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 CITI-GCP Training Working Group discussed and published a report providing a set of key elements for GCP training. The group included representatives from academia, industry and government to develop recommendations for increasing efficiency of current GCP training efforts.

Results: The working group reviewed the current literature and the content of public and private initiatives related to GCP training. They identified key elements for GCP training that should be included to ensure knowledge of the regulations, guidelines, and local laws that relate to conducting clinical trials. They also identified the goal of GCP training to protect the rights and safety of study participants and the quality of study results. They reviewed regulatory expectations and to foster GCP training of clinical trials generally require that all investigators and site personnel involved in clinical research complete training prior to participating in each trial, which may result in burdensome and inefficient occurrences of multiple trainings each year. They may be beneficial to develop recommendations for GCP training to encourage organizations to adopt similar training criteria, thereby enabling wider across-acceptance of training to alleviate inefficiencies. A CTI-initiated project aimed 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. 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 adapt existing training criteria, thereby allowing cross-acceptance of training and reducing 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 training of clinical trials generally require that all investigators and site personnel involved in clinical research complete 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 across-acceptance of training to alleviate inefficiencies. A CTI-initiated project aimed 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

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**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 experiences with the program.

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**RESULTS**

**Literature Review Results**

GCP training usually includes the following components:

- Institutional review board/independent ethics committee oversight
- Investigator responsibilities
- Start 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.

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**CONCLUSIONS**

This endeavor involves a multi-stakeholder team and has explored existing practices, identified challenges, and sought solutions from a wide variety of perspectives on streamlining current GCP training efforts. This effort may encourage organizations to adapt 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.

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**DISCLOSURE**

Affiliations of this presentation have the following to disclose concerning possible financial or personal interests:

- Shapley: Nothing to disclose
- Gretchen Wild: Employee — St. Jude Medical and own stock in the company

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**REFERENCES**

- [References](#)

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**APPENDIX**

- [Appendix](#)

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- [Acknowledgments](#)