Introduction to the Clinical Trials Transformation Initiative (CTTI)

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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**
  - **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

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Category	# organizations
Academic institutions	16
Pharmaceutical companies	9
US Government Members & Liaisons	7 (FDA [OC,CDER, CBER, CDRH] AHRQ, CDC, CMS, NIH, OHRP, VA)
Biotechnology companies	6
Clinical research organizations	5
Professional societies	4
Trade organizations	4
Clinical investigator groups	3
Device companies	3
Institutional Review Boards	2
Patient representatives	2
Private equity firm	1
Regulatory law firm	1
Standard Setting Organization	1

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**