



Presented by
Management Forum

Global Market Access for Medical Device Software

8-9 June 2026

+ 30 November-1 December 2026

Navigate global market access for medical device software with insights on international regulations, reimbursement strategies, and Health Technology Assessment (HTA) to improve your product's chances of commercial success



Format:
Live online



CPD:
6 hours for your records



Certificate of
completion

Course overview

This course will provide a clear understanding of different market access requirements for medical device software.

As demand surges for Digital Health (DH) solutions worldwide, understanding and navigating international regulations is paramount for market access success. This course will equip professionals with the knowledge to successfully enter into different international markets, improving the chances of commercial success by understanding country-specific requirements.

With an increased impact on clinical management, a higher bar for evidence is required for regulatory approval and adoption, but also an increased stakeholder willingness to pay for the service provided. Although at the moment, there's no one-size-fits all approach, there is a global trend to increase DHT adoption through value-based pricing and reimbursement mechanisms. This growing trend has prompted countries, both within and outside the European Union (EU), to pilot various market authorization and access schemes, providing guidelines for coverage, and/or clear pathways for reimbursement of DHTs. This intensive course provides a comprehensive overview of the different national DHT market access and reimbursement strategies, presenting an overview of the current state of affairs.

The program will be highly interactive, using real-life examples and state-of-the-art practices across different global jurisdictions. Practical insights will be provided, hands-on exercises, and case studies to guide you through the intricate decisions needed that affect your market access processes.

The course will cover:

- Impact categories of digital health technologies (DHTs)
- Market Authorization vs. Market Access
- Coverage and Health Technology Assessment (HTA)
- Specifics of reimbursement pathways for DHTs across EU Member States
- The new Health Technology Assessment (HTA) Regulation, EDiHTA, and ASSESS-DHT
- Outside of the EU Member States: global reimbursement landscape (e.g., USA, UK, South Korea, Japan, among others)

Benefits of attending

- **Gain** an in-depth knowledge to navigate complex market access environments
- **Ensure** successful entry into international markets
- **Streamline** product development to entry different markets
- **Improve** the chances of commercial success by understanding country-specific requirements and approval processes.

Who should attend?

This course is for any professionals involved in market access for medical devices, including:

- Regulatory Affairs Managers
- Business Strategists
- Product and Service Managers
- Sales and Marketing Managers
- Legal Professionals
- Compliance Officers
- Research and Development Engineers
- Clinical Research Associates
- Project Managers

Programme

Day 1

Impact categories of digital health technologies (DHTs)

Market Authorization vs. Market Access

Coverage and Health Technology Assessment (HTA)

Day 2

Specifics of reimbursement pathways for DHTs across EU Member States

The new Health Technology Assessment (HTA) regulation, EDiHTA, and ASSESS-DHT

Outside of the EU Member States: Global reimbursement landscape (e.g., USA, UK, South Korea, Japan, among others)

Presenter



Catarina Carrao

Catarina Carrão from BioSciPons, is a clinical evaluation and benefit-risk assessment specialist. Previously, she studied Biochemistry and worked in academic research. In 2006, she was a Marie-Curie Early Stage Researcher in the Universitätsmedizin Charité Berlin. In 2011, she was a Postdoctoral fellow at the University of Yale Cardiovascular Research Centre (YCRC). In 2012, she received the European Science Slam title. In 2013, she was awarded Fellow of the American Heart Association (FAHA). In 2021 she was nominated Young Science Journalist of the Year by the Association of British Science Writers (ABSW).

Her scientific expertise in neuroscience, cardiovascular, oncology, molecular biology and biostatistics allows her to understand the needs of innovative medical device manufacturers; and support them in navigating the regulatory waters of certification. By understanding the importance of evidence, not only in written form to peers but also to deliver valuable information to the consumer, BioSciPons is favoured by start-ups in the fields of artificial intelligence, wearables, implants, among other innovative technologies.

Course dates

8-9 June 2026	Live online 09:00-12:30 UK (London) (UTC+01) <i>Course code 16295</i>	GBP 649 749 EUR 909 1,049 USD 1,043 1,199 Until 04 May
30 November-1 December 2026	Live online 09:00-12:30 UK (London) (UTC+00) <i>Course code 16587</i>	GBP 649 749 EUR 909 1,049 USD 1,043 1,199 Until 26 Oct

How to book



Online:
ipi.academy/3091

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



Email:
info@ipiacademy.com



Phone:
[+44 \(0\)20 7749 4749](tel:+442077494749)

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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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

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IPI
Academy

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