



Medical Devices Roadmap

 **24th June 2025**

 **9h00 - 17h00**

 **Instituto Pedro Nunes, Coimbra**

09h00 Event Opening

[remote] **09h30 EATRIS Digital HUB**
Florence Bietrix (EATRIS)

09h55 From Concept to Implementation of AI models: A Researcher's Perspective
Luis Mendes (AIBILI)

10h20 Clinical Investigation of Medical Devices
Mário Ribeiro (AIBILI)

10h45 Coffee Break and Networking

11h15 Navigating the CE Marking Process for AI-Enabled Medical Devices
Ana Brito (IPN)

[remote] **11h45 Industry Perspective: Challenges in Implementing the European Medical Device Regulation**
Mariana Tiberio (APORMED)

[remote] **12h10 Regulatory Scrutiny: The Notified Body's Role in AI Medical Device Certification**
Agnese Mengoli (TUV SUD)

12h35 AI in Medical Devices: Compliance from a Competent Authority's Lens
Mariana Madureira (Infarmed)

13h00 Lunch and Networking

14h00 Neurotechnology and BCIs: From Innovation to Clinical Validation – The g.tec Journey
Christopher Guger (gTec Austria)

**14h45 Clinical Applications of Brain Computer Interfaces: the BCIAUT and PowerAut/
CaixaImpulse Trials**
Miguel Castelo-Branco (CIBIT/ICNAS)

15h15 Clinical Trials Using Brain Stimulation Devices: The STIPED Project
Catarina Pereira (CIBIT/ICNAS)

15h40 Coffee Break and Networking

16h10 Integrating Patient Associations in Medical Device Research and Validation
Elsa Vieira/ Marta Teixeira (APPDA)

16h30 Closing Session