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

<table>
<thead>
<tr>
<th>Category</th>
<th># organizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic institutions</td>
<td>13</td>
</tr>
<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>
</tr>
<tr>
<td>Professional societies</td>
<td>6</td>
</tr>
<tr>
<td>Clinical research organizations</td>
<td>5</td>
</tr>
<tr>
<td>Device companies</td>
<td>4</td>
</tr>
<tr>
<td>Biotechnology companies</td>
<td>4</td>
</tr>
<tr>
<td>Clinical investigator groups</td>
<td>4</td>
</tr>
<tr>
<td>Trade organizations</td>
<td>3</td>
</tr>
<tr>
<td>Patient representatives/at-large</td>
<td>3</td>
</tr>
<tr>
<td>Private equity firm</td>
<td>1</td>
</tr>
<tr>
<td>Regulatory law firm</td>
<td>1</td>
</tr>
<tr>
<td>Institutional Review Board</td>
<td>1</td>
</tr>
<tr>
<td>Standard Setting Organization</td>
<td>1</td>
</tr>
</tbody>
</table>

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