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We are pleased to share that the **NoBoCap project has been extended until November 30, 2026**, opening the way for even more opportunities for the European MedTech community.

This extended period allows us to build further on the progress achieved so far - with new training programmes, additional short courses, continued development of the NoBoCap platform, and more community-driven initiatives.

As the regulatory and innovation landscape continues to evolve, NoBoCap remains committed to supporting Market Operators, Innovators, and Professionals with the tools, knowledge, and connections needed to move forward with confidence.

➔ Discover what's coming next within the NoBoCap Community 📌

# NOBOCAP TRAINING PROGRAMS

 **NoBoCap**  Co-funded by the European Union

## MODULE 2

### Generating Data for Technical Documentation (MDR)

**REGISTRATION OPEN**

-  Starts **May 5, 2026**
-  10-week online course
-  5 CPD credits
-  Post-graduate Certificate

 [www.portal.nobocap.eu](http://www.portal.nobocap.eu)

## Expand Your Expertise with NoBoCap's Final Training Modules in 2026

## ✓ Module 2: Generating Data for Technical Documentation (MDR)

 **Start Date: 5 May 2026**


 Online

 ***This is the final opportunity to attend this course within the NoBoCap project.***

One of the biggest challenges for manufacturers today is the preparation of robust Technical Documentation in line with MDR (EU 2017/745). This module provides in-depth guidance on two critical aspects:

✓ Technical File preparation - learn how to structure and compile the necessary documentation for regulatory submission.

✓ Clinical Evaluation Report (CER) - understand the essential elements of clinical evaluation and how to meet the regulatory expectations of Notified Bodies.

 This module runs for 10 weeks (including 8 weeks of course delivery and 2 weeks for assessment preparation), totaling 100 hours of structured learning.


Upon completion, participants will receive a **Postgraduate Certificate (EQF Level 7, 5 ECTS credits)**, accredited by the University of Medicine, Pharmacy, Science and Technology of Târgu Mureș.


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## SHORT COURSES

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### ✓ SHORT COURSE ON EU MDR/IVDR & FDA QMSR

 **Dates: 7 May 2026**

 **Duration: 10:00-11:15 AM CET**

 Online

As regulatory frameworks for medical devices continue to evolve on both sides of the Atlantic, staying informed is essential for maintaining compliance and ensuring market access.

The EU MDR and IVDR are undergoing targeted revisions to address supply challenges and safeguard patient access to critical devices, while maintaining high safety standards. At the same time, the FDA's new Quality Management System Regulation (QMSR) integrates ISO 13485:2016, marking a significant step toward global regulatory alignment.

In parallel, increasing FDA expectations around AI, cybersecurity, and submission quality are reshaping how manufacturers prepare their documentation and approach regulatory approval.

This short course brings together expert insights to help MedTech professionals understand these changes and translate them into practical actions for their quality management systems.

**What You Will Learn:**

- Key updates under EU MDR/IVDR and FDA QMSR, and their underlying rationale
- How AI and cybersecurity requirements impact documentation and validation
- Common pitfalls in FDA submissions and how to avoid them
- Practical implications for QMS implementation, audits, and inspection readiness
- Practical implications for QMS implementation, audits, and inspection readiness

**Don't miss this opportunity - [Register now](#) and take the next step in your MedTech journey!**

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 **UPCOMING NOBOCAP COURSES**

New training opportunities are on the way within the NoBoCap Community.

📌 **AI Short Course – 4th Cohort**

📌 **C-Level Management Training – 5th Cohort**

📌 **"Are You a Medical Device?" Masterclass**

📌 **Executive Programme for SME Leadership**

📌 **Workshop for Start-Ups and SMEs (focused scope)**

Stay tuned for registration details and upcoming announcements!

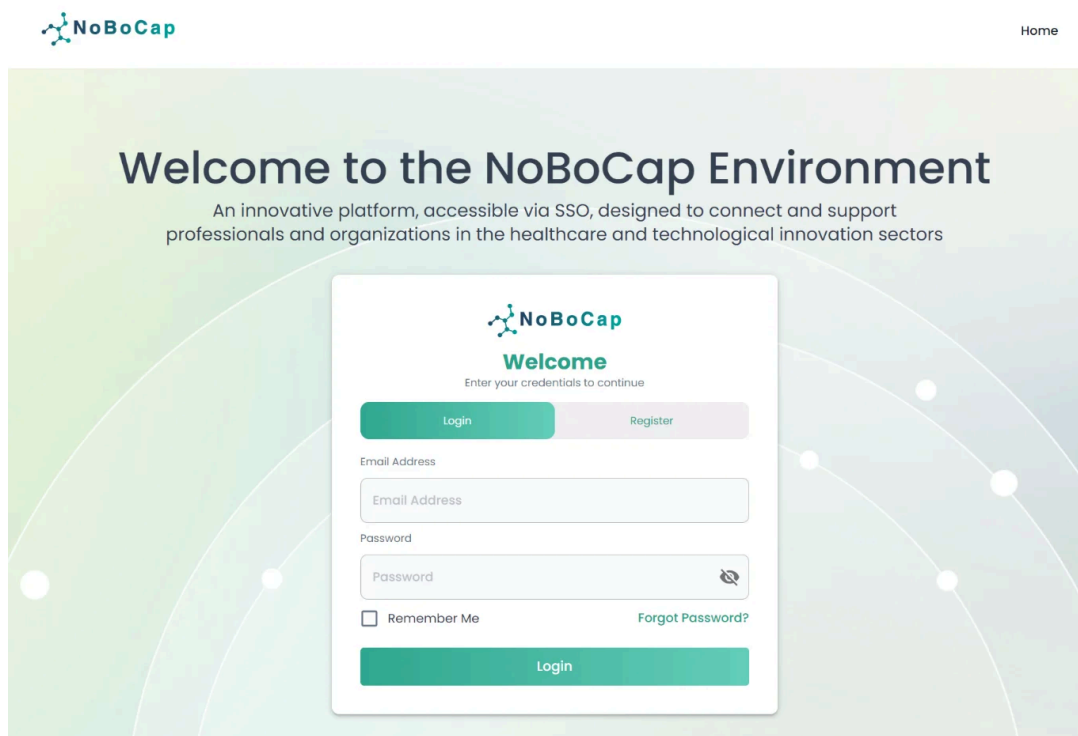
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Don't miss your chance to join the final NoBoCap trainings – [register now via the NoBoCap Portal](#).

To apply in any of these courses, follow these simple steps:

👉 **How to Register:**

1. Visit <https://portal.nobocap.eu>

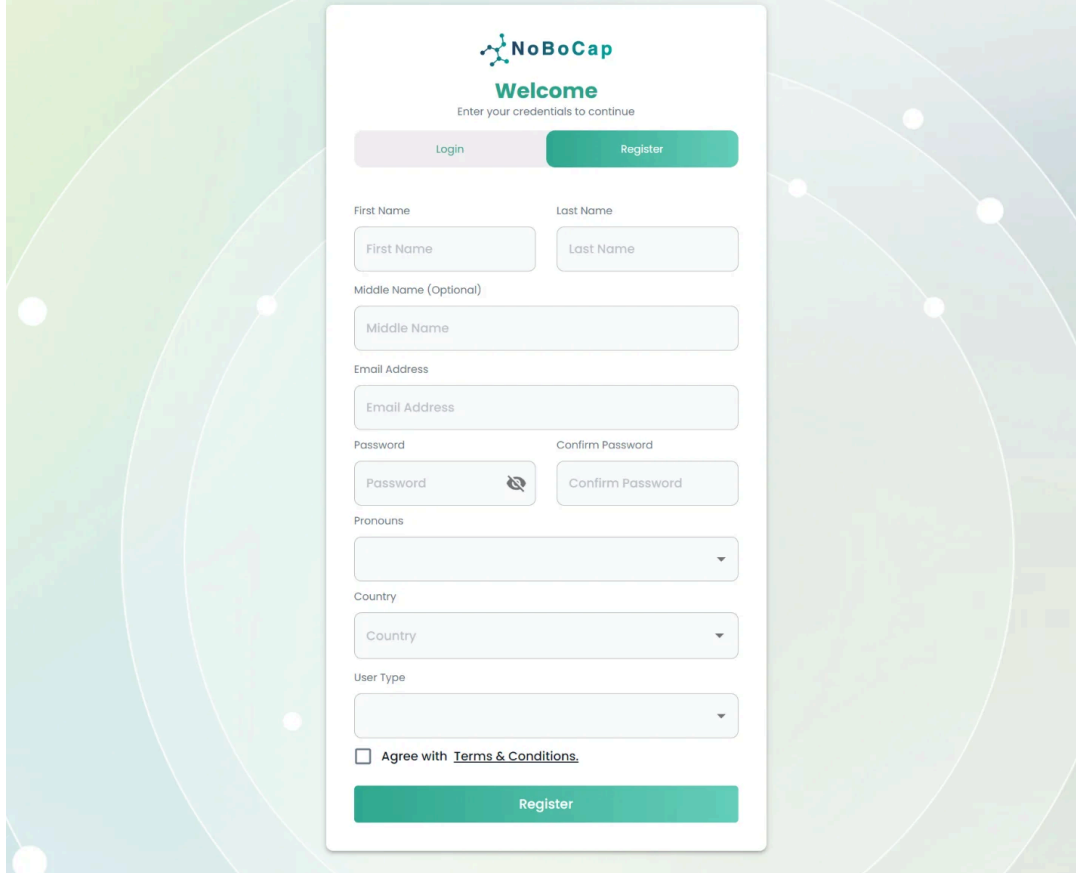


The screenshot shows the NoBoCap portal interface. At the top left is the NoBoCap logo, and at the top right is a 'Home' link. The main heading is 'Welcome to the NoBoCap Environment', followed by a subtitle: 'An innovative platform, accessible via SSO, designed to connect and support professionals and organizations in the healthcare and technological innovation sectors'. Below this is a white login/register form. The form has a 'Login' button on the left and a 'Register' button on the right. It contains an 'Email Address' input field, a 'Password' input field with a toggle icon, a 'Remember Me' checkbox, and a 'Forgot Password?' link. A 'Login' button is positioned at the bottom of the form.

2. Create your account:

# Welcome to the NoBoCap Environment

An innovative platform, accessible via SSO, designed to connect and support professionals and organizations in the healthcare and technological innovation sectors



The image shows a registration form for the NoBoCap environment. The form is centered on a light green background with a subtle pattern of white dots and lines. At the top of the form, the NoBoCap logo is displayed, followed by the word "Welcome" and the instruction "Enter your credentials to continue". Below this, there are two buttons: "Login" (light purple) and "Register" (teal). The form fields are as follows:

- First Name: Input field with placeholder "First Name"
- Last Name: Input field with placeholder "Last Name"
- Middle Name (Optional): Input field with placeholder "Middle Name"
- Email Address: Input field with placeholder "Email Address"
- Password: Input field with placeholder "Password" and a toggle icon for visibility
- Confirm Password: Input field with placeholder "Confirm Password"
- Pronouns: Dropdown menu
- Country: Dropdown menu with placeholder "Country"
- User Type: Dropdown menu

At the bottom of the form, there is a checkbox labeled "Agree with [Terms & Conditions](#)" and a large teal "Register" button.

3. Navigate to the **NoBoCap Courses** section, check the upcoming sessions, and register for these final courses offered within the NoBoCap project:

- **Module 2: Generating Data for Technical Documentation (MDR)**
- **Short Course on EU MDR/IVDR & FDA QMSR**

## Welcome to NoBoCap Courses

NoBoCap training courses help MedTech professionals understand and apply MDR and IVDR regulations with confidence. Whether you're an executive, a regulatory expert, or part of a market operator team, our courses offer clear and practical guidance on compliance, AI-supported medical devices, and technical documentation. With flexible options—online, in-person, and accredited programs—you can learn at your own pace while keeping up with your daily work.

Courses	Next session start date	Status
Post-Graduate Module 1 Implementing Regulatory Requirements for Medical Devices	September 16, 2025	<a href="#">Register</a> ⊕
Post-Graduate Module 3 Generating Data for Technical Documentation IVDR	September 16, 2025	<a href="#">Register</a> ⊕
Short C-level Management Training	November 7, 2025	<a href="#">Register</a> ⊕
Short Performance Evaluation of AI as/in a Medical Device	October 21-23, 2025	<a href="#">Register</a> ⊕
Short Short course training on MDR for investors*	December 2025	<a href="#">Register</a> ⊕
Short MedTech Winter School: From Design to Clinical Evidence	26-28 January 2026	<a href="#">Register</a> ⊕
Short The NoBoCap Short Course on Performance Evaluation of AI-based MDSW	12-16 January 2026	<a href="#">Register</a> ⊕

# NOBOCAP ENVIRONMENT

**Discover the NoBoCap  
Environment - your portal for  
MDR & IVDR success**



Whether you're a Market Operator, a Notified Body, or part of the EU MedTech ecosystem, the NoBoCap Environment is your gateway to collaboration, compliance, and capacity building.

Created under the EU4Health programme, this platform brings together all key actors involved in medical device and IVD certification – supporting a more efficient, transparent, and innovation-friendly regulatory process across Europe.

Here's what you'll find inside once you register on [www.portal.nobocap.eu](http://www.portal.nobocap.eu):

- **E-guided MDR/IVDR learning** – understand requirements and NB codes
- **Matchmaking tool** – connect Market Operators with Notified Bodies
- **Job Board** – explore and share opportunities within the MedTech and IVD ecosystem
- **NoBoCap Courses** – build your regulatory knowledge
- **Community space** – share insights, news, and expertise
- **Project resources & video** – learn about the mission and impact of NoBoCap

✓ **NOBOCAP JOB BOARD**

## What if your next MedTech opportunity is already waiting for you?

The NoBoCap Job Board connects talent with opportunities across the MedTech and IVD sectors. With dedicated dashboards for professionals and Notified Bodies, users can explore, follow and engage with opportunities as they become available within the growing NoBoCap ecosystem.

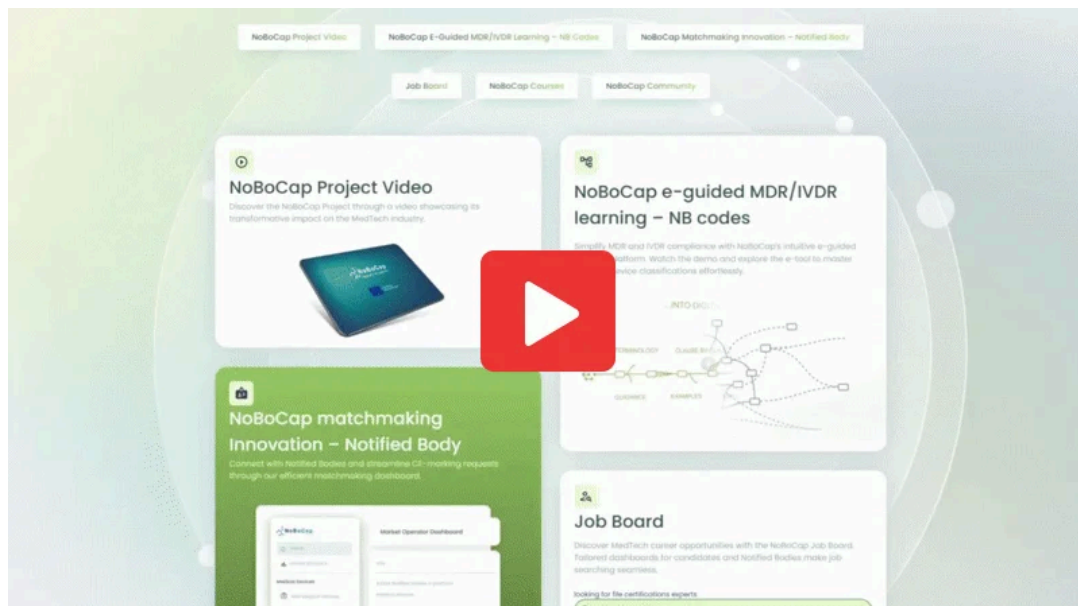
As part of the **NoBoCap Environment**, the **Job Board** provides a dedicated space where organisations active in the regulatory landscape can make opportunities visible, while professionals can discover roles aligned with their expertise.

### Getting started

To help you get started, we've prepared a short video showing:

- How to **register on the NoBoCap Environment**
- How to **access the Job Board**
- How to **publish or explore opportunities**

 **Watch the video below to see how to get started with the NoBoCap Job Board**



**NOBOCAP COMMUNITY**

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# Calling All Innovators!

## Join NoBoCap Community!

NoBoCap Community Members & Partners to Unlock EU Regulations



MEMBERS - CLUSTERS & INNOVATION HUBS

[Register here](#)

PARTNERS - KNOWLEDGE/ KNOW-HOW

[Register here](#)

PARTNERS - SUPPORTIVE

[Register here](#)

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EU regulatory challenges, innovative solutions and initiatives toward strengthening the MedTech industry by enhancing the efficiency of Notified Bodies and Market Operators is more important than ever before.

We are calling Innovators to join the NoBoCap Community and become a part of our network driving change to Qualify to Certify! This could be the beginning of an unbelievable journey. At NoBoCap Community, our pioneering and agile spirit keeps us interconnected with EU Regulatory challenges trying to increase knowledge and preparedness of Market Operators (MOs) in the application of MDR and IVDR.

NoBoCap Community allows you to be part of an innovation ecosystem designed to Unlock the EU regulation. Be one of those striving to bring innovation into healthcare and join the NoBoCap Community today!

Be innovative, bring unexpected ideas, push the boundaries, and contribute to solving complex challenges!

👉 Visit our page: <https://nobocap.eu/community/>

If interest to join the community, please visit the What to Offer page and complete the application form.

👉 **Application form:** [https://eu4healthsolutions.formstack.com/forms/nobocap\\_community\\_application\\_clusters\\_hubs](https://eu4healthsolutions.formstack.com/forms/nobocap_community_application_clusters_hubs)

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# NoBoCap Community Webinar Series

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## NOBOCAP COMMUNITY WEBINAR

 Date: 30 April 2026

 10:00 AM CET

 Online

This upcoming session brings together innovation, regulation, and practical tools to support your journey in the evolving MedTech landscape.

During the webinar, participants will:


- explore [iVITA's IRHIS](#) initiative, join the [event "Opportunities in Action: Funding, Insights, and Matchmaking for Health Innovators"](#), and learn how AI-driven remote care and smart health technologies are transforming healthcare across Europe,
- gain insights into IVDR through the policy paper "Intended Purpose and Classification of IVD devices under EU Regulation 2017/746", authored by Davide Rigamonti, SGS,
- discover the NoBoCap Backbone Services & Tools
- connect with experts, innovators, and potential partners within the NoBoCap Community.

👉 **Join the webinar on Zoom:**

<https://us02web.zoom.us/j/83024696157?pwd=pOzp85UQDmEFnPOBHoXpaa9wSQJ5JX.1>


Meeting ID: 830 2469 6157

Passcode: 668595



**WEBINAR**  
NOBOCAP COMMUNITY TO UNLOCK EU REGULATION

**DATE**  
 **APRIL 30, 2026**

**TIME**  
 **AT 10:00 AM (CET)**

- ✓ **WELCOME**
  - Our Community: Extension NoBoCap
  - Plan On Building A Legal Entity (RoHealth And Founding Partners)
  - Community Meeting And Summit/Final Project Meeting
- ✓ **A CHANGING ENVIRONMENT: INNOVATION ENHANCING REGULATORY ENVIRONMENT**
  - Did You Miss The Latest Development: Summit 2025 Recording Now Available
  - Breakthrough Guidance
  - First Pilot Of EMA Scientific Advice
  - Revision Of Regulation With Specific SME Supportive Proposals
- ✓ **EXCHANGE OF INITIATIVE PLANNED BY NOBOCAP (NEW BACKBONE AND VOICE PROJECT DURING EXTENSION)**

**BACKBONE SERVICES:**

  - Educational Programs (Overview)
  - New Initiatives (Including Innovation Mapping)

**VOICE:**

  - Intended Purpose And Classification Of IVD Devices Under EU Regulation 2017/746, Author: Davide Rigamonti, SGS
  - Planned Survey To Seek View Of Innovation Hub Community/ Innovators
  - Dialogue With European Commission
- ✓ **BEST PRACTICE SHARING**
  - NoBoCap Consortium Member Initiatives
  - Innovation Hubs Initiatives
  - Partner Initiatives: iVITA: IRHIS initiative & Event: Opportunities In Action: Funding, Insights, And Matchmaking For Health Innovators



 <https://nobocap.eu/community>

NoBoCap webinars are accessible for NoBoCap COMMUNITY MEMBERS/PARTNERS and the Members of CLUSTERS and INNOVATION HUBS.

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**Join the NoBoCap Community Webinar Series and connect with experts, innovators, and regulatory professionals across the European MedTech ecosystem!**

The next NoBoCap Community webinars are scheduled for:

 18 June 2026

 17 September 2026

 19 November 2026

Stay connected for upcoming topics, speakers, and opportunities to engage with the NoBoCap Community!

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**NoBoCap**

[www.nobocap.eu](http://www.nobocap.eu)



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