Role and Responsibilities of the Principle Investigator (PI)

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GCP Workshop on Clinical Trials

Clinical Trial

- Is an investigation in human subjects intended to discover the following effects of a drug
  - clinical., pharmacological and the pharmacodynamics of an investigational product
  - identify adverse reactions
  - To study the absorption, distribution, metabolism and excretion to assess its safety

Basic requirements in any clinical Trial

- The **safety of the patient**

- The **manner - the trial is conducted**
  - In compliance with the approved protocol
  - Is the reported data accurate, complete and verifiable from the source document

Good Clinical Practice

Defined as :

"an international ethical and scientific quality **standard** for designing, conducting, recording and reporting trials that involve participation of **human subjects**"

International conference on harmonising of technical requirements for registration of pharmaceuticals for human use.

Good clinical practice : consolidated guideline

- May 1, 1991

ICH Guidelines for - GCP
08 sections

1. Definitions – Glossary
2. Principles of GCP
3. Ethics Committee
4. Investigator's responsibilities
5. Sponsor's responsibilities
6. Clinical Trial Protocol
7. Investigator's Brochure
8. Essential Documents for the conduct of a clinical trial

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Roles and the responsibilities of the

Principle investigator

Key people in an clinical trial

- **Sponsor**
  - An individual / company which takes the responsibility for the initiation, management and financing of the clinical trial
- **Investigator**
  - A person responsible for the conduct of the clinical trial at a trial site
- **Subject**
  - An individual who participates in a clinical trial as a recipient.

Others who are involved in the clinical Trial

- **CRO**= Contract Research Organisation
  - A person contracted by the sponsor to perform the sponsor's trial related duties and functions

- Site Management Organisation (**SMO**)
  - Monitors the trial at the trial site
  - Gives all the necessary administrative assistance to the principle investigator

Basic requirements to consent as a PI

- Should be interested in the clinical trial
- Adequate time
- Adequate infrastructure
  - Space
- Adequate equipment
  - Telephones/ Fax machines/ Internet facilities/ Photocopying facilities
- Adequate qualified staff

The role of the Principle investigator

- Team leader
- Take all clinical decisions
- Follow the guidelines given in the GCP manual

The role of the **Principle investigator**

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- Take all clinical decisions
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GCP rules for the Investigator

Know the study protocol

- Read it
- Ensure you can carry out the clinical trial
  - Inclusion & exclusion criteria
  - Study period
- Sign it
- Follow it
- Make it available
- File it

Select, train and Log suitable study Personal

- Study personal
  - Medical staff
  - Nurses
- Maintain log of study personal
- Investigators’ GCP training

Record all data carefully

- Supervise the entries made by the sub-investigators

Ensure Study Equipment is Adequate

- Suitable
- Calibrated
- Available
- Maintained

Maximise Trial subjects' protection

- Ethics

- Informed consent

How to obtain Informed consent

- Inform the subject(Patient) about the trial, in a non-technical manner and focus on practical details
- Provide the subject with up to date and approved version of the product information
- Record the date and time when the drug information sheet was provided.
- Give enough time for the subject to read and understand about the drug in order to come to a decision whether to participate in the trial

How to obtain Informed consent

- Once they return for the consent
  - Summarise the details about the drug
  - Allow any questions related to the Investigation Product (IP)
  - Once the subject consents to participate
    - Complete the documentation

Meticulously Document Product

- Keep extremely detailed records of trial product
- Follow the instructions relating to the storage and handling of the study product
- Do not destroy or dispose of unused study drug

Ensure Timely and Efficient Safety Reporting

- Adverse events – Record in the Case Report Form (CRF)
- Serious adverse events (SAE)- immediately report to the Contract Recourse Organisation (CRO) using SAE Report form
  - Death
  - Life threatening
  - In-patient or prolonged hospitalisation
  - Persistent or significant disability / incapacity
  - Congenital anomaly or birth defect
- Pregnancy – to be reported as soon as information obtained

Ensure the quality of Laboratory evaluation

- Follow method of sample collection
- Focus on sample quality
- Review lab results for AEs (indicate clinical significant or not)
- Lab documentation needed
  - Signed reference ranges
  - Details of analytical methods
  - Quality assurance information

Maintain good Trial files and archives

“IF not documented it did not happen”

- Correct and good documentation will confirm that the trial has adhered to GCP.
- Keep all documents in a safe, secure and confidential environment
- Documents exclusively kept at site:
  - Source document (Patient notes)
  - Informed consent forms
  - Subject ID log

Source documents – (Patient notes)

- Record each study assessment
  - Date / time
  - Outcome
- Adverse events
  - Record every change
  - Start date ‘ stop date
  - Any changes and correction to notes
    - Should initial and date the change
- Do not use the Case Report Form (CRF) as a source document

Documents to record patent events

Source document

- Original document where the case notes are written

Case report form (CRF)

- A printed form designed to record all the protocol required information to be reported to the sponsor on each trial subject

Principle Investigator

- Has overall responsibility for the conduct of the study at the site

- Should retain all paper copies of study records for at least 2 years marketing approval or discontinuation of the clinical programme

Keep everyone fully informed

- Inform everyone
  - Sponsor
  - Study subject
  - Ethics committee
  - Primary Care Physician / GP

Should permit monitoring and auditing

- Monitoring done by
  - CRO
  - Auditors

Investigators site Audit

- Protocol compliance
- Informed consent
- Regulatory approval
- Documentation
- Drug Accountability
- Data handling
- Confidentiality
- SAE reporting
- Training and training documentation / Records of qualifications

My experiences as a PI

- It was very interesting
- Improve my care for the patients
- Insight in to the tedious process involved before a drug comes to the market


Thank
You