Good Clinical Practice
Sponsor Responsibility

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GCP(Good Clinical Practice)

- International ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.
- Compliance with this standard provides public assurance
  that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

Medical Expertise

- The sponsor should designate appropriately qualified medical personnel who will be readily available to advise on trial related medical questions or problems

Trial Design

- The sponsor should utilize qualified individuals (e.g. biostatisticians, clinical pharmacologists, and physicians) as appropriate, throughout all stages of the trial process, from designing the protocol and CRFs and planning the analyses to analyzing and preparing interim and final clinical trial reports

Trial Management

- The sponsor should utilize appropriately qualified individuals to supervise the overall conduct of the trial, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports
- Independent Data-Monitoring Committee (IDMC)

Data Handling & Record Keeping

- Electronic trial data handling and/or remote electronic trial data systems
  - System validation

- SOP
- Audit trail, data trail, edit trail
- Security
- Backup of the data
- Blinding during data entry

Data Handling & Record Keeping

- 품목 허가일부터 3년간 보존
- 의뢰자는 자료의 보존 필요성 및 보존 기간에 대해 시험자 및 시험기관의 장에게 문서로 알려야하고, 더 이상 자료의 보존이 필요없다고 의뢰자가 판단한 경우 의뢰자는 반드시 이 사실을 문서로 시험책임자 및 시험기관의 장에게 알려야 한다.

Investigator Selection

- Each investigator should be qualified by training and experience
- Should have adequate resources
- Sponsor should provide the investigator(s) and institution(s) with the protocol and an up-to-date Investigator' s Brochure, and should provide sufficient time for the investigator/institution to review the protocol and the information provided.

Investigator' s/Institution' s Agreement

- In compliance with GCP, with the applicable regulatory requirement(s) and with the protocol
- To comply with procedures for data recording /reporting;
- To permit monitoring, auditing and inspection and
- To retain the trial related essential documents

Allocation of Responsibilities

- Prior to initiating a trial, the sponsor should define, establish, and allocate all trial-related duties and functions.

Compensation

- Insurance or should indemnify (legal and financial coverage) the investigator/ institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence.
- Should address the costs of treatment of trial subjects in the event of trial-related injuries in accordance

with the applicable regulatory requirement(s).

Notification/Submission to FDA

- Before initiating the clinical trial(s), the sponsor (or the sponsor and the investigator, if required by the applicable regulatory requirement(s)) should submit any required application(s) to FDA for review, acceptance, and/or permission (as required by the applicable regulatory requirement(s)) to begin the trial(s)

Confirmation of Review by IRB/IEC

- The name and address of the investigator' s /institution s IRB/IEC.
- A statement of IRB/IEC that it is organized and operates according to GCP and the applicable laws and regulations.
- Documented IRB/IEC approval/favourable opinion

Information on Investigational Product(s)

- Sufficient safety and efficacy data from nonclinical studies and/or clinical trials are available to support human exposure by the route, at the dosages, for the duration, and in the trial population to be studied.
- Updated Investigator' s Brochure

Manufacturing, Packaging, Labelling, & Coding

- GMP
- Storage
- Coding
- Packaging
- Formulation change

Supplying and Handling

- 관리약사
- After IRB/Agency approval
- Written SOP
- 인수, 취급, 보관, 조제, 반납 및 폐기
- Recall of Clinical supply
- Stability

Record Access

- Protocol & Agreement
- Agreement of Subjects

Safety Information

- Ongoing safety evaluation of the investigational product(s).
- The sponsor should promptly notify all concerned investigator(s)/institution(s) and KFDA of findings

Adverse Drug Reaction Reportingl

- Serious & Unexpected ADR
- Life threatening or Death-within 7days
- Other Serious & Unexpected ADR-within 15 days
- Periodic Safety Update

Monitoring

- Qualified Monitor
- Objective
  - the rights and well-being of human subjects are protected
  - the reported trial data are accurate, complete, and verifiable from source documents
  - the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s)

Monitoring - continued

- Communication
- Resources of investigator
- Clinical supply
- Protocol
- ICF
- Essential document
- Delegation
- Eligibility
- Recruitment rate
- Contact report
- SDV
- Correction of CRF
- AE reporting
- Noncompliance
- Monitor s SOP

Audit

- Qualified Auditor
- Independent of and separate from routine monitoring or quality control functions
- Should be to evaluate trial conduct and compliance with the protocol, SOPs, GCP, and the applicable regulatory requirements

Procedure of Audit

- What to audit, how to audit, the frequency of audits, and the form and content of audit reports
- Guided by the importance of the trial, the number of subjects in the trial, the type and complexity of the trial, the level of risks to the trial subjects, and any identified problem(s).
- Observations and findings
- Audit report
- Audit certificate

Noncompliance

- Prompt action by the sponsor to secure compliance.
- Noncompliance reporting

Premature Termination or Suspension

- 임상시험이 조기종료되거나 일시중지된 경우 의뢰자는 시험책임자 및 식품의약품안전청장에게 해당 사실과 사유를 신속히 문서로 보고하여야 하며, 다기관임상시험의 경우에는 다른 시험기관의 시험책임자에게도 해당 사실과 사유를 문서로 보고하여야 한다.

Clinical Trial/Study Reports

- 임상시험이 완료 또는 조기종료된 경우 의뢰자는 결과보고서를 작성하여 식품의약품안전청장에게 관련규정에 따라 제출하여야 한다.