

Presented by  
Management Forum

# Clinical Trial Monitoring

21-22 July 2025

This course will assure monitors understand the importance of compliance with latest ICH GCP R3 requirements, and how these apply to monitoring clinical trials in the future.



**Format:**  
Live online



**CPD:**  
12 hours for your records



Certificate of completion

# Course overview

**With regulatory inspectors increasingly finding GCP issues with monitoring clinical trials, it is becoming even more important for the biopharmaceutical industry, study sites, and CROs to employ efficient and accurate strategies for monitoring clinical trials.** Also, the global COVID-19 pandemic has changed the ways clinical trials are monitored and resulted in remote and centralized monitoring techniques at the forefront of monitoring. This has created an environment that requires monitors to not only purely focus on site visits. Regulatory authorities promote these alternative ways of monitoring trial data and the future is likely to include a more hybrid monitoring approach.

This highly interactive course, which includes group discussions, ensures that monitors not only understand the importance of compliance with the latest GCP standards but also gain insights into how new monitoring approaches are shaping the future of clinical trials.

## Benefits of attending

- **Ensure** GCP compliance for monitoring clinical trials including during Covid and monitoring approaches for the future
- **Evaluate** the development of monitoring plans through protocol analysis for remote risk management
- **Discuss** tools and risk evaluation approaches for remote monitoring
- **Ensure** appropriate site selection, initiation, monitoring, and close out visits are carried out including during a pandemic
- **Review** sponsor and CRO oversight of monitors

## Who should attend?

- Monitors
- Clinical research associates (CRA)
- Clinical trial managers
- Study coordinators
- Project managers
- Research nurses
- Study site assistants
- Those responsible for oversight of monitoring
- Investigators seeking to move into clinical trial monitoring

This course will benefit those involved in the monitoring of clinical trials, including new and soon-to-be monitors. This will also be an ideal refresher including how monitoring has changed because of the pandemic and those responsible for oversight of monitors.

# Programme

## Day 1

### **ICH GCP R3 Compliance considerations for monitoring clinical trials for the future**

- What is the role of the monitor/CRA to comply with GCP and changes as a result of the pandemic and technological advances?
- The monitoring role in the context of having a quality system for clinical trials
- ICH E6R3 and update and impact on monitoring

### **Site selection**

- Criteria for selecting suitable sites
- Site Feasibility Assessment

### **Site initiation**

- Preparing for site initiation
- Agenda and content of site initiation visit report to comply with GCP
- Risks of inappropriate site initiation & resulting issues

### **Monitoring visit procedures**

- Preparing for site monitoring
- Important consideration during SDV and virtual clinical trials
- Identifying issues and developing solutions
- Monitoring visit report to comply with GCP

## Day 2

### **Study close-out visits**

- Preparing for site closure
- Final preparing of documentation and entering data
- Content of closeout visit and follow-up to comply with GCP

### **Planning Patient recruitment strategies**

- Optimising recruitment to clinical trials
- Common recruitment problems in clinical trials and how these may be managed

### **Oversight of monitoring**

- Co-monitoring visits including by the sponsor and CRO management
- Preparing a sponsor monitoring oversight visit
- Follow-up with the monitor/CRO

### **GCP, documentation and archiving**

- Requirements of the GCP Inspectors
- TMF considerations

### **Reporting serious breaches and preventing fraud: what monitors need to know**

- What are the signs a monitor should look for serious breaches and fraud?
- What actions should the monitor take?
- How to report serious breaches

### **Preparing for audit and inspection visits to comply with GCP**

- How to prepare effectively for a study site audit and/or regulatory inspection
- What do QA departments and inspectors look for?
- A brief review of regulatory authority inspections findings

# Presenter



Dr. Laura Brown is an independent pharmaceutical QA and training consultant. Laura is an expert in GCP compliance for running and monitoring clinical trials. She has more than 20 years of experience in the pharmaceutical industry in several senior roles and has worked for several companies, including GSK, Hoechst Marion Roussel, and Phoenix International in quality assurance of clinical trials.

Laura is an international expert in regulatory requirements in clinical research and was Chair of the Institute of Clinical Research (ICR) Forum for over ten years. She writes regularly on clinical research regulatory requirements and is the author of several articles on the ICR Clinical Trial Regulation, 'The Planning of International Drug Development' in the Clinical Research Manual, and has written a chapter on International Pharmaceutical Product Registration.

# Course date

21-22 July 2025

Live online

09:30-17:00 **UK (London)** (UTC+01)

Course code 14825

GBP **1,299** ~~1,499~~

EUR **1,819** ~~2,099~~

USD **2,087** ~~2,399~~

Until 16 Jun

## How to book



**Online:**

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Alternatively contact us to book, or if you have any queries:



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**Phone:**

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## Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

## Further information

### Fee

The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

### Please note

IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

### Terms and conditions

The rest of our terms, the event cancellation policy and the terms and conditions are on our website, please visit [ipi.academy/content/terms-and-conditions](https://ipi.academy/content/terms-and-conditions)

# Reviews




**Fantastic, energetic, and positive. Very clear describing of the topics and good structure. Discussions. It made me feel more involved in the webinar.**

 **Viktoriiia Kyrylenko**  
Project Manager  
BIOPHARMA PLASMA LLC  
Jul 29 2024



**The speaker was knowledgeable, and made an effort to incorporate videos & discussions to break up a dry subject.**

 **Beatrice Millward**  
Data Manager  
Liverpool Clinical Trials Centre - University of Liverpool  
Jul 29 2024



**It was good to actively take part as this makes you think harder about what you have been told.**

 **Vicki Paterson**  
Senior Research Associate  
Frontier Science Scotland  
Jun 5 2023

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