VALESTA ACADEMY

Share Knowledge. Develop Talent.

Adverse Events: Site and Side Effects Needing Special Monitoring

Practical information: **Number of participants: Between 5 and 15**
Duration: ½ day (09:00 – 12:30)
Price per person @ Valesta office: €450

Course Overview

An adverse event is any side effect a person experiences when participating in a clinical trial. In clinical research, these side effects are the focus points in any trial. It is critical that the reporting is executed correctly and comprehensively by site staff so the sponsor is fully aware of any developments. The Clinical Research Associate is responsible, on site visits, for verifying in medical files whether all side effects have been reported.

This half day course teaches the participant the specific definitions of Adverse Events (AE) and Serious Adverse Events (SAE) and the specific country regulations on reporting AEs and SAEs to the relevant authorities.

The focus of the training is on the safe reporting of adverse events in oncology and haematology trials, due to their often complex studies and large files. Theory and practice questions are alternated for the participant to gain maximum knowledge.

By attending this course you will gain:

- A deeper insight into the reporting of adverse events in oncology and haematology clinical trials
- Expertise allowing you to define an unexpected medical occurrence that doesn't necessarily has a relationship with the treatment of a patient and clinical trials subject

Course Content

The content of this course is grounded in theoretical framework but also focuses on several real life cases to illustrate these theories. The course will provide an overview of AEs including assessment, documentation, recording and reporting. It will focus on the importance of documentation for evaluating the subject's safety and AEs during the trial period. The course, although theory focused, requires active participation, and the trainer may call upon the attendees to provide real life examples to draw on and learn from.

Topics covered during the training are:

- Defining the following terms and common uses of the terminology:
  - (Serious) Adverse event
  - Suspected adverse reaction
  - (Serious) Adverse reaction
  - Life-threatening
- Distinguishing an adverse event from common medical history
- Assessing the causality of an adverse event
- Monitoring of side effects and the need for special attention

Completion of this half day course using the theoretical framework provided, will ensure you are able to assess the causality of an adverse event and distinguish it from common medical history. It will also aid in the correct and comprehensive reporting of Adverse Events and Serious Adverse Events in complex clinical trials.

For more information or to reserve a seat on this training course please contact us today!

We are flexible! Should you require training to be carried out in-house, we would be happy to discuss your needs and come up with a suitable solution for you.
Call our office on +32 15 28 15 05!