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**BRINGING TOGETHER EUROPE TO UNLOCK
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Bringing together Europe To Unlock Medical Device Regulations & the AI Act For Innovators and SMEs in Europe



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STATE OF PLAY AND EU – EC POLICY INITIATIVES



Attractiveness of Europe for SME driven Medical Technology Innovation – Aydin Burçak, Deloitte

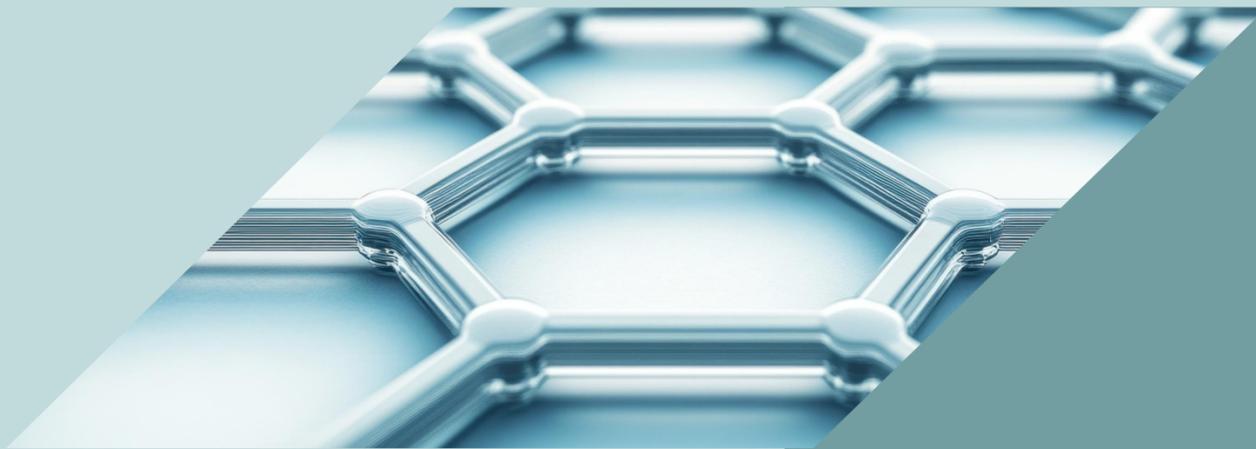


Impact of MDR/IVDR on (SMEs) Innovation and recommendations – EC Commissioned EY Study – Daan Bijwaard, EY



Legislative and Non-legislative EU Policy initiatives – European Commission – Flora Giorgio, Head Unit D3 Medical Devices

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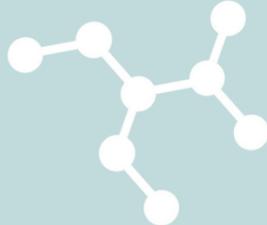
STATE OF PLAY AND EU – EC POLICY INITIATIVES



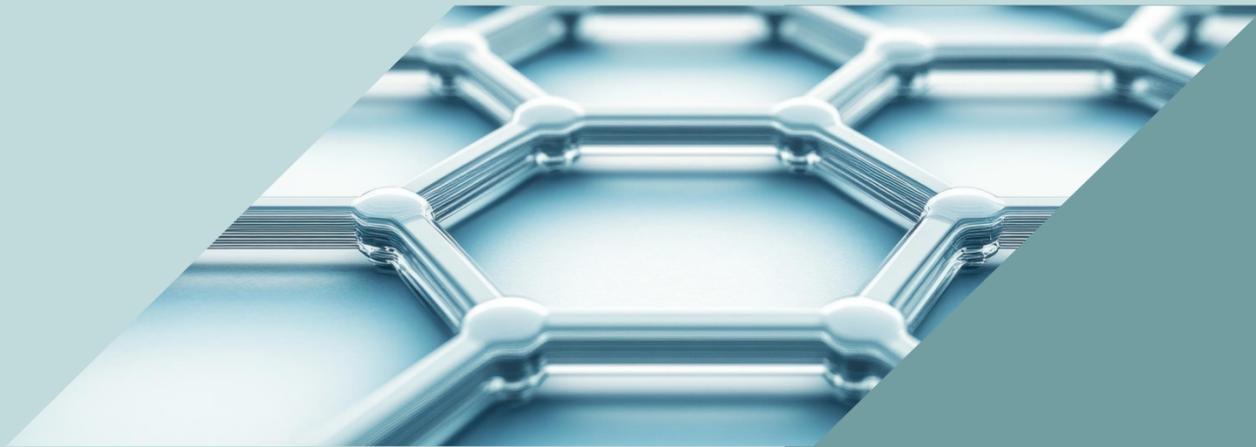
Attractiveness of Europe for SME driven Medical Technology Innovation

Aydin Burçak, Deloitte

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A white icon of a molecular structure with several nodes and connecting lines, positioned below the "NoBoCap" text.

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Deloitte.



NoBoCap Summit –2025
Europe's MedTech Attractiveness

Introduction



Dr. Burcak Aydin
Director
Deloitte Life Sciences Strategy

Speaker funding disclosure

My participation as speaker is supported by Deloitte Belgium which is a sponsor of the NoBoCap Summit 2025

Europe's MedTech Attractiveness

STUDY METHOD

- Targeted literature review (inc. reports 40 in total)
- OECD, Eurostat, and Statista used for quantitative analysis
- 29 MedTech global industry experts consulted, E2E value chain

Socioeconomic robustness

Strength of ecosystem

Fiscal and financial competitiveness

Talent availability

Easy of doing business

Site availability



Prepared in collaboration with MedTech Europe, 2024

Background and Context

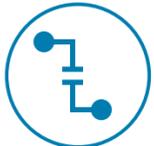
KEY TRENDS IMPACTING MEDTECH INVESTMENTS



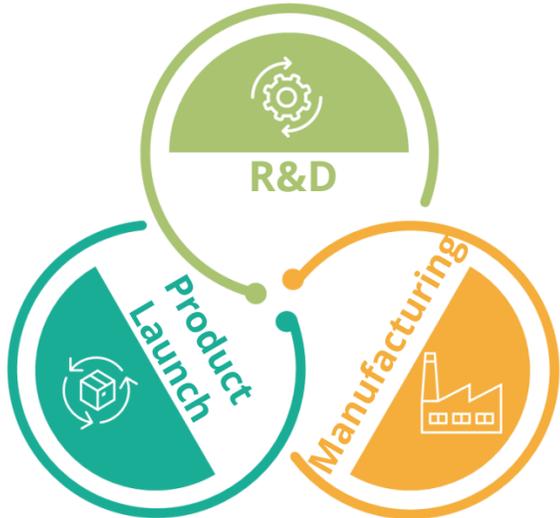
Growing demand for MedTech to manage chronic diseases in the **ageing population** and for **preventive technologies**



MedTech companies are innovating towards **sustainable medical technologies**, prompting a shift in design strategies



Increasing possibility of **supply chain** disruptions due to more stringent **sustainability** requirements (supplier risk, substance bans) and hard to predict **demand surges**



MedTech talent crunch leading to increasing competition among industry players to attract and retain top talent



Focus on **digital health solutions** to compensate for **healthcare workforce shortages** and support remote monitoring



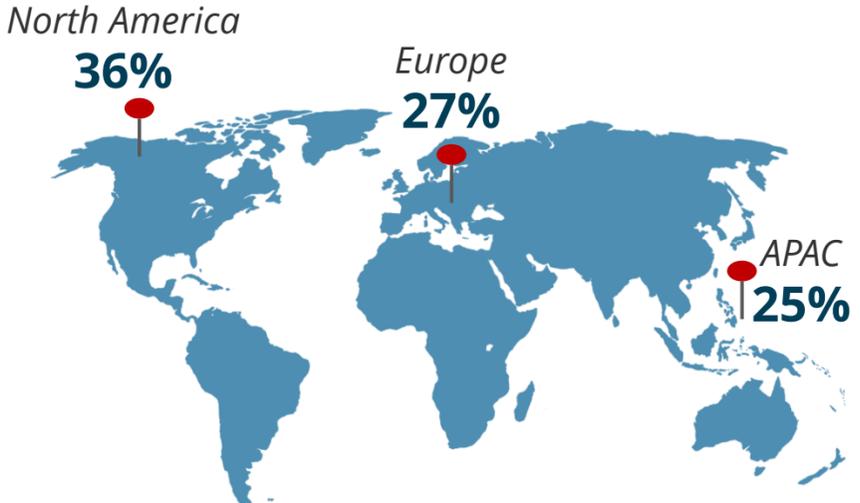
Increasing focus on **value-based care** to promote cost reduction and health equity



Increasing need for **regulations** around **5G, AI, digital health, data interoperability**, and **sustainability** in MedTech, due to their growing adoption and importance

CONTEXT

Market Shares



Global MedTech Market **\$510 B**

With APAC is poised to overtake Europe and a diminishing inclination among companies to invest in the region, Europe faces the imperative to proactively enhance competitiveness

Current MedTech trends and market dynamics dictate that industry and policymakers work collaboratively and proactively to enhance the attractiveness of the European innovation and MedTech investment landscape

Europe's MedTech research ecosystem is bolstered by fiscal incentives, innovation hubs and attractive labor laws...



Attractive **tax incentives** and **public funding schemes** for R&D with **high success rates**



Potential booster by EHDS for the R&D environment



Collaborative networks and hubs of universities, companies and startups, with **high patent** and **publication activity**



Ability to **attract and retain talent** and **foster employee loyalty** due to **favorable labor laws**

- **Variety of financial incentives** – including tax benefits, cash grants, loans, and patent boxes
- **Higher success rates** with availing grants vs US
- **Fewer post-award monitoring and reporting** requirements vs US's NIH grants (e.g., auditing and contract life cycle management)



De-risk investments in MedTech innovation on sustainability, digital health, preventive health through wide variety of R&D incentives

- **Well-funded** MedTech clusters, e.g., Medicon Valley (Denmark), Emilia-Romagna (Italy) supported by **local governments**

42% of **MedTech patents** filed with the EPO were by **European companies**, compared with **37% from US companies**

2k MedTech startups, leading China (2022)



Allows companies to be present in an innovative ecosystem with **access to highly skilled talent, research ideas and infrastructure**

10,1 years average time spent with one employer in Europe vs **4,1 years in the US** across industries (2022)

- Greater **job security, benefits, social protections, and more favorable working conditions** than US and APAC, fostering **employee loyalty**



Allows companies to **attract and retain world-class MedTech talent**

Europe presents a clear opportunity for investments in R&D because of its well-developed research ecosystem, favorable R&D incentives in multiple Member States and a working environment that attracts and nurtures world-class talent

...But innovation is hampered by a risk-averse culture, bureaucracy and MedTech-specific skills shortages



Lack of high-risk investment funding and support for product commercialization due to the risk-averse nature of European investors



Bureaucratic administrative processes make it difficult to avail state incentives and slow down decision making



Global **skills shortages** that are required to support the next wave of MedTech advancement present an opportunity for Europe to **differentiate itself**

\$2,1B worth of MedTech VC funds raised in Europe vs **\$4,5 Bn** in APAC and **\$6,7 Bn** in the Americas (2021)

1/2 the number of **MedTech startups** compared to the US (2022)

“European investors are **risk-averse and look for guaranteed returns**. While funding is available for research and development, it is a challenge to get public or private funding to bring higher risk products to market.”
- Innovation Expert and Entrepreneur

“We spent nearly **18 months** trying to get funding for one of our projects. Ultimately, we went to the US for funding. There is a greater willingness to be efficient in the US.”
- R&D Head at MedTech Company

“European State requires **high degree of bureaucratic administration**. It can be overwhelming. But often the juice is worth the squeeze.”
- Head of Grants at MedTech Company

>60% Of **EU businesses** face shortages of **digital and ICT skills** (2021); vs. **US**, where **65-80%** of firms struggle to hire AI talent (2022)

40% Of doctors aged 55 or more in 13 out of 44 European countries. US faces shortage of up to **124 000 physicians** by 2034

To drive greater innovation and bridge the gap between development and commercialization, implementing strategies to create a differentiated MedTech talent pool, streamline bureaucracy, and encourage risk-taking is pivotal

Europe is a pioneer in influencing global legislation and creating MedTech regulations...



Europe is the **trailblazer in legislative innovation** on sustainability, AI, and other key areas



Due to its consensus-driven culture, Europe offers businesses **regulatory stability and business predictability**



Europe acts like a **springboard** to other markets, unlocking **multiple markets** through a single regulatory process



Cross-border harmonization across regulatory, HTA and regulatory to boost

- **EU regulations** set the agenda for global companies given the size and importance of the European market, e.g., **GDPR**
- **EU's AI Act** and **Green Deal** are influencing other regions to follow or create their own legislations



Existing legislation on data usage, AI, and sustainability, provides a **clear framework for industry to innovate within**

22

out of the **top 50 countries on the global political stability index** are in Europe (2021)

- US regulatory environment **undergoes shifts** with each new administration, introducing uncertainty and unpredictability



Predictability of the regulatory landscape in Europe fosters a **stable environment for MedTech investments**

“

*“About **30 markets** are unlocked by the CE mark, and about a **100 more** around the world have facilitated access if you have the CE mark, including emerging markets”*

-CEO, MedTech Europe



Higher entry barriers than in the pre-MDR / IVDR era, but benefits are enormous given the **size and strategic importance of the market**

Despite the regulatory process becoming more complex in recent times, companies that continue to invest in Europe can reap the benefits of unlocking multiple markets with a single regulatory process, and enjoy business predictability

...But the regulatory landscape is complicated by multiple overlapping and risk-averse regulations



Multiple **overlapping sectoral and cross-industry regulations**, with limited guidance on how they interact with each other, e.g., PLD and MDR/IVDR



Multiple **sustainability initiatives**, e.g., restriction of substance usage, more stringent reporting requirements, proposed / implemented in parallel



Missed opportunities for the industry as **regulations lag the pace of innovation** in key areas due to culture of **risk-aversion**

- Complex, overlapping regulations, e.g., MDR / IVDR, AI Act and EHDS, as well as new directives, e.g., revised Product Liability Directive (PLD), Representative Actions Directive, can make **compliance challenging**
- Further, PLD revision may make Europe **less competitive** as MedTech companies may face **a rise in litigation** and speculative claims

- Increasing number of initiatives to restrict use of certain substances, e.g., PFAS, not considering the **time needed to transition sustainably**
- More stringent reporting requirements necessitate **greater resource allocation, training, and potential changes in partnerships**

“Multiple sustainability expectations are thrown at us and because they’re **not harmonized** across Member States, **we don’t know where to start**, which requirement do I engage with first?”

- MedTech Industry Leader

“There is a risk that **EU overshoots with new EU regulations**, e.g., AI Act and development becomes **too complex** for companies to navigate. EU is **very risk averse** in a way that US and China are not – sometimes can go too far and can stifle innovation”

- MedTech Industry Leader

“We want to innovate in certain areas, for example, **Electronic Information For Use (eIFU)** but here the regulations are missing, which is becoming a **barrier for us to innovate**”

- MedTech Industry Leader

Embracing a culture of 'permitting' and agile course-correction, and moving away from over-regulation and risk-aversion, is pivotal to fostering innovation in the MedTech landscape

Europe has efficient healthcare systems and has taken steps towards new healthcare models...



Universal health care coverage creates larger market opportunities for MedTech

- European health care systems outperform the US on **quality, affordability and access**
- Europe **invests in primary care systems, reduces administrative burdens** on patients and clinicians and **invests in social services** to increase equitable access to care

 Greater **demand for preventive technologies** and **opportunities for collaboration** between MedTech companies and healthcare providers



Europe leads other regions in **value-based procurement (VBP)**

- EU Directive on Public Procurement encourages public authorities to move towards **high-value, high-quality products and services**

“*While there is room for VBP to expand in Europe, no other market in the world has better VBP than Europe; we are ahead of the pack.*”
- MedTech Industry Leader

 Greater adoption of VBP will **shift tender discussions away from the upfront purchase price** towards holistic exploration of value, and help companies, providers, procurers build partnerships of mutual benefit

Europe promotes affordable care, health equity, and value-based procurement, thereby creating greater market opportunities for MedTech manufacturers

...But return on investment is hindered by slow reimbursement, low adoption of VBP, and high pricing pressures



Challenges in MedTech **reimbursement** due to **diversity in pathways** across Europe

5-6 years, or even more, to get reimbursement for MedTech innovations, similar to the US (average **5,7 years**)

Not all European countries have **established pathways** for reimbursement of digital health solutions

Limited number of countries have **Innovative Payment Schemes** in place



Low adoption of VBP coupled with high **pricing pressures** due to price-only tendering frameworks in most countries

- EU-wide adoption of VBP among providers and procurement bodies is **low despite the directive**
- “Value” means different things to different stakeholders – currently lack a **common definition of “value”** for MedTech products
- **No limitations** on price-only tendering frameworks



Austerity schemes pose legal, financial and operational burdens on MedTech companies

- Cost containment measures, e.g., **payback systems**, pose a risk to the long-term competitiveness and attractiveness of the European market
- Potential activation or expansion of such systems would exacerbate the situation, stifle innovation, and can **erode patient access to MedTech**

There is an opportunity to make reimbursement quicker, and shift the focus away from price-only tendering and cost containment measures that may hinder innovation, to a more standardized value-based approach

The regulatory landscape for breakthrough innovation considers critical regional needs



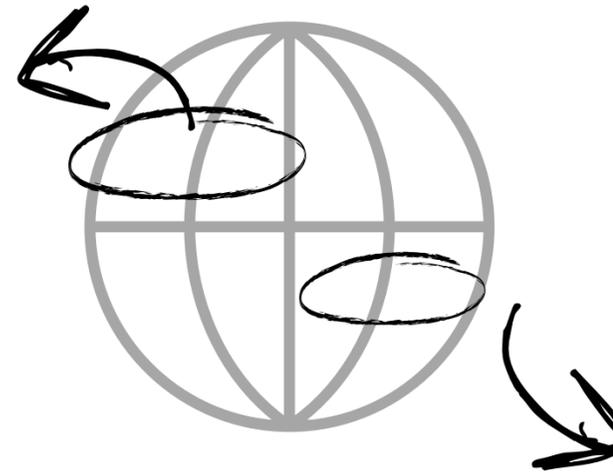
US

- › **Breakthrough Devices Program***, by FDA formalized in 2016
- › Eligibility:
 - ✓ It must provide for more effective treatment or diagnosis of life threatening or irreversibly debilitating human diseases or conditions.
 - ✓ It must satisfy at least one of four secondary criteria: represent breakthrough technology, offer significant advantages over existing alternatives, address an unmet medical need, or its availability must be in the best interest of the patient
- › In 2023, **health equity** criteria introduced



JAPAN

- › **The pioneer designation**** system started in 2015, fully enacted in 2019
- › Covers pharmaceuticals, MDs and regenerative medicines
- › Specific to medical devices, the eligibility criteria
 - ✓ Innovative therapy or diagnostic method
 - ✓ Severe target disease
 - ✓ High efficacy or safety
 - ✓ Commitment and capability to pursue early development and approval in Japan
- › Priority for products for serious diseases with unmet medical needs, especially if there is limited or no overseas approval



Regional specifications

*Gupte T, Nitave T and Gobburu J (2025) Regulatory landscape of accelerated approval pathways for medical devices in the United States and the European Union, ** Deloitte research, local expert input

Making the European MedTech innovation landscape more attractive will require strategic actions from policymakers and industry

Create a single, clear and accountable structure building on existing regulatory infrastructure, **empowering existing actors**. The structure should be **specific to MedTech** to provide oversight and ensure the goals of the present regulatory framework are met in full in line with the specificities of the MedTech business

Establish a **unified digital health and single health data market**, harmonizing EU countries' approaches to digital health technologies

EU and Member States can **simplify and streamline** the **administrative procedures** associated with availing state incentives

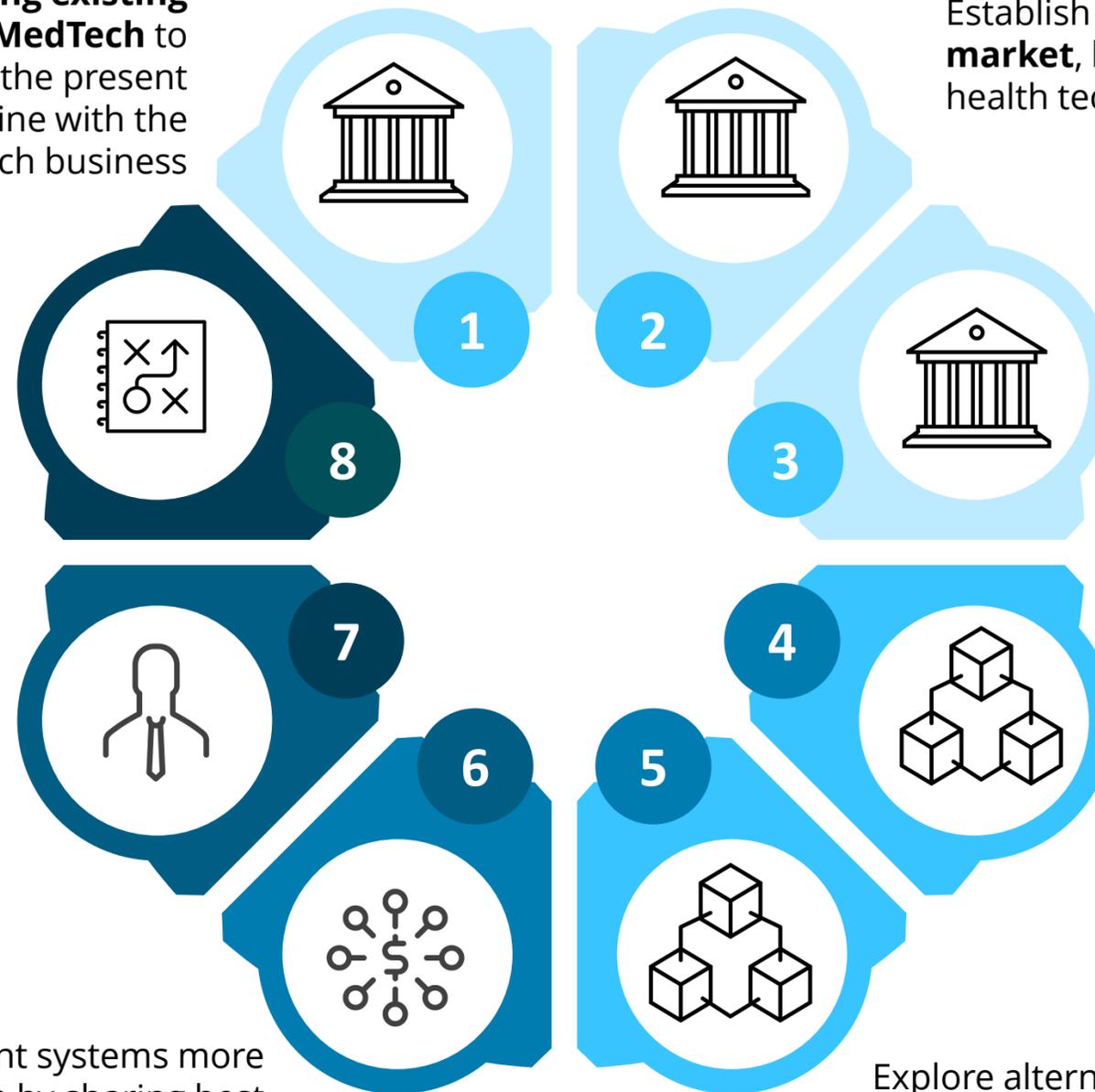
Base environmental regulations on **industry capabilities and scientific progress**, and incentivize compliance, innovation, and environmental responsibility

EU can continue efforts to promote STEM, close skill gaps, and facilitate cross-border movement of talent. **Industry must play a key role** in identifying specific skills gaps, training, and matching recruitment process and flexible work expectations to attract and retain the right MedTech talent

Promote and **standardize value-based procurement** (VBP) through value-based tendering frameworks and value-based pricing

Make MedTech reimbursement systems more **harmonized and predictable** by sharing best practices / criteria across EU Member States and utilizing the potential of real-world data

Explore alternatives to Member State-level austerity schemes and focus on a **balanced value-based healthcare approach** that does not hinder innovation



STATE OF PLAY AND EU – EC POLICY INITIATIVES

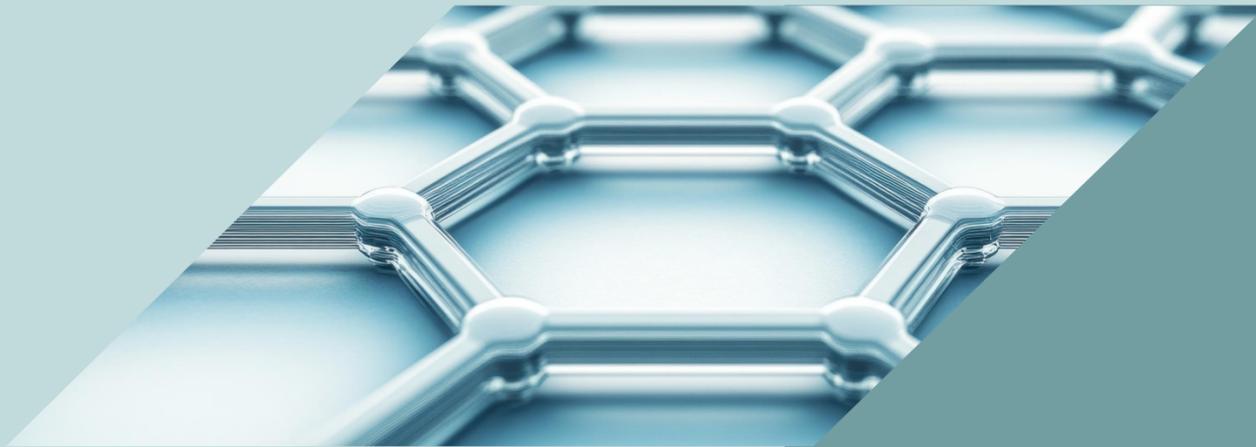


Impact of MDR/IVDR on (SMEs) Innovation and recommendations – EC Commissioned EY Study

Daan Bijwaard, EY

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Study on Regulatory Governance and Innovation in the field of Medical Devices

NoBoCap Summit 2025

16 October 2025



Key objectives

- ▶ Map **key benefits and challenges** of the **regulatory governance structure** of the MDR/IVDR and look at its **impact on innovation and patient safety** in the EU medical devices sector.
- ▶ Provide input for the **evaluation** of the regulatory framework.
- ▶ Make **proposals to optimise the framework** in the short, medium and long term.

Scope of the study

- ▶ Focus on assessing the **governance structure** (MDCG, expert panels etc.), and analyse if its application contributes to meeting the objectives set out in the MDR/IVDR, i.e. patient safety and innovation.
- ▶ Look at **specific elements of the regulatory framework** the governance structure is part of, to assess how its implementation meets the objectives set out in the MDR/IVDR.

Research questions

1	What is the state of play of the application of the Regulations in terms of the governance structure and tasks assigned to key actors in the medical devices sector?
2	Has the governance structure and the tasks performed by key actors been <u>effective</u> in meeting the objectives set out in the Regulations*?
3	Has the governance structure and the tasks performed by key actors been <u>efficient</u> in meeting the objectives set out in the Regulations?
4	To what extent does the regulatory framework (in particular governance structure) and its identified benefits and challenges impact the innovation capacity and competitiveness of the medical devices and <i>in-vitro</i> diagnostic devices industry in the EU?
5	To what extent does the regulatory framework (in particular governance structure) improve patient safety and public health protection?
6	How does the EU regulatory framework (in particular governance structure) in the field of medical devices compare to selected systems around the world?

**i.e. creation of a robust, transparent, predictable and sustainable regulatory framework for medical devices, which ensures a high level of patient safety whilst supporting innovation*

Geographical scope



- ▶ EU27
- ▶ Relevant data from non-EU countries

Key actors



- ▶ EU institutions
- ▶ Authorities of the 27 EU MS
- ▶ Notified bodies
- ▶ Trade associations and economic operators, incl. SMEs
- ▶ Associations representing healthcare professionals and patients
- ▶ Other organisations/institutions (academia, RTOs, innovations hubs/clusters, investors, WHO, consumer organisations, etc.)

Timeline



- ▶ Study completed/approved
- ▶ Planned to be published in support of and together with the European Commission evaluation of the MDR and IVDR (tbc)

Online survey



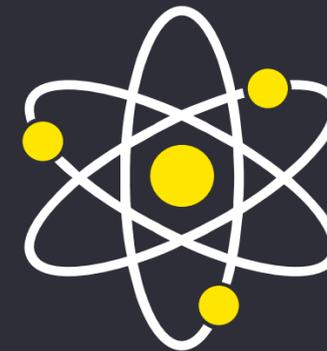
- ▶ **Who:** Available to all interested key actors
- ▶ **How:** Online survey with targeted invitations + open link (n=470 resp., incl. 91 SMEs)
- ▶ **Why:** Collect quant and qual data from identified interest groups

Targeted interviews



- ▶ **Who:** Representatives of the different key actors
- ▶ **How:** 43 semi-structured interviews tailored to different groups
- ▶ **Why:** Collect in-depth information and perspectives on the defined research questions

Thematic workshops



- ▶ **Who:** Selected actors based on the thematic
- ▶ **How:** 4 online workshops on identified key themes (governance, patient safety, innovation and SMEs)
- ▶ **Why:** Identify key issues and solutions to the identified challenges

Consultation workshops



- ▶ **Who:** EU27 MS authorities and/or relevant stakeholders
- ▶ **How:** 3 hybrid workshops throughout the project
- ▶ **Why:** Validation of the study design and findings

MDR/IVDR study | SMEs and the EU medical devices and IVD sector

Specific focus on **smaller and medium-sized enterprises (SMEs)** throughout study – including on **micro and small firms (MSEs)** – in recognition of their vital role in the market:

- ▶ **Key market players:** Of the ~35,000 European medical technology firms, 92% are SMEs. Most of these firms employ <50 people.
- ▶ **Drivers of innovation:** Because of their size and flexibility, SMEs often have the ability to innovate faster and adapt better to the changing needs and demands of the healthcare sector.
- ▶ **Drivers of customisation:** SMEs excel in accommodating specific needs in terms of design, materials used, and functionalities of MDs/IVDs, including e.g. for orphan devices.
- ▶ **Vital partners:** SMEs often collaborate with research labs and hospitals to conduct research and clinical trials, making them vital contributors to the overall medical device ecosystem.





Disclaimer: The reported findings are not yet published and are not endorsed by the European Commission.

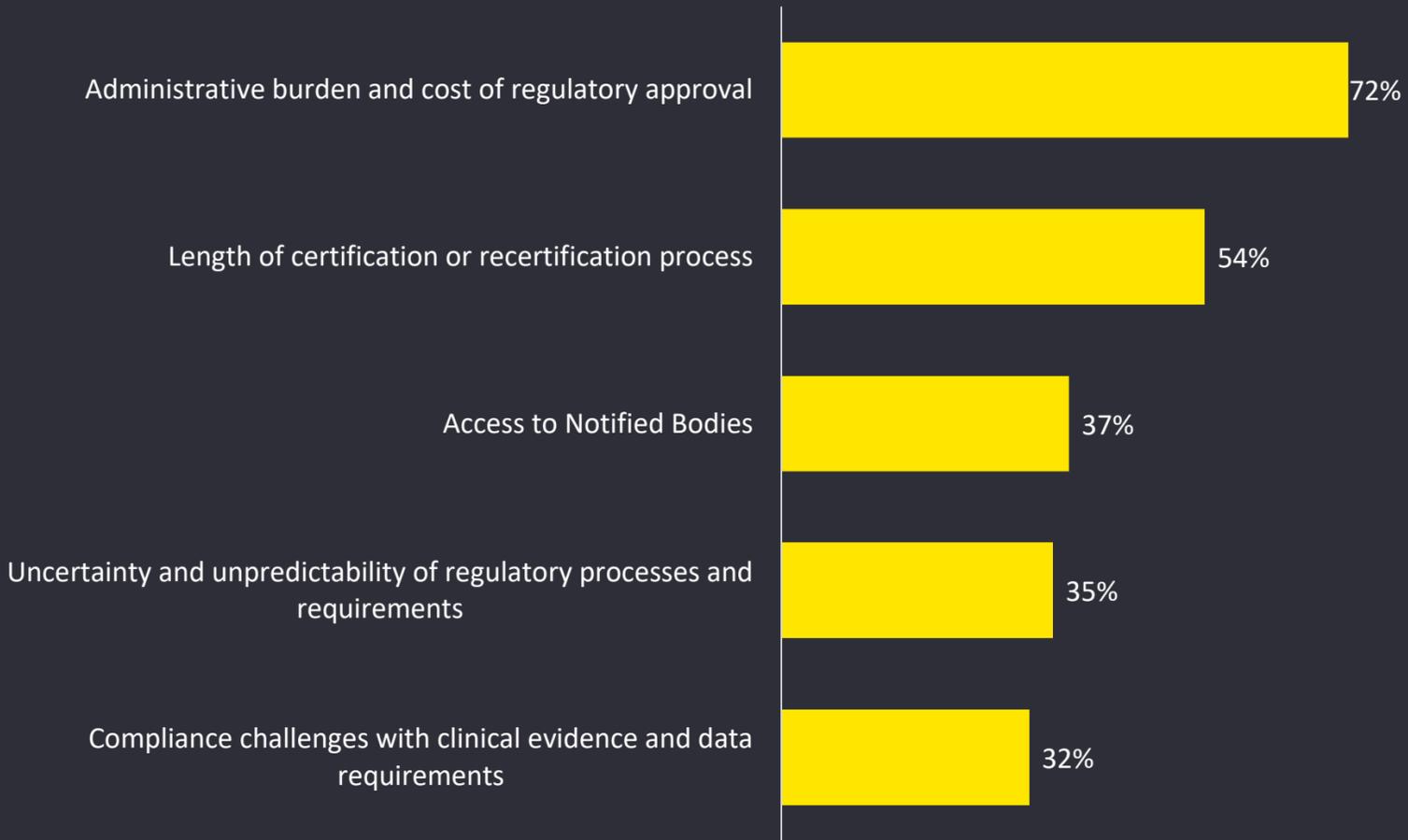
Issues experienced

- ▶ Actors/stakeholders expressed scepticism about the regulatory framework's support for new and emerging technologies.
 - ▶ A clear majority in the survey disagreed it stimulates the placing on the market of highly innovate devices, incl. 81%-85% of MSEs and medium and large firms.
- ▶ Barriers to innovation identified include high administrative costs, lengthy and unpredictable certification processes, and stringent clinical evidence demands.
- ▶ Compared to larger peers, MSEs generally are affected more by such barriers:
 - ▶ Certification costs take up a larger share of MSEs' budgets;
 - ▶ MSEs find it difficult to obtain financing for the design and manufacturing of MDs/IVDs;
 - ▶ MSEs regulatory knowledge tends to be lower, which can result in longer certification timelines and a higher dependence on (expensive) external consultants;
 - ▶ Access to NBs can remain challenging for smaller firms, especially those developing IVDs.

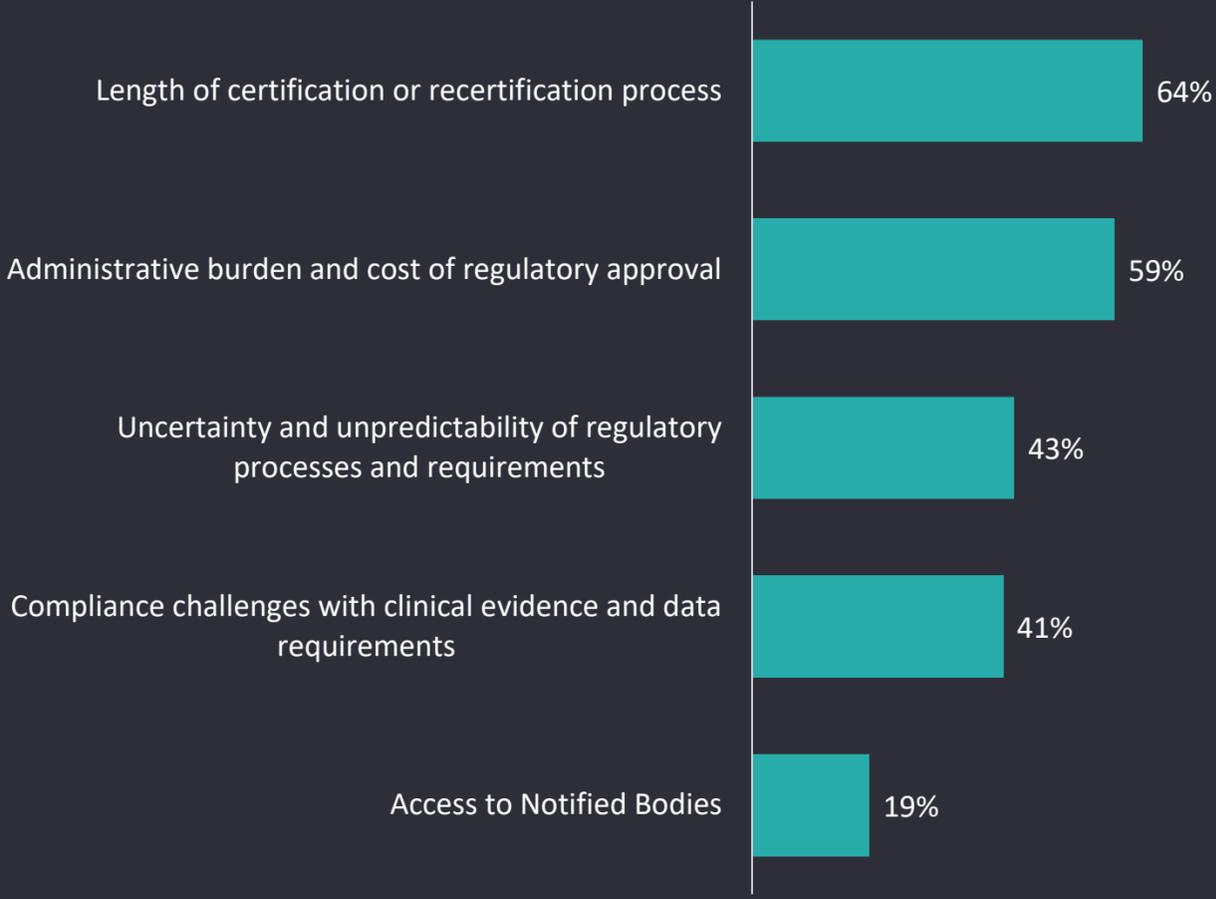
MDR/IVDR study | Key regulatory barriers – Top 5 – MSEs vs large and medium firms

MD/IVD13 - In your experience, which of the following (if any) are the **key regulatory barriers** for the industry to bring innovative devices to the EU market?

Micro and small enterprises



Medium and large enterprises



% Total; Micro and small firms (n=98); Medium and large firms (n=110)
Source: MDR/IVDR survey (February 2024)

Disclaimer: The reported findings are not yet published and are not endorsed by the European Commission.

Effects observed (I)

- ▶ Findings suggest the MDR and IVDR have had an **impact on device offering** in the EU*.
 - ▶ An important share of firms report to have *reduced device portfolios, cancelled new device introductions, or ceased production for the EU market* as result of the introduction of the Regulations.
- ▶ As **smaller firms** tend to have less resources and smaller device portfolios, effects are different than for their larger peers.
- ▶ E.g., compared to medium and large firms, MSEs are:
 - ▶ *less likely* to have allocated more resources (65% of MSEs vs 92% of medium and large firms) or to have reduced their device portfolio (45% vs 78%);
 - ▶ *relatively more likely* to have postponed the introduction of new devices (2nd most important effect for MSEs vs 4th for larger firms).

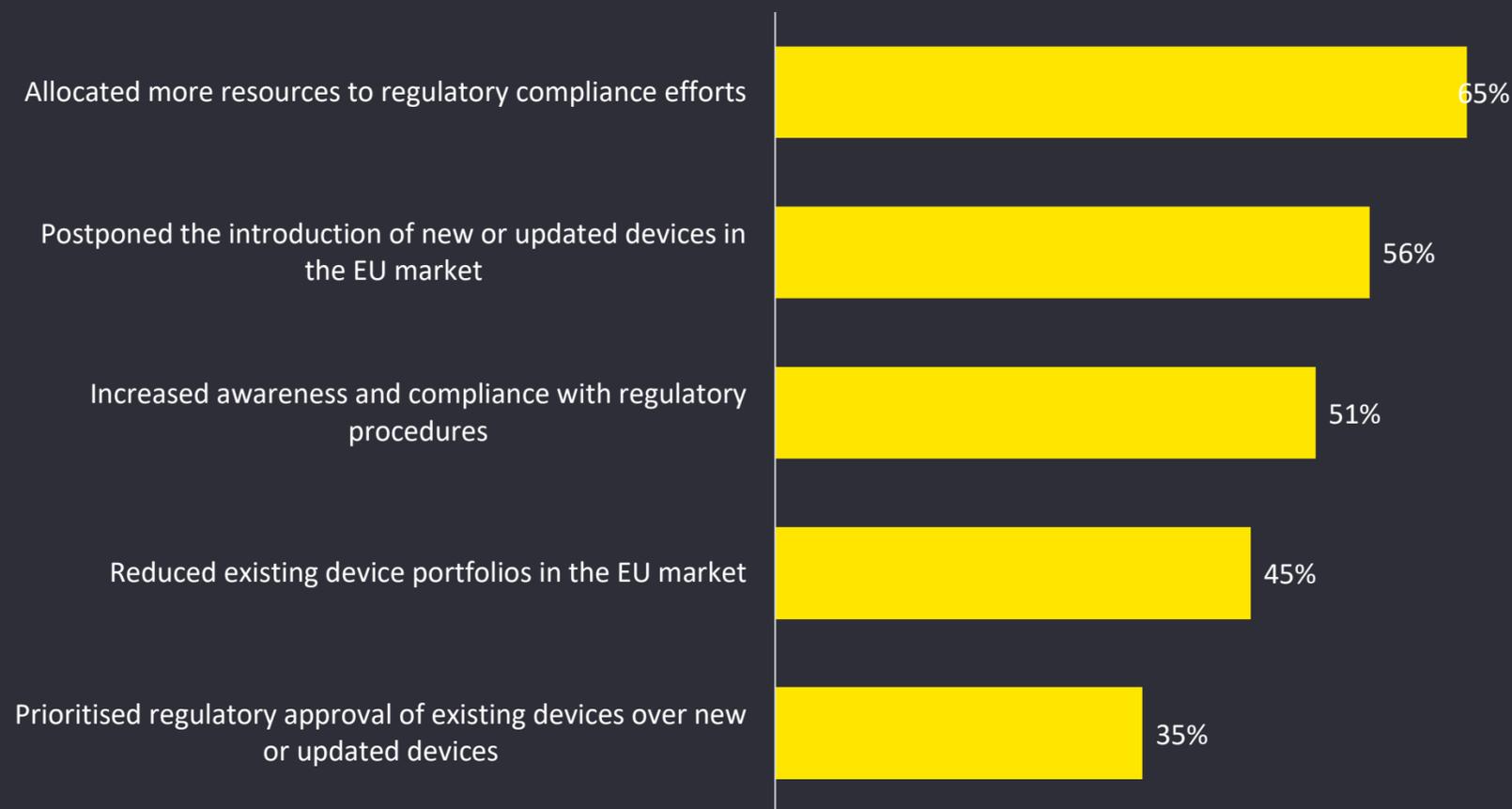
Disclaimer: The reported findings are not yet published and are not endorsed by the European Commission.

*Note that in the study it could not be established with certainty that these changes are due to the MDR/IVDR.

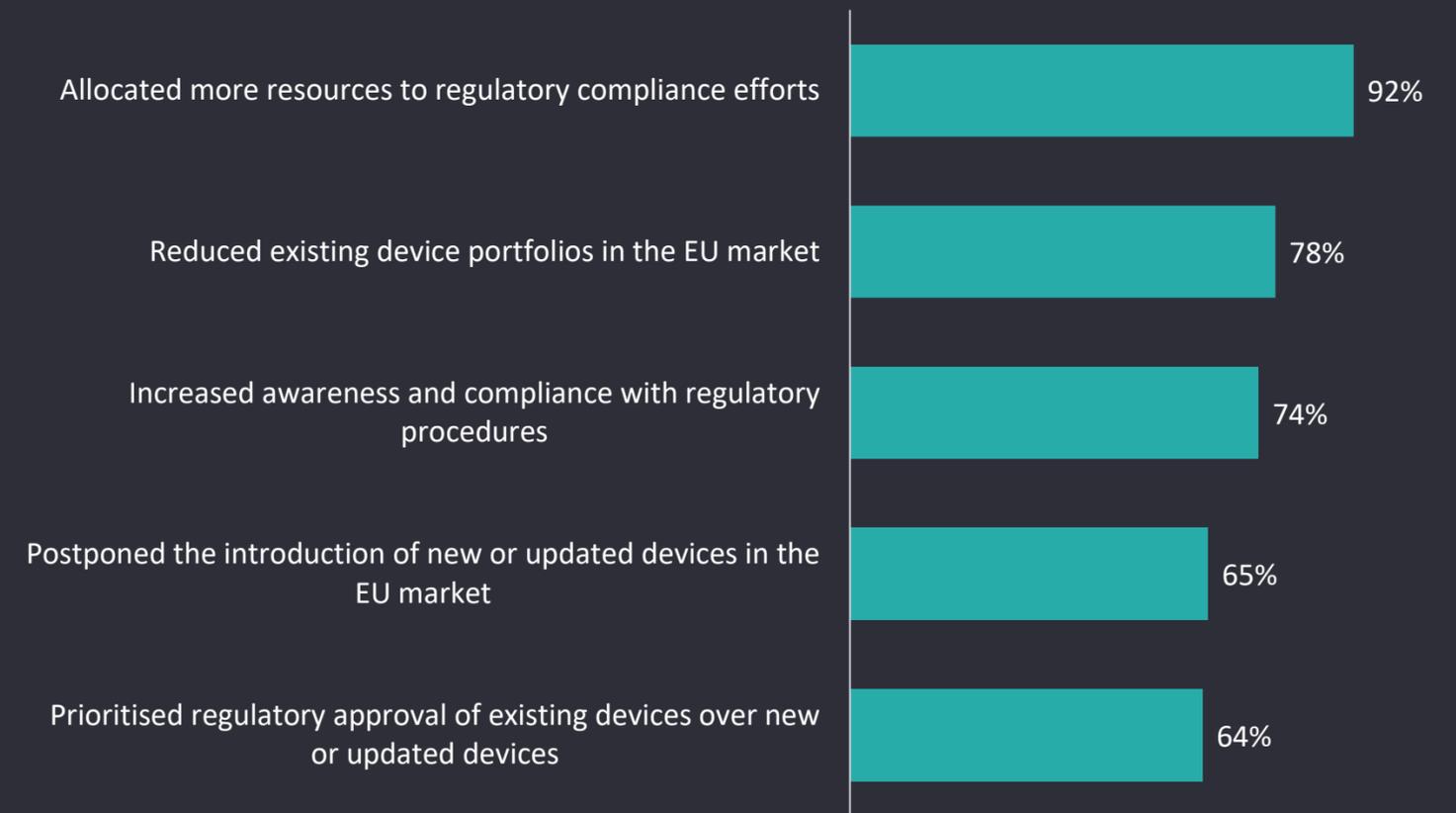
MDR/IVDR study | Impact on EOs – Top 5 – MSEs vs medium and large firms

MD/IVD15 - As a result of the introduction of the [MDR/IVDR], has your organisation/have the organisation you represent done any of the following?

Micro and small enterprises



Medium and large enterprises



% Total (multiple response), Base: Those who selected 'Trade association' or 'Economic operator (manufacturer, authorised representative, distributor or importer)' in D1a – Micro and small firms (n=98); Medium and large firms (n=110)

Source: MDR/IVDR survey (February 2024)

Disclaimer: The reported findings are not yet published and are not endorsed by the European Commission.

Effects observed (II)

Findings suggest that the reported effects impact innovation in the MD and IVD sector in the EU:

- ▶ Various interviewed actors and stakeholders stated that EU-based manufacturers – and especially SMEs – seek market access / certification outside the EU first or relocate to other regions entirely.
 - ▶ The main destination mentioned was the USA, due to the perceived predictability of its regulatory system and dedicated regulatory pathways for innovative devices.
- ▶ Various stakeholder anticipated that MDR and IVDR will reduce the number of economic operators based, manufacturing and marketing devices in the EU, in particular SMEs.
 - ▶ Could lead to a more concentrated market for MDs and IVDs, with fewer and larger manufacturers, possibly reducing the overall level of competition and innovation in the EU single market.

Disclaimer: The reported findings are not yet published and are not endorsed by the European Commission.

MDR/IVD study | Opportunities to enhance innovation while ensuring patient safety

- ▶▶ Options to reduce the regulatory burden on manufacturers: a) shorten and streamline the certification process, b) provide clear guidelines on clinical data requirements, notably for legacy devices, c) promote use of digital technologies to facilitate certification process
- ▶▶ Specific measures to promote innovation in the sector: a) explore potential of specific regulatory pathways for innovative and/or orphan devices, b) support manufacturers with funding and knowledge access.
- ▶▶ Address complexities linked to interconnections with horizontal legislations – Provide guidance on fulfilling requirements across different legislations and clarify which legislation takes precedence.
- ▶▶ Specific measures to reduce the regulatory burden on SMEs and research ecosystem: provide a) targeted financial assistance, b) tailored guidance and training programs, and c) foster collaboration and networking opportunities.

Disclaimer: The reported findings are not yet published and are not endorsed by the European Commission.

MDR/IVDR

Thank you

For any questions/remarks, please contact:
MDRstudy@be.ey.com & Daan.Bijwaard@be.ey.com

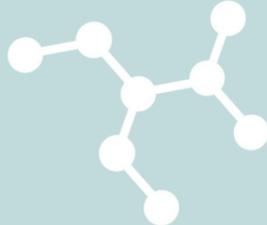
STATE OF PLAY AND EU – EC POLICY INITIATIVES



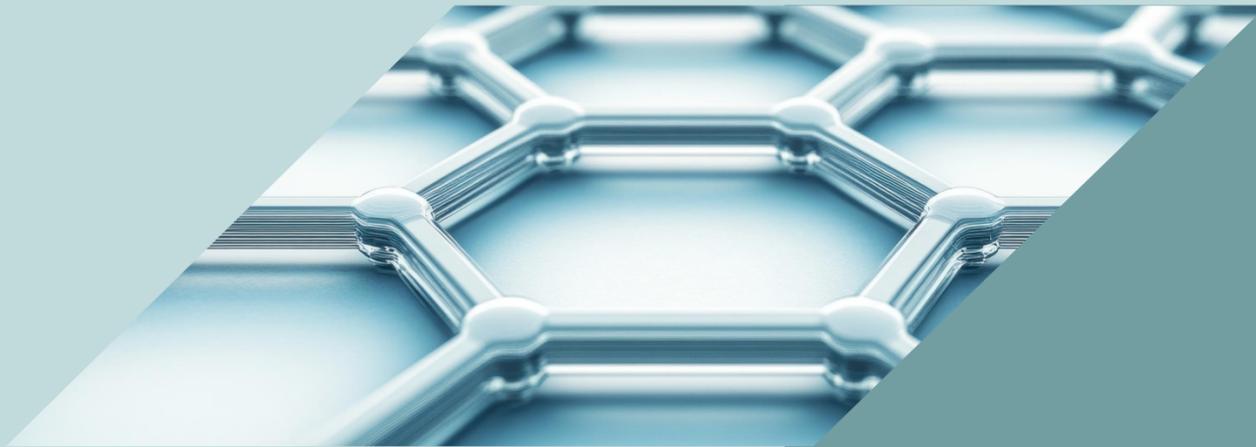
Legislative and Non-legislative EU Policy initiatives

Flora Giorgio, Head Unit D3 Medical Devices, European Commission

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A graphic logo for NoBoCap consisting of several white circles of varying sizes connected by thin white lines, resembling a molecular or network structure.

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Legislative and non-legislative policy initiatives to support innovation

Flora Giorgio
European Commission
Directorate-General for Health and Food Safety (DG SANTE)
Unit D.3 – Medical Devices

A portrait of Ursula von der Leyen, the President of the European Commission, smiling and standing in front of the European Union flag. She is wearing a light-colored blazer and has her hands clasped in front of her.

Europe's choice – Political guidelines 2024-2029

Political guidelines for the European Commission:

Medical devices perspective:

- Sustainable **competitiveness**
- **Digitalisation** – prioritizing AI
- **Simplification** - of legislation to reduce red tape
- **Innovation** – Strategy for European Lifesciences & Biotech Act
- **Resilience** – Critical Medicines Act & European Action Plan on Cybersecurity of hospitals and healthcare providers

Priorities

Continue	Implementation of the MDR/IVDR
Accelerate	Short-term actions: both legislative and non-legislative
Revise	Targeted evaluation and review of MDR/IVDR (planned for Q4 2025)



Implementation



Implementation of MDR/IVDR



Coherent and pragmatic application of **extended transitional provisions** for different types of devices to prevent potential shortages of existing and new/innovative devices



Availability and capacity of notified bodies (currently 51 for the MDR and 18 for the IVDR in the NANDO information system)



Availability of harmonised standards (currently 32 for the MDR and 17 for the IVDR in the OJEU – including ISO 13485 (QMS), IEC 60601 series, ISO 14971 (RMS) (*more publications under preparation*))



Adoption and enforcement of implementing and delegated acts for different aspects of the Regulations (most-recently: Master-UDI delegated act, Electronic instructions for use, orphan expert panel...), short-term measures



MDCG guidance documents (updates and new)



Development of EUDAMED ongoing and **mandatory use** of the following four modules: **Actors, Devices, Notified Bodies and Certificates and Market Surveillance**





Three hybrid workshops organised by COM



21 May 2025



Stuttgart (DE)



08 October 2025

Rome (IT)



03 December 2025

Brussels (BE)

Register NOW!

All actors are
welcome



<https://tinyurl.com/4k864h5c>

What to expect:

- Hands-on guidance on MDR/IVDR requirements related to EUDAMED
- Live navigation through the first four modules
- 38- Practical aspects in data management and legal compliance



Short-term Actions



Short-term actions – Legislative



1 Implementing regulation for e-IFUs for medical devices

- Public feedback closed
- Planned adoption date: **Q2 2025**

2 Establishment of an Expert Panel on orphan and paediatric devices

- Planned adoption date: **Q2 2025**

3 **Reclassification** of well-established technologies (WET)

- Request for evidence: processing input
- Planned adoption date: **Q4 2025**

4 Expansion of the **list** of well-established technologies (WET)

- Request for evidence closed and analysed
- Consultation with MDCG ongoing
- Planned adoption date: **Q4 2025**

5 **Implementing rules regarding requirements to be met by Notified Bodies**

Implementing act according to Article 36 (3) MDR / Article 32 (3) IVDR will include;

- Timelines for conformity assessment, including clock-stops;
- Requirements for a reliable quotation;
- Monitoring of timelines and costs (KPI);
- Recertification
- Planned adoption date: **Q4 2025 /Q1 2026**



Implementing regulation for e-IFUs for medical devices (Reg. 2021/2226)



- Amended by Commission **Implementing Regulation (EU) 2025/1234** on 16 July 2025
- **Scope of the amendment:** broadly expanded to
 - ✓ allowing possibility to issue e-IFUs for most **medical devices intended for professional users,**
 - ✓ Inclusion of **devices without an intended medical purpose** listed in Annex XVI of Regulation (EU) 2017/745,
- **Streamlined the conformity assessment process** by removing the separate requirement for Notified Body review, eliminating redundancy with other assessment activities.
 - ✓ Including **link to e-IFUs** in the UDI module of **EUDAMED.**



Note: dual-use medical devices (both professional and lay-user): the IFU intended for the lay person must be provided in paper form.

Implementing Decision (EU) 2019/1396 designating an additional **expert panel** in the field of **paediatrics and rare diseases**



- Amended by Commission **Implementing Decision (EU) 2025/1324** on 7 July 2025
- **Scope of the amendment:**
 - ✓ Designation of a new expert panel dedicated to **paediatrics and rare diseases**,
 - ✓ Clarification of the role of the European Medicines Agency (EMA), now fully responsible for the panels' secretariat.
 - ✓ **Support the ongoing pilot by securing adequate scientific expertise**
- **Aim:** to foster innovation and accessibility by offering expertise on the safety and performance of devices for rare diseases and children.
- **Expected output:** The new panel will enhance the regulatory process by providing opinions to support manufacturers and notified bodies under the EU Medical Device Regulation.

FAQ on interplay between MDR/IVDR and the AI Act, MDCG 2025-6 published in June 2025



1. Purpose and scope

- The document provides guidance on how the MDR, IVDR, and the AI Act intersect when it comes to Medical Device Artificial Intelligence, including software, Annex XVI products, and IVDs.
- It emphasizes **complementary application**, ensuring AI systems meet both medical device and AI-specific requirements without duplicating regulatory burdens.

2. Applicability of the AI Act to MDSW

- AI systems used for medical purposes (MDAI) are subject to the AI Act if they meet the definition in Article 3(1) AIA.
- MDSW is considered high-risk under Article 6(1) AIA if:
 - It acts as a safety component or the device itself.
 - It requires a third-party conformity assessment by a notified body (e.g., MDR Class IIa/IIb/III, IVDR Class B/C/D).

3. Quality Management System (QMS)

- Both MDR/IVDR and the AIA require a QMS, ensuring safety, performance, and risk mitigation throughout the AI system lifecycle.
- Manufacturers can integrate AIA QMS elements into their existing MDR/IVDR QMS to avoid redundancy.

4. Risk Management (RM)

- Risk management under MDR/IVDR focuses on health and safety, while the AIA extends to fundamental rights.
- Continuous risk evaluation, including AI-specific risks like data bias, algorithmic errors, and system robustness, is mandatory.



Short-term actions – Non-legislative



- 1 Guidance on **breakthrough technologies (BtX)**
- 2 Guidance on **orphan IVDs**
- 3 Guidance on **sampling of technical documentation**
- 4 Guidance on **certificates under conditions**

- 5 **IMDRF Guidance of high priority:** Pre-Determined Change Control Plans, Good Machine Learning Practices, Quality Management Systems, IVD Clinical Evidence and the Reliance Playbook
- 6 **MDSAP mapping activities** (NBCG-Med and MDCG)
- 7 **Support to other activities** : e.g. Horizon scanning, orphan devices, JAMS 2.0



Horizon Scanning System - MDs & IVDs

 **HADEA/2024/OP/0024**

Objectives

Put in place a **horizon scanning system**  in the area of **MDs and IVDs**   in order to maintain an up-to-date overview of **new & emerging technologies** .

Aim:

-  **Screen available sources** for novel & emerging technologies
-  **Assess features** that may impact medical devices & IVDs
-  **Identify opportunities, risks & trends** related to these technologies

This horizon scanning was identified as a need in the context of implementing **MDR/IVDR legislation** to support **competitiveness & innovation** in the EU market, while ensuring a **high level of protection of health** for patients and users. 

 **Contract value:** €896 400

 **Contractor:** TECHNOPOLIS FRANCE

 **Period:** 30 months (contract signed on 06/06/2025)

 **Status:** Ongoing

 [Read the contract award notice](#) for more details.

Long-term Actions



Update on MDR/IVDR targeted revision

The initiative aims to:

- reduce administrative burden, including reporting obligations
- enhance the predictability and cost-efficiency of notified body conformity assessment and certification processes
- make the conformity assessment requirements more proportionate, especially for low and medium risk devices and those for special patient needs (e.g. orphans, breakthrough, pediatric, in-house)
- enable further digitalisation
- streamline procedures, including governance
- enable the EU medical device sector to benefit from international reliance
- better align with other relevant EU legislation

441 contributions submitted through [call for evidence](#) (deadline was 6 October 2025)



Update on MDR/IVDR targeted revision

 Adoption planned by December 2025

 Proposal to amend MDR/IVDR → ambitious, but targeted revision building on evaluation results and ongoing consultations with member states and stakeholders supported by:

 Staff Working Document on the results of the targeted evaluation

 Staff Working Document on the Cost-Savings analysis

Thank you!

Contacts:

[European Commission - Directorate-General for Health and Food Safety \(DG SANTE\)](#)
[Unit D.3 Medical Devices](#)
SANTE-MED-DEV@ec.europa.eu



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STATE OF PLAY AND EU – EC POLICY INITIATIVES



Attractiveness of Europe for SME driven Medical Technology Innovation – Aydin Burçak, Deloitte



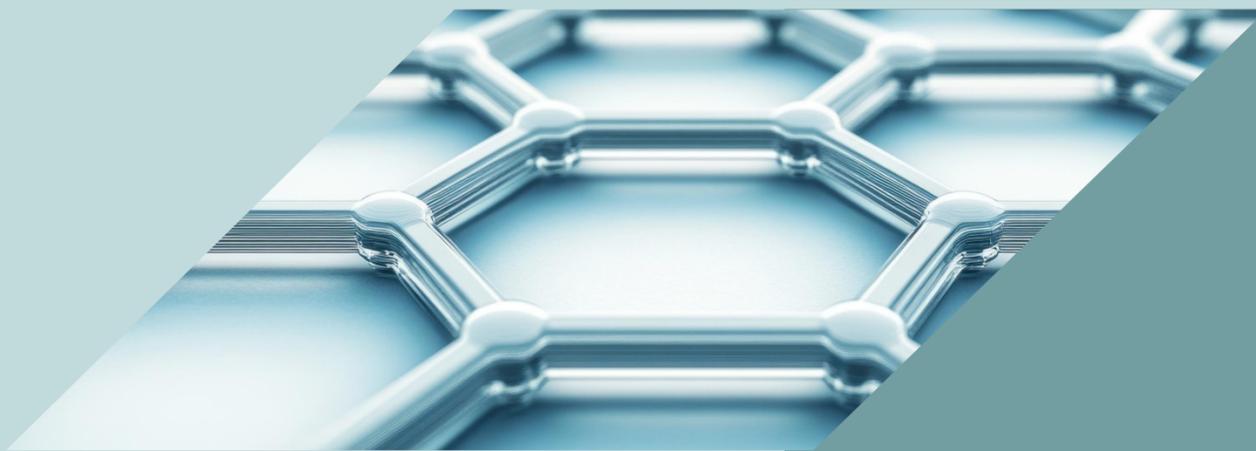
Impact of MDR/IVDR on (SMEs) Innovation and recommendations – EC Commissioned EY Study – Daan Bijwaard, EY



Legislative and Non-legislative EU Policy initiatives – European Commission – Flora Giorgio, Head Unit D3 Medical Devices



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Federica Zanca,
Program Manager
Medical
Imaging and AI in
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MDCG-NET - TF
Breakthrough MD
Donal B O'Connor,
Co-Chair/Clinical
Manager HPRA, Ireland



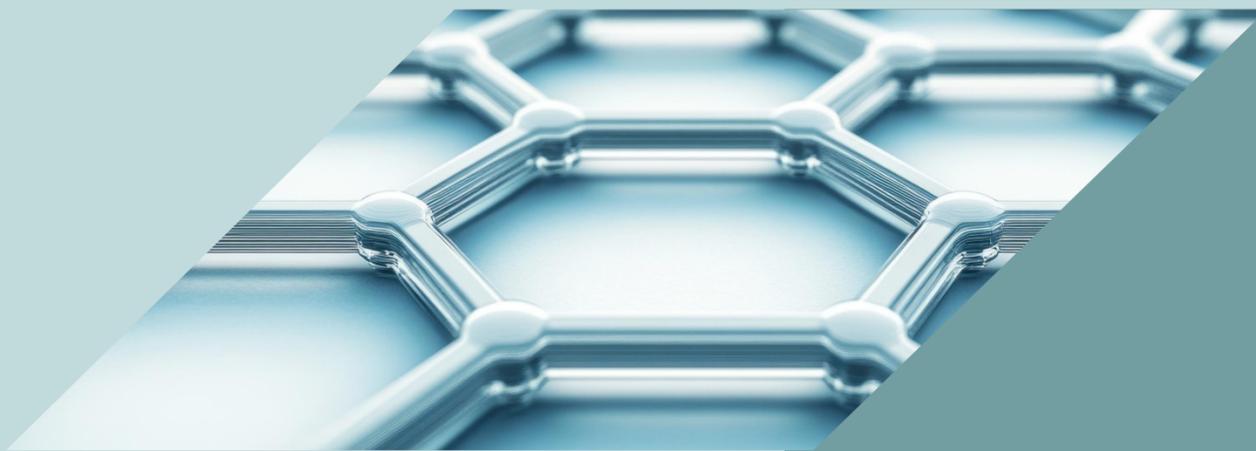
Notified Body
Florian Heffeter,
CEO QMDServices,
Austria (Online)



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Some regulatory limitations perceived by SMEs and innovative consortia



- No EU-wide multicenter trial mechanism
- Ethics boards give their authorization only after validation by the National regulation Agency (eg ANSM in France)
- Misalignment in ethics board practices across countries
- Lack of expertise in non-CE devices at national regulation agencies. cfr US
- Additional preclinical and clinical trial demands
- Overly strict requirements for early feasibility trials
- Full technical documentation demands are disproportionate for TRL 4-6 projects
- No MedTech-specific market pathway (pharma model doesn't fit)

Expectations from EIC beneficiaries/ SMEs

European
Innovation
Council



Priority	Description
Limited CE Mark	For early testing in expert settings, allowing clinical iteration
Simplified QMS	ISO 13485 proportional to maturity stage
Independent MDR Interpreters	EU entity to support early-stage innovators
Harmonized Ethics & Trial Mechanism	EU-wide framework for early studies (e.g. EU-wide ethics fast-track/ light track)
Pre-submission Advisory Access	Dialogue with NBs/ Experts before full engagement Shared templates for Validation



- dedicated **portfolio activities** to help innovators anticipate regulatory, clinical, and translational hurdles.
- “**fast-track**” pathway or a form of “**Seal of Excellence**” for projects that achieve a regulatory breakthrough designation.
- **Business Acceleration Services:** regulatory readiness coaching, targeted matchmaking with investors and corporate partners
- **collaboration across EU instruments** — such as with DG RTD, DG SANTE, or IHI — will be key to ensuring continuity and coherence from early-stage research to market access and patient benefit

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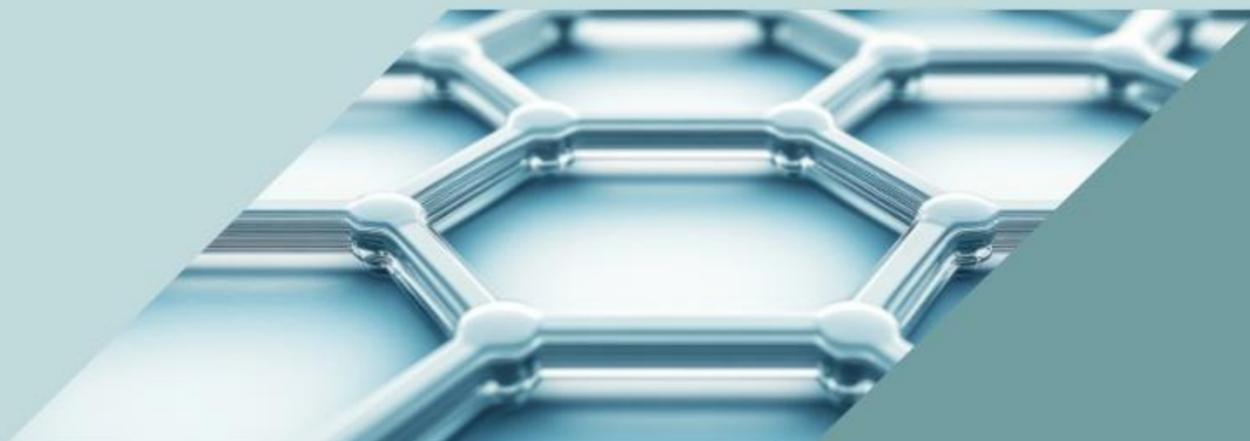


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MDCG Draft Guidance on breakthrough devices

Breakthrough criteria and evaluation considerations

NoBoCap Summit

Donal O'Connor, MD FEBS
Clinical Manager HPRA
MDCG BtX TF co-chair

16 October 2025

Breakthrough device criteria

'Breakthrough Device' if the following criteria are met:

- **Novelty**
 - *Technology and/or application in clinical practice*

and
- **Positive clinical impact on patient or public health, for a life-threatening or irreversibly debilitating disease or condition**
 - *Compared to alternatives or fulfilling an unmet need*

Justification of breakthrough device status

- **Degree of novelty**
 - Novelty with respect to technology
 - Novelty with respect to the clinical application
- **Significant positive clinical impact on patient or public health**
 - Clinical impact on individual patient or population level
 - Nature of disease or condition
 - Alternatives and state of the art

MDCG Guidance breakthrough technology

- **Clinical /Performance evaluation considerations**
 - Balance of Pre-market and Post-market Clinical (Performance) Data collection
 - Role of non-clinical data and pre-clinical evaluation
 - Pre-market Clinical Investigations / Performance Studies
 - Post-Market Surveillance and PMCF/PMPF

MDCG Guidance breakthrough technology

Procedural considerations and supports

- EMA expert panels
 - Designation
 - Scientific advice for MFRs
 - Support for NB in conformity assessment
- Notified body activities
- National competent authorities
- Signposting funding opportunities

Guidance on orphan devices

- Procedural considerations
 - Notified body activities and responsibilities
 - Early structured dialogue
 - Certificates with conditions
 - Involvement of EMA expert panels
 - Designation
 - Scientific advice to manufacturers and notified bodies



Medicines ▾ Human regulatory ▾ Veterinary regulatory ▾ Committees ▾ News & events ▾ Partners & networks ▾ About us ▾

[Home](#) > [News](#) > [New pilot programme to support orphan medical devices](#)



New pilot programme to support orphan medical devices

2 August 2024

Free advice and guidance available for manufacturers and [notified bodies](#)

Medical Devices

Medical Device Coordination Group Document

MDCG 2024-10

MDCG 2024-10

Clinical evaluation of orphan medical devices

June 2024

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

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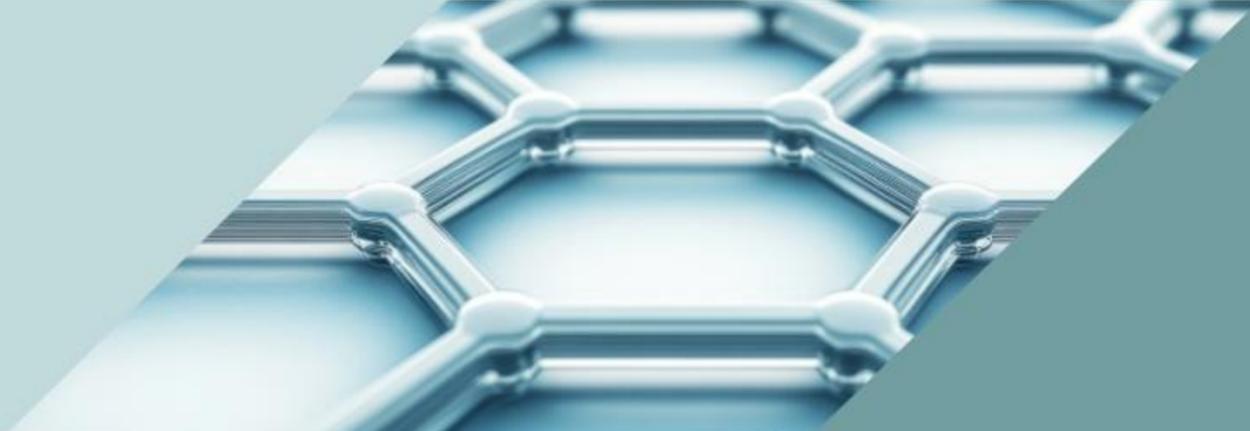


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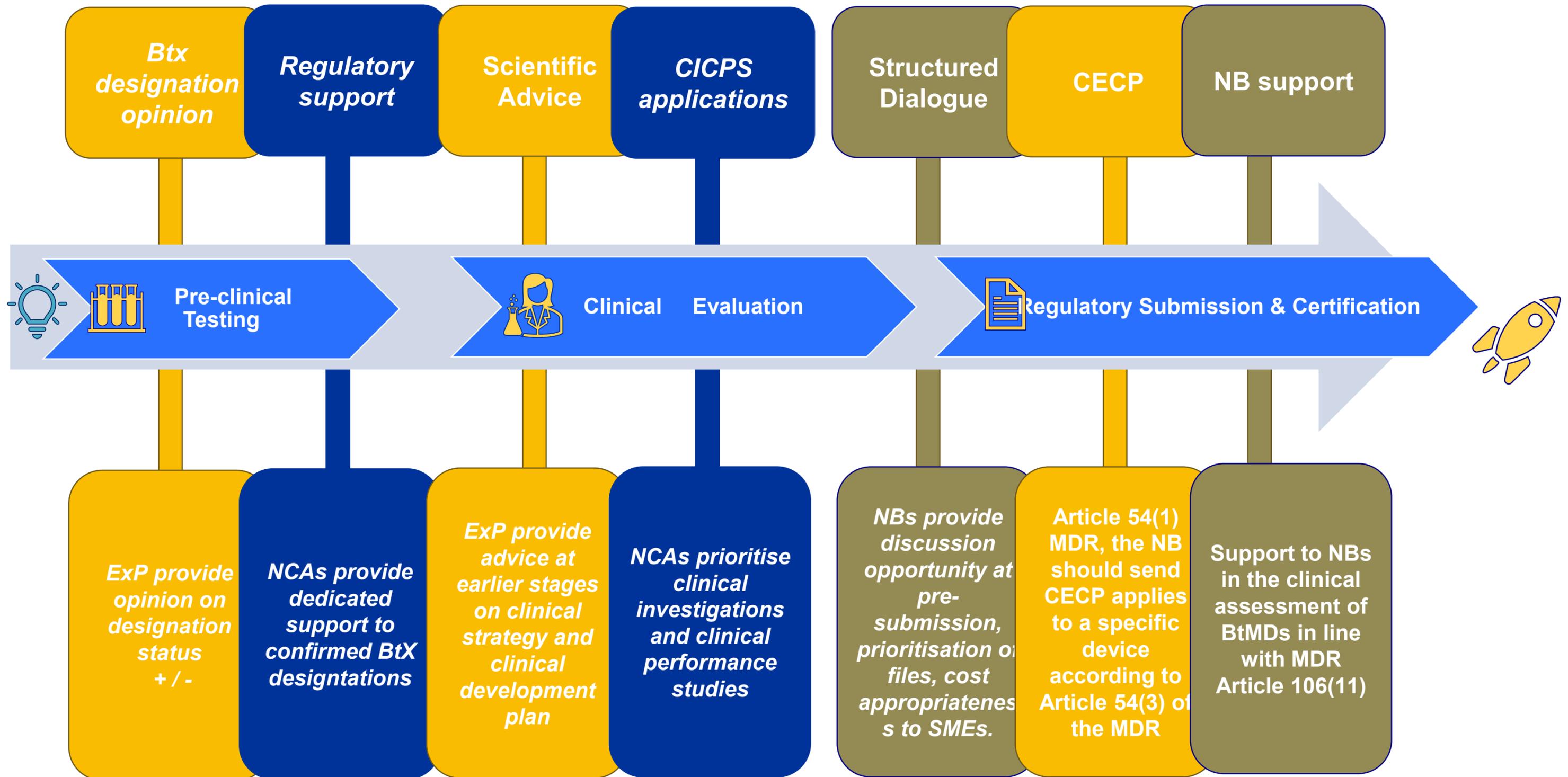


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Breakthrough pilot support mechanisms



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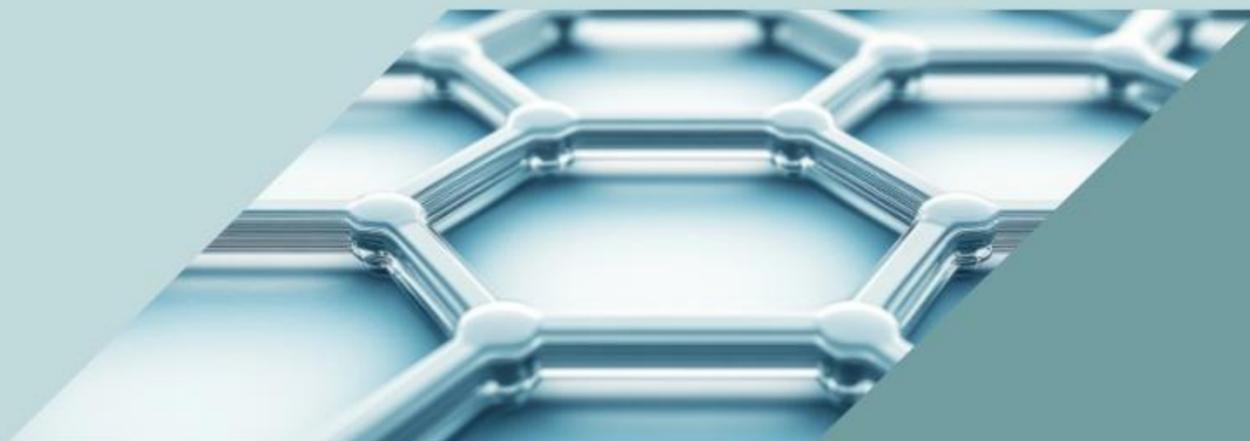


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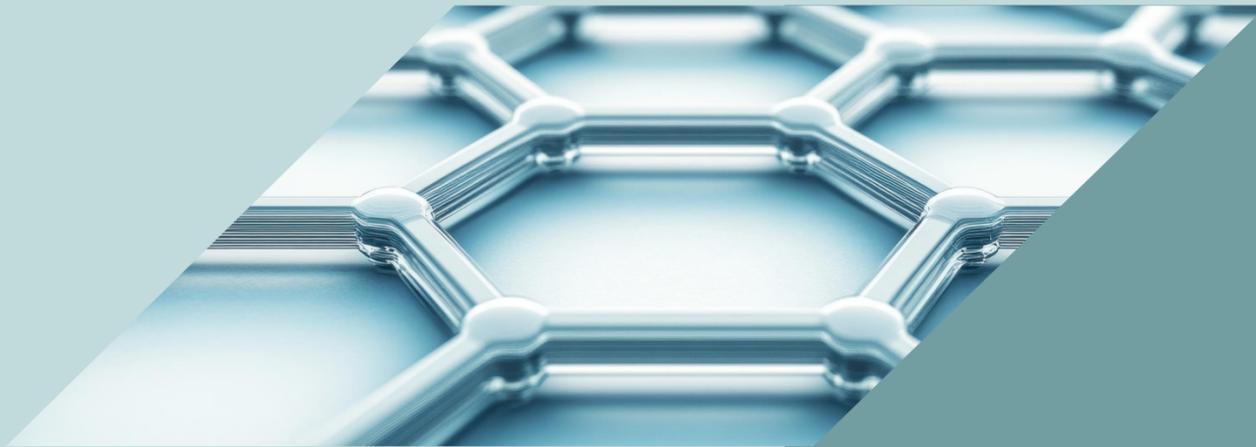
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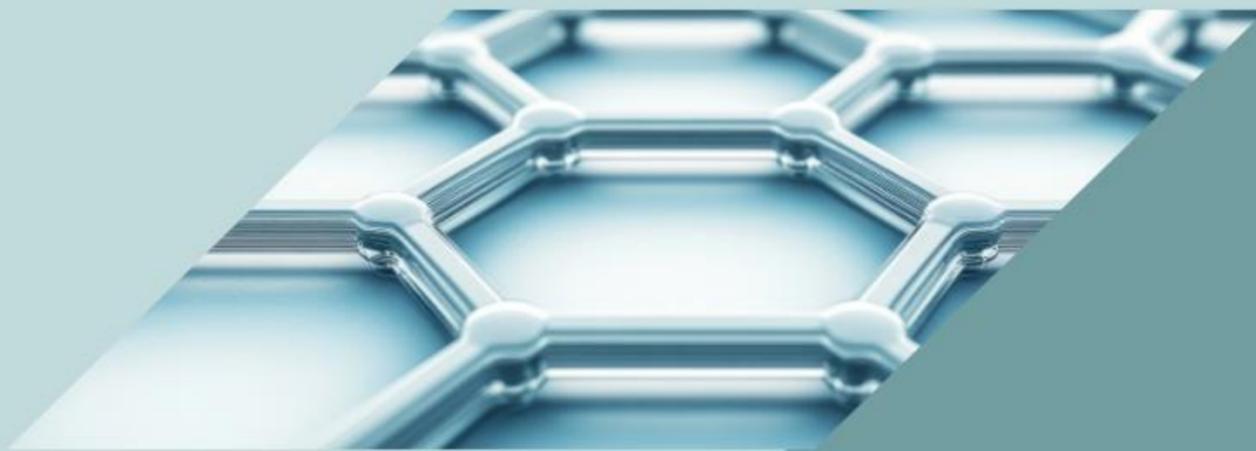


AI LAB and Certification
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LNE,
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SME perspective
Miguel Amador,
Chief Innovation Officer
Complear

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NB STRUCTURED DIALOGUE, SCIENTIFIC ADVICE – JOINT CONSULTATION AND CERTIFICATION WITH PROVISION



Competent Authority:
Dr. Matthias Neumann
MDCG NET and TF
Breakthrough – Federal
Ministry of Health, Germany



Notified Body:
Richard Holborow
Global Head of Clinical
Compliance – BSI

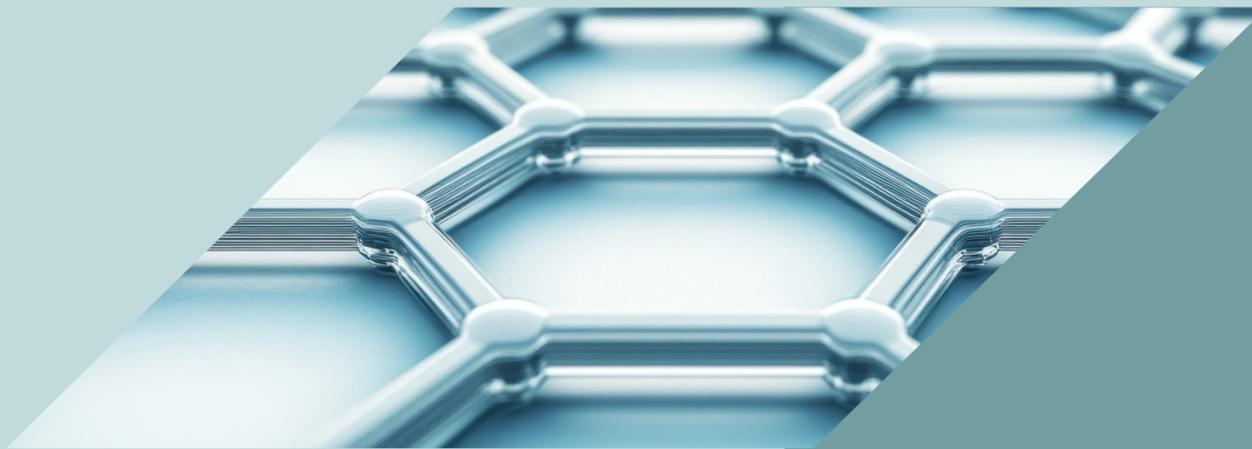


EMA
Alberto Gañán Jiménez
Head of Committees



MedTech Europe
Oliver Bisazza
CEO

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Framework for Structured Dialogue.

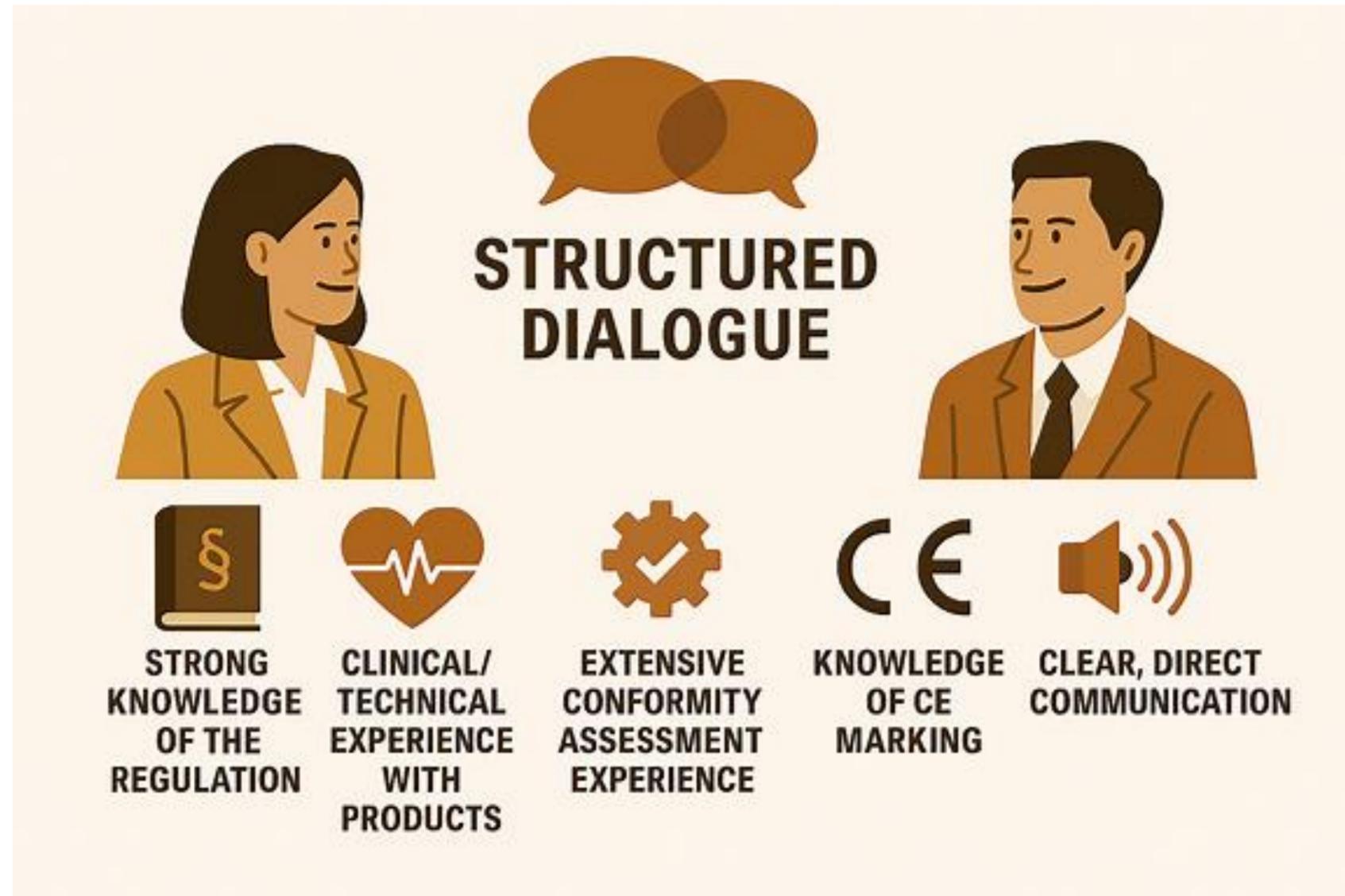


- ✓ **Legislative Change** – *The EU system has to change to help bring predictability for manufacturers.*
- ✓ **Structured Dialogue** – *To provide commentary on the manufacturers methodology but not to provide the methodology.*
- ✓ **Transparency.** - *Importance of independence, impartiality and objectivity as a conformity assessment body.*
- ✓ **Predictability** – *Manufacturers need conversations need to happen early well before conformity assessment*
- ✓ **Patient Safety** - *Importance of ensuring commitment from manufacturers and preventing ‘Notified Body Shopping’ .*

What is needed for predictability...



Council Directive 90/385/EEC (3) and Council Directive 93/42/EEC (4) constitute the Union regulatory framework for medical devices, other than in vitro diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a **robust, transparent, predictable and sustainable regulatory framework for medical devices** which ensures a high level of safety and health **whilst supporting innovation**. (Opening Statement)



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MDCG NET and TF
Breakthrough – Federal
Ministry of Health, Germany



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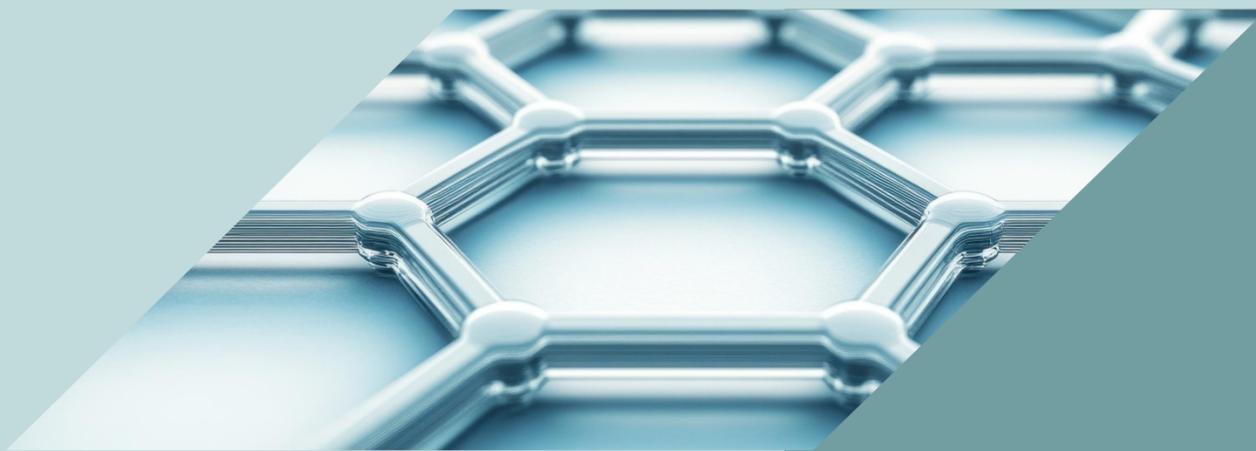
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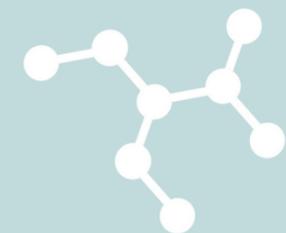
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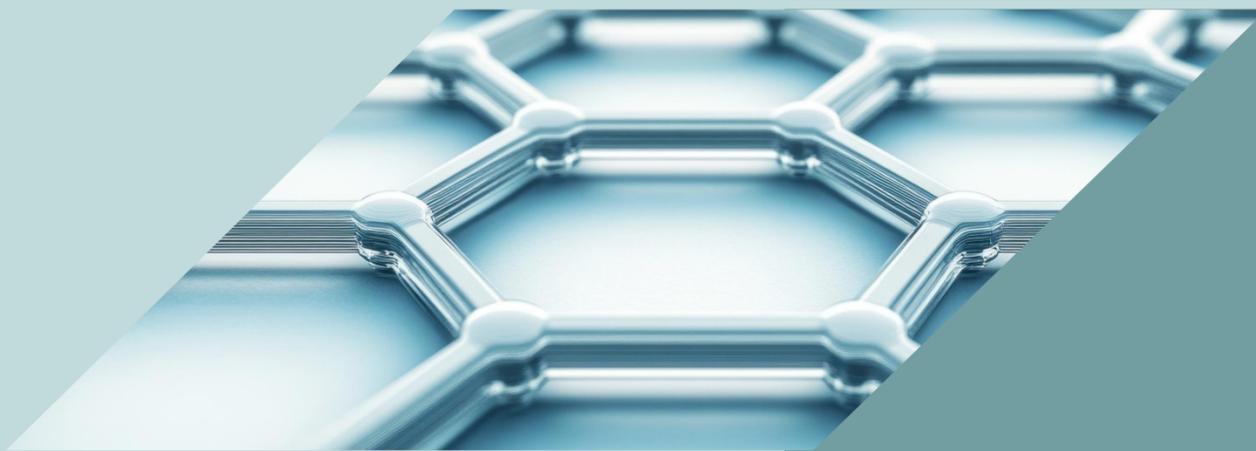
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ON THE ROAD TO QUALITY AND UNLOCKING MDR/IVDR REGULATION FOR INNOVATION: COMMUNITY IN ACTION

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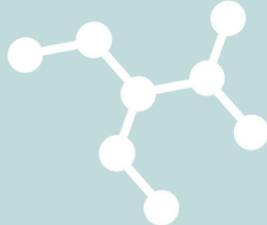


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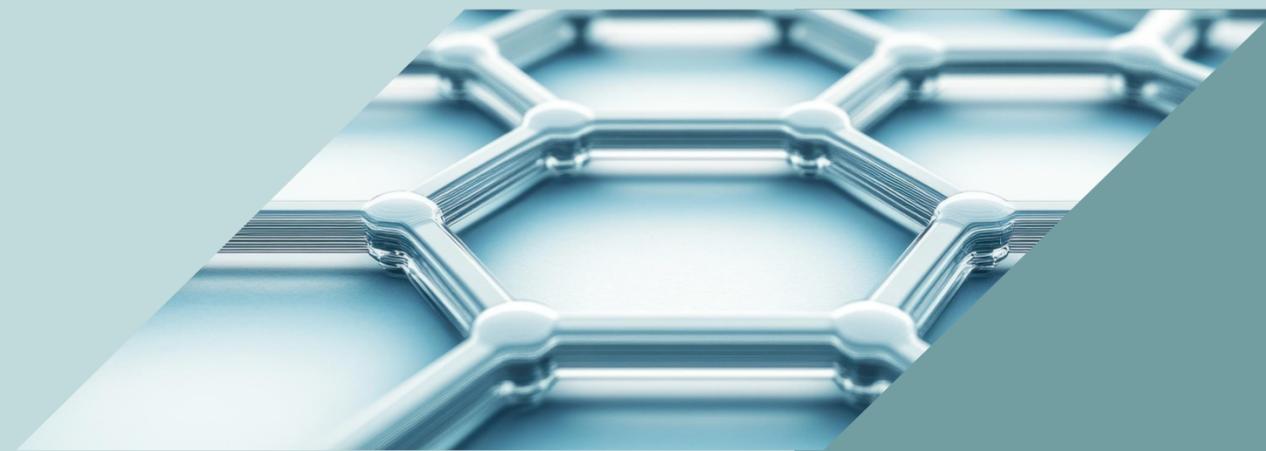
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Oct. 16, 2025, Brussels



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NoBoCap Project in a Snapshot

**639 representatives trained
in 3 long-term MDR & IVDR modules**

**95 representatives trained
in 3 short-term courses**



NoBoCap Project in a Snapshot

36 workshops in various EU countries
12 webinars
2 NoBoCap Summits (Belgium)
3 BEHEALTH Panels (Romania)
2 Pulse Reports (industry updates)
8 newsletters



NoBoCap Project in a Snapshot

NoBoCap Environment www.portal.nobocap.eu

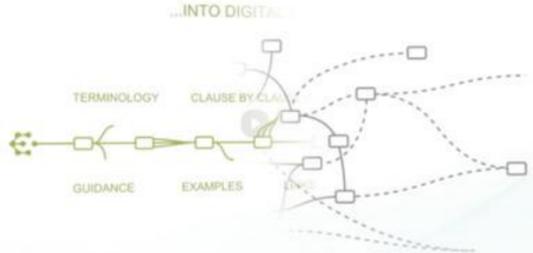
 **NoBoCap Project Video**

Discover the NoBoCap Project through a video showcasing its transformative impact on the MedTech industry.



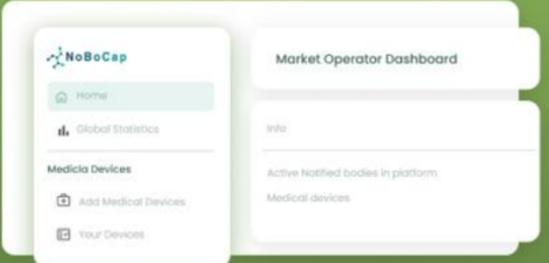
 **NoBoCap e-guided MDR/IVDR learning – NB codes**

Simplify MDR and IVDR compliance with NoBoCap's intuitive e-guided learning platform. Watch the demo and explore the e-tool to master medical device classifications effortlessly.



 **NoBoCap matchmaking Innovation – Notified Body**

Connect with Notified Bodies and streamline CE-marking requests through our efficient matchmaking dashboard.



 **Job Board**

Discover MedTech career opportunities with the NoBoCap Job Board. Tailored dashboards for candidates and Notified Bodies make job searching seamless.

looking for file certifications experts



 **NoBoCap Courses**

Advance your career in MedTech with NoBoCap's focused courses. Explore detailed offerings and register easily to gain targeted knowledge.



 **NoBoCap Community**

A dynamic community uniting start-ups, SMEs, and partners to navigate and influence the European regulatory ecosystem with expertise, collaboration, and tailored support.




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International Hybrid
Event in Healthcare
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Why Attend?

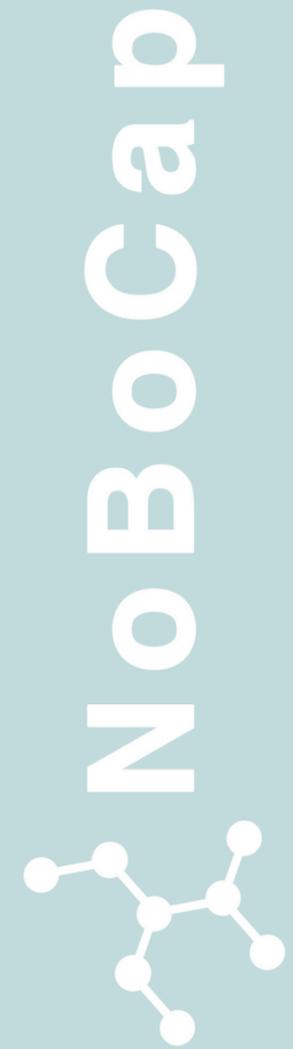
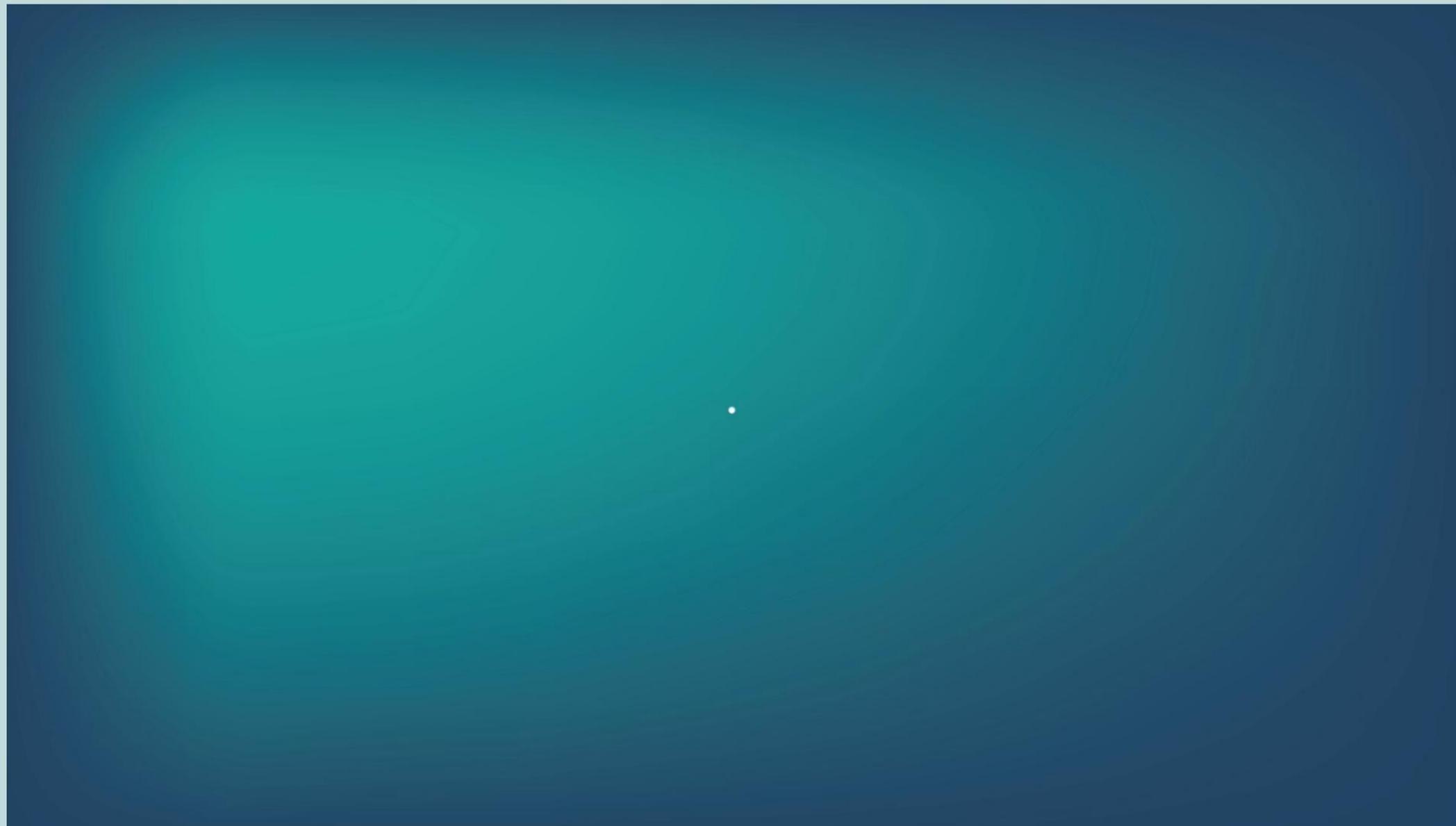
 20–24 October 2025 | Bucharest & Online

 8th Edition – International Hybrid Event

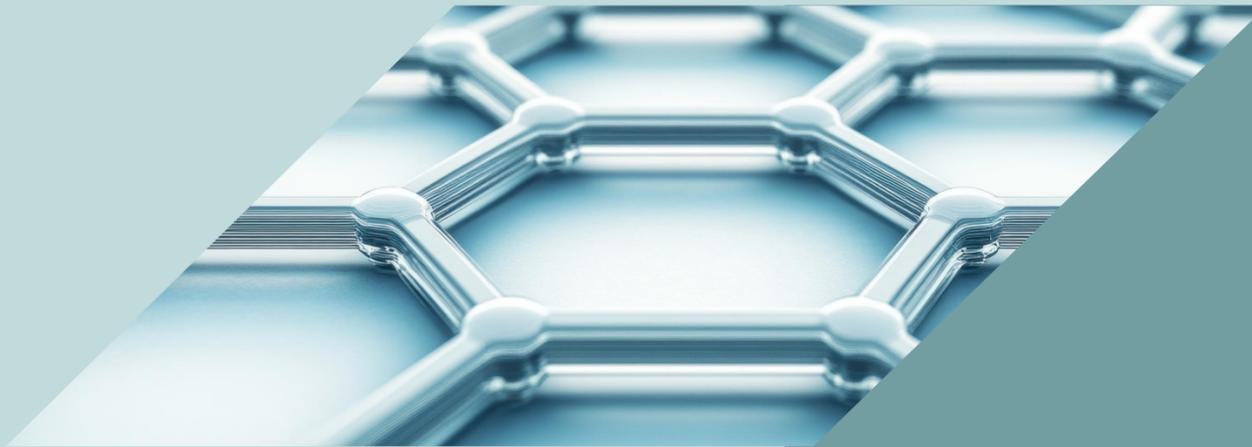
- 500 participants
- 100+ speakers
- 18 thematic panels & workshop
- Funding opportunities & EU programmes
- Networking with key stakeholders
- 24h of B2B meetings
- Matchmaking platform

Participants will gain insights into the latest trends, regulations and opportunities while building valuable connections for future collaborations.

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**Nobocap: Services & Tools
for a Faster, Safer Medtech Path to
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The Challenge & Our Mission

Challenges

- Complex EU-MDR / EU-IVDR pathways
- Limited NB capacity & slow matchmaking
- Talent bottlenecks in notified bodies

Our Mission

- Enable confident navigation of regulations
- Accelerate compliant innovation across Europe



Services at a Glance

- Registration to Trainings via Dedicated Forms
- Collaborative Platform (Market Operator & Notified Body interfaces)
- Matchmaking Module (scope-aligned pairing)
- eGuided NB Codes Tool (MDR/IVDR guidance)
- AI-Powered Recruitment (job board + soft-skills insights)
- Community





Nobocap environment

In Nobocap, we created a unified digital environment, where users can access the services and tools available, and collaborate efficiently: guidance, matchmaking, recruitment, course registration and community.

The platform is live on the portal and organized into clear modules: Matchmaking platform, eGuided tool, Job Board, Courses registration, and community — each with role-based access.



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Matchmaking platform

Nobocap provides two tailored interfaces:

- **Market Operators (MO):** create organization and device profiles, follow guided regulatory steps, and access list of matched NBs for conformity assessment.
- **Notified Bodies (NB):** manage scope information, signal availability, and view statistics and analytics on the innovation pipeline.

Result: structured, comparable data on both sides, less friction, and clearer expectations.



Matchmaking platform

Matchmaking Module:

- **Scope matching:** find NBs designated for the relevant MDR/IVDR codes.
- **Capacity signal:** factor in NB availability (now or planned) to reduce dead ends.

Results: Operators get a focused shortlist; NBs receive better-qualified requests. Everyone saves time getting to technical assessment.



eGuided NB Codes Tool

Regulation can feel like a maze. The eGuided tool turns it into a path:

- Explains how MDR/IVDR applies to each technology.
- Suggests relevant **NB codes** and indicates **designated NBs**.
- Integrates guidance and examples; borderline cases are being expanded.

Outcome: quicker orientation, fewer trial-and-error loops.



Registration to Trainings via Dedicated Forms

- Registration into Nobocap Environment
- Select Course from the available options published:
 - ✓ 3 modules accredited long-courses
 - ✓ Executive short course (C-level)
 - ✓ AI-supported medical devices masterclass
- Complete the registration form with detailed information



AI-Powered Recruitment for NB

To ease staffing bottlenecks:

- **Job board + AI matching** aligns CVs to roles on hard and soft skills.
- A **secure AI chat** runs short, scenario-based prompts to surface soft skills and enrich profiles.

NB recruiters see the human behind the résumé, and shortlists get more relevant over time.



Impact & How to Engage

What improves:

- Faster MO↔NB alignment thanks to structured data and availability signals.
- Clearer regulatory navigation via eGuided Tool.
- Scalable learning through training modules.
- Quicker, smarter hiring in NB teams.



Impact & How to Engage

Your next steps:

- **Market Operators:** onboard your profile, add your device, use eGuided tool, start matchmaking; register for the right course via its dedicated form.
- **Notified Bodies:** activate your profile, confirm scope and availability, try the Job board and AI screening, and explore Analytics.



NOBOCAP ENVIRONMENT INITIATIVES – CONTINUED



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INNOVATION HUBS/CLUSTER, PARTNERS AND IN-COUNTRY INITIATIVES – EXCHANGE OF GOOD PRACTICES



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WHERE DO WE GO FROM HERE? – EU COMMUNITY IN 2026



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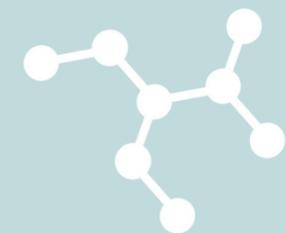


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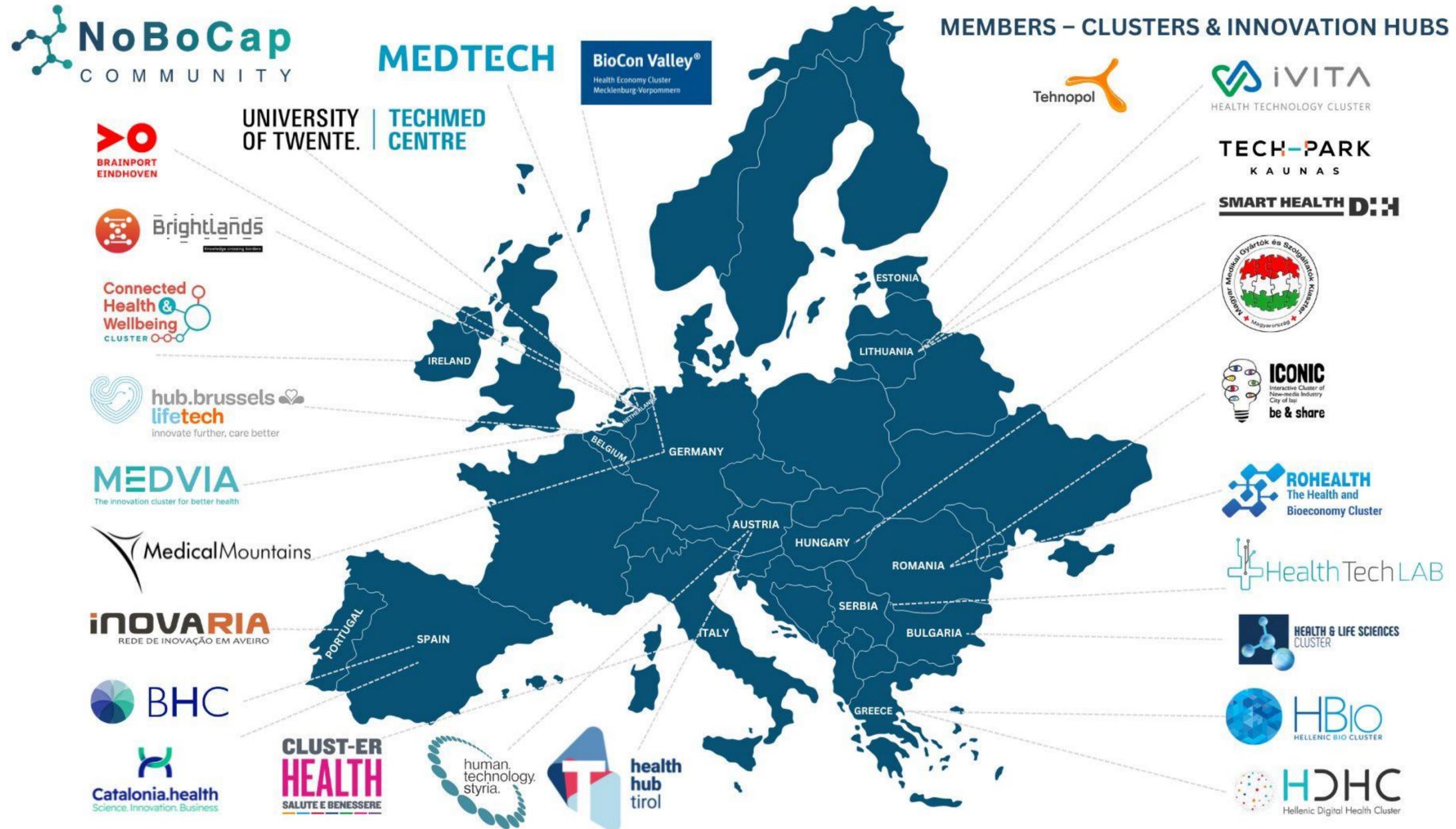
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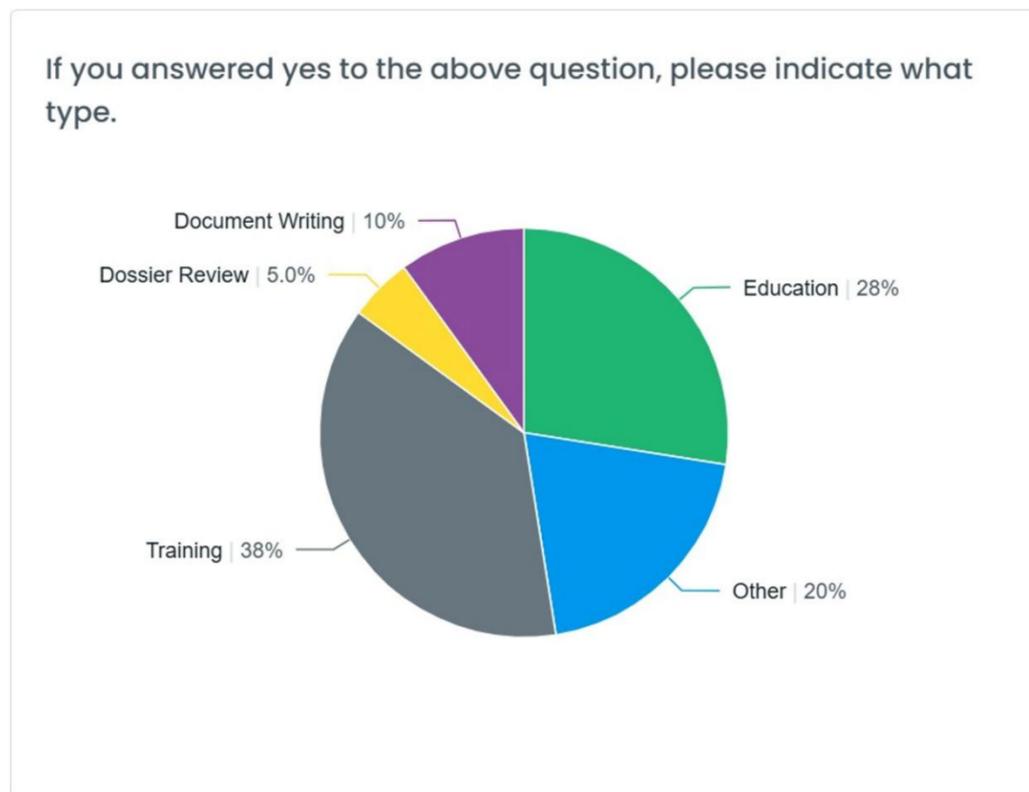
A Legal entity Non-For-Profit European Community
of Innovation Hubs/Clusters, MSE and Partners.

*To unlock EU Regulations and National Health System
Innovation accessibility*

in support of local initiatives and EU initiatives.
building on the Nobocap Community

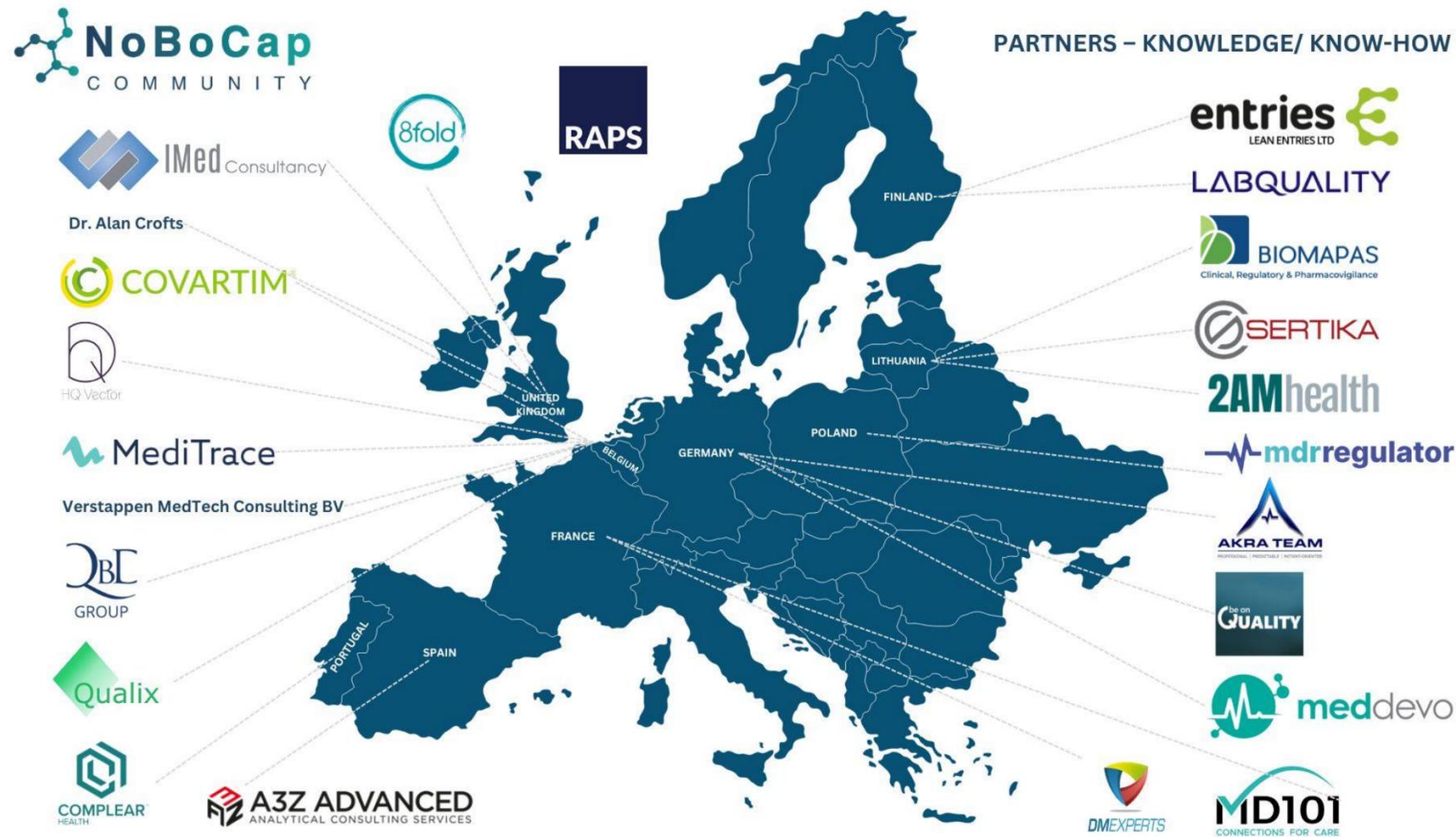


Nobocap Community Innovation Hubs/Clusters @ time of joining community.



Through Community and other channels, 500+ participants in nobocap learning modules and shortcourses to date.

Know-How/Knowledge Partners



Supportive Partners

Selective Notified Bodies

Committed to engage in matchmaking and engaging with MSE Innovation

Letter of Support, MoU

Targeting European organization as EISMEA, EIT-Health, MedTech Europe, TEAM-NB ... fostering exchange - alignment
Welcome the Investor Community

PILAR : VOICE and EXCHANGE at EU level and across Europe

(1) Enable an exchange of Best Practices amongst members

(2) Information on national/local supportive initiatives

(3) Build out a dialogue on regulation implementation & SUMMIT @ EU Level

(with EC, MDCG-Competent authorities, NB and other key actors)

to strive for an MSE innovation enabling European regulatory environment taking into consideration the MSE Innovation **PULSE and Evaluations.**

(4) Foster to build out Innovation accessibility pathways for European Health Systems* (competitive to the US and Japan), with incentivizes by **specific mechanism of innovation financing. (innovation funding pathways, conditional or adaptive reimbursement, performance-based agreements,)**

PILAR : BACKBONE SERVICES for MSE-INNOVATION BUSINESS

***Complementing and supporting partners and/or
to be leveraged by Innovation hubs/cluster, MSE, ...)***

Of Value to address e.g.

(1) Regulatory Literacy, Preparedness, Predictability and Accessibility NB

- *(in terms of processes, quality and clinical evidence requirement, costs, and consistency)*

(2) Specific Innovation pathways and timely obtaining CE certification

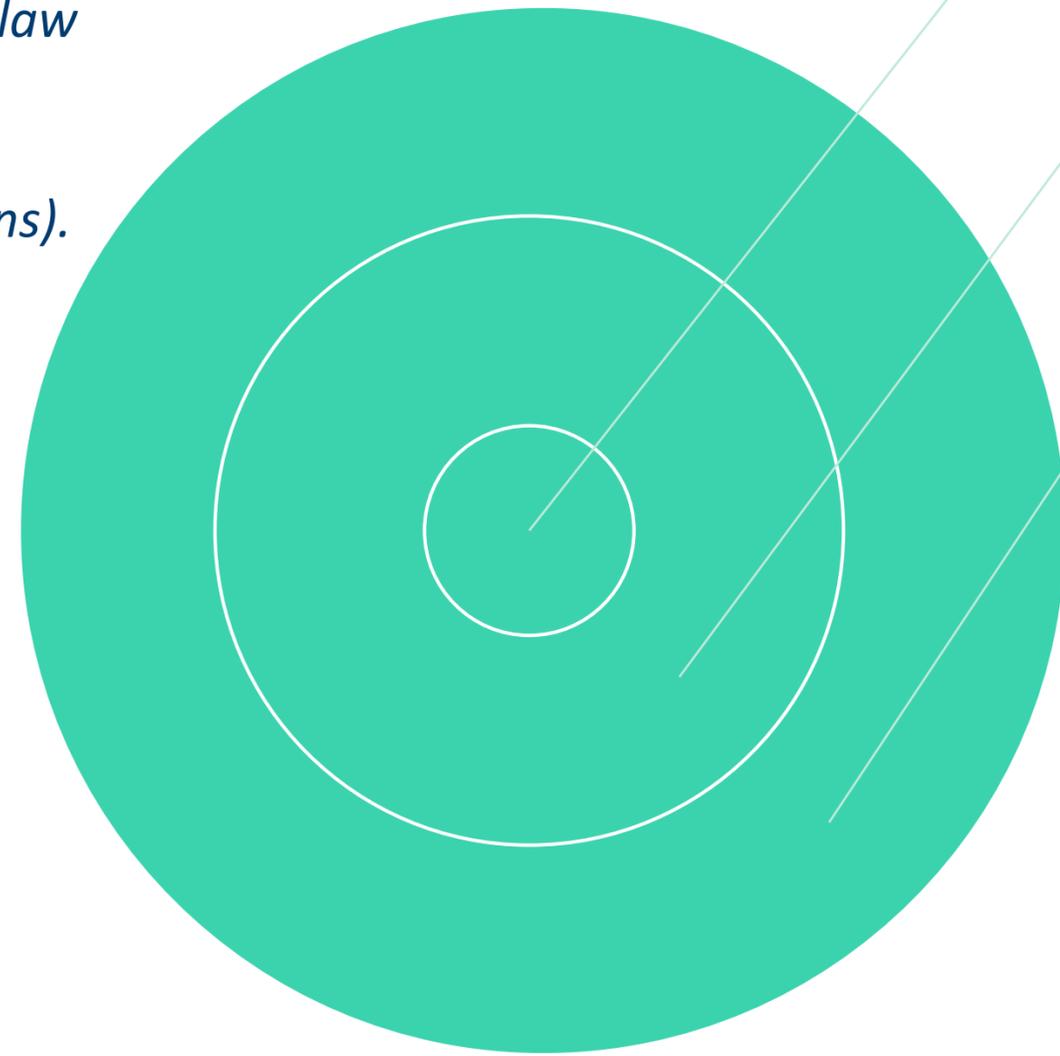
- *(through efficient processes, adequate capacity, opportunity of dialogue and expert guidance)*

(3) Effective use of financial means and opportunities for financial support

A European Community

A Legal Entity : Aisbl

- *non-profit international association by Belgian law*
- *inclusion in European Transparency register (Dialogue EU institutions).*

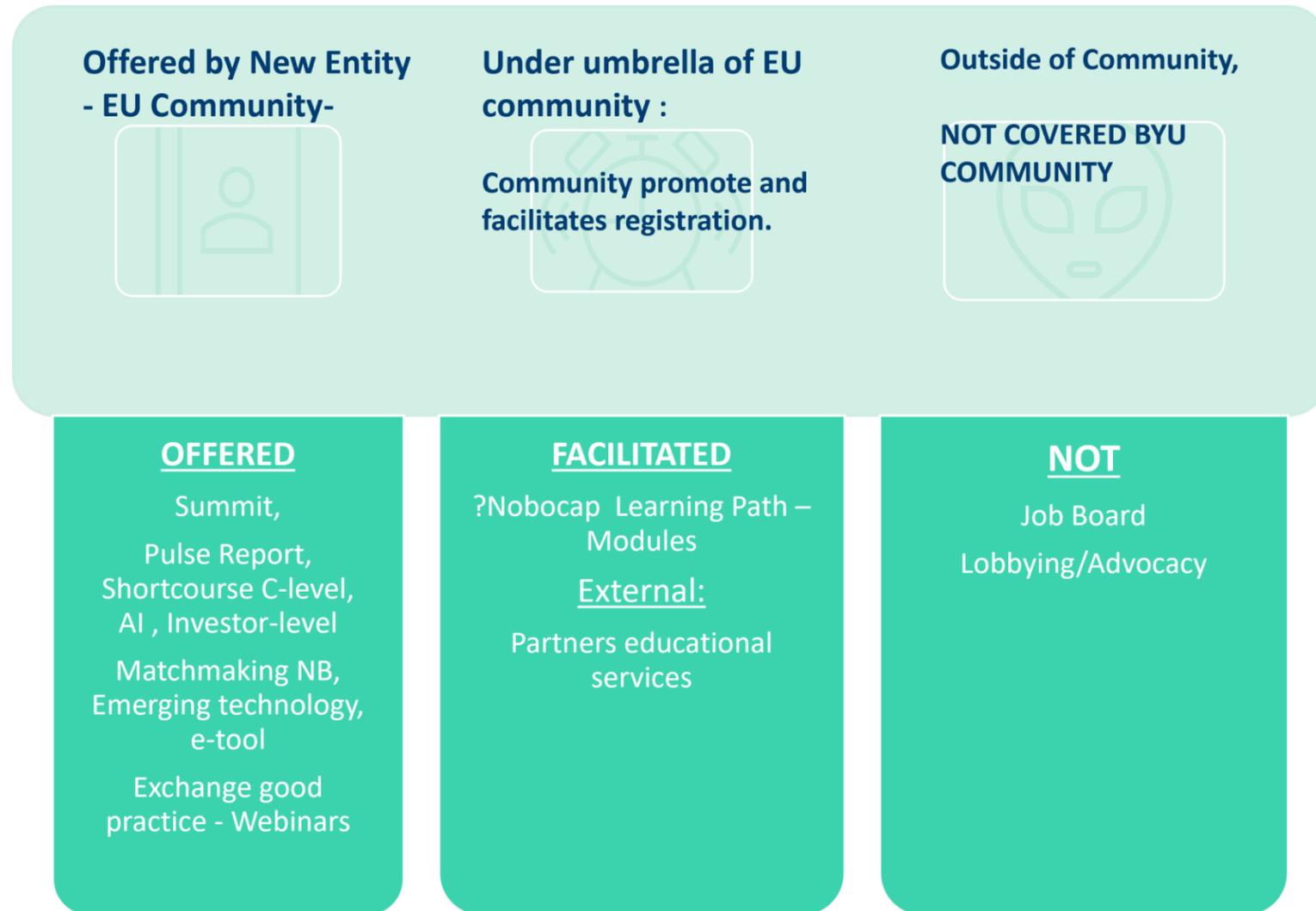


Founding and Core Organizations (Board) – Invest financial and/or in-kind
Secretariat

Members : Innovation – SME Hubs/Clusters & **Partners** : Know-How –Consultants,...
Beneficiaries (Innovators, SME, NB, Hospital innovators, investors,...)
Contributing – members fee

Supportive Organization : MoU, Lol
European (trade) organization, EIC, EIT Health, EU clusters, National supportive organizations, ...

BACKBONE SERVICES for individual MSE - INNOVATION BUSINESS: UNDER DISCUSSION



What for Innovators – SME by the New Entity

Seminar : Evolving EU Regulatory Environment

Short-Courses : C-level, AI Conformity

Investor, Breakthrough MD

Tools : E-guided tools with NB Codes ...

Matchmaking : Emerging Technology – NB designated

Matchmaking : *Know-How partner*

Seminar : *Structured dialogue NB – Scientific advice & methodologies on adaptive evidence generation*

Seminar : *Access to co-financing prepare TD MDR*

Seminar : *Accessibility and innovation financing*

What facilitated (under umbrella) by the New Entity :

Promotion - Access to Learning Journey – Courses

Overview of Consultancy Services in Europe

Matchmaking for all SME – NB

What not in scope :

Policy lobbying activities → other associations

Job Board



This to become a reality – Time to Speak Up

THANKS !

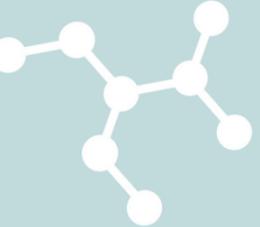
Y.Verboven@eu4healthsolutions.eu

UNFILTERED AND CLOSING REMARKS – EU COMMISSION

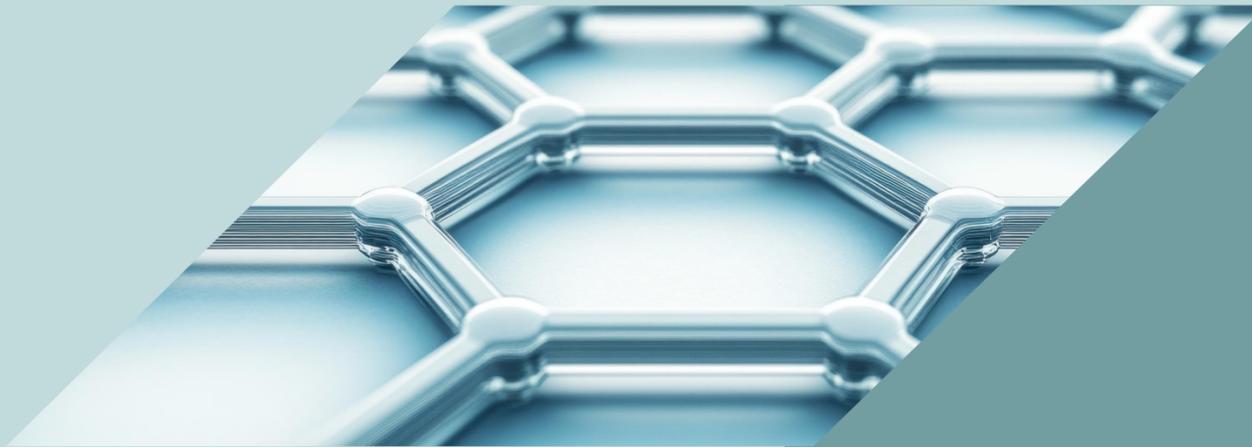


Mr. Rainer Becker
Director DG SANTE Medical Products and Innovation

NoBoCap

A white icon of a molecular structure, consisting of several small circles connected by lines, representing a chemical or biological molecule.

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