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
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
Methodology

- Identify Research Impediments
  - Gather Evidence
  - Build Consensus
  - Formulate Recommendations
  - Disseminate Results
  - Promote Implementation

- Data Analysis
- Focus Groups
- Surveys
- Literature Reviews
- Workshops
- Expert Meetings
- Team Leader Discussions
- Working Group Discussions
- Publications
- Presentations
- Posters
- Workshops
- Pilot Studies
- Stakeholder Engagement
# GCP Training Project

## Objective
- To improve the efficiency of GCP training imparted to investigators and site personnel conducting clinical trials

## Deliverables
- Summary of current practices and issues related to GCP training
- Recommendations on key elements of GCP training content and frequency
- Recommendations to facilitate a more efficient GCP training process

## Anticipated Impact
- Improving the efficiency and reducing the cost of clinical trials by streamlining the GCP training requirements
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
THANK YOU.

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