Introduction to the Clinical Trials Transformation Initiative

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Senior Clinical Project Manager, CTTI

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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

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<th>ACI Clinical</th>
<th>Alexion</th>
<th>Amgen</th>
<th>AstraZeneca</th>
<th>Bard</th>
<th>Celgene</th>
<th>Genentech</th>
<th>GlaxoSmithKline</th>
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<th>Medidata</th>
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<th>Merck</th>
<th>Pfizer</th>
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<th>St. Jude Medical</th>
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<td>Foundation for Prader-Willi Research</td>
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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

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

<table>
<thead>
<tr>
<th>Completed projects</th>
<th>Investigational plan</th>
<th>Study start up</th>
<th>Study conduct</th>
<th>Analysis and dissemination</th>
<th>Specialty areas</th>
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<tbody>
<tr>
<td></td>
<td>• Large simple trials&lt;br&gt;• Uses of electronic data</td>
<td>• Central IRB&lt;br&gt;• Site metrics</td>
<td>• Adverse event reporting&lt;br&gt;• IND safety&lt;br&gt;• Monitoring</td>
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<td>• Long-term opioid data</td>
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<tr>
<th>Current projects</th>
<th>Investigational plan</th>
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<td>• Patient groups and clinical trials&lt;br&gt;• Pregnancy testing&lt;br&gt;• QbD&lt;br&gt;<strong>Trials based on registries</strong>&lt;br&gt;• Remote Clinical Trials</td>
<td>• Central IRB advancement&lt;br&gt;• GCP training&lt;br&gt;• Informed consent&lt;br&gt;• Investigator turnover&lt;br&gt;• Recruitment and retention</td>
<td>• Safety case studies&lt;br&gt;• IND safety advancement</td>
<td>• State of clinical trials&lt;br&gt;• DMCs</td>
<td>• Streamlining HABP/VABP trials&lt;br&gt;• Pediatric Antibiotic trials&lt;br&gt;• Unmet need in Antibiotic development&lt;br&gt;• HABP/VABP pilot study</td>
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Registry Trials Project Team

**Team Leaders:**
- John Laschinger (FDA/CDRH)
- Theodore Lystig (Medtronic)
- James Tcheng (Duke)

**CTTI Project Managers:**
- Steve Mikita (Patient Advocate)
- Sara Calvert (CTTI)

**Team Members:**
- Lauren McLaughlin (MJFF)
- Chunrong Cheng (FDA/CBER)
- Alan Clucas (Galderma)
- Christopher Dowd (CFF)
- E. Dawn Flick (Celgene)
- Nicolle Gatto (Pfizer)
- Kristen Miller (FDA/CDER)
- Daniel Mines (Merck)
- Jules Mitchel (Target Health)
- Magnus Petersson (AstraZeneca)
- Sunil Rao (Duke)
- Arlene Swern (Celgene)
- Emily Zeitler (Duke)
Thank you.

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