NoBoCap COMMUNITY





NoBoCap Summit

Date/Time:

Thursday, 16 October 2025

Location:

Hilton Grand Place, Europakruispunt 3, Brussels, Belgium

www.nobocap.eu



NoBoCap

Description

BRINGING TOGETHER EUROPE TO UNLOCK MEDICAL DEVICE REGULATIONS & THE AI ACT FOR INNOVATORS AND SMES IN EUROPE

The Summit will bring together the NOBOCAP Community of Innovation Hubs, Clusters, and Partners, along with Notified Bodies, National Competent Authorities of the Medical Device Coordination Group, and the European Commission.

The state of play of current impact of MDR/IVDR and supportive backbone services for our SME ecosystem—spanning spin-offs, start-ups, and scale-ups will be exchanged. SME with breakthrough MD innovations and AI MD in scope of AI act will be invited to join the Summit. Their participation will further enrich dialogue, foster exchange of best practices, and support discussions on unlocking the MDR/IVDR and AI Act for innovation and to advance towards a regulatory environment that enables timely accessibility to innovation of value.

The Summit takes place in Brussels.

NoBoCap

Program.

PRE-CONFERENCE WORKSHOPS

October 15, 2025

13:00 -18:30

We will have the 1,15 h workshop run twice and streaming available/ virtual connection and a recording will be done.

13:00 -13:30 — **Registration**

13:30 -14:45 — **Workshop Round 1**

14:45 -15:00 — **Break**

15:00 -16:15 — **Workshop Round 2**

ROUND 1 & 2:

On the Pulse: Unlocking the MDR & IVDR for SMEs

- Insight on Pulse report
- Interactive workshop for SMEs and other market players

Beyond the Algorithm: Certifying Software and AI MD

- Classification Software – AI (A NB – SGS perspective)
- E-learning
- Testing labs and Conformity Assessment AI
- Interactive feedback to be voiced during the Summit

The Breakthrough MD Pathway: Fast-Tracking Medtech Innovation

- Initial guidance framework
- What will make a Breakthrough Innovation pathway of true interest for Innovators in Europe to seek
- Breakthough designation.= Guiding principles by SME Innovators
- Interactive feedback to be voiced during the Summit

16:15 -16:30 — **Break**

16:30 -17:30 — **Turning Insight into Action: Unlocking EU Medical Device Regulations for All**

- Interactive feedback to be voiced during the Summit
- How can we best support the further unlocking of EU regulations for MedTech SMEs

17:30 -18:30 — **Networking drink**

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

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

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

08:30-08:45 **WELCOME**

THE SUMMIT PROGRAM

08:45-10:00 **STATE OF PLAY AND EU - EC POLICY INITIATIVES**

Presentations will address the attractiveness of Europe for the SME ecosystem in MedTech innovation, the ability to foster timely accessability to innovative healthcare solutions across Europe. The impact of the MDR/IVDR for SME ecosystem, the state of play on concrete impact and the road ahead towards an innovation enabling regulatory in Europe will be part of the summit scene settings.

The European Commission will present ongoing initiatives and longer-term policy considerations, drawing on surveys and the recent evaluation of the MDR/IVDR.



The Summit will discuss with first hand information the latest development in the field of Breakthrough MD Guidance under development, the interplay with AI act and the further implementation of Structured dialogue and scientific advice to support of an innovation enabling regulatory environment and to go from Policy to Practice.

PRESENTATIONS:

- Attractiveness of Europe for SME driven Medical Technology Innovation - Aydin, Burçak, Deloitte
- Impact of MDR/IVDR on (SMEs) Innovation and recommendations - EC Commissioned EY Study - Daan Bijwaard, EY
- Legislative and Non-legislative EU Policy initiatives - European Commission - Flora Giorgio, Head Unit D3 Medical Devices

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

The Task Force on Breakthrough MD guidance co-chairs of European Commission and Competent Authorities, will provide 1st hand insights and discuss the latest development and plans in building out the guidance and planned implementation.

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Within the current regulatory MDR/IVDR framework provision will be put forward in support of a streamlined process with NB, on a balanced pre-post market clinical and non-clinical evidence generation and provision specific related to SME. Considerations on SME supportive initiatives of the European Innovation Council and SME executive Agency (EISMEA) will be discussed. The specific value and how the guidance compares to Breakthrough innovation pathways in other jurisdictions will be open for a moderated discussion.

PANEL:

- MDCG-NET - TF Breakthrough MD
  Donal B O'Connor, Co-Chair/Clinical Manager HPRA, Ireland
- European Innovation Council and SMEs

Executive Agency (EISMEA) Federica Zanca, Program Manager Medical Imaging and AI in Healthcare

- Notified Body: QMD - Florian Heffeter, CEO QMDServices, Austria (Online)
- European Commission -Nada Alkhayat, Policy Officer Unit D3 Medical Devices

11:00-11:30 **BREAK**

11:30-12:00 **INTERPLAY MDR/IVDR AND THE AI ACT - PRESENTATION**

Presentation: Tatjana EVAS DG CNECT, EUROPEAN COMMISSION
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.

12:00-13:00 **FROM POLICY TO PRACTICE (2) : AI MEDICAL DEVICES CONFORMITY ASSESSMENT**



AI Medical Technologies are transforming healthcare and are regulated in the EU under both the AI Act and MDR/IVDR. To help SME innovators navigate these frameworks, the panel will discuss specific provisions on testing and how to align with the conformity assessment requirements by both regulations. The discussion will feature the MDCG Co-Chair of New Technologies, experts from AI labs and certification bodies, as well as SME representatives who will share their experience and expertise in fostering conformity assessment in practice.

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PANEL:

- MDCG - New Technologies Co-Chair, Mariana Madureira, INFARMED Portugal
- AI LAB and Certification: Alexander von Janowski, TEF-HEALTH / TUV-LAB AI
- AI LAB and Certification: Guillaume Bernard, LNE, France
- SME perspective: Miguel Amador, Chief Innovation Officer Complear - Nobocap partner

13:00-14:15 **LUNCH**

14:15-15:15 **FROM POLICY TO PRACTICE (3) STUCTURED DIALOGUE NB, SCIENTIFIC ADVICE / JOINT CONSULTATION AND CERTIFICATION WITH PROVISION FOR INNOVATION. THE OPPORTUNITIES AND GOVERNANCE**



The EU MDR/IVDR provide for structured dialogue with notified bodies, access to scientific advice, and certification with provisions. However, uncertainties remain regarding implementation, the acceptance of data and evidence in practice, and their utility for SMEs.

Recent MDCG guidance on Orphan Medical Devices, Breakthrough Medical Devices, and joint scientific consultations (in EU HTAR) introduces further provisions to enable structured dialogue and access to scientific advice. These cover evidence expectations for CE certification (with provisions) in both pre- and post-market phases, as well as comparative evidence generation post-market to support joint clinical assessments and inform health technology assessments.

The panel will provide insights into EU and countries policy consideration and implementation initiatives in practice and have an open discussion on the way forward and challenges overcome to make structured dialogue and certification with provisions more accessible, and provide a view on the interplay with scientific advice opportunities. Leading Competent Authority and notified body will share their perspectives, with specific consideration for SME-driven (breakthrough) innovation. The utility will be discussed and compared to other jurisdictions including US-FDA.

PANEL:

- Competent Authority: Dr. Matthias Neumann - MDCG NET and TF Breakthrough Member - Federal Ministry of Health - Germany
- Notified Body: Richard Holborow- Global Head of Clinical Compliance - BSI
- EMA - Alberto Gañán Jiménez - Head of Committees
- MedTech Europe - Oliver Bisazza - CEO

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15:15-16:30

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

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 NOBOCAP Consortium Partners and External Nobocap Contractors : incl. ROHEALTH, TUDublin SGS, UMFST, VITO, QUALIX, ALTFACTOR

15:45-16:15

INNOVATION HUBS/CLUSTER , PARTNERS AND IN-COUNTRY INITIATIVES - EXCHANGE OF GOOD PRACTICES



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 with on stage with others in room on the new initiatives presented, possibly with a survey before the summit.

By NoBoCap Consortium partners: BIOVIA, HBIO, ROHEALTH, iVITA and EISMEA

16:15-16:30

WHERE DO WE GO FROM HERE? - EU COMMUNITY IN 2026

With the NOBOCAP project finishing early 2026, an updated will be provided on the plans taking the Nobocap initiatives and community of innovation hubs/clusters and partners forward.

By NOBOCAP Consortium partner : EU4HEALTHSOLUTIONS et co.

16:30-17:00

UNFILITERED AND CLOSING REMARKS - EU COMMISSION

The EU Commission will highlight the policy consideration on evolving the EU legislative frameworks and flagships in the creation of a competitive European SME driven innovation enabling environment enabling a timely accessibility of innovative solutions of value while safeguarding patient and population health. Closing remarks will be given.

Mr. Rainer Becker - Director DG SANTE Medical Products and Innovation

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17:00-17:15 **SUMMIT CLOSING**

17:15-18:00 **POST CONFERENCE DRINK**

REGISTRATION

REGISTRATION TO THE SUMMIT VIA LINK:

https://ofcores.idloom.events/nobocap-summit/register

OR SCAN ME FOR REGISTRATION:



ROHEALTH The Health and Bioeconomy Cluster

TU DUBLIN

iVITA HEALTH TECHNOLOGY CLUSTER

ALTFACTOR EDUCATIONALLY YOURS

biovia Health Innovation Cluster

SGS

GHENT UNIVERSITY

HBIO HELLENIC BIO CLUSTER

EU 4 HEALTH SOLUTIONS

GEORGE EMIL PALADE UNIVERSITY OF MEDICINE, PHARMACY, SCIENCE, AND TECHNOLOGY OF TARGU MURES

Co-funded by the European Union