Site Metrics for Study Start-Up Stakeholder Meeting

Rockville, MD
May 4, 2011
- Welcome
- Meeting Objectives
- Rules of Engagement
- Introductions
- CTTI Overview
Meeting Objectives

- Review the results from retrospective analysis
- 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
- Discuss plans for Workstream 3 prospective data collection pilot designed to facilitate and encourage sites to measure themselves against “sites like me” to identify opportunities for improving their internal processes and cycle times
  - Strategies for success
  - Potential obstacles
  - Scope, duration
  - System requirements for web based data collection model
Rules of Engagement

- Participate!
- Everyone is responsible for the success of the meeting
- All ideas and opinions will be respected
- One person talks at a time
- Use table mikes so teleconference participants can hear
- Keep an open mind
- Appreciate other points of view
- Share your knowledge and experience
- Relax. Be yourself. Be honest.
## Introductions: Representation

<table>
<thead>
<tr>
<th>Sector</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory</td>
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<tr>
<td>Industry</td>
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<tr>
<td>Academia</td>
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<tr>
<td>US government agencies</td>
<td>7</td>
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<tr>
<td>Clinical investigator groups</td>
<td>4</td>
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<tr>
<td>Patient representatives</td>
<td>2</td>
</tr>
<tr>
<td>Others</td>
<td>10</td>
</tr>
<tr>
<td>CTTI</td>
<td>6</td>
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<td><strong>Total</strong></td>
<td><strong>55</strong></td>
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Introduction of Meeting Participants

- Name and Institutional Affiliation
CTTI Overview
Questions to consider

- Do clinical trials have to be so time consuming and difficult to conduct?
- What can we do to accelerate clinical trials while maintaining quality?
  - Potential benefits:
    - Speed availability of new therapies
    - Address more clinical questions through randomized comparisons
    - Compare alternative therapies
Setting—Late 2007 when CTTI was created

- U.S. clinical trials in crisis
  - Trial start-up times lengthening
  - Enrollment slowing
  - Costs increasing
  - Many investigators pulling out of clinical research
It’s a “Systems Problem”

- All members of the clinical research enterprise have played a part in this problem
- Fixing it will require a collaborative effort
  - FDA/global regulators
  - Industry
  - Academia/NIH
  - Investigators in clinical practice
  - Consumers
U.S. FDA Takes Action

- U.S. FDA’s Office of Critical Path Programs established a public-private partnership: The Clinical Trials Transformation Initiative (CTTI)

- All stakeholders involved

- Through a memorandum of understanding with FDA, Duke University serves as the host of CTTI
Mission

To identify practices that through broad adoption will increase the quality and efficiency of clinical trials
How Does CTTI Propose to Effect Widespread Change?

- Involve all sectors in selection, conduct, and interpretation of projects
- Develop evidence that may generate recommendations for improvement and inform regulatory guidance
- Identify and eliminate activities in the conduct of trials that do not add value
- Understand incentives to maintain non–value-added activities
- Maintain an open and respectful dialogue across sectors
- Develop solutions that are mindful of the needs of patients and all sectors in the clinical research enterprise
CTTI’s Dual Approach

- Seek incremental improvements to current system
- Identify and shape potential transformational changes to the system
Seeking Incremental Improvements

- Generate empirical data on clinical trials and proposed improvements
- Identify incentives for non-value-added activities in conduct of clinical trials
- Seek solutions to remove non-value-added activities
  - Maintain respect for perceived needs of all parties (patients, regulators, investigators, industry)
- Drive change through member organizations and related initiatives with similar goals
Generating Empirical Data on Clinical Trials and Proposed Improvements

“Completed” projects

- Effective and efficient monitoring
- Reporting unexpected serious adverse events to investigators

Current projects

- Improving the public interface for use of aggregate data in ClinicalTrials.gov
- Use of central IRBs for multicenter clinical trials
- Site metrics for study start-up
- Follow-on projects from monitoring and SAE
Clinical Trials Transformation Initiative
Organizational Overview

CTTI Executive Committee
- Robert Califf, MD
  EC Co-Chair
  Duke University
- Rachel Behrman, MD, MPH
  EC Co-Chair
  FDA

CTTI Steering Committee
- Elliott Levy MD
  SC Co-Chair
  Bristol-Myers Squibb
- Bev Lorrell MD
  SC Co-Chair
  King and Spaulding

CTTI Projects
- Effective and Efficient Monitoring
- Reporting Unexpected Serious Adverse Events to Investigators
- Improving Public Interface for Use of Aggregate Data in ClinicalTrials.gov
- Site Metrics for Study Start-up
- Use of Central IRBs for multicenter clinical trials
- Monitoring Follow on activity
- Quality by Design Learning Exchange
- SAE Follow on activities
- Follow on activity

CTTI Staff
- Judith Kramer, MD, MS
  Executive Director
  Duke University
- Leanne Madre, JD, MHA
  Director of Strategy
  Duke University
- Cheri Janning, RN, BSN, MS
  Senior Clinical Project Manager
  Duke University
- Jean Bolte, RN, BSN, MSN
  Senior Clinical Project Manager
  Duke University
- Michael Fontanilla
  Project Manager
  Duke University
- Rhonda Bartley
  Asst. to Executive Director
  Duke University
- Mari Jo Mencini
  Staff Specialist
  Duke University
Executive Committee

- Co-Chairs: Rob Califf (Duke) and Rachel Behrman (FDA)
- Academia*: David DeMets
- At-large representative: Ken Getz
- FDA: Bob Temple, CDER, and Bram Zuckerman, CDRH
- Industry*: Glenn Gormley, Jay Siegel, Susan Alpert, Alberto Grignolo
- Patient representative: Nancy Roach
- NIH liaison: Amy Patterson (Kathy Kopnisky, alternate)
- Non-US regulatory liaison: Hans-Georg Eichler, European Medicines Agency
- Steering Committee Co-chairs: Elliott Levy and Beverly Lorell
- Steering Committee Immediate Past Co-chair: Briggs Morrison
- CTTI Executive Director: Judith Kramer

*Academic position and 2 industry positions in transition
## Steering Committee Representation

<table>
<thead>
<tr>
<th>Category</th>
<th># organizations</th>
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<tbody>
<tr>
<td>Academic institutions</td>
<td>15</td>
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<tr>
<td>Pharmaceutical companies</td>
<td>8</td>
</tr>
<tr>
<td>US Government Members &amp; Liaisons</td>
<td>7 (FDA [OC,CDER, CBER, CDRH] AHRQ, CDC, CMS, NIH, OHRP, VA)</td>
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<td>Professional societies</td>
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<td>Clinical research organizations</td>
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<tr>
<td>Biotechnology companies</td>
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<tr>
<td>Trade organizations</td>
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<tr>
<td>Clinical investigator groups</td>
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<td>Device companies</td>
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<tr>
<td>Institutional Review Boards</td>
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<tr>
<td>Patient representatives/at-large</td>
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<tr>
<td>Private equity firm</td>
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<tr>
<td>Regulatory law firm</td>
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<tr>
<td>Standard Setting Organization</td>
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62 member organizations; 1 patient rep; 1 at-large rep
Questions?