



NoBoCap Summit

Date/Time:

Thursday, 16 October 2025

www.nobocap.eu

Location:

Brussels



BRINGING EUROPE TOGETHER TO UNLOCK THE MDR/IVDR FOR INNOVATION IN EUROPE

The Summit will bring together the NOBOCAP European Community of Innovation hubs/clusters in Europe and know-how/knowledge/supportive partners, with Notified Bodies, National Competent authorities as representatives of the Medical Device Coordination Group and the European Commission.

Spin-off, Start-ups, Scale ups (Innovator SME), Investors and other key actors will be invited to join the summit in-person. A streaming will be made available for all those interested. The Pre-summit workshops offer valuable insights and hands-on experience with Nobocap Services to support the unlocking of MDR/IVDR and AI Act for Innovation.

The Summit takes place in Brussels.

NOBOCAP COMMUNITY SUMMIT 2025



SUMMIT

Thursday, October 16, 08:00-18:30

08:00-08:30 **REGISTRATION AND COFFEE**

08:30-09:00 **WELCOME**

VIDEO STATEMENT and OPENING PRESENTATION: EUROPEAN COMMISSION
THE SUMMIT PROGRAM: MODERATOR

09:00-11:00 **SCENE SETTING AND EU POLICY:**

The attractiveness of Europe for Medtech, the impact of the EU MDR/IVDR and the AI Act on innovation and the road to an innovation enabling regulatory system in Europe will be discussed.

09:00-10:00 **STATE OF PLAY - PRESENTATIONS**

(1): ATTRACTIVENESS OF EUROPE FOR MEDICAL TECHNOLOGY INNOVATION and ADOPTION OF INNOVATION IN HEALTHCARE SYSTEMS IN EUROPE (DELOITTE - TBC) ;

(2): IMPACT AND UNLOCKING MDR/IVDR FOR INNOVATION (PULSE REPORT : SPECIFIC CHALLENGES AND SUPPORTIVE INITIATIVES FOR SME in EUROPE) - (NoBoCap - Yves Verboven);

(3): LEGISLATIVE AND NON-LEGISLATIVE INITIATIVES SUPPORTING MEDTECH INNOVATORS IN THE EU (Flora Giorgio, EC Unit D3);

The EC will present its short-term actions supporting the implementation of the Regulations and aiming to foster innovation and competitiveness for medical and digital technologies in Europe.

10:00-11:00 **FROM POLICY TO PRACTICE (1) : BREAKTHROUGH INNOVATION PATHWAYS**

The Panel will present and discuss the ongoing work of the MDCG taskforce on Breakthrough Technologies, supporting timely access to innovative technologies in the EU. The panel will look at the guidance and challenges of financing these breakthrough pathways for innovative technologies often being developed by SMEs, the uptake of those technologies in the healthcare system and the challenges of monitoring the safety and performance of these innovative devices.



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PANEL:



- European Innovation Council and SMEs
Executive Agency (EISMEA) Federica Zanca – Program Manager Medical Imaging and AI in Healthcare
- MDCG–New Technologies – TF Breakthrough Devices
Co–Chair Donal B O’Connor,
Clinical Manager – Medical Devices Health Products Regulatory Authority (HPRA), IE (TBC)
- Notified Body / NBCG–Med (TBC)
- European Commission

Followed by a discussion with audience including consideration from Hospital Research, Industry-incubators and Investors Community partners of the ecosystem.

11:00–11:30

BREAK

11:30–12:00

INTERPLAY MDR/IVDR AND THE AI ACT - PRESENTATION

Presentation : DG CNET – Tatjana Evas (Unit CNET A2) (TBC)

The EC will provide an update on the implementation of the AI Act and different initiatives to support/ensure a smooth interplay with MDR/IVDR, incl. FAQ

12:15–13:00

FROM POLICY TO PRACTICE (2) : DIGITAL MEDICAL DEVICES AND AI



AI technologies are medical technologies transforming our healthcare systems. The AI Act regulates these new emerging technologies and a good interplay with MDR/IVDR is essential.

To unlock EU regulation the panel will introduce in more detail the initiatives ongoing to foster a streamlined and innovation-friendly regulatory environment, namely legislative initiatives as AI sandboxes, NB testing labs, ... as well as to provide insights on the requirements to ensure conformity with continued evolving and new forms of AI will be discussed.

PANEL:

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AI Office (TBC)

MDCG – New Technologies Co-Chair, Mariana Madureira, INFARMED PT

TEF-HEALTH – AI Sandboxes (TBC)

NB – Testing Lab

SME: Nobocap Partner Miguel Amador, Chief Innovation Officer Compear

13:00–14:15

LUNCH

14:15–15:15

FROM POLICY TO PRACTICE (3) STRUCTURED DIALOGUE AND SCIENTIFIC ADVICE AND CERTIFICATION WITH CONDITIONS AND PROVISION



In EU Regulation there are provision for manufacturers/innovators to get regulatory or scientific advice. The panel will provide an overview of the different forms of advice to the manufacturer, including scientific advice by EMA expert panels, structured dialogue with notified bodies and Joint Scientific Consultations described in Regulation on HTA.

A core element in the submission of technical documentation for conformity assessments is the Clinical/Performance Evaluation Report to demonstrate the benefits outweigh the risk of the technology and a continued monitoring in the post market phase with multiple reports to be provided.

Health system and Clinical Professional Societies expect further specific evidence on the comparative effects, and degree of certainty of the new technology provides to inform decision on use, adoption and financing. Initial piloting is now ongoing and the utility will be discussed and compared to other jurisdictions.

PANEL:

- SME / PILOT
- NOTIFIED BODIES – (2)
- EMA (SILVY DA ROCHA (EMA) / CLINICAL EXPERTS
- MDCG
- EUROPEAN COMMISSION / JSC

15:15–16:45

ON THE ROAD TO QUALITY AND UNLOCKING MDR/IVDR REGULATION FOR INNOVATION: COMMUNITY IN ACTION

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15:15–15:45

NOBOCAP ENVIRONMENT INITIATIVES - CONTINUED



With an additional 6 months in the project the future planned backbone services and availability of tools will be indicated by NOBOCAP Consortium project partners as well as the planned continuation of services after Nobocap project ends.

By ROHEALTH, MEDVIA, EU4HS, SGS , ... (TBC)

15:45–16:15

INNOVATION HUBS/CLUSTERS AND IN-COUNTRY INITIATIVES



Innovation hubs/clusters, member of the Community will express their planned initiatives to foster preparedness in unlocking the EU regulation on innovation and contribute to creating of an innovation enabling regulatory environment.

4 of Members Innovation Hubs will be on stage with others in room on the new initiatives presented, possibly with a survey before the summit. (TBC)

16:15–16:45

PARTNER INITIATIVES ON CONSULTANCY AND MATCHMAKING

Sponsor partners provide a view on specific supportive planned initiatives for innovators and NB supportive partner on support on matchmaking for emerging technologies. (TBC)

16:45–17:00

COMMUNITY OF INNOVATION HUBS AND PARTNERS IN 2026 AND CLOSING REMARKS

17:00–18:30

POST CONFERENCE DRINK

PRE-CONFERENCE WORKSHOPS

October 15, 2025

We will have the 1,5 h workshop run twice and streaming available/ virtual connection and a recording will be done. Workshop will be on

13:00 AM

Nobocap Pulse and Preparedness

- o Insight on Pulse report and valley of Death for Innovators are presented.
- o Key to success: Unlocking regulation – Preparedness : The Nobocap package for Innovation Hubs to offer.
 - Overview is provided of Nobocaps backbone services and tools, future planned exploitation of community:
 - Incl. Nobocaps' Training, Shortcourses, Nobocap C-Level , Investors, Learning Path, e-learning, ... and Community Partners Offerings.

Certification of Software and AI Accessibility Pathways:

- o E-learning applicability of MDR/ AI Act
- o Classification Software – AI
- o Testing and Experimenting across Europe
- o Certification: VITO short course

Evaluation of Guidance of Guidance on Breakthrough Emerging Technological Innovation Certification

- o Analysis of value Guidance in development
- o Supportive tools and process
 - NB initiatives and Structured Dialogue
 - Use of Emerging Technology Form
 - Nobocap Matchmaking Innovators – NB of Community
 - Investor due diligence

Evaluations of MDR/IVDR and your Voice

- o Review Input Public Consultation
- o INTERACTIVE INPUT priority (to be voiced next day)

15-25 participant + virtual connect + streaming for future play dedicated page.

Between 2 workshops, know-how partners (2-4) , member of community will be offered the provide a workshop (being a sponsor of summit)



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