NoBoCap

Building a Community for Innovators to unlock EU Regulations

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Background

- **Notified Body Increased Capacity (NoBoCap)** – a project to educate and ensure preparedness of Market Operators (MOs) in the application of MDR and IVDR and build out a quality and accessible Notified Bodies and Regulatory ecosystem
- **NoBoCap** is funded under EU4Health Programme (EU4H).
- **NoBoCap Community of innovation hubs / clusters to Unlock EU Regulation for Innovation**: a group of organizations working towards increasing knowledge and preparedness of the EU Regulatory system and access to NBs for innovators and be a player to voice and address EU regulatory challenges.

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NoBoCap Community

What is offered by the Community to unlock EU Regulations for innovation

A BACKBONE SERVICE PLATFORM

- To obtain the KEY (MDR/IVDR applicable code(s)) and be matched to Notified Bodies designated to certify your specific technology.
- To obtain first-hand updates on the latest EU Legislative initiatives (Horizontal and sector-specific) of the changing regulatory environment in Europe and guidance to address specific issues.
- To interact directly with a network of supportive and knowledge partners to foster the creation of quality dossiers for timely conformity assessments. Nobocap will also offer c-level information session to define investment and resource needs to address regulatory requirements.
- To Interact with Peers, foster best practices and enable direct interaction with key players and initiatives of the implemented regulatory ecosystem and the EU services offered.

A VOICE OF START-UPS – INNOVATORS

- Annual pulse report compiling intel on the opportunities and challenges related to CE marking based on feedback provided by market operators (esp. start-ups/ SMEs).
- Opportunities to interact and provide feedback to EU institutions on EU initiatives.
- Feedback from the NoBoCap Platform on a quarterly basis regarding unanswered questions and comments, open applications, and other community-related content.

A CAPACITY FOR EUROPE'S REGULATORY ECOSYSTEM

- Training for people in regulatory functions or seeking to enter into a regulatory role within a Notified Body or Market Operator.
- Connecting people within the HealthTech and MedTech regulatory ecosystem in Europe.

https://nobocap.eu/community/

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Joining the Community (1)

What commitment we expect from you – Levels of Engagement:

- **An Informing contribution** – you will inform startup + SME companies about (1) project surveys to report the impact of EU Regulation, (2) Community offered services & (3) attend NoBoCap community organized events (webinars, conferences, etc.).

- **An Active engagement contribution** – you will engage with start-ups and/or SMEs and foster the use of NoBoCap initiatives and knowledge partner services & actively promote and participate in community organized events (webinars, conferences, etc.).

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Joining the Community (2)

Benefits:

- Intel on the latest development of EU regulations and be the intermediary to voice the implication for Innovators (your members) in the regulatory ecosystem.
- Connection with other organizations and initiatives across Europe to support members to understand and address MDR/IVDR
- Access for your members to Nobocap Conferences - Training – Tools

  Overview of additional resources to help with MDR/IVDR.
- Listed as and recognized as member of the community to unlock EU Regulations for medical technology and services offered.

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NoBoCap Community Includes

European HealthTech/MedTech Clusters and Innovation Hubs as members

Intermediary to the innovation ecosystem driven by start-ups, SME

Supportive partners

European level organizations that can offer insights and connections

Knowledge & Know-How partners

Companies and institutions that can provide education and training courses and consultancy to the members of our community.

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Preliminary Relevant Meetings Dates

- Online Meetings:

November, 2023 | October, 2024 | September, 2025 | February, 2026

- Pulse Reports:

March, 2024 | March, 2025

- Conferences:

June, 2024 | June, 2025

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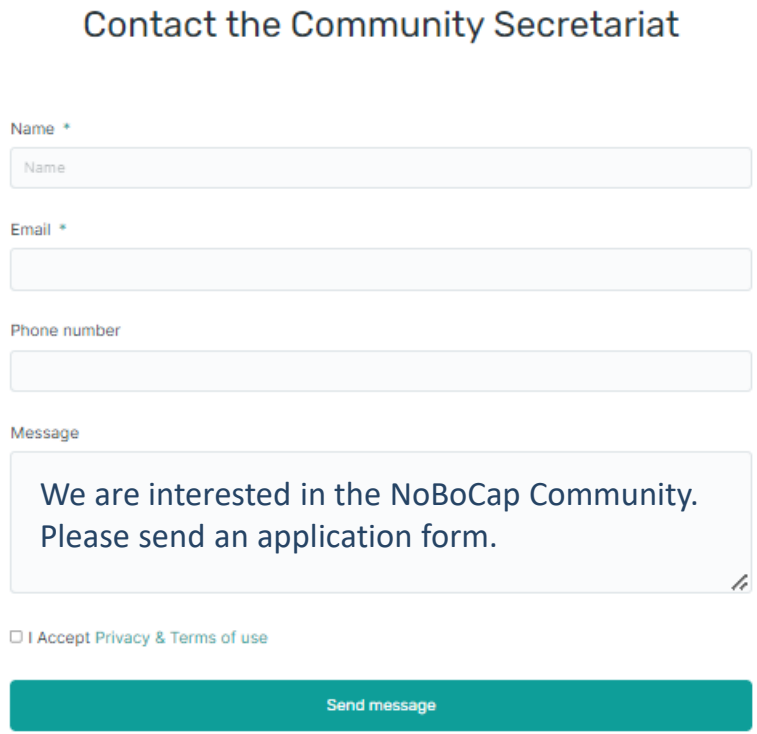
How to Join the Community (1)

Step 1: Obtain and Complete Application Form



To Know More & Apply
Scan for more information:

https://nobocap.eu/what-to-offer/

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How to Join the Community (2)

Step 2 : Be Accepted* into the Community

Criteria of acceptance:

- Mandatory:
  - Connected to SME, Start-up with products in phase of regulatory submission (TRL >6);
- Committed to:
  - communicate, inform your members of Community activities, request for information, participate to e-meet/conference;
- Welcomed to :
  - Active engagement to facilitate contact of your members to knowledge partners – tools;
  - Initiatives ongoing in support of unlocking the EU regulation for members.

**NoBoCap secretariat of community reviews applications*

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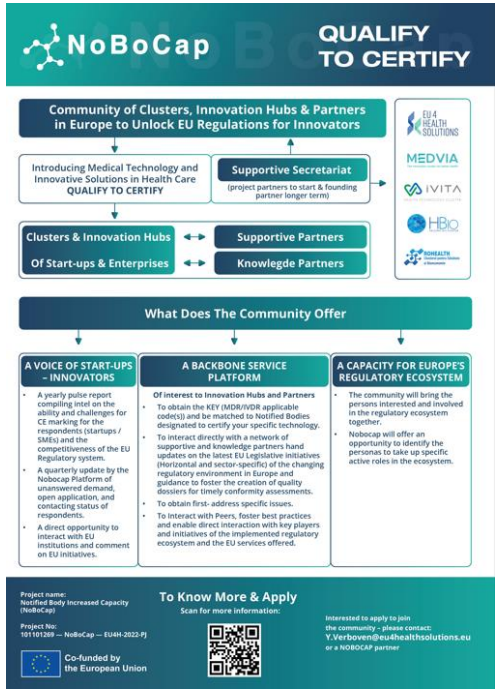
More Detailed Information

https://nobocap.eu/community/



Leaflet

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Next Steps

➢ Your interest in EU Regulation

- Do you currently have supportive activities on addressing EU regulation? Or is it a topic of interest ?

➢ Interest to join: active or informative

- Who to send application form to ?
- Who will decide in your organization to join?

➢ Interest to know more and first activities:

- E-meeting on 14th of November.

➢ Interest in staying informed:

- Agree to receive newsletter;
- Agree to receive the surveys to have a voice.

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Thank You

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Back up

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How to provide Voice of Innovators

Surveys and Direct Contacts

- **EU initiated Surveys on implication MDR/IVDR**
  - Governance and Innovation (EY lead) (Nov. ‘23 – Jan.’24)
  - NB and Market Operators (GOEG lead) (Nov. ‘23
  - Accessibility and Efficiency for Innovators (Nobocap lead) (in dev.)
- **Pulse Reports**
  - Insight on the status and evolution over time compiling EU, Associations and national, local and anecdotical reports with a specific focus on innovation, innovators (March 2024 – Annual)
- **Meeting with EC**
  - NOBOCAP e-meet and conference (Nov. ‘23 – Mar ‘24 / Jun ‘24
  - Governance and Innovation workshop (TBC)

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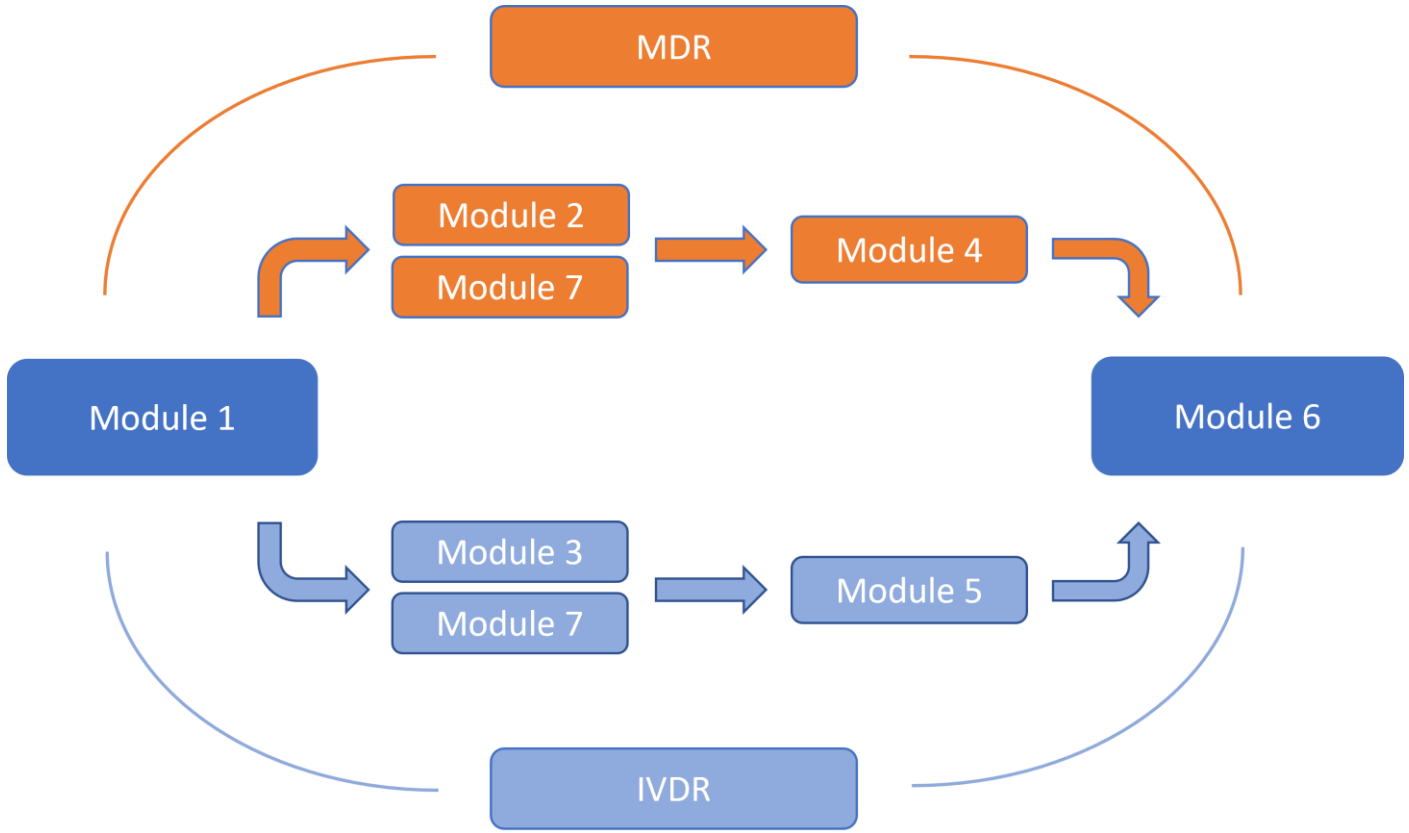
A CAPACITY FOR EUROPE'S REGULATORY ECOSYSTEM

What training NOBOCAP Offers

Building out a Regulatory Ecosystem (1)

LEARNING PATHWAYS



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NoBoCap Training

Building out a Regulatory Ecosystem (2)

INITIAL MODULES – Post-Graduate Accreditation

Module: 1. Implementing regulatory requirements (MDR and IVDR) for medical devices (April 2023, October 2023)

Target Market: Quality, regulatory and other relevant personnel at manufacturers, aspiring NB auditors. Note not of interest to NB staff as they should know this already.

Aim: Provide full overview for required implementation of QMS and MDR requirements.

Module: 2 / 3 . Generating data for technical documentation (MDR) (Q1 2024) / (IVDR (TDB)

Target Market: product engineers and developers, quality staff, aspiring NB Product assessors, i.e. people in industry who would like to transit to NB.

Aim: instruction on construction of a TF including general principle of clinical evaluation reporting.

NOTE: Modules 2 & 3 are parallel modules that relate to MDR & IVDR. The advantage of these 2 modules is that the better the files provided by MOs (given they get the training to ensure best possible files) , the less time NBs have to spend on them, thus increasing the capacity of the NB, as well improving the 'first time' compliance.

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Building out a Regulatory Ecosystem (3)

Next : SPECIALIZED MODULES M4 / M5

- **A SURVEY TO IDENTIFICATION NEEDS**

  Of Market Operators –

  Of Notified Bodies – via DIALOGUE NBCG-MED / TEAM NB

Next: DEVELOPMENT OF COURSES FOR 2024 – 2025

- **SPECIALIZED COURSE TECHNICAL AND REGULATORY FOR AI**

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Building out a Regulatory Ecosystem (4)

LEARNING PATHWAYS – PERSONAS TARGETED

Persona	Short Term		Long Term	
	MDR - general	specialised	MDR - general	specialised
Product Assessor (PA) NB		M4 M5	M1 + M2 M1 + M3	M4 + M6 M5 + M6
Product Development				
Auditors NB		M4 M5	M1 + M2 + M7 M1 + M3 + M7	No
Quality Assessors				
Product Development				
Clinician NB		No	M1 + M2 M1 + M3	No
Clinical Reviewer NB				
Clinical Research				
New Entry		No	M1 - M6 M1 - M6	No

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NoBoCap Community of Clusters, Innovation Hubs & Partners

A Backbone Service Platform (1)

Meeting in person and repository of initiatives across Europe

- The community identifies and involves knowledge and know-how partner to have foster direct contact to quality services in market.
- A repository of initiatives and external services will be compiled.
- In development – operational Q1, 2024

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A Backbone Service Platform (2)

Tool: MO Guided e-tool to master EU regulation to and apply it to specific technology

- The key to reach out and prepare a quality dossier is an understanding how the regulation applies and what are the codes that apply to your technology.

- The e-tool will guide by means of Q&A to the applicable pieces of regulation, provide further insights, and at the end of the process provides the codes that characterizes the technology. A further overview of Notified that are designated to cover those codes is provided.

- In development – operational **Q1, 2024**

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A Backbone Service Platform (3)

Tool: Nobocap Matchmaking Platform

- The e-guided tool defining codes and matching NB.

Q1, 2024

- Additional features to foster timely NB expertise of novel innovation and efficient process of innovation.

Q3, 2024

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A Backbone Service Platform (4)

Tool: Market Operator C-level information sessions

A series of information sessions for C-Level

Focus:

- Strategic priority for market entry/development- urgency
- Staffing requirement
- Budget requirement

Feb 6 2024. 19.00 CET

- 1. Established Medical Devices manufacturers

Feb 13 2024. 19.00 CET

- 1. Established Medical Devices manufacturers (repeat)

Feb 20 2024 19.00

- 2. Start ups, early stage SMEs

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Financial set-up

2024

T&L partially (per EU requirement)

- Compensated

Innovation hubs:

- In-kind support (not compensated);
- Any fee waived during the project.

Supportive partner general

- In-kind input – no fee.

Investors/incubator community & Knowledge Partners:

- Option Sponsorship of conference;
- Option Sponsor for webinar;
- Activities by Newsletter.

2025

T&L partially (per EU requirement)

- Compensated

Innovation hubs:

- In-kind support (not compensated).

Supportive partner general

- In-kind input – no fee.

Investors/incubator community & Knowledge-know-how Partners:

- Fee-based with specific benefit (fee possibly waived when supportive activities for NOBOCAP);
- Listed as sponsor and presence at a conference;
- Possibility of planned webinar, and activities by newsletter.

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Long term sustainability

Under Discussion

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