



ASSOCIATION OF AMERICAN CANCER INSTITUTES  
**CLINICAL RESEARCH INITIATIVE**

# 5th Annual CRI Meeting

**2013 CRI Abstract and Poster Winners**

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Roswell Park Cancer Institute*

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Stanford Cancer Institute*

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All abstracts and submitted presentations and posters are available online at  
<http://aaci-cancer.org/cri/crimeeting/abstracts.asp>

## AACI Clinical Research Initiative Overview

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The Association of American Cancer Institutes (AACI) comprises 95 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.

### 2013 AACI CRI Steering Committee Members

**Tony R. Reid, MD, PhD – Chair**

*UC San Diego Moores Cancer Center  
University of California at San Diego*

**Rhoda Arzoomanian, RN, BSN, MSM**

*University of Wisconsin  
Paul P. Carbone Comprehensive Cancer Center*

**Leigh A. Burgess, MHA, MEd, MA**

*Duke Cancer Institute  
Duke University Medical Center*

**Henry Durivage, PharmD**

*Yale Cancer Center  
Yale University School of Medicine*

**Alyssa DellaCroce Gateman, MPH**

*Dana-Farber Cancer Institute  
Harvard Medical School*

**Janie Hofacker, RN, MS**

*Association of American Cancer Institutes*

**Randall F. Holcombe, MD**

*Tisch Cancer Institute, Mount Sinai Medical Center*

**Vicki Keedy, MD, MSCI**

*Vanderbilt-Ingram Cancer Center*

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

*UNC Lineberger Comprehensive Cancer Center School of  
Medicine  
University of North Carolina at Chapel Hill*

**Douglas Stahl, PhD, MBA**

*City of Hope National Medical Center and  
Beckman Research Institute*

**Jeanine Stiles**

*UC Davis Comprehensive Cancer Center*

**Barbara Duffy Stewart, MPH**

*Association of American Cancer Institutes*

**Teresa L. Stewart, MS, CRCP**

*University of New Mexico Cancer Center*

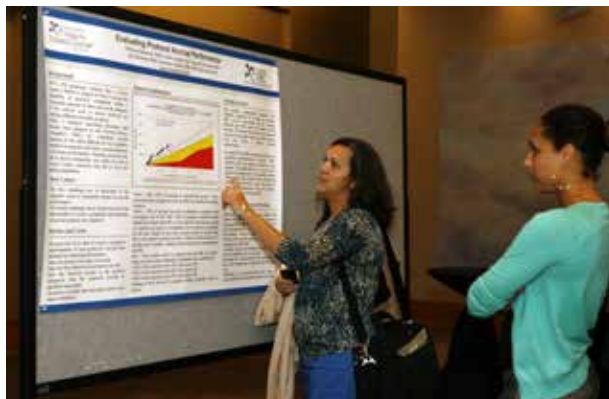
**James P. Thomas, MD, PhD – Immediate Past Chair**

*Medical College of Wisconsin Cancer Center*

## 2013 AACI CRI Annual Meeting Abstracts

In February 2013, the CRI Steering Committee issued a call for abstracts to AACI member cancer centers for presentation at the fifth annual CRI general membership meeting, held July 11–12 in Chicago. The call

focused on clinical trial operational problems and solutions, researched and implemented in a systematic fashion, which addressed clinical research challenges. The CRI annual meeting is attended by clinical trials operations leaders who convene annually to discuss three common challenges. The CRI Steering Committee received a record high



26 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.

This year's abstracts were developed utilizing the Toyota manufacturing problem solving approach and A3 template which provides a guideline for systematically

addressing the root causes of problems in clinical trials offices. The “plan, do, act” problem-solving approach outlined in the abstracts allow teams to focus on solving the right problems, while making progress (or lack thereof) visible to the organization. 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 Steering Committee thanks everyone who submitted an abstract for their review. The concepts described demonstrated the creative and thoughtful methods being employed at the cancer centers to address the clinical trial process issues.



## FIRST PLACE

### **Quality Improvement Initiative to Enhance Regulatory Compliance and Reduce Submission Errors Utilizing an Optimal Outcome Procedure System (OOPS)**

*Julie Haney, RN, MSL, CCRC and Virginia Doran, MLT, BS, MBA, CCRP  
Roswell Park Cancer Institute*

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

Study submission through the regulatory process requires attention to detail for federal, state, and local regulatory requirements. Incomplete or inaccurate submission forms can cause delays and increase timelines. A well prepared submission can go through the process without delay, be released for implementation in a timely fashion and lead to enhanced patient accrual.

Regulatory and Submissions Management within our organization developed a quality improvement (QI) initiative in 2010, to identify areas of discrepancy with submissions. This was titled Optimal Outcome Procedure System (OOPS). We plan to respond with enhanced education, improved Standard Operating Procedures, work instructions and form revisions.

#### **B. List the problem's root causes or obstacles to overcome, if applicable:**

Submission packages require accuracy, in order to reduce the submission errors it was determined that we needed to identify the errors prior to posting for Scientific Review. Once the errors were identified we could develop a process for form revision, education or procedural change. The purpose of the OOPS QI Program is to capture indicators of discrepancy and capture trends in data to determine areas for improvement and education. Outcome would aid in the quality, accuracy, and timeliness of the submissions through the review process. Information will be compiled utilizing reports generated from the OOPS electronic data system.

## WINNING ABSTRACTS AND POSTERS

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

Regulatory and Data Managers worked together to develop a database system that would allow entry of errors/omissions by individual assigned to a submission.

Quality Assurance issues were compiled according to the following categories:

- Consent Issues
- Copies
- Investigator Form
- Protocol Issues
- Electronic documents
- Signature
- Incomplete Forms

These items were listed the database field and quantified. Items that produced increased incidence were assessed for process improvement and/or education. The OOPS QI includes the following components:

- Assessment - Quality Checks and Data Capture
- Measurement – Compiling information and analysis
- Resolution Response – Corrective action through policy or form update
- Communication/Education
- Process re-evaluation/Assessment

Assessment: Personnel were assigned to perform a pre-review of all submission documents and enter omissions/errors into the system for data capture.

Measurement: Data compiled quarterly utilizing the OOPS component.

Results are compared to the previous quarter data. An error rate is calculated manually by taking the number of reported errors and dividing by the number of submissions. This produces an Error Rate (ER) Comparative reflected in a percentage.

The overall outcome goal was to fortify a culture of education and awareness with staff, which would enhance accuracy of submissions with an overall error rate reduction over a 2 year period.

### **D. Describe the solutions implemented:**

Resolution Response: Mechanism will be determined based on the data measurement. This may result in an update to a Standard Operating Procedure (SOP) or Work Instructions (WI) for clarity, or may result in revision of submission

forms. WI provides staff with precise guidelines for adherence to regulatory SOP (s). Both Policies and WI are posted for access by all staff.

Communication / Education: Utilized to ensure best practices are used for process improvement and updates. SOPs and WIs are presented at monthly staff meetings. Staff are given the opportunity to provide input or ask questions. Pre-Review personnel also utilize the SOPs and WIs to re-educate and direct staff to applicable references.

### **E. Describe what happened when solutions were implemented or data showing a positive or negative outcome:**

Data collection commenced in the second half of 2010. The following metrics were produced:

2010 by QTR

- 3rd: 337 Submissions (Sub), 91 errors = 27.0% error rate (ER)
- 4th: 281 Sub, 57 Errors, 20.3% ER 2011 by QTR
- 1st: 300 Sub, 101 Errors, 33.7% ER
- 2nd: 309 Sub, 81 Errors, 26.2% ER
- 3rd: 319 Sub, 95 Errors, 29.8% ER
- 4th: 336 Sub, 60 Errors, 17.9% ER 2012 by QTR
- 1st : 281 Sub, 41 Errors, 14.6% ER
- 2nd: 293 Sub, 49 Errors, 16.7% ER
- 3rd: 254 Sub, 20 Errors, 7.9% ER
- 4th: 264 Sub, 16 Errors, 6.1% ER

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

Managers communicated to staff that this QI approach was developed to be proactive and interactive mechanism of re-education to enhance submission accuracy, rather than disciplinary in nature.

Reduction of submission errors over the 2 year period was achieved and is continually monitored for process improvement considerations.

In the future, we would like to track Continuing Review submissions and consider solutions to reduce errors with these types of submissions.



# Quality Improvement Initiative to Enhance Regulatory Compliance and Reduce Submission Errors Utilizing an Optimal Outcome Procedure System (OOPS)



Julie Haney, RN, MSL, CCRC and Virginia Doran, MLT, BS, MBA, CCRP

## BACKGROUND

Study submission through the regulatory process requires attention to detail for federal, state, and local regulatory requirements. Incomplete or inaccurate submission forms can cause delays and increase timelines. A well prepared submission can go through the process without delay, be released for implementation in a timely fashion and lead to enhanced patient accrual.

Regulatory and Submissions Management within our organization developed a quality improvement (QI) initiative in 2010, to identify areas of discrepancy with submissions. This was titled Optimal Outcome Procedure System (OOPS). We plan to respond with enhanced education, improved Standard Operating Procedures, work instructions and form revisions.

## CHALLENGE

Submission packages require accuracy, in order to reduce the submission errors it was determined that we needed to identify the errors prior to posting for Scientific Review. Once the errors were identified we could develop a process for form revision, education or procedural change.

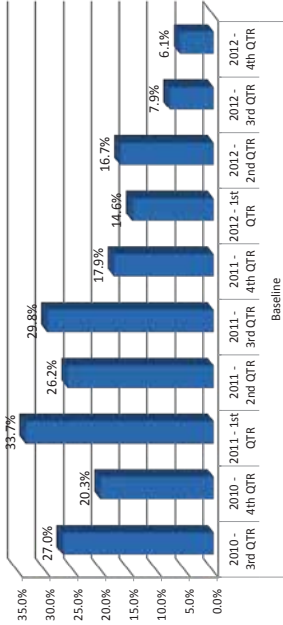
The purpose of the OOPS QI Program is to capture indicators of discrepancy and capture trends in data to determine areas for improvement and education. Outcome would aid in the quality, accuracy, and timeliness of the submissions through the review process. Information will be compiled utilizing reports generated from the OOPS electronic data system.

## DATA CAPTURE

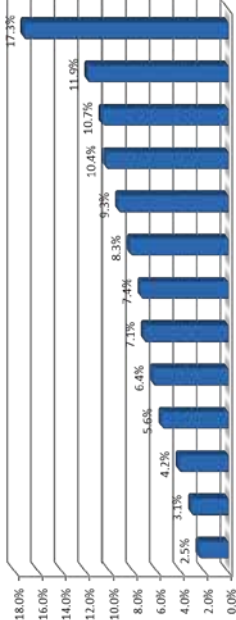
Regulatory and Data Managers worked together to develop a database system that would allow entry of errors/omissions by individual assigned to a submission. Quality Assurance issues were compiled utilizing the following categories: [Consent Issues](#), [Copies](#), [Investigator Form](#), [Protocol Issues](#), [Electronic documents](#), [Signature](#), [Incomplete Forms](#) and [Other](#)

## METRICS

% Error rate by Quarter



2012 % Error rate by Regulatory CRA





These items were listed the database field and quantified. Items that produced increased incidence were assessed for process improvement and/or education.

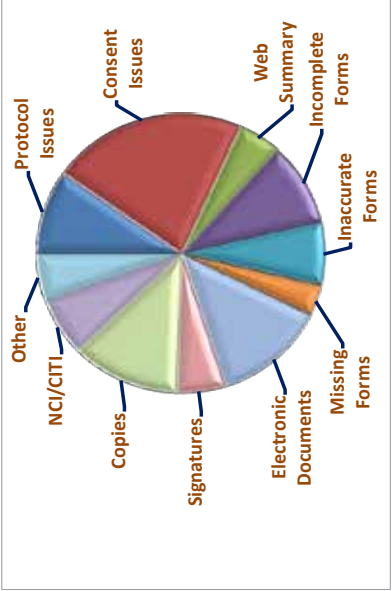
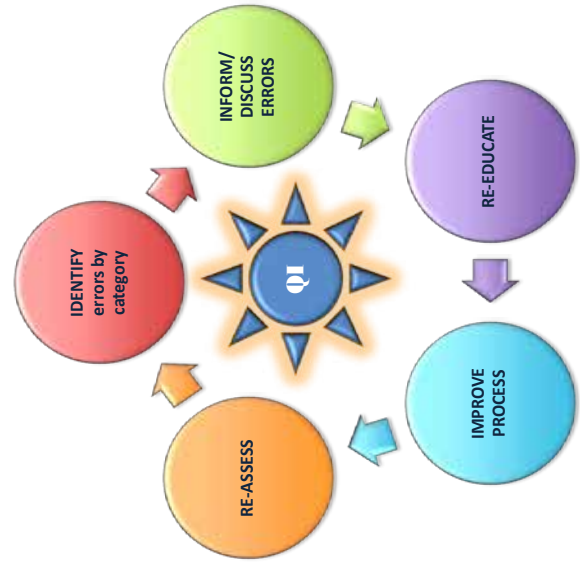
The OOPS QI includes the following components:

- Assessment - Quality Checks and Data Capture
- Measurement - Compiling information and analysis
- Resolution Response - Corrective action through policy or form update
- Communication/Education
- Process re-evaluation/Assessment

**Assessment:** Personnel were assigned to perform a pre-review of all submission documents and enter omissions/errors into the system for data capture.

**Measurement:** Data compiled quarterly utilizing the OOPS component. Results are compared to the previous quarter data. An error rate is calculated manually by taking the number of reported errors and dividing by the number of submissions. This produces an Error Rate (ER) Comparative reflected in a percentage.

The overall outcome goal was to fortify a culture of education and awareness with staff, which would enhance accuracy of submissions with an overall error rate reduction over a 2 year period.



## CONCLUSION

The outcome goal was achieved. OOPS helped to display a reduction of submission errors over the 2 year period.

OOPS error reduction can be attributed to the following components:

- Identify areas of concern
- Quantification and analysis
- Improvements in SOP and Work Instruction
- Form improvements
- Staff Education
- Tracking and accountability

QI approach was developed to be proactive and interactive mechanism of re-education to enhance submission accuracy, rather than being disciplinary in nature. We will continue to monitor for process improvement considerations.

In the future, we would like to track other types of regulatory submissions and consider solutions to reduce errors within these areas.



## SECOND PLACE

### Accounts Receivable Management of Commercially Sponsored Clinical Trials

*Joanne Brechlin, MBA, MPH and Meaghan Stirn, MBA  
UC San Diego Moores Cancer Center*

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

A Clinical Trials Office's (CTO) accounts receivable (AR) is constantly fluctuating. Outstanding revenue is affected by patient activity, variable events, invoicing, and payment. Given the complexity of clinical trial budgets, financial activity, and AR, few systems are adequate to support clinical trial financial management.

Tracking and collecting commercially sponsored clinical trials accounts receivable (AR) is a time intensive, complicated process involving interpreting contract terms, tracking patient and administrative activities, and follow-up for timely collection of payment. Due to the complexity of these protocols and associated contract budgets, it is critical that management of clinical trials finances be performed by experts in both clinical trials and accounting/collections. Insufficient tracking of AR and inadequate follow-up can easily lead to financial losses of hundreds of thousands of dollars already expended by the CTO.

#### **B. Problem's root causes/obstacles:**

The Moores UCSD Cancer Center CTO financial management system has historically been composed of discrete Excel workbooks designed and maintained by individual project managers. Tracking of accrued revenue and budget costs was performed via manual entry of patient activity and variable items into the spreadsheets, requiring review of the contract and budget, participant medical records or case report forms, and regulatory files. Invoicing required manual entry or copying of line items from the Excel workbooks into Excel invoice templates for submission to the sponsor. This process was time intensive and not performed on a consistent basis. Follow-up and collection of AR was irregular and sometimes resulted in non-payment of large outstanding costs due to drug pipeline failures combined with late invoicing.

Consistency in tracking revenue accrued, invoicing, and payment application requires a single database or system and standard procedures for communication and follow-up by knowledgeable experts.

### **C. Metrics on outcome:**

The objective is to describe the effectiveness of financial management practices enacted via implementation of Clinical Conductor, and to compare pre- and post- implementation clinical trial financial management methods, associated AR, and payment received metrics. Effectiveness in practices are measured quantitatively by comparing historic estimates of AR with current known AR, and comparing historic and current AR collection.

### **D. Describe the solutions implemented:**

In July 2011 the CTO contracted with Bio-Optronics Clinical Conductor, a CTMS using a financial management module built on QuickBooks. The intended solution was to use Clinical Conductor as the sole financial management system in the CTO.

### **E. Describe outcome:**

CTO project managers completed entry of 60% of the active commercially sponsored trials in the initial 3 months of system access. Estimated total AR for all 193 financially active commercially sponsored trials was \$2.89 million in June 2011. According to Clinical Conductor entries, total AR for 60% of approximately 224 financially active commercially sponsored trials was \$2.77 million in April 2012. We calculated that 2011's AR was underestimated by approximately 16% based on our known AR in 2012.

Since the last report, approximately 43 trial accounts have been closed-out due to completion of study and financial activity. To date, the CTO project managers have entered 97% of all financially active commercially sponsored trials into Clinical Conductor. According to Clinical Conductor entries, total AR for 176 financially active commercially sponsored trials is \$3.70 million in April 2013. Based on last year's estimates and our current entries, we have meticulously captured AR via implementation of Clinical Conductor as our primary financial tracking system.

## WINNING ABSTRACTS AND POSTERS

In Q3/Q4 2012, the CTO piloted a plan to regularly update subject and variable financial activity for each study in Clinical Conductor to coincide with the university's monthly ledger closing dates. This was not feasible due to project management workloads and entry was still performed irregularly, but more frequently than with the previous system. It was determined that specialists in accounting and AR collection are needed to ensure timely follow-up and receipt of payment. In April 2013, the CTO hired two accountants with the specific intent to collect the current outstanding \$3.70 million AR and keep future AR low. The accountants will work with the CTO management team to develop standardized activity entry procedures for Clinical Conductor, regulate invoicing practices and documents, and collect AR at a rate equal to accrual.

### **F. Lessons learned, others to involve, or ideas/initiatives to pursue:**

Our determination of need for accounting/collection specialists stemmed from our accurate measurement of AR in Clinical Conductor. We will continue refining our financial management process as our ability to track and collect AR improves. Beginning May 2013, we will collect metrics on collection of AR per accountant as a measure of performance.

# Accounts Receivable Management of Commercially Sponsored Clinical Trials

Joanne Brechlin, MPH, MBA; Meaghan Stirn, MBA

## BACKGROUND OF PROBLEM

A Clinical Trials Office's (CTO) accounts receivable (AR) is constantly fluctuating. Tracking and collecting commercially sponsored clinical trials accounts receivable (AR) is a time intensive, complicated process involving interpreting contract terms, tracking patient and administrative activities, and follow-up for timely collection of payment. Due to the complexity of these protocols and associated contract budgets, it is critical that management of clinical trials finances be performed by experts in both clinical trials and accounting/collections. Insufficient tracking of AR and inadequate follow-up can easily lead to financial losses of hundreds of thousands of dollars already expended by the CTO.

## PROBLEMS ROOT CAUSES

The CTO financial management system has historically been composed of discrete Excel workbooks designed and maintained by individual project managers. Tracking of accrued revenue and budget costs was performed via manual entry of patient activity and variable items into the spreadsheets, requiring review of the contract and budget, participant medical records or case report forms, and regulatory files. Invoicing required manual entry or copying of line items from the Excel workbooks into Excel invoice templates for submission to the sponsor. This process was time intensive and not done on a consistent basis. Follow-up and collection of AR was irregular and sometimes resulted in non-payment of large outstanding costs due to drug pipeline failures combined with late invoicing.

## METRICS ON DESIRED OUTCOME

The objective is to describe the effectiveness of financial management practices enacted via implementation of Clinical Conductor, and to compare pre- and post-implementation clinical trial financial management methods, associated AR, and payment received metrics. Effectiveness in practices are measured quantitatively by comparing historic estimates of AR with current known AR, and comparing historic and current AR collection.

## SOLUTIONS IMPLEMENTED

In July 2011 the CTO contracted with Bio-Optronics Clinical Conductor, a CTMS using a financial management module built on QuickBooks. The intended solution was to use Clinical Conductor as the sole financial management system in the CTO.

**BEFORE**

**AFTER**

- Per-patient budget entry at set-up
- Check-off patient visits
- Add visits to invoices
- Apply payments to invoices
- Associate invoices with patients
- Track PI fees
- Track other unique fees/costs
- Financial reporting
- Track invoice aging
- AR reporting/tracking



**Study Balance Sheet v3**

## OUTCOME

CTO project managers completed entry of 60% of the active commercially sponsored trials in the initial 3 months of system access. Estimated total AR for all 193 financially active commercially sponsored trials was \$2.89 million in June 2011. According to Clinical Conductor entries, total AR for 60% of approximately 224 financially active commercially sponsored trials was \$2.77 million in April 2012. We calculated that 2011's AR was underestimated by approximately 16% based on our known AR in 2012.

Since the last report, approximately 43 trial accounts have been closed-out due to completion of study and financial activity. According to Clinical Conductor entries, total AR for 176 financially active commercially sponsored trials is \$3.70 million in April 2013. Based on last year's estimates and our current entries, we have meticulously captured AR via implementation of Clinical Conductor as our primary financial tracking system.

In Q3/Q4 2012, the CTO piloted a plan to regularly update subject and variable financial activity for each study in Clinical Conductor to coincide with the university's monthly ledger closing dates. This was not feasible due to project management workloads and entry was still performed irregularly, but more frequently than with the previous system. It was determined that specialists in accounting and AR collection are needed to ensure timely follow-up and receipt of payment. In April 2013, the CTO hired two accountants with the specific intent to collect the current outstanding \$3.70 million AR and keep future AR low. The accountants will work with the CTO management team to develop standardized activity entry procedures for Clinical Conductor, regulate invoicing practices and documents, and collect AR at a rate equal to accrual.

## DELIVERABLES AND NEXT STEPS

Our determination of need for accounting/collection specialists stemmed from our accurate measurement of AR in Clinical Conductor. We will continue refining our financial management process as our ability to track and collect AR improves. Beginning Q3 2013, we will collect metrics on collection of AR per accountant as a measure of performance.

## CONTACT INFORMATION

Joanne Brechlin, MBA, MPH ([jbrechlin@ucsd.edu](mailto:jbrechlin@ucsd.edu))  
3855 Health Sciences Drive Room 2014  
La Jolla, CA 92093-0698



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## THIRD PLACE

### Using the FDA Electronic Submission Gateway for IND applications at an Academic Cancer Center

*Boris Breznen, PhD and Lee Doherty, EdM  
Stanford Cancer Institute*

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

The Food and Drug Administration (FDA) Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions over a secure website. Many academic cancer centers do not utilize the FDA ESG due to a lack of regulatory and technical knowledge required to successfully gain access; however continuing to utilize paper submissions long term is inefficient in terms of cost and time to submit applications. Our own attempts to access the ESG were unsuccessful until we identified a dedicated resource to implement the ESG technical requirements and re-design our internal standard operating procedures.

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

Submitting Investigational New Drug (IND) applications using paper documents is standard at many institutions. Paper applications remain popular as the submission procedures are well developed, and the obstacles to adopting the FDA ESG requirements seem substantial. The main obstacles to implementing the FDA ESG at academic cancer centers include:

- Achieving software compatibility as required by the FDA ESG technical guidelines.
- Developing standard operating procedures that comply with Electronic Common Technical Document (eCTD) formats.
- Establishing document archival procedures with capabilities to:
  - o Allow smooth transition from paper to electronic format submission while maintaining existing archives
  - o Allow tracking of progress for all ongoing submission
  - o Allow transparent and quick access to past submissions
  - o Allow integration with other forms of electronic communication with the FDA e.g. e-mail

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

By transitioning from paper to electronic IND submissions, academic centers can reduce the time and cost to submit applications. Compared to paper submissions, among the most prominent advantages of electronic submission are:

- Time from the submission to the reviewer's desk under 2 hours, compared to 1 week for paper submissions.
- FDA estimates that electronic submissions are 3-4 times less expensive in terms of labor and material expenditures. For example, the cost of shipping a paper application is often over \$50.00, however submitting using the ESG website is free.
- Environmental impact: savings in paper, printing consumables, and transportation fuel.

### **D. Describe the solutions implemented:**

In early November of 2012, the Cancer Clinical Trials Office identified a dedicated resource with the technical and regulatory background required to achieve software compatibility with the FDA ESG technical guidelines. After completing the preparatory activities, the ESG production account was activated in late December. The solutions involved:


- Dedicated PC running MS Windows 7 Professional with customized installation of Java runtime environment and dedicated browser (Mozilla Firefox v. 19.0.2)
- Purchase and installation of x.509v3 digital certificate from GlobalSign
- Letter of Non-Repudiation Agreement for digital signatures was submitted to the FDA
- Successful test submissions including 2GB upload test file
- Creating shared network volume with dedicated folder for electronic submission
- Adopting file and directory naming conventions for all future submissions

### **E. Describe what happened when solutions were implemented or data showing a positive or negative outcome:**

In the 5 months following the opening of the ESG production we used it for 20 successful submissions to the FDA:

- The average time from submission to reviewer's desk is 10-15 minutes, well under the FDA promised 2 hours and much less than approximately 1 week compared to paper documents.



- 
- Cost per submission reduced to almost zero. Paper, copying, and shipping were eliminated.
  - Overall communication exchange occurred more expediently.

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

Our overall experience with the FDA ESG is positive. Although the process of obtaining access seemed substantial at first, the Clinical Trials Office Regulatory Manager easily maintains access. There are still some limitations to note:

- Our experience is mostly with IND submissions to the Center for Drug Evaluation and Research (CDER). FDA ESG cannot be used to submit IDE applications and applications to the Center for Devices and Radiological Health utilize “eSubmitter”.
- The web portal can be down for some periods of time (occasionally for hours).
- FDA ESG is only a tool for submitting applications over secure web access. The review process does not take place in ESG but over email, phone and FAX.



# Adopting the FDA Electronic Submissions Gateway (FDA ESG) for Investigational New Drug Applications at an Academic Cancer Center

Boris Breznen, Ph.D., Lee Doherty, Ed.M.  
Stanford Cancer Institute, Cancer Clinical Trials Office

## Electronic Submission of Investigational New Drug Applications

Academic Institutions have been slow to adopt electronic methods for submitting IND applications to the FDA. In the first quarter of FY2012, 69% of Industry IND submissions to CDER were electronic compared to only 11.5% of Academic IND submissions.

	FY2010	FY2011	FY2012*
IND Research	14,816	16,039	7,377
IND Commercial	77,402	77,013	37,634
IND Total	92,218	93,052	45,011
IND Research Electronic	721	1,185	640
IND Commercial Electronic	36,794	48,116	26,079
IND Electronic Total	37,515	49,301	26,719
% IND Electronic	40.48%	52.98%	59.36%

## FDA ESG Web Interface (WebTrader)

FDA ESG is a solution for sending electronic IND submissions to CDER and CBER. The web portal routes submissions to the proper FDA center and reviewer. Subsequent communication is by email and phone. FDA does not charge for use of ESG.

## Opening the FDA ESG

Opening the FDA ESG may be challenging. After an initial failed attempt, we identified support staff who understood both the technical and procedural requirements of the ESG. Production access to FDA ESG was obtained in February 2013 after approximately 8 weeks of interaction with the agency.

## Key Obstacles to Overcome

### Technical

- Account holders need to load required Java and Browser on desktop and set specific proxy/firewall to communicate with ESG.
- ESG requirements constrain desktop technologies to Internet Explorer 6,7,8.
- Must obtain a x.509 version 3 class 1 digital certificate in order to utilize the FDA ESG. Certificate should be 1-3 years in duration.

### Procedural

- WebTrader account digital certificate is for only one staff person. Academic Cancer Centers may require several WebTrader accounts.
- IND documents must use digital signatures. This includes FDA Forms 1571, 1572, and 3674.
- Submissions should follow eCTD format, in general.

## Measuring Outcome of using the FDA ESG

After 4 months of utilizing the ESG we compared paper and electronic submissions in three specific areas: staff hours to prepare IND submissions, cost of printing and shipping INDs submissions, and time to reach the agency. (Source: FDA ESG Webinar, Aug. 2011)



**Benefits of the FDA ESG included:**

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## Resources for Opening the ESG

Information on how to open the ESG can be found on the FDA website: <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>

**For more information please contact:**

Lee Doherty, Ed.M., Regulatory Manager  
Stanford Cancer Institute  
Cancer Clinical Trials Office  
[lee.doherty@stanford.edu](mailto:lee.doherty@stanford.edu)  
650-736-0176

## Additional Abstract Submissions

All abstracts and submitted presentations and posters are available online at <http://aaci-cancer.org/crimeeting/abstracts.asp>

### **Optimizing Process for Committee Review While Revamping Timelines and Metrics**

**Shannon Hernandez, Michelle Davis, MS, Ennis Hodges, Ellen Jones, Shobhana Krishnakumar and Melissa Nashawati, MPA**

*Cancer Therapy and Research Center of the University of Texas Health Science Center at San Antonio*

### **Envisioning Accrual Performance**

**Melissa Nashawati, MPA, Chris Loudon, MS, Anand Karnad, MD, Joel Michalek, PhD, Jonathan Gelfond, MD, PhD, Bill Sanns, MS and Susan Padalecki, PhD**

*Cancer Therapy and Research Center of the University of Texas Health Science Center at San Antonio*

### **Development of a Minority Accrual Plan for Clinical Trials**

**Amelie Ramirez, PhD, Ian Thompson, MD, Anand Karnad, MD, Steve Weitman, MD, PhD, Albert Parra, MD, Susan Padalecki, PhD, Brad Pollock, PhD, Melissa Nashawati, MPA and Monica Trevino, MA**

*Cancer Therapy and Research Center of the University of Texas Health Science Center at San Antonio*

### **Development of a Research Program Scorecard**

**Melissa Kadar, Anne Ness, Bob Lanese, MSME, MSM, Sherrie Reynolds, Michael Sainz, Jennifer Gibbons, Mary Bilancini, Latoya Strickland, Mary Corl, Smitha Krishnamurthi, MD and Neal Meropol, MD**

*Case Comprehensive Cancer Center, Case Western Reserve University, Seidman Cancer Center at University Hospitals Case Medical Center*

### **Sponsor-Investigator Education and Tools Program**

**Sherrie Reynolds RN, BSN, Melissa Kadar, Emily Collins, MA and Alison Campbell**

*Case Comprehensive Cancer Center, Case Western Reserve University, Seidman Cancer Center at University Hospitals Case Medical Center*

### **Protocol Document Management System an Electronic Regulatory Binder**

**Tad McKeon, MBA, CPA**

*Comprehensive Cancer Center, St. Jude Childrens Research Hospital*

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### **Electronic Sign-off process for Clinical Investigations**

**Tad McKeon, MBA, CPA**

*Comprehensive Cancer Center, St. Jude Childrens Research Hospital*

### **A New Clinical Research Office Staffing Model: Restructuring to Improve Quality and Efficiency of Research Operations**

**Linda Battiato, MSN, RN, OCN and Kerry Bridges, MBA, RN, CCRC**

*Indiana University Melvin and Bren Simon Cancer Center*

### **Online Patient Consenting**

**Catie Wiernasz, MSN and Nina Wadhwa, MSPH, CCRC**

*Moffitt Cancer Center*

### **Peer Monitoring of NCI Cooperative Group Studies**

**Rebecca Carson Rogers, MA, CIP and Nancy J. Rollings, RN, MEd, CCRC**

*Norris Cotton Cancer Center, Dartmouth-Hitchcock Medical Center*

### **Performance Based Web-Application Accelerates Clinical Trial Activation in a Pilot Study**

**Therica Miller, MBA, Sheilah Hurley, MA, Mahendra Yatawara, MBA, Rebecca Flores-Stella, CIP, Keren Dunn, CIP, Ryan Schroeder, Haibin Wang, PhD, Shao-Chi Huang, Kevin Dudley, Robert Figlin, MD, Monica Mita, MD, Christine Szekely, PhD, Howard Sandler, MD and Steven Piantadosi, MD, PhD**

*Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center*

### **U10 Grant Accrual Challenge**

**Jennifer Davis, CCRP**

*Simmons Comprehensive Cancer Center, The University of Texas Southwestern Medical Center at Dallas*

### **Electronic Integration – Is it Worth the Effort?**

**Meaghan Stirn, MBA and Joanne Brechlin, MPH, MBA**

*UC San Diego Moores Cancer Center*

## Additional Abstract Submissions

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### **Streamlining Start-Up: A Site's Solution to Enhancing Activation Timelines**

**Carolyn Revta, MPH, Meaghan Stirn, MBA and Joanne Brechlin, MBA, MPH**

*UC San Diego Moores Cancer Center*

### **Building Oncology Clinical Research Partnerships between NCI Designated Comprehensive Cancer Centers in Community and Regional Settings Through Community - Based Participatory Research**

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

*UNC Lineberger Comprehensive Cancer Center School of Medicine, University of North Carolina at Chapel Hill*

### **Clinical Research Acuity Tool for Studies and Staff**

**Karen Braddy and Colleen Kellackey, RN**

*University of Colorado Cancer Center, University of Colorado Health Sciences Center*

### **Improving Efficiency and Implementation of Standard Data Sets for IND annual Reporting**

**Melissa Mietzel, MS, CCRP, Beesea Hsieh, MS, Jeanne Wright, RN, BSN, RAC, Mathew Innes, MBA and Elizabeth Vasher, RN, BSN, CCRP**

*University of Michigan Comprehensive Cancer Center*

### **Improving Efficiency in the Management of Investigator Initiated-Centered Clinical Trials in an Academic Setting**

**Melissa Mietzel, MS, CCRP, Stefanie Lieland, MS, CCRP and Elizabeth Vasher, RN, BSN, CCRP**

*University of Michigan Comprehensive Cancer Center*

### **Steps To Achieve Shorten Study Activation Time Without Compromising Quality**

**Zeno Ashai, MPH, Kay Johnson, RN and Nonna Snider**

*USC Norris Comprehensive Cancer Center, University of Southern California*

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**Clinical Research Implementation Committee: A disciplinary and department approach to facilitate clinical trial implementation**

**Debra Wujcik, PhD, RN, FAAN and Vicki Richard, RN, MBA, NEA-BC**  
*Vanderbilt-Ingram Cancer Center*

**A Pilot Study of Patient Satisfaction with the Experience of Participation in Clinical Trials at Winship**

**Mersiha Torlak, BS, Bassel El-Rayes, MD and Kathleen Rodger, RN, BSN, MS**  
*Winship Cancer Institute of Emory University*

**Development and Implementation of a Centralized Clinical Trials Orientation Program**

**Jennifer Jarrell, MPH, CCRP, Mersiha Torlak, BS and Kathleen Rodger, RN, BSN, MS**  
*Winship Cancer Institute of Emory University*

**Quality Management Plan (QMP)**

**Mersiha Torlak, BS, Jennifer Jarrell, MPH, CCRP and Kathleen Rodger, RN, BSN, MS**  
*Winship Cancer Institute of Emory University*



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