OVERVIEW OF "GOOD CLINICAL PRACTICE"

APRIL 10, 2024

General

GCP stems from the work of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH"). Section 6 of the ICH Efficacy Guidelines deals with GCP, and can be found here. These guidelines have been adopted in virtually all developed countries, including the U.S.

GCP concepts are self-evident, and consistent with the manner in which all good physicians behave. They can be summarized as follows:

"All clinical trials should be conducted in accordance with ethical principles, sound scientific evidence and clear detailed protocols. The benefits of conducting trials should outweigh the risks. The rights, safety and well-being of trial participants are of paramount importance and these should be preserved by obtaining informed consent and maintaining confidentiality. The care must be given by appropriately qualified personnel with adequate experience. Records should be easily accessible and retrievable for accurate reporting, verification, and interpretation. Investigational products should be manufactured according to Good Manufacturing Practice." (See here.)

GCP And Real-World Evidence

GCP is relevant to real-world evidence studies. In its December 2019 guidance on the use of RWE for regulatory decision-making, the FDA explicitly stated:

"Many of the considerations and best practices for generating RWE are derived from the same principles that govern generation of clinical evidence from traditional clinical studies, which are generally referred to as good clinical practice (GCP)."

GCP Certificates

A study sponsor depends on GCP compliance. They typically require that each investigator (or his/her organization) holds a GCP certificate. GCP certificates are issued by independent parties.

The CITI Program is commonly used. Programs are available for organizations as well as individuals. The current cost is about $130 per person, and the course requires about 4 hours of time.

GCP certificates provide value for independent physicians. They support the ability to participate in industry-sponsored studies. They offer legal protection. They give comfort to patients. They satisfy typical IRB requirements. They provide a useful checklist for study protocols.
A clinician will want to refer to GCP in the context of any article, post or conference presentation based on a study design and/or results.

InCytes™, Circles And GCP

Much of GCP depends on proper, auditable record-keeping. This and other GCP elements are accommodated by inCytes™ and associated processes.

Reference Materials

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3097692/pdf/biij-04- e5.pdf. (History of GCP.)

https://www.fda.gov/media/174819/download. (FDA December 2023 Draft Guidance on real-world evidence studies.)

https://www.ich.org/page/efficacy-guidelines

https://www.youtube.com/watch?v=6pAtb4X1UPU (FDA presentation on data integrity.

https://www.fda.gov/about- fda/center-drug-evaluation-and- research-cder/good-clinical-practice

https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials

https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/good-clinical-practice-gcp-inspection- collaboration-international- regulators-drug-development