GCP training Expert Meeting

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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
Methodology

1. Identify Research Impediments
2. Gather Evidence
   - Data Analysis
   - Focus Groups
   - Surveys
   - Literature Reviews
3. Build Consensus
   - Workshops
   - Expert Meetings
4. Formulate Recommendations
   - Workshops
   - Think Tanks
   - Team Leader Discussions
   - Working Group Discussions
5. Disseminate Results
   - Publications
   - Presentations
   - Posters
6. Promote Implementation
   - Workshops
   - Pilot Studies
   - Stakeholder Engagement

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## GCP Training Project

<table>
<thead>
<tr>
<th>Objective</th>
<th>Deliverables</th>
<th>Anticipated Impact</th>
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<tr>
<td>• To improve the efficiency of GCP training imparted to investigators and site personnel conducting clinical trials</td>
<td>• Summary of current practices and issues related to GCP training</td>
<td>• Improving the efficiency and reducing the cost of clinical trials by streamlining the GCP training requirements</td>
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<td>• Recommendations on key elements of GCP training content and frequency</td>
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<td>• Recommendations to facilitate a more efficient GCP training process</td>
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GCP Training Working Group

- Jamie Arango (CITI)
- Tina Chuck (North Shore-LIJ Health System)
- Susan Ellenberg, (U Penn)
- Bridget Foltz, (FDA-OGCP)
- Colleen Gorman (Pfizer)
- Heidi Hinrichs (St Jude)
- Susan McHale (AZ)
- Stephanie Shapley, (FDA-OMP)
- Jonathan Seltzer, (ACRP & ACI)

Project Manager: Kunal Merchant (CTTI)

Literature review conducted by:
Evidence Synthesis Group, Duke Clinical Research Institute

- Megan Chobot
- Amy Kendrick
- Gillian Schmidler
- Liz Wing

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