IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Clinical Evaluation of Medical Device Software and Software as a Medical Device

22 January 2025
+ 13 May 2025, 1 October 2025

This one-day course will provide a clear understanding of the clinical evaluation requirements and their practical application for software products, including AI/ML-based devices.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

Whether developing new medical software for more precise diagnosis and targeted treatment or a healthcare app for individuals concerned about their health, manufacturers are tasked to appreciably prove to authorities the safety, quality, and effectiveness of their products. The evaluation of clinical safety and performance, as well as the overall benefit-risk profile of the product, through a critical assessment of relevant data, is one of the key requirements for the manufacturers of a medical device software and a focus area for regulators.

This course will provide a clear understanding of the the clinical evaluation requirements and their practical application for software products, including AI/ML-based devices. It will also provide advice on how to determine the type and amount of data needed to sufficiently support the intended medical purpose and (individual) clinical claims, with many practical examples and analysis of differences between EU MDR and FDA approach.

Benefits of attending

- **Gain** an in-depth understanding of the requirements for clinical evaluation and how to apply them to different types of medical device software, including AI/ML-based devices
- **Understand** how to establish measurable endpoints for clinical claims
- **Find** out how to define and generate sufficient clinical and/or performance data to meet the safety and performance requirements of your software device
- **Witness** the role of human factors and risks
- **Learn** how to retrieve and use literature data effectively
- **Identify** residual clinical risks and determine whether post-market clinical follow-up is required
- **Provide** robust documentation in support of the clinical safety and performance of your device
- **Hear** about frequent pitfalls of clinical regulatory submissions
- **Ensure** continuing compliance throughout software lifecycle

Who should attend

- Clinical and regulatory affairs professionals
- Medical software R&D engineers and scientists
- Product and programme managers
- Quality assurance professionals

Programme

Introduction to clinical evaluation

- The regulatory framework of gathering clinical evidence for devices and international differences (EU, US and UK…)
- Clinical evaluation during software lifecycle
- Clinical vs performance evaluation
- Definitions, purpose, deliverables
- Process and key characteristics
- Role of literature and state of the art
- Selecting data sources
- Defining acceptance criteria
- Evaluation of indirect benefits and risks

How to define a scope and a level of clinical evidence for medical device software

- Validation of clinical association, technical performance and clinical performance
- Role of validation and usability
- Considerations for AI/ML – devices

Case studies – clinical evaluation of medical device software

Clinical trials and validation studies

- Selecting appropriate study design and implications
- Development and validation of AI/ML-devices (cohort, case-control)
- Clinical performance studies
- Application of standards
- Generating evidence of effectiveness
- Evidence for Heath Technology Assessment

Clinical trials and validation studies – continued

- Reporting guidelines and checklists
- Challenges of mHealth trials
- Regulatory and ethical considerations

Clinical evaluation post-market

- Implementing post-market clinical follow-up for medical device software
- Real-world evidence

Presenter

Zuzanna Kwade

Zuzanna Kwade is Software Clinical Evaluation Lead at Dedalus Healthcare. Zuzanna holds a PhD in Biochemistry and has 15 years of experience in clinical and medical research. She is the co-author of several white papers on regulatory aspects of clinical research and clinical evaluation.

Since 2016, she has been actively involved in Clinical Evaluations according to MEDDEV 2.7.1 (Rev.4) for multiple devices, including high risk hardware devices and medical software. She also represented COCIR in the European Union Task Force on clinical evaluation of software and co-authored MDCG2020-1 guidance on clinical evaluation of MDSW.

Course dates

22 January 2025	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 15205*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 18 Dec**
13 May 2025	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 15206*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 08 Apr**
1 October 2025	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 15207*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 27 Aug**

How to book

Online:
ipi.academy/2818

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

Run this programme in-house for your whole team

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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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