CTTI History and Methodology
ABDD Program History

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Clinical trials in crisis

The changing structure of industry-sponsored clinical research: pioneering data sharing and transparency.

Kuntz RE.
Addressing This Need

To identify and promote practices that will increase the quality and efficiency of clinical trials

Public-Private Partnership
Co-Founded by FDA and Duke
involving all stakeholders
70+ members
CTTI Membership
How CTTI Works

- Engage & value all stakeholders equally
- Understand incentives to maintain non-value added activities and have solutions that are mindful of those incentives
- Plant the seeds for change throughout all phases of a project
- Develop actionable, evidence-based, consensus driven recommendations
- Create and share knowledge, tools & resources to facilitate change that improves clinical trials
CTTI projects focus on streamlining and accelerating clinical trials, while ensuring the highest standards of quality and human subjects protection. We provide actionable, evidence-based, consensus-driven recommendations designed to:

- Accelerate study start-up times & streamline protocols
- Leverage new technologies to improve efficiency of clinical trials
- Enhance the quality of clinical trials without adding undue burden
- Identify streamlined strategies to meet regulatory requirements
CTTI Methodology

1. **State Problem**
2. **Gather Evidence**
   - Literature Reviews, Multi-stakeholder Meetings, Surveys, Interviews
3. **Identify Gaps/Barrriers**
   - Issue Statement, Project Plan
4. **Find Solution**
   - Team Meetings, Multi-stakeholder Meetings
5. **Refine Ideas**
6. **Analyze & Interpret Findings**
   - Team Meetings, Multi-stakeholder Meetings
7. **Develop Recommendations/Tools**
   - Team Meetings, Multi-stakeholder Meetings
8. **Disseminate & Implement**
   - Workshops, Pilot Studies, Measure Impact
## Portfolio of CTTI Projects

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CTTI Program: Antibacterial Drug Development (ABDD)

Background:

- Prevalence of antibacterial resistance continues to rise
- Pressing need for drug development in this area
- Resistant infections are a burden to society with serious consequences of morbidity and mortality and healthcare costs
- In 2012, FDA established a task force and engaged CTTI and other organizations to tackle this issue on several fronts
ABDD Program and Projects

- Antibacterial Drug Development (ABDD)
  - Unmet Need in multi resistant bacterial infections
  - Hospital Acquired and Ventilator Associated Bacterial Pneumonia (HABP/VABP)
    - Protocol elements
    - Data collection
    - Site Networks
    - Design Challenges & Barriers
    - Parent/Caregiver Perceptions
  - Pediatric trials
  - Provider Interviews
  - Expert Meetings and Think Tanks

Next step: Demonstration HABP/VABP pilot study
Evidence guides the journey to solutions

We use quantitative & qualitative research methods, selecting those best aligned with each project’s objectives, to:

- Identify/describe “what is going on” to gain a better understanding of a particular phenomenon
- Move beyond individual views to a more complete and objective understanding of the disincentives and motivators for change

Equipped with data, we then challenge assumptions, identify roadblocks, build tools and develop recommendations to change the way people think about and conduct clinical trials.
Work-Stream 2 Team

Team Leaders:
- Thomas Holland (Duke)
- Stephen Mikita (Patient Rep)
- Rose Tiernan (FDA)
- Joseph Toerner (FDA)

Team Members:
- Deborah Collyar (PAIR)
- Carrie Dombeck (Duke)
- Helen Donnelly (Northwestern)
- Jeff Loutit (The Medicines Co.)
- Jonas Santiago (FDA)
- Pamela Tenaerts (CTTI)
- Edward Cox (FDA)
- Kevin Weinfurt (Duke)
- Vance Fowler (Duke)
- Lisa LaVange (FDA)
Thank you.

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