CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

GCP Training Expert Meeting

The CTTI GCP Training Project and Literature Review Findings

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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

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

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

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

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

Literature Review: Results

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 raged 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

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THANK YOU

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