Brookwood International Academy

Applied Course in Clinical Research & GCP

2007 Cert CRGCP Part 2 (Applied) Course

Day 1:

09.30 Introduction to course

09.40 to 11.00
Overview of important Regulations and Directives affecting clinical trials in Europe
- Directive 2001/20/EC
- Directive 2005/28/EC
- GCP-GMP interface: role of Annex 13
- EU Paediatric Regulation

11.00 to 11.15: Break

11.15 to 12.30
Essential processes for setting up a clinical trial in Europe
Sponsor requirements relating to obtaining a EudraCT number, making a CTA application, obtaining ethics committee opinion, reporting SUSARs, substantial amendments, notification of end of the trial

12.30 to 13.30: Lunch Break

13.30 to 14.30
Solving and preventing problems encountered in clinical research
Group exercises: problems based on common problems relating to ethics, consent, product accountability, protocol adherence and records forms

14.30 to 14.45: Break

14.45 until completion**
Study design and project management
Briefing: designing, planning and organising logistics for a multicentre clinical trial using critical path analysis to improve efficiency and to determine key performance indicators.

*** approx 3-4 hours needs to be allocated to this project. Time management will be left to the discretion of the group members. There will be minimal tutor input.*

Day 2:

09.00 to 10.45
Presentation and discussion of group projects
(short break at a convenient time)

Recruitment to clinical trials
Interactive exercise to identify and record ways to improve recruitment of subjects to clinical trials
(start time dependent on group presentations)

10.45 to 11.10: Break

11.10 to 12.30
Important Regulations, Directives and guidelines affecting clinical trials (Part 2)
- Data protection in trials
- EU Volume 10, Clinical trials
- Safety in Phase I trials (Duff Report)
- Specific modalities for non-commercial trials
- Computerised systems in clinical trials (interactive)
- 21 CFR Part 54 (financial disclosure)

12.30 to 13.30: Lunch Break

13.30 to 14.45
The monitoring and audit of critical clinical trial documents
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

14.45 to 15.00: Break

15.00 to 16.15
Classification and management of audit and inspection findings
Learning by involvement activity to consider breaches of GCP and protocol

16.15
Concluding remarks and close

PO Box 9, Guildford, Surrey, GU3 2WZ, UK
Tel: +44 1483 811383: Fax: +44 1483 812163
Training with Certification: www.brookwoodacademy.org

V1060207