Training / Hand over process Script # 4

Inspector: How was training organized for this study?

Responder: The study specific training was completed by all team members before the activation of the site. The training was provided by the MTN Leadership and Operations Center (LOC). Training covered protocol, all study manuals, study SOPs. Whenever new member joined the team, she/he had to complete all required training prior to being assigned to the study related tasks.

Inspector: During the review of Regulatory Binder, I did not find the Site Initiation Visit (SIV) report and ICH GCP section 8.2.20 requires filing of such report.

Responder: That is correct. The formal onsite SIV was not conducted. The site was trained during the study initiation call. The agenda, the list of participants and training materials are filed in Regulatory Binder and we believe that these documents provide an evidence that trial procedures were reviewed with the investigator and the trial staff as required by ICH GCP.

Inspector: Have you been trained on ICH GCP?

Responder: Yes.

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Inspector: When was your last GCP training and what was covered?

Responder: I completed last GCP training in 2015.The following topics were covered: Informed Consent Process, Investigator responsibilities, Sponsor responsibilities, Investigational Product Management, Monitoring, Investigator Brochure, Protocol design. This was online course followed by assessment test. The score of 80% was necessary to pass the test. The individuals who failed the test had one chance to repeat the test. Those who failed more than twice had to repeat the training. (volunteering Information, providing information which could raise additional questions/concerns)

Correct answer in red: I completed last GCP training in 2015. The following topics were covered: Informed Consent Process, Investigator responsibilities, Sponsor responsibilities, Investigational Product Management, Monitoring, Investigator Brochure, Protocol design.

Inspector: So how many individuals failed the assessment test? (this question was triggered by volunteering Information so will probably not be raised)

Responder: This will not be documented in the training records because only the final certificate is filed but as far as I remember at least five people had to repeat the training.

Inspector: What is the deadline to complete GCP training for new personnel joining the study team after the study activation?

Responder: 90 days of assignment to MTN study.

Inspector: 3 months? This is really too long.

Responder: I completely disagree with you. The timeline is defined in the procedure and we are obligated to follow this procedure. (too strong disagreement not holding good arguments)

Whenever possible the new staff will complete the training as soon as possible and until the training is completed the person will work only under direct supervision.

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Inspector: What kind of training was provided to individuals who were delegated to consent study participants?

Responder: I was not involved in this process but as far as I know besides GCP they were also trained on Standard Operating Procedure (SOP) on consenting and there was a training session to review and discuss the content of the study specific consent form (do not speak to the others responsibilities and/or try to guess)

I was not involved in this process. Based on the training records I reviewed they were trained on ICH GCP Standard Operating Procedure (SOP) on consenting and there was a training session to review and discuss the content of the study specific consent form.

Inspector: Have you been trained on CFR regulations?

Responder: Yes, do you want to see the training documentation?(volunteering Information)

Yes.

Inspector: Have you been trained on study SOPs?

Responder: Yes.

Inspector: How are you trained on SOPs updates?

Responder: When SOP is significantly revised the SOP author is responsible for making sure that all relevant staff is trained before SOP becomes effective.

Inspector: Who is responsible for ensuring that all study staff are adequately trained to serve their designated site and study specific functions for the particular protocol?

Responder: It will be study sponsor and study monitor. (Incorrect answer. It will be always IoR responsibility)

I'm responsible for verification that training records are updated.

Inspector: Do you have a procedure that is followed in case of staff changes after study activation?

Responder: Yes. It will be SOP on study hand over.

Training / Hand over process Script # 4

Inspector: Talk me through the hand over process.

Responder: The hand over meeting is conducted between a current team member (wherever possible) and replacement team member to discuss the hand over tasks including training, responsibilities, issues that require follow-up. All hand over tasks are listed on the hand over checklist which serves as evidence of the hand over process.

Inspector: So the hand over checklist will be completed for all staff changes during the course of the study?

Responder: In general, yes. If any are missing the Note to File will be available to document that hand over checklist is missing. Please see the example. Note to File handed over to inspector read as follows, “the hand over checklist was not completed because of omission.” (inappropriate use of Note to File, documenting that document is missing will not add any value)

In general, yes. If any are missing the Note to File will be available to document the date and the scope of hand over.

Inspector: I can see many changes in the site staff during the course of the study. How could you ensure that these changes did not affect continuity of the study management, safety of the participants, and quality and integrity of collected data?

Responder: In majority of the cases, we were informed in advance that study team member would be leaving the team so we were able to complete hand over process in timely manner. If there was a gap between the current team member leaving and the new team member being assigned we always made sure that current team member responsibilities are covered until a replacement is identified and hand over is completed.

Inspector: How was it possible?

Responder: For each single study role, we have at least, two people assigned so the back-up person was always available to immediately replace the leaving team member.