



Presented by
Management Forum

AI & ML in Clinical Trials: Fundamentals, Applications, and Regulatory Aspects

30 June 2025
+ 6 November 2025

AI and Machine Learning are revolutionising clinical trial data management by enhancing efficiency, streamlining processes, and minimising human error. This course will be of use in both the pharmaceutical and medical device industry.



Format:
Live online



CPD:
6 hours for your records



Certificate of
completion

Course overview

Artificial Intelligence (AI) and Machine Learning (ML) are rapidly reshaping the clinical trials landscape, driving innovation in how research is designed, conducted and evaluated. While these technologies hold immense promise to enhance efficiency, reduce costs, and improve outcomes, their adoption is paired with ethical concerns, prompting the development of robust regulatory frameworks to guide their responsible use. For professionals in the field, understanding the fundamentals of AI and ML and their implications is becoming increasingly essential.

This comprehensive one-day training course provides an overview of AI and ML, focusing on their applications in clinical trials and the regulatory and ethical considerations that accompany their use. Participants will explore how AI and ML are being used to optimize trial efficiency, predict patient outcomes, and support adaptive trial designs. The course will also examine the regulatory frameworks, including the EU AI Act and related regulatory initiatives, to ensure compliance and ethical use of these technologies in a highly regulated environment.

Through engaging lectures, real-world case studies, and interactive assessments, attendees will gain valuable insights into the transformative potential of AI and ML in clinical trials while understanding the challenges and responsibilities associated with their implementation. Join us to enhance your knowledge of these cutting-edge technologies and their role in advancing clinical research.

Benefits of attending

- **Explore** the fundamental concepts of AI and ML
- **Learn** how to address common challenges with cutting-edge solutions
- **Explore** real-world use cases of AI-powered tools for clinical trial optimization
- **Understand** the ethical and regulatory requirements essential to adopting AI in clinical settings
- **Reflect** on change management in people, process, and tools for implementing an AI based tools
- **Prepare** for the future of clinical trials and stay ahead of industry advancements

Who should attend?

This course is aimed at anyone working in clinical research, clinical operations, data management, regulatory and compliance, and associated functions seeking to leverage AI and ML in clinical trials. Whether you're new to AI/ML or looking to deepen your understanding, this course provides valuable insights into how these technologies are reshaping the clinical research landscape.

Programme

Introduction to AI and ML

- Key concepts and terminologies
- Types of machine learning
- Applications in healthcare, trends and innovations

Applications of AI and ML in clinical trials

- Opportunities and challenges
- Real-world data analysis
- Trial design and simulation
- Patient recruitment and retention optimization
- Predictive modelling for outcomes

Applications of AI and ML in clinical trials cont'd

Patient monitoring and safety surveillance

Clinical data management and analysis

Workflow optimization

Regulatory landscape for AI in clinical trials

- Overview of FDA, EMA, and other relevant agencies' positions on AI and ML
- Validation and approval processes for AI-based tools
- Requirements for data handling and reporting

Ethical aspects

- Transparency, fairness, and accountability
- Mitigating bias in AI models
- Balancing innovation with patient safety

Integration and future directions

- Steps to incorporate AI into clinical trial workflows
- Overcoming common obstacles in AI/ML adoption
- Future directions

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


30 June 2025	Live online 09:00-17:00 UK (London) (UTC+01) <i>Course code 15483</i>	GBP 749 EUR 1,049 USD 1,199
6 November 2025	Live online 09:00-17:00 UK (London) (UTC+00) <i>Course code 15484</i>	GBP 649 749 EUR 909 1,049 USD 1,043 1,199 Until 02 Oct

How to book

 **Online:**
ipi.academy/2896

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

 **Email:**
info@ipiacademy.com

 **Phone:**
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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.

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