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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<tr>
<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
- Monitoring Follow on activity Quality by Design
- Learning Exchange
- SAE Follow on activities
- Use of Central IRBs for multicenter clinical trials

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>
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<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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<td>Patient representatives/at-large</td>
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<tr>
<td>Private equity firm</td>
<td>1</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?