The CTTI GCP Training Project and Literature Review Findings

Susan McHale
Sr. Director Clinical Development
AstraZeneca

January 31st, 2014
GCP Training: Introduction

- Good Clinical Practice (GCP) refers to the regulations, guidelines, and local laws that relate to conducting clinical trials.
- The goal of GCP is to protect the rights and safety of study participants, and the quality of study results.
- All investigators and site personnel involved in clinical research complete GCP training to promote GCP and meet regulatory expectations.
- Investigators who participate in clinical trials with more than one sponsor often complete GCP training multiple times due to sponsors’ practices to comply with regulations.
GCP Training: Project Overview

- **Project goals:**
  - Gather information about current practices in GCP training with a US focus
  - Facilitate discussion of strategies to reduce the burden of redundant GCP training
  - Develop recommendations to facilitate a more efficient GCP training process

- **Project deliverables:**
  - Summary of current practices and issues related to GCP training
  - Recommendations on key elements of GCP training content, frequency and format of GCP training

- **Anticipated Impact:**
  - Improving the efficiency and reducing the cost of clinical trials by streamlining the GCP training requirements
GCP Training Project Conduct

Data Collection:
- Literature reviews
- Review of some common training programs within academic, public, and private sectors
- Collaboration with other initiatives with similar goals

Working Group Meetings:
- A multi-stakeholder group of CTTI members share and discuss available information
- Identify impediments/issues with current practices regarding GCP training
- Summarize findings
- Discuss solutions
- Draft recommendations

Experts Meeting:
- Facilitate an informed discussion of the current practices and challenges with a group of experts who impart, receive and benefit from GCP training.
- Top issues and solutions to these will be discussed in moderated sessions

Deliverable: Summary of current practices and issues, and a recommendation on the essential GCP elements, including future approaches for more efficient GCP training (Such as frequency, testing for competency, and format of training)
Literature Review: Methods

2961 citations identified

MEDLINE search criteria
Inclusion:
• U.S. focused
• clinical research
• GCP training
• English language
• Published ≤10 years

Exclusion:
• only HIPAA related
• Building clinician-researcher workforce

258 full text screened

Refined in consultation with the GCP training working group:
• article type
• training audience
• frequency of training
• proof of training
• GCP elements covered in training

31 passed full text screen

Further refined based on specific GCP training for clinical research within the US

Classification
1. Qualitative and Survey
   • Summaries and qualitative reviews
2. Investigator and Site Staff Training
   • Recommendations
3. Research Networks
   • Implementing GCP training across a research network
4. Policy and Guidance
   • Interpretation of regulations
5. Online Training Modules
   • Software developed to implement GCP training
The following points briefly summarize our findings:

- GCP training is an important way to safeguard clinical research integrity.
- In the past 10 years, a variety of training programs have been developed.
- The heterogeneity in the content and training expectations of programs may have introduced inefficiencies in initiating clinical research.
- Clarifying GCP training recommendations and increased guidance will help to streamline GCP training practices.
- Online GCP training has the benefits of flexibility and convenience.
Literature Review: Results

- **GCP training usually includes the following components:**
  - IRB/IEC oversight
  - Investigator responsibilities
  - Staff training and delegation of responsibilities
  - Protocol adherence
  - Data management
  - Informed consent
  - Vulnerable populations
  - Serious adverse event and adverse event reporting
  - Monitoring

- **Limited information exists regarding the optimum frequency for GCP training and demonstration of competency**
Summary of Working Group Review

A sampling of GCP training programs that appear to represent academic, public, and private sectors were chosen

- **The content of training programs**
  - All programs included elements of GCP based on ICH E6
  - Most programs contained additional elements such as: Operational and regulatory compliance with GCP for investigational drugs and devices, OHRP regulations and additional aspects of human subject research

- **The competency requirement of training programs**
  - End of course quiz, with passing grade, certification or transcript, qualification test to opt out of training.
  - Some programs are tiered and/or differentiated based on job function

- **The frequency of training**
  - Variable, typically ranged from 1-3 years
Working Group Recommendations

Key elements of GCP Training

► 13 elements from the investigator section of ICH E6*

Additional elements for consideration when applicable, for:

► Investigator-initiated studies
► Considerations for social and behavioral studies
► Additional ethics and/or human subject protection issues

* The Working Group reviewed the ICH E6 GCP Guidance and has identified 13 key elements to include in a GCP training program. Except for a few modifications, these 13 key elements were also referenced by TransCelerate’s site qualification and training initiative.
Working group Recommendations:

**Frequency and Competency of GCP Training**
- Tiered (role-based) training
- Minimum of every 3 years
- End-of-training quiz with minimum passing score
- Proficiency testing (i.e., “testing out of training”)
  - The working group is of the opinion that the frequency of training will dictate if a testing out option is needed

**Format of GCP Training**
- Preference is to not to make any specific recommendations, allow flexibility to the administering institution to fulfill their specific needs.
  - The working group is of the opinion that online training may be the best format
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

www.ctti-clinicaltrials.org
THANK YOU