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

Sector	Number
Regulatory	**4**
Industry	**12**
Academia	**10**
US government agencies	**7**
Clinical investigator groups	**4**
Patient representatives	**2**
Others	**10**
CTTI	**6**
Total	**55**

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

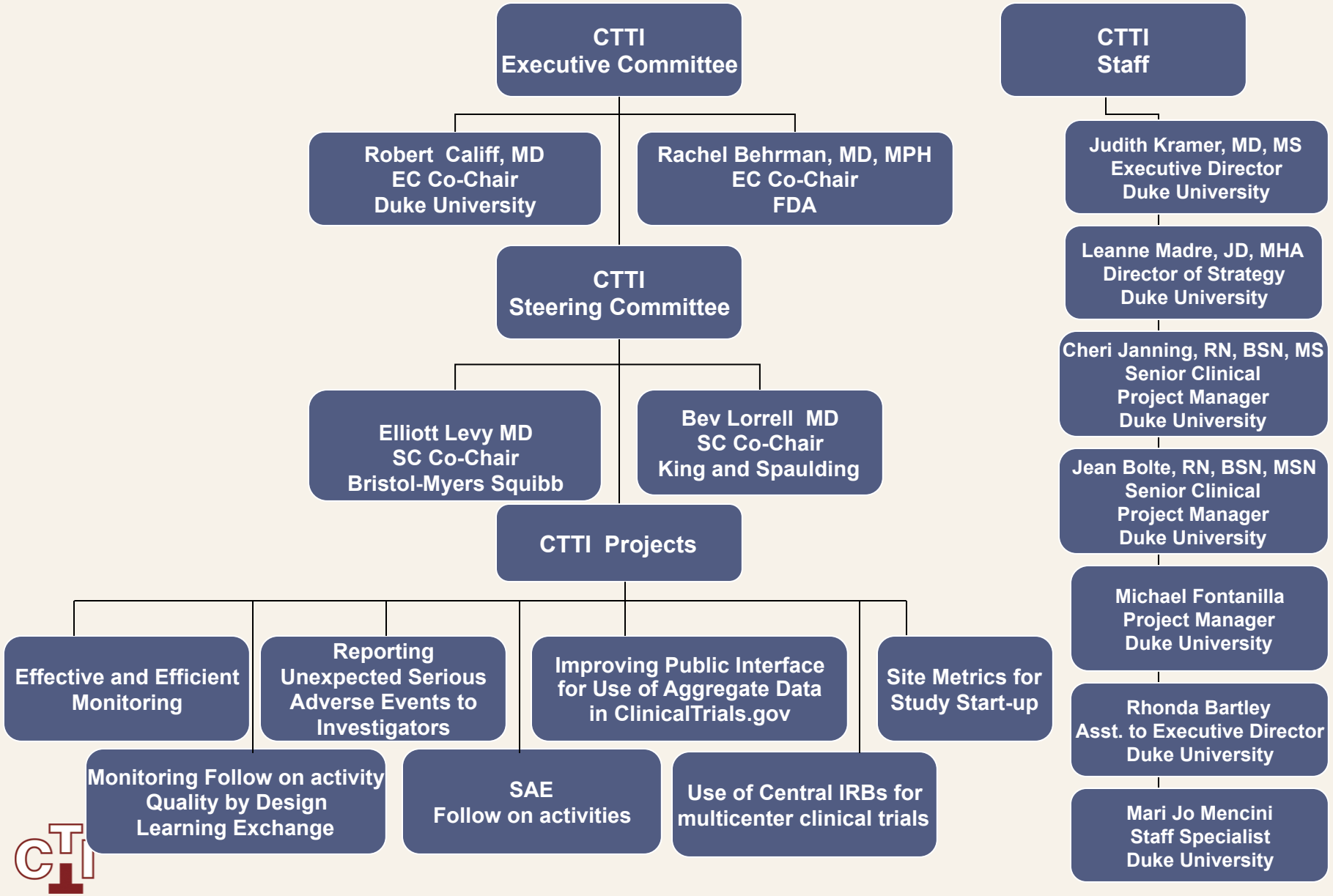
“Completed” projects

- 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



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

Category	# organizations
Academic institutions	15
Pharmaceutical companies	8
US Government Members & Liaisons	7 (FDA [OC,CDER, CBER, CDRH] AHRQ, CDC, CMS, NIH, OHRP, VA)
Professional societies	5
Clinical research organizations	5
Biotechnology companies	5
Trade organizations	4
Clinical investigator groups	4
Device companies	3
Institutional Review Boards	3
Patient representatives/at-large	2
Private equity firm	1
Regulatory law firm	1
Standard Setting Organization	1

62 member organizations; 1 patient rep;
1 at-large rep

Questions?