Clinical trial Initiation and site start up

Initiation Visit

Module 6 Topic 1_3

Site Initiation Visit

- Starts after a successful PSSV and Sponsor & site are committed to proceed with study

- Purpose is to ensure site is:
  - Familiar with protocol and CRFs
  - Roles of site personnel are clearly defined
  - Common understanding of required procedures
  - All necessary supplies & equipment are ready

Site Initiation (Training)

- Site training can be conducted three ways
  - Investigator Meetings
  - On-site-initiation visits (SIV)
  - Combination of both

- Investigator Meetings
  - Large, multicenter studies
  - Selected study personnel trained at common location

Site Initiation (Training) (contd)

- Advantages
  - All investigators hear same information
  - Open forums
- Disadvantages
  - Does not allow one-on-one attention
  - Not all site personnel may attend
  - CRA can not check site supplies/drug

Before SIV

- SIV Check List
  - Arrange visit so each team member attends the portion of visit pertinent to their study role
  - Ensure each team member has read study related documents
  - Be prepared to discuss roles & responsibilities of each team member
  - Prepare list of questions/issues as they may relate to:
    - Scheduling of procedures
    - Reporting of AEs/SAEs
    - Sponsor contact numbers
    - Regulations/Guidelines

SIV Preparation

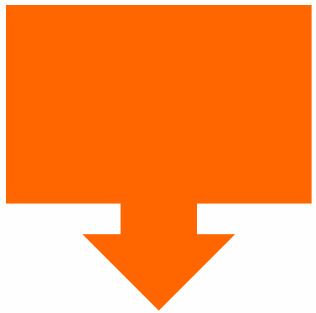
- SIV Check List
  - Process & store CTMaterials
  - Sponsors may ask site to unpack & do CTM Accountability with CRA
  - Assemble/calibrate equipment
  - Reserve space to conduct SIV
  - Keep investigator informed about visit
  - Ensure that PSSV issues addressed
  - Organize TMF with documents collected to date

Pre-requisites

- All agreements in place?
- All documents in hand?
- Material received at site?
- All personnel trained? More Training?
- Site ready for the first patient?

Study Initiation Visit

- Evaluate, whether the prerequisites for study are available at a specific site
- Training of the site staff on the specific study requirements and procedures
- No enrolment of any study participant before the Initiation visit



START THE STUDY

Study Initiation Visit - Preparation of the Monitor

- Read and understand study protocol and CRF
- Inform yourself about the study drug
- Inform yourself about GCP
- Inform yourself about the medical study background
- Inform yourself about brand names for un allowed concomitant medications

Prepare checklists