Brief Introduction
Clinical Trials Transformation Initiative (CTTI)

Judith M. Kramer, MD, MS, Executive Director
Associate Professor of Medicine, Duke University

Introduction of Meeting Participants

- **Name and Institutional Affiliation**

Setting— Late 2007 when CTTI was created

- **US 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**

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 (Phil Budashewitz)
- Non-US regulatory liaison: Hans-Georg Eichler, European Medicines Agency
- Steering Committee Co-chairs: Briggs Morrison, Michael Katz
- CTTI Executive Director: Judith Kramer

Mission

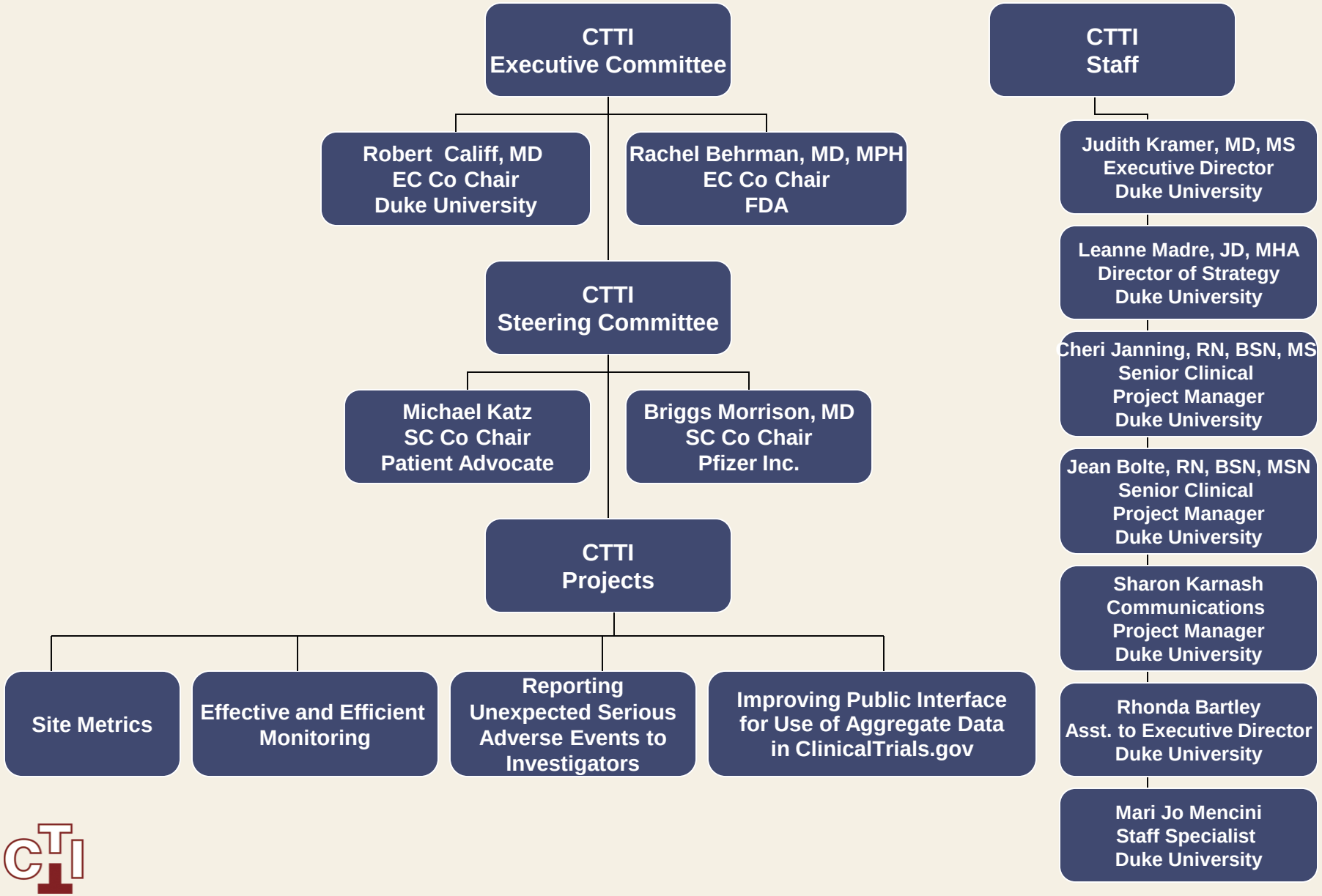
- **To identify practices that through broad adoption will increase the quality and efficiency of clinical trials**

Steering Committee Representation

Category	# organizations
Academic institutions	13
Pharmaceutical companies	8
US Government Members & Liaisons	7 (FDA [OC,CDER, CBER, CDRH] AHRQ, CDC, CMS, NIH, OHRP, VA)
Professional societies	6
Clinical research organizations	5
Device companies	4
Biotechnology companies	4
Clinical investigator groups	4
Trade organizations	3
Patient representatives/at-large	3
Private equity firm	1
Regulatory law firm	1
Institutional Review Board	1
Standard Setting Organization	1

58 member organizations; 2 patient reps; 1 at-large rep

Clinical Trials Transformation Initiative
Organizational Overview



Finances

- **Membership fees support infrastructure for CTTI and projects**
  - **Fees differ by membership category and financial resources of organizations**
    https://www.trialstransformation.org/members/membership-fees/
  - **No fee required for government representatives, patient representatives, or at-large member**
- **Awarded an FDA Cooperative Agreement Sept 2009**
  - **Further enables the conduct of projects**

Initial Priority Areas* for Projects

- **Design principles**
- **Data quality and quantity (including monitoring)**
- **Study start-up**
- **Adverse event reporting**

*Defined by CTTI's Executive Committee

How do we effect widespread change?

CTTI's Approach

- 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