IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Medical Device Studies: Clinical Evidence

15-16 October 2025

Gathering and using clinical evidence for CE marking and post-market compliance in line with the new MDR.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Clinical evidence is crucial to bringing a device to market and is a very important aspect of post-market compliance to meet the requirements of current legislation. The collection of clinical data to demonstrate safety and performance is pivotal to CE marking a medical device and the collection of post-market data is key to the continued safety and performance considerations once the device is on the market.

This practical and intensive two-day course has been designed specifically for those who are involved in gathering clinical evidence required for medical devices. It will cover the full range of activities that should be applied during the collection of clinical evidence for both pre- and post-market studies and will also provide delegates with information on the European regulations for gathering clinical evidence and conducting medical device studies. Participants will benefit from advice and tips from industry experts on the practicalities of conducting studies within Europe as well as the types of clinical data to collect in order to be compliant with the new MDR.

Benefits of attending

- **Understand** the regulatory requirements and guidance applicable to clinical evidence
- **Clarification** on Clinical Evaluations (Literature Reviews)
- **Know** what is required in terms of clinical data prior to CE marking and post CE mark
- **Explore** what documentation is needed for the pre-and post-market phases of clinical data collection
- **Discover** how to conduct a clinical investigation and post market clinical follow-up study
- **Plan** how to prepare regulatory notifications to the competent authorities and obtain other necessary approvals
- **Learn** the key aspects of pre and post market study setup, management, monitoring and close down
- **Discuss** how to prepare a paper or presentation for publication and marketing
- **See** the differences between drugs and devices

Who should attend?

- Personnel involved in setting up, managing and monitoring studies
- Setting up, managing and monitoring studies
- R&D
- Marketing
- Regulatory affairs
- Those who conduct clinical evaluations/investigations/post market follow up studies
- Those moving from pharma to medical device studies

Programme

Day 1

The regulatory aspects of gathering clinical evidence for devices

- An overview of the regulations governing the clinical evidence aspects of devices
- How the regulations impact on clinical data for regulatory studies and post market studies
- Standards and guidelines applicable to medical device clinical evidence, ISO, GHTF (IMDRF), MEDDEV and NBMED

Conducting a pre-market clinical evaluation and the literature review

- The Clinical Evaluation (Literature Review)
- What's involved and how it should be conducted
- What documents are required – how is clinical data used?
  Example documents and templates will be provided to help delegates understand this process

Conducting a pre-market (regulatory) clinical investigation

- What types of studies and study designs are applicable to pre-market studies?
- What to consider in designing and implementing appropriate pre-market studies

Documentation for pre-market (regulatory) clinical investigation

- What documentation is needed?
- How this should be produced and what detail is required
  This presentation will include template documentation for clinical investigation plans, investigator brochures, case report forms and consent forms

How to obtain the necessary approvals for pre-market studies

- How to obtain Research Ethics approval
- How to obtain National competent authority approvals
- Other necessary approvals
- What to provide, timescales and practicalities

Day 2

Study management and monitoring of regulatory clinical investigation

- Key aspects study set up
- Management, monitoring and close down
- Getting the best data

How to write a final study report for a regulatory clinical investigation pre-market study

- Practical considerations for final study reports, publications and presentations of study results
  Examples and templates will be provided to help delegates understand the processes
- How to prepare a paper or presentation for publication and marketing

PMCF

- Practical considerations for conducting PMCF studies
- The differences between PMCF and regulatory studies
- When to conduct PMCF studies and other PMC data requirements

Current key issues affecting clinical evidence for medical devices

- The effect of changes to the directives and current initiatives throughout Europe

The differences between drugs and devices

Course date

15-16 October 2025

Live online
09:30-17:00 **UK (London)** (UTC+01)
Course code 15053

GBP **1,299** ~~1,499~~
EUR **1,819** ~~2,099~~
USD **2,087** ~~2,399~~
Until 10 Sep

How to book

Online:
ipi.academy/2156

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

★★★★☆

The presenters were incredibly knowledgeable in their subject areas and was able to convey complex information, in an easily digestible way. Overall, a very good summary of Clinical evidence for medical devices.

Hannah Vince-Drew
Clinical Research Supervisor
Bedfont Scientific
Jul 12 2023

★★★★★

Janette is a very good speaker; she is very prepared and provided lots of contents and information during these 2 days.

Giulia Carli
Global Clinical Affairs Programme Manager
Corin Ltd
Nov 24 2022

★★★★★

Good knowledge and information provided

Valerie Hart
Clinical Development Manager
Dermal Laboratories Limited
Nov 24 2022

★★★★★

It was perfect.

Jiwoo Hwang
Student
Dongguk University
Nov 24 2022

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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