CLINICAL TRIALS TRANSFORMATION INITIATIVE

Good Clinical Practice (GCP) Training: Identifying Key Elements and Strategies for Increasing Training Efficiency

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ABSTRACT

Objective:

To develop recommendations to ensure knowledge of GCP while facilitating a more efficient GCP training process.

Method:

The Clinical Trials Transformation Initiative (CTTI) convened a multidisciplinary working group involving partners from academia, industry, and government to develop recommendations for streamlining current GCP training efforts.

Results:

The working group reviewed the current literature and the content of public and private initiatives related to GCP training, and drafted recommendations to define the minimal key elements required for GCP training. Draft recommendations were presented to a broader group of experts from the clinical research enterprise to foster discussion on the issues, and seek consensus on proposed solutions before finalization.

The recommendations that define strategies to providing more-efficient training, (including a frequency for repeat training), the format to deliver the training, and approaches for competency assessment after the training is complete will be discussed.

Additional strategies on designing training programs that integrate GCP elements into clinical research will also be discussed.

Conclusion:

The recommendations for GCP training requirements generated through this effort may encourage organizations to adopt similar training criteria, thereby allowing cross-acceptance of training. This may serve to reduce the burden of repeated training, and improve the efficiency of clinical trials.

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INTRODUCTION

- 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.
- To meet regulatory expectations and to foster GCP, sponsors of clinical trials generally require that all investigators and site personnel involved in clinical research complete GCP training prior to participating in each trial, which may result in burdensome and inefficient occurrences of multiple trainings each year.
- It may be beneficial to develop recommendations for GCP training to encourage organizations to adopt similar training criteria, thereby enabling wider cross-acceptance of training to alleviate inefficiencies.
- This CTTI-initiated project aims to develop recommendations on:
  - Key elements of GCP training
  - Approaches that may facilitate the creation of a more-efficient GCP training program and process for clinical investigators and site personnel

METHODS

Methods for Recommendations Development

These recommendations are based on data gathered through a literature review; assessment of some common GCP training programs within academic, public, and private sectors; and group members' expertise and experiences. Recommendations were vetted at an expert meeting. The methods for recommendation development and literature review are described in Figure 1 and 2 respectively.

Method for Sampling Typical Programs

Numerous GCP training programs that have been designed for investigators and a few programs that appear representative of academic, public, and private sectors were chosen by the working group based on the team members' familiarity and experience with the programs.

Figure 1: Recommendations Development

Working Group Formed:
- A multi-stakeholder group of CTTI members who impart, receive, and benefit from GCP training was formed to evaluate and discuss information and develop recommendations

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:
- Identified impediments/issues with current practices regarding GCP training
- Summarized findings
- Discussed solutions
- Drafted recommendations

Expert Meeting:
- Facilitated an informed discussion of current practices and challenges with a group of experts that included attendees from academia, industry, patient advocacy groups, and FDA
- Top issues and solutions 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, competency assessment, and format of training)

Figure 2: Methods for Literature Review

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

MEDLINE search criteria
Inclusion:
- US 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 United States

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

RESULTS

Literature Review Results

GCP training usually includes the following components:

- Institutional review board/independent ethics committee 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.

Sampling of Typical Programs and Training Recommendations Across Sectors

Organization	Content	Competency	Frequency of Training
Collaborative Institutional Training Initiative (CITI)	GCP courses for investigational drugs, biologics, and medical-device trials based on International Conference on Harmonisation (ICH) guidelines with a US FDA focus	End-of-course quiz, with a minimum passing score requirement	1 to 2 years
Academy of Physicians in Clinical Research (APCR)	Recommendations include: • Elements of GCP in human-subject research • Elements of GCP in operational and regulatory compliance	APCR recommends acknowledgment of distinct levels of investigator research training and proficiency (levels 1–3)	• Level 2: Complete GCP program and participate in related continuing medical education (10 hours every 2 years) • Level 3: Maintain certification qualification process (5 to 10 years)
FDA Investigators Training Course	• Investigator responsibilities • Fundamental issues in the design and conduct of clinical trials • Informed consent and ethical considerations in clinical trials • Safety considerations and assessments • Investigational product considerations	None	No recommendation
TransCelerate BioPharma	13 ICH E6 GCP principles	Certification issued by member organization or third-party GCP training provider meeting TransCelerate criteria	GCP training repeated or updated at least every 3 years
National Institute of Allergy and Infectious Diseases (NIAID)	• ICH E6 • FDA and Office for Human Research Protections (OHRP) regulations	• Accepts certification or transcript from recognized course or completion of competency test for NIAID course • Option to "test out"	GCP training repeated or updated at least every 3 years

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 programs

- Variable, typically ranged from 1–3 years.

Recommendations Development

The working group is in the process of developing the recommendation based on the information gathered and the viewpoints of experts who attended a meeting on January 31, 2014.*

*More information on the expert meeting "Good Clinical Practice (GCP) Training: Current Practices and Challenges" can be found at http://www.ctti-clinicaltrials.org/what-we-do/ctti-projects/gcp-training/expert-meeting.

CONCLUSIONS

This endeavor involves a multi-stakeholder team and has explored exisiting practices, identified challenges, and sought solutions from a wide variety of perspectives on streamlining current GCP training efforts. This effort may encourage organizations to adopt similar training criteria, thereby allowing cross-acceptance of training and serving to reduce the burden of repeated training and improve the efficiency of clinical trials.

DISCLOSURE

Author(s) of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:

Jamie Arango: Director — CITI Program

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