IPI Academy

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Presented by
Falconbury

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

28 November 2025
+ 18 March 2026, 2 July 2026, 24 November 2026

This intensive half-day programme focuses on CTAs in the life sciences sector where legal, policy and IP considerations underpin this highly regulated area.

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 short 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 seminar 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 Medicines Regulations
- **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 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

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 Medicines Regulations 2012
- 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.

Peter Rudd-Clarke

Peter Rudd-Clarke specialises in helping businesses navigate regulatory challenges and liability risks, particularly in the life sciences, healthcare and consumer products sectors.

Peter advises a range of businesses including medical device companies, software producers, pharmaceutical manufacturers, service providers and producers of lifestyle products.

His regulatory experience includes advising on the regulation of medical devices and consumer products, as well as CE/UKCA marking, clinical trials, regulatory investigations, the application of industry codes and ongoing compliance matters.

The litigation and risk management side to Peter's practice involves defending manufacturers of complex products against liability claims, often across multiple jurisdictions; as well as advising clients on product recalls and corrective actions.

Peter is ranked in the Legal 500.

Florian Reiling

Dr Florian Reiling, MBA, has more than 10 years of experience in advising his clients in relation to all matters of intellectual property law. His main focus, however, lies on the commercialisation of IP rights in the Life Science & Healthcare sector.

Among his further key areas of expertise are R&D and collaboration agreements, the protection of AI-generated works (including the issues arising from the underlying legal frameworks), the protection of trade secrets, joint ventures and IP-related transactions.

Florian is an active member of the Life Science & Healthcare sector and has comprehensive experience in supporting clients from these industries in all contractual aspects involving the protection, the development and the commercialisation of IP Rights as well as regulatory issues.

Since many years, Florian is ranked in Legal 500, Best Lawyers, Handelsblatt and other directories for his work and experience in complex IP matters.

Julia Kaufmann

Julia Kaufmann, Partner, Osborne Clarke, advises both national and international companies on all legal matters relating to information technology, data licensing and data privacy law, cyber security, AI, ecommerce, marketing, and digital transformation. She focuses on the industry sectors Technology, Media and Communications as well as Life Sciences & Healthcare.

Julia has strong expertise with multi-jurisdictional privacy and data protection as well as ecommerce compliance projects. Furthermore, Julia has a focus on privacy law compliance and legal challenges with AI in the Life Science and Health Care Sector.

She has been assisting numerous multi-national companies with global data protection compliance programs, M&A-related privacy due diligence and integration, global digital marketing strategies, implementation of IT tools with AI components, investigations by data protection authorities, internal investigations, and legal requirements for the distribution of digital content and services.

Julia studied law in Munich at the Ludwig-Maximilians-Universität and obtained her LL.M. degree from the University of Texas at Austin, USA. She was admitted to the German bar in 2007 and to the New York bar as Attorney-at-Law in 2009. Before joining Osborne Clarke, Julia was a partner at an international law firm headquartered in the US.

She is named "Name of Next Generation" in data protection by Legal 500 in 2024 and ranked among "Best Lawyers" for data protection and "Best Lawyers" for information technology by Handelsblatt in cooperation with Best Lawyers in 2021 through 2024.

In 2022, Julia was named as one of only three German women in the second edition of Women in Data. Women in Data focuses on women who are at the forefront of legislation, regulation and technology.

In addition, Julia has been named one of 565 BTI Client Service All-Stars 2022, where clients identify lawyers who stand above all the others in delivering the absolute best in client service.

Presenters

Roderick Dirkzwager

Roderick Dirkzwager, Associate at Covington & Burling LLP, advises clients in the life sciences sector on a broad range of regulatory, transactional and intellectual property matters relating to the discovery, development and commercialisation of their products. Roderick is a member of Covington's Diversity and Inclusion Committee and is a co-lead of the LGBT+ Affinity Group in London.

With a broad life sciences practice, Roderick regularly advises on:

- EU, Irish, and UK regulatory issues relating to pharmaceutical products and medical devices;
- commercial agreements that span the product life-cycle in the life sciences sector, including collaborations and other strategic agreements, clinical trial agreements, distribution arrangements and manufacturing and supply contracts;
- regulatory and commercial due diligence for life sciences transactions; and
- intellectual property issues arising in corporate transactions and IP-related contracts.

Roderick is also a member of Covington's Life Sciences in Africa team and advises clients on regulatory and commercial strategies for the supply of medical products across Africa, including through international recognition procedures such as WHO pre-qualification. Prior to joining the firm, Roderick completed his Ph.D. in Biochemistry, focusing on the development of novel, low-cost malaria diagnostic technologies using DNA aptamers.

Course dates

28 November 2025	**Live online** 13:30-17:00 **UK (London)** (UTC+00) *Course code 16621*	GBP **350** ~~400~~ EUR **490** ~~560~~ USD **562** ~~640~~ **Until 24 Oct**
18 March 2026	**Live online** 13:30-17:00 **UK (London)** (UTC+00) *Course code 16622*	GBP **350** ~~400~~ EUR **490** ~~560~~ USD **562** ~~640~~ **Until 11 Feb**
2 July 2026	**Live online** 13:30-17:00 **UK (London)** (UTC+01) *Course code 16623*	GBP **350** ~~400~~ EUR **490** ~~560~~ USD **562** ~~640~~ **Until 28 May**
24 November 2026	**Live online** 13:30-17:00 **UK (London)** (UTC+00) *Course code 16624*	GBP **350** ~~400~~ EUR **490** ~~560~~ USD **562** ~~640~~ **Until 20 Oct**

How to book

Online:
ipi.academy/3295

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

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Discounts

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- 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
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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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