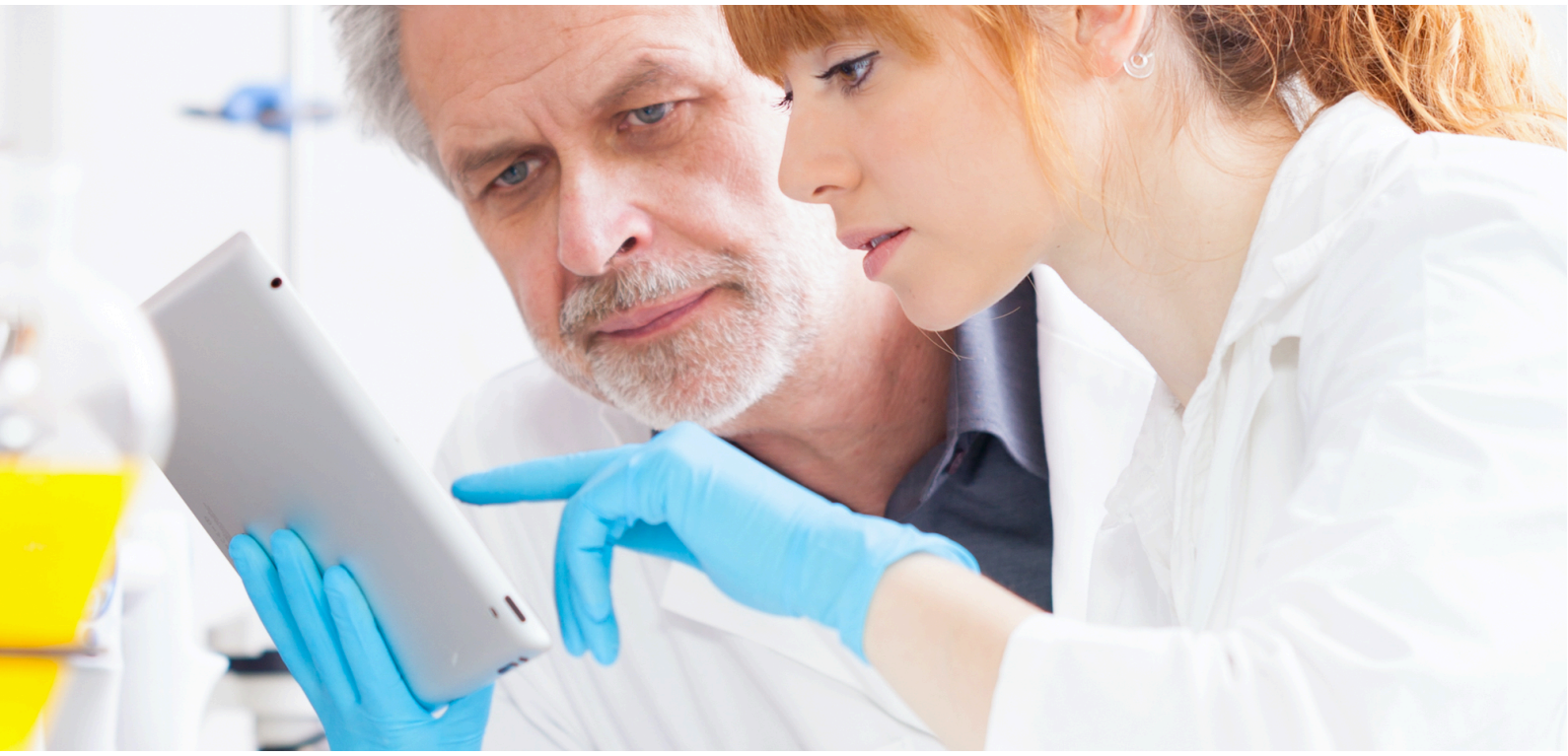
IPI Academy

MANAGEMENT forum



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

Laura Brown

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 on regulatory requirements in clinical research and was Chair of the Institute of Clinical Research GCP Forum for over six years. She writes regularly on clinical research regulatory requirements and is the author of several articles on the EU Clinical Trial Regulation, "The Planning of International Drug Development" in the Clinical Research Manual, and has written a chapter in International Pharmaceutical Product Registration.

Course date

21-22 July 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 14825*	GBP **1,499** EUR **2,099** USD **2,399**

How to book

Online:
ipi.academy/2620

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

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% 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 the our terms, the event cancellation policy and the terms and conditions are on our website, please visit 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.

Viktoriia 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

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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