

Safety First: Managing Participant Safety And Adverse Events in Clinical Trials

Who is this course aimed at?

Investigators, study co-ordinators, research nurses and any person in the clinical research team who is involved in the safety management of human participants in a clinical trial.

What will be covered?

- Components of the safety management of participants
- Components of safety reporting in clinical trials
- The role players in safety management
- What makes an event adverse?
- The seven domains of an adverse event including the medical term, severity, duration, status, expectedness, causality, and seriousness
- Serious adverse events
- Common pitfalls and audit findings

To get the most out of this course, we highly recommend that participants have attended a prior GCP course.

What is the focus of the course?

The focus is on applying principles in the field, and on the translation of policies and guidelines into practical steps. This is not only about the theory but is approached from a ground level perspective. A number of real-life case scenarios are presented.

What is the format of the course?

The course is completed through an online interactive learning platform. The course can be completed in one session, or piece by piece, whichever is most convenient. Complete it at your own pace, in your own time, at your convenience.

Upon successful completion, a certificate of completion is immediately available for download. The course is accredited for CPD points.

Who are the facilitators?

CREDE is known for its customized and interactive courses in, amongst others, GCP, GDP and consultancy work with clinical research sites. The facilitators have ground-level experience combined with in-depth knowledge and are proficient in this style of training.

What about cost and logistics?

The cost of the course is R575.00 (VAT inclusive) which includes the entire course, all the materials and CPD certification.

For further information and to register for the course:
contact CREDE at admin@crede.co.za; tel. 0609550417