CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

GCP Training Expert Meeting

GCP Training Guidance and Expectations

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International Guidance on GCP

- **ICH E6 Good Clinical Practice (GCP) Consolidated Guidance**
  - Defines GCP
  - Describes general principles of GCP
  - Describes specific and shared responsibilities of investigators, institutional review boards, and sponsors
- **ISO 14155:2011- Clinical Investigation of medical devices for human subjects – Good clinical practice**
  - International standard for medical device GCP
  - GCP principles consistent with ICH E6
  - Addresses issues specific to medical device clinical investigations

FDA Regulations

- **Incorporate GCP principles, for example**
  - Responsibility
  - Human subject protection
  - Documentation
  - Reporting
  - Quality

Expectations for GCP Training

- **FDA regulations require**
  - A sponsor to select investigators qualified by training and experience (21 CFR 312.53(a), 812.43(a))
  - A sponsor to obtain a written commitment from investigators (312.53(c), 812.43(c))
  - An investigator to ensure the investigation is conducted according to the signed commitment, investigational plan, and regulations (312.60, 812.100)

GCP for Foreign Clinical Trials

- **Drugs and biologics**
  - Conduct in accordance with GCPs is necessary for acceptance of a foreign clinical trial not conducted under an IND (312.120(a)(i))
  - A sponsor must describe the actions taken to ensure the research conformed to GCP and a description of how investigators were trained to comply with GCP (312.120(b), 312.120(b)(11))
- **Medical devices**
  - February 2013 proposed rule - Acceptance of data from clinical investigation studies for medical devices

THANK YOU

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