



## The key goal of NoBoCap

The project NoBoCap funded under EU4Health Programme (EU4H) has the goal to improve the accessibility and capacity of Notified Bodies (NBs) and the Medical Device Industry (MDI) to efficiently submit, review and approve dossiers within the context of Medical Devices Regulation (MDR) and *In Vitro* Diagnostic Medical Devices Regulation (IVDR). As such NoBoCap secures the pathways for MedTech innovation in Europe.

## Key Expected Outputs of NoBoCap

- Long and short-term training courses on high-priority topics for both new recruits and specialist workforce in NBs and Market Operators (MOs), coaching and internship sessions;
- NoBoCap matchmaking platform that connects MOs with the appropriate NBs.

## What are the benefits for Notified Bodies and Conformity Assessment Bodies?

### NBs and CABs staff development



HOW

- Long and short-term training courses;
- Internships;
- Matchmaking.



Notified Bodies and Conformity Assessment Bodies will benefit by increasing demand for their services, enhancing their reputation, improving quality control, and increasing market access for their clients. Dedicated training modules will increase the NBs capacity to provide services for new and emerging technologies. Finally, a dedicated job board facilitates them to attract new staff with adequate soft and hard skills.

## What are the benefits of the long and short-term training for the key stakeholders?

### Short term:

- NBs: access to immediate technology training;
- Training partners: training with high value towards employment for applicants;
- Market Operators: improve the quality of file submission;
- Industry associations: promoting skill development in the MDI.

### Long term:

- NBs: Qualified to serve the customers/ industry and stay aligned with technological developments, such as AI;
- NBs: Have access to staff that requires less training (presently takes up to 1 year);
- NBs: Appropriate matchmaking to reduce administrative overhead;
- Innovators/ Market Operators: A clear mechanism of timely identification of areas of expertise for efficient regulatory pathways;
- Training partners, industry associations, and healthcare systems: upskilling the MDI workforce.

HOW

HOW



# What are the benefits for the Market Operators?

## Market operators' staff development

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- Technical staff oriented courses on technical and clinical evaluation to better prepare the dossiers;
- Long-term regulatory education to prepare industry staff for NB positions.

Improving the access of Market Operators to Notified Bodies can help ensure that Medical Devices and *In Vitro* diagnostics meet the regulatory requirements and are safe and effective for their intended use.

The increased capacity will shorten the go-to-market time and will increase the cost-efficiency of taking new innovative technologies to market.

This can be achieved through measures such as increasing the number of NBs, streamlining the conformity assessment process, improving communication between NBs and Market Operators, and ensuring that NBs have the necessary expertise and resources to provide high-quality services.

# What are the benefits of NoBoCap platform?

## Market Need

HOW

- Platform to capture the immediate and future needs for NB of MedTech and IVD industry;
- Matching NB staff competency recruitment needs with potential applicants';
- Stimulate recruitment of personas with skill & behavioural competencies for regulatory compliance roles of both NBs and MOs.

s MOs with the appropriate Notified Bodies.

# NoBoCap

is a unique consortium of 11 members comprising:

3 academia, 4 health clusters, 2 SMEs, 1 large enterprise, and 1 global leader NB.

## Project coordinator



## Partners



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