

The Clinical Trials Transformation Initiative: Leveraging the Power of a Public-Private Partnership

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October 18, 2016



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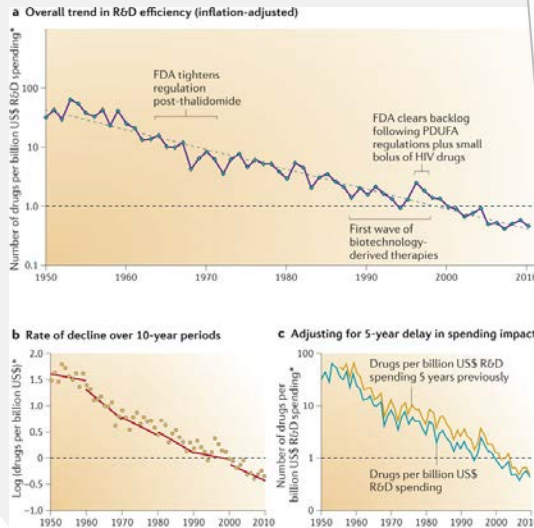
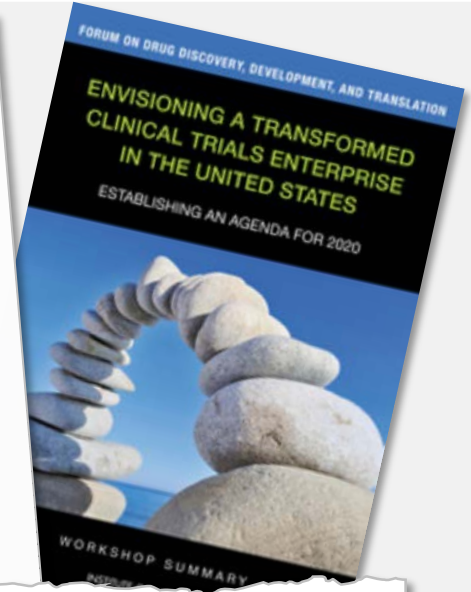
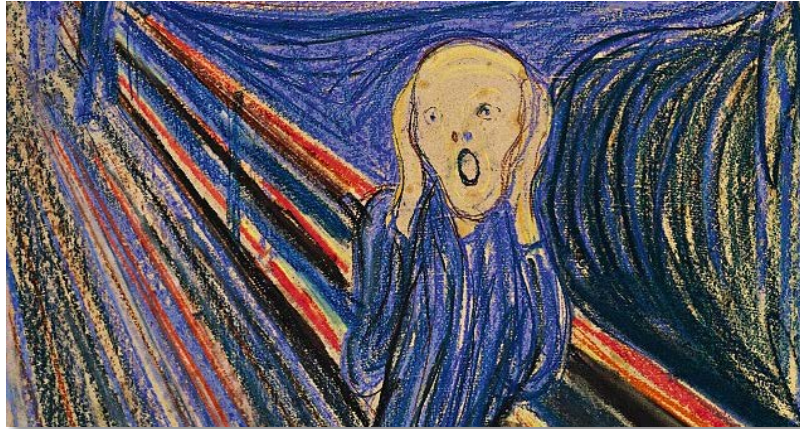


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The presenter is an Employee of Duke University. Salary support comes from pooled membership fees of the Clinical Trials Transformation Initiative and from FDA Cooperative agreement.

Clinical trials in crisis



[Ann Intern Med, 2013 Jun 18;158\(12\):914-5. doi: 10.7326/0003-4819-158-12-201306180-00011.](#)

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

Kuntz, R

BROOKINGS

RESEARCH ▾

EVENTS

EXPERTS

ABOUT ▾

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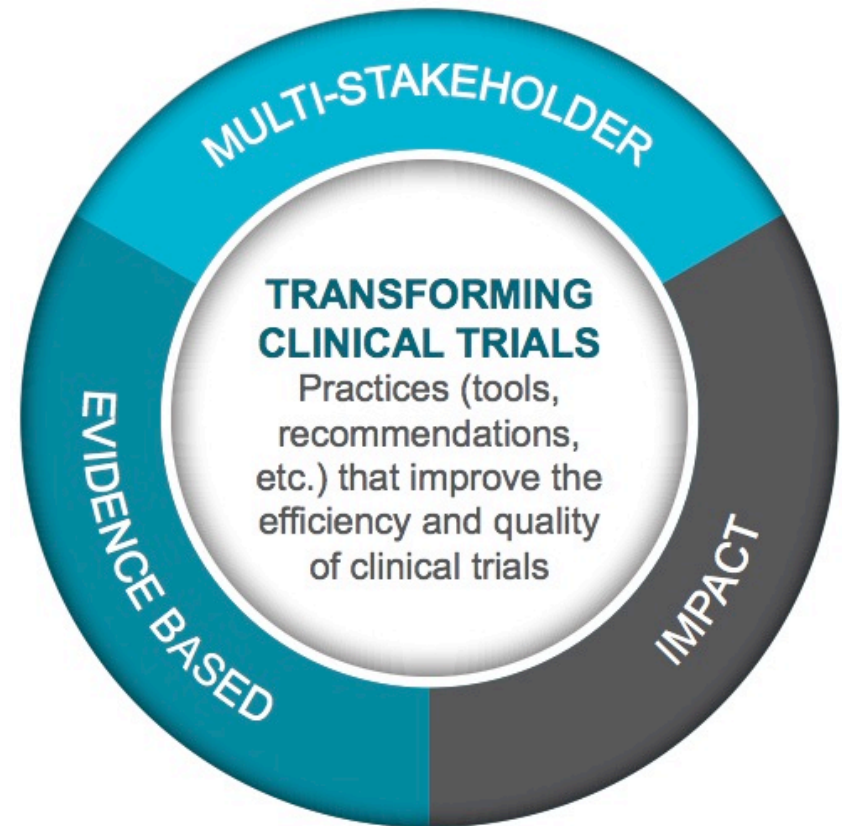
PAST EVENT

Biomedical Innovation: Identifying Challenges and Prioritizing Needs

Addressing This Need



Public-Private Partnership
co-founded by Duke University & FDA
involves all stakeholders
80+ members



CTTI Strategic Plan

MISSION STATEMENT

To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials

GOALS

Create recs & tools

Make data publicly available

Communicate broadly

Demonstrate impact

Characterize clinical trial landscape

AREAS OF STRATEGIC FOCUS

Systematic evidence generation

Patients as equal partners

Clinical trials designed with a focus on quality & efficiency

Trials addressing emerging public health concerns

Safe & ethical trials that are streamlined

CTTI organization

Executive Committee

- Oversight and strategic direction

Steering Committee

- Input into strategy and project selection
- Conducts projects and develops strategies for implementation

Staff

- Project support and organization in pursuit of mission

CTTI Membership



*Version: September 29, 2016



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 Methodology



Project Portfolio Sep 2016

| Areas of Strategic Focus | Systematic Approach to evidence generation including use of non-traditional CT data sources and technical innovations | Patients as equal partners across the R&D continuum | CTs designed with a focus on efficiency and quality | Trials that address emerging public health concerns | Safe and ethical trials that are streamlined |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Project Recommendations/Findings Complete | Large Simple Trials | | GCP Training Monitoring Recruitment Site Metrics QbD | Opioid ABDD HABP/VABP | Central IRB (2) DMCs Informed Consent Safety Reporting (3) |
| Active Projects | Registries State of Clinical Trials MCT <ul style="list-style-type: none"> • Leg & reg • Devices • Novel endpoints • Stakeholders | PG&CT | Investigator Turnover GCP Follow On | ABDD <ul style="list-style-type: none"> • Unmet need • Peds • Pilot studies | |
| Completed Collaborations | Uses of Electronic Data | | CV Endpoints Investigator Training Course | | |
| Active collaborations | Uses of Electronic Data Application | | | ABDD PTN | |

CTTI Recommendations & Tools

- Streamline *HABP/VABP Trials*
- Organize *DMCs* to ensure accumulating data do not suggest undue harm to patients
- Move *Recruitment* planning upstream to reduce barriers to participation: Create Recrutable protocols
- Develop a better *IND Safety Reporting* system (3)
- Perform higher quality *Informed Consent* process
- Involve *Patient Groups* as equal partners *in Clinical Trials: Engage Early Engage Often*
- Apply *Quality by Design (QbD)* principles to create better protocols: Just think!
- Improve ethics review process via use of *Central IRB* (2)
- Reduce inefficiencies of investigator *GCP Training*

Real-World Impact

▶ WITHIN ORGANIZATIONS

- UCB adopted Patient Group in Clinical Trials (PGCT) project framework and recommendations in their patient centricity program
- Australian Clinical Trials Alliance (ACTA) using DMC project guidelines as best practices for their clinical trials
- Central IRB project results considered in development of NIH funded neuro-cardio emergency treatment network

▶ AT THE POLICY LEVEL

- NIH draft Policy on single IRB of record
- FDA's newest draft guidance on IND safety reporting
- FDA Guidance and an EMA Reflection Paper (QbD)
- U.S. House and Senate efforts on medical innovation



Managing a Public-Private Partnership: Lessons Learned

- Value all perspectives
- Optimize team performance
- Foster member engagement
- Identify opportunities to create unique contributions
- Evolve

Value All Perspectives

- Open discussion is fostered by respect and collaboration with diverse members of the team
 - Choose collaboration and cooperation
 - Respect and listen to hear all perspectives
 - Empower solutions; hear feedback, brainstorm
- Value and design for actionable solutions that address multiple stakeholder concerns
- Recognize that there will be setbacks and disagreement along the way

Value All Perspectives

Patient Engagement 1.0

- Patient advocates on EC, SC, and project teams
- PLC established Jan 2013
 - Increased patient representative participation
 - Patient reps began serving as team leads
 - Fast-tracked PG&CT project

Normed inclusion of patients as equal partners into every aspect of clinical trial

Patient Engagement 2.0

- PLC full integration into the Steering Committee with proportional representation
- Annual patient stipend

Value All Perspectives

CTTI Team composition

- Seek a well-balanced representation of members and leads that have a significant expertise in the issue and interest in addressing the problem/issue
- Identify stakeholder groups to be represented as both team leaders members
- Composition should be fit for purpose and should include change agent stakeholder groups as appropriate

Optimize Team Performance

- Provide orientation to CTTI and how projects work
- Set expectations early
- Anticipate and address team conflict right away
- Ensure team members feel that their concerns are heard and validated
- Meet people where they are
- Re-visit the project plan, workflow, and timeline with the team frequently
- Create balance: engaging the team without creating a significant work load burden for busy volunteers

Foster Member Engagement

Member Responsibilities

- ▶ Actively participate in activities and discussions
- ▶ Seek opportunities to advance the mission
- ▶ Engage in constructive conversations with a variety of stakeholders with divergent views on issues
- ▶ Promote adoption of recommendations within the clinical research enterprise
- ▶ Keep abreast of and communicate with parallel initiatives
- ▶ Contribute an annual membership fee to support activities and projects

Foster Member Engagement

Provide multiple opportunities to engage

- ▶ Participate on project team
- ▶ Contribute to evidence generation
- ▶ Engage in consensus building around potential solutions
- ▶ Provide input – issues to address, project plan, proposed recommendations and tools
- ▶ Consider opportunities to adopt recommendations
- ▶ Share experiences
- ▶ Encourage others
- ▶ Provide feedback

Foster Member Engagement

Communications and Participation

Meetings

- Face-to-face meetings
- Webinars

Information to Members

- CTTI website and social media
- SC newsletters and other emails
- Advance notice of major announcements
- Member visits (opportunity for feedback as well)

Opportunities to Participate

- Ad-hoc committee or workgroup
- Project team and activities
- SC liaison to EC

Identify opportunities to create unique contributions

- Communicate and collaborate with related organizations
- Consider how work of the organization fits in the larger Clinical Trials Enterprise and mission
- Consider stakeholder priorities
- Example: CTTI concept development process

Evolve!

CTTI Mission

2016

To develop and drive adoption of practices that will increase...

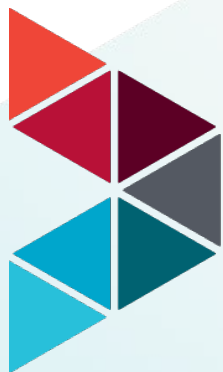
2013

To identify and promote practices that will increase...

2008

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

Thank you.



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