Clinical Trials Transformation Initiative (CTTI)
The Clinical Trials Transformation Initiative is hosting this meeting to facilitate a broad scientific discussion about optimal ways to generate additional evidence to help inform the safe and effective use of extended-release and long-acting opioid analgesics for chronic non-cancer pain.
Housekeeping

- Meals – Elm 1 & 2, Breaks – in foyer
- Parking vouchers – see registration desk
- Sessions are being recorded
- Teleconference attendees
- Wireless log on and password on tables
- Materials provided: agenda, participant list, efficacy protocol synopsis
- Please state name and organization prior to posing question/comment
How to use the push to talk microphones

- Push and release the middle white button
  - Please do not hold down the button for an extended time, this will cause the microphones to reset.
- Only push the microphone button when ready to speak.
  - Do not use the button/light to be called upon, only 4 can be activated at 1 time.
- 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>
<thead>
<tr>
<th></th>
<th>Safety</th>
<th>Quality</th>
<th>Start-up</th>
<th>Design</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete</td>
<td>SAE reporting</td>
<td>Monitoring</td>
<td>Central IRB Site Metrics</td>
<td></td>
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<tr>
<td>Current</td>
<td>IND safety SAE case studies</td>
<td>QbD/QRM workshops</td>
<td></td>
<td>LST Pregnancy Testing ABDD</td>
<td>ClinicalTrials.gov ABDD Mini Sentinel HAP/VAP pilot Opioids</td>
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<td>2013</td>
<td></td>
<td>Central IRB 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
   - 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