



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.



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.



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<https://nobocap.eu/community/>

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.).



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.

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.



Preliminary Relevant Meetings Dates

- **Online Meetings:**



- **Pulse Reports:**



- **Conferences:**



How to Join the Community (1)

Step **1**: Obtain and Complete Application Form

Contact the Community Secretariat

Name *

Email *

Phone number

Message

We are interested in the NoBoCap Community.
Please send an application form.

I Accept Privacy & Terms of use

Send message

To Know More & Apply

Scan for more information:



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

How to Join the Community (2)

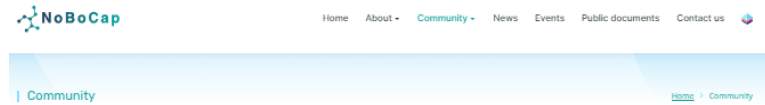
Step 2 : Be Accepted* into the Community

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.



More Detailed Information



About the community



The Community provides:

- A Voice for start-ups and SMEs in the regulatory ecosystem.
- A Backbone service platform to unlock EU regulation for all.
- A Source of expertise and personas for the regulatory ecosystem.

The Community is composed of the following members:

- Clusters and Innovation hubs in Europe striving to bring innovation into healthcare.
- Supportive and Knowledge Partners.

And supported by NoBoCap partners as secretariat (during the project) and founding partners longer term.

To obtain additional information, you can download a brochure, or scroll down to view a description of the participants, and learn more about what the community will offer [here](#).

[Download](#)

The Clusters and Innovation Hubs

Clusters and Innovation hubs are interested in EU regulations that influence access to innovation within the European market. They also connected with start-ups and/or SMEs involved in introducing medical technology and health solutions into the healthcare sector. We do not target at clusters/innovation hubs or other entities solely focused on basic research & low Technology Readiness Levels (TRL). The clusters and Innovation hubs are in **direct contact** with start-ups and SMEs, preferably as their members of the cluster or innovation hub or by available channels of direct

As a Member of the Community, the cluster or innovation hub **commits a minimum of in-kind resources** to (1) participate in gatherings (webinar/conference), (2) communicate the services offered and (3) provide market intel survey to the start-ups and SMEs in their network.

Being a part of the Community, the cluster or innovation hub can enroll in more proactive involvement by being a voice and enabling its members to interact with knowledgeable and supportive partners within the community.

The clusters and Innovation hubs may be at the European level, local hubs of EU initiatives or national – regional- or local level initiatives.

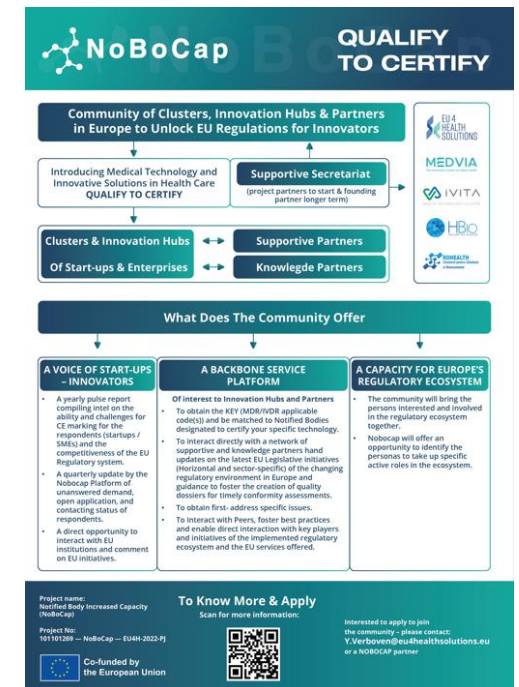
The Supportive Partners:

Are EU level organisations that are interested in being part of this community and cover some of the following activities:

1. Help identify the "innovation hubs" and initiatives,
2. Help define and provide intel (through specific surveys) to be used in the pulse reports on the impact of the regulatory ecosystem (e.g., on shortage of lifechanging technologies in hospitals),
3. Support as a speaker at webinar/conference and may also make further contributions as a knowledge partner (e.g., scientific advice, training, etc.),
4. Support logistics for the conduct of training and education.

The Knowledge Partners:

- Include public or private organisations active in the regulatory ecosystem with specific expertise to support the clusters and Innovation hubs – especially their start-ups and SMEs – to master the regulatory requirements. This includes training, scientific advice, and consultancy services.
- NoBoCap's offering of training and tools are one of the knowledge partners.
- Nobocap will evaluate knowledge partner applications and facilitate contact with the chosen parties.
- Knowledge partners will provide an unrestricted grant/ fee to the Community and offer paid services. The role of the community is to facilitate the contacts.



Project name:
Notified Body Increased Capacity (NoBoCap)
Project No:
101101269 – NoBoCap – EU4H-2022-FJ
Co-funded by
the European Union

To Know More & Apply
Scan for more information:



Interested to apply to join
the community – please contact:
Y.Verboven@eu4healthsolutions.eu
or a NOBOCAP partner

If interest to join the community, please visit the What to Offer page and contact the community secretariat.



Stay In Touch

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.





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 anecdotal reports with a specific focus on innovation, innovators (March 2024 – Annual)

➤ Meeting with EC

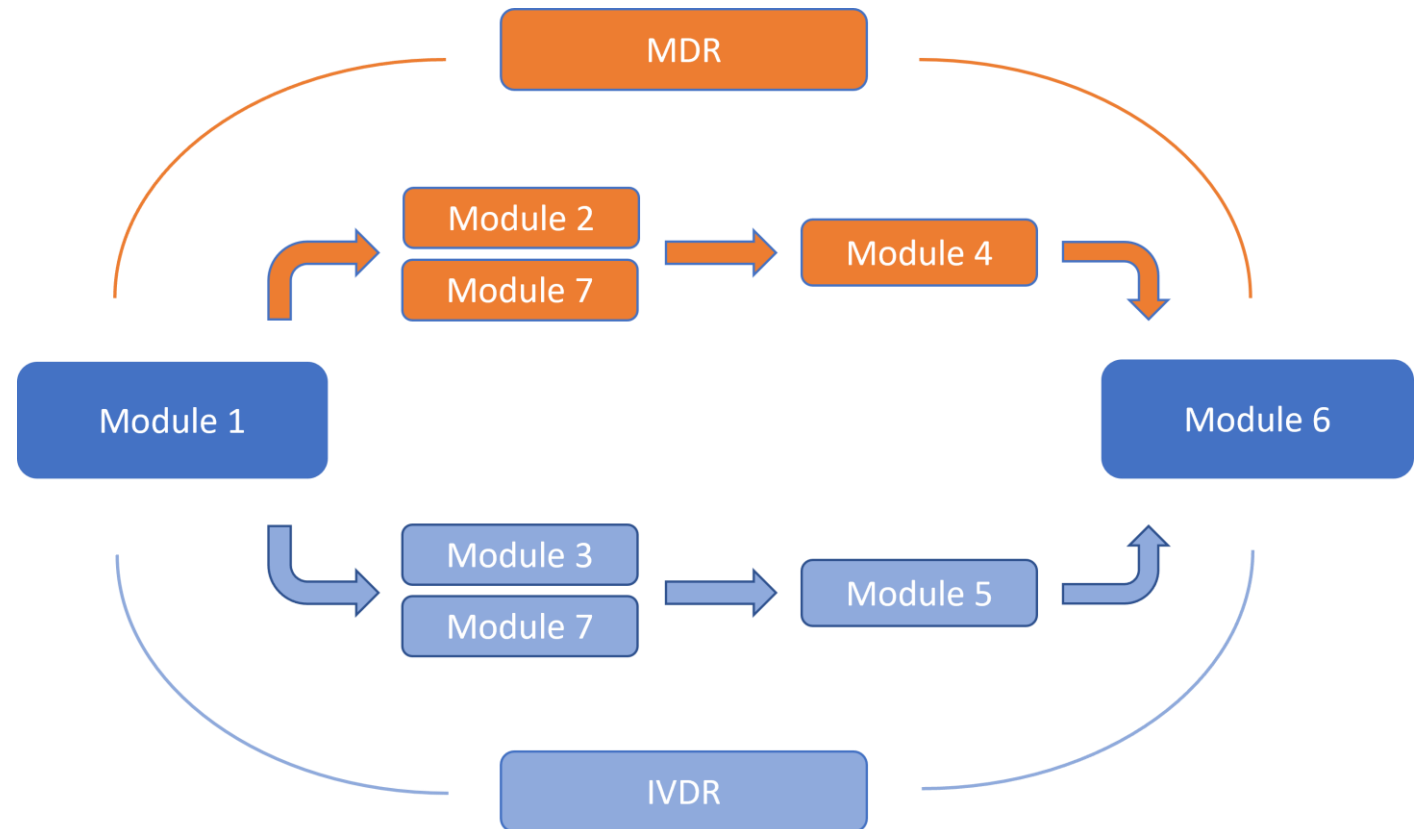
- NOBOCAP e-meet and conference (Nov. '23 – Mar '24 / Jun '24)
- Governance and Innovation workshop (TBC)



What training NOBOCAP Offers

Building out a Regulatory Ecosystem (1)

LEARNING PATHWAYS



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.***

NoBoCap Training

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**



NoBoCap Training

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	M1 + M2	M4 + M6
Product Development		M5	M1 + M3	M5 + M6
Auditors NB		M4	M1 + M2 + M7	No
Quality Assessors		M5	M1 + M3 + M7	
Product Development				
Clinician NB		No	M1 + M2	No
Clinical Reviewer NB			M1 + M3	
Clinical Research				
New Entry		No	M1 - M6	No
			M1 - M6	

A Backbone Service Platform (1)

Meeting in person and repository of initiatives across Europe



NoBoCap Community of
Clusters, Innovation Hubs &
Partners

- 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



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





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



NoBoCap Matchmaking Platform

NoBoCap matchmaking platform that connects MOs with the appropriate NBs



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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

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.



Long term sustainability

Under Discussion

