Introduction to the Clinical Trials Transformation Initiative (CTTI)

April 25, 2012

Judith M. Kramer, MD, MS,
Associate Professor of Medicine, Duke University Medical Center
Executive Director, Clinical Trials Transformation Initiative
A public private partnership co-founded by FDA and Duke in late 2007

All stakeholders involved

Through a memorandum of understanding with FDA, Duke “hosts” the initiative

Mission: To identify practices that through broad adoption will increase the quality and efficiency of clinical trials
Finances

- Membership fees support infrastructure for CTTI and projects
  - Fees differ by membership category and financial resources of organizations [https://www.ctti-clinicaltrials.org/about/membership/membership-categories-and-fees](https://www.ctti-clinicaltrials.org/about/membership/membership-categories-and-fees)
  - No fee required for government or patient representatives
- Awarded an FDA Cooperative Agreement Sept 2009
  - Initial award and option to renew yearly for 4 additional years, depending on availability of funds
  - Further enables the conduct of projects
# CTTI Members

<table>
<thead>
<tr>
<th>Category</th>
<th># organizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic institutions</td>
<td>16</td>
</tr>
<tr>
<td>Pharmaceutical companies</td>
<td>9</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>Biotechnology companies</td>
<td>6</td>
</tr>
<tr>
<td>Clinical research organizations</td>
<td>5</td>
</tr>
<tr>
<td>Professional societies</td>
<td>4</td>
</tr>
<tr>
<td>Trade organizations</td>
<td>4</td>
</tr>
<tr>
<td>Clinical investigator groups</td>
<td>3</td>
</tr>
<tr>
<td>Device companies</td>
<td>3</td>
</tr>
<tr>
<td>Institutional Review Boards</td>
<td>2</td>
</tr>
<tr>
<td>Patient representatives</td>
<td>2</td>
</tr>
<tr>
<td>Private equity firm</td>
<td>1</td>
</tr>
<tr>
<td>Regulatory law firm</td>
<td>1</td>
</tr>
<tr>
<td>Standard Setting Organization</td>
<td>1</td>
</tr>
</tbody>
</table>

62 member organizations; 2 patient reps
How does CTTI propose to effect widespread change?

- Conduct projects to develop evidence for change
  - Evidence may generate recommendations for improvement and inform regulatory guidance
- Involve all sectors in selection, conduct, and interpretation of projects
- 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 the way trials are currently conducted
- Identify and shape potential transformational changes to the system
CTTI projects focused on incremental change

Completed projects

- Effective and efficient monitoring as a component of quality
- Improving unexpected SAE reporting to IND investigators

Current projects

- Use of central IRBs for multicenter clinical trials
- Site metrics for study start-up
- Workshops on “quality-by-design” in clinical trials
- IND safety assessment and communication
Benchmark of the clinical trials enterprise

- “Improving the public interface for use of aggregate data in ClinicalTrials.gov”
  - User-friendly version of CT.gov data structured to facilitate aggregate analyses (AACT)
    - Publicly available on CTTI website (https://ctti-clinicaltrials.org)
  - Detailed data dictionary and tips for analysts accompanies AACT
  - AACT will facilitate an annual review of the status of clinical trials in the United States
Identifying and shaping transformational change

- Predictions
  - Use of fully penetrated electronic health records to capture data for clinical trials
  - Broader application of informatics
  - Reusable community-based networks to conduct trials
  - Creative use of the Internet to facilitate enrollment and conduct trials
  - Greater use of personal health records
  - Use of smart phone technology in clinical trials
  - Greater engagement of the public

- New technology will require new business models; collaboration among sectors can best develop them
CTTI’s use of multi-sector, expert meetings

Premise:
- Multi-sector participation necessary to solve “systems” problems

Ground rules
- Engage in respectful dialogue
- Seek to understand the perspective of all sectors
- Propose solutions that address the concerns/risks to patients and to each sector