



Association of American Cancer Institutes
CLINICAL RESEARCH INITIATIVE

Paving the Way to a Better Understanding of Clinical Trials

7th Annual AACI CRI Meeting
2015 Abstracts and Posters



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University of Kansas Cancer Center¹, American Society of Clinical Oncology²

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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.

2015 AACI CRI Steering Committee Members

Tony R. Reid, MD, PhD – Chair
UC San Diego Moores Cancer Center

Elizabeth Anderson, MPH, BSN
*Knight Cancer Institute
Oregon Health and Science University*

Paul Barr, MD
*Wilmot Cancer Institute
University of Rochester Medical Center*

Leigh Burgess, MHA, MEd, MA
*Duke Cancer Institute
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Randall F. Holcombe, MD
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Vicki L. Keedy, MD, MSCI
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*Cancer Therapy and Research Center
University of Texas Health Science Center*

Erin Williams, MBA
*Simmons Cancer Center
UT Southwestern Medical Center*

7th Annual AACI CRI Meeting Abstracts



In January 2015, the AACI CRI Steering Committee issued a call for abstracts to AACI cancer centers for presentation at the seventh annual AACI CRI meeting, held July 8–9 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 21 abstracts and selected three for presentation at the meeting. All abstract authors were invited to submit posters for display at the meeting.



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



FIRST PLACE

Cancer Center's Experience with Insurance Denials for Clinical Trial Participation after ACA Mandate

Christine Mackay, RN¹, MSA, CCRP; Kaitlyn Antonelli²; Suanna Bruinooge²; Shellie Ellis, MA, PhD¹

University of Kansas Cancer Center¹, American Society of Clinical Oncology²

Describe the background of the problem:

Enrollment into cancer clinical trials for adults is a challenge; 97% of patients do not participate in clinical trials despite nearly one-third of American adults indicating a willingness to participate if asked.^{1,2} Lack of adequate enrollment to cancer clinical trials limits the generalizability of the results, causes trials to be cancelled prematurely and increases the length of time required to get effective treatments into widespread practice.^{3,4} One identified barrier to clinical trial enrollment is lack of insurance coverage for clinical trial participation. The 2010 Patient Protection and Affordable Care Act (ACA) includes a provision requiring coverage for clinical trial participation as of January 1, 2014. Nonetheless implementation of the law may lag enactment.

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

We initiated a study of cancer organizations to assess the impact of this legislation on trial enrollment and to identify barriers to mandate implementation. Surveying organizations to evaluate the manner in which health insurance coverage for clinical trial participation is ascertained may lead to improving organizational processes for increasing trial enrollment. Specifically, we will: (1) assess the number of patients enrolled to clinical trials January 1, 2014 to December 31, 2014, (2) describe specific institutional processes for precertification, and (3) identify the degree to which individuals are interested in participating in barrier reduction intervention teams.

Describe the solutions or methods implemented:

We used a convenience sample of cancer organizations from professional society listservs (American Society of Clinical Oncology, Association of American Cancer Institutes, Oncology Nursing Society) to solicit participation in an on-line survey. An initial screening survey was used to identify qualified individuals to respond to a more detailed survey. The detailed survey is currently being administered. The University of Kansas-Lawrence, Human Subjects Committee exempted this project.

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

The initial survey was sent to 1,412 individuals who are members of at least one of the participating organizations. These represented cancer centers, but also sponsors and CROs. We received 309 responses with the majority of respondents (63.6%) reported having experienced insurance denials. Of the centers that responded, 78.2% reported having a precertification process.

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

Insurance denial for obtaining treatment via a clinical trial persists despite the ACA mandate, potentially limiting treatment options for patients with cancer. Detailed survey results are expected to provide guidance in the design of a "best practice" for performing precertification.

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Cancer Center and Community Research Program Experience with Insurance Denials for Clinical Trial Participation after ACA Mandate

Christine Mackay, RN, MSA, CCRP¹, Kaitlyn Antonelli², Suanna Bruinooge², Shellie Ellis, MA, PhD¹
¹University of Kansas Cancer Center, ²American Society of Clinical Oncology

Introduction

Lack of certainty and uniformity about insurance coverage impacts clinical trial participation, access to care and healthcare disparities. Since January 1, 2014, the 2010 Patient Protection and Affordable Care Act (ACA) requires most insurance providers to cover routine costs associated with clinical trial participation. However, implementation of the law may be incomplete. A comprehensive assessment of implementation of the ACA provision has not been reported.

We initiated a study of organizations conducting cancer clinical trials to describe factors associated with insurer's denial of cancer clinical trial coverage, particularly the precertification process. Understanding how insurance coverage for clinical trial participation is ascertained may lead to improving organizational processes, thus increasing trial enrollment.

Methods and Materials

Individuals who are part of a professional society listserv or email list from the American Society of Clinical Oncology's Community Research Forum, Association of American Cancer Institutes' Clinical Research Initiative, Oncology Nursing Society's research nurses special interest group and the Midwest Cancer Alliance, were emailed an invitation to participate in an online screening survey. This screening survey was used to identify qualified individuals to respond to a more detailed survey. The detailed survey is currently being administered. The University of Kansas-Lawrence, Human Subjects Committee exempted this project.

Results

The initial survey was sent to 1,412 individuals associated with at least one of the participating organizations. These individuals represented cancer centers and community-based research programs. We received 309 responses. After removing duplicates and incomplete entries, 252 responses were analyzed (Figure 1).

Of those responding, 158 (62.7%) reported experiencing an insurance denial for patients participating in clinical trials in 2014 (Figure 2). Sites performing precertification are more likely (60.3% vs. 41.7%, $\chi^2=14.9$, $p<0.001$) to experience denials (Figure 3). Sites with state laws or agreements experienced similar rates of denials as states without (82.3% vs. 85.1%, $\chi^2=50.7$, $p<0.001$) (Figure 4).

After controlling for volume of enrollment and presence of a state law or agreement mandating coverage already in place, sites with a precertification process were three times more likely to experience denials than sites without a precertification process (OR 3.04, 95% CI 1.55-5.99) (Table 1).



Figure 1

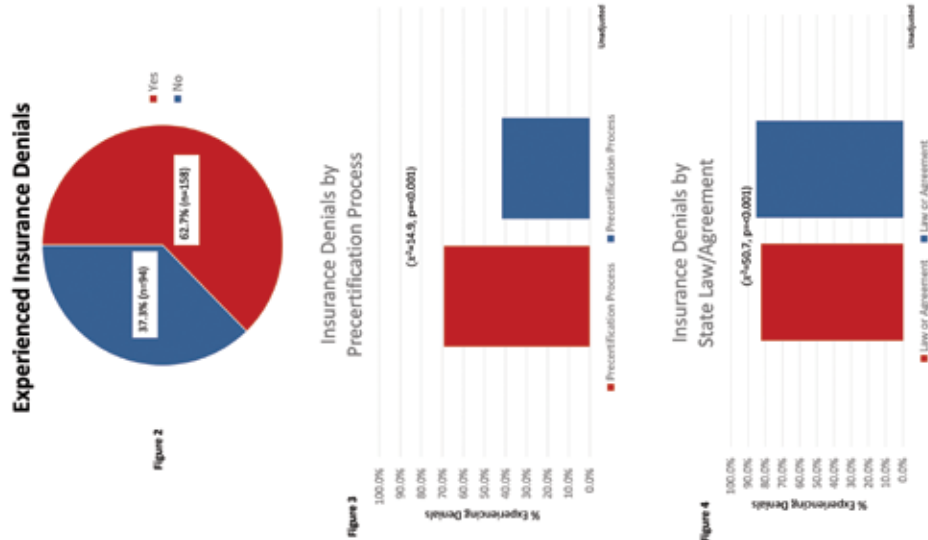


Table 1

	Odds Ratio	95% Confidence Interval
Precertification Process	3.04	1.55 5.99
Enrolled Patients	2.14	1.66 2.76
State Law or Agreement	0.67	0.3 1.51

Adjusted

Discussion

The objective of this study was to describe the implementation of the ACA's mandate requiring insurance companies to cover routine costs for participation in cancer clinical trials. We found that denials persist and that precertification is significantly associated with experiencing denials.

Although 62% of sites experienced denials, we do not know what proportion of individual participants were denied. Planned analyses of our second survey may inform this discussion. Denials may persist after the ACA mandate because some insurers remain exempt from both state and federal mandates, i.e. self-insured plans or Medicaid.

There are 2 possible reasons for the association between conducting precertification and experiencing denials. First, sites who do not conduct precertification may not be aware that patients are experiencing denial. Alternatively, the precertification process itself may be engendering higher levels of scrutiny from the insurers than what might otherwise be provided. When alerted to a "clinical trial", insurers may evaluate individual coverage elements rather than evaluating whether the specific policy provides coverage. Planned analyses of subsequent survey results will clarify how sites with and without a precertification process experience denials.

Although sites in states where laws or agreements exist reported similar rates of denials as sites without similar regulations, this finding was not significantly related to experiencing insurance denials. Nonetheless future research should assess the degree to which these laws are enforced.

This study has several limitations. As a convenience sample of people associated with specific email lists, the results cannot be generalized to all sites conducting cancer clinical trials. As with all survey data, self-reported data is subject to recall bias.

Conclusions

- Insurance denials for obtaining treatment through a clinical trial persist despite the ACA mandate, especially for sites seeking precertification approval, potentially limiting treatment options for patients with cancer.
- A comprehensive evaluation of the implementation of federal requirements for insurance companies to cover clinical trial participation is needed.

Next Steps

- Evaluate the responses from the detailed survey to better understand the processes sites are using to perform precertification and learn how they respond to an initial denial.
- Detailed survey results are expected to provide guidance in the design of "successful practices" for performing precertification.
- Use data related to denials and delays to inform ongoing advocacy with insurance companies and policy makers to ensure adequate access to care and to decrease health disparities.

Collaborators

Association of American Cancer Institutes-Clinical Research Initiative
Midwest Cancer Alliance
Oncology Nursing Society

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SECOND PLACE

Leveraging AACI CRI Listserv Benchmarking and Technology to Reduce the Administrative Burden of Conducting Clinical Trials

Kate Huffman, RN, BSN, CCRA
University of Michigan Comprehensive Cancer Center

Describe the background of the problem:

The regulatory team is under constant pressure to activate trials as quickly as possible. However, the volume and complexity of trials continues to increase every year without the addition of incremental staff. Solutions to alleviate the administrative burden of trials needed to be addressed to allow effort to be focused on core regulatory tasks.

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

Goals	Target
Reduce effort spent on processing external safety reports	50% decrease in 18 months
Reduce effort on clerical tasks (filing & printing)	10% decrease in 18 months
Reduce operational costs (paper & binder tabs)	50% decrease in 18 months

Describe the solutions or methods implemented:

Eliminated non-value added tasks

Created a new policy regarding the processing of External Safety Reports (CRI Listserv topic)

- The policy eliminated the need to print and obtain the investigators signature on each individual report received and transferred the responsibility of assessing the event to the sponsor per FDA guidance.

Revised our protocol training policy to address amendment training (CRI Listserv topic)

- The policy relies on self-training of materials sent via email. It eliminated the use of training logs or the need to document confirmation from each study team member that they have reviewed the material.

Eliminated duplication of effort

Created a single location for the storage of University of Michigan non-protocol specific reference documents that is accessible by external customers.

Established an M+ box account where UM essential documents could be stored and accessed by sponsors/monitors reducing the need to email these documents at start up and each time they are updated.

Reduced operational costs and effort

Converted to an electronic regulatory binder.

- Created a regulatory eBinder file structure that is consistent with a traditional paper binder and developed a standard process for use and review of the eBinder during monitoring visits and audits.

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

We are not able to quantify the most significant impact these studies have had in the table below. The affect it has had on the morale of the regulatory coordinators enabling them to feel like they can focus on more significant issues than printing & filing, chasing down study team members for confirmation of training, and obtaining signatures on hundreds of INDs all of which pulled their time and effort away from ensuring our patients have access to the latest clinical trials.

Goals	Target	Actual
Reduce effort spent on processing external safety reports	50% decrease in 18 months	53% at 18 months
Reduce effort on clerical tasks (printing & filing)	10% decrease in 18 months	12% at 1 year
Reduce operational costs (paper & binder tabs)	50% decrease in 18 months	63% at 1 year

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

Implementation of all of these practices has been very successful with no significant set-backs. A few tips include:

- eBinder
 - Have a back-up copy of the master eBinder
 - Keep file names to a minimum to avoid issues transferring files to flash drives
- M+box
 - Best to have a single person responsible for maintaining the essential documents
 - Be firm who is given access to reduce remote monitoring

Leveraging AACI CRI Listserv Benchmarking and Technology to Reduce the Administrative Burden of Conducting Clinical Trials

Kate Huffman, RN, BSN, CCRA
University of Michigan Comprehensive Cancer Center

Introduction

The Clinical Trials Office Regulatory Team provides management of regulatory affairs for the clinical investigator, from protocol submission to study close-out. The regulatory team is under constant pressure to activate trials as quickly as possible.

In the last 5 years, the number of active studies we are putting effort towards has grown by 40%. In addition, we are adapting to new trends in industry with personalized trials that either involve quick activation times for a single patient or studies that have numerous arms based on the patients' specific genetic alterations. Both models require more effort than previous studies to get up and running.

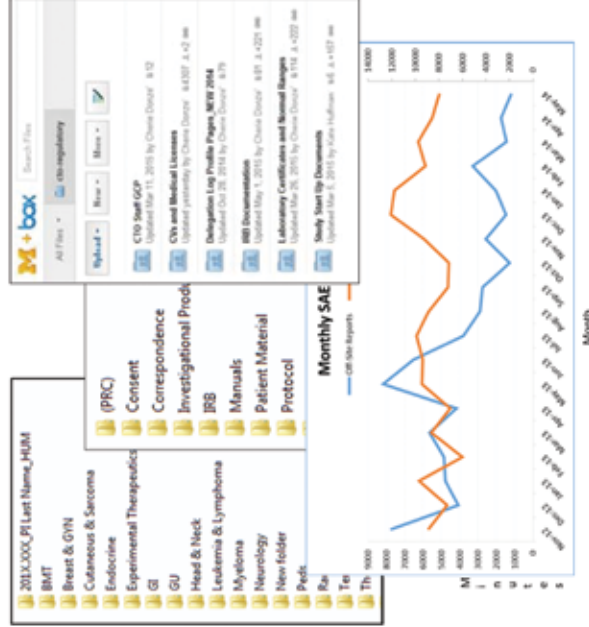
Despite the volume and complexity of trials increasing every year, our staffing has remained constant. Solutions to alleviate the administrative burden of trials needed to be addressed to allow effort to be focused on core regulatory tasks.

Goals

Goals	Target
Reduce effort spent on processing external safety reports	50% decrease in 18 months
Reduce effort on clerical tasks (filing & printing)	10% decrease in 18 months
Reduce operational costs (paper & binder tabs)	50% decrease in 18 months



Figures 1 and 2. Traditional Regulatory Binders



Methods and Materials

Goal: Eliminate non-value added tasks

- Created a new policy regarding the processing of External Safety Reports. The policy eliminated the need to print and obtain the investigators signature on each individual report received.

- Revised our protocol training policy to address amendment training. The policy relies on self-training of materials sent via email. It eliminated the use of training logs or the need to document confirmation from each study team member that they have reviewed the material.

Goal: Eliminate duplication of effort

- Established an M-Box account where UM essential documents (CV's, medical licenses, CAP/CLIA, IRB Rosters, etc.) could be stored and accessed by outside customers reducing the need to email these documents to multiple people each time they are updated.

- Transferred UM essential document management from individual Clinical Research Coordinators to the Clinical Subjects Associate position to reduce duplication of work.

Goal: Reduce operational costs and effort

- Created a regulatory eBinder file structure that is consistent with a traditional paper binder and developed a standard process for use and review of the eBinder during monitoring visits and audits.
- Created a "master eBinder" on our department shared drive with pre-filled Notes to File that are standard to the majority of studies (i.e. long term storage location & location of CVs, medical licenses).

Goals	Target	Actual
Reduce effort spent on processing external safety reports	50% decrease in 18 months	53% at 18 months
Reduce effort on clerical tasks (printing & filing)	10% decrease in 18 months	12% at 1 year
Reduce operational costs (paper & binder tabs)	50% decrease in 18 months	63% at 1 year

Conclusions

We are not able to quantify the most significant impact these policies have had in the table above. The affect it has had on the morale of the regulatory coordinators enabling them to feel like they can focus on more significant issues than printing & filing, chasing down study team members for confirmation of training, and obtaining signatures on hundreds of INDs, all of which pulled their time and effort away from ensuring our patients have access to the latest clinical trials.

Implementation of all of these practices has been very successful. A few tips include:

Electronic Regulatory Files

- Have a back-up copy of the master file structure
- Keep file names to a minimum to avoid issues transferring files to flash drives

Central Storage of Essential Documents

- Best to have a single person responsible for maintaining the essential documents
- Be firm on who is given access to reduce remote monitoring

Amendment Training and INDsR Policy

- Be clear about how and when you will implement them, i.e. will they be applied to INDs not yet processed
- Everyone on your team needs to follow the policies, one exception can lead to another and another



Figure 3. Flash drives for monitoring visits

AACI CRI Listserv Discussions

I would like to thank everyone who participated in the following listserv discussions:

- External Sponsor AE Policy (August 2013)
- Documentation of Amendment Training (July 2014)

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THIRD PLACE

Protocol Information Management Systems (PIMS) Regulatory Binder: Streamlining Regulatory Binder Documentation Maintenance & Improving Compliance

Abdul Karim Abdullah; Michelle Thomas; Roy Cambria; Bonnie Edelman; Marcia Latif; Dawn Caron; Jaclyn Nunner; Michael Ayerov; Gary Dranch; Elsa Hwang; Collette Houston
Memorial Sloan Kettering Cancer Center

Describe the background of the problem:

Prior to the implementation of the PIMS regulatory binder, the storage of regulatory documents were either in paper binders or electronically on a network drive at MSK.

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

The objective of the PIMS regulatory binder is to maintain compliance with federal requirements and regulations, standardize document filing management and nomenclature, simplify access for external monitors/auditors and also return time and effort to the local research study assistants (RSA).

Describe the solutions or methods implemented:

In an effort to streamline regulatory documentation processes across departments, our Center's Office of Clinical Research (OCR) decided to create an electronic regulatory binder. Currently, we utilize an in-house developed electronic document management system known as the Protocol Information Management System (PIMS) for the protocol review process. It was decided to further leverage our capabilities in PIMS to include our protocol regulatory binders.

A thorough review was conducted to ensure all pertinent regulatory binder documents would flow from the PIMS Institutional Review Board/Privacy Board IRB/PB protocol document folders directly into the designated study specific regulatory binder section and electronic sub folders were created to capture non IRB/PB related documents. Lastly, educational tools were created to serve as a resource for staff and to ease the transition to this new practice.

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

The development of the PIMS Regulatory Binder has positively influenced the capability of storing and accessing regulatory documents. Research staffs, internal and external monitors/auditors are now able to review documents within the binder under custom access levels. Additionally, it has improved the real time availability of IRB approved protocol documents within designated regulatory binder folders.

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

It is best to ensure the scope of a project is outlined with extreme specificity. It may be challenging to anticipate how a change in one area may affect the processes of another; however, the success of a project is highly dependent on accounting for such modifiers.

In the future we hope to streamline document naming convention across institutional committees. We also hope to create a medical licenses and CV depository for the regulatory binder which will further reduce RSA time and effort.



Protocol Information Management System (PIMS) Regulatory Binder: Streamlining Regulatory Binder Documentation Maintenance & Improving Compliance

Abdul Karim Abdullah, Michelle Thomas, Roy Cambria, Bonnie Edelman, Marcia Latif, Dawn Caron, Jaclyn Nunner, Elsa Hwang, Collette Houston, Gary Dranch, Michael Ayerov
Memorial Sloan Kettering Cancer Center

BACKGROUND:

Prior to 2015, MSK staff did not have a central location for storage of regulatory documents. Clinical departments maintained regulatory binders in either paper format or electronically on a network drive.

ISSUES WITH PREVIOUS PRACTICE

- ❖ 'Green Issue': large amounts of paper printed; stationery supply cost
- ❖ Binder storage cost and maintenance
- ❖ Inconsistency in naming regulatory binder documents
- ❖ Difficult security maintenance
- ❖ Staff time and effort spent organizing and printing documents

Shared Drive/SharePoint Binders



Paper Binders



OBJECTIVES:

- ❖ Maintain compliance with federal requirements and regulations
- ❖ Standardize document filing management and nomenclature
- ❖ Simplify access for external monitors/auditors
- ❖ Return time and effort to the local Research Study Assistants (RSAs)

PIMS REGULATORY BINDER CREATION PROCESS:

STEP 1: Reviewed PIMS document types from MSK institutional protocol review committees (e.g. IRB/PB) that were already housed in PIMS and also required to be in the regulatory binder.



STEP 2: Newly created document types were mapped within PIMS. Each type was mapped to flow into the designated binder section in a specific sort order. Staff no longer have to manually upload **over 85 documents**.

MAPPING AND OUTLINE OF REGULATORY BINDER



STEP 3: Stakeholders were consulted to ensure all required items from each institutional protocol review committee and industrial sponsored requirements were properly accounted for each type of clinical study.

EDUCATIONAL TOOLS AND ROLLOUT

STEP 4: An informational session was conducted to acclimate staff with the new PIMS regulatory binder. Resources were created and provided to the staff to ease the transition.



FUTURE GOALS:

- ❖ Mandatory maintenance of all MSK regulatory binders in PIMS
- ❖ Creation of an online platform for monitor/auditor routine visits with introduction of the streamlined process
- ❖ Creation of a CV and medical license repository that will automatically populate within the PIMS regulatory binder
- ❖ Reduction of research time and effort spent on regulatory maintenance

ACCESS AND VIEWS:

In order to maintain the security of the protocol documents, different access groups were created for each type of user. Each specific access group has different viewing and usage privileges managed by the Office of Clinical Research (OCR). Local RSAs are allowed to upload regulatory documents into the appropriate tabs (i.e. CVs).

ADMINISTRATIVE MAINTENANCE VIEW (Full access)



MSK RESEARCH STAFF VIEW (Read & upload access)



MONITOR VIEW (Read access)



MULTICENTER (MCT) STAFF VIEW (Read & upload access)



Operationalizing Clinical Research Compliance Activities in an Academic Cancer Institute: Implementation & Challenges

Vijaya Chadaram, RN, MSN, CCRP; Leigh Burgess, MHA, MEd, MA; Bonnie Vernarelli, RN, MSN, MBA; Patrick Barrera

Duke Cancer Institute, Duke University Medical Center

Describe the background of the problem:

To provide oversight for cancer-related clinical research to assure data integrity and maximize human subject protection at DCI. The NCI Data Safety and Monitoring Plan (DSMP), DCI policies and Standard Operating Procedures (SOP) are utilized as a guide to recognize areas of research noncompliance and define processes to address findings and implement corrective action plans in a supportive and timely manner to enhance research integrity.

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

The goal is to implement a compliance plan with multifaceted approach to support internal and externally sponsored oncology research. The DCI Clinical Research portfolio in 2014 consisted of 640 clinical trials with 167 Investigators & 150 clinical research staff. A portfolio of this magnitude requires a robust compliance plan to proactively identify noncompliance and implement appropriate corrective and preventive actions.

Describe the solutions or methods implemented:

A successful research compliance plan is contingent upon robust institutional infrastructure to foster research, resources and education.

Infrastructure: The faculty and staff in DCI Clinical Trials Office (CTO) provide quality assurance and research compliance services to all oncology research projects. The CTO services are a joint effort between Cancer Protocol Committee (CPC), clinical trials monitoring team, and Safety Oversight Committee (SOC). Both CPC & SOC membership is multidisciplinary; consisting of oncologists, biostatisticians, pharmacists, nurses, regulatory and data coordinators with oncology expertise. The DCI clinical research administration & CTO teams not only implement processes but also evaluate the effectiveness of the processes to ensure that there is continuing research compliance services for all oncology research projects. The CPC focus is to evaluate scientific value of all cancer-related research, and the focus of the monitoring team & SOC is to ensure subject safety and that the research is conducted, recorded and reported in accordance with the protocol, SOPs, Good Clinical Practice (GCP), and applicable regulatory requirements.

Onboarding and training of research staff: The most critical mass required for regulatory & protocol compliance includes regulatory, research and data coordinators. Onboarding these staff members can be challenging but the Duke institutional organizational structure provides governance by establishing Clinical Research Units (CRU). Oncology CRU includes a medical director and Research Practice Manager (RPM) for streamlining the onboarding and continuing education of clinical research faculty & staff.

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

The DSMP, CTO and CRU infrastructure facilitated 238 protocol reviews and 64 therapeutic oncology studies monitoring in 2014. Noncompliance findings resulted in constructive dialogues with the Investigators and refresher courses for regulatory staff. The Corrective and Preventive Action Plans (CAPA) included protocol amendments, timely eligibility verification of research participants and implementation of operational SOPs.

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

Systematic implementation of compliance activities is critical throughout the conduct of a research project and requires a well-trained team. Communication with both internal and external partners will benefit in identifying noncompliance trends and appropriate change in processes. Research compliance education must be integrated into clinical research faculty and staff onboarding and ongoing training programs. Finally, research compliance and quality management is a collaborative mission between the investigators, sponsors, research professionals, institution, & IRB and necessitates preemptive measures from cancer center leadership to reduce or eliminate any major research noncompliance.

eTrials: Significantly Reducing Staff Time and Effort by Directly Parsing Clinical Research Data from MSKCC Source to Industry Sponsors

Michael Buckley; Milena Silverman; Dawn Caron; Kai-Hsiung Lin; Alessandra Garwin; Gloria Guman; Jonathan Wills; Stu Gardos; Paul Sabbatini; Collette Houston

Memorial Sloan Kettering Cancer Center

Traditional industry-sponsored clinical trial data entry into electronic data capture (EDC) systems, transfer of Radiology images to the sponsor via CD, and onsite sponsor source data verification from the EMR is inefficient, consumes valuable site and sponsor time and effort (T/E), and can introduce errors into the dataset from manual transcription processes.

In an effort to address these shortcomings, MSKCC launched its eTrials Program in 2014. The MSKCC eTrials Program is composed of 3 distinct projects at various stages of maturation: 1) eData Parsing of MSKCC local labs, eLab Toxicity Attributions, vitals, eRECIST, and demographics, 2) Radiology Image and EKG Transfer, and 3) eMonitoring.

The eData Parsing Program improves data entry accuracy by sending data elements directly to sponsor EDC systems from the MSKCC Clinical Research Data Base. The standard clinical trial contains 352 data eCRF pages per patient per visit, and 107 eCRF pages (30%) can be removed using this process (Figure 1, eTrials: Data Flows). In partnership with Information Systems, MSK Radiology can securely transfer PET, CT, and MRI images directly to sponsors, and obviate the need for burning and mailing CDs (2 hours of RSA T/E for each instance). Since 2011, the MSK eMonitoring Program provides secure and offsite access to the EMR for approved monitors to source verify data. eMonitoring reduces historical face time with study coordinators from 4 hours per monitor visit to 1 hour (fixed appointment) per visit, and allows MSK to reclaim 3 hours of time and effort from each visit.

The eTrials Program is able to decrease the cost of clinical research by exploiting technology advances and is able to reduce current sponsor, CRO, and data management staff time and effort by leveraging existing systems to streamline current work flows. As scalability of the program is confirmed, eTransfer of data will be offered to all investigators.

Improving the Process and Tracking of Expedited Amendments Involving Translations

Jenny Anopa; Jenny Deighan; Timothy Downey-Zayas; Dustin Rathbone; Michael Trinos; Margaret Isaacs; Sandy Iyer-Horan; Marissa Kehoe

Memorial Sloan Kettering Cancer Center

Background:

In accordance with the federal regulations, located at 45CFR46.116 and 46.117, which states that informed consent information be presented "in language understandable to the subject", the MSK Institutional Review Board/Privacy Board (IRB/PB) Standard Operating Procedures require that the consent and other participant documents are submitted for translation within 2 business days of enrolling a Non-English Speaking (NES) participant and are updated within 30 days of amending the corresponding English document(s). These non-English documents must continue to be translated for the life of the study. In 2013, the Office of Clinical Research processed 130 initial translations and 108 amended translations.

Metrics or goals:

From 2011 to 2014 submissions were received by the IRB/PB Office and processed by the IRB/PB Analysts; then reviewed via the expedited review process. During the pre-review process, individual spreadsheets were used as a tool to track submissions and capture any related errors or delays.

Solutions or method implemented:

The portfolio of studies seeking to enroll NES participants was growing exponentially, but no methods were in place to effectively monitor and track the compliance and quality of these submissions. As a result, an internal Translations Database was created within the IRB/PB Office to track deadline compliance and submission quality.

Outcomes:

The Translations Database has substantially improved the IRB/PB Office's workflow and efficiency. The Database sends an email to the Analysts when they have been assigned to process an expedited amendment that includes translated documents. It is also set up to capture standardized variables, each of which presents a particular issue, or enter a unique issue in a free-text field. Over the last 12 months, initial translation submissions have increased by 27.7%, while amended translation submissions has increased by 99.1%.

Changes to the methods to achieve a better outcome:

This data prompted a review of current policies and processes, resulting in the development of several strategies for future improvements to the database in order to capture more accurate data on translations, including transitioning the Translations Database into our internal Protocol Information Management System (PIMS) and incorporating the dates of requests for exceptions into the deadline to determine cause and effect of late submissions.

MSK IND Office Operations - Looking In, Expanding Out, Moving Forward

Richard Ellis, CCRP; Xhenete Lekperic; Lauren Richardson; Alan Ho, MD

Memorial Sloan Kettering Cancer Center

Describe the background of the problem:

The Investigational New Drug Office is responsible for the regulatory oversight for all institutional sponsored IND trials.

We would like to show the institutional importance that is placed on the IND Office and the decision making process that involves the FDA, research staff and most importantly our patients.

Given that our institution has one of the largest research portfolios in the country, we would also like to explain the rationale behind the creation of a centralized IND Office and the historical regulatory relationship that has been forged and built over the years between the FDA and the institution. The fact that we have a centralized IND Office, it sets us apart from other institutions that allow their investigators to hold their own INDs. We will show how our model has taken the regulatory burden away from the individual investigator and has placed the onus on the institution but has allowed the institution to function in a much more robust and dynamic way.

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

As our institution's research portfolio continues to grow, the regulatory complexities have also multiplied so managing and prioritizing the IND Office's workflow to meet the institution's needs is pivotal. The IND Office is embarking on many new and exciting frontiers; Institution sponsored Multicenter INDs, public and private partnerships including various collaborations with the biotech industry to commercialize our manufactured drug products, partnering with our alliance hospital affiliates in conducting IND trials along with many other projects that will continue to set the IND Office and our institution apart from our competitors.

With this poster presentation, we intend to look at the overall operations of the IND Office, the uniqueness and the importance of having such a centralized office along with describing the IND portfolio which is one of the largest in the country.

Describe the solutions or methods implemented:

Centralizing the IND Office

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

- Faster Decision Making Process between regulators, researchers, clinicians, pharmaceutical company
- Removal of the regulatory burden from investigator
- Institution functions in a more dynamic and robust way

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

We will outline some of the important and ground-breaking projects that the IND Office will be taking on with the goal of adding additional value to the clinical research enterprise.

Multicenter Protocol Management at a Large Comprehensive Cancer Center

Stephanie Karpoff; Ann Jenckes; Jaclyn Nunner; Ann Rodavitch; Dion Harris; Andrew Zarski; Joseph Lengfellner; Collette Houston; Paul Sabbatini, MD

Memorial Sloan Kettering Cancer Center

Describe the background of the problem:

In 2009, the Office of Clinical Research (OCR) at Memorial Sloan Kettering Cancer Center (MSK) created the Multicenter (MCT) Office to oversee the growing number of MSK-coordinated multicenter trials (MCTs). The MCT Office compiled best practices, established an institutional MCT policy, monitored policy compliance, and conducted standardized trainings.

The number of MCTs has since doubled, studies have become more complex, and the MCT Office has expanded in size and scope. As of March 1, 2015, there were 130 active MCTs spanning 8 clinical departments, and including 237 sites.

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

Create new initiatives and optimize infrastructure to better meet the increasing growth and complexity of MCTs.

Describe the solutions or methods implemented:

New initiatives include (1) the Multicenter Protocol Executive Committee (MPEC) (2) the Multisite Research website and (3) the transfer of MCTs from the Department of Medicine to the MCT Office.

Established in 2014, MPEC is charged with reviewing and approving complex MCTs prior to the formal protocol review process. Reviews focus on logistical feasibility and resource availability and are required for MCTs where: MSK holds or cross-references the IND/IDE, international sites will accrue, and/or more than 5 sites will accrue. The committee is comprised of various clinical research stakeholders.

The Multisite Research website, created with the Technology Exchange Core also in the OCR was launched in August 2014. Staff at participating sites receive a login and password that provide access to a dedicated study webpage. The webpage, maintained by the MCT Office, allows MSK to distribute protocol documents, training slides, and other study specific material. Emails can be sent to defined groups, alerting users to important announcements (e.g. cohort availability, posting of new documents).

There was a transfer of 35 MCTs and 8 research staff from the Department of Medicine to the MCT Office on January 1, 2015. Whereas previous study implementation was done by the clinical departments, the MCT Office now has two subparts- one which focuses on institutional policy and one that conducts the studies.

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

To date, the committee has reviewed 22 proposals, which include:

- 11 for MCTs where MSK holds or cross-references the IND/IDE
- 6 for international sites accruing patients
- 5 for studies that include more than 5 sites that will accrue participants

Of these proposals, 17 have been approved, 4 are under review and 1 was withdrawn.

The Multisite Research website has decreased email traffic and streamlined communication away from individual email accounts.

The transfer of MCTs from the Department of Medicine to the MCT Office has eliminated redundancies in staff responsibilities. Quality assurance is now handled uniformly between MSK and the external sites to ensure consistent standards and protocol conduct. Budget and protocol development are streamlined, saving time and effort.

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

Future plans for these initiatives include:

- Establish electronic and automated MPEC reviews within the institution's Protocol Information Management System
- Gain ability to securely post protected health information (e.g., safety reports) to the Multisite Research website
 - Centralize the management of all MCT across the institution in order to concentrate expertise and realize the most efficient processes possible.

Real-Time Feedback from Industrial Monitors Collection and Review Process

Saray Simo; Bonnie Edelman; Joe Lengfellner; Collette Houston; Paul Sabbatini, MD; Hector Pacheco; Matthew Koch; Jaclyn Regan

Memorial Sloan Kettering Cancer Center

Describe the background of the problem:

Previous to implementation of MSK's Online Monitoring Feedback Form, the collection and review process for feedback received from industrial monitors on sponsored trials was not consistent across all departments/services. Identified issues or deficiencies were not always escalated to appropriate staff and there was no centralized database to track changes over time. In addition, there was no mechanism in place to track the number of industrial monitors onsite on any given day.

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

The overall goal for the system is to improve quality. By reviewing the feedback received from the industrial monitors in real-time, issues and deficiencies can be escalated to the appropriate staff and addressed quickly. The system will facilitate the evaluation of available space for monitor seating and will allow for the space to be used efficiently. The research staff and system administrators are able to track trends in the number of deficiencies identified and see changes over time.

Describe the solutions or methods implemented:

Through an automated, online feedback system, the monitor's feedback is collected, shared with MSK study teams in real-time and subsequently stored in a database. The data is reviewed by the PI, research staff, Office of Clinical Research Clinical Research Quality Assurance (OCR CRQA) and the Deputy Physician-in-Chief's office. The data is also used to evaluate trends across all departments/services. The following methods were implemented:

- Develop a web application to manage the scheduling and data collection for all monitoring visits.
- Provide dashboards to facilitate review and analysis of data.
- Appoint a Monitoring Program Coordinator to coordinate presentations of the new system, troubleshoot issues, and to provide guidance to departments/services.
- Follow-up with departments/services based on feedback received.

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

Since the implementation of the Online Monitoring Visit Feedback Form (9/2014), a total of 726 monitoring visits have been scheduled. Outcomes include:

- All departments/services at MSK with industrial sponsored trials are now using the system.
- Issues and deficiencies are being escalated to appropriate staff in real-time.
- During the Pilot Phase, the form was reviewed with select sponsors and the feedback received was positive and encouraging. Since then, additional sponsors and CROs have provided additional positive feedback.

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

The following lessons have been learned:

- Legal restrictions from some monitoring companies prevent completion of the feedback form, in this instance monitor letters are requested and uploaded to a database.
- Inconsistencies with interpretation of questions on the feedback form.
- Support required at all levels, from leadership, investigators, sponsors, monitor company, and Clinical Research Associates.
- Variations in the feedback received from studies that are monitored by multiple monitors.

Since the initial rollout, the following system changes have been made:

- Change the frequency of reminder e-mails sent to the industrial monitors.
- Change in the initial e-mail notification to the Principal Investigators regarding the feedback received from the monitors.
- Filters built in the dashboard to facilitate the review and tracking of the data collected.
- Incorporated memorandums from the Deputy Physician-in-Chief to the PI acknowledging the feedback received from

Violation Submissions Via PIMS- Phase II

Jenny Deighan; Marissa Kehoe; Jenny Anopa; Timothy Downey-Zayas; Dustin Rathbone; Margaret Isaacs; Sandy Iyer-Horan; Michael Trinos

Memorial Sloan Kettering Cancer Center

Background:

Prior to 2013 violations were submitted as memorandums signed by the Principal Investigators (PI) and emailed to the MSK Institutional Review Board/Privacy Board (IRB/PB). After receipt, these memos were pre-reviewed, forwarded to the IRB/PB Chair for review; and then manually stamped received and provided back to the research staff for filing. The accepted memo was also uploaded into Protocol Information Management System (PIMS) for documentation purposes. The content of the memos were often inconsistent and provided little data to evaluate trends or areas of concern.

Metrics or goals:

In 2013 the IRB/PB transformed the process for submitting violations which enabled research staff to enter all violations into the PIMS. This change was implemented in an effort to increase efficiency of IRB/PB Office processing procedures, to standardize the information being received, and to allow for tracking of data on the type of violations occurring at our institution.

Solutions or method implemented:

Since 2013, violations have been submitted via the PIMS electronic form. While the flow from research staff to IRB/PB Chair remains the same, the submission process has moved entirely to PIMS. This form has provided standardization of the incident and data types.

Outcomes:

The use of this electronic submission via PIMS has created a database in which useful data is collected including: IRB/PB protocol number, PI, Department/Service, date of violation submission, participant MRN number, date of violation event, location, violation category, corrective action plan, participant injury due to the violation, and if there is follow-up required from the IRB/PB and/or the PI. The IRB/PB office has been able to analyze this data in a meaningful way and produces an annual Protocol Violation Summary.

Changes to the methods to achieve a better outcome:

These reports help to identify trends in the types of violations that are occurring, inform which areas require future initiatives directed at reducing violations, and allow the IRB/PB Office to tailor the PIMS violation form in a manner consistent with the demands of reporting.

Sponsor Monitoring Assessment and Improvements

Rebecca Turner, MS, CCRP

Moffitt Cancer Center

Describe the background of the problem:

Changes in the drug development landscape have resulted in a more aggressive rush to initial approvals for novel therapeutics or expanded labeling for approved drugs. The downstream effect has led to more demanding sponsor monitoring to ensure compliance as well that timely and high quality data are submitted for safety and response claims.

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

From the site perspective, monitoring is a high burden activity. The goal is to determine current and innovative practices employed by the AACI member sites to balance sponsor expectations with site resources.

Describe the solutions or methods implemented:

Utilizing the AACI CRI listserv, member sites were asked to complete a 10 question survey using SurveyMonkey® to compile current practices around sponsor monitoring. Sites were also able to provide site specific comments. Topics included site resources, reimbursement, budget/contract terms, and use of remote monitoring. Responses were compiled for each question to determine trends, similarities, and outliers.

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

Key learnings included:

Few sites (<20%) have dedicated resources to manage sponsor monitoring activities at their sites and allow sponsors to utilize remote monitoring in between site visits. While not a deal breaker for conducting a given trial, the majority of sites (50% +) negotiate reimbursement for monitoring visits with most included in budgets as an invoiced item rather than incorporated in subject milestone (visit) payments. The majority of sites also negotiate for additional efforts requested by sponsors at times of database locks.

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

Surveying non-cancer center sites would allow for an interesting comparison of practices.

Enhancing the Review Process for Radiation Safety in Human Subjects Research

Rosemarie Gagliardi, MPH, cEdD; Randall Holcombe, MD; Mary Sano, PhD; Jeffrey H. Silverstein, MD; Bradley Delman, MD

Mount Sinai Health System Tisch Cancer Institute

Describe the background of the problem:

Historically all human subjects research protocols involving ionizing radiation required review by Mount Sinai Radiation Safety Committee (RSC) before submission to the Institutional Review Board (IRB). This included submission to RSC for all cancer-related protocols even if ionizing radiation was “medically indicated” for diagnosis or clinical management of patients. This process also resulted in lengthy consent forms that discussed exposure levels for procedures that were considered standard of care for an existing cancer, disease progression or suspected medical condition.

Approximately fifty new protocols are submitted annually to the IRB by the Cancer Clinical Trials Office (CCTO). Requirements for RSC review significantly added to the regulatory workload, causing delays in study activation and also creating inconsistencies across protocols and consent forms.

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

The following best-practice policy was achieved:

- Eliminate the need to submit to RSC protocols that did not include radiation exposure beyond standard of care practice.
- Eliminate the need to add in the consent form the risk of total radiation exposure rather than the additional exposure resulting from participation in the research.

Describe the solutions or methods implemented:

- For protocols involving only standard of care procedures: IRB form now includes PI attesting to the assertion that radiation exposure is provided as per standard of care. These attestations are reviewed by IRB to ensure RSC review has been waived appropriately.
- For protocols involving radiological procedures performed for research: Only protocols that involve radiation exposure beyond standard of care may require RSC review. RSC revised policy so that review and management of human subject research protocols are now stratified based upon the highest level of anticipated research specific radiation in mSv by subject participation-year:
 - <5 mSv: IRB reviewing such protocols have appropriate expertise to assess radiation safety, either by standing members or external consultants.
 - ≥5mSv but <50 mSv: A Subcommittee of IRB will determine acceptability of radiation exposure.
 - >50 mSv: The protocol is referred directly to RSC for evaluation to determine acceptability of the radiation exposure. For those protocols employing radiation that exceeds standard of care, or for irradiation of healthy subjects, a novel interactive dosimetry table (Image I) was created to calculate total effective dose and provide standardized radiation exposure consent form language.

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

The revised RSC policy impact on cancer-related clinical trials:

- The number of cancer related protocols requiring RSC review has been reduced.
- IRB submission to approval dropped from 55 to 42 average days (2012-2014).
- Investigators using the dosimetry table have guidance to write safer protocols.
- Consistency in consent form risk has helped improve the patient consenting process.

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

Institutional collaboration is critical to implement any changes in research related policy. This initiative included local experts such as our Radiation Safety Officer, IRB Chair, Medical Oncologist, Radiologist, Radiation Oncologist, and Regulatory personnel. A Compliance Attorney was consulted to advise on the NY Official Compilation of Codes, Rules and Regulations related to the control of safety of ionizing radiation and the NIH Radiation Safety Committee also provided guidelines for research radiation.

Resource Allocation Review — An Objective, Transparent Evaluation Performed by CCTO

Rosemarie Gagliardi, MPH, cEdD; Jennifer Cocco; Alyssa Ryan, MBA; Richa Upadhyay, MD; Nancy Lowe, MBA; Ajai Chari, MD; Matthew Galsky, MD; Marshall Posner, 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 caused 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 (Image 1).

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 and December 2014, fifty one (51) clinical trials requesting CCTO resources were reviewed. 33 studies (65%) were approved at initial RAE while 18 studies (35%) were deferred back to either the PI/DFG or TCI's Clinical Population Research Committee (CPRC). 12 of 18 deferred studies (67%) went back to the PI for clarification in which 8 were re-reviewed and approved at RAE while 4 were withdrawn by the PI. 6 of 18 deferred studies (33%) were sent to the CPRC of which 5 were approved to receive additional resources and 1 study was withdrawn by the investigator before CPRC review. A total of 5 clinical trials (10%) did not continue to PRMC after RAE review. Furthermore, as a result of RAE we have had a 30% increase in negotiated budgets compared to the year before RAE because of unseen costs related to complicated study procedures that were not originally reimbursed, such as lengthy pharmacokinetics and specimen processing, serial ECGs, and post-treatment adverse event monitoring.

We also identified and addressed logistical issues that required special consideration early in the RAE process which facilitated study activation. IRB submission to trial activation went from 155 to 86 average days (2012-2014).

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. Also, to avoid any submission deadlines from being missed, we have incorporated RAE reviews as part of our standard protocol review process performed during weekly CCTO Leadership meetings.

Using EPIC Electronic Health Record System to Assist with Screening Patients for Cancer Clinical Trials

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 EPIC as an automated recruitment tool. The aim was to achieve a higher level of enrollment to clinical trials through this method.

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:

- In 2014, the MPD Program enrolled 28 patients onto therapeutic clinical trials.
- The EPIC pilot accounted for 21% of these new subjects (6 enrollments).
- The EPIC Pilot project “go-live” date was 1/24/14 - 1/25/15

Outcome:

- 205 unique patients were identified for the 4 MPD trials
- 141 “pre-screen failures”- did not meet other eligibility criteria
- 64 identified as potential candidates (31%)
- 21 patients already enrolled in a trial
- 43 added to MPD “pre-screening” log
- 32 patients did not continue on to screen*
- 6 patients successfully enrolled (14%)
- 5 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 will be extended to other disease groups within CCTO to augment clinical trial accrual in TCI.

Data Driven Application Examines Precision Medicine Clinical Trial Operations

Therica Miller, MBA¹; Regina Schwind, BA²; Laura Hilty, BA³; Wendy Tate, MS³

Samuel Oschin Comprehensive Cancer Institute (SOCCI), Cedars-Sinai Medical Center¹; University of Illinois Cancer Center²; Forte Research Systems, Inc.³

Describe the background of the problem:

In the heightened dynamic clinical research (CR) landscape, academic medical centers (AMCs) experience increasing pressure to improve efficiency. Concurrently, technological advances and precision medicine initiatives (individual molecular status driving treatment) challenge the archetype, requiring CR transformation. In spite of rapid technological and scientific advancements, and increased focus on patient-centered research, CR offices have been slow to adapt.

List the problem's root causes or obstacles to overcome if applicable:

CR performance metrics are largely unstandardized. Anecdotally, most AMCs have cumbersome serial processes, resulting in unpredictable activation times. Despite greater focus on efficiencies, few studies exist on the topic, and those that exist are dated, qualitative, and institution-specific. This paralyzes AMCs from responding quickly to dynamic industry shifts. Reengineering CR operations is critical to the advancement of science and achieved only through objective performance analysis.

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

This study assessed the impact of precision medicine on CR operations by analyzing study activation timelines and workload metrics between precision and non-precision trials among cancer centers participating in the Research Resonance Network (RRN; Forte Research Systems®). RRN is a site-centric, web-based platform, which collects and aggregates standard datasets to quantitate site CR performance for evaluation.

This analysis represents seven NCI designated institutions and 126 national group studies. Institutions contributing data to RRN on the protocol review and monitoring system (PRMS) or institutional review board (IRB) submission date and First Activation (FA) date since 2013 were included. Studies were defined as "precision" if at least one eligibility criterion on the NCT record included specific sequenced genetic mutation(s). Study activation effort tracking data was abstracted and summary statistics calculated. Differences in mean values for precision vs. non-precision trials were tested using a two-sided t-test with an a priori significance level of 0.05.

Describe the solutions implemented:

Activation time for both groups was approximately three months; time to first accrual averaged 128 days. Zero-accruing protocols constituted 43 vs. 56% of trials, non-precision vs. precision, respectively ($p=0.22$). Protocol accrual was statistically different (2 vs. 0.9, non-precision vs. precision, $p=0.016$). There was no difference in the amount of effort required for activation (mean=26.6 hours, $p=0.11$).

Describe what happened when solutions were implemented or data showing a positive or negative outcome:

The project goal was to provide preliminary data supporting the formulation of a collaborative community (RRN) that provides consistent data to calculate standardized, meaningful CR operational metrics. This feasibility project was not powered to measure statistically significant differences; however, it is only a limitation because the RRN platform is not being used to its greatest extent and possibly does not capture a representative sample. The analysis does demonstrate that the RRN platform can help identify problems, bottlenecks and proactive analysis of issues that inhibit CR progress. Further, collective data across multiple institutions empowers the CR community to objectively evaluate CR performance and stimulate national change.

Show lessons learned, others to involve in the future, or ideas of other initiatives to pursue:

In the next phase, an operations working group, whose mission is to collaboratively identify, measure, and close gaps in precision medicine trials, will focus on effort tracking to analyze study prioritization/activation, costs, recruitment, and screen failures. This will be achieved through group expansion, creation of homogeneous data sets, national benchmark evaluation, leveraging the RRN platform to generate empirical evidence to correlate recruitment, accrual and effort tracking.

AR and AP Tracking Using Access Database

Hannah Phan; Samichha Shahi; Erin Williams, MBA

Simmons Comprehensive Cancer Center, UT Southwestern Medical Center

Describe the background of the problem:

Accounts Receivables:

- Unable to track outstanding invoices and update the payment efficiently
- Billing terms and negotiated amount from the study contract are not easily accessed, which creates loss of revenue and incorrect billing
- Unable to generate reports for outstanding, overdue invoices to follow up with the sponsor
- Overwhelming and not user friendly invoice format and billing process

Accounts Payables:

- Unable to manage large volume of payables from different departments and outside vendors
- Unable to track invoices at various departmental approval levels
- Duplicate invoices resulting from delays in payment, further resulting in duplicate payments
- No information of available balance to pay the invoices

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

- Manage AR efficiently to improve cash flow by better managing the receivables and consistently increasing the revenue to help support the trials.
- Generate report for accurate tracking of revenue, timely process invoices for studies with payment due.
- Properly manage and track payables for various departments, decrease payment delays for the vendors and inter-departments.
- Able to generate reports reflecting how much is owed on each of the studies at any given point in time and especially, at study closing.

Describe the solutions or methods implemented:

Having a centralized mechanism to track and record the data and accurately generate reports on demand. This serves to minimize human errors and eliminate redundancy.

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

Accounts Receivables:

- Efficient processing of invoices and payments received.
- Increase in cash flow and revenue with appropriate tracking and follow-ups.
- Update study changes, important billing information in one central location
- Run reports for any outstanding invoices

Accounts Payables:

- Track payments and run reports for expenses incurred on a particular study at any given time.
- Release invoices based on the available balance.
- Easy to access any date, user friendly, saves time

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

- Focusing on improving billing process and accurately tracking, billing and reconciliation of payments. Update data in a consistent manner.
- Improve research operation by providing other departments information for their monthly reconciliation and reports.
- Provide access to Research Managers to view the database so they can be informed of the status of their trial revenues.
- Provide information to departmental leadership regarding overall clinical trials revenues for the CRO

Features of the database:

- List all relevant study information on one screen, which will further assist to create an invoice and payables.
- Generate an invoice based on a customized invoice template
- Update payments corresponding to the invoice billed.
- Track bills with unique invoice number and reconciling with the posting voucher number.
- Print, email, and store invoices
- Generate reports for payables, receivables, and pending statuses

Validation of a Clinical Trial Accrual Predictive Model

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Describe the background of the problem:

The costly and extensive process to drug approval highlights the need to streamline the drug pipeline process. In order for a clinical trial to draw scientifically sound conclusions, the study must meet its accrual goal. Dilts et al. reported that, at four comprehensive cancer centers, approximately 20-40% of trials will not accrue any subjects locally (Dilts, 2010). With increasing cost to conduct clinical trials, it is imperative to select trials rationally for local activation. We previously reported a novel predictive model with the outcome of anticipated accrual to be used when considering a prospective clinical trial at our center. Here, we present the results of the validation study.

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

We sought to validate a predictive model using factors known prior to study activation with the outcome of anticipated accrual that can be used when considering activation of a prospective clinical trial.

Describe the solutions or methods implemented:

Eligible studies include treatment and supportive care intervention studies permanently closed to accrual between 10/2013 and 01/2015 at our center. Data abstracted from the clinical trials management system (OnCore, Forte Research Systems, Madison, WI) included: use of investigational drug, disease management team (DMT), use of local IRB, local start date, DMT accrual prediction value, actual total accrual, and clinicaltrials.gov (NCT) number. Abstracted from clinicaltrials.gov were protocol-specific data: number of national sites, national enrollment goal, national start date, and national date of expected primary endpoint completion.

Studies were run through the model and actual accrual plotted against predicted accrual. Actual, team- and model-predicted subjects accrued; percent of trials meeting cut-off values; and model sensitivity and specificity were calculated.

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

Sixty-one trials met study inclusion criteria. Total accrual was 373 subjects (mean: 6.1 ± 17.2); 16 (26.2%) studies had zero accrual, 23 (37.7%) accrued 88.7% of the total subjects. The model predicted accrual of 513 subjects (138% of actual) versus the DMT predicted accrual of 1111 subjects (298% of actual). The model correctly predicted whether a study would accrue 4+ subjects 75% of the time. Twenty-seven studies (44.3%) correlated perfectly at the category level. Model sensitivity is 70%; specificity is 78%. For the 17 studies not correctly categorized using a cutoff of four, nine (60%) would have been incorrectly opened (predicted 4+, <4 accrued) and six (40%) would have incorrectly not opened (predicted <4, 4+ accrued).

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

The identified national and local factors to predict clinical trial accrual at our center are valid, showing it to be an accurate, quick and valuable metric in assessing trial success as well as planning resource allocation. Further research includes national expansion of the model to cancer centers.

Utilizing the C.O.S.T. (Comprehensive Oversight Support Tool) Analysis for Accurate Budgeting and Workload Evaluation for Modern Complex Clinical Trials

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Describe the background of the problem:

Clinical trials have experienced a paradigm shift from treating broad disease pathologies to focusing on “personalized medicine” (Levin, 2014). This patient specific approach to clinical care uses diagnostic tests to isolate biological differences in patients helping to dictate a treatment course and drive improved clinical outcomes. With the increased necessity of “up-front” testing, interdisciplinary coordination, and overall trial complexity, the demand of the staff necessary for the safe and effective administration of modern clinical trials has never been higher. Additionally, with qualification for trials largely based on the presence of a biological factor of interest, we believe that the industry will see a large increase in screen failures and a decline in overall patient enrollment.

In our experience, sponsors expect to pay staff oversight based on the actual visit date in a schema; however, the majority of work actually happens outside of the patient visit. Furthermore, sponsors appear to only be willing to pay for a small percentage of screen fails. As the evolution toward complex clinical trials continues, it is imperative that effective budgeting strategies as well as tools for accurate projections of total trial compensation are developed to provide support for the site staff.

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

We reviewed a closed complex clinical trial to assess if we budgeted appropriately for our staff oversight. This trial required a pre-screening phase, archival tissue, and a fresh biopsy. We discovered that we did not properly budget for staff oversight and were compensated for approximately half of the staff time that was necessary to complete the trial. These findings strongly suggested that we needed a modernized budgeting strategy.

Describe the solutions or methods implemented:

We designed the C.O.S.T. analysis (Figure 1.), which not only captures trial complexity but also correlates actual staff cost into a per-patient schema. The tool has four sections:

- 1.) Trial Complexity
- 2.) Screening
- 3.) Treatment
- 4.) End of Study

Trial Complexity is broken into 11 components, which are given scores from 0 (least complex) to 3 (most complex). Based on the trial complexity score, a variable effort fee is assessed to the hourly calculations through the next 3 components.

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

We are in the early stages of implementing the new C.O.S.T. analysis; however, we have found that the tool increases transparency and provides justification both internally and externally on actual cost of staff time. The tool also provides the ability to accurately project the potential financial toxicity of a trial when budgets do not appropriately account for staff time.

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

We plan to continue to roll out the C.O.S.T. analysis tool on all future trials, and create versions applicable to other departments at the University of Chicago (e.g. BMT trials, surgery, and radiation oncology). Furthermore, we hope to partner with our sponsors and CROs so that they better understand how the tool works so that staff oversight negotiations are not reinvented at the initiation of every new trial.

Reference:

Carter, J. L. (2014). New Clinical Trials Designed to Better Leverage Precision Medicine. OBR Green, 8(3). Retrieved May, 2015, from <http://obroncology.com/obrgreen/print/New-Clinical-Trials-Designed-to-Better-Leverage-Precision-Medicine>

Employing a Clinical Trial Nurse Navigator to Increase Oncology Clinical Trial Awareness and Enrollment

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Describe the background of the problem:

Patients who participate in clinical trials benefit from the latest advances in cancer research and closer monitoring of their disease. Referrals of new patients to KUCC are received from numerous sources and through various media, creating challenges for identification of trial candidates. Every new patient should be informed about the possibility of participating in a clinical trial as part of their cancer treatment.

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

The goal was to capture and track all new patient referrals and inquiries and follow these to resolution utilizing a Clinical Trial Nurse Navigator (CTNN). Specifically, the CTNN provides: 1) patients, families and providers one point of contact for initial assessment of the appropriateness of a therapeutic treatment trial; 2) follow-up to ensure referral was assessed until resolution, 3) provide summaries to research team.

Describe the solutions or methods implemented:

A new patient tracker (Excel spreadsheet) was developed and utilized as outlined below.

1. Coordinate with KU disease-specific nurse navigators to receive records of new patients allowing CTNN to prescreen records for trial eligibility.
2. If CTNN assessment determines possible patient eligibility, patient's information is logged into tracker noting the trial(s) the patient may be eligible and forward the patient's records to assigned study coordinators (SC) for further evaluation.
3. If SC determines patient is eligible, SC alerts clinical team by sending an email prior to patient's clinic appointment listing possible study(ies).
4. The day of appointment, SC writes on white board (used for patient clinic flow) the name of study(ies) for which patient appears eligible.
5. Trial project directors work with the CTNN to ensure follow-up and outcomes are recorded (i.e. patient signed consent, patient not eligible-why)
6. If patient has a condition for which no trial is available, this is logged to identify conditions we are unable to serve through a trial, and thus pursue locating a trial to fill this need.

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

Project initiated across the clinical trial enterprise in January 2015. Data below represents total number of new patients identified for possible trial participation and actual enrollment. (Data is being further analyzed and will be available in the poster.)

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

- Prescreening of new patients has contributed to a 24% increase from last year.
- CTNN prioritizes prescreening of new patients, ensuring prescreen is accomplished vs. SC having many competing demands resulting in inconsistent prescreening.
- Systematic evaluation of new patient data allows for identification of appropriate trials to complete the total trial portfolio.

Impact of IWS/IVRS in Clinical Trials on Resource Utilization

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Describe the background of the problem:

There has been an increase in sponsor use of electronic inventory management and patient treatment assignment systems. These systems may be either web-based (IWS: Interactive Web-based System) or telephone-based (IVRS: Interactive Voice Response Systems), and require that staff have unique account logins and passwords for access.

Typical activities using IWS/IVRS include inventory receipt and acknowledgment. More importantly, patient visit and treatment assignments are increasingly obtained via IWS/IVRS, and these often need to occur in real-time once the patient has been evaluated on site, so that patient weight or other factors may be assessed prior to obtaining the assignment.

The problem is understanding the full impact on resource utilization as this affects multiple groups (research pharmacy, clinical study coordinators and study data coordinators).

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

Goal from understanding the staffing impact across the three groups is to consider potential consolidation of effort to one group.

Describe the solutions or methods implemented:

Conduct time study to understand how much effort the additional step of IWS/IVRS across all three groups utilizing our effort tracking system.

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

Time studies in Research Pharmacy (RP) indicate a 25% increase in effort for a given task when IWS/IVRS is involved. In addition, Cancer Center study coordinator time studies in November 2015 showed that 0.25 FTE is currently required to obtain patient treatment assignments across all the studies managed by the CTO.

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

Research Pharmacy and CC study coordinators' increased effort is currently not captured in fee/effort estimates or staffing models. An IWS/IVRS Workgroup comprised of CC CTO Leadership and RP Leadership has determined that due to staffing patterns and RP current roles with patient care, RP staff are optimally positioned to obtain IWS/IVRS assignments needed for patient care activities. A transition of these activities from CC study coordinators will require a corresponding increase in FTE in Research Pharmacy.

Bringing Community-Based Researchers Together to Advance Cancer Research: ASCO's Community Research Forum

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American Society of Clinical Oncology (ASCO)

Describe the background of the problem:

There are many barriers to participating in community-based research while maintaining a successful clinical practice. There is growing pressure to participate in clinical trials, despite limited time and resources to do so, increasingly complex clinical trial protocols, burdens of regulatory requirements, and less funding to support research. ASCO's Community Research Forum (CRF) was convened to create opportunities, initiatives, and resources for community-based researchers to facilitate their participation in clinical trials.

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

Ultimately, the opportunities and tools created by the CRF facilitate participation in and access to clinical trials, benefiting both patients and practices. Key goals of the CRF are to facilitate and promote:

- Networking and collaboration
- Sharing and developing tools, strategies, and experiences with colleagues
- Standards for quality research programs and strategies to ensure these standards are met, maintained, and/or exceeded
- Solution-oriented CRF projects and resources

Describe the solutions or methods implemented:

The CRF has developed the following initiatives and resources to assist community-based researchers:

- The CRF's website serves as a go-to resource for investigators and research staff and provides a repository of resources for conducting and managing clinical trials.
- The CRF Annual Meeting brings together physician investigators and research staff to network and collaborate with colleagues to discuss ongoing challenges and potential solutions.
- The ASCO Research Program Quality Assessment Tool is designed to help community-based research sites exceed the minimum quality standards of conducting clinical research, and enables sites to conduct an assessment of their program and to also proactively develop an internal quality assurance program. This Tool is available for free at <http://www.asco.org/practice-research/asco-research-program-quality-assessment-tool-questionnaire>.
- The ASCO Clinical Trial Workload Assessment Tool is a user-friendly online resource that aims to help research administrators assess clinical trial-associated workload, based on the complexity of research protocols and the number of patients assigned to staff. The tool enables administrators to effectively monitor and manage staff capacity, productivity, and needs. This tool is available for free at <http://workload.asco.org>.
- The CRF continues to tackle challenges and barriers for community-based sites and has created two new working groups to address billing compliance and contract negotiations.

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

The CRF has received positive feedback about its various initiatives, including how the tools have met needs and helped sites to improve the functioning, management, and/or quality of their research programs. As word has spread about the CRF, there has been a steady increase in attendance at each CRF Annual Meeting and in the uptake of resources. Since their release in 2014, there have been over 220 users of the Research Program Quality Assessment Tool from 10 countries, and 130 accessing the Workload Assessment Tool.

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

ASCO's CRF is a solution-oriented venue that provides an opportunity for research sites to address barriers to conducting research in the community setting. There has been a tremendous reception to and interest in the CRF, both nationally and internationally, and beyond the community setting; including larger cancer centers who have requested affiliate sites use the tools. The key objective of this presentation is to share information about the CRF and its previous and new initiatives to raise awareness of their availability.



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