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 any clinical trial, these side effects are the focus points. 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 for verifying in medical files whether all side effects have been reported.

This half day course teaches the participant the specific definitions of (Serious) Adverse Events ((S)AE) and the specific regulations on reporting (S)AEs to the relevant authorities. The focus of the training is oncology and haematology trials, due to their often complex trials and large files.

By attending this course you will gain:

- ✓ A deeper insight into the reporting of (S)AEs 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 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.

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

Completion of this course using 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 (S)AEs 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.