NOBOCAP COMMUNITY SUMMIT 2024

TUESDAY & WEDNESDAY, SEPTEMBER 24-25

The Hotel Brussels, Bd de Waterloo 38, 1000 Bruxelles, Belgium

EU COMMUNITY TO UNLOCK EU MDR/IVDR REGULATION FOR INNOVATION

PRE-SUMMIT WORKSHOPS

Tuesday, September 24, 13:00-17:30

NOBOCAP & PARTNERS BACKBONE SERVICES - WORKSHOPS TO UNLOCK MDR/IVDR

Workshops are organized for attendees of the NoBoCap Community Summit. These workshops will provide an in-depth understanding and hands-on experience of the services and tools offered by NoBoCap and NoBoCap Community Partners.
A one-hour workshop with 5-15 participants and streamed with virtual connections for SMEs and innovators associated with Innovation hubs and Know-how Partners of our community.
The workshop will cover the following NoBoCap initiatives and 2 sessions are planned:

- NoBoCap E-Guided Tool and Emerging Technology Identification Form - Matchmaking Platform latest update & hands-on experience.
- NoBoCap Learning Pathway: Pathway Module 3 and short courses for C-level executives. Detailed content and benefits for participants will be discussed.
- NoBoCap AI and Regulation: Short course by VITO and TEF-Health, exploring its content and significance.
- NoBoCap Current Reality: Surveys, Pulse Report/Survey results, facts & figures, and case studies by NoBoCap Community Members (Innovation Hubs). This will provide an in-depth overview of initiatives and metrics for change management.

An additional session or workshops will be provided by our Know-how Partners. We aim to have at least four different knowledge partners involved.
The four workshops run in parallel, with three sessions. We will facilitate participation for 5-15 individuals per session, and virtual connections.

WORKSHOPS SESSIONS

Tuesday, September 24, 13:00-17:30

13:00-14:00

and

16:30-17:30

THE 4 NOBOCAP WORKSHOPS

NOBOCAP E-GUIDED TOOL FOR NB CODES AND MATCHMAKING TOOL & PLATFORM INNOVATION - NOTIFICATION BODIES

- By EU4HEALTHSOLUTIONS - Yves Verboven / LEANENTRIES - Heikki Pitkanen / NOTIFIED BODIES - SGS - Geofrey De Visscher / ALTFACTOR - Luminita Arhip / Mihai Vlase

NOBOCAP POST-GRADUATE LEARNING MODULES MDR / IVDR AND C-LEVEL COURSE FOR START-UPS

- By TU DUBLIN - Claire Brougham, Graham Gavin / SGS - Education / QUALIX - Ruth Beckers, Pascale van Hoydonk / MEDVIA

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WORKSHOPS SESSIONS

Tuesday, September 24, 13:00-17:30

CERTIFICATION AI SHORTCOURSE AND RE-CERTIFICATION ROADMAP

- By VITO - Bart Elen, Principal deep learning research scientist / TEF-HEATH - Alexander Janowski, TUV-Verband / MEDVIA - Roel Smolders

REGULATION AND INNOVATION - PULSE

- By HBIO - Stamatiki Krita / ROHEALTH- Ana Duca / IVITA - Diana Vertelkiene / MEDVIA Liz Renzaglia

14:30-16:00

THE 4 KNOW-HOW PARTNERS - INITIATIVES

MEDDEVO: Regulatory Affairs Automation and the Future of a Digital Conformity Assessment
Michael M Kania - Ruben Galle

EU projects: TEF- HEALTH: The European Initiative that accelerates medical innovation in AI and Robotics // REALM
Anne-Laure Cadji - Ariana Sliwa - TUV-Verband // Gokhan Ertaylan

Health Innovation- NL: Roundtable -The whole system in the room for your innovation
Karl G.M. Moons - Egbert Smit

QUALIX: Medical device software in EU, is the strict MDR impacting healthcare digitalisation?
Ruth Beckers - Pascale van Hoydonck

PRE-SUMMIT SOCIAL EVENT

Tuesday, September 24, 18:00-23:00

THE NOBOCAP EU COMMUNITY TO UNLOCK EU MDR/IVDR REGULATION FOR INNOVATION

The evening event will bring together the community representatives to meet in an informal and pleasant setting.
An unique opportunity to get to know colleagues and those having already a wide experience of the medical devices regulations and support innovation access in Europe.

18:00-19:30

GET TOGETHER RECEPTION AND GET TO KNOW EACH OTHER (GAME)

Address: Park Ballroom - The Hotel

SUMMITT BY NOBOCAP COMMUNITY UNLOCKING THE MDR/IVDR REGULATION FOR INNOVATORS IN EUROPE

SUMMIT

Wednesday, September 25, 08:00-17:45

The Summit will bring together the NOBOCAP Community, MedTech Innovation and Notified Bodies in person in Brussels and provide virtual access for the MedTech innovation ecosystem in Europe. The aim is to meet up with EU policymakers and initiatives, extend the NOBOCAP network, learn from each other and become aware of the NoBoCap offered services to enhance the preparedness for Innovators and SME, provide quality dossiers and have an improved accessibility to Notified Bodies fostering an innovation friendly ecosystem in the EU.

A robust, competitive and innovation friendly MedTech industry is needed to build resilient health systems. Looking at the challenges MedTech SMEs and Start-ups are facing to navigate the MDR/IVDR regulatory framework, we want to showcase best practices at national level that foster innovation by SMEs, present the different NOBOCAP tools that focus on helping SMEs navigate the challenges faced under the EU regulatory landscape of MDR and IVDR and hear from the Commission on the steps taken to support SMEs and Innovators.

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

08:30-09:00 **WELCOME** - Moderator Amanda Maxwell - MedTech Insight

THE COMMUNITY TO UNLOCK THE MDR/IVDR FOR SME/INNOVATORS - Yves Verboven - EU4HealthSolutions / NoBoCap

OUTLINE OF SUMMIT - Moderator

09:00-11:15 **UNLOCK THE REGULATIONS (MDR/IVDR) FOR SMEs AND INNOVATORS IN EUROPE**

09:00-10:00 **IMPACT OF MDR/IVDR ON INNOVATION AND THE NOBOCAP COMMUNITY "A VOICE FOR INNOVATORS/SMEs in EUROPE TO KEEP THE PULSE "**

A set of short presentations will set the scene and provide data from different (ongoing) studies and reports, experiences looking at how the new regulatory framework of MDR and IVDR is impacting MedTech SMEs and the innovation accessibility in Europe. A benchmark to other jurisdiction is planned This provides the current starting point that will be reflected in the NOBOCAP PULSE REPORT to keep the PULSE of the Initiatives to build out a supportive MDR/IVDR regulatory environment for innovation of value to innovate and transform healthcare across EUROPE.

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- EU4Health Study supporting the monitoring the availability of medical devices on the EU market; Austrian National Public Health Institute - GOEG-
  Friederike Windisch - Nina Zimmermann
- EU Commissioned Study on MDR/IVDR and Innovation: EY Consulting - Joke Wiercx, Executive Director
- Innovation and Regulation - Pulse report and stakeholder perspective - Business Development HBIO - Stamatiki Krita; Surgi-Tec - Karen Scheerlinck

The floor will then be given to the attendees to further highlight recent reports - cases to capture the latest status on preparedness and accessibility.

10:00-11:15

NATIONAL INITIATIVES AND BEST PRACTICES AND EU -NOBOCAP BACKBONE SERVICES

The panel will present activities organised by member states supporting SMEs and INNOVATORS EU NOBOCAP backbone services aimed at helping SMEs and Start-ups navigate and master the regulatory framework of MDR and IVDR will be presented as well the community partners provide insights in their supportive services. The idea is to identify best practices and tools to help SMEs and Start-ups to build the knowledge and ensure the preparedness to address timely the new EU regulatory requirements avoiding a death value and ensure a positive socio-economic contribution.

- NOBOCAP:
  Learning Pathways, shortcourses for Innovators/start-up, Backbone Service and Tools
  NOBOCAP CONSORTIUM: Flaviana Rotaru - RoHealth and NoBoCap Partners

- National Initiatives:
  Health Innovation Netherlands (HI-NL) - Karl.M.G. Moons - Egbert Smit
  Medical Mountains (Germany) - Meinrad Kempf

- NOBOCAP Community Knowledge and Know-How Partners - Service Overview

The floor will be given to the attendees to further highlight initiatives by the innovation hubs/cluster or National Initiatives of interest in support of SME/Innovators to address regulatory requirements.

11:15-11:45

BREAK PARTNERS - MEMBERS GET TO KNOW INITIATIVES - EXHIBITION

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11:45-12:30

A CHANGING EU REGULATORY ENVIRONMENT – LOOKING AT HORIZONTAL LEGISLATION AFFECTING THE MEDICAL DEVICES SECTOR AND INNOVATION ACCESS PATHWAYS IN PARTICULAR

This session will provide an overview of different horizontal and sector specific EU legislation in place or on the horizon that is affecting medical (and digital) technologies (in addition to MDR and IVDR (i.e. HTA-R, AI-Act, EHDS and Environmental/Sustainability legislation). The session will then focus in more detail on new environmental legislation impacting innovators. The new MDCG taskforce on monitoring horizontal legislation of an environmental nature that is relevant also to medical devices and IVDs will present its work and activities undertaken so far.

- The Changing Regulatory Environment for Medical Devices, IVD, Digital-AI and Combination Products by European Commission - Flora Giorgio, Head of Unit
- In depth evaluation of EU Environmental an due diligence Legistion impacting Medical Technology by Stefan Berggren, Head of unit for Sustainability and Environment - Medical Product Agency Sweden / MDCG Co-chair of TF Environment
- Q&A

12:30-13:15

LUNCH AND PARTNERS – MEMBERS GET TO KNOW INITIATIVES- EXHIBITION

13:15-14:30

EU REGULATION – A CHALLENGING ENVIRONMENT - ROAD AHEAD FOR MDR/IVDR – EU POLICY AND EU INITIATIVES

13:15-13:45

KEY NOTE : EU INITIATIVES TO FOSTER AN INNOVATION SUPPORTIVE REGULATORY ENVIRONMENT -

FLORA GIORGIO - HEAD OF UNIT MDR/IVDR - EUROPEAN COMMISSION **(20')**

The presentation will outline the European Commission supported efforts undertaken to implement the EU Regulations on medical devices and in-vitro diagnostics, that intend to give access to safe and effective innovation in the EU. The Commission will also reflect at challenges faced with the implementation of the regulations, especially for SMEs and Start-ups and explain measures and initiatives taken, to support this important group of actors. Among the initiatives are the Horizon Europe Call on New Methodologies, Testing and Experimenting Facilities (TEF) in Health for testing Robotics AI enabled devices, the horizon scanning of emerging technologies, the investment in reference laboratories, the build out of scientific advice by EMA Expert Panels, the MDCG initiative in the conformity assessment of orphan medical devices and the structured dialogue between manufacturer and notified body, beyond the work done within NOBOCAP.

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13:45-14:45

PANEL DISCUSSION: THE ROAD TO MAKING THE EU THE LEADING AND INNOVATION FRIENDLY MEDICAL DEVICES/IVD/ DIGITAL HEALTH TECHNOLOGIES REGULATORY SYSTEM

MDCG NEW TECHNOLOGY

Mariana Madureira - Infarmed, Co-chair MDCG NT

MEDTECH EUROPE

Petra Zoellner, Director Regulator Affairs

EIT HEALTH

Cristina Bescos, Director of Innovation / Chief Growth Officer

INNOVATIVE HEALTH INITIATIVE (IHI)

Nathalie Seigneuret / Hugh Laverty

14:45-15:00

COFFEE BREAK

15:00-16:15

A CHANGE IN TODAYS REALITY FOSTERED BY THE NOBOCAP COMMUNITY: INNOVATION HUBS AND NOTIFIED BODIES INVOLVED IN NOBOCAP COMMUNITY AS KEY ENABLERS TO BUILD OUT AN INNOVATION SUPPORTIVE REGULATORY SYSTEM

15:00-15:45

This panel will look at actions undertaken and openness by notified bodies in support of an accelerated and timely/efficient access pathway for innovation of high need for patient in Europe to have timely access. Consideration are given also on timely matchmaking, use of conditional certification and other instrument to support innovative devices reach the Union market and foster a competitive regulatory environment.

Panel:

- NB - BSI Richard Holborow - Global Head of Clinical Compliance
- NB- SGS Geofrey De Visscher - Head of Notified Body

The final word is given to the participating innovation hubs/clusters in member states. The idea is to have an interactive discussion also with the audience - the innovation hubs present at the summit to highlight their initiatives and commitments.

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15:45-16:15 **CLOSURE AND SUGGESTION - ON THE ROAD BOX**

INPUT TO CHARTER OF COMMITMENTS (checked by NOBOCAP over the next year)
Innovation Hubs are asked to indicate which initiatives presented during the Summit they will support and implement in the coming months (to be followed up at the next summit)
From the discussion during the day 5 dimension for a successful change (METRIC will be identified to be considered as key drivers to build out a supportive MDR/IVDR regulatory environment for innovation of value to innovate and transform healthcare across EUROPE.

16:15-17:30 **NETWORKING DRINKS - EXCHANGE**

Co-funded by the European Union


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