

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

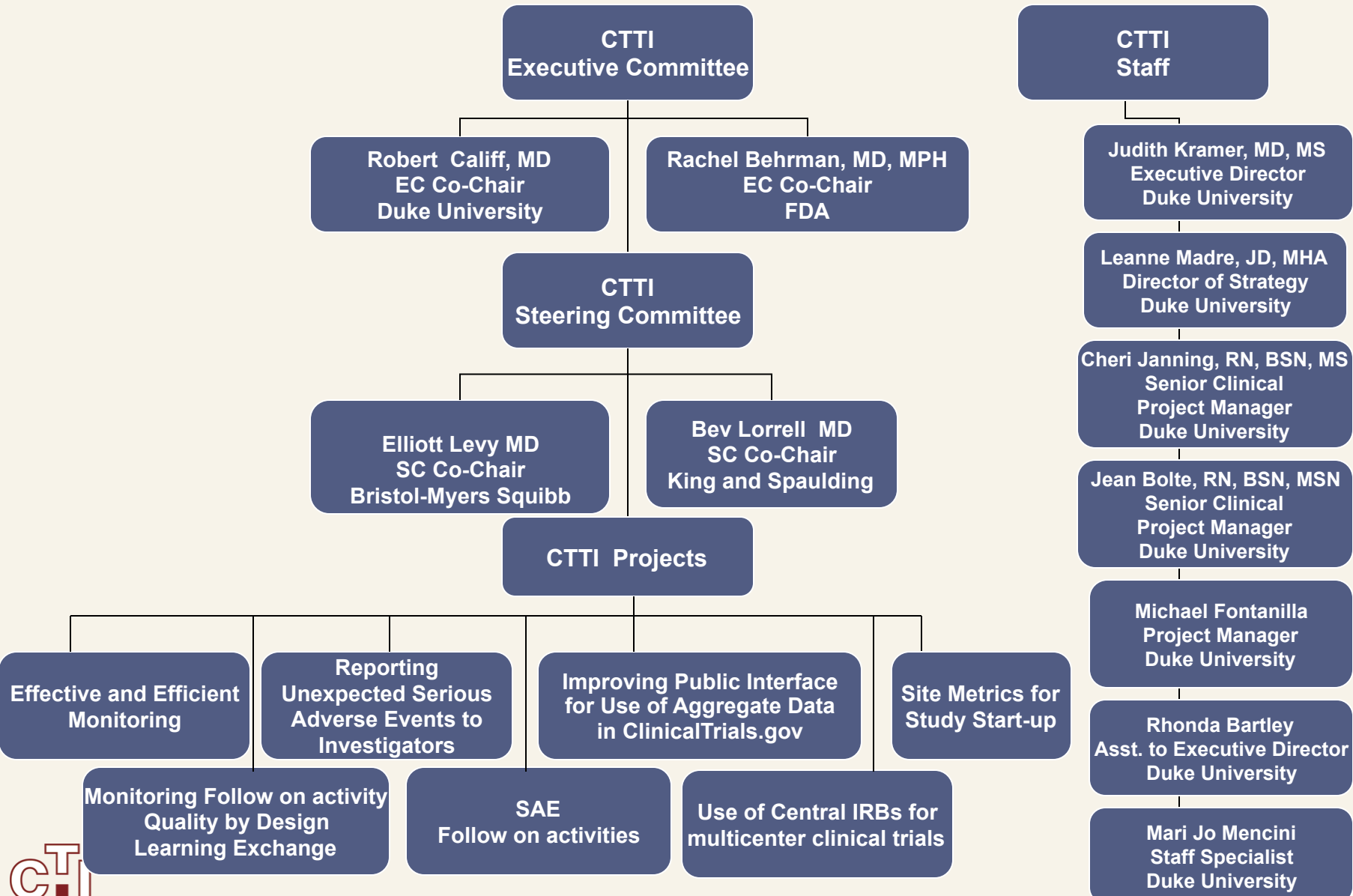
- Effective and efficient monitoring
- Reporting unexpected serious adverse events to investigators

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?