Clinical Trials Transformation Initiative (CTTI)
- A public private partnership co-founded by Duke and FDA in late 2007
- All stakeholders involved
- To identify and promote practices that will increase the quality and efficiency of clinical trials
# Portfolio review

<table>
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<tr>
<th>Complete</th>
<th>Safety</th>
<th>Quality</th>
<th>Start-up</th>
<th>Design</th>
<th>Other</th>
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<td></td>
<td>SAE reporting</td>
<td>Monitoring</td>
<td>C IRB Site Metrics</td>
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<td>Current</td>
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<td>QbD/QRM workshops</td>
<td></td>
<td>LST Pregnancy ABDD</td>
<td>CT.gov ABDD Mini Sentinel HAP/VAP pilot</td>
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<td>CIRB f/o Inf. Consent GCP Training Recruitment /retention</td>
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Project Methodology

1. Identify Research Impediments
2. Gather Evidence
   - Surveys
   - Literature review
   - Data analysis
   - Focus groups
   - Interviews
3. Analyze data Consensus
   - Workshops
   - Expert meetings
4. Formulate Recommendations
   - Workshops
   - Presentations
   - Publications
   - Posters
5. Promote implementation
   - Continuation projects
   - Workshops
   - Pilot studies
   - Stakeholder engagement
Key Accomplishments

• Generated evidence and formulated implementable recommendations
• Created an inclusive forum that is influencing policy
• Increased patients’ voice to improve clinical research
• Raised questions about the portfolio of clinical trials as it relates to public health needs
“Because of the broad array of engaged stakeholders, CTTI is in a unique position to drive major changes in the clinical trial system in the midst of massive global reforms.”

Rachel Sherman, M.D.,
Director for the Office of Medical Policy at the FDA’s CDER
Co-chair of the CTTI Executive Committee