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

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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 comply with the requirements of good clinical practice (GCP). GCP training is usually included in the following components: the content of training programs, the competency requirement of training programs, and the frequency of training.

METHODS

ABSTRACT

1. Objective: To develop recommendations to ensure knowledge of GCP while facilitating more efficient GCP training programs.

2. 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.

3. Results: The working group reviewed the current literature and the content of public and private initiatives related to GCP training, while facilitating a more efficient GCP training process. To meet regulatory expectations and to foster GCP, sponsors of clinical trials generally require that all investigators and site personnel be properly trained in the regulations, guidelines, and local laws that relate to conducting clinical trials.

4. Conclusions: The recommendations for GCP training efforts are generated through this process to encourage organizations to adopt similar training criteria, thereby allowing cross-acceptance of training and reducing the burden of repeated training and improving the efficiency of clinical trials.

RESULTS

1. 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

2. Sampling of Typical Programs and Training Recommendations Across Sectors

- Data management
- Informed consent
- Vulnerable populations
- Serious adverse-event and adverse-event reporting
- Monitoring

DISCLOSURE


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 adopt similar training criteria, thereby allowing cross-acceptance of training and serving to reduce the burden of repeated training and improving the efficiency of clinical trials.