IPI Academy

falconbury

Presented by
Falconbury

Drafting and Negotiating Clinical Trial Agreements

5 November 2024

This intensive and interactive one-day programme focuses on CTAs in the pharmaceutical industry where legal, policy and ethical considerations underpin how these agreements are drafted

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Why you should attend

The life science 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 and interactive one-day programme focuses on CTAs in the pharmaceutical industry where legal, policy and ethical considerations underpin how these agreements are drafted. Participants will receive an overview of the legal framework regulating clinical trials in the European Union (and UK), before taking a closer, comprehensive look at specific issues that must be considered when drafting a CTA. Using a case study, participants will also look at some example clauses and will have the opportunity to practise negotiation skills in the safe environment of the course room under the guidance of our expert faculty.

By the end of the programme, you will be more confident in spotting and addressing the key issues that arise when negotiating and drafting CTAs, understand how best to mitigate against the risks and deal with them effectively when they do arise.

Key topics covered in this intensive and interactive seminar:

- An overview of the legal, ethical and policy considerations that underpin the conduct clinical trials as these affect how the terms of clinical trials agreements are drafted
- Recognising and dealing with key commercial and regulatory issues (including in particular relating to Brexit and the "flexibilities" adopted during the pandemic) that arise when drafting clinical trials agreements
- Drafting and negotiating techniques to minimise disputes and maximise efficiency

Attending this seminar will enable you to:

- **Understand** the legal framework concerning clinical trials in the EU and the UK
- **Recognise and address** the issues that arise when drafting and negotiating CTAs
- **Gain** a better understanding of the

Who should attend?

This course will be particularly beneficial to:

- Contract managers
- Clinical contract specialists
- Clinical trial managers
- R&D staff
- Regulatory specialists
- Lawyers and in-house legal teams
- Legal executives

Please note:

- This event assumes that the attendees have familiarity with commercial contracts (and ideally clinical trial agreements and clinical investigation agreements).
- The speakers will explain the dynamic and increasingly demanding regulatory and data protection landscape to better inform those negotiations and drafting these agreements.
- The mock negotiations are aimed at people who want to obtain a better understanding of how to manage negotiations and to consider alternative approaches to common negotiation impasses.

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
- EU regulatory framework:
  - The current Clinical Trials Directive (Directive 2001/20/EC)
  - The new Clinical Trial Regulation (Regulation 536/2014/EU)
- UK framework post Brexit
- Who the stakeholders are and their roles and obligations
- Ethics approval and policy issues (eg NHS approval)
- What could happen if a clinical trial is not conducted in accordance with the law

Specific considerations relevant to the conduct of clinical trials

- Informed consent – what is it and why is it needed?
- 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)
- Product liability – what is the law (and crucially current practice) on product liability and the requirement of clinical trials insurance
- Confidentiality and intellectual property rights:
  - the tension between principle of transparency and protecting confidential information
  - protecting intellectual property rights

CASE STUDY: Drafting and negotiating CTAs – Part 1

- The anatomy of a CTA and some typical clauses and issues that might arise. We look at these issues from the perspective of each party and the negotiation tactics that could be used to reach an agreed position.
- Structure of a CTA (and the UK model CTAs updated in March 2020)
- Common sticking points in negotiation:
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  - Ownership and use of intellectual property
  - Use of data generated during the trial
  - Liabilities and insurance requirements for both parties
  - Warranties and indemnities
- Manufacture and supply
- Disclosure of payments to healthcare professionals and healthcare organisations
- Freedom of information requests
- Termination and consequences of termination

PRACTICAL EXERCISE: Negotiation

This interactive session allows participants to practise negotiating specific clauses concerning liabilities and indemnities using skills and techniques to minimise disputes and maximise efficiency. Example clauses will be provided and considered within the group. Participants will be divided into small groups representing the opposite party to practise their negotiation skills.

CASE STUDY: Drafting and negotiating CTAs – Part 2

- Discussion of points arising from the negotiation exercise
- Standard contracts
- Practical tips
- Specific ideas arising from a very large contract with a CRO to whom the pharma company outsourced all of its clinical trial management requirements. Making the CRO *de facto* (and in a couple of cases *de jure*) sponsor.

Additional considerations relevant to drafting and negotiating CTAs

- Multi-jurisdictional trials
- The implications of Brexit

Course date

5 November 2024

Live online
09:30-17:00 **UK (London)** (UTC+00)
Course code 14011

GBP **499** ~~599~~
EUR **719** ~~859~~
USD **823** ~~979~~
Until 01 Oct

How to book

Online:
ipi.academy/1948

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

Email:
info@ipi.academy

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

★★★★★

The content, speakers and their presentations were great. It's a complicated subject and they mostly presented it clearly. Also they provided links to guidance which may help in the future.

Tracy Spraggon
Senior Contracts Manager
London School of Hygiene and Tropical Medicine
May 11 2023

★★★★☆

Al three speakers were extremely knowledgeable and approachable.

Elizabeth MacRae
Contracts Manager
Sitryx Therapeutics Limited
Nov 7 2023

★★★★☆

Very useful. I wish I could listen to it again as a recording, as I feel that I did not necessary grasp everything in one go

Viktor Zsuffa
Legal Counsel
Société des Produits Nestlé SA
May 11 2023

★★★★☆

Very useful. I wish I could listen to it again as a recording, as I feel that I did not necessary grasp everything in one go

Samantha Verhaeghe
In-house lawyer
Genfit SA
May 11 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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