Clinical trial Initiation and site start up

IP Handling

Module 6 Topic 1_4

IP Handling

- Investigational drug is the pharmaceutical form of an active ingredient generally tested in a clinical trial and used for an unapproved indication, or used to gain further information about an approved product

Investigator Responsibilities:

- Receipt and Inventory
- Storage requirements
- Dispensing & administering
- Return of unused supplies
- Alternative disposition
- Final accountability

Receipt/Inventory/Storage:

- Recipient verifies shipment and signs receipt
- Inventory logs are maintained by Investigator/ staff
- Storage conditions

Storage Conditions: Room Temperature Storage

- Min/Max thermometer should be read, temperature recorded on a temperature log and thermometer reset at least once per week
- Temp Logs should be reviewed by second person once per month
- Thermometer should be calibrated or at least come with a “certificate of conformity with the accuracy requirements” issued by the manufacturer. Device needs to have accuracy of +/- 0,5 degrees. The recommended supplier can provide these thermometers in the required amount along with the necessary documentation

Use of Data Loggers

- The most comprehensive temperature monitoring at a site can be achieved by using so called data loggers. These are devices that continuously record the temperature in the room they are placed in

- In regular intervals (typically once per month) the data is downloaded onto a computer with the adequate software (which has to be purchased separately)

Dispensing, Administering, and Documenting IP accountability:

- **Investigator responsibilities**:
  - Dispense only to subjects enrolled in the study
  - Perform patient compliance checks

- **Documentation of IP includes:**
  - Patient diaries, Case Report Form entries
  - Inventory log entries, Source documentation

CRA Responsibilities for IP (ICH 5.18):

- During routine monitoring visits, the monitor will:
  - Review dispensing procedures and documentation with pharmacy and/or clinical staff at regular intervals
  - Check storage conditions, including any measurement logs (temp, humidity, light)
  - Check adequacy of supplies
  - Ensure IP dispensed to eligible trial subjects only
  - Ensure documentation that subjects received instruction in using, handling, storing, and returning IP

CRA Responsibilities for IP (ICH 5.18):

- During routine monitoring visits, the monitor will: (Contd)
  - Check that receipt, use, and return of IP are controlled and documented
  - Verify that IP labels remain unopened (protect the blind)
  - Check that disposition of unused IP at sites complies with applicable regulatory requirements
  - Document monitoring of IP in the site visit report and follow up letter

IP Recordkeeping at Sites

- All shipping and receiving invoices indicating the type and quantity of the drug or device, and the date of shipment
- Sponsor letters that extend expiration dates
- Record of dispensing, waste and return reflecting the subject, reason and batch or lot number
- Destruction done according to institutional policy (if applicable)

Return of IP from Site:

- Sponsor responsibility with ***investigator cooperation***
- All unused/partially used supplies
- Drug return form (disposition form)
  - Copy in investigator file
  - Sponsor copies
- Confirmation of receipt