Clinical Trials Transformation Initiative

- Established by Duke University and the FDA as a public-private partnership in 2007
- All stakeholders working together to improve the clinical trials enterprise

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

Vision
A high quality clinical trial system that is patient-centered and efficient, enabling reliable and timely access to evidence-based prevention and treatment options

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Strategy

- Identify and shape potential **transformational** changes to the system
- Seek **incremental** improvements to current system
- Consider **portfolio** improvements of clinical trials being done relative to public health needs

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CTTI Project Roster 2014

Incremental Improvements
- Central IRB
- IND Safety
- Monitoring
- SAE Reporting
- Central IRB Advancement
- GCP Training
- Informed Consent
- Large Simple Trials
- Patient Groups & Clinical Trials
- Pregnancy Testing
- QbD & QRM
- Recruitment & Retention
- Site Metrics
- Data Monitoring Committees
- Site Performance & Quality

Transformational Improvements
- Uses of Electronic Data
- Trials Using Data Registries

Portfolio Improvements
- Antibacterial Development
- Long-Term Opioid Data
- State of Clinical Trials

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Methodology

Identify Research Impediments

Gather Evidence
- Data Analysis
- Focus Groups
- Surveys
- Literature Reviews

Build Consensus
- Workshops
- Expert Meetings

Formulate Recommendations
- Workshops
- Think Tanks
- Team Leader Discussions
- Working Group Discussions

Disseminate Results
- Publications
- Presentations
- Posters

Promote Implementation
- Workshops
- Pilot Studies
- Stakeholder Engagement

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Quality by Design (QbD) & Quality Risk Management (QRM)

<table>
<thead>
<tr>
<th>Monitoring Recommendations</th>
<th>Adoption</th>
<th>Anticipated Impact</th>
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<tr>
<td>Quality needs to be built into the design and conduct of trials</td>
<td>QbD principles document</td>
<td>Clinical trials will be more streamlined, fit for purpose and quality driven focusing on the absence of errors that matter</td>
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<td>Monitoring approach for a given clinical trial should be tailored to the needs of that trial</td>
<td>Workshops to teach QbD and QRM and allow stakeholders to practice using the principles document</td>
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Adoption:
- QbD principles document
- Workshops to teach QbD and QRM and allow stakeholders to practice using the principles document
- Anecdotes that industry is adopting

Anticipated Impact:
Clinical trials will be more streamlined, fit for purpose and quality driven focusing on the absence of errors that matter
Team Leaders

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Special thanks to the Expert Working Group

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