The Clinical Trials Transformation Initiative – Who We Are

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CTTI Strengths

Public-Private Partnership
Co-founded by Duke University & FDA
Involves all stakeholders
80+ members

MISSION: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials
CTTI Methodology

State Problem
- Issue Statement, Project Plan

Gather Evidence
- Literature Reviews, Multi-stakeholder Meetings, Surveys, Interviews

Find Solution
- Team Meetings, Multi-stakeholder Meetings

Refine Ideas
- Team Meetings, Multi-stakeholder Meetings

Action
- Workshops, Pilot Studies, Measure Impact

IDENTIFY RESEARCH IMPEDIMENTs

IDENTIFY GAPS/BARRIERS

ANALYZE AND INTERPRET FINDINGS

DEVELOP RECOMMENDATIONS/TOOLS

DISSEMINATE & DRIVE ADOPTION
## Project Portfolio

*May 2017*

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<tr>
<th>Areas of Strategic Focus:</th>
<th>SYSTEMATIC EVIDENCE GENERATION</th>
<th>PATIENTS AS EQUAL PARTNERS</th>
<th>EFFICIENT &amp; QUALITY TRIALS</th>
<th>PUBLIC HEALTH CONCERN</th>
<th>SAFE &amp; ETHICAL TRIALS</th>
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<tr>
<td>Active Projects:</td>
<td>MCT Legal &amp; Regulatory</td>
<td>Patient Groups &amp; Clinical Trials</td>
<td>Investigator Community Investigator Qualification</td>
<td>ABDD HABP/VABP Studies</td>
<td>Pregnancy Testing</td>
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<td>MCT Mobile Devices</td>
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<td>MCT Novel Endpoints</td>
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<td>MCT Stakeholder Perceptions</td>
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<td>State of Clinical Trials</td>
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<td>Complete Projects:</td>
<td>Large Simple Trials</td>
<td>GCP Training Monitoring Quality by Design Recruitment Site Metrics</td>
<td>ABDD Peds Trials ABDD Streamlining HABP/VABP Trials ABDD Unmet Need Long-Term Opioid Data</td>
<td>Central IRB Central IRB Advancement DMCs Informed Consent IND Safety IND Safety Advancement SAE Reporting</td>
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Why Mobile?

Mobile technology has been used in a variety of ways, but it has yet to be widely incorporated into clinical trials for regulatory submission.

Mobile technologies offer the potential to increase the quality and efficiency of clinical trials:
- Reducing the burden of participation for research volunteers
- Creating opportunities to develop novel endpoints

*Mobile Technology is defined as encompassing mobile applications, telemedicine, and remote sensor devices.*
CTTI Mobile Clinical Trials (MCT) Program

PURPOSE:

Develop evidence-based recommendations that affect the widespread adoption and use of mobile technology in clinical trials

ANTICIPATED IMPACT:

Increase the number of clinical trials appropriately leveraging mobile technology

4 PROJECTS

- Legal & Regulatory Issues
- Novel Endpoints
- Mobile Devices
- Stakeholder Perceptions

*Scope: FDA-regulated clinical trials after the time of initial research volunteer consent*
Creating a Comprehensive Set of Tools

Issue recommendations related to

- Overcoming barriers to the use of mobile technology in clinical trials as perceived by key stakeholders
- Legal and regulatory barriers that inhibit widespread use of mobile technology in clinical trials
- Pathways by which to developing novel endpoints, generated using mobile technology, for use in clinical trials
- The scientific and technological challenges inhibiting the widespread use of mobile devices in clinical trials
MCT Novel Endpoints Products

Recommendations

Tools

- Novel endpoint development benefit framework
- Selection tool to support decisions between viable novel endpoints for development
- Guide to interacting with FDA regarding novel endpoint development
- Flowchart of steps for novel endpoint development
- Detailed description of steps for novel endpoint development, with suggested approaches and considerations
- Four use cases to provide tangible examples of novel endpoint development
  - Parkinson’s disease, diabetes, heart failure, Duchenne’s muscular dystrophy
Accessing CTTI Materials

- Visit https://www.ctti-clinicaltrials.org/projects/novel-endpoints to access and download the full suite of CTTI’s MCT Novel Endpoints Recommendations and Tools

- Sign up for CTTI updates and follow us on social media to get the latest on new findings, recommendations, and tools released from all of the projects in the MCT Program
Some Rules of Engagement

- Everyone participate, no one dominate
- Disagree without being disagreeable
- Stay open to new ways of doing things
- Respect each others’ thinking and value their contributions
- Articulate hidden assumptions
- Listen for the future to emerge
THANK YOU.