Trial-Specific Training Guidance Document

Trial-specific training

"Each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s).”

"The Investigator should be thoroughly familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator’s Brochure, in the product information and in other information sources provided by sponsor.”

"The Investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.”

If it is not documented, it did not happen!

Who should complete Trial-specific Training?

Trial-specific training must be completed by all members of staff with delegated trial duties and must be listed on the delegation log before they commence any trial related activities.

How is Trial-specific Training conducted?

Trial-specific training can be carried out at study team meetings. The initial training meeting, which is often the Trial Initiation Meeting, should be attended by as many members of the trial team as possible before commencing patient recruitment.

Members of the trial team who are not able to attend the team training meetings should complete alternative training at an individual level prior to the start of trial related activities.

Training is an on-going process. Any amendments to trial documents leading to a change in procedures would require staff to be trained in the new procedures. This should be documented on the trial specific training log.

What should be covered as part of Trial-specific Training?

Some recommended topics are:

- Protocol: including trial schedule, procedures including and any procedures which differ from routine standard of care, eligibility criteria
- Consent procedure: including trial specific consent procedure if applicable
- Pharmacovigilance reporting requirement: including Sponsor’s requirement and trial specific requirement
- Investigational Medicinal Products: including safety information from available documentation, treatment schedule according to the protocol
- Trial documents: what is required, from whom and by when

The list above is not exhaustive and additional training may be necessary depending on the trial.

Trial-specific training at an individual level can be tailored and completed according to the role and responsibilities of the delegate.

**How to document Trial-specific training?**

If trial-specific training is carried out as part of team meetings, an attendance log together with the agenda of the meeting will be sufficient to record that the training was completed.

For trial-specific training completed at an individual level, CCTU/FRM051 Trial-specific Training Record can be used to record training completed by delegates throughout the life of the trial.

When completing the CCTU/FRM051 Trial-Specific Training Record:

- Record the name of trainee, the date of training and tick the elements completed for each individual
- Training for the same individual but done on a separate day should be recorded on a separate row
- For any elements not listed, please specify in the “Others” column;
- Both trainee and trainer must sign for each entry row completed
- Self-training can be recorded where staff members have read trial documents and/or training documents