

Advanced Monitoring And CRA Skills

This practical course will introduce experienced monitors and CRAs to the more complex aspects of clinical trial monitoring and prepare them to work at a more senior level.

What Is The Course About?

This topic covers advanced study site management and monitoring of clinical trials. Topics include how to plan monitoring visits more effectively and proactively, how to use the criteria matrix to select the most appropriate investigators, monitoring various data collection methods (eg e-source). It also focuses on co-monitoring, dealing with difficult sites and how to motivate staff, problem solving, working under tight timelines, detecting fraudulent data, patient recruitment and retention issues, and appropriately documenting and reporting issues. This course will take you through these important areas of advanced monitoring to help ensure that you will be effective and meet the more stringent GCP inspection requirements that we now have in Europe.

By The End Of This Course, You Will Be Able To:

- significantly have improved your monitoring performance to an advanced level
 - work much more efficiently and understand how to plan monitoring visits much more proactively
 - have gained expertise in how to co-monitor other monitors
 - developed strategies for dealing with clinical trial monitoring issues
 - developed superior strategies for investigator selection, improving patient recruitment and for motivating investigator sites
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The Trainer

Dr Laura Brown

Laura is an independent training consultant and Director of the MSc in Clinical Research at Cardiff University. Laura has more than 18 years experience in the pharmaceutical industry. She has worked for several companies as a Clinical Research Manager, Audit Director and as Head of a Training Department.

Laura is an international expert on monitoring and Clinical Research issues. She was Chairman on the Institute of Clinical Research GCP Forum for six years, and writes regularly on clinical research and GCP.

She is a member of the Editorial Board of the Good Clinical Practice Journal and is author of SCRIP's latest GCP guide, and a practical guide to the Clinical Trial Directive.

Course Fee: £1,290 +vat

If you book on the course more than 9 weeks in advance, a 10% discount will be applied.

Location: The Regency Hotel, 100 Queens Gate, South Kensington, London, SW7 5AG

For more information about this or any of our other courses or services, please call us on +44 (0)118 975 4512 or visit our website www.rostrumtrainingsolutions.com

Programme

Advanced Monitoring & CRA Skills

Introduction & Objectives

How applying project planning principles to monitoring can improve monitoring efficiency and save the monitor time

- brief overview of project management principles to help plan more effectively and proactively

Brief discussion on what the expectations of an Advanced monitor are and how the role may differ in different organisations

Fraud prevention and detection

- what should the monitor look for?

Investigator selection including discussion of additional considerations for recruitment of GPs as investigators

Patient recruitment and retention

Monitoring issues

- SDV, e-source, inspection, ethical approval, informed consent issues

Monitoring electronic data

- EDC and electronic notes, considerations for future EMEA inspections

Co-Monitoring

- how to prepare for a co-monitoring visit, what you should look for during the visit, how to document the visit and give feedback to the monitor

Motivating the investigator team

Time Management

- identify and manage the most common time wasting activities, maximise your prime time to improve your personal performance, improve your ability to prioritise what is important