



Association of American Cancer Institutes  
**CLINICAL RESEARCH INITIATIVE**

# **The Impact of Precision Oncology on Clinical Trials: Solving the Puzzle**

## **6th Annual CRI Meeting**

**2014 CRI Abstract and  
Poster Winners**



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All abstracts and submitted presentations and posters are available online at [http://aaci-cancer.org/cri/crimeeting/2014\\_abstract\\_winners.asp](http://aaci-cancer.org/cri/crimeeting/2014_abstract_winners.asp)

# AACI Clinical Research Initiative Overview

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The Association of American Cancer Institutes (AACI) comprises 93 leading cancer research centers in the United States. 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 affecting cancer centers' ability to activate and conduct cancer clinical trials. Examples of the challenges facing the cancer centers include the growing complexity of clinical trials' expanding staffing requirement, administrative barriers and increasing trial costs, regulatory constraints prolonging trial activation, and lagging patient accrual. CRI examines and shares best practices that promote the efficient operation of cancer center clinical research facilities and leverages the ability of the AACI cancer center network to advocate for improvement in the national clinical trials enterprise. A steering committee composed of clinical trial administrators and medical directors guides and implements the activities of the CRI, leading to dissemination of proven means of effectiveness and best practice models across the AACI cancer center clinical trials offices.

## 2014 AACI CRI Steering Committee Members

### **Tony R. Reid, MD, PhD – Chair**

*UC San Diego Moores Cancer Center*

### **James P. Thomas, MD, PhD**

#### **– Immediate Past Chair**

*Froedtert Medical College of Wisconsin Cancer Center*

### **Paul Barr, MD**

*Wilmot Cancer Center*

*University of Rochester Medical Center*

### **Leigh Burgess, MHA, MEd, MA**

*Duke Cancer Institute*

### **Alyssa K. Gateman, MPH, CCRP**

*Yale Cancer Center*

### **Janie Hofacker, RN, MS**

*Association of American Cancer Institutes*

### **Randall F. Holcombe, MD**

*Mount Sinai Health System Tisch Cancer Institute*

### **Vicki L. Keedy, MD, MSCI**

*Vanderbilt-Ingram Cancer Center*

### **Paul Martin, MD**

*UW School of Medicine*

*Fred Hutchinson Cancer Research Center*

### **Sorena Nadaf, MS, MMI**

*UCSF Helen Diller Family Comprehensive Cancer Center*

### **Joy Ostroff, RN, BSN, OCN**

*UNC Lineberger Comprehensive Cancer Center*

### **Barbara Duffy Stewart, MPH**

*Association of American Cancer Institutes*

### **Teresa L. Stewart, MS, CCRP**

*University of New Mexico Cancer Center*

### **Jeanine Stiles**

*UC Davis Comprehensive Cancer Center*

### **Erin Williams, MBA**

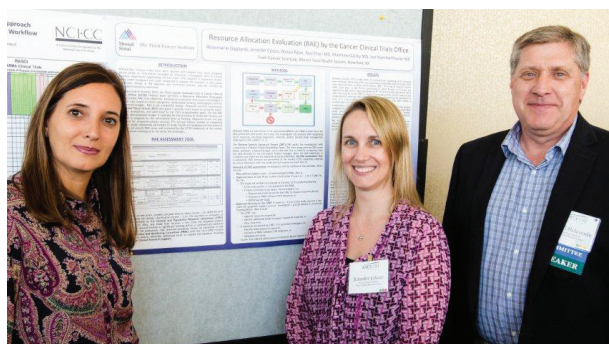
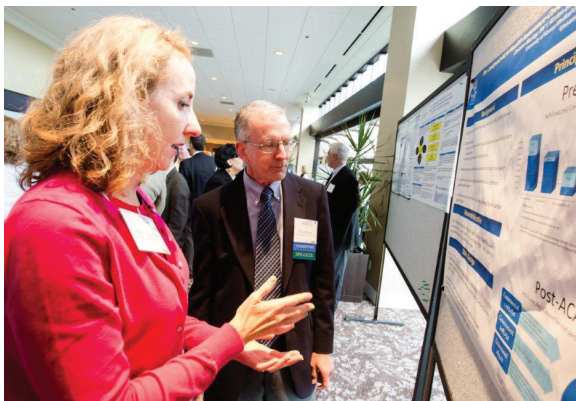
*Simmons Comprehensive Cancer Center*

*University of Texas Southwestern Medical Center  
at Dallas*

## 2014 AACI CRI Annual Meeting Abstracts

In January 2014, the AACI CRI Steering Committee issued a call for abstracts to AACI member cancer centers for presentation at the sixth annual CRI general membership meeting, held July 9–11 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 annually to discuss common challenges. The AACI CRI Steering Committee received 24 abstracts and selected three for presentation at the meeting. All abstract authors were invited to submit posters of their abstracts for display at the meeting.



The abstract and poster sessions were among the highlights of this year's annual 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

### Improving Clinical Trial Activation Efficiency Through Technology, Systems Integrations and Analytics

**Joe Lengfellner, Ann Rodavitch, Collette Houston, Joe Larkin, Paul Sabbatini, Sarah Wise**  
*Memorial Sloan-Kettering Cancer Center*

#### **A. Describe the background of the problem:**

The clinical trial activation process requires a number of regulatory and operational steps demanding coordination between several different groups/committees, often utilizing an uncoordinated array of electronic and paper document management strategies. The lack of a centralized mechanism for real-time tracking further compounds the problem and makes the overall activation status impossible to ascertain and bottlenecks difficult to identify. Lengthy clinical trial activation periods are problematic to cancer centers, investigators, patients and sponsors. Longer development timelines delay patient accruals and the ability to deliver novel and potentially effective treatments to patients. Furthermore, cancer centers with lengthy activations periods are less likely to be selected for future trials when competing against centers with proven track records of efficient activations.

#### **B. Provide metrics or goals to be achieved with the solutions to address the problem:**

By leveraging technology cancer centers can reduce the time required to activate clinical trials. The goal of our initiative is to reduce the time to activation (TTA) from 165 to 90 days (median days) or less. TTA starts from review of the protocol in its primary clinical department (e.g., Pediatrics) to the time it is opened for accrual at the Institution Review Board/privacy board. A secondary goal is to bring transparency to the process, allowing investigators and other research staff to view real-time status updates on their protocol, allow for immediate intervention, and reduce questions to the operational teams and review committees which further compromises efficiency.

### **C. Describe the solutions or methods implemented:**

While the overall solution involved changes impacting a number of different processes, the cornerstone was an increase in the information technology infrastructure used to support the clinical trial activation process. This involved the following changes:

- Enhanced existing Protocol Information Management System (PIMS), a document management system used to track regulatory reviews. The enhancements included adding all required review committees into the system and sharing data between PIMS and other electronic systems.
- New web applications to centralize tracking of various processes (i.e., budget development, contract negotiation).
- Provide dashboards of protocol status for studies in development.
- Appoint a Protocol Review Manager to manage clinical trial activation process.
- Use analytics tools to run metrics on all aspects of the activation.

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

Since fully implementing the technology solutions (7/1/2013) we have activated 42 industry-sponsored trials. Initial outcomes include:

- New web applications and dashboards well received.
- Central location for tracking, rather than sharing files on network drives.
- Push-button reports and visual dashboards have been extremely useful for center leadership and research staff to stay on track with protocols.
- Median time to activation for our industrially sponsored trials has decreased by 24 days from baseline.

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

Since the initiative began, several lessons have been learned which are applicable to any cancer center looking to shorten their trial activation process:

- Support required at all levels, from leadership, IT staff, investigators and clinical research associates.
- Identify local “change champions” to assist in rollout.

- When exploring new systems evaluate the pros and cons of developing in-house versus purchasing pre-built software. Both can be appropriate in different situations.

Continued enhancements to the system include:

- Automated email alerts when protocol development falls off schedule.
- Expanded rollout of analytic tools to all research staff.
- Explore electronic data sharing with outside entities.



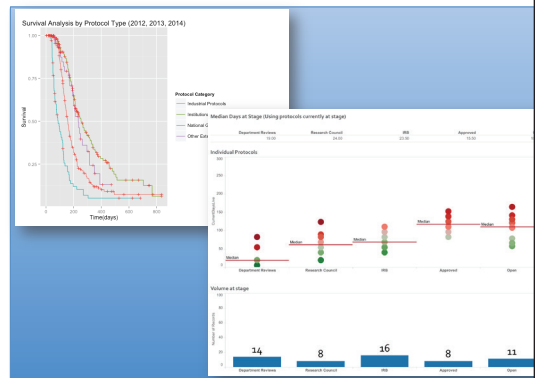
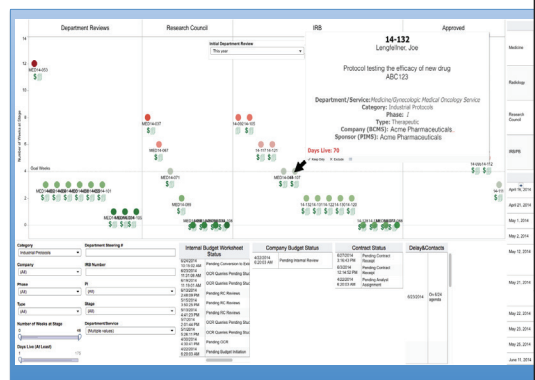
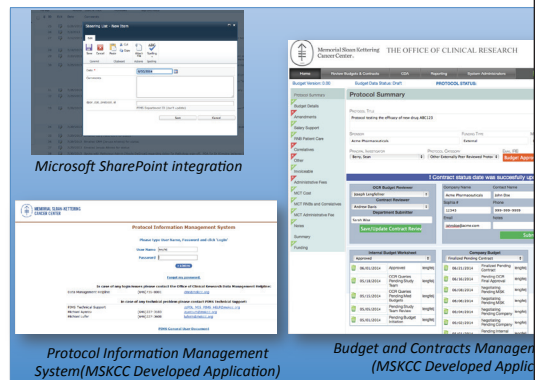


## Background

The clinical trial activation process requires a number of regulatory and operational steps demanding coordination between several different groups/committees, often utilizing an uncoordinated array of electronic and paper document management strategies. The lack of a centralized mechanism for real-time tracking further compounds the problem and makes the overall activation status impossible to ascertain and bottlenecks difficult to identify. Lengthy clinical trial activation periods are problematic to cancer centers, investigators, patients and sponsors. Longer development timelines delay patient accruals and the ability to deliver novel and potentially effective treatments to patients.

## Project Goals

The goal of our initiative is to reduce the time to activation (TTA) from 165 to 90 days (median days) or less. TTA starts from review of the protocol in its primary clinical department (e.g. Pediatrics) to the time it is opened for accrual at the IRB/Privacy Board. A secondary goal is to bring transparency to the process, allowing investigators and other research staff to view real-time status updates on their protocol. While many process changes have been made, the focus of this poster is to show how IT has been leveraged to improved process and transparency.





# Protocol Activation Efficiency Through Technology, Systems Analytics

, Collette Houston, Joe Larkin, Paul Sabbatini, M.D., Sarah Wise  
Center

## System Integration

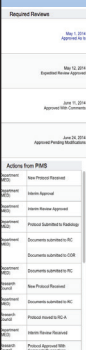
- New systems were built to eliminate all paper-based or email-based processes.
- Both off-the-shelf and homegrown systems were integrated to allow data sharing and eliminate duplication of effort.
- Existing Protocol Information Management System was enhanced to allow increased tracking of protocol review committees.



Protocol System  
(Activation)

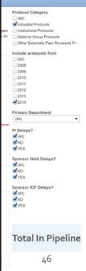
## Visualize

- Dashboards were created to show, in real-time, the protocol review process.
- Users are able to select a protocol to view detail data on the review process (i.e. budget/contract negotiation status).
- Access to the dashboard was given to all levels, leadership through research staff ensuring transparency.



## Analytics

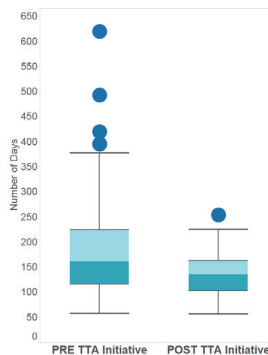
- All systems data generated by the review process is captured for later analysis.
- Analysis of time spent on each development phase has allowed the team to target bottlenecks in the process.
- Detailed reports are made available to all departments for use during research meetings.



## Success Factors

- Support from all levels, including leadership, IT, investigators and clinical research associates.
- Use dashboards/analytics to identify and modify bottlenecks.
- Buy vs. Build is an important consideration when proposing new systems.

## Results



Under the new initiative, 72 industry sponsored trials have activated, with a decrease in the median TTA of 29 days.

## Future IT Enhancements

- Automated email alerts to PI when protocol development falls off schedule.
- Protocol "Report Card" for PI at time of activation to show comparison to other similar protocols.



## SECOND PLACE

### **Tumor Imaging Metrics Manager: The Complete Workflow Solution for Quantitative Imaging Assessment of Tumor Response for Oncology Clinical Trials**

**Richard A. Bronen, Trinity Urban, Kimberly Hall, William B. Hanlon, Annick D. Van den Abbeele, and Gordon J. Harris**  
*Dana-Farber/Harvard Cancer Center and Yale Cancer Center*

#### **A. Background of the problem:**

Oncology clinical trials increasingly depend on imaging as a surrogate endpoint to demonstrate efficacy and safety of therapeutic agents. Uniform and reliable analysis of imaging data can be quite challenging across sites, particularly when imaging reviews are not sufficiently timely or accurate in the implementation of response assessment criteria. An in-house centralized service can improve the management of tumor metrics for oncology clinical trials. However, most cancer centers currently do not have a formalized system in place.

#### **B. Provide metrics or goals hoped to be achieved with the solutions to address the problem:**

The following goals have been achieved through the implementation of an in-house centralized tumor metrics service:

- Elimination of paper measurement forms
- Establishment of an image-based longitudinal record
- Improved management of tumor metric requests
- Reduction of incorrect requests (i.e., wrong patient, study, or response criteria)
- Improved results turnaround time and accessibility
- Improved protocol adherence
- Increased reliability and reproducibility of results
- Improved efficiency in preparing for data locks, monitoring visits, and audits
- Improved financial compliance
- Adherence to NCI vision/requirements for Cancer Center shared resources

#### **C. Describe the solutions or methods implemented:**

The Tumor Imaging Metrics Core (TIMC) offers a complete web-based workflow solution for independent site reviews.

#### System Highlights:

- Clinical trial staff can access the secure, password-protected website –any scan, anytime, anywhere – to request scan assessments and view results, including annotated images and graphs.
- On-line training and certification ensures that reviewers assess the scan according to the specific study protocol with the help of integrated imaging response criteria conformance checks.
- After electronic sign-off, the assessment is locked and the clinical team is automatically alerted that results are ready.
- On-time results ensure that the clinical team receives independent confirmation of progression/response before the patient is evaluated in the clinic.

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

Prior to the TIMC, over 25% of scans had assessment problems due to errors in percent change calculations, misidentification of baseline/nadir scans, selection of inappropriate overall response, application of incorrect response criteria, or incomplete/conflicting data records. After implementation of the TIMC, assessment errors decreased to 3% after response criteria logic checks were applied.

Utilization of TIMC services at patient accrual sites provides greater standardization, reliability and confidence, which improves the assessment of treatment response or tumor growth, resulting in time and cost savings for sponsors, and improved efficiency and confidence for investigators. Show lessons learned, others to involve in the future, changes to the methods to achieve a better outcome.

As TIMC expanded beyond Dana Farber/Harvard Cancer Center (DF/HCC) to include Yale Cancer Center (YCC), there was a need to systematize processes for widespread multi-institutional usage, which was not completely anticipated prior to deployment at the first external site. After configuration changes, TIMC has been fully operational at YCC since September 2013. The system will be rolled out at Huntsman Cancer Institute at the University of Utah this summer and is available for use at other cancer centers. V2.0, which includes added functionality and improved usability, is scheduled to be deployed in late 2014.

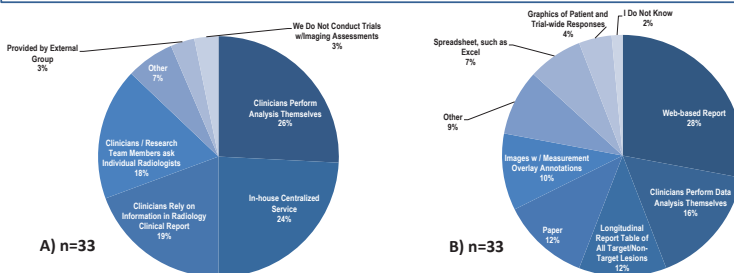
# Tumor Imaging Metrics Manager: The Complete Assessment of Tumor Response



Richard A. Bronen<sup>1</sup>, Trinity Urban<sup>2</sup>, Kimberly Hall<sup>1</sup>, William B. <sup>1</sup>Yale Cancer Center, <sup>2</sup>Dana-Far

## Introduction: The Problem

Oncology clinical trials increasingly depend on imaging as a surrogate endpoint to demonstrate efficacy and safety of therapeutic agents. Uniform and reliable analysis of imaging data can be quite challenging across sites, particularly when imaging reviews are not sufficiently timely or accurate in the implementation of response assessment criteria. An in-house centralized service can improve the management of tumor metrics for oncology clinical trials. However, most Cancer Centers currently do not have a formalized system in place.



**Figure 1: Cancer Center survey responses: A) How are imaging assessments for clinical trials conducted at your institution? B) In what format do clinicians receive image analysis results?**

## Goals

The following goals have been achieved through the implementation of an in-house centralized tumor metrics service:

- Elimination of paper measurement forms
- Establishment of an image-based longitudinal record
- Improved management of tumor metric requests
- Reduction of incorrect requests (i.e., wrong patient, study, or response criteria)
- Improved results turnaround time and accessibility
- Improved protocol adherence
- Increased reliability and reproducibility of results
- Improved efficiency in preparing for data locks, monitoring visits, and audits
- Improved financial compliance
- Adherence to NCI vision/requirements for Cancer Center shared resources

## Solution

The Tumor Imaging Metrics Core (TIMC) offers a complete web-based workflow solution for independent site reviews.

### System Highlights:

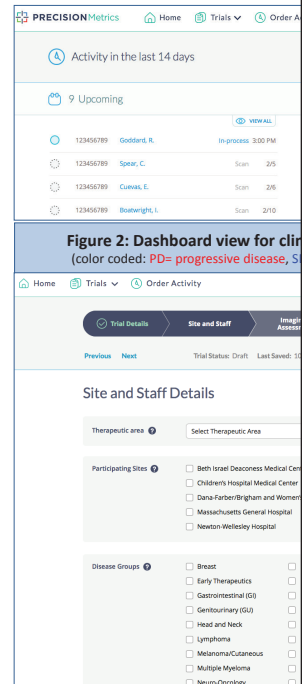
- Clinical trial staff can access the secure, password-protected website –any scan, anytime, anywhere – to request scan assessments (Fig 2, 3) and view results (Fig 4), including annotated images (Fig 6) and graphs (Fig 5).
- On-line training and certification ensures that reviewers assess the scan according to the specific study protocol with the help of integrated imaging response criteria conformance checks.
- After electronic sign-off, the assessment (Fig 4, 6) is locked and the clinical team is automatically alerted that results are ready (Fig 2).
- On-time results ensure that the clinical team receives independent confirmation of progression/response before the patient is seen in the clinic.

## Contact Information

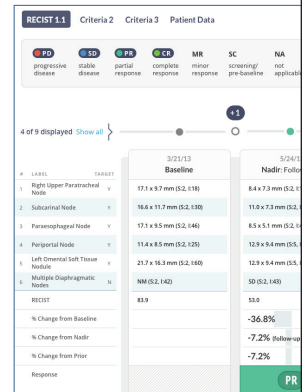
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Phone: 617-726-9464

**Note: Names/numbers used in screenshot comply with HIPAA guidelines. No real data.**



**Figure 3: Trial Request workflow with improved imaging protocol sub**



**Figure 4: Response assessment**

DF/HCC  
DANA-FARBER / HARVARD CANCER CENTER

ent results reporting page

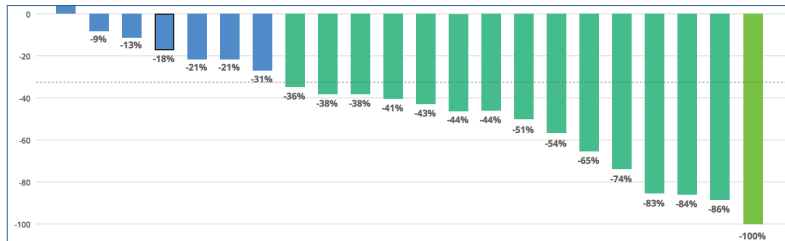


Figure 1 displays two side-by-side screenshots of a medical imaging workstation. The left window, titled "CHEST ABD PELVIS A...", shows a CT scan of the chest with a yellow rectangular region of interest (ROI) in the right lung. The right window, titled "ART ABD/CHEST PV A...", shows the same CT scan with a green rectangular ROI in the same location. Both windows display patient information: 29-Dec-2010, Acq: 1341:39, Seq: 2/1, Im: 137/141, Loc: P95.0. The right window also shows a table of image data.





## THIRD PLACE

### Less Is More: Specializing Regulatory Responsibilities to Decrease Time to IRB Approval

**Chloe Fournier and Nicholas Fisher**

*Siteman Cancer Center*

*Barnes-Jewish Hospital at Washington University School of Medicine*

#### **A. Describe the background of the problem:**

In 2011, the Siteman Cancer Center recognized that in order to remain competitive and meet sponsor and PI needs, we needed to increase the number of new studies able to be submitted each month while simultaneously decreasing the timeline from Scientific Review Committee (SRC) submission to Institutional Review Board (IRB) approval. That year, our Medical Oncology program submitted 52 new pharmaceutically sponsored studies; those trials had a median time from SRC submission to IRB approval of 105.5 days (average: 114.8). In addition to the new study submissions, the regulatory coordinators handled all aspects of regulatory study management, including but not limited to: annual renewals, protocol amendments, minor modifications, ancillary regulatory document management, and monitoring visits.

#### **B. Provide metrics or goals to be achieved with the solutions to address the problem:**

Our goal was to increase the number of studies submitted each month, decrease the timeline from SRC submission to IRB approval, and not increase our staffing needs.

#### **C. Describe the solutions or methods implemented:**

Rather than increasing expense through additional staffing, our Medical Oncology team piloted an altered workload model in search of increased efficiency. We hypothesized that a small group of staff focusing exclusively on study activation (SRC submission to activation) would be able to process more new studies at a faster rate than a large group of staff handling all regulatory responsibilities (from SRC submission to IRB closure). Instead of “owning” studies throughout the lifetime of a study (from SRC submission to IRB closure), regulatory staff were assigned task-specific, specialized roles. Eight staff were divided into two teams, with half focused on new study submission and half on active study management. The new submission team managed studies from SRC submission to study activation. The active study team managed studies from activation to IRB closure.

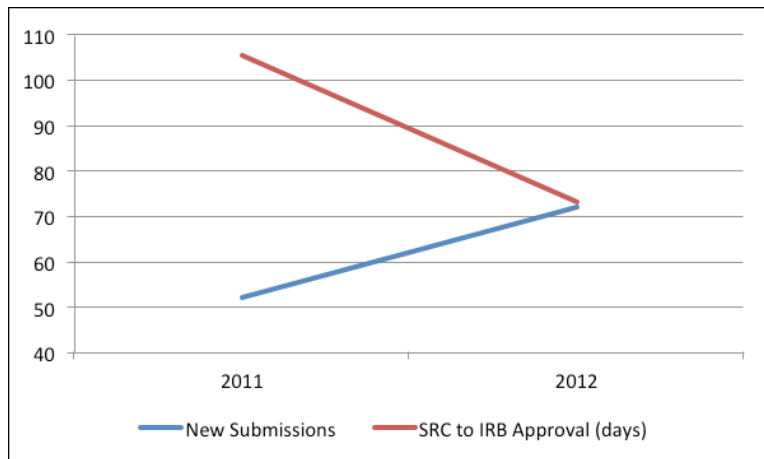
#### **D. Describe the outcome of the solutions implemented or show data representing a change whether positive or negative:**

In 2012, after implementing the aforementioned strategy, the same team submitted 72 pharmaceutically sponsored studies with a median time from SRC submission to IRB approval of 73 days (average: 78.7). The realigned team was able to manage a 38% increase in new study submissions while successfully decreasing the approval timeline by > 5 weeks. See appendix 1. Meanwhile, the active study team was able to manage all active trials with no noticeable decline in quality. Finally, the ratio of total studies to total staff remained unchanged: 71.3/person in 2011 and 75.7/person in 2012.

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

A task-specific, specialized regulatory team has proven able to handle higher volumes while improving essential quality standards, including time from SRC submission to IRB approval. Planned future improvements focus on increased specialization within the active study team, where trial management will be divided by study type and specific task (renewals versus amendments). Additional improvements must be made to shorten timelines from IRB approval to study activation.

*Appendix 1: Number of New Pharmaceutical Study Submissions vs Time from SRC Submission to IRB Approval (days)*



	2011	2012
New Submissions	52	72
SRC to IRB Approval (days)	105.5	73



# Less Is More: Specializing Regulatory Responsibilities to Decrease Time to IRB Approval



Chloe Fournier, CCRP; Nicholas Fisher, MBA  
Siteman Cancer Center

## Abstract

In the face of increasing pressure to grow our program and obtain IRB approval more quickly, the Medical Oncology team needed to determine a viable long term staffing model for the regulatory team. Rather than increasing expense through additional staffing, our Medical Oncology team piloted an altered workload model in hopes of gaining increased efficiency. We hypothesized that a small group of staff focusing exclusively on study activation (SRC submission to activation) would be able to process more new studies at a faster rate than a large group of staff handling all regulatory responsibilities (from SRC submission to IRB closure).

We found that we were able to decrease approval time by 31% while increasing our annual submissions by 38% under our new, specialized model. We plan further specialization within the active study management team to increase their efficiency as well.

## Methods and Materials

The regulatory team worked to realign responsibilities with the priorities of the program. Our primary focus was increasing number of industrial studies submitted annually, while decreasing the time from SRC submission to IRB approval. We instituted an approval goal of 80 days from SRC submission to IRB approval. This represents a 25% decrease in approval time compared to the 2011 median.

In order to accomplish this goal, we divided our existing staff into two teams. Instead of "owning" studies throughout the lifetime of a study (from SRC submission to IRB closure), regulatory staff were assigned task-specific, specialized roles. Four coordinators focus on new study submission while the other four coordinators focused on active study management. The new submission team manages studies from SRC submission to study activation. The active study team manages studies from activation to IRB closure. After one year, we reviewed metrics from this pilot to determine if this was a long term solution.

## Introduction

In 2011, the Siteman Cancer Center recognized that in order to remain competitive and meet sponsor and PI needs, we needed to increase the number of new studies able to be submitted each month while simultaneously decreasing the timeline from SRC submission to IRB approval. That year, our Medical Oncology program submitted 52 new pharmaceutically sponsored studies; those trials had a median time from SRC

## Results

In 2012, after specializing our staff, our team submitted 72 pharmaceutically sponsored studies with a median time from SRC submission to IRB approval of 73 days (average: 78.7). 80% of studies submitted were IRB approved within the goal timeframe of 80 or fewer days, compared to only 16% in 2011. Additionally, the realigned team

## New Study Submissions

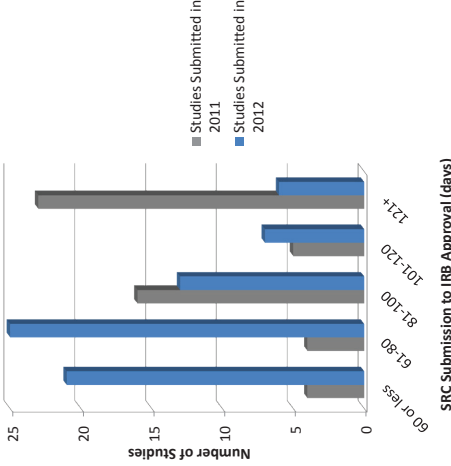


Chart 1. New Study Submissions SRC to IRB approval.

## Discussion

As we have found this pilot to be successful, we have implemented the same model within other Oncology teams. Beginning in June 2014, all new submissions are handled by the new submission team.

Moving forward, we continue to look for ways to improve our team. We have decreased our time to approval goal to 60 days, and continue to look for ways to decrease our time to approval.

submission to IRB approval of 105.5 days (average: 114.8). In addition to the new study submissions, these regulatory coordinators handled all aspects of regulatory study management, including but not limited to: annual renewals, protocol amendments, minor modifications, ancillary regulatory document management, compliance reporting and monitoring visits.

Our goal was to increase the number of studies submitted each month, decrease the timeline from SRC submission to IRB approval, and not increase our staffing needs.

was able to manage a 38% increase in new study submissions while successfully decreasing the approval timeline by > 5 weeks. See chart 1. Meanwhile, the active study team was able to manage all active trials with no noticeable decline in quality. Finally, the ratio of total studies to total staff remained essentially unchanged: 71.3/person in 2011 and 75.7/person in 2012. See table 1.

This model eliminated the conflict of competing top priorities for staff. As expected, we saw a sharp increase in number of studies submitted per coordinator—on average, each new submitter submitted 18 studies in 2012. This increased familiarity with IRB and SRC expectations and applications lead to fewer contingencies and a decreased time for approval.

Table 1. New study submissions.

	2011	2012
Number of New Industry Submissions	52	72
Median Time to Approval (days)	106	73
Approval Time less than 80 Days	16%	80%
Studies Per Coordinator	71	76

Contact

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Phone: 314-747-4235

We are also working on improvement of other initial submission metrics including consent length and consent quality.

Additionally, we are currently working to further expand our model of specialization within the active study team. Specifically, we have realigned workload by study type rather than staff handling all types (industrial, IIT, cooperative group, institutional, secondary). Additionally, we have separated regulatory document management and safety letter assessment into two unique positions.

Conclusions

A task-specific, specialized regulatory team has proven able to handle higher volumes while improving essential quality standards, including time from SRC submission to IRB approval. By specializing our staff, we were able to increase the number of industrial submissions by 38%. We surpassed our 80 day approval goal, and decreased the average time to IRB approval by 32%. Additionally, 80% of our studies submitted in 2012 took less than 80 days to receive IRB approval. All of this was accomplished without increasing our overall staffing of the team.

Planned future improvements focus on increased specialization within the active study team, where trial management will be divided by study type and specific task (renewals versus amendments). Within the new submission team, we have implemented a shorter time to IRB approval of 60 days. We are also looking at other metrics within this team such as consent quality and length. Finally, additional improvements must be made to shorten timelines from IRB approval to study activation.

# Additional Abstract Submissions

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All abstracts and submitted presentations and posters are available online at [http://aaci-cancer.org/crimeeting/2014\\_abstract\\_winners.asp](http://aaci-cancer.org/crimeeting/2014_abstract_winners.asp)

## **Development of a Predictive Model for Cancer Clinical Trial Accrual**

Wendy R. Tate, MS and Lee D. Cranmer III, MD, PhD

*The University of Arizona Cancer Center*

## **Applying a Risk Based Methodology in Driving Protocol Selection for Audit**

Nareg Grigorian and Alyssa Gateman

*Dana-Farber/Harvard Cancer Center*

## **CTMS/EMR Integration: Notifying the Research Team and Providers about Participation in a Clinical Trial and Potential**

Nancy J. Rollings, RN, MEd, CCRC, Mark A. Carey, MS, Rebecca C. Rogers, MA, CIP

*Norris Cotton Cancer Center Geisel School of Medicine at Dartmouth*

## **Data Driven Workload Management & Resource Allocation in the Genomic Age of Clinical Trials**

J.T. Diener, CCRP, Linda Battiato, MSN, RN OCN, CCRP, Kerry Bridges, MBA, RN, CCRP

*Indiana University Simon Cancer Center*

## **Utilizing an Epic-based Clinical Trial Alert System to Improve Accrual at a Community Cancer Center**

Mary Martell, Ashley Spaulding, Hope Krebill, Kayla Carpenter, Carmelle Hays

*University of Kansas Cancer Center; Stormont-Vail Cancer Center*

## **Electronic Integration of a Clinical Trials Management System (CTMS) and an Inexpensive Accounting Software Program**

Brenda V. Stewart, MEd, Kris Streeter, Ted Noravong, MBA

*University of Kansas Cancer Center*

## **How the ACA Could Affect Accrual to Oncology Clinical Trials at a Midwest NCI Designated Cancer Center**

Christine Mackay, BSN, RN, MSA, CCRP, Kirsten Erickson, PhD, Maxine Stoltz, PhD,

Tami-Curley-Galvez, PhD

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## **Preliminary Findings of Employing a Clinical Trial Nurse Navigator to Increase Oncology Clinical Trial Awareness and Enrollment**

Christine Mackay, BSN, RN, MSA, CCRP, Maxine Stoltz, PhD, Kirsten Erickson, PhD

*University of Kansas Cancer Center*

## **Time for CTOs to get “RASCI” [pronounced “racy”]! Executing a Coordinated, Team-based Approach to Accelerate Protocol Activation and Improve Clinical Trial Management Workflow**

Kirsten Erickson, PhD, MPH, Susan Johnson, MT (ASCP), Sabine Whitehouse, ProSys Inc. (consultant to KUCC), Maxine Stoltz, PhD

*University of Kansas Cancer Center*

## **How to Manage the Accounts Payable for Hundreds of Studies with a Single Process**

Kristopher Streeter, Brenda Stewart, Ted Noravong, MBA, Anna Nguyen, MBA

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All abstracts and submitted presentations and posters are available online at [http://aaci-cancer.org/cr/crimeeting/2014\\_abstract\\_winners.asp](http://aaci-cancer.org/cr/crimeeting/2014_abstract_winners.asp)

**Profits and Loss Reporting – Financial Communication Key to CTO Survival**

Ted Noravong, MBA, Kris Streeter, Brenda Stewart, BS, Anna Nguyen, MBA, Kirsten Erickson, MPH, PhD  
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**Total Cost of Ownership of “Smart” Electronic Data Capture Systems (EDC)**

Beth Kiefer and Katie Allen Ziegler  
*Mayo Clinic Comprehensive Cancer Center*

**Implementing Epic Beacon: Successes and Challenges for an Oncology Clinical Trials Office**

Rebecca Selle, BS, CCRP, Theresa Rudnitzki, MS, RN, ACNS-BC, AOCNS, Nebojsa Jovanovic, DVM, MS, Betty Oleson, RN, BSN, CCRP, James Thomas, MD, PhD  
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**Medicare Coverage Analysis — Is That Your Final Answer?**

Joanne Brechlin, MBA, MPH, Meaghan Stirn, MBA, Gina Varner, MPH  
*Moore's UC San Diego Cancer Center*

**Clinical Trial Monitoring: A Remote Real-Time Source Document Verification Program between Memorial Sloan Kettering Cancer Center (MSKCC) and Industry Sponsors**

Michael Buckley, Paul Sabbatini, Collette Houston, Gregory Riely, Kristen Ahearn, Rich Jankowski, Jonathan Walland, Janet Murdock, Ann Dilworth  
*Memorial Sloan Kettering Cancer Center*

**Resource Allocation Evaluation (RAE) by the Cancer Clinical Trials Office**

Rosemarie Gagliardi, Jennifer Cocco, Alyssa Ryan, Ajai Chari, MD, Matthew Galsky, MD, Marshall Posner, MD  
*The Tisch Cancer Institute at the Mount Sinai Medical Center*

**Working Together to Achieve EMR Access for Monitoring**

Brenda Hann, RN, MBA, Bernice Zander, RHIT, Maria Pitsiouni, PhD  
*Stanford Cancer Institute*

**Increasing Awareness of Cancer Clinical Trials Using an Information Kiosk**

Sarah Pelta, MA, Miriam Bischoff MS, MBA, Rachel Mesia, MPH  
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**Smartphrases: Smart Tool for Documentation in Cancer Clinical Trials**

Sophie Bertrand, Prachi Nandekar, MS, Brenda Hann, RN, MBA  
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**Screen Failures - Are We Failing to Compensate? Resource Planning in the Era of Personalized Medicine**

Gina Varner, MPH, Madeline Treschuk, MPH, Joanne Brechlin, MBA, MPH, Meaghan Stirn, MBA  
*UC San Diego Moore's Cancer Center*

**Implementation of a Forms Committee to Reduce Protocol Non-Compliance**

Melissa Nashawati, MPA, Marsha Zimmerman, RN; Angela Rodriguez, MS; Jeffrey Fissel, RPH, Karly Lim, RPH, Yvette Skelton, Leslie Wood, RN, BSN, OCN, CCRP, Miranda Villarreal, LVN, Gerardo Medina, RN, BSN, CCRP  
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