IPI Academy

MANAGEMENT forum

Presented by
Management Forum

EU Clinical Trial Regulation 536/2014: Overview and Implementation Experience

13-14 October 2025

This course will provide an update on the experience of working to the regulation since Go-live, to help your implementation and compliance including transferring clinical trials from the directive to the regulation.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

The CTR, which became applicable on 31st January 2022, is directly effective in all EU Member States and introduced the biggest change to the legal framework surrounding clinical trials since the Clinical Trials Directive was implemented. The CTR has already had a global impact as all interventional trials that take place even partially in an EU Member State need to comply with its regulatory requirements, at every stage of the trial life cycle.

This course will provide an essential understanding of the new Regulation and key associated implementing acts and other texts for carrying out clinical trials in the EU. It will provide an essential understanding to help with compliance with the new Regulation and key associated implementing acts and other texts for carrying out clinical trials in the EU. The programme will highlight the most important of these key requirements and how these have impacted so far on trials for biopharmaceutical companies, vendors and study sites since going live in 2022.

This will include explaining how the regulation has harmonised procedures for carrying out clinical trials across the EU and to simplify the clinical trial approval dossier by submission through a new clinical trial CTIS (Clinical Trial Information System).

Benefits of attending:

- **Gain** an overview of the Clinical Trial Regulation and changes for trials in the EU
- **Understand** the new Clinical Trials Information system (CTIS) and experience so far
- **Share** experiences of implementing the Clinical Trials Regulation
- **Discuss** the Clinical Trial Regulation implementation documents
- **Understand** the EU clinical trial authorisation process and experience

Key topics to be covered include:

- Clinical Trials Information System
- Clinical trial authorisation process
- Safety reporting
- Requirements for managing investigational medicinal products
- Clinical trials conducted on children
- Regulatory inspection

Who should attend?

This event is ideal for anyone requiring an understanding and update on the EU Clinical Trials Regulation (536/2014). The course is relevant for those working in regulatory, clinical research, clinical operations, project management, pharmacovigilance, quality assurance (GCP auditors), vendor/CRO professionals, study sites and other professionals in pharmaceutical and biotechnology organisations conducting trials with drugs, biologics or combination products.

It will also be of interest to those departments who liaise with/support clinical trial personnel, and all other professionals who want to know more about this important new regulation.

Programme

Day 1

Background to the EU Clinical Trial Regulation

- The development of European clinical trial legislation
- The framework of clinical trial regulations in Europe
- Experience and challenges so far since Go Live

Overview of the key requirements and changes

Including:

- Roles and responsibilities
- Non-EU sponsors
- Transparency
- Co-sponsorship

Harmonisation templates

- Investigator Curriculum Vitae
- Declaration of interest template
- Site suitability
- Informed consent and patient recruitment procedure
- Compensation for trial participants

Clinical Trial Regulatory Authorisation

- The significant changes in clinical trial approval in the EU
- The new clinical trial authorisation process
- Substantial modifications
- Notices
- Requests for information
- End of study reports

Day 2

The new CTIS (Clinical Trial Information System)

- What is CTIS?
- How to use CTIS
- CTIS training
- Transitioning to the regulation

Clinical Trial Ethical Approval and Informed Consent

- Ethical approval considerations under the Regulation
- Informed consent changes under the regulation

EU Clinical Trial Regulation Documents

- Serious breaches
- Risk-proportionate approaches in clinical trials
- Summaries of clinical trial results for laypersons
- Q&A document

Manufacturing

- GMP requirements
- Key requirements for IMPs and auxiliary medicinal products
- Labelling and packaging

Safety reporting

- Adverse event reporting – requirements and definitions
- Safety reporting requirements
- Safety reporting including RSI (reference safety information)

Clinical Trials in Children

- Considerations for running clinical trials on children
- Assent and consent
- Key differences and requirements for running clinical trials on children compared to adults

Inspection preparation under the new regulation

- GCP and GMP inspection guidelines
- How to prepare for inspection in the EU under the new EU Clinical Trial Requirements
- TMF guideline documentation considerations for inspection

Presenter

Laura Brown

Dr Laura Brown MBA, BSc (Biochemistry), BSc (Psychology), PhD, Diploma in Clinical Science, FICR, is a Pharmaceutical Management and QA Consultant.

Laura has more than 25 years of experience in the pharmaceutical industry including clinical trial regulations. She has worked as a clinical research manager, audit director and head of a training department. 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 Trials Regulation, The Planning of International Drug Development in the Clinical Research Manual and has written a chapter in International Pharmaceutical Product Registration.

Laura has consulted with several companies for the implementation of the CTR internationally.

Course date

13-14 October 2025

Live online
09:30-16:30 **UK (London)** (UTC+01)
Course code 15052

GBP **1,299** ~~1,499~~
EUR **1,819** ~~2,099~~
USD **2,087** ~~2,399~~
Until 08 Sep

How to book

Online:
ipi.academy/2265

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 **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 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

★★★★☆

Laura is a good speaker, keep the attention. The content was in line with the expectation.

Margherita Lerro
Study Manager
Menarini Ricerche
May 23 2022

★★★★☆

Very nice webinar which gave a good overview of the CTR and the CTIS portal. I liked the parts where the part 1 and part 2 was presented as I think this is not straightforward to understand. Also, I like the small quizzes that were done.

Ellen Due Horup
Compliance Manager
ALK-Abelló
Feb 21 2022

★★★★★

This was a very detailed and great overview of the CTR and I would recommend following this course if this new CTR has impact on your work or your company.

Leyla Nematollahi
Regulatory Affairs Liaison
Galapagos
Apr 22 2021

★★★★☆

I think overall the webinar very good, instructive and informative.

Ban Eshqi
Scientific Affairs Pharmacist
CHEMIDEX PHARMA LTD
Apr 22 2021

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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