



Site Metrics for Study Start-Up

A Clinical Trials Transformation Initiative (CTTI)-Sponsored Meeting

May 4, 2010

Hilton Washington DC/Rockville Hotel and Executive Meeting Center

1750 Rockville Pike

Rockville, MD 20852

Background:

The Clinical Trials Transformation Initiative (CTTI) has been conducting a project to identify core data elements that should be collected by all clinical trial sites to allow measurement and improvement of important timeframes for study start-up.

Key Objectives:

- Review the results from retrospective analysis to describe the current state of study start-up at sites participating in multicenter clinical trials
- Review, discuss and agree on a proposed list of standard metrics for site start-up activities including a standard, specific, and measurable definition for each metric that will be utilized in a prospective data collection pilot coordinated by CTTI
- Discuss strategies for success and potential barriers for engaging sites to participate in the prospective data collection pilot that will be designed to facilitate and encourage sites to measure themselves against “sites like me” to identify opportunities for improving their internal processes and cycle times

Participants:

- Representatives from a broad cross-section of the clinical trial enterprise including regulators, government sponsors of clinical research, academia, industry, patient advocates, clinical investigators, and other interested parties
- Participants are expected to be actively engaged and ask questions

Location: Plaza Ballroom I & II

Meeting Facilitator: Robert Califf, Duke Translational Medicine Institute

AGENDA

8:30 Continental Breakfast

9:00 Welcome, introductions, meeting objectives and CTTI overview
Robert Califf, Duke Translational Medicine Institute

9:30 Overview of CTTI Site Metrics for Study Start-Up Project
Christine Pierre, Rx Trials

9:45 Presentation & Discussion WS-1 Findings
Diana Abbott, Duke Translational Medicine Institute

10:45 Break

11:00 Proposed Data Elements and Cycle Time Metrics for WS3 Prospective Data Collection
Soo Bang, Pfizer

12:00 LUNCH

1:00 Proposed Data Elements and Cycle Time Metrics for WS3 Prospective Data Collection Continued
Soo Bang, Pfizer



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2:15 Break

2:30 Prospective Data Collection Pilot - Planning Discussion

Robert Califf, Duke Translational Medicine Institute

- *What are potential obstacles & strategies for success in planning prospective collection?*
- *What's in it for me? What are major benefits of having metrics to different stakeholder groups?*
- *What are major considerations / system requirements for a web based model for collection of prospective metrics by sites?*
- *How do we ensure integrity of the data if it is self-reported?*
- *What should scope of prospective data collection be?*
 - *Number sites, type of sites, study phase etc.*

4:00 Summary of recommendations and next steps

Robert Califf, Duke Translational Medicine Institute

4:30 Adjournment