

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 CTM
 - 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

