IPI Academy

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*Presented by*
**Falconbury**

# Clinical Trial Agreements: Key Legal, Regulatory and IP Considerations for the EU and UK Markets

**12 May 27**
+ 23 November 27

Essential training course for lawyers, contract managers, and clinical professionals covering liability risks, transparency obligations, and IP protection in clinical trial agreements (CTAs).

**Format:**
Live online

**CPD:**
3 hours for your records

Certificate of completion

# Course overview

**The life sciences sector is heavily regulated and CTAs are some of the most important agreements for companies operating in this sector.** Having appropriate CTAs in place is therefore essential for managing relationships between the different stakeholders, and apportioning risk and responsibilities between them. If appropriate contractual arrangements are not in place, a clinical trial may not receive approval or issues may arise with the integrity or validity of the data collected. Further, disputes between the parties can arise if responsibilities are not clearly defined in the agreement.

This intensive training course provides essential insights into the legal framework governing clinical trials in the EU and UK, ensuring compliance, protecting intellectual property and managing liability risks.

The expert speakers will explain the dynamic and increasingly demanding regulatory and data protection landscape to better inform those negotiations and drafting these agreements.

## Benefits of attending

By attending this training course you will:

- **Learn** about the regulatory framework concerning clinical trials in the EU and the UK
- **Understand** the EU Clinical Trial Regulation and UK Human Use (Clinical Trials) (Amendment) Regulations 2025
- **Examine** the roles and obligations of stakeholders including sponsors, CROs, investigators, and ethics committees
- **Navigate** clinical trials approval, ethical approvals, policy issues, and the legal risks of non-compliance
- **Master** informed consent, clinical trial transparency, and compensation models to mitigate legal exposure
- **Learn** how to protect IP rights in clinical trials, draft strong confidentiality agreements, and manage publication clauses.

## Who should attend?

This training course has been specially designed for:

- Lawyers and in-house legal teams
- Contract managers
- Clinical contract specialists
- Clinical trial managers and professionals
- R&D staff
- Regulatory specialists
- IP lawyers and professionals

And CROs, sponsors and healthcare organisations looking to stay ahead in an evolving legal landscape.

# Programme

**Overview of the regulation of clinical trials – the legal framework governing clinical trials in the EU and the UK**

- What a clinical trial is and the types of clinical trial
- Who the stakeholders are and their roles and obligations
- EU regulatory framework under the Clinical Trial Regulation 536/2014/EU and the Clinical Trials Information System (CTIS)
- UK framework post Brexit under the Human Use (Clinical Trials) (Amendment) Regulations 2024
- Clinical trial approval, ethics approval and policy issues (eg Health Research Authority approval)
- What could happen if a clinical trial is not conducted in accordance with the law

**Consent, data and IP rights**

Sponsors and CROs must meet obligations relating to transparency, participant consent and data protection in clinical trials. In turn, those obligations have an impact on parties' liability risks and IP rights. This session will examine:

- Participant consent and liability risks:
  - Transparency obligations and the publication of clinical trials outcomes
  - How transparency and consent interact with liability risks, including:
    - Compensation models
    - Clinical trials insurance
    - Product liability risks for licensed products
- Data protection:
  - Overview of the requirements
  - Use of patient data during and after a clinical trial (particularly in light of the 3/2019 guidance from the European Data Protection Board)
- Intellectual property rights:
  - Relevant IP rights associated with clinical trials
  - How to best protect any accruing IP rights
  - Drafting and negotiating of IP rights, confidentiality and publication clauses

**Final questions**

# Presenters



**Sarah Cowlishaw**

**Sarah Cowlishaw** is a Partner at Covington & Burling LLP. She advises clients on a broad range of life sciences matters. She supports innovative pharmaceutical, biotech, medical device, diagnostic and technology companies on regulatory, compliance, transactional, and legislative matters.

Sarah is a partner in London and Dublin practicing in the areas of EU, UK and Irish life sciences law. She has particular expertise in medical devices and diagnostics, and on advising on legal issues presented by digital health technologies, helping companies navigate regulatory frameworks while balancing challenges presented by the pace of technological change over legislative developments.

Sarah is a co-chair of Covington's multidisciplinary Digital Health Initiative, which brings together the firm's considerable resources across the broad array of legal, regulatory, commercial, and policy issues relating to the development and exploitation of digital health products and services.



**Robin Blaney**

Robin Blaney is a partner in Covington & Burling's Life Sciences practice. He advises pharmaceutical, biotechnology, medical device and cosmetic manufacturers and trade associations on a wide range of regulatory, compliance, transactional and legislative matters, as well as the full range of commercial agreements that span the product life-cycle in the life sciences sector. His expertise includes clinical trial agreements, manufacturing and supply agreements, distribution and other marketing agreements, regulatory services agreements and tenders. He has particular experience structuring and documenting EU pharmaceutical distribution arrangements and transitional arrangements relating to product acquisitions.

# Course dates

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|---|---|---|
| **12 May 27** | **Live online**<br>13:30-17:00 **UK (London)** (UTC+01)<br>*Course code 17277* | GBP **350** ~~400~~<br>EUR **490** ~~560~~<br>USD **562** ~~640~~<br>**Until 17 Mar** |
| **23 November 27** | **Live online**<br>13:30-17:00 **UK (London)** (UTC+00)<br>*Course code 17513* | GBP **350** ~~400~~<br>EUR **490** ~~560~~<br>USD **562** ~~640~~<br>**Until 28 Sep** |

## How to book

**Online:**
ipi.academy/3295

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

## 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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