Clinical Trials Transformation Initiative (CTTI)

Robert Califf, MD
Bray Patrick-Lake
Clinical Trial 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
CTTI overview

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

Strategy
Seek incremental improvements to current system
Identify and shape potential transformational changes to the system
CTTI organizational approach

- Raise awareness of important issues and the need for change
- Convene and engage diverse stakeholders
- Open discussion of critical research issues
- Inform industry and regulators on improved approaches
- Transform clinical trial enterprise through adoption and implementation of our recommendations
CTTI project methodology

1. Identify Research Impediments
2. Gather Evidence
   - Surveys
   - Literature review
   - Data analysis
   - Focus groups
3. Build Consensus
   - Workshops
   - Expert meetings
4. Formulate Recommendations
   - Workshops
   - Presentations
   - Publications/Posters
5. Promote implementation
   - Workshops
   - Pilot studies
   - Stakeholder engagement
CTTI conducted exploratory interviews in July 2012 with key thought leaders in patient advocacy to gain an understanding of the patient perspective on clinical trials.

Issues were raised around:

- Informed consent
- Inefficiencies in the system such as multiple IRB reviews
- Waste of patient time and participation
- Lack of access to research findings
- Lack of meaningful inclusion of patient advocates in the clinical trial enterprise from study design to dissemination of research results
Key accomplishments

• Generated evidence and formulated implementable recommendations
• Created an inclusive forum that is influencing policy
• Increased patients’ voice to improve clinical research
• Raised questions about the clinical trials enterprise portfolio
Future milestones

• Present recommendations to facilitate the use of Central IRB in multi-center studies
• Present recommendations to improve safety reporting
• Strengthen collective voice of patients in clinical research
• Assess feasibility of using distributed datasets in clinical research
Financing

• Financial resources from public and private sources
  • Annual membership fees
    • CTTI infrastructure expenses and projects
  • Cooperative agreement from the FDA
    • Some support for all current projects
• In-kind contributions from FDA and member organizations on projects
CTTI Executive Committee

Co-chairs
Robert Califf (Duke)  Rachel Sherman (FDA/CDER)

Members
Hans-Georg Eichler (EMA)  Freda Lewis-Hall (Pfizer)
Michael Lauer (NIH/NHLBI)  Elliott Levy (CTTI SC chair, BMS)
Briggs Morrison (AstraZeneca)  Garry Neil (Apple Tree Partners)
Jean Rouleau (Montreal Heart Institute)  Robert Temple (FDA/CDER)
Tom Walley (NIHR)  Bram Zuckerman (FDA/CDRH)
## CTTI members

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<thead>
<tr>
<th>Category</th>
<th># Organizations</th>
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<tr>
<td>Academic institutions</td>
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<td>Pharmaceutical and biotech companies</td>
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<td>Device companies</td>
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Summary

Improving clinical trials
Engaging all stakeholders
Starting transformational work

Looking forward to putting ourselves out of business and having an optimally efficient high quality clinical trial enterprise
Thank You

• Want to be part of the solution?
  • Engage
  • Implement
  • Join

• www.ctti-clincialtrials.org