NoBoCap

PULSE REPORT

MILESTONE MS16- Second Annual MD/IVD Industry pulse report

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Project: 101101269 — NoBoCap — EU4H-2022-PJ

Co-funded by the European Union

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VERSIONS TABLE

Issue	Date	Description	Author(s)
1.0	12/02/2025	First version of MS16	iVita, EU4HS, MEDVIA, ROHEALTH
2.0	14/02/2025	First version of MS16	iVita, EU4HS
3.0	17/02/2025	First version of MS16	iVita, EU4HS, ROHEALTH
3.1	17/03/2025	Final Version of MS16	iVita, EU4HS, MEDVIA, ROHEALTH

ABBREVIATIONS

EMA	European Medicines Agency
FTE	Full-time equivalent
GÖG	Gesundheit Österreich GmbH / Austrian National Public Health Institute
INNOVATORS	Enterprises (primarily start-up – SME) part of Innovation Hubs/ Clusters to provide technological innovation and innovative solutions including MD, IVD as standalone of in combination products, possible from other life science sectors
IVDR	In-Vitro Diagnostics Regulation
MDR	Medical Device Regulation
MNE	Multi-National Enterprise
MNEs	Multi-National Enterprises
MO	Market Operators
MS	Milestone
NB	Notified Body
PMCF	Post-Market Clinical Follow-up
QMS	Quality Management System
ROI	Return On Invest
SME	Small and Middle-sized Enterprises
TDA	Technical Documentation Assessment
TEAM-NB	The European Association for Medical Devices of Notified Bodies
WP	Work Package

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FOREWORD

The milestone document MS16, which precedes the creation of Deliverable D5.1, will serve as a state of play ("The Pulse") for NoBoCap WP5 ("Matchmaking the Demand with Supply"). Its purpose is to support the achievement of Objective O5.1: "Landscaping and surveying the Life Science association network and other stakeholders, including innovation hubs and end-user organizations such as hospital associations, insurers, and patient organizations." Additionally, it contributes to Objective O5.3: "Developing a white paper on needs and capacity."

The objective of Milestone MS16, titled "Second Annual MD/IVD Industry Pulse Report," is to compile an interim report based on multiple data sources, providing a comprehensive analysis of industry trends, stakeholder perspectives, and market dynamics.

The authors acknowledge the time invested by Frederike Windisch & Nina Zimmermann of the Austrian National Public Health Institute, by Daan Bijwaard & Joke Wiercx of EY Consulting BV, by Maaika Sabido of the Basque Health Cluster to review and provide input on the correctness of interpretation of the sections we refer to of source data their organizations originated. The final content of the report remains however at the responsibility of the authors.

INTRODUCTION

This report aims to provide an analysis of Europe's evolving regulatory landscape with a focus on the MDR/ IVDR.

The content of the report is based on a compilation of data reports, NoBoCap project initiatives, desk research, and insights gathered at the NoBoCap Community organized Summit." Unlocking MDR/IVDR Regulation for Innovation. This interim pulse report will not be comprehensive, and will over time include additional input sources,

The Pulse Report emphasizes the importance of understanding the overarching challenges faced by the evolving MedTech and HealthTech ecosystems, as well as identifying the unique needs and obstacles encountered by specific market operators (start-ups, scale ups, SME part of the innovation ecosystem). While the NB capacities are increasing in the last year, a key concern remains the accessibility for start-up, SME, for specific innovation and conformity assessment timelines of Notified Bodies remain an challenge, which significantly impacts the timeliness and efficiency of obtaining certifications. The NoBoCap project and the NoBoCap Community is dedicated to delivering targeted tools and services to effectively tackle these pressing issues.

1. POLICY INITIATIVES AND DATA-DRIVEN POLICYMAKING

This section provides an update on EU parliament, EU Council **policy** initiatives that specifically impact the implementation and application of the Medical Devices Regulation (MDR) and *In-Vitro* Diagnostics Regulation (IVDR) for innovators and SMEs seeking to obtain CE marking. It highlights efforts to ensure conformity with regulatory requirements as defined by these frameworks, including specific policy initiatives supported by governments (regional and national health authorities) to help the innovation ecosystem comply with the regulations.

Additionally, the section examines European Commission initiatives to evaluate and implement data-driven policies. It incorporates data input from the innovation ecosystem, including reports and insights, to shed light on the current state of play, key issues, challenges, and the competitiveness of the existing regulatory framework.

1.1 EU Parliament, EU Council (EPSCO) and National/Regional Health Authorities – Government Initiatives

The initiatives at the European level are presented in Table 1.

Table 1 Initiatives at European level

Initiative	Country/Region	Description	Data source
EU Parliament Resolution	European Union	The European Parliament adopted a resolution on October 23, 2024, emphasizing the urgent need to revise the Medical Devices Regulation (MDR)[1].	JOINT MOTION FOR A RESOLUTION on the urgent need to revise the Medical Devices Regulation | RC-B10-0123/2024/REV1 | European Parliament)
EPSCO Health Ministers Initiative	European Union	The European Commission and EPSCO (Ministers of Health) are working on (1) extending the transition period, (2) streamlining certification processes, and (3) supporting SMEs to reduce regulatory burdens.[2]	MedTech Europe post-EPSCO statement on the necessary reforms of MDR/IVDR

[1] https://www.europarl.europa.eu/doceo/document/RC-10-2024-0123_EN.html
[2] https://www.medtecheurope.org/wp-content/uploads/2024/12/epsco-statement-1.pdf

National policy initiatives

National governments call for close collaboration with regulatory bodies to help navigate MDR and IVDR compliance challenges. This includes encouraging innovators' participation in regulatory consultations and support programs.

National and regional healthcare authorities across Europe acknowledged the challenges posed by the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) on innovation. In response, they have issued initiatives and calls to the innovation community to actively engage in Innovators participation in Regulatory Consultations, utilization of support programs:

Table 2 National initiatives

Initiative	Country	Description
Danish Local Notified Body Initiative	Denmark	The Danish government put out an EU tender to have obtain a Local Notified Body under the Life Science Strategy 2024-2027, aimed at supporting SMEs while ensuring regulatory compliance does not hinder innovation.
Austrian Notified Body Initiative	Austria	Austria launched a national notified body, QMD Services, a subsidiary of Quality Austria, to assist SMEs in complying with MDR regulations.
French SME Funding Programs	France	France introduced financial aid programs to help SMEs cover compliance-related expenses, including clinical studies, quality management system implementation, and consultancy services. (See details in 3.3.1)
Dutch Regulatory Compliance Call	Netherlands	The Dutch Health and Youth Care Inspectorate (IGJ) issued a call in August 2023 urging manufacturers to ensure timely compliance with IVDR, providing key recommendations.

1.2 European Commission Survey – Data-Driven Policy

EU Commissioned: EY (Ernst & Young) STUDY ON REGULATORY GOVERNANCE AND INNOVATION IN THE FIELD OF MEDICAL DEVICES, 2024[3]

[3] ***Disclaimer:*** *The reported draft findings are preliminary and may change in the final report. The current findings are not endorsed by the European Commission.*

Background & Objectives

This study aims to map the key benefits and challenges of the regulatory governance structure of the MDR/IVDR and look at their impact on innovation and patient safety in the EU medical devices sector. This is done by 1) mapping the state of play of the application of the MDR and IVDR and their governance structure; 2) assessing whether the governance structure has been effective and efficient in meeting the objectives of the Regulations; and 3) assessing whether the regulatory framework and especially its governance structure improve patient safety and support innovation.

This data will support the "evaluation" of the MDR/IVDR which as an objective the creation of a robust, transparent, predictable and sustainable regulatory framework for medical devices, which ensures a high level of patient safety whilst supporting innovation.

Key Findings & Insights (Preliminary reported at the NoBoCap Summit with a focus on SME and Third Stakeholder workshop)

1. **Challenges to Innovation**
    - Findings suggest that industry has responded to the MDR and IVDR by increasing resources spent on regulatory compliance. The available data suggest a substantial increase in the regulatory burden. While it is difficult to determine the exact extent to which the Regulations have reduced manufacturers' device portfolios, evidence suggests a significant reduction in device offerings. Actors and stakeholders expressed skepticism about the regulatory framework's support for new and emerging technologies - 60% of actors/stakeholders in the study's survey disagreed it fosters innovation
    - Barriers to innovation identified by some stakeholders in the consultation activities include administrative burdens, lengthy certification processes, clinical evidence demands, and unpredictability of the conformity assessments.
    - Lack of preparedness and awareness among industry also play a role.
2. **Impact on SMEs and Startups**
    - SMEs, and especially micro enterprises, face resource limitations, making compliance disproportionately expensive.
    - Financial hurdles: Obtaining funding is harder due to regulatory uncertainties.
    - SMEs are more reliant on (costly) external consultants.
    - **Access to notified bodies** remains challenging for SMEs, even if the number of designated NBs has increased.

Some SMEs exit the EU market, switch to supplier roles, or relocate outside the EU. The stakeholder feedback suggests that while the MDR/IVDR have enhanced patient safety, they have also slowed innovation, particularly for smaller firms. Stakeholders advocate for a

streamlined regulatory process that balances safety with market competitiveness, ensuring continuous medical advancements in the EU.

EU Commissioned : STUDY SUPPORTING THE MONITORONG OF AVAILABILITITY OF MEDICAL DEVICES ON THE EU MARKET.

The European Commission commissioned reports conducted by the Austrian National Public Health Institute (Gesundheit Österreich GmbH, GÖG) to monitor the implementation and impact of the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR). These reports focus on surveying notified bodies and economic operators to assess the availability of medical devices within the EU market. Initiated in December 2022, this ongoing study aims at analysing the availability of medical devices in the context of MDR and IVDR implementation. Conducted by GÖG in collaboration with Areté and Civic Consulting, the study spans 36 months, concluding in December 2025. It involves regular surveys targeting key stakeholders (e.g. notified bodies, economic operators, including manufacturers, authorized representatives, importers, and distributors, and health service providers) to identify challenges affecting device availability and the conformity assessment process. The findings are compiled into a publicly accessible dashboard[4].

- **Notified Bodies (NB) Survey on Certifications and Applications:** This series of surveys, conducted periodically, gathers data from notified bodies designated under MDR and IVDR. The 10th NB survey, with data up to June 30, 2024, achieved a 100% response rate from all 50 notified bodies. The surveys provide insights into certification activities, application volumes, and the capacity of notified bodies, offering valuable information for stakeholders about the current state of conformity assessments under the new regulations
- **Economic operators:** The first comprehensive survey for economic operators (targeting manufacturers, authorized representatives) of MDs and IVDs was launched in November 2023 including questions on applications lodged, certificates obtained, time periods and transition progress towards the new Regulations. The results by 658 respondents were published a the publicly available dashboard. The second survey for economic operators (targeting manufacturers, authorized representatives, importers and distributors) was launched in December 2024.

1.3 European Innovation Ecosystem – Reports

This section provides a thematic overview based on data presented at the NoBoCap Summit (September 2024) and published reports, including:

- **MedTech Europe Report** – This report provides a comprehensive analysis of the regulatory impact, including a dedicated sub-analysis on SMEs that can be used in this document. It also offers further insights into the effects of regulations on innovation (*mte_report_ivdr_mdr_2024-v7.pdf*[5]). While the SME analysis primarily covers medium-sized companies, it serves as a useful reference as indication for the minimum expected impact on the innovation ecosystem, particularly for start-ups and scale-ups.

[4] https://ppri.goeg.at/Study_MD_Availability?utm_source=chatgpt.com
[5] https://www.medtecheurope.org/wp-content/uploads/2025/01/mte_report_ivdr_mdr_2024-v7.pdf

Key elements include the time and cost considerations for Notified Body certification, as well as post-market compliance requirements. A total of 73 IVD and 138 MD manufacturers participated in the survey, with 45% of respondents in both categories being SMEs member of European or National Trade Associations.

- **MedicalMountains -** The report provides an assessment of German medical device manufacturers regarding the effects of the EU Medical Device Regulation (MDR). Conducted in December 2023, the survey presents the results of a nationwide company assessment by the German Chamber of Commerce and Industry (DIHK), MedicalMountains, and SPECTARIS, with 541 respondents.
- **Basque Health Cluster** – The report, based on a **May 2023** survey, analyzes regulatory challenges under MDR and IVDR, highlighting difficulties in accessing Notified Bodies, consultancy services, and CROs. It addresses financial burdens, language barriers, and their impact on compliance. Additionally, it examines investor sentiment and the influence of regulatory uncertainties on new business models.

Timelines for SME Conformity Assessment - Certification Quality Management System and Technical Documentation

Summary: A lengthy conformity assessment time with a high variability.

A **preparation time** for most companies reported including Multinationals (MNE) and SME member of trade association was up to 1 year , but for 40% it was up to 2 year and more. This time does not include the ability – time to enter into contact and obtain a locked application. In the monitoring survey 57% of the MFs that provided information on this question (n=396) indicated that it took less than a year to prepare an application for MDR; for almost 80% less than 18 months

Once an application to a NB is accepted the total time is on average for QMS or TDA for IVD is 18 months, for QMS MD is 19.6 month and TDA - 22 months, but with a wide variability e.g. For Technology Documentation Assessment (TDA) for 40% it took more than 2 years.

A significant part of the time (often more than 50% is taken up in the pre-review phase and to issue a certificate by NB).

There are multiple causes for the challenges for SME on the accessibility and locking an application and on the high variability in the total amount of time to obtain a certification from NB for CE mark, but the completeness and quality of submission is a key factor. **Taking a weighted average there is only around 40% of completeness in submitted dossiers.**

A non-acceptance of an application for multiple causes described below will of course be further detrimental.

The average time are expected to be conservative estimate for the innovation community of start-ups, scale-up, innovators as from informal input it is indicated this community is even less prepared. Given the key factors identified impacting to have a lengthy process, an appropriate and timely investment ensuring a well informed and high-quality dossier can provide a significant business advantage.

General:

For the IVD Certification the total average time for SMEs and large companies on average to complete either the QMS (Quality Management System) or TDA (Technical Documentation Assessment) certification is around 18 months for each. Also, for the IVD Certification the Notified Body spends >55% of the total average time from application to certificate issuance of a QMS outside of the Review phase (i.e. in Pre-review + Certificate issuance).

For *MD Certification* QMS certification is approximately 19.6 months and TDA 22 month, but a wide variability applies. For MD Certification this is comparable with 50% of the total time from application to QMS certificate issuance to phases outside the Review phase (Pre-review and Certificate issuance); This is 42% in case of TDA

For SME – A more outspoken challenge and lengthy timelines.:

For the **IVD certification**, especially SME have a higher number (i.e. 40%) of companies in the longer duration categories of **9-15 and > 15 month already for Pre-Review Phase**, as well as for the Review phase and the certification Certificate issuing. **For Technical Documentation the longer duration** is especially in the review phase with almost 60% of SME, an amount is **almost double of MNEs**, and have **longer assessment times of 9- 15 months**.

For **Medical Devices** certification especially in the review phase a much higher number of companies with a longer review time with > then 15 months (25% for QMS and 50% of Cie for TDA.

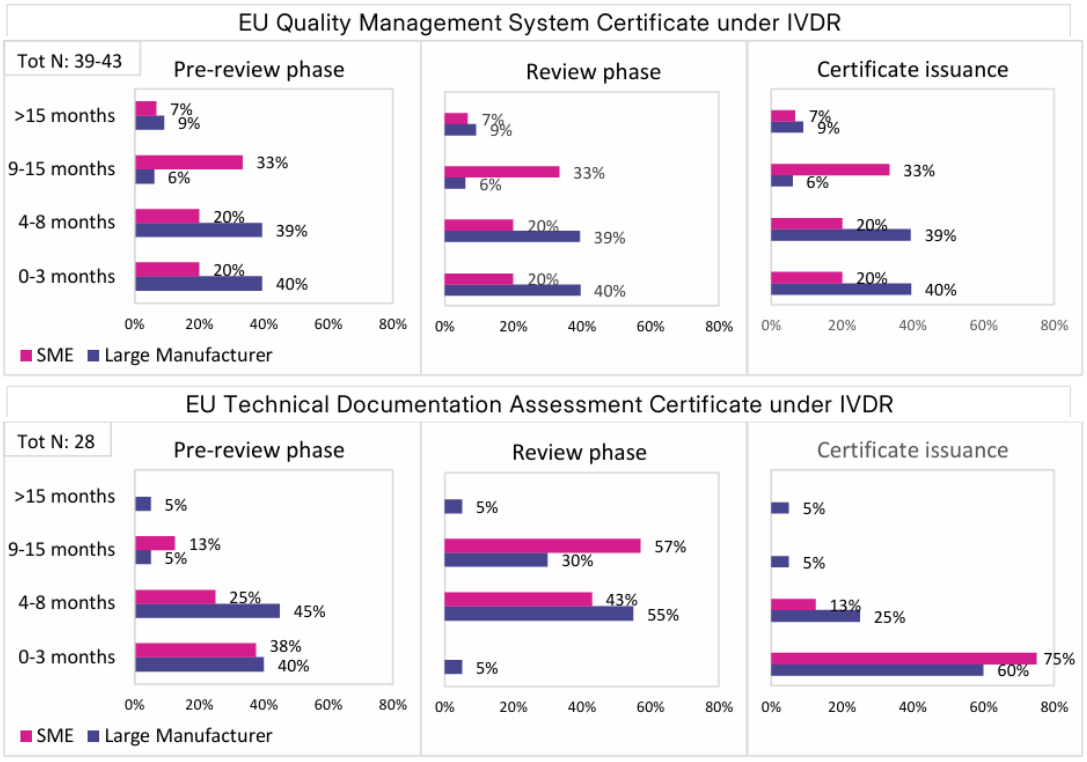

Figure 1 Certification timelines under IVDR per different phase
Source: MedTech Europe

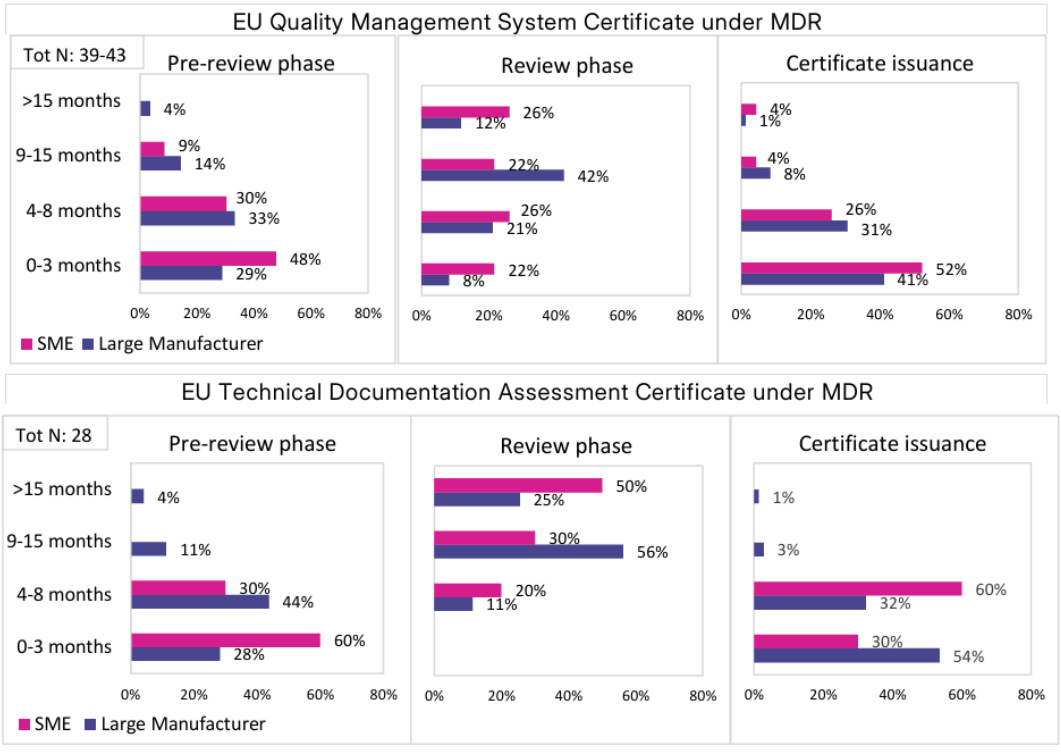

Figure 2 Certification timelines under MDR per different phase
Source: MedTech Europe

A confirmation at the NoBoCap summit and significant high variability in the certification times. These includes all companies.

During the NoBoCap Summit on 25/09/2024 in Brussel more details were provided by the Austrian National Public Health Institute (GÖG)on the difference in reporting by NB and Manufactures on the length of certification time but as well on the **variability of MD certification times**:

with **40% of companies more than 18 months for QMS and**

almost 50% of companies needing more than 18 months if also needing product certification.

Based upon Replies of 249 MD MFs and for comparison data of the 6th NB survey (covering the same data period until 31/10/2023): Data of 39 notified bodies.

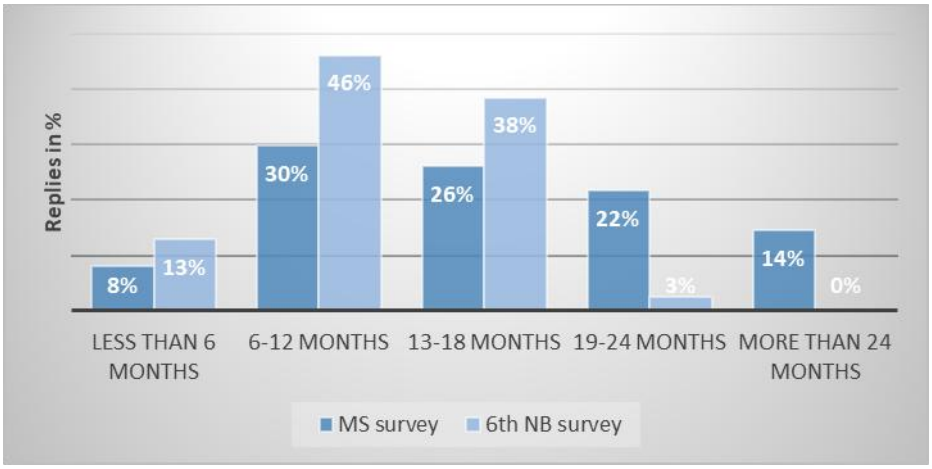

Figure 3 Comparison data of surveys
Source: GOEG

Based upon replies of 284 MD MFs; 217 MFs indicated “No information available” for comparison data of the 6th NB survey (covering the same data period until 31/10/2023): data of 39 Notified bodies.

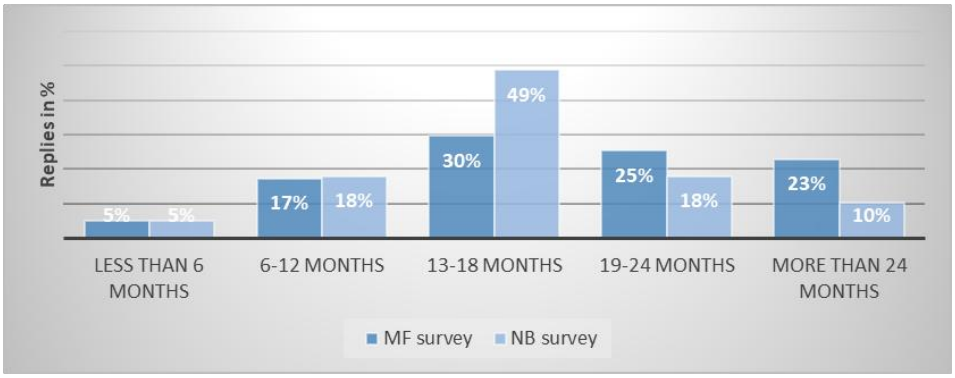

Figure 4 Comparison data
Source: GOEG

From the MedTech Europe Survey for their SME members that responded: For QMS & TDA, the median time for the **Notified Body Pre-Review Phase**, i.e. the time from submission of the application to review start, Pre-Review time depends on several factors, such as the completeness of the documentation and the scheduling times of the Notified Bodies. The median time for SME - IVD is 8.8 months and for TDA 4.5 months and MD 4 months and 3 months respectively.

For the **median Review time** we have respectively for **IVD QMS 7 month and TDA 9 and for MD QMS 10 and TDA 14 month.**

Issuing the Certificate adds respective 2.8 month for IVD and 4 months for MD both for QMS and TDA.

Causes of lengthy times for certification – Completeness

With the extensive requirement, some inconsistency in interpretation and further clarity on expectations needed, there is a multitude of reasons for lengthy certification times (besides the availability of NB) Before the evaluation of the content, the **completeness of dossier submission as considered by NB is an indicator for the variability in times to be expected**.

Taking a weighted average there is only around 40% of completeness in submitted dossiers.

For Medical Devices (overall MNE, SME) – Vertical axis - # NB

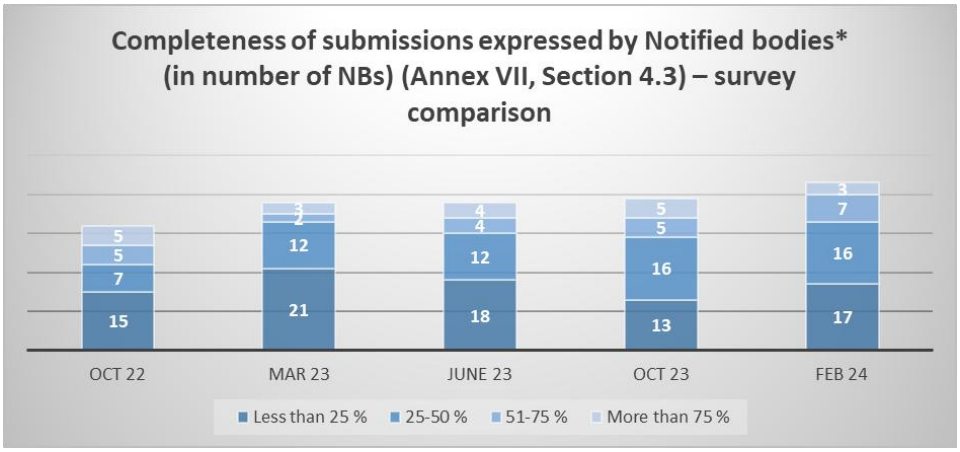

Figure 5 Survey comparison (in number of NBs) [6]
Source: GOEG

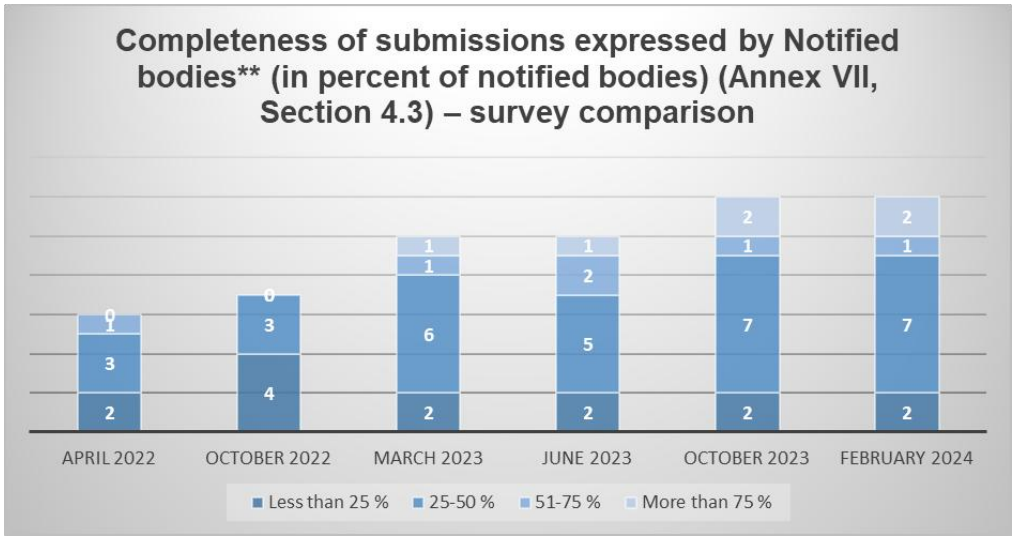

Figure 6 Survey comparison (in percent of NBs) [7]
Source: GOEG

Source: GOEG

Causes of lengthy times for certification – Refusal of Application

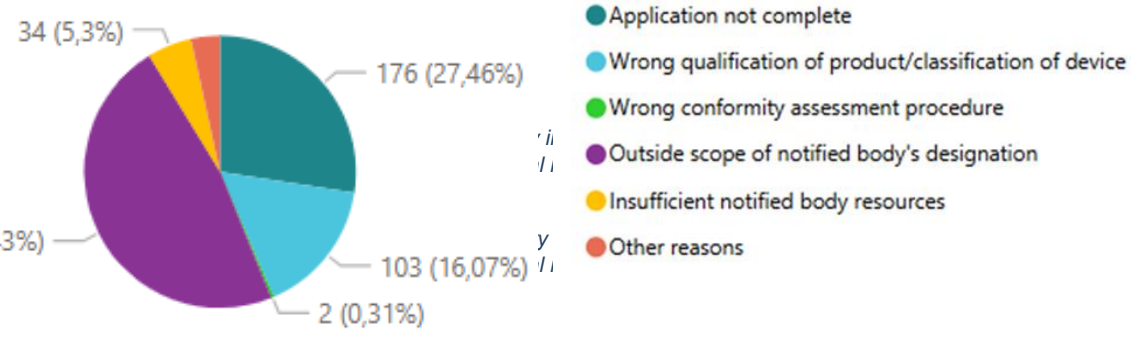

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Figure 7 Causes of lengthy times for certification – Refusal of Application

Source: MedTech Europe

As reported in the Dashboard monitoring the input of the Notified Bodies[8].

Preparation timelines

Following timelines on preparation were mentioned during the NoBoCap Summit – September, 2024 by Goeg institute based upon 396 MD manufacturers whereby 105 did report no information available.

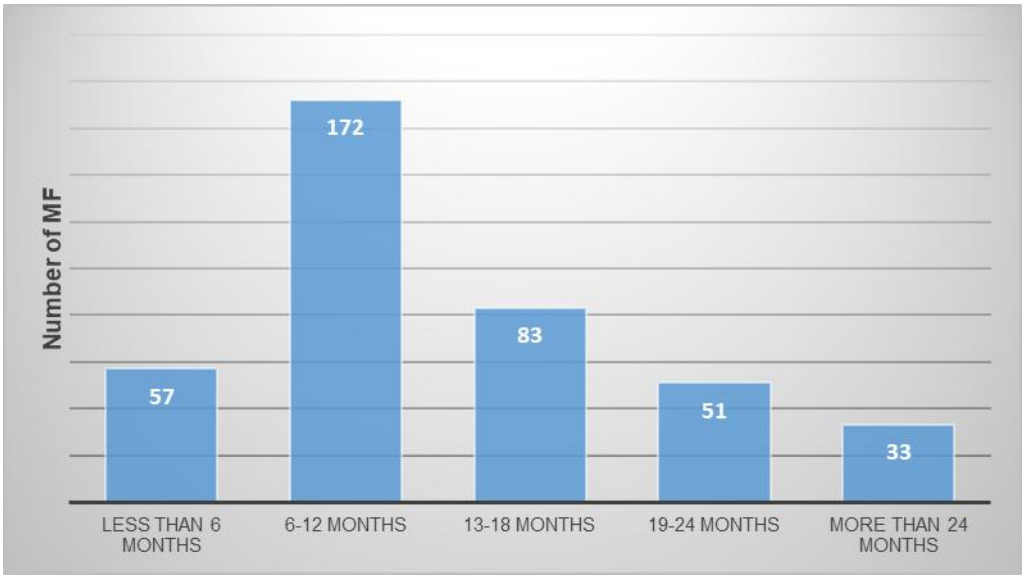

Figure 8 Timelines to prepare an application for MDR (before submission NB)
Source: Goeg institute

[8] https://app.powerbi.com/view?r=eyJrIjoiMmRhNTZkOTAtNTM4YS00NmE5LWExYjYtZjIzYzI5YjUwMzRiIiwidCI6ImIyNGM4YjA2LTUyMmMtNDZmZS05MDgwLTcwOTI2ZjhkZGRiMSIsImMiOjh9

Cost of certification

For the certification there is a significant increase in Cost: As compared to the former MD directive the increase in requirements results in a significant increase on the total investment needed was report in the survey by MedTech Europe .

There is for MD a **more than doubled for the required investment:**

in "clinical evaluation "for 2/3 of the respondents

in for the post-market surveillance 1/2 and

as well as for obtaining a conformity assessment for 1/2 .

For IVD there is for the "performance evaluation and post-market surveillance a doubled vestmentet in ¼ and respectively 1/3 of the respondents. Here obtaining conformity assessment costs doubled for ½ of the respondents.

(Total N: number of respondents per each area is between 61—67 respondents).

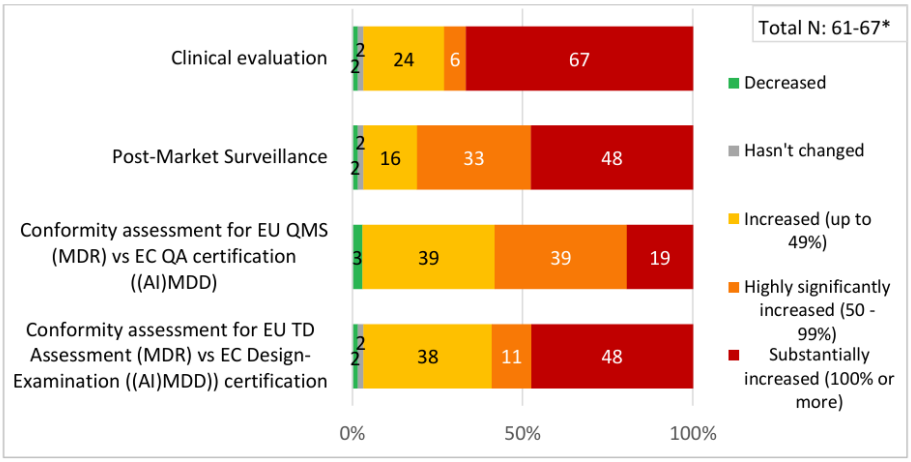

Figure 9 Changes in MDR costs as compared MDD/(AI) MDD (% of total per area)
Source: MedTech Europe

For the respondents of IVD companies the **more than doubled cost** was mainly for the **conformity assessment** vs the former design examination **and 1/4 for the performance data.**

(Total N:30-32*- *The number of respondents per each area is between 30 - 32 respondents of those who were able to answer this question).

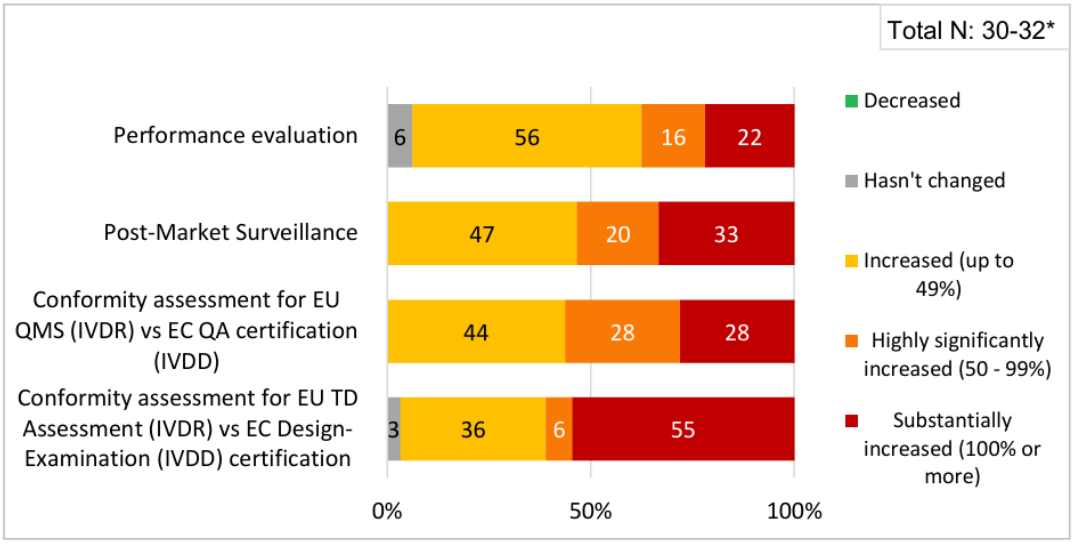

Figure 10 Changes in IVDR costs as compared IVDD (% of total per area)
Source: MedTech Europe

To note that while there are more safety and information requirements implemented through the regulation, such as transparency and oversight requirements, while the devices themselves have not necessarily changed. This high cost is then also one of the causes that certain current products will not go through the certification process.

The total certification absolute cost estimate

To compile a picture of total certification costs for IVDR and MDR, the MedTech Europe survey asked for information on both external costs (Notified Body fees) and internal costs (manufacturer's full-time equivalent (FTE)/personnel costs).

Hereby to take into consideration the

1. The cost for the initial certification but as well
2. the cost to maintain the certification, and
3. the cost for vigilance reports.

The absolute cost lined to certification, depends heavily on a multitude of influencing factors, and these cannot (and should not) be viewed in isolation. Therefore, in this cost analysis the presented certification costs took into account some of these factors, such as fees paid to the Notified Body, the number of devices and sampling parameters to have an indication of costs – investment need.

Indirect cost – opportunity costs due to time of not having the products available on the market and a needed continued financing of the Start-up/Scale-up/SME are NOT taken into consideration.

Specific items contributing to the Total Absolute Cost to Notified Bodies ": initial certification and maintenance cost.

Initial Certification: QMS

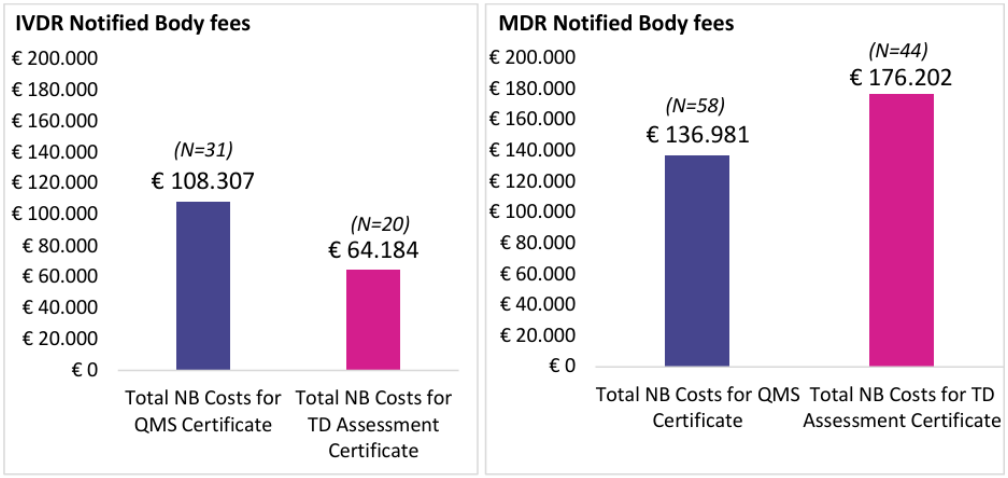

Figure 11 Average costs paid to Notified Body for QMS&TDA Certificate
Source: MedTech Europe

Whereby there is a high variability as further details which is not surprising given the many influencing factors that affect these costs. Based on data collected in the survey, the below listed factors are associated, albeit weakly, with the costs manufacturers pay for Notified Bodies for certification and they can at least partially explain the variation in IVDR/MDR certification cost. This leads to cost for QMS in function of the number of devices covered.

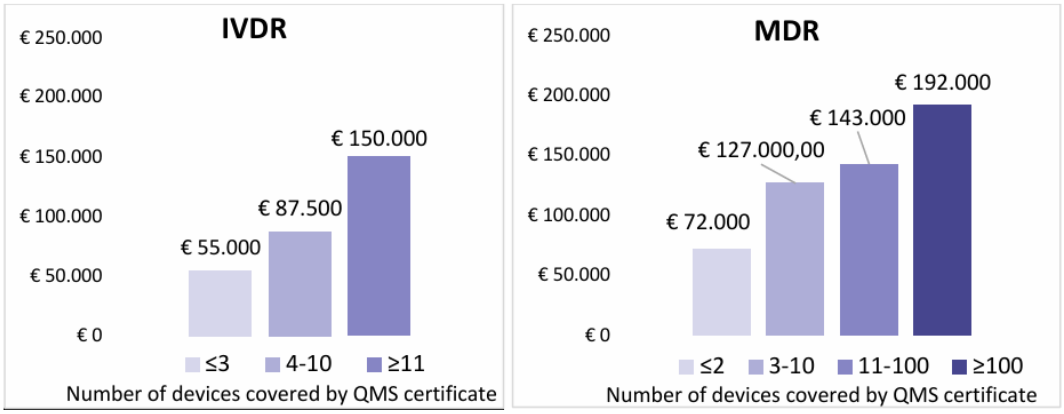

Figure 12 The impact of the number of devices covered by one QMS certificate on the costs paid to Notified Body for the QMS assessment
Source: MedTech Europe

The variability in more detail: overall, the respondents provided the QMS certification costs within a variety of cost ranges which clearly indicates outstanding variability in Notified Body fees required to complete EU QMS certification under current regulations (see figure 14).

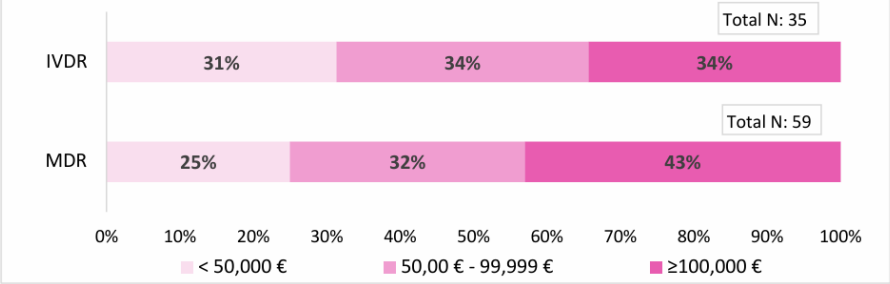

Figure 13 Variation in average QMS certificate costs paid to Notified Body
Source: MedTech Europe

Certification Technology:

The costs paid to Notified Body for the assessment of one technical file for sampled devices: costs for sampling one technical file seem to be substantially higher for MD sector (~ € 60K) than for IVD sector (~ € 38K) (see figure 21). The costs for the assessment of one technical file for sampled devices also seem to have an impact on Notified Body certification fees: the higher the sampling cost – the higher the overall Notified Body certification fees for QMS certificate (weak positive correlation R=0.285).

Hereby is it important to note that the initial expected cost by the Notified body might well be significantly lower than the ultimate cost in case of a low-quality submission, which can further explain the large difference in cost for the assessment of a technical file.

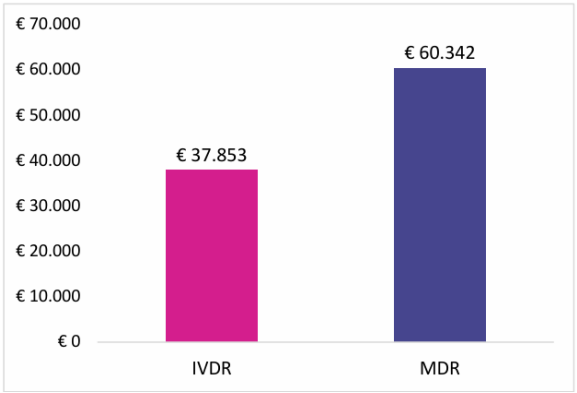

Figure 14 The average costs paid to Notified Body for the assessment of one technical file for sampled devices
Source: MedTech Europe

High certification cost variability also is observed in EU TDA certification costs. Although TD assessment costs also vary profoundly, in 65% of cases, TDA certification costs fall either in the lowest (< €50,000) or the highest (≥ €150,000) cost range.

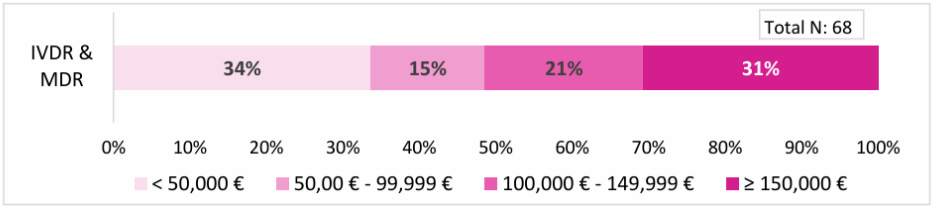

Figure 15 Variation in average TDA certificate costs paid to Notified Body
Source: MedTech Europe

Maintenance Cost

'Maintenance costs' can be understood as the costs invested by the manufacturer to remain in compliance with the IVDR or MDR following CE-marking of the device. (Hereby did most respondent not include internal FTE cost). This is a significant area of investment for the industry: costs for post-market surveillance under IVDR and MDR have increased by at least half (or more) since the medical devices directives, for almost all respondents of this survey. In this section, we look more closely at these increased maintenance costs with the focus on the vigilance fees paid to Notified Body, the costs for yearly surveillance audits and the costs needed for continuous update of required documentation during the lifecycle of the device.

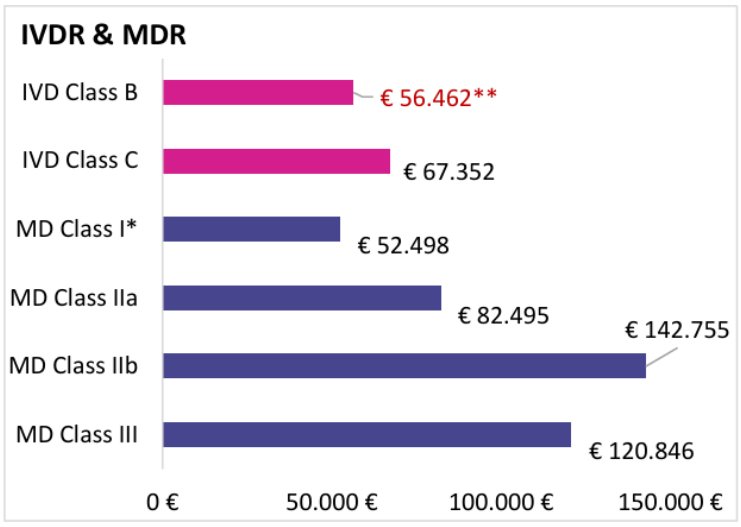

Figure 16 Average yearly IVDR/MDR certification maintenance costs per class (per one device)
Source: MedTech Europe

* Class I sterile, measuring, reusable

** Total number of responses for average yearly costs for Class B devices is less than 15 therefore the data must be interpreted with caution. There were insufficient numbers of responses for Class A and Class D to be aggregated.

Vigilance case cost

On average, manufacturers pay 285 € to the Notified Body per one vigilance case under IVDR & MDR but with a variance where even > 600 Euro per vigilance was charged.

Note: Specific Notified Bodies do not charge on a case basis to mitigate an underreporting,

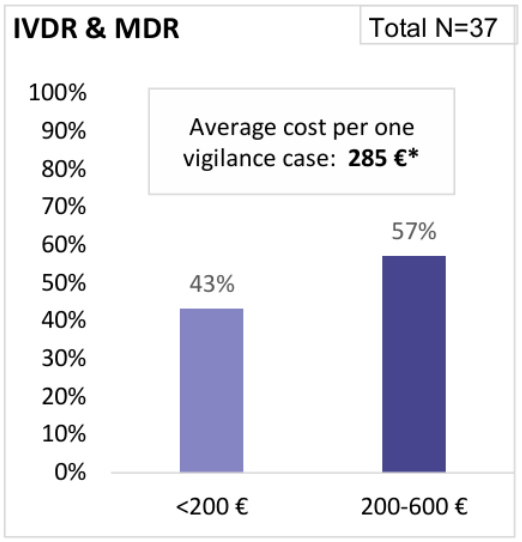

Figure 17 Costs paid to Notified Body per single vigilance case (average cost and cost variation)
Source: MedTech Europe

* Please, note that some substantial outliers above the highest value in average (max 600 EUR) have been removed for data accuracy

Total absolute cost of certification over lifecycle

Internal FTE cost: The initial certification fees paid to Notified Bodies are high compared to the previous directives, but they are only the 'tip of the iceberg', with manufacturer's internal (FTE), maintenance and re certification costs adding significantly to the total cost package over the certificate lifetime.

It is noteworthy that the higher the Notified Body fees, the higher the manufacturer's internal costs to complete certification which may be related to the long certification timelines and associated administrative burden. Moreover, high maintenance and re-certification costs show that when considering product's revenue in relation to costs, the manufacturers should not only account for regulatory costs needed to obtain certification, but they must also bear in mind the costs needed to maintain that certificate, which are considerable for all devices.

Cost visibility – predictability

Within the MedTech Europe Survey, the survey asked about the visibility of cost over the coming year, whereby **only around 20% of SME indicate to have a visibility.**

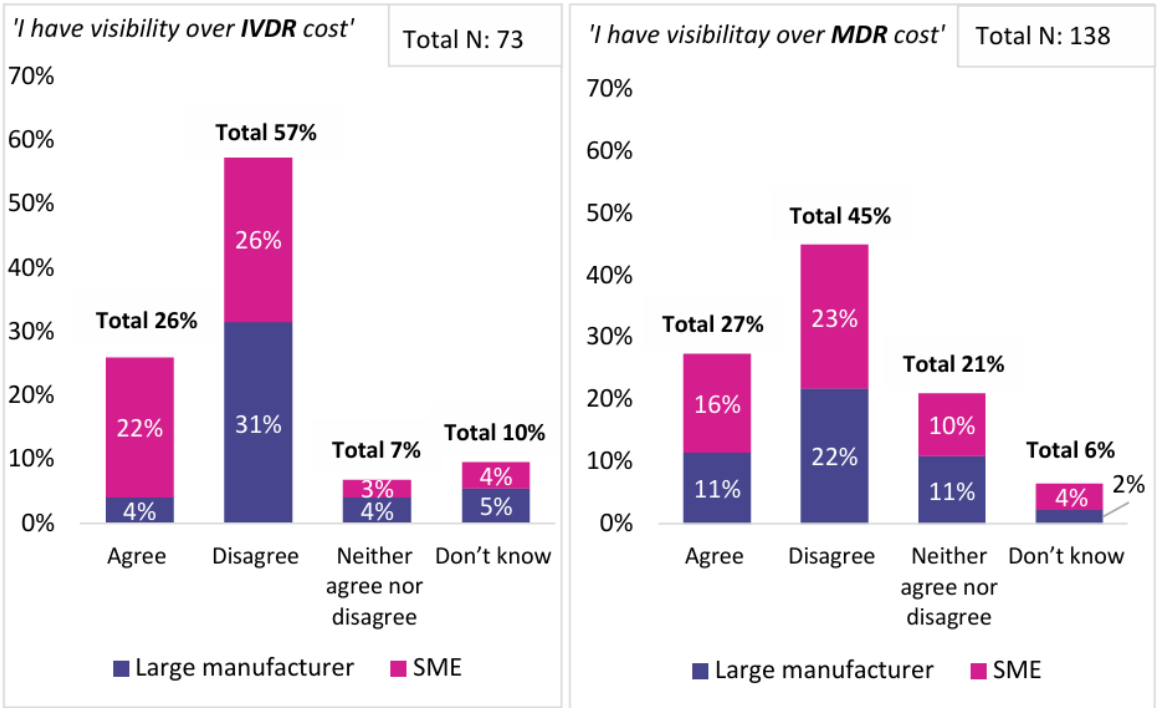

Figure 18 Manufacturers' visibility over certification and maintenance costs for next year (% of total)

There are certainly many reasons that may impact the cost planning of manufacturers for both sectors, and there are certainties that a low-quality file causing many non-conformities -TCAR will result in significant additional cost and timelines.

However, the current system allows Notified Bodies also high flexibility to set up their fee structures and change their cost structure not only based on inflation but other internal factors where costs may be passed on to manufacturers. While costs are required to be made publicly available by Notified Bodies with a 'fee per hour', the total costs visibility to be paid for conformity assessment and for maintenance activities remain unclear.

Many manufacturers have contracts with a duration shorter than the five-year certification cycle which leads to yearly or bi-yearly budget discussions. this results in budgeting uncertainties for the manufacturers, even for those which already went through successful certification under IVDR or MDR.

Innovation

Preferred geography to go to market and seek conformity assessment

Within the MedTech Europe survey the MNE, SME member of the EU or National Trade Association responded the IVDR and MDR is affecting the choice of the EU as the primary market option for first regulatory approvals as follows.

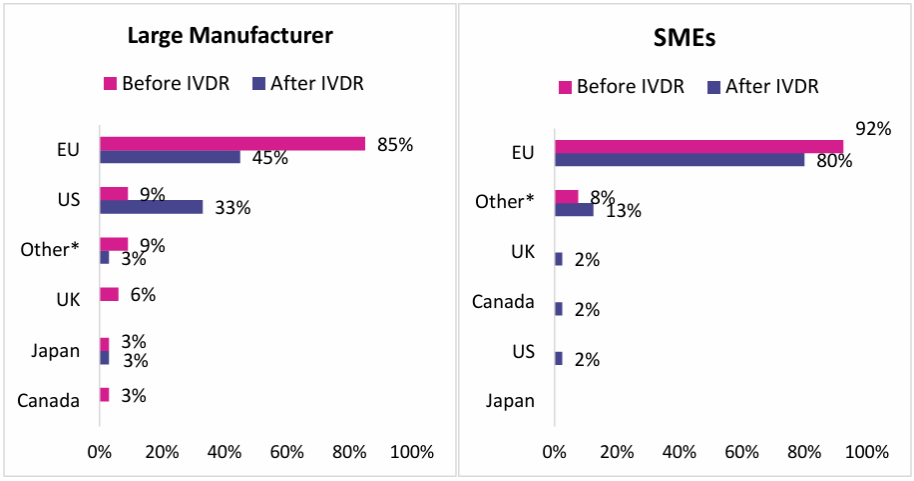

Figure 19 Preferred geographical regions for initial regulatory approval before and after the implementation of IVDR
Source: MedTech Europe

* Other, e.g., Australia/New Zealand

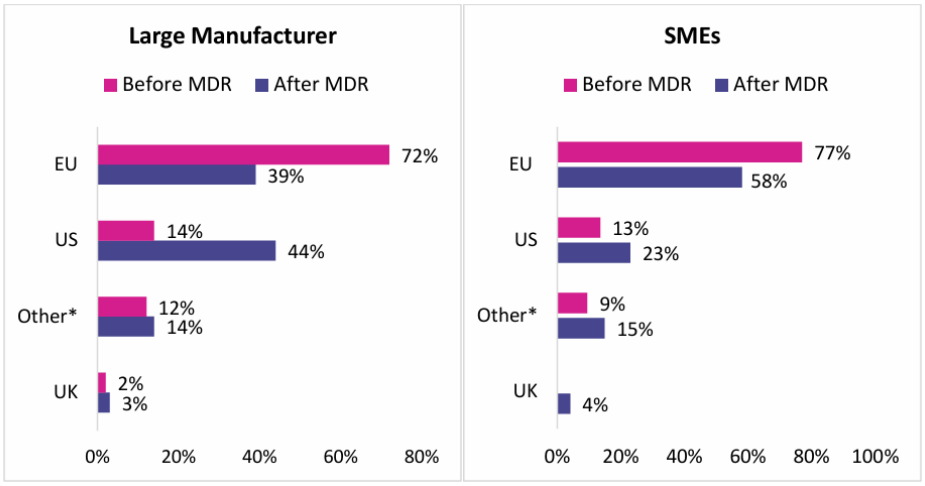

Figure 20 Preferred geographical regions for initial regulatory approval before and after the implementation of MDR
Source: MedTech Europe

* Other, e.g., Australia/New Zealand, Canada, China

The report of MedicalMountains

With a survey (December, 2023) and detailed view on the innovation ecosystem in Germany and presented at the NoBoCap summit provided for in their survey of 514 companies including start-up and scale ups (with investor financing) that

for 88% the US is the preferred market and

58% will discontinue product offering in EU due to certification cost (91%) and bureaucracy (74%).[9]

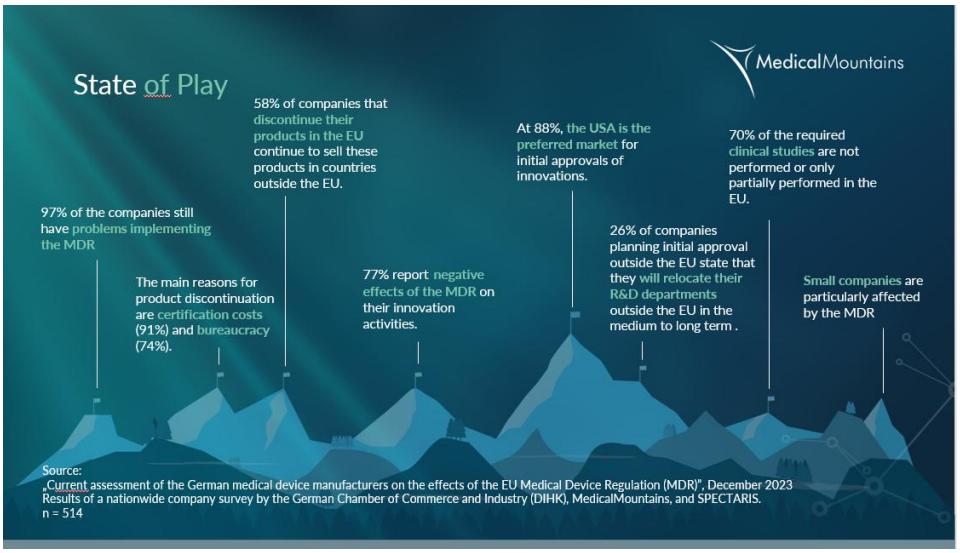

Figure 21 Innovation ecosystem in Germany, 2023
Source: MedicalMountains

The observed decline in companies choosing Europe for a first regulatory approval is particularly notable, given that CE-marking currently acts as a complete or partial passport to over 100 jurisdictions around the world.

Some regions such as Switzerland, Brazil, UK and Australia are reviewing their policies in terms of allowing devices with regulatory decisions from other jurisdictions such as the US, to access their markets.

[9] Source: „Currentassessment of the German medical device manufacturers on the effects of the EU Medical Device Regulation (MDR)", December 2023. Results of a nationwide company survey by the German Chamber of Commerce and Industry (DIHK), MedicalMountains, and SPECTARIS. N = 514

Innovation

Investment in Research & Innovation in SME

In the MedicalMountains report for **77% of respondents a negative impact** on innovation activities.

In the MedTech Europe (which cover more median size SME) report it was indicated that for IVD the budget in SME's for R&D projects decreased for 34% and increased for 37%.

For MD the budget for R&D projects decreased for 33% of SMEs and increased for 41%.

But Innovation activities/projects for <u>new</u> devices declined with 59% in IVD and 54% in MD SME.

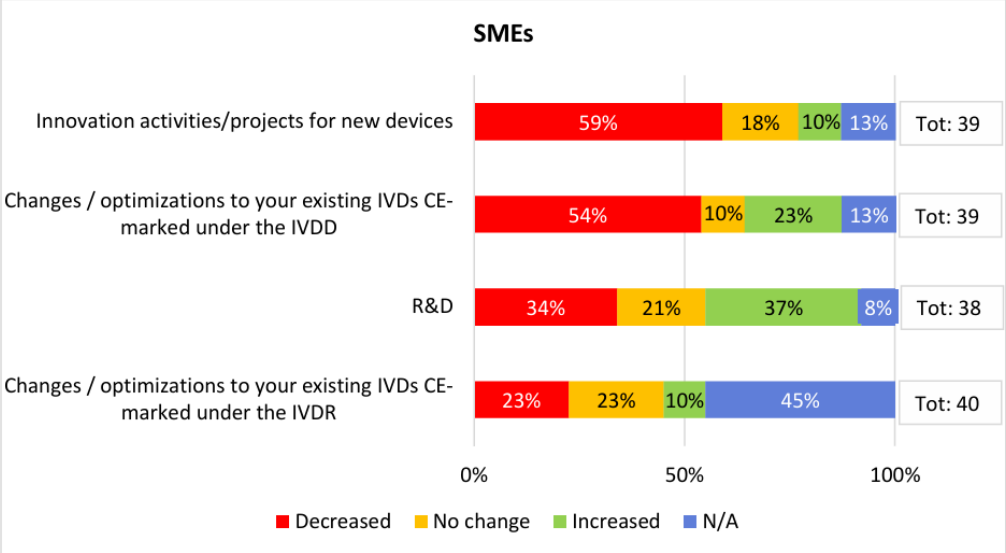

Figure 22 Impact on SMEs activities related to IVD
Source: MedicalMountains

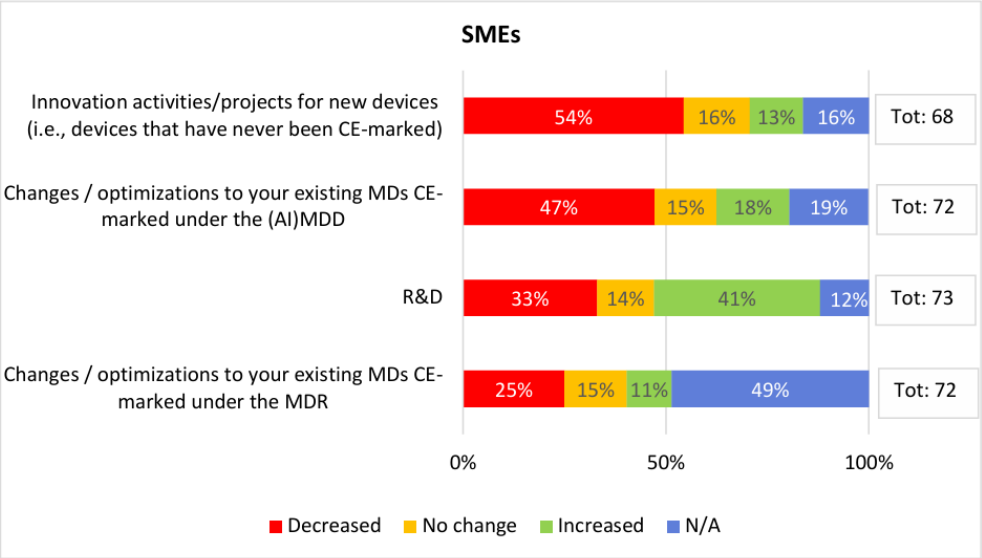

Figure 23 Impact on SMEs activities related to MD
Source: MedicalMountains

The report of Basque Health Cluster

The survey titled "Impact of MDR/IVDR on Innovation and Market Access in the Health Sector of the Basque Country" was conducted by the Basque Health Cluster to assess the challenges faced by companies in navigating the regulatory landscape under the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR). The results of the survey were published on May 15, 2023.

The survey was carried out using an online methodology, allowing for broad participation and efficient data collection. The participants consisted of companies associated with the Basque Health Cluster, representing a range of stakeholders within the healthcare, medical device, and diagnostics industries. The primary objective of the survey was to identify regulatory obstacles, access issues related to Notified Bodies (NBs), and the broader impact of MDR/IVDR on business operations and investment sentiment.

Summary of Key Aspects

Challenges with Local Access to Supportive Consultancy, CRO, and Notified Bodies (NB), Resulting in Additional Language Barriers and Costs

The report highlights significant challenges in accessing local consultancy, Contract Research Organizations (CROs), and Notified Bodies (NBs). Companies face difficulties due to the limited availability of such services within their region, requiring engagement with international providers. This reliance introduces language barriers, increases communication complexity, and adds regulatory compliance burdens. Additionally, working with international consultancy firms and NBs imposes higher financial costs, as translation, travel, and cross-border regulatory adaptation generate additional expenses. These factors collectively cause delays in certification and market entry, affecting the overall efficiency of the regulatory process.

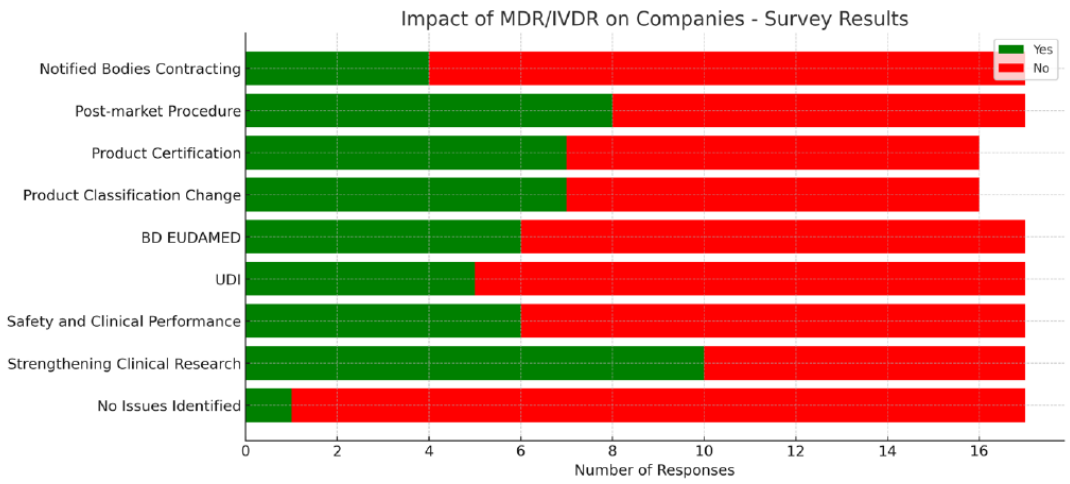

Figure 244 Impact of MDR/IVDR on Companies
Source: Basque Health Cluster

The Sentiment of the Investor Community with Focus on New Models

Investor sentiment, as presented in the report, reflects a cautious yet evolving perspective on new business models within the medical device and diagnostics sector. While there is interest in innovative regulatory and commercialization strategies, investors remain wary of the uncertainties introduced by evolving regulatory frameworks such as MDR and IVDR. The lack of streamlined pathways and prolonged certification timelines creates hesitancy toward early-stage investments. However, there is growing recognition of the need for adaptive business models that integrate regulatory expertise early in the development process, making companies more attractive for funding. Investors favour businesses that demonstrate proactive regulatory planning and risk mitigation strategies.

2. VIEW FROM THE INVESTOR COMMUNITY

Additionally, the section examines how investors evaluate start-ups and scale-ups, specifically focusing on the importance they place on regulatory competencies and preparedness to address regulatory hurdles as part of their investment criteria.

The European investor community, encompassing seed investors, venture capitalists, and other stakeholders, plays a pivotal role in advancing innovation within the MedTech, HealthTech, and Life Sciences sectors, particularly concerning Medical Devices (MD) and In Vitro Diagnostics (IVD). Investment decisions in these fields are intricately linked to the prevailing regulatory frameworks, jurisdictional competitiveness, and the regulatory preparedness of emerging companies.

Regulatory Framework and Investment Decisions

Investors in the European MedTech and Life Sciences sectors carefully evaluate the regulatory environments of potential investment destinations. A supportive and predictable regulatory framework is essential for fostering investor confidence. The transition from the Medical Devices Directive (MDD) and In Vitro Diagnostics Directive (IVDD) to the Medical Devices Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR) represents a significant shift in the regulatory landscape. This transition introduces more stringent requirements for clinical evidence, post-market surveillance, and supply chain transparency. While these regulations aim to enhance patient safety and product efficacy, they also present challenges (as noted above) for companies, particularly small and medium-sized enterprises (SMEs), in terms of compliance costs and timelines. Investors must consider these factors when making funding decisions, as regulatory hurdles will impact the time-to-market and return on investment.[10]

Jurisdictional Competition

In assessing investment opportunities, investors conduct competitive analyses of various jurisdictions. Factors such as regulatory efficiency, availability of skilled labor, tax incentives, and market size are critical in these evaluations. A report by EuropaBio highlights that for LifeScience sector in general, that countries like Germany and Switzerland lead in several indicators, including the availability of qualified staff and the size of the MedTech market. Ireland is noted for its strong position in manufacturing, attributed to high labor productivity and favorable tax policies. These disparities influence investment flows, as investors may prefer jurisdictions that offer a conducive environment for MedTech innovation and commercialization.[11]

Competitive Analysis of Start-ups and Scale-ups

When evaluating start-ups and scale-ups in the MedTech and HealthTech sectors, investors prioritize the companies' ability to navigate complex regulatory landscapes. A firm's regulatory preparedness is often a determinant of its potential for success. Investors favour businesses that demonstrate a comprehensive understanding of relevant regulations and have strategies in place to address compliance challenges. According to a report by Deloitte, there has been

[10] https://www.medtecheurope.org/wp-content/uploads/2024/07/medtech-europes-facts-figures-2024.pdf
[11] https://www.europabio.org/wp-content/uploads/2023/10/Life-Science-Attractiveness-2023-October-22-Final.pdf

a decline in investment and startup activity in MedTech, which could put future innovation at risk. This trend underscores the importance of regulatory competence in securing sustained investment.[12]

Regulatory Preparedness: Venture Capital Perspective

From the venture capital perspective, regulatory preparedness is a critical investment criterion. Firms that proactively engage with regulatory requirements and exhibit robust compliance frameworks are more likely to attract investment. The European Investment Bank's report on the scale-up gap highlights that many European companies face difficulties in raising capital during their growth phases, making them vulnerable to economic downturns. This underscores the importance of regulatory competence in securing sustained investment.[13]

In conclusion, the investor community in the EU places significant emphasis on regulatory frameworks, jurisdictional competitiveness, and the regulatory preparedness of start-ups and scale-ups within the MedTech, HealthTech, and Life Sciences sectors. Efforts to harmonize regulations and enhance compliance capabilities are essential to attract and retain investment within the European Union.

Despite existing insights, key gaps remain in understanding how investors assess regulatory risks in MedTech, HealthTech, and Life Sciences. There is limited quantitative data on how MDR/IVDR influences investment decisions, delays time-to-market, and impacts funding allocation. Additionally, investor perspectives on jurisdictional competitiveness, exit strategies, and early-stage funding challenges are unclear. A deeper understanding of how investors evaluate regulatory preparedness in startups is still missing. Addressing these gaps through targeted data collection would provide critical insights for improving investment conditions and to address Europe’s competitiveness and leadership in medical innovation.

[12] https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-medtech-innovation.pdf
[13] https://www.europabio.org/wp-content/uploads/2023/10/Life-Science-Attractiveness-2023-October-22-Final.pdf

3. SPECIFIC OPERATIONAL INITIATIVES TO FOSTER TIMELY ACCESSIBILITY OF INNOVATION WITHIN THE EUROPEAN MDR/IVDR REGULATORY ENVIRONMENT

This section outlines concrete initiatives undertaken to foster a preparedness, accessibility and an innovation-enabling regulatory environment in Europe. It provides insights into concrete and tangible efforts (complementary to the general policy initiatives described in section 1.1) aimed at addressing and overcoming challenges posed by the regulatory framework and its implementation, with a particular focus on supporting innovators and ensuring timely access to innovation within European healthcare systems.

The initiatives discussed are those most prominently targeting innovators such as startups, scale-ups, and micro and small enterprises part of innovation hubs and clusters. Initiatives include actions by Notified Bodies, EMA, and national/ regional health authority but a special attention is given to those led by EU4Health initiative NoBoCap and by those organizations involved in the NoBoCap Community, including contributions from knowledge and know-how partner as well as innovation hubs/hubs.

Additionally, the section highlights EU-level efforts in the field of regulatory science, which further contribute to play a critical role in building an innovation-friendly regulatory environment in Europe. These initiatives aim to bridge the "valley of death" for innovators, creating a competitive, attractive, and predictable regulatory landscape that supports timely market accessibility and growth.

3.1 Notified Bodies

The MedTech Europe report indicated following supportive activities by their Notified Bodies for them:

Structured Dialogue:

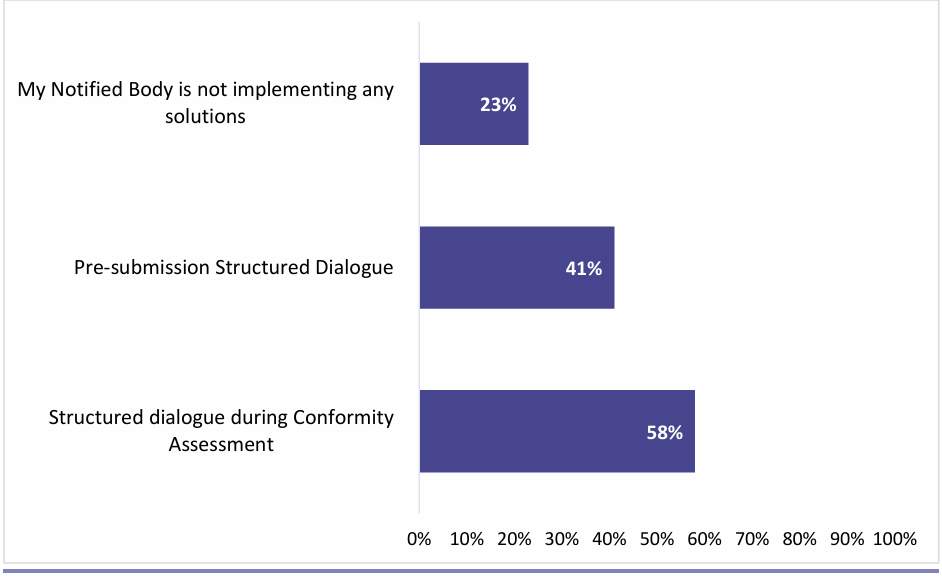

Figure 25 Supportive activities by the manufacturers' Notified Bodies
Source: MedTech Europe

Structured dialogue during Conformity Assessment was chosen 47 times and Pre-submission Structured Dialogue 33 times. This taken from the MedTech Europe report. The degree that micro and small companies can rely on these remains unclear.

Further clarified in the recent revision of the MDCG2019-6 Revision 5, of 5 February 2025, a structure dialogue (given a contractual agreement with NB is in place) may exchange views on the sufficiency of clinical data on which the clinical evaluation is based, including possible applicability of Article 61(10) of MDR, equivalence of the device under assessment with another device as well as the appropriateness of the post-market clinical follow-up plan

Such kind of structured dialogue in the early phase after submission of the application can significantly increase the predictability of the conformity assessment process without jeopardising the notified body's independence or impartiality.

In the context of the structured dialogue, questions by the manufacturer should respect the notified body's independence, objectivity and impartiality requirements, i.e., they should not be open-ended and need to avoid expecting solutions on "how to comply" thus ensuring that no consultancy services are taking place (see also Q&A I.6.1). The responsibility to meet the regulatory requirements remains with the manufacturer.

Conditional Certification:

At the NoBoCap Summit, a session was dedicated to the use of Conditional Certification and its conditions for use. The key insights discussed included:

Certificates with Conditions play an essential role in regulatory compliance under EU MDR 2017/745 and EU IVDR 2017/746, allowing Notified Bodies to issue approvals when pre-market data is limited or when enhanced post-market surveillance is needed.

While historically rare (<1% under previous directives), these certificates were primarily used for novel devices in controlled market releases. MDCG 2022-14 promotes their broader application to support MDR/IVDR implementation, while MDCG 2024-10 highlights their importance for orphan devices, ensuring post-market clinical data collection. They provide a pathway for innovative devices with limited preliminary data to enter the market while maintaining safety and performance through real-world monitoring.

These certificates typically require frequent reporting via Post-Market Clinical Follow-up (PMCF) reports, ensuring continuous oversight. However, they should not be used as a workaround for pre-market data requirements but rather as a regulatory tool to address legitimate challenges in medical device certification.

NB preparedness for emerging innovative technologies

Multiple NB have initiative to perform a horizon scanning to build out the necessary expertise for emerging technologies. Within the context of the NoBoCap project a cooperation is set-up to conjointly define a standardized form to the identification of emerging technologies.

A scope matching platform by a NoBoCap Matching platform is in development to enable for the innovators to have a structural description of their novel technological development and indication of NB Code expression and clinical application, so NB part of the NoBoCap community can provide matching expertise and be in timely dialogue.

Further to have a timely view on emerging novel technologies that will require an adjustment of the MDR/IVDR, the Medical Devices Coordination Group on New Technologies commissioned a Horizon Scanning for an early identification and recommendation.

3.2 EMA

The European Medicines Agency (EMA) in plays especially for Pharmaceuticals and Advanced Therapies a pivotal role in shaping regulatory practices and advancing regulatory science to foster innovation in the healthcare sector. As secretariat for the “expert panel” the EMA also established (as foreseen in the MDR) a **scientific advice procedure** which in as of Feb. 2025 available, after reviewing the findings of a pilot project of February 2023, where the agency provided free scientific advice to 10 companies.

The EMA scientific advice portal is now open to manufacturers of class III devices and class IIb active devices intended to administer or remove medicines that have questions about clinical matters. The questions can only cover clinical investigations that are yet to start.

While in the pilot, the EMA prioritized devices for unmet medical needs and novel devices with a possible major clinical or health impact. Going forward, the agency said it will only use those criteria to prioritize requests “should the number of submissions for a given time slot exceed the capacity of the expert panels.”

The pilot also prioritized devices for use against rare diseases. However, the EMA subsequently started a separate pilot focused on orphan devices for rare diseases. The

agency is encouraging manufacturers of orphan devices to consider seeking advice via the rare disease pilot, which it plans to run until the end of 2025.

The EMA strategic approach to regulatory science emphasizes continuous improvement and adaptability, ensuring that European healthcare remains at the forefront of innovation. Notably, the Regulatory Science to 2025 initiative and the European Platform for Regulatory Science Research are key efforts aimed at addressing gaps in regulatory practices, but primarily focusing on medicine development.

Table 3 EMA Initiatives

Initiative	Description	Source
Regulatory Science to 2025	The European Medicines Agency's strategy to advance regulatory science, aiming to build a more adaptive system that encourages innovation in human and veterinary medicine.[14]	EMA
European Platform for Regulatory Science Research	An initiative by EMA and the Heads of Medicines Agencies to identify research needs and foster collaboration in regulatory science, addressing gaps in medicine development and evaluation.[15]	EMA

3.3 Specific Initiatives Supporting SMEs, Startups, and scale ups to unlock MDR/IVDR Regulation for Innovation

3.3.1 National/Regional Health Authorities Initiatives and Investments to unlock MDR/IVDR regulation for Innovation

The European Union member states have implemented various initiatives to support innovators, particularly small and medium-sized enterprises (SMEs). These initiatives aim to facilitate innovation by providing guidance, financial aid, and streamlined regulatory processes. Below is a table summarizing some key supportive government initiatives:

Certainly, here is the information organized in the Table 4.

Table 4 Initiatives to support innovators

Initiative	Country	Description	Data Source

[14] https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-strategy
[15] https://www.ema.europa.eu/en/about-us/what-we-do/regulatory-science-research

Arclimed	France	ARCliMeD is a French initiative funded by the Agence Nationale de la Recherche (ANR) to address the shortage of qualified professionals in the medical device sector, especially in regulatory and clinical affairs. It responds to the stricter European regulations (EU 2017/745 and 2017/746) that require companies to have personnel ensuring compliance. The project aims to provide personalized training for students and professionals specializing in quality management, regulatory affairs, and clinical evaluations, focusing on small and medium-sized enterprises (SMEs) in the medical device sector.	Arclimed
Guichet National Innovation et Orientation (GIO)	France	Managed by ANSM, this initiative supports innovators in health product development by providing regulatory navigation assistance.[16] **Diagnostic Dispositif Médical by Bpifrance:** This service helps startups and SMEs navigate regulatory, quality, and clinical research processes, including implementing quality management systems, obtaining CE marking, and developing clinical study protocols. A co-financing is provided for use of a supportive Consultancy Network in France. **France 2030 Plan:** This strategic plan allocates €400 million to the medical device industry, aiming to support the 1,500 companies in the sector.	ANSM
Le Guichet d'Innovation	France	A French national platform providing regulatory and financial tools for digital health projects to accelerate market entry.[17] **Regulatory Guidance.** The platform offers tools (resources, guidance, and	G_NIUS

[16] https://ansm.sante.fr/vos-demarches/industriel/guichet-innovation-et-orientation-gio
[17] https://gnius.esante.gouv.fr/fr

		connections) to help digital health companies navigate complex regulations, ensuring compliance and accelerating market entry. **Financial Support for Compliance & Innovation.** France offers several financial aids to support innovation, particularly for small and medium-sized enterprises (SMEs). The **Crédit d'Impôt Recherche (CIR)** supports R&D through tax credits, benefiting SMEs by fostering innovation and growth. However, its impact is greater on smaller firms, sparking discussions on reallocating funds. The **Crédit d'Impôt Innovation (CII)** complements CIR by funding SME prototypes and technological innovations. In 2021, about 10,300 companies received an average of €35,000. With the CII set to expire soon, its renewal is crucial to sustaining SME innovation.	
HI-NL Evidence Generation Advice	Netherlands	Health Innovation Netherlands (HI-NL) offers evidence generation advice through its Round Table service, providing multi-stakeholder guidance to innovators. This service is co-funded by the Dutch Ministry of Health, Welfare and Sport, which granted €1.5 million to expand HI-NL's innovation services.[18]	Health Innovation Netherlands

3.3.2 European Initiatives

NoBoCap Initiatives

Initiatives developed under NoBoCap project to support SMEs, Startups, scale-ups to unlock MDR/IVDR for Innovation follows training programs and matchmaking platform.

- Training programs – included short-term and long-term courses that addressed specific topics related to MDR and IVDR.

[18] https://www.healthinnovation.nl/news/hi-nl-receives-eur-15m-grant-expand-its-innovation-services

The NoBoCap training program was designed based on research that followed 2 directions: existing training program on the market as well as needs analysis.

Existing training program on the market. Desk research conducted by the NoBoCap Team to landscape MDR and IVDR training programs was based on keywords collected by the report team from discussions, feedbacks and surveys targeted towards NBs representatives as well as EC representatives, such as: Artificial Intelligence, Machine Learning & Big Data; Advanced Materials, Nanotechnology and Surface Coatings; Cyber Security; Drug-device Combination Product; IoT, Wearables and Connected Health; Generative Design, Advanced & Additive Manufacturing; Robotics; Related regulations, legislation (specifically those of greater interest such as Article 117, Annex XVI, Art 61.10, UDI Art. 22); Clinical and PMS Manufacturing process validation; Clinical evaluation; Risk management connection to CEP / CEAR; Post Market Surveillance; MDR QMS requirements exceeding what is provided by ISO 13485; Software as a medical device. Other criteria considered: provider (focus was on the providers within the EU space, but not exclusively), format (online / offline), price, duration, level (beginner, intermediate, advanced), audience (specialists / non-specialists). Most of the identified courses were online, very short courses / training sessions are free of changer and the subjects / themes are interconnected. But more specialized themes are subject to trainings offered by consultancy companies with relevant experience in the field and educational platforms with contracted specialists, with prices varying from several hundreds to several thousands (over 3,000 euros) per participant. This makes the training process of companies' staff a pretty expensive one and often without the possibility to exclude them for paying consultancy firms to actually work on the dossiers needed for certification of their products. Durations of these courses also vary from 10 hours to 200 hours.

Table 5 Training programs

Initiative	Description	Details	Timeline / Participants
Learning Pathway Modules	Training program based on identified gaps in MDR/IVDR knowledge.	Modules developed through desk research & stakeholder feedback, covering AI, cybersecurity, risk management, post-market surveillance, etc.	Course durations vary (10-200 hours), cost ranging from free to €3,000+ per participant

Needs analysis. In order to perform an extensive need analysis, the project team collected information that implementation of the project provided at different steps from both market operators as well as regulatory authorities: an online market operators survey (continuous research), First Course Requirements Report, First Technical Course Report, Learning Needs analysis (technical) report, Landscaping MDR and IVDR training programs as well as feedback from different entities (EC, SMEs, NBs, MDCG IVD WG).

This research let to a complex training program that include:

2 short courses developed and provided under the coordination of project partner MEDVIA:

- MDR/IVDR Implementation and Resource Allocation for C-level management of MOs;
- AI-supported Medical Devices.

MDR/IVDR Implementation and Resource Allocation for C-level management of MOs is a specialized short course for C-level executives that offers practical training on effectively allocating time, budget, and other essential resources needed by market operators to prepare comprehensive dossiers for Notified Bodies. The course was delivered in a hybrid format in 6 sessions of 2-hours each on a weekly basis, in order to interfere as little as possible with the executives' usual activity. In 2024, there have been provided 2 sessions of this course for a total of 35 participants. Two more sessions are planned to be provided in 2025 (Q2 and Q4).

AI-supported Medical Devices short course dives deeper into the complexity and specificities of AI supported medical devices. The course was delivered in person to specialists from market operators in a 3-day training period. Both sessions of this course will be provided in 2025, first one starting on 10th of February and the second one in Q4, for a number of 25 participants / session.

- 3 modules of long courses, accredited by two partners in the project: TU Dublin and UMFST Tg. Mures:

- **Module 1** - Medical Device Regulation (MDR) - Implementing Regulatory Requirements for Medical Devices.

The program is designed to meet the requirements of the medical device industry and professionals who wish to develop advanced capabilities, building on their knowledge and experience in science and/or engineering and working in the medical device sector. Ideally, candidates should be responsible, individually or as part of a team, for ensuring full regulatory compliance, now and for years to come. The program is primarily intended for manufacturers (or virtual manufacturers) and focuses on integrating medical device risk management into quality and risk management systems. It is also relevant for distributors, importers or authorized representatives.

- **Module 2** - Medical Device Regulation (MDR) – Generating Data for Technical Documentation.

The program is designed to meet the requirements of the Medical Devices industry and professionals who wish to develop advanced capabilities, building on their existing knowledge and experience in science and/or engineering and working in the Medical Devices sector. The content of the course, however, focuses on two very technical issues with which manufacturers are currently affected by the implementation of the Medical Devices Regulation (EU 2017/745); that is, the construction of the Technical File and the Clinical Evaluation Report.

- **Module 3** - Generating Data for Technical Documentation (IVDR).

The program is designed to meet the requirements of the in vitro diagnostic medical device industry and professionals who wish to develop advanced capabilities, building on their knowledge and experience in science and/or engineering and working in the in vitro diagnostic medical device sector. The course content focuses on two very technical issues currently affecting manufacturers due to the implementation of the In Vitro Diagnostic Devices

Regulation (IVDR EU 2017/746); that is, the construction of the Technical File and the Performance Evaluation Report.

Each of the module has a 10-weeks duration (8 weeks course delivery and 2 weeks assessment preparation) with a total of 100 hours (for both teaching and self-directed learning), and are awarded with 5 credits EQF7 Certificate.

The most important features of the profile of the candidate for each of the 3 modules are: holding a university graduation diploma and working experience in a company with activity in the medial field that is established within the European Union borders. Also, students that accomplished one of the modules will be invited to follow the others, too (especially with regards to Module 1 and 2).

During the first 2 years of the project, 3 sessions of Module 1 have been organized within Technological University of Dublin for a total number of 123 participants. One session of Module 2 and one session of Module 3 were also organized within Technological University of Dublin with 50 and respectively 46 students. In the following year, more sessions will be delivered under UMFST accreditation: 2 more sessions for Module 1 (first one starting on 7th of February) and 2 more sessions of Module 2 (first one planned to start in March). One more session on Module 3 is under discussion for 2025.

Table 6 NoBoCap Training Programs

Initiative	Description	Details	Timeline / Participants
Short Courses	Specialized short courses addressing MDR/IVDR implementation challenges.	- *MDR/IVDR Implementation and Resource Allocation for C-level management of MOs* (Hybrid, 6 sessions of 2 hours) - *AI-Supported Medical Devices* (In-person, 3-day training)	- *MDR/IVDR*: 2 sessions (2024), 35 participants; 2 sessions planned (2025, Q2 & Q4) - *AI-Supported MD*: First session (Feb 2025), second session (Q4 2025), 25 participants/session
Long Courses (Accredited Modules)	In-depth regulatory courses accredited by TU Dublin & UMFST Tg. Mures.	- *Module 1:* MDR Implementation for Medical Devices - *Module 2:* Generating Data for Technical Documentation (MDR) - *Module 3:* Generating Data for Technical Documentation (IVDR)	- *Module 1:* 3 sessions in TU Dublin, 123 participants; 2 more sessions planned in UMFST Tg. Mures (2025-2026) - *Module 2:* 1 session in TU Dublin (50 participants); 2 more planned in in UMFST Tg. Mures (2025-2026) - *Module 3:* 1 session in TU Dublin in 2024 (46 participants); 1 more

			session under discussion for 2025

Matchmaking platform and digital tools

The platform was built around the identified needs of its envisaged main beneficiaries: manufacturers - seen as innovators (to guide them to an appropriate NB to begin the process of achieving the necessary certificate(s) of conformity to validate that the technology developed adheres to the stipulated regulations), NBs (to offer a high-level overview of specific demand and supply based on the availability and requirement of capacity at Code-level), policy makers (to identify potential sign of market / policy failure that require policy interventions and enhance the accessibility of novel technologies).

Specific features to help MO:

1. **Matchmaking modules** that will specifically allow manufacturers to input their data during the product development phase and match it against the available services of Notified bodies within the relevant scope (match by scope).
2. **Emerging Technology Information Form** - completed by the market operators early in the lifecycle to enable Notified Bodies to have sufficient information to prepare a matching expertise knowledge to evaluate such novel technologies (match by availability).
3. **E-guided tool** - a guided learning on how the MDR/IVDR is applicable and to obtain the NB Codes to identify the NB designated for conformity assessment of your technology. The e-tool translate the complex structure to find the information into a streamlined information flow.

Table 7 Matchmaking Platform & Digital Tools

Initiative	Description	Features
NoBoCap Matchmaking Platform[19]	Platform designed to connect manufacturers, Notified Bodies, and policymakers.	- Match by Scope: Helps manufacturers find Notified Bodies based on product scope. - Match by Availability: Uses an Emerging Technology Information Form to enable Notified Bodies to prepare expertise for novel technologies.
NoBoCap E-Guided Tool[20]	Interactive tool to enhance understanding of MDR and IVDR regulations.	- Interactive guidance through MDR/IVDR applicability. - Short demo video for user navigation. - The NB Codes to identify the NB designated for conformity assessment of your technology. - Clarification on definitions, examples,

[19] https://portal.nobocap.eu/nexus
[20] https://portal.nobocap.eu/codes

		and references to MDCG Guidance. - Report generation with applicable NB-Codes and designated Notified Bodies.

3.3.3 NoBoCap Community

Table 8 NoBoCap community

Initiative	Description	Features
NoBoCap Community[21]	A collaborative platform for Innovation Hubs/Cluster of start-ups, SMEs, and partners, to unlock the MDR/IVDR for innovation by facilitating access to backbone services and tool and have a voice to inform EU policymaking.	- Access to regulatory expertise and knowledge partners. - Connection to innovation hubs and supportive organizations. - Opportunity to voice concerns, share insights, and shape the ecosystem. - Training and updates on EU legislative developments. - Direct interaction with peers and stakeholders to enhance collaboration.

Specific support provided by the NoBoCap project can be accessed by signing up to the NoBoCap ENVIRONMENT: portal.nobocap.eu .

Specific support that NoBoCap Community know-how and knowledge partners provide to Start-ups /SME you can find in the NoBoCap Repository of EU Regulatory Support here.[22]

3.3.4 EU Initiatives on Regulatory Science and Harmonization in Testing and Clinical Investigation (“Common Specifications”)

The European Union (EU) has implemented several initiatives to advance regulatory science, aiming to foster innovation while ensuring public health and safety. Below is a table summarizing key EU initiatives in this domain.

Table 9 EU Initiatives on Regulatory Science

Initiative	Description	Data source

[21] https://nobocap.eu/community-members-partners/
[22] https://nobocap.eu/repository-of-eu-regulatory-support/

EU4Health: Horizon Scanning for Medical Devices and In Vitro Diagnostic Medical Devices	Assess the adequacy of existing regulatory framework and areas to provide guidance and common specifications	European Commission
Horizon Europe: MDOT Project	The EU-funded MDOT project helps SMEs navigate MDR requirements by developing a digital data platform tailored to regulatory needs.	cordis.europa.eu Helping MedTech innovators navigate a river of regulation
Horizon Europe: EU Methodological Frameworks for Medical Devices and In Vitro Diagnostic Medical Devices (IVDs) –-HLTH-2024-IND-06-08	A specific call under Horizon Europe aiming to develop and harmonize methodologies for assessing medical devices and IVDs, enhancing their safety and performance evaluations.[23]	European Commission
Testing and Experimentation Facilities (TEF) – Health	Part of the Horizon Europe framework, TEFs provide environments for testing AI-based solutions in real-world settings, particularly in healthcare. They aim to bridge the gap between research and market deployment.[24]	European Commission
Innovative Health Initiative (IHI) Calls	Successor to the Innovative Medicines Initiative, IHI launches calls for proposals to fund cross-sectoral health innovations, focusing on areas like digital health, advanced therapies, and medical technologies.[25]	IHI Official Website

3.3.5 Local public and private service providers

A multitude of public and private service providers provide a consultancy – know-how / knowledge support.

Within the NoBoCap Community know-how/knowledge partners can apply and following a quality scrutiny can join. Currently, there are 23 partners from YY countries. The accepted Know-How partners are listed under Community Members & Partners – NoBoCap .

Furthermore, a comprehensive list is available at www.nobocap.eu/community/repository-of-eu-regulatory-support under the **Repository of EU Regulatory Support – NoBoCap**, which includes initiatives we have identified.

[23] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2024-ind-06-08
[24] https://digital-strategy.ec.europa.eu/en/activities/testing-and-experimentation-facilities
[25] https://www.ihi.europa.eu/

4. Recommendations from the Innovation Community

MedicalMountains Presents Concrete Recommendations for MDR Implementation Improvements

Position Paper: "Suggestions for Changes by MedicalMountains GmbH for More Planning Security, Reasonable Effort, and Lower Costs When Implementing the MDR[26]"

This position paper, a collaborative effort developed by approximately 30 medical device manufacturers, was published in July 2024. It articulates a series of practical recommendations aimed at enhancing the implementation of the Medical Device Regulation (MDR). While primarily focused on addressing the challenges faced by small and medium-sized enterprises (SMEs), the paper has garnered endorsement from larger companies within the sector as well. The core objective of these recommendations is to advocate for swiftly implementable, sub-legislative measures that can streamline processes, improve efficiency, and alleviate undue burdens associated with MDR compliance.

Key Challenges Identified by Manufacturers

The position paper highlights several critical challenges currently facing medical device manufacturers under the MDR framework:

- Excessive administrative burden due to unnecessary regulatory requirements.
- Disproportionate costs that are not aligned with the risk and value of the product.
- Lack of predictability and planning security for manufacturers.

Proposed Solutions for MDR Implementation Enhancement

To address these challenges, the position paper puts forth the following proposed solutions:

1. **Unlimited Certification Validity**
   - Eliminate the mandatory five-year re-certification cycle for all risk classes following successful initial certification.

2. **Simplified Clinical Evaluation for Low-Risk Devices**
   - For medical devices in risk classes I, I*, and certain non-active IIa products that have been on the EU market for at least five years, a full Clinical Evaluation Plan (CEP) and Clinical Evaluation Report (CER) should no longer be mandatory.

3. **Adjusted Post-Market Surveillance (PMS) Reporting Intervals**
   - Modify the Periodic Safety Update Report (PSUR) intervals for risk classes IIa to III: after four years of market presence, the interval should be extended to two years for class IIb and III devices and to four years for class IIa devices.

4. **Practical Application of Equivalence and Established Technologies**
   - Allow equivalence assessments without requiring contractual agreements between competing manufacturers.
   - Provide clearer definitions for “well-established technologies” and “similar” products.

[26] https://medicalmountains.de/wp-content/uploads/2024/10/MDR_Suggestions-for-short-term-changes_2024.pdf

5. **Digitalization and Language Simplification**
   - Enable electronic Instructions for Use (eIFU) to reduce time, costs, and resource consumption.
   - Limit the number of required translation languages within the EU to streamline processes.

6. **Harmonized Digital Approval Processes**
   - Implement a uniform, digitized approval process between manufacturers and Notified Bodies.
   - Abolish the requirement to populate national databases once the relevant EUDAMED modules become mandatory.

7. **"Total Cost" Model and Binding Notified Body Deadlines**
   - Establish a pre-agreed, transparent cost model for compliance assessments, ensuring consistency across the EU.
   - Implement binding deadlines for Notified Bodies to prevent delays.

8. **Creation of a Central MDR Office at the EU Level**
   - Establish a dedicated office to harmonize MDR requirements across Notified Bodies, EU member states, and manufacturers.
   - Ensure uniform interpretation and resolution of regulatory issues.

By effectively addressing these identified challenges and diligently implementing the proposed solutions, the MedicalMountains position paper aims to contribute significantly to the creation of a more predictable, cost-effective, and ultimately innovation-friendly regulatory landscape for medical device manufacturers operating within the European Union.

5. A CHANGING ENVIRONMENT – NEW REGULATIONS TO UNLOCK FOR INNOVATION ACCESS

This section covers further European horizontal and sectorial regulation that is /will be applicable to medical devices and in-vitro diagnostic medical devices,

The Artificial Intelligence Act (AI Act)

The Artificial Intelligence Act (Regulation (EU) 2024/1689), henceforth referred to as the AI Act, published in the Official Journal of the European Union on 12 July 2024. This pivotal legislation establishes a comprehensive regulatory framework designed to govern artificial intelligence (AI) within the European Union.

To fully understand the scope of the AI Act, it's crucial to consider the following provisions:

- **Establishment of Uniform EU Rules:** The AI Act introduces horizontal legislation at the European Union level, setting forth standardized requirements for AI systems intended for the EU market. This ensures a consistent and harmonized approach to regulatory oversight across member states.
- **Alignment with Product Safety Standards:** Mirroring existing internal market product safety regulations, the AI Act is applicable to the placement on the market, putting into service, and utilization of AI systems. This integration underscores the importance of safety considerations throughout the lifecycle of AI technologies.
- **Core Objectives:** The AI Act is driven by several core objectives, notably:
    - To effectively address and mitigate the risks to health, safety, and fundamental rights that may arise from the development and deployment of AI technologies.
    - To cultivate a unified and robust single market within the EU specifically for trustworthy and reliable AI solutions.
- **Risk-Based and Innovation-Supportive Approach:** The regulatory framework of the AI Act is predicated on a risk-based methodology. This approach ensures intervention is proportionate and targeted, avoiding unnecessary regulatory burdens that could stifle innovation and progress within the AI sector.
- **Transparency Obligations for Generative AI:** Recognizing the unique characteristics of generative AI, the Act includes specific transparency obligations for operators of these systems. This measure aims to promote accountability and effectively mitigate potential risks associated with generative AI technologies.
- **Support Mechanisms for Innovation:** To actively encourage AI development and innovation, the regulation facilitates the establishment of regulatory sandboxes. These controlled environments provide a safe and supportive space for the testing and validation of novel AI systems and applications.
- **Enhancement of Legal Certainty and Market Trust:** A primary goal of the AI Act is to provide clear and unambiguous legal guidance for AI operators. This clarity is

intended to foster greater confidence in AI technologies, thereby contributing to the development of a competitive and equitable market environment.

- **Global Scope of Applicability:** The AI Act's provisions are designed to apply to AI systems regardless of the geographical origin of the producer or user. This global applicability ensures a level playing field for entities operating within the EU market, whether they are based within or outside of the European Union.

In conclusion, the AI Act represents a significant and forward-looking step in the governance of artificial intelligence within the European Union. It is strategically designed to balance the imperative of ensuring safety and upholding fundamental rights with the need to foster competitiveness and maintain a dynamic environment conducive to ongoing technological advancement in the field of AI.

NoBoCap project and its community partners provide supporting initiatives on this topic:

- **AI Act and NoBoCap Shortcourse** to comply with regulatory requirements (see section 3.3.2, Table 6, page 42). Registration is possible through NoBoCap portal here.[27]
- **AI Act and understanding the applicability** using NoBoCap partner Lean Entries released AI Act E-tool (see section 3.3.3, Table 7, page 43).

New EU Rules for Health Technology Assessments

As of 12 January 2025, the new EU regulation on health technology assessment (HTAR) (Regulation (EU) 2021/2282) comes into effect, marking a significant advancement in accelerating and expanding access to innovative medicines and medical technologies. The European Medicines Agency (EMA) is prepared to support the implementation of these new measures, working in collaboration with the European Commission and Member States[28].

Key Implications:

- **Enhanced Coordination and Access:** The regulation establishes a structured EU framework for Joint Clinical assessment (JCA) to be taken into consideration at time of National Health Technology Assessment.
- **Support for Decision-Makers:** By facilitating collaboration on clinical evidence expectation of HTA bodies, the regulation aims to improve access to medical devices.
- **Expansion Over Time:** For Medical Devices a selected group of products will have a JCA. A selection of those in scope of the regulation which are the high-risk medical devices Class III, IIb with a drug delivery that have an MDR / IVDR expert panel opinion/view. For all other technologies a voluntary cooperation of member states in the context of HTA can take place A primary focus is foreseen for digital medical devices. **EMA's Role in Implementation:**
- **Joint Scientific Consultations (JSC):** EMA will collaborate with the HTA Coordination Group (HTACG) to provide a possibility to request in parallel scientific advice to technology developers, on the planned generation of evidence for regulatory and JCA.

[27] https://portal.nobocap.eu/short-courses
[28] https://www.ema.europa.eu/en/news/new-eu-rules-health-technology-assessments-become-effective

- **Information Exchange and Horizon Scanning:** The emerging health technology subgroup will seek to perform a Horizon Scanning and evaluate the expected impact and organisation and financial consequences expected. **Operational Considerations:**
- The first request period for JSCs will commence in June 2025, with and 1 to 3 for medical devices planned for the year.

Conclusions & Key Findings

The **Second Annual MD/IVD Industry Pulse Report** highlights the significant challenges that the evolving regulatory landscape presents for innovation, market access, and investment in Europe. Lengthy certification timelines, often exceeding 18–24 months, remain a critical barrier, particularly for SMEs. The high costs associated with compliance, including certification, post-market surveillance, and regulatory adjustments, place an additional financial strain on companies, with many struggling to meet the demands of the MDR/IVDR framework. Furthermore, limited access to Notified Bodies (NBs) and inconsistencies in requirements contribute to bottlenecks, delaying approvals and discouraging new market entrants.

Financial and market pressures are also reshaping the strategies of SMEs and startups. Rising costs have forced some companies to reconsider their presence in the EU, while investment uncertainty due to unpredictable certification expenses has made securing funding more difficult. As a result, an increasing number of businesses are shifting their focus to other regions, such as the US, where regulatory processes may be perceived as more predictable and cost-effective for early market entry.

Despite some government-backed initiatives aimed at supporting innovators, the level of assistance varies significantly across countries. While financial aid and compliance guidance exist in some regions, there is still a widespread need for structured training and regulatory support. Many companies struggle with dossier preparation, which prolongs approval timelines and increases costs. Additionally, platforms like NoBoCap are playing a key role in addressing these gaps by connecting innovators with regulatory expertise and fostering collaboration across the ecosystem.

To enhance regulatory efficiency and maintain Europe's competitiveness in MedTech and HealthTech, stakeholders are calling for adjustments to MDR/IVDR implementation. Proposed solutions include more flexible certification processes, particularly for low-risk and well-established technologies, as well as improved transparency around costs and approval timelines to help SMEs plan effectively. Additionally, with emerging technologies such as AI and digital health solutions becoming increasingly important, better integration of the AI Act and Health Technology Assessment regulations with existing MDR/IVDR frameworks is essential to ensure a cohesive and innovation-friendly regulatory environment.

Next Steps & Community Input

To improve the regulatory landscape and support innovation, the Pulse Report seeks additional input from community members and partners:

- **Country-specific initiatives**: Review and provide data on national support programs.
- **Local surveys & insights**: Share findings on MDR/IVDR impact within innovation hubs.
- **Feedback on regulatory gaps**: Identify critical areas requiring EU-level reforms.

By addressing these challenges and fostering collaboration, the NoBoCap Community can help shape a more innovation-friendly regulatory environment in Europe.