

## Fundamentals of Clinical Research

**Practical information:** Number of participants: Between 4 and 10  
Duration: 1 day (09:00 – 17:00)  
Price per person @ Valesta office: €750

### Course Overview

This Fundamentals of Clinical Trials course is intended as an introduction to clinical trials for all clinical research professionals who are new to clinical research and those from a non-clinical background. This one day course will provide the participants with a clear overview of the different elements within clinical trials.

The course will also explore the terminology used in clinical trials, the clinical trial phases and how to liaise with competent authorities and ethics committees whose responsibility it is to review and approve clinical trials to produce the best data for health care decision making.

A Good Clinical Practice certification is required to enroll in this workshop. If you need a GCP certification, this course can be combined with the “Introduction to Good Clinical Practice” course provided by Valesta Academy.

### By attending this course you will gain:

An understanding of the fundamentals of clinical trials in accordance with GCP guidelines and applicable regulatory requirements where the goal is to improve:

- ✓ The knowledge on the industry’s terminology
- ✓ The understanding of the phases in a clinical trial
- ✓ The understanding of quality requirements of essential documents

### Course Content

- The importance of Clinical Research terminology
- The different phases in a Clinical Trial and related actions
- Informed Consent - required content, process and necessary documentation
- Essential documents - what is the purpose and the quality requirements
- Requirements Protocol content
- Ethics Committee approval - process and requirements
- Good Documentation Practices

This course will be an interactive day of training alternating between theory, practical exercises and quizzes to ensure that attendees increase their knowledge through practice.

**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.***