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GCP Training Expert Meeting

The CTTI GCP Training Project and Literature Review Findings

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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

258 full text
screened

31 passed full
text screen

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

▶ THANK YOU



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