implemented:

Survey results indicated that enrollment barriers specific to minorities fell in the Acceptance domain (mistrust and conflict with religious beliefs). These barriers develop long before patients are seen at SCC and must be addressed in a multi-pronged approach, including community outreach initiatives, CT education, and supportive services. Outreach will focus on partnerships with local churches, advocacy organizations, news outlets, and federally qualified health centers; such institutions have established relationships with patients and will act as conduits to deliver CT education as well as address mistrust and religious conflict. Community-based partnerships can assist in the dissemination of information and use existing relationships to present the option of CT participation in a relatable way. SCC will also provide services to clinic teams by developing learning modules to reinforce best practices when discussing CTs with minority patients and provide a basis for understanding and addressing barriers to participation. Additionally, a patient navigator identifies potential obstacles and coordinates with social services to ensure appropriate resources are obtained. The navigator also provides general CT education to address misconceptions regarding research.

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

Success will be measured by the number of minority patients reached by the navigator and the percent change in minority enrollment at 1 and 5 years.

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

Increased minority representation in CTs will not only provide more equitable care but also increase the scientific rigor of our investigations. It is our hope that this will prove to be an effective model in overcoming minority patients' barriers to participation.

Focus on Improving Quality: Develop, Pilot and Revamp a QA Program

Melanie Hines, MPH; Suzanne Friedrich, CCRC; Prudhvi Mandala, MS, CCRP; MaryAnne McNulty;

Miriam Bischoff, MS, MBA

Stanford Cancer Institute

Describe the background of the problem:

New faculty researchers, turnover in clinical research staff, an increased number of new trials, and rapid accrual can create the perfect storm and negatively affect quality in clinical research. Limited external and internal monitoring of trials can prolong discovery of issues, and multiply risk to the participants and institution. Identifying issues before they become pervasive requires vigilance and prioritization of resources toward the effort.

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

To develop strategies and processes with the goal of increasing internal monitoring and oversight, and to identify quality issues across all study types as they occur, so re-education and corrective action can be implemented to mitigate risk to participants and the institution.

Describe the solutions or methods implemented:

A multi-pronged approach was implemented, which included moving the existing quality program (2FTE) from clinical operations to the oversight organization to facilitate its efficacy and impact. Additional staff was hired to focus on quality efforts. The quality processes were developed and/or revised as follows:

- Protocol review and trial complexity scoring of new investigator initiated studies,
- Monitoring of first participant on NCI sponsored and high risk investigator initiated trials,
- Interim monitoring of NCI and investigator initiated trials,
- Monitoring of first participant by a new coordinator,
- Random quality checks across all study types including sponsored trials and low risk studies,
- Eligibility review.

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

The QA team became fully staffed (3 FTE) at the end of 2015, and has reviewed a total of 229 participants to date since June 2015. Investigator initiated trials are audited annually by the SCI DSMC until they are closed to accrual. This is separate from monitoring and not included in the following table.

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

Increased monitoring and addressing findings from the QA random checks requires coordinator effort and can affect morale. Making the process as collegial as possible helps to alleviate the fear of punitive action when issues are identified. Structuring the department as a service provided to coordinators to help them improve the quality of their work is important. It is also helpful to communicate changes before they are implemented, and to work directly with the Clinical Research Managers in order to have their support for new policies and necessary remediation. All of this can help to ease coordinator concerns about this additional level of oversight. Piloting and optimizing new processes based on feedback will improve outcomes. Providing training, and assisting with correction of small issues will enable the staff to view the QA team as collaborative and helpful. One indicator of success will be when coordinators proactively reach out to their assigned Quality Specialist for assistance to ensure their work and practices are compliant with federal and institutional guidelines.

Molecular Profiling for Eligibility to Complex Clinical Trials – Improving Operational Efficiencies to Expedite Enrollment

Lauren Wall, MS; Laura Hoffman, MA; Kelly O'Connor

The University of Chicago Medicine Comprehensive Cancer Center

Describe the background of the problem:

The paradigm shift in oncology clinical trials requires molecular profiling for eligibility. This patient-specific approach is designed to improve clinical outcomes; however, it has added a layer of complexity to clinical trials for which we are trying to improve operational efficiencies. These trials require patients to pre-consent so that we can send their tumor tissue to a central lab for mandatory molecular tumor testing. Patients who pre-screen might have their diagnostic tumor tissue available locally; however, many of these patients are referred to our center and their tissue is at an external pathology department.

With the increased necessity of “up-front” testing, there is a huge demand to improve efficiencies and reduce administrative barriers that hinder our ability to enroll patients in a timely manner, which could inevitably cause a delay in treatment for some patients. We wanted to understand the current process and come up with potential solutions to streamline and facilitate more rapid accrual to clinical trials.

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

- 1.) Understand the length of time between all the steps involved in the screening process (date patient signed pre-ICF -> date of enrollment).
- 2.) Look at the difference in time between patients who have tumor tissue locally vs. patients with tissue at external pathology departments.

Describe the solutions or methods implemented:

The Clinical Research Coordinators (CRCs) tracked the following time points for each patient on one clinical trial:

- Patient Name/Screening ID
- Date Patient signed Pre-Screening ICF
- Pathology Location
- Date Tissue Requested
- Date Tissue Received
- Date Tissue Resulted
- Date of Screening Visit (if applicable)
- Date 1st Treatment (if applicable)

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

The majority (83%) of the tissue requests came from external pathology departments, which increased the timeline for tissue acquisition and results. In some cases, the external tissue requests did not yield enough tumor content for eligibility, which caused even further delay. For internal tissue requests, it took less time to obtain the samples and there were no issues with non-evaluable tissue content.

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

Adequate research support staff is needed in order to expedite tissue requests and improve timeliness to enrollment. We plan to develop standards and expectations to help staff and streamline the process.

Examples include:

- Immediate notification to CRCs when a patient signs a pre-screening ICF
- CRC to request tissue within 24 hours
- Develop an escalation plan for when tissue is delayed (e.g. physician involvement).

There is great opportunity for us to collaborate with external pathology departments to improve timely tissue requests. Further investigation is needed to ensure external tissue samples come back evaluable.

Data Table 3 Analysis of a NCI Comprehensive Cancer Center: Identifying Specific Accrual Barriers in Breast Oncology Team

Zoneddy Dayao, MD; Teresa Stewart, MS; Olivier Rixe, MD, PhD

University of New Mexico Comprehensive Cancer Center

Describe the background of the problem:

Many NCI designated centers struggle to meet the 10% accrual benchmark, even with common malignancies such as breast cancer for which several trials are available. Published barriers include patient, physician, site and trial-related factors.

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

The goal of this retrospective study is to objectively identify UNMCCC's barriers to breast cancer trial accrual, debunk or affirm perceptions and create targeted operational solutions.

Describe the solutions or methods implemented:

All breast cancer cases from our 2014 Data Table 3 (DT3) were retrospectively reviewed, NCI-defined eligibility validated, and reasons for non-accrual were categorized as: 1) Trial specific: no trial available, or trial available but patient ineligible, 2) Patient specific: trial available, patient declined, 3) Patient not screened. And 4) other reasons. The No Trial Available cohort was categorized by stage and tumor subtype.

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

Of the 145 cases evaluated:

1. 99.5% met the criteria for NCI-defined registered patient.
2. 11% were enrolled in trials.
3. Despite 21 therapeutic trials open, no trials were available for 66%.
4. For 11%, trials were available, but patients were ineligible.
5. 4% declined participation.
6. 3% were not screened.

In the No Trial Available group:

1. 68% were Stage 0 (DCIS 12%, LCIS 4%), or Stage I/II (52%), node negative ER+, Her2-.
2. 16% were triple negative.
3. 10% were Her2+.

These results are discordant with long held perceptions regarding UNMCCC's patient population and breast cancer accrual barriers.

Previously, it was perceived that UNMCCC, a major referral center, has a large patient population with advanced disease. This study showed the majority have early stage (0/I/II) cancer.

It was also suspected that patients' unwillingness to participate is a main barrier, given New Mexico's geographic and cultural diversity (40% Hispanics, 10% Native Americans). However, this study showed that only 4% declined participation. It was believed that trial restrictions greatly limited accrual, but only 10% were ineligible. Contrary to the notion that screening is suboptimal, this study showed that only 3% were not screened.

It was perceived that the extensive trial menu matched the patient population. However, a major trial gap was identified for early stage node negative ER+, Her2- disease, for which standard of care is largely established and no major future therapeutic trials are anticipated.

This analysis improves the understanding of UNMCCC's true accrual barriers for which targeted strategies can be formulated.

Action plans:

- Symptom control trials for early stage disease are highly relevant and will be prioritized. Investigator Initiated trials will be a priority for this population to fill the specific gap in the breast portfolio for this large population of early stage patients.

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

Published barriers do not always reflect an institution's own accrual obstacles. A detailed analysis of DT3 by clinical working group is encouraged to optimize the selection of trials to match the site population.

This single center experience may also reflect a trend across institutions. If so, this may provide insight to the NCI regarding the root causes of low accruals and be utilized in prioritizing future study concepts that will match the largest US patient population for which trials are lacking.

The Value of Multidisciplinary Approach to the Creation of Research Orders

Neera Jagirdar, MS; Cathy Sharp, RN, MN, OCN

Winship Cancer Institute of Emory University

Describe the background of the problem:

Patient access to clinical trials can be challenging and research patients are particularly at risk for medication errors, especially in the face of complex protocols. Research pharmacy orders are essential to the success of clinical trials involving experimental drugs. A systematic, multi-disciplinary approach, in the form of a Research Order Committee, could be effective in reducing the number of medication errors and improving data integrity. The effectiveness such an approach to medical research has been shown in both adult and pediatric care. However, the creation of research orders that accurately convey multifaceted protocol requirements and ensure protocol adherence is difficult and the usefulness of a multi-disciplinary approach has yet to be established.

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

The objective of the Pharmacy Order Committee is to reduce the time required to study start up, decrease medication errors and adverse drug events, limit protocol deviations, and lessen the financial impact in adult cancer clinical trials.

Describe the solutions or methods implemented:

In January of 2014, after extensive collaboration with executive clinical trials leadership, a cancer clinical trials Research Order Committee was created. A solid tumor and blood cancer committees was created, comprised of pharmacists, physicians, infusion nurses and clinical research coordinators. Each committee member was assigned to a particular section of the protocol and timelines were given for its completion. Each person completed their given section, added it to the draft orders template, and ultimately the pharmacist was responsible for combining all the information and creating a full order set.

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

There was a significant reduction in time to study order creation and implementation. At the inception of the committee, orders took over 11 months to be completed. During the early stages of the committee, January 2014 to June 2014 saw an approximate 6 to 8 month turn-around time. From July 2014 to December 2014, orders took 4.5 months for completion. 2015 shows an approximate 4 month turn-around time for activation. The average introductory cost of opening up a clinical trial at Emory University is over \$15,500. Orders not created in a timely fashion often led to studies opening with negative funds because of the lag between study submission and patient enrollment.

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

The introduction of a multi-disciplinary process can clearly offer cost savings, consistency, quality, and enhancements in clinical trial productivity. However, the clinical benefit of a research order committee for cancer clinical trials in the adult setting yet to be fully demonstrated. The quality of the implementation process could be a decisive factor in determining its overall success or failure. A qualitative assessment of studies revealed the implementation process of a pharmacy research orders committee as a critical factor for outcome. We are not able to quantify the effect on protocol deviations. Infusion nurses reported more concise order sets allowed for improved clarification of required procedures and led to fewer questions as a result. Incorporation of a quantitative review of errors is an essential part the ongoing assessment of the Research Order Committee.

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