

## ICH GCP Key Learning Points

### Chapter 1: Introduction and the Principles of ICH GCP.

1. GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects.
2. Compliance with GCP provides public assurance that the rights, safety and well-being of trial subjects are protected.
3. The ICH-GCP provides unified standard for international community to facilitate the mutual acceptance of clinical data by the regulatory authorities.
4. The ICH-GCP guideline was developed with consideration of the current good clinical practices all over the world.
5. The principles established in the ICH-GCP may also be applied to other clinical investigations.
6. The ICH is a tripartite collaboration of the European Union, Japan and the United States of America to harmonise technical requirements for registration of pharmaceuticals for human use.
7. The objective of technical harmonisation is a more economical use of human, animal and material resources for the development of new medicines.

## **Chapter 2: Informed Consent.**

1. Informed consent is a statutory requirement for clinical research/trial.
2. Consent is given freely after that person is informed of the nature, significance, implications and risks of research.
3. Consent may be in writing or given orally in the presence of at least one witness and recorded in writing if the person is unable to mark a document to indicate his/her consent.
4. Special protection is provided in the law to people who are incapable of giving legal consent to participate in clinical trials/research.
5. In case of children, some-one with parental responsibility must give consent on behalf of children.
6. Penalties of up to 3 years imprisonment or a fine, or both are provided in the Human Tissue Act 2004 as a deterrent to failing to obtain or to missing consent for scheduled purposes.
7. The Mental Capacity Act 2005 states that every adult has the right to make his or her decisions, and must be assumed to have capacity to do so unless it is proved otherwise.

### Chapter 3: Ethics.

1. The purpose of an IRB/IEC review is to safeguard the rights, safety, and well being of all trial subjects. Special attention is paid to trials that include the vulnerable and children.
2. The IRB/IEC should review and approve all trial documents within a reasonable time.
3. The IRB/IEC should consider the qualifications of the investigator(s).
4. The IRB/IEC should review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence on the trial subjects.
5. The IRB/IEC must have at least 5 members and one member with non-scientific background, who collectively have the qualifications and experience to review all aspects of the trial.
6. The IRB/IEC should establish Standard Operating Procedures (SOPs) and follow those procedures.
7. The IRB/IEC should retain all relevant records for a period of at least 3 years after completion of the trial.

#### **Chapter 4: Responsibilities of Investigator.**

1. The Investigator is responsible for the conduct of the clinical trial at a trial site.
2. The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial.
3. The investigator should be thoroughly familiar with the appropriate use of the investigational product(s).
4. The investigator should permit monitoring and auditing by the sponsor/institution, and inspection by the appropriate regulatory authorities.
5. The investigator should maintain a log of delegated trial-related duties to sub or co-investigators and other qualified person.
6. The investigator is responsible for medical care of trial subjects and for all trial-related medical decisions.
7. The investigator is responsible for keeping trial data and submission of progress and safety reports to sponsor, IRB/IEC and regulatory authorities.

## **Chapter 5: Sponsor Responsibilities.**

1. The sponsor is responsible for the initiation, management and/or financing of a clinical trial.
2. The sponsor is responsible for quality assurance and quality control.
3. The sponsor is responsible for trial design, trial management, data handling and record keeping.
4. The sponsor is responsible for investigator/institution selection for the trial.
5. The sponsor is responsible for providing insurance or indemnity to investigators/institutions against claims arising from the trial.
6. The sponsor is responsible for obtaining ethics and regulatory approvals (Clinical Trial Authorisation).
7. The sponsor is responsible for auditing, monitoring and safety reporting.

## **Chapter 6: Clinical Trial Protocol and Protocol Amendments.**

1. Clinical trial protocol should provide background information for the trial.
2. A detailed description of the trial objectives and purpose is an important component of the clinical trial protocol.
3. The scientific integrity of the trial and the credibility of the data from the trial depend on the trial design.
4. Clinical trial protocol must define subject inclusion and exclusion criteria.
5. The treatments to be administered to subjects must have detailed information for investigators.
6. Protocol must specify efficacy parameters for assessment.
7. Specification of safety and statistical parameters is essential.

**Chapter 7: Investigator's Brochure.**

1. The Investigational Brochure (IB) is a compilation of the clinical and nonclinical data on the investigational product(s).
2. The purpose of IB is to provide to facilitate understanding of the rationale for trial and compliance with key features of the protocol.
3. The IB information should be presented in a concise, simple, objective, balanced, and non-promotional form.
4. A medically qualified person is recommended for the editing of an IB.
5. Multi-discipline teams involved in the preparation of the IB should normally approve its contents.
6. The IB should be reviewed at least annually.
7. Any changes to the IB contents should be approved by the IRBs/IECs and/or regulatory authorities.

## **Chapter 8: Archiving of Essential Documents for a Clinical Trial.**

1. Archiving of essential documents is a key element of compliance with ICH-GCP guideline.
2. Essential documents are critical for trial evaluation and the quality of data collection.
3. Essential documents are grouped as pre-study, during study and completion of study according to GCP.
4. A staff member should be dedicated for filing and updating of essential documents.
5. Trial Master File should be established after first contact with sponsor or as soon as outline protocol is available.
6. Essential documents are required for audit by the sponsor, host institution and regulatory authorities to confirm validity of trial and integrity of data.
7. Source documents must be traceable.

**Chapter 9: Safety Reporting.**

1. The Investigator shall report all serious adverse events immediately to the sponsor and host institution except for those that the protocol or investigator's brochure identifies as not requiring immediate reporting.
2. The initial report shall be promptly followed by a detailed, written report.
3. The sponsor is responsible for the ongoing safety evaluation of the IMPs and responsible for the prompt notification to all concerned of safety evaluation findings that could adversely affect the health of subjects and impact on the conduct of the trial.
4. The sponsor is responsible for reporting all SUSARs within 7 calendar days and follow-up detailed reports within an additional 8 calendar days.
5. The sponsor is not required to report non-serious and serious reactions which are identified in the protocol.
6. The sponsor must submit an annual safety report within 60 days of the data lock point, The report should list the safety data of subjects, a line listing of all SUSARs and an aggregate summary of SUSARs.
7. After termination of the clinical trial, any unexpected safety issue that is likely to have an impact on the trial subjects should be reported to the competent/regulatory authorities with proposed actions.