

## Effective Monitoring Visits

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What every monitor should know to be able to comply with the regulatory requirements for carrying out effective monitoring visits.

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### What Is The Course About?

Monitoring clinical trials to comply with ICH GCP, FDA, ISO 14155 the Clinical Trial and the new GCP Directives is vitally important to meet regulatory requirements and sponsor SOPs. This interactive course will cover all the key aspects of how to carry out the different monitoring visits effectively and also to ensure compliance with the latest requirements. This will include planning and preparation for carrying out different types of monitoring visits such as site selection, initiation, routine monitoring, and close out. This course will enable you to gain an understanding of the responsibilities at both the study site and the sponsor site, and how to carry out the crucial study site visits. You will also cover how to prepare for a monitoring visit when you are audited and/or regulatory inspection. This highly enjoyable course will help ensure you will meet the stringent audit and inspection requirements that we now have in Europe.

This course has been specifically designed for monitors, CRAs, medical research associates and other clinical research professionals wanting to learn about how to carry out effective and compliant monitoring visits including study site professionals who have responsibility for monitoring.

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### The Trainer

Dr Laura Brown

Laura is an independent training consultant and Director of MSc in Clinical Research at the School of Pharmacy, University of Cardiff. Laura has extensive of monitoring and auditing/QA experience in the pharmaceutical industry. She has worked for several companies including Glaxo Wellcome, Hoechst Marion Roussel, Good Clinical Research Practices and Phoenix International. She has worked as a Monitor, Clinical Research Manager, Project Manager, Audit Director and as Head of a Training Department.

Dr Brown is an international expert on GCP and Clinical Research issues. She was Chairman of the Institute of Clinical Research Forum for six years, regularly writes on clinical research, GCP and the Clinical Trial Directive, and is a member of the Editorial board of the Good Clinical Practice Journal. She 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

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# Programme

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### DAY ONE

Introduction & Objectives

What is the role and responsibilities of the monitor?

Develop effective monitoring visits to the study site

Preparing for study set up visits: planning and preparation so as to comply with all key GCP requirements

How to select Investigators and study site personnel able to comply with GCP and the CT Directive

Conducting initiation visits

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### DAY TWO

Review of Day One

Conducting initiation visits (continued)

Conducting monitoring visits

Close-out visits

How to manage Inspection and Audit visits of your sites

Summary & Close