

WORKSHOP
June 23-24, 2008
6711 Democracy Blvd
Bethesda, MD 20817

Title: Enhancing Clinical Investigation by Improved Management

Proposed Audience:

- 4 Individuals from each 2006 and 2007 CTSA site = 96
- 1 Attendee from each 2008 CTSA site
 - Champion of Change at CTSA site, Dean or equivalent
 - Grants/Contracts official or IRB chair/Regulatory official
 - PI or other investigator
- 8 NCRR
- 20 other NIH Representatives (TBN)
- 1 Industry Stakeholder (Nancy Jean Trapp, Eli Lilly)
- 12 Participants to include: Other Speakers: Califf, Ennever, Ford, Joyner, Johnson, Moran, Perez, Rockwell, Trapp

Proposed Objectives:

- The 96 site participants should
 - Develop a dialog that will continue beyond the meeting regarding strategies and tools for achieving efficiency in clinical research management
 - Learn definitions and applications of common metrics in the measurement of efficiency in clinical research management for each site to improve its quality improvement process
 - Understand and begin a process of working towards consensus regarding Standardized Metrics for the CTSA Consortium
 - Focus on prioritization and implementation of process improvement

To Achieve the Objectives:

- Each topic will be introduced and explored by a speaker or a group of speakers with experience/expertise in that field
- The discussion of each topic will be enhanced with specific case presentations
- The participants will break up into voluntary groups for "round table discussions" about each topic
- The round table discussions will be summarized for the entire group of participants
- A poster session will be held on the 2nd day. Each site will submit a poster for publication and present it at the meeting. The poster will include the following: Name of CTSA, Goals of Process Revision, Information Technology used to support Process, 3 – 6 Tips (what helped/what did not help), and Contact Information. NCI will also submit a poster (Diane Wara will work on it). Post-Its® will be used for comments on each poster.

Outcome of Meeting:

- Develop a plan for recurrent meetings of the CTSA Clinical Research Management Taskforce
- Develop a tentative schedule for workshops
 - Frequency
 - Proposed topics
- Develop a plan for retrieving and analyzing data related to use of metrics at CTSA site

Monday, June 23, 2008 Day 1

- 7:30 a.m. **Coffee/Continental Breakfast**
- 8:00 a.m. **Welcome** Barbara Alving
Director, NCRR
- 8:05 a.m. **NIH Perspective:** Walter Koroshetz
Deputy Director,
NINDS
Title: Protocol processing at academic centers from the NIH perspective.
- 8:20 a.m. **Keynote Address** Robert Califf
Title: Why is Improved Clinical Research Management Important?
- 8:40 a.m. **Purpose and Plan for Day 1** Michael Joyner
- 8:45 a.m. **Metrics and Measurements** Dan Ford
Title: Metrics and Measurements, justification, definition, application
- 9:15 am **IRB metrics** Tony Perez
Title: IRB and Regulatory, metrics and measurement
- 9:45 am **Break**
- 10:00 am **Case Presentation** Tony Perez
Title: IRB Metrics, alternative processes Gary Chadwick
- 10:15 am **Round Table Discussions (#8 – 12/group)**
Ford and Perez will provide questions
- 11:45 am **Facilitator Breakout/ Working Lunch**
(Representatives from each table to meet separately at reserved lunch table to discuss and condense round table discussions)
- 12:45 pm **Contracts and Grants** Jim Moran
Title: Contract Negotiation Metrics & Measurements
- 1:15 pm. **Case Presentations:** Jim Moran
Title: Industry & Site Perspectives on Improving Contract Nancy Trapp,
Completion Eli Lilly
- 1:45 p.m. **Round Table Discussions (#8 – 12/group)**
Moran and Trapp will provide questions
- 2:45 p.m. **Break/ Facilitator Breakout**
- 3:15 pm **Summary of Round Table Discussions on IRBs** A facilitator
(panel of 8 facilitators)
- 4:00 pm **Summary of Round Tables Discussions on Contracts** A facilitator

(panel of 8 facilitators)

4:45 p.m. **Panel Discussion on Metrics** John Ennever
Dan Ford, Jim Moran, Tony Perez, Nancy Trapp, Walter Koroshetz

5:30 p.m. **Adjourn Day 1**

Tuesday, June 24, 2008 Day 2

7:30 am **Coffee/Continental Breakfast**

8:00 am **Purpose and Plan for Day 2** Michael Joyner

8:05 am **Quality Improvement** Tesheia Johnson
Title: Using Metrics for Quality Improvement

8:20 am. **Process Engineering** Sara Rockwell
Title: Faculty Perspective: Challenges of Implementing Change

9:00 am **Poster Session** Tesheia Johnson
Title: Process Changes in Study Management

11:00 am **General Discussion** Michael Joyner
Take Home Tasks: An Action Your CTSA Will Initiate by October 1, 2008

11:45 am **Recommendations for Further Action** John Ennever
Panel: Rob Califf, Michael Joyner, Dan Ford, Jim Moran, Tony Perez

- Plans for CTSA Clinical Research Management Taskforce
 - Workshop
 - Taskforce meetings
 - Analysis of Metric Outcomes – Data Collection
- Recommendations to CCOC

1:00 p.m. **Adjournment**