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

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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**

**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

**MEDLINE search criteria**

**Inclusion:**
- U.S. focused
- Clinical research
- GCP training
- English language
- Published ≤10 years

**Exclusion:**
- Only HIPAA related
- Building clinician-researcher workforce

2961 citations identified
258 full text screened
31 passed full text screen

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

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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

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THANK YOU