

Fundamentals of Clinical Research and GCP

*A course designed for the School of Biomedical & Life Sciences,
University of Surrey
16-18 May 2007*

Wednesday 16 May

09.30 Introduction to course

How a new medicine is discovered and then developed through the traditional phases of clinical research

Clinical Trial Terminology and Methodology in Plain English
Randomisation, study blinding

11.00 Break

11.20 **Clinical Trial Terminology and Methodology in Plain English**
Types of study design

Introduction to Good Clinical Practice
What is it, why do we need it? Who does it affect?

12.30 Lunch break

13.15 **The Critical Path of the Typical European Clinical Trial**
Review of the stages involved in setting up a clinical trial in Europe from planning to final report and the major GCP requirements, including study protocol and CRFs

14.30 Questions and Close

We suggest that you spend the rest of the afternoon revising the topics covered

Thursday 17 May

09.30 **Subject Protection in Clinical Trials**
An overview of how subjects are protected when taking part in trials: Declaration of Helsinki, Ethics Committee Approval, Written Informed Consent procedures, Payment and Compensation.

10.45 Break

11.00 **Trial Logistics and Monitoring**
Role and duties of the trial monitor; investigator selection and site assessment, monitoring visits; data monitoring, source data verification; subject recruitment

12.15 Lunch break

13.00 **Safety Reporting**
Serious and non-serious adverse events, adverse drug reactions, causality assessment, reporting requirements to the regulatory authorities

13.30 **Trial Completion**
Analysis, reporting, data protection, archiving, audit, archiving, and inspection of trials by the regulatory authorities

Abbreviations and acronyms

14.30 Questions and Close

We suggest that you spend the rest of the afternoon revising the topics covered

Friday 18 May

10.00 **Examination for the "Certificate in Basic Clinical Research Competence"**
A 1 hour formal exam, multichoice format, which will be marked and validated by the Brookwood International Academy of Healthcare Research.

Short break

12.00 **Careers in clinical research: opportunities available and how to find that first job**
An insight into opportunities for new graduates by Bob Gammon of PDR Partners incorporating Bob Gammon Associates
<www.bobgammon.com>
<www.pdrpartners.co.uk>

12.45 Close

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*An Academy dedicated to training and independent certification in clinical research and GCP
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