

Advanced Course in Clinical Research

Generic Programme

Day 1:

Course starts at 09.30
(with two 15 min breaks and 45 mins for lunch)

Introduction to course

Session 1

How much do you know about GCP?

Interactive

Q&A to refresh your GCP knowledge

Session 2

What's new and coming up

A brief heads up on the latest developments in EU and USA

Session 3

Data protection in clinical research

Overview of how the data protection directive affects clinical trials: processing and transfer of data

Session 4

Electronic records and documents workshop

Group exercise to consider questions relating to e-source data based on the EMA Reflection Paper and e-TMF basics

Interactive

Session 5

Emergence of GCLP

Group exercise on GCLP requirements

Interactive

Session 6

GCP problem solving using root cause analysis, CAPA and SMART approaches – including the identification and management of breaches of GCP and study protocol

Case studies: common breaches of GCP and protocol – determining root cause, SMART corrective and preventative action plans and testing CAPA effectiveness.

Interactive

Course closes at 17.00

Day 2:

Course starts at 09.00
(with one 15 min break and 45 mins for lunch)

Session 7

Risk based approaches to implementation of regulation and trial monitoring

An overview of the key guidance followed by an exercise on the pro's and con's of risk based monitoring

Interactive

Session 8

Investigator oversight of clinical trials

Good and poor practices relating to the oversight of trials and delegation of responsibilities

Interactive

Session 9

Critical review of the consent process

Your chance to critique a consent process and assess its compliance with GCP. Discussion to consider the impact of the consent process on the recruitment and retention of trial subjects.

Interactive

Session 10

The monitoring and audit of critical clinical trial documents **Interactive**

Group exercise to evaluate the quality and content of some key clinical trial documents, including the detection of fraud in trial data followed by discussion

Course closes at 15.30

Each course is different and dependent on participant questions and interaction.

Timings may vary to meet specific course needs.