



# NoBoCap

*Clusters meets Regions*  
*21 – 24 November 2023, Iași, Romania*



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# NOBOCAP Objectives

- **Build out a Regulatory Capacity**
  - To train Market Operators and NB and educate, ensure preparedness of Market Operators (MOs) in the application of quality dossier for MDR and IVDR. Improve the accessibility to Notified Bodies and a Regulatory ecosystem with adequate capacity.
- **Build out a NoBoCap European Community of innovation hubs / clusters to Unlock EU Regulation for Innovation:**
  - Organizations working towards (1) increasing knowledge, know-how and preparedness to ensure the accessibility to the EU Regulatory system and efficient matchmaking for innovators and (2) to voice and address EU regulatory challenges.



## Consortium

- 3 academia (BE, EI, RO)
- 4 health clusters (BE, EL, LT, RO)
- 2 SMEs (BE, RO)
- 2 global leader NBs (BE, EI)

# Project duration

1° of March 2023-  
1° of March 2026



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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.



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# NoBoCap Community Composition



## 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.



## What we can offer to MOs?

- Information sessions for senior manager/C level – February 2024
- Online self learning basic introduction to MDR/iVDR for Mos – it will be available on [www.nobocap.eu](http://www.nobocap.eu) available in Q1, 2024
- Long term courses, ECT accredited, Module 2 available in March 2024





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