MedTech Europe
from diagnosis to cure

Report on Administrative Burden under IVDR and MDR

MedTech Europe's Proposal for IVDR/MDR Targeted Evaluation

18/03/2025

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Introduction

This document is dedicated to the European Commission as part of the targeted evaluation of EU rules on medical devices and *in vitro* diagnostics.

The European Commission President Ursula von der Leyen has stated her Number 1 priority is competitiveness and prosperity. Within this area, Europe needs less reporting, less bureaucracy, and more trust, better enforcement and faster permitting. A focus on Small and Medium Sized Enterprises (SMEs) also is needed, and here she wants to reduce administrative burden and simplify reporting requirements, amongst other points. In addition, the Mission Letter for Health and Animal Welfare Commissioner Olivér Várhelyi calls on him to "ensure the availability and competitiveness of medical devices, including by stepping up the implementation of the current framework and evaluating the need for potential legislative changes."

Administrative burden has been identified as a key barrier for *in vitro* diagnostic medical devices (IVD) and medical devices (MD) innovation in Europe. Based on recent data from the EY survey on the Study on Governance and Innovation, which was contracted by the European Commission, approximately 60% of IVD and medical device manufacturers refer to administrative burden and costs of regulatory approval as the most important regulatory barriers for bringing innovative devices to the EU market[i]. Due to IVD Regulation (EU) 2017/746/EU (IVDR) and MD Regulation (EU) 2017/745/EU (MDR)[1], over 70% of IVD and MD manufacturers had to allocate more resources to regulatory compliance efforts[i].

While it is evident that administrative burden creates significant hurdles for bringing and maintaining IVDs and medical devices on the EU market, to date there has been no specific investigation into the sources of administrative burden directly or indirectly caused by IVDR and MDR. More precisely, the administrative burden that have no or little added value and/or are very inefficient as compared to the effort and cost invested in achieving regulatory compliance. Any administrative burden imposed on the manufacturers should be well-justified and valuably contribute to achieving compliance. With this report, MedTech Europe aims to identify the main areas of administrative burden under IVDR and MDR that are unnecessary or inefficient in achieving compliance and proposes recommendations how it could be reduced without adverse impact on the objectives of the IVDR and MDR as laid down in their preambles 1 and 2 (including providing for a robust, transparent, predictable and sustainable regulatory framework for IVDs and MDs which ensures a high level of safety and health whilst supporting innovation, a smooth functioning of the internal market as well as the great many SMEs which are active in the sector[2]). It is almost impossible for any such review to be comprehensive; nonetheless this report aims to collect as much information as possible.

[1] Further in this document term 'regulation(s)' refers to MDR and/or IVDR (depending on the context), unless otherwise specified, and 'directive(s)' refers to Directive 93/42/EEC (MDD) and/or Directive 90/385/EEC (AIMDD) and/or Directive 98/79/EC (IVDD) (depending on the context), unless otherwise specified

[2] See first and second preambles to IVDR and MDR. The objectives have been paraphrased.

In addition to the specific areas which are called out in the below report, it is important that the European Commission considers where to reduce administrative burden in IVDR and MDR by looking at how governance, requirements and resources are allocated within the overall regulatory system. The current governance system can lead to a patchwork of interpretation, lack of risk-based approach throughout the whole certification lifecycle or different paperwork expectations which is confusing and burdensome. Often, administrative burden is created by layering requirements on top of other requirements. While each requirement may seem to have good reasons when seen in isolation, their layering creates an overall cumulative effect leading to inefficiencies and complexity which can be devastating especially for SMEs. It should be considered which requirements really are needed and which requirements are 'nice to have' in order to achieve the objectives laid out in preambles 1 and 2 of IVDR and MDR. In effect, the current system should be adjusted and simplified to achieve those objectives in the least burdensome way.

What is administrative burden?

Based on the European Commission's Action Programme for Reducing Administrative Burden in the European Union and other relevant literature, administrative burden can be defined as the cost to business or citizens of carrying out administrative activities that they would not carry out in the absence of regulations that impose information obligations, but that they have to undertake in order to comply with it [ii,iii,iv]. A distinction ought to be made between:

- **necessary administrative burden** (areas of burden that ensure the realization of underlying policy objectives and regulatory compliance) and
- **unnecessary administrative** burden (areas of burden that either do not ensure the realization of underlying policy objectives or which do but are either duplicative or highly inefficient in achieving policy objectives and regulatory compliance) [v].

Objective:

- **What?** This paper aims to map out the main areas of administrative burden under IVDR/MDR which could be considered unnecessary due to their little or no added value to IVDR/MDR policy objectives and regulatory compliance, namely:
  "… robust, transparent, predictable and sustainable regulatory framework for in vitro diagnostic medical devices [and medical devices] which ensures a high level of safety and health whilst supporting innovation".
- **Why?** The identified areas of unnecessary administrative burden (What?) are followed by justification as to why they should be considered unnecessary or inefficient in achieving regulatory compliance. Data and/or examples are provided where available.
- **How?** This paper identifies strategies where administrative burden can be simplified by streamlining administrative processes or improving/eliminating requirements and practices that have little to no added value to help businesses and citizens to comply with EU legislation or national obligations to achieve regulatory compliance [vi]. The criteria for identifying appropriate administrative burden reduction strategies used in this paper are listed in the table below. These eight administrative burden reduction criteria were adapted from European Commission's Action Programme for Reducing Administrative Burden in the European Union and European Commission's public consultation "Administrative burden – rationalisation of reporting requirements" [iv,vii].

1 Changing frequency/timing	2 Eliminating duplication
Reduce the frequency/timing of reporting requirements to the minimum levels necessary to meet the substantive objectives of the legislation and align the frequency of reporting across different related pieces of legislation, where possible;	Review whether the same information obligation is requested several times through different channels and eliminate overlaps;
3 Introducing digitalisation	**4 Considerations for SMEs**
Require the transition from paper-based information gathering to electronic and web-based reporting, utilizing intelligent portals where feasible. Optimise electronic processes already in place;	Introduce thresholds for information requirements, limiting them wherever possible, or rely on sampling; *(it is well known that SMEs particularly suffer strongly from administrative burden – data collection for information purposes should take this into account)*
5 Applying risk-based approach	**6 Eliminating unnecessary requirements**
Consider substituting information requirements on all businesses in a sector by a risk-based approach – targeting information requirements on those operators that perform the highest risk activities or have high risk class devices taking a least burdensome and risk-based approach which considers the limited resources available to manufacturers, Notified Bodes (and authorities);	Reduce or eliminate information requirements where these relate to substantive requirements that have been dropped or modified since the information requirement was adopted (e.g., there are still information obligations in road transport dating back to the time that permits were required to carry out international transport);
7 Providing guidance	**8 Applying 'Once only' principle (OOP) (EU added value)**
Provide official clarification of complex pieces of legislation that may either slow down business activities or require acquiring legal expertise;	Applying the 'once only' principle that implies that businesses will not have to provide the same data for different obligations or replacing when possible 27 different points of entry with one at EU level;

- **When?** In addition to the proposed improvement strategies, MedTech Europe also proposes the most suitable timeframe to best achieve these improvements:
  - **Short-term measure**: proposed improvements could be best achieved relatively fast within months, without changing MDR/IVDR, for example through guidance;
  - **Mid-term measure**: proposed improvements which should be achieved in the mid-term, using the tools foreseen within the IVDR or MDR (e.g., implementing and delegated acts) or by other means;
  - **Long-term measure**: proposed improvements which need more time to be implemented, for example could only be achieved through legislative reform or structural changes.

How to read this document?

The administrative burden listed in this paper has been divided per these IVDR/MDR areas:

- IVD Performance Evaluation
- MD Clinical Evaluation and Clinical Investigation
- Notified Body assessment
- Post-Market Surveillance
- European Database on Medical Devices (EUDAMED)
- European Medical Device Nomenclature (EMDN)
- Economic Operators requirements

- Digitalisation
- Other (outside of the scope of the above areas).

The listed burden has been defined in terms of what constitutes the unnecessary administrative burden (**What?**), why it is unnecessary or inefficient in achieving regulatory compliance, including details about the process, data and examples (**Why?**), and proposals for improvement (**How & When?**). The **Top 5** in each area have been prioritized based on their level of impact: where the most resources, costs, and time could be saved for manufacturers. Please, note that the top 5 list of administrative burden in each area are not listed in an order of priority (e.g. top 5 can be as important as top 1). Each improvement proposal is categorized according to the principles of administrative burden (table mentioned above) and ranked as either a short-, mid- or long-term measure.

Most of the administrative burdens are applicable for both MD and IVD sectors, however, where a sector specific burden is applicable it is labelled as '**IVD specific**' or '**MD specific**'.

Note: this report attempts to be as concise as possible, however, MedTech Europe is happy to provide more comprehensive information where needed.

IVD Performance Evaluation

The submission and notification of performance studies under IVDR face challenges at both national and EU levels due to fragmented processes, inconsistent requirements, and high administrative burdens. Lack of coordination among ethics committees and regulatory authorities causes delays, while the absence of a harmonised EU approach adds complexity. Uncertainty around Competent Authorities' roles further exacerbates inefficiencies, driving companies to relocate studies to other jurisdictions, limiting patient access and weakening Europe's role in clinical research. Aligning the requirements for Performance Studies with a streamlined approach used in pharmaceutical clinical trials would help reduce fragmentation and improve efficiency.

Another area of inefficiency is the requirement of Summary of Safety and Performance (SSP). Complex content requirements and inconsistent Notified Body expectations, as well as mandatory translation into all EU languages are burdensome on manufacturers and complicates compliance. Simplifying SSP requirements would improve efficiency and reduce unnecessary costs.

What?	Why?	How & When?
TOP 1 **IVD specific: Authorization and notification process for performance studies is burdensome, non-harmonised and costly in terms of time and financial investment**	The submission and notification of performance studies under IVDR faces several challenges both at national and EU levels. At the national level, there is a lack of coordination and harmonization among various ethics committees and regulatory authorities, leading to inconsistencies in requirements and delays in approvals. At the European level, the absence of a unified approach between different countries further exacerbates these issues, creating complexity for manufacturers. Additionally, the evolving processes and uncertainty surrounding the roles of Competent Authorities contribute to confusion and inefficiencies. These factors, combined with cumbersome and time-consuming procedures, result in significant administrative burden and increased costs, particularly in terms of high fees for submissions and notifications. Moreover, many companies are currently relocating their performance studies to the US to avoid delays. This shift limits patient access to innovative medications and diagnostic solutions in Europe. Furthermore,	In the pharmaceutical industry, the assessment and supervision of clinical trials has been harmonised across the EU by eliminating the fragmented assessment process for multinational clinical trial applications. This has allowed for a single approval decision from the National Competent Authority and Ethics Committee per member state, streamlining the process. Applying a similar approach to the IVD sector and taking the experience gained would help reduce the current fragmentation and uncertainty surrounding performance study (PS) requirements, which vary significantly across countries, regions, and hospitals. To further enhance efficiency and coordination, the following solutions should be implemented: **Short-term measure** **Eliminating duplication** of efforts by ensuring that assessments and approvals are only required once for multinational studies. A common European IVD Ethics Committee should be established. Additionally, we

What?	Why?	How & When?
	it diminishes Europe's scientific contribution to clinical research, particularly regarding cost-benefit analysis. These challenges highlight the need for greater alignment and simplification to ensure smoother and more efficient processes for submission and notification of performance studies under the IVDR. Examples for burdensome, non-harmonised and costly IVDR authorization and notification process for performance studies can be consulted at Annex I.	suggest the use of hramonised application forms/templates (standardized submission packages) across the countries. **Mid-term measure** **Introducing digitalization** to modernise and simplify the submission process, improving transparency and data management. Templates already exist to enable a harmonised submission process. **Long-term measure** **Applying the 'Once Only' Principle (OOP)**, a key EU initiative, to minimize the administrative burden and streamline regulatory processes across member states. These changes would not only increase regulatory efficiency but also provide added value at the EU level, creating a more cohesive and predictable framework for IVD performance study approvals. Additional solutions are proposed in Commission's analysis of the requirements for submitting PS alongside clinical trials, see COMBINE project report[3].
TOP 2 **IVD specific: Coordinated assessment start date is too late**	Current submissions per Member State are cumbersome with Member States creating their own additional requests and sponsors are burdened with many discrepancies and manage different processes at the same time. Coordinated assessment is foreseen in the IVDR. However, the legal due date/date when it becomes binding is projected to be in 2033 due to the delay of EUDAMED. A pilot coordinated assessment is about to be launched for medical devices but this will not be legally binding, and the sponsors participating in the pilot may have to repeat the process at national level. Even if the national level process gets expediated it still remains burdensome as opposed to having one coordinated assessment.	**Long-term measure** **Applying 'Once only' principle (OOP) (EU added value)** Bring forward the legal start date for using coordinated assessment as the only way to assess applications to 2028 to align with the launch of the CIPS module. Additionally, applications going through the pilot coordinated assessment process before 2028 should be deemed assessed without having to apply again at national level.

[3] COMBINE CTR-IVDR-MDR ANALYSIS PHASE REPORT

What?	Why?	How & When?
TOP 3 IVD specific: Summary of Safety and Performance (SSP)	The **Summary of Safety and Performance (SSP)** was intended for device transparency, but there are several important aspects that are inefficient when it comes to implementing SSPs in practice which create burden and costs for the manufacturer. Average costs per SSP are between 3,519€ and more than 5,000€ per one SSP document for Notified Body review fees (this excludes 'internal' development and translation costs by the manufacturer)[26]. The burdensome SSP aspects include: 1. **SSP content**: The SSP is meant to be a summary, but the current requirements for it are very detailed and specific. This is resulting in additional burden as the level of detail consistently opens the SSP to be considered incorrect or incomplete. This mandates more updates and creates more burden of translation. Content has become heavily regulatory focused on terminology and text which is too detailed to be understood by the target audience. Simplifying and harmonising SSP requirements would reduce these inefficiencies and better serve its purpose as a concise summary. In addition, there is inconsistency between Notified Bodies regarding the level of supporting information required to be submitted to them when they perform SSP review (e.g., IFU, PMPF, Risk Management are required by some Notified Bodies). 2. **SSP translation**: Requirement to translate SSP into all languages accepted in the Member States where the device is envisaged to be sold, brings a significant administrative burden. Management of translations within EUDAMED is expected to be an additional complex exercise in the near future. For many languages the translated SSP is not likely to be consulted, hence we question the need for proactive translation. For example, some manufacturers report that an SSP has only been requested once and that was for the English version. In addition, some manufacturers report the Notified Body validation of SSP taking a year or longer, and after it	**Short-term measure Simplify SSP content requirements** The focus should be shifted back to the original purpose of the SSP to provide information in a way that is concise and understandable to lay users and patients. SSP should not present information in detail like the Performance Evaluation Report (PER) or other regulatory documents, it needs to be simple summary report. In addition, requirements for the Notified Body's review process and what supporting information is to be provided needs to be harmonised. The MDCG 2022-9 should be updated to clarify this, e.g. by removing footnote 4 which states that SSP should be more detailed that IFU. **Eliminate unnecessary requirements:** • **Short-term measure** Remove unnecessary translations: based on experience of very low rate of translations requests, SSP translations should be provided only upon request in a reasonable timeframe. In addition, only English translations should be validated by Notified Bodies while other translations validation can be based on the manufacturer Standard Operating Procedure (SOP), as it already happens for the IFUs. • **Short-term measure** Make the review of SSPs for sampled devices part of the sampling rather than requiring 100% of SPPs to be reviewed. Amend MDCG 2022-9 footnote 4. • **Long-term measure** Remove SSP requirement for class C and D devices other than self-test IVDs.

What?	Why?	How & When?
	has been validated, the manufacturer has little time to translate to all languages (sometimes as little as 90 days). 3. **SSP for class C and D devices other than self-test IVDs**: SSP is currently required for all SSP class C and D IVDs. While SSP seems to be an important summary document for lay users using self-tests, it seems to be of little added value for professionals who are using these devices daily, given that SSP currently is mostly a duplication of Instructions for Use. Furthermore, tests ordered for patient samples by healthcare professionals for which the patient receives quantitative or qualitative results often are interchangeable to the professional user and therefore not subject to a discussion with the patient. The healthcare professional receives results from testing and provides a diagnostic and therapeutic picture to the patient, where a single test result often plays only one part of the overall picture. It should also be considered that providing the SSP to lay-users with information on how to read professional-use test results, without healthcare professional interpretation, raises additional risk of misinterpretation where the patient attempts to read test results in isolation. 4. **Frequency of review:** MDCG 2022-9 footnote 8 states that "Draft SSPs that are not validated at the initial conformity assessment should be validated against relevant documents in the technical documentation at least once during the period of validity of the certificate." This means that every single SSP for class C devices – even devices which are subject to sampling – needs to be reviewed within the first 5-year cycle and again at least once every 5 years. This directly conflicts with the principle of sampling of technical documentation – since every SSP must be compared with its technical documentation. A disproportionately large cost for the IVD sector and investment in time by Notified Bodies is needed, since class C represents ~25 % of the total market. This also means that	

What?	Why?	How & When?
	review of SSP is given a higher priority than the review of devices themselves – which makes little sense from a risk perspective and from a resources-allocation perspective when looking at how resources should be distributed across the system to achieve the objectives under IVDR preambles 1 and 2.	
TOP 4 IVD specific: article 58.1(a) should not be applicable to performance studies involving routine blood draws	**Performance studies where venous and capillary blood is drawn in low-risk subjects and also studies involving sample taking by swab are not a high risk and therefore classifying them as such pose a significant burden to the system when included in the scope of art 58.1 (a) due to:** • Delay in getting new IVDs and novel therapies to European laboratories and patients. • Delay and reduction of treatment options for European citizens in clinical trials. • manufacturer's financial and administrative resources to pursue regulatory authorisations could be used for other areas, e.g., Research and Innovation. This is especially true for small and medium enterprises. • Diverging resources of Competent Authorities. • Adverse impact on other initiatives. A detailed overview of the delays and the impact to patients can be consulted in the MedTech Europe document 'IVDR article 58.1(a) should not be applicable to performance studies involving routine blood draws, Proposal for discussion'.[4]	**Long-term measure Eliminate unnecessary requirements** Exempt prospective blood draws where the amount of collected blood is not adding further risks to the patient from art 58.1(a).
TOP 5 IVD specific: The lack of a risk-based approach to the frequency of periodic	IVDR Article 56 requires the update of the Performance Evaluation Report for class C and D when necessary, but at least annually, even if there is no change in the benefit-risk ratio. There seems to be little added value for patient safety to keep updating the PER yearly when there are	**Long-term measure Changing frequency** Adapt frequency of PER update to follow necessary amendments e.g. changes in product Benefit-Risk ratio.

[4] MedTech Europe position paper Exemption of Routine Blood Draws from Article 58.1(a) of the IVDR

What?	Why?	How & When?
performance evaluation reports (PER) for high-risk class IVDs	no changes on the benefit-risk ratio of the product, no PMPF study in progress and no substantial changes that could impact patient safety. The need to update the PER (or not) is documented in the PSUR. Requirement for annual updates regardless of value towards patient safety, results in unnecessary administrative burden and potentially diverts resources away from more targeted safety and performance monitoring.	PER update for class C and D should be done when necessary and at least when there is a negative impact on the Benefit-Risk ratio of the device.
6. IVD specific: Divergent requirements for submission of performance studies for Companion Diagnostic tests	Submission approaches for companion diagnostic (CDx) studies differ across countries. Some require simultaneous submission of both diagnostic (Dx) and therapeutic (Rx) studies for concurrent evaluation, while others assess the trials separately. Since Dx studies still need to be submitted individually in each country, coordinating simultaneous submissions becomes challenging and requires additional resources. An interesting data source here comes from EFPIA's survey, Critical impacts of IVDR implementation on patient access to clinical trials.	**Short-term measure** **Introduce digitalisation and a Coordinated Assessment of submissions** **Long-term measure** **Simplifying the processes and shortening the time of assessments/making them more efficient** The challenges have been extensively described and solutions identified by the EU Commission's COMBINE project. The report is publicly available[5]:
7. IVD specific: the clinical evidence requirements are challenging to interpret, the lack of structured dialogue to discuss clinical strategy further exacerbates this complexity	Similar to the MD sector, the IVD sector would greatly benefit from the opportunity for structured dialogues. Currently, without pre-submission discussions between the Notified Body (NB) and manufacturer, the manufacturer applies a clinical strategy that may later be rejected by the NB, despite months or years of documentation. Moreover, the lack of clarity regarding the expectations for clinical evidence and the acceptable duration for follow-up means that some clinical studies conducted may ultimately prove unnecessary. 93% of respondents of a recent MedTech Europe survey highlighted that no clear definition of sufficient clinical evidence is an obstacle for legacy devices (as highlighted in the MedTech Europe Survey Report[6]). Moreover, for 30% of IVD respondents, certification was significantly	**Short-term measure** **Provide guidance** To increase predictability and ensure timely availability of devices to patients, it is crucial to allow a clearly defined and minuted discussion on clinical strategy between manufacturer and Notified Body to take place **before submission of the application for conformity assessment**. We strongly urge the European Commission and the EU Member States to **clarify in the foreseen implementing act for application of uniform rules for Notified Body requirements that high level discussion of clinical strategy can take place 'before submission of the application'.**

[5] COMBINE CTR-IVDR-MDR ANALYSIS PHASE REPORT
[6] MedTech Europe 2024 Regulatory Survey: Key Findings and Insights (IVD: Performance Evaluation section)

What?	Why?	How & When?
	delayed or threatened to fail due to Notified Body challenging their Performance Evaluation.	Please see MedTech Europe proposal in detail in the position paper on clinical strategy[7].
8. IVD specific: Redundant basic device information in different clinical and post-market reports	**Main source of admin burden**: requirement in regulation legal text The number of post-market and clinical reports under the regulation as compared to directive have increased substantially: there are in total approximately 11 new reports under IVDR that manufacturers have to maintain. In addition to the many new reports under the regulation, many of these clinical and post-market surveillance documents under IVDR repeat the same basic device information. The European Commission and the MDCG have made clear that each of the IVDR clinical and post-market surveillance documents should be standalone. The administrative burden to continuously maintain so many documents and ensure alignment in their verbiage is high. There is no need to have the same basic information spread across several different clinical and post-market documents, especially when it remains unchanged most of the time. For example, the device description, indications for use, warnings, etc. are used across Post-Market Surveillance Plan, Periodic Safety Update Report, Post-Market Performance Follow-Up Plan, Post-Market Performance Follow-Up Evaluation Report, Clinical Performance Evaluation Plan, and Performance Evaluation Report (see Annex III for report overview).	Short-term measure **Eliminating duplication** Leave it to the discretion of the manufacturer to clearly identify one document as a main source for the basic information (i.e., PMPF Evaluation Report and/or PSUR and/or PER) and other documents refer back to it. This would suffice to comply with the regulatory requirements whilst eliminating the quantity of duplicative information across documentation and reducing the unnecessary maintenance burden for manufacturers and Notified Bodies. This process and identification of the source document(s) should be included in the QMS.
9. IVD specific: Companion Diagnostic tests – requirements for the intended	In Europe, a Companion Diagnostic tests (CDx) is specifically linked to a particular medicinal product through the International Non-proprietary Name (INN) of the drug it is associated with. As a result, if a new drug for the same disease, or a different disease within the same category is introduced, the existing companion diagnostic cannot be used. In such	Short-term measure **Provide guidance** • Recognise that the intended purpose for CDx can include a broader medicinal group category, additional drugs within the same disease category can be covered by the CDx if supported by scientific evidence.

[7] Position Paper: Urgent call for clarity on clinical strategy discussions

What?	Why?	How & When?
purpose are unnecessarily stringent	cases, a new conformity assessment would be required. In contrast, other jurisdiction's agencies (e.g. U.S., Japan etc.) have the possibility, when the biological mechanism is common across the drug class (e.g. PD-L1 expression for multiple checkpoint inhibitors or EGFR mutations for different TKIs), for approval of the whole group of these drugs. This approach streamlines regulatory approvals and broadens clinical utility of the test. This regulatory discrepancy places the EU at a disadvantage, as it hampers innovation and slows down the availability of CDx especially for emerging therapies. Moreover, this rigidity delays patient access to personalized therapies.	• Issue (MDCG) guidance on structuring the intended purpose to be broad and cover disease category and the group of medicinal products, under the current framework. • Launch pilot programs to test flexible regulatory approaches for CDx in real-world scenarios, gathering evidence to support future regulatory changes, including a mechanism to extend the intended purpose post certification. **Long-term measure Eliminate duplication** Implement a streamlined conformity assessment process for multiple indications (drugs) in the single conformity assessment procedure.

MD Clinical Evaluation and Clinical Investigations

Clinical evaluation remains a complex part of MDR implementation. In the MedTech Europe MDR/IVDR survey[9], 50% of respondents indicated that their clinical evaluation for at least one application, was significantly challenged by their Notified Body. The top obstacle for those respondents was lack of clarity about clinical evidence expectations. This section outlines clinical evaluation challenges, as well as challenges specific to clinical investigations.

What?	Why?	How & When?
Clinical Evaluation		
TOP 1 MD specific: Maintenance / frequency of updates and redundancy of basic information in	The number of post-market and clinical reports under the regulation as compared to the directives has increased substantially: there are in total approximately 15 new reports under MDR that manufacturers have to maintain. In addition to the many new reports under the regulation, many of these clinical and post-market surveillance documents under MDR repeat the same basic device information. Maintenance of clinical	**Short-term measure Eliminate duplication & Provide guidance** 1) Leave it at the discretion of the manufacturer to clearly identify one document as a main source for the basic information (i.e., PMCF ER and/or PSUR and/or CER) and other documents refer back to it. This would suffice to comply with the regulatory requirements whilst

What?	Why?	How & When?
different clinical and post-market reports	documents (CEP, CDP, CER, PMCF-ER and SSCP) remains complex in terms of time, resources and content, despite improvements that have been put in place. Many of the clinical and post-market surveillance documents (PMS Plan, PSUR, PMCF Plan, PMCF Evaluation Report, CEP, CER) repeat the same manufacturer details, basic device information, for example the device description, indications for use, warnings, etc. The administrative burden to continuously maintain so many documents and ensure alignment in their verbiage is very high. On top of this CERs can be easily hundreds of pages long which adds to complexity of maintenance. Maintenance of clinical documents and post market reports can take up to 4 months every year (indicated by majority of respondents in MedTech Europe Survey Report[8]). Another challenge is that many of these documents need to be done sequentially, so this is part of the reason that updating these documents takes so long and by the time the data is submitted to the NB, it might be old.	eliminating the quantity of duplicative information across documentation and reducing the unnecessary maintenance burden for manufacturers and Notified Bodies. This process and identification of the source document(s) should be included in the QMS. 2) With regards to **frequency of update of CER and SSCP**: the need for an update of the clinical evaluation documentation (CER and related annexes) and of the SSCP for class III and implantable devices should be **determined after thorough analysis** by the manufacturer **of the current findings and conclusions of the annual PMCF evaluation report and PSUR**. CER and SSCP should be updated based on clinical data which may impact the device's risk/benefit profile, clinical performance, or safety. Both points can be addressed by the Clinical evaluation guidance currently under development by MDCG CIE.
TOP 2 MD specific: Lack of clarity on clinical strategy acceptance	Currently, without a pre-submission dialogue between Notified Body and manufacturer, a clinical strategy is applied by the manufacturer which later may not be accepted by the Notified Bodyafter MNF has applied it for months and years of documentation. Clarity is missing on what is expected in terms of clinical evidence and what kind of follow up (length of time) will be accepted. 50% of MD manufacturers have experienced at least one of their certificates being significantly delayed or closed negatively in many cases due to lack of	**Short-term measure** **Provide guidance** In order to increase predictability and ensure timely availability of devices to patients, it is crucial to allow a clearly defined and minuted discussion on clinical strategy between manufacturer and Notified Body to take place at an early stage **before submission of the application for conformity assessment**. We urge the European Commission and the EU Member States to **clarify in the foreseen implementing act for application of uniform rules for Notified Body requirements that high level discussion of clinical strategy can take place 'before**

[8] MedTech Europe 2024 Regulatory Survey: Key Findings and Insights (Post-Market Surveillance section)

What?	Why?	How & When?
	clarity about clinical evidence expectations (also see MedTech Europe Survey Report[9]).	**submission of the application'.** Please see MedTech Europe proposal in detail here[10].
TOP 3 MD specific: Overemphasis on Clinical investigations (clinical data coming therefrom): • **PMCF associated by Notified Bodies almost by default to PMCF investigations only;** • **Clinical investigations often expected for legacy /Well-established Technologies (WET)**	1. This 'overinterpretation' by authorities and Notified Bodies in asking for data from clinical investigations both pre- and post-market creates burden for new and legacy products. This was also indicated among the top 3 challenges during clinical evaluation in MedTech Europe survey[9]. It is time consuming and complex to run a PMCF clinical investigation as opposed to for instance a PMCF survey (e.g. 2 years versus 9 months for a PMCF survey). Clinical investigations should only be carried out when really needed considering that the MDR does allow for other sources of PMCF data and running of clinical investigations are an inefficient use of resources where not strictly needed. Costs of PMCF clinical investigations can be high, contributing to the manufacturer's decision to not make that device available on the EU market. 2. Perspective of ''every device is new and needs new clinical data'' leads to discontinuation of many legacy devices/WET with a safe profile and a long history on the market, plus it can be unethical to run such studies: Well-known devices do not bring any new benefit to the patient to justify risks and inconveniences of running a clinical investigation as per MDR art 62.4.(e). In addition, HCPs are not interested in such investigations. The principle of asking for clinical investigations by default, seems to persist in the recent drafts of MDCG guidance on clinical evaluation under the EU MDR. A more nuanced approach should be taken to ensure that clinical investigations are conducted where <u>really</u> needed.	**Long-term measure Eliminate unnecessary requirements** Include in implementation of the MD regulatory system, more emphasis on other **PMCF activities as allowed per MDR**. Possibly making this clearer in the text revision so Notified Bodies do not feel they must ask for PMCF clinical investigations as a default. **Legislative text in MDR should clearly distinguish between PMCF activities and PMCF clinical investigations.** **Short-term measure Provide guidance** More emphasis on PMS, PMCF data (use of RWE also from outside of Europe) and surveys for legacy devices based on risk-based approach.
TOP 4 MD specific: Inconsistency of	1. Sufficient clinical evidence; (also among the top 3 clinical evaluation challenges in recent Medtech Europe survey[9]) different	**Short-term measure Provide guidance**

[9] MedTech Europe 2024 Regulatory Survey: Key Findings and Insights (MD: Clinical Evaluation section)
[10] Position Paper: Urgent call for clarity on clinical strategy discussions

What?	Why?	How & When?
interpretations affecting key clinical evaluation concepts (sufficient clinical evidence & Well-established Technologies - WET)	opinions (Manufacturer/Notified Body and also between Notified Bodies and between reviewers within the same NB) that delays MDR certification as manufacturers' clinical strategy is not accepted, which leads to more discussions and longer timeline. 2. WET definition in section 1.2 of MDCG 2020-6 is only being used by some Notified Bodies, many do not accept it (due to exigencies by their CAs), instead they keep to the list provided in the MDR Art. 61. This leads to unrealistic clinical evaluation expectations for devices that have been on the market for years and have no safety issues but happen to not be called out specifically in the MDR text. This delays/hinders certification of standard of care devices and creates significant inconsistency between Notified Bodies.	Use the sufficient clinical evidence concept from MDCG 2020-6 for ALL devices and encourage early structured dialogue (prior submission for conformity assessment) between manufacturer and Notified Body to discuss sufficiency of clinical data. Also see point 2 of this section. **Long-term measure** **Apply risk-based approach** Include the definition from MDCG 2020-6 in the MDR text. Highlight that any device falling into this definition is to be examined with a risk-based approach – it might be *de facto* WET even if not specified on the list. **Mid-term measure** **Provide guidance** Expand the list of well-established technologies (WET) via a delegated act (initiative already in preparation by the COM). The act should equally mention the WET definition as a basis. Note, this list will need to be updated in a few years as more technologies become WET. Also, the WET concept should be expanded beyond the category of implantable and class III devices.
TOP 5 MD specific: Summary of Safety and Clinical Performance (SSCP) • **SSCP frequency of updates** • **SSCP content** • **SSCP translations**	MDCG 2019-9 Rev. 1 outlines that "When the PMCF evaluation report and the periodic safety update report (PSUR) are updated at least annually, **the SSCP shall be reviewed and updated** if needed to ensure that any clinical and/or safety information in the SSCP remains correct and complete". However, based on manufacturers' experience, some Notified Bodies are still expecting the manufacturers to update SSCPs with every PMCF evaluation report (PMCF-ER) and PSUR update, even if safety and performance data – the information which is most relevant to the user – has not changed. Doing so yearly without clear added value to the user creates an unnecessary costs and administrative burden for manufacturers and Notified Bodies. Costs can be reduced considerably.	**Short-term measure** **Eliminate unnecessary requirements** **Update the SSCP guidance MDCG 2019-9:** 1) clearly state that SSCP should not be updated annually with the PMCF-ER and PSUR unless there is essential information related to device safety and performance relevant to healthcare professional, patient, or user. Essential information constitutes new safety or performance clinical data (e.g., clinical investigations, literature, PMS, PMCF/PMPF) that changes the benefit-risk profile for the device or identifies new and/or unforeseen risks. New clinical data with no impact on the established benefit-risk profile should not, by default, be

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	Costs per SSCP can reach, on average, 3,519 € and range from <1000 to >5000 € per one SSCP document Notified Body review (excluding 'internal' development and translation costs by the manufacturer)[26]. In addition, there is inconsistency between Notified Bodies regarding the level of supporting information required for SSCP review (e.g., IFU, PMCF, Risk Management are required by some Notified Bodies). Example from one manufacturer working with 2 Notified Bodies: one Notified Body requires SSCP update when the PSUR and CER are updated, second one said that annual update is not required if the safety and performance information of the device is not affected. Content within the SSCP has been driven to be increasingly detailed and specific. This results in additional burden as the level of detail consistently opens the SSCP to be considered incorrect or incomplete, more updates and associated burden of translation. Content (as defined in guidance and based on Notified Body feedback) has become heavily regulatory focused. Resulting in terminology and content which is not understood by the target audience. **The SSCP is meant to be a SUMMARY, but this is becoming increasingly not the case.** **Requirement to translate SSCP** into all languages accepted in the Member States where the device is envisaged to be sold. With each update of the SSCP this brings a significant administrative burden to process translations and management within EUDAMED (once available). For many languages this may never be viewed hence proactive translation is unnecessary.	interpreted as essential information requiring an update to the SSCP. 2) drive harmonisation through agreed requirements for the Notified Body's review process & what supporting information is to be provided. 3) The SSCP revision number only as per manufacturer's QMS should be included This will help simplify maintenance of the SSCP. Return guidance and reviewers' focus to the original purpose of the SSCP, e.g. to provide information in a way that is concise and digestible to ensure understanding by patients and HCPs. Remove perspective that SSCP should present information in detail like the CER or other regulatory documents. Short-term measure **Eliminate unnecessary requirements** **Update the SSCP guidance MDCG 2019-9** Based on actual experience of very low rate of requests to provide translated SSCPs, solely English version of SSCP should be provided by default. Any SSCP translations should be provided upon request within a reasonable timeframe. Translated SSCPs should not be subject to Notified Body validation. The Notified Body validation was already being addressed by the draft revision of the SSCP guidance MDCG 2019-9. We suggest that the streamlined provisions on translations and English version only as a default are included in this ongoing guidance revision.
6. MD specific: Analysis of the clinical data required	manufacturers shall conduct a clinical evaluation in accordance with Article 61 and Annex XIV of the MDR, including a Post-Market Clinical Follow-up (PMCF). Per MDR Annex XIV Part B, paragraph 5, PMCF is a	Long-term measure **Remove duplicating requirements**

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in the Post-Market Clinical Follow-Up Evaluation Report (PMCF-ER)	continuous process that updates the clinical evaluation. When conducting PMCF, the manufacturer proactively collects and evaluates clinical data with the aim of confirming the safety and performance throughout the expected lifetime of the device. This data gets added to the CER. Per MDR Annex XIV Part B, paragraph 7, the manufacturer analyses the findings of the PMCF and documents the results in a PMCF evaluation report (PMCF-ER) that shall be part of the CER and the technical documentation of the device. MDCG 2020-8 guides manufacturers with respect to the compilation of the PMCF-ER. However, the template requires an analysis of the same clinical data included in the CER but is not the same as that in the CER while achieving the same purpose. This makes the documentation confusing, highly burdensome and duplicative, as well as adds to high maintenance costs. The average costs for the PMCF-ER can reach 3,519 € and there is a great variation in costs being paid to Notified Body for PMCF evaluation which can range from less than 1,000 € to more than 5,000 €[26].	The original CER requirement should be slightly altered in the MDR text as follows: MDR Annex XIV Part A, paragraph 4 4. The results of the clinical evaluation and the clinical evidence on which it is based shall be documented in a clinical evaluation report which shall support the assessment of the conformity of the device and **include the results of the PMCF.** MDR Annex XIV Part B, paragraph 7 7. The manufacturer shall analyse the findings of the PMCF and document the results **in a PMCF ER or the CER** that shall be part of ~~the CER that~~ the technical documentation of the device.
7. MD specific: Clinical benefits	1) Devices with indirect clinical benefits As indicated in Annex XIV part A (1), a clinical evaluation shall include a detailed description of **intended clinical benefits to patients with relevant and specified clinical outcome parameters;** However, as indicated in MDCG 2020-6, section 1.1: "*It should be noted that clinical benefits may be either direct or indirect; for example devices such as guidewires may assist other medical devices in achieving their intended purpose, without having a direct therapeutic or diagnostic function themselves.*" An example of a device with an indirect clinical benefit is a Universal image viewer (MDSW): as the device is a workflow support tool, clinical	**Short-term measure** **Provide guidance** 1. Elaboration of a guidance document by MDCG regarding devices with indirect clinical benefits and the use of surrogate endpoints of clinical benefits and how this relates to the requirement in the MDR to provide a detailed description ***of intended clinical benefits to patients with relevant and specified clinical outcome parameters (Annex XIV part A (1)).*** For some of the devices with indirect clinical benefits, it makes sense to interpret 'relevant clinical outcome measure' to mean the evidence that would be required to demonstrate the device is safe and performs as intended, requiring a combination of design validation, compliance to standards and post-market surveillance data.

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	benefits cannot be expressed in terms of measurable, patient-relevant clinical outcomes. Another example is a guidewire. 2) Devices with a broad intended use Some devices are used in so many different kinds of procedures that it would not be practical or beneficial to define the clinical benefits associated with them. CT scanners may be used in a wide variety of different imaging applications, and sutures in a wide variety of soft tissue approximations. In general, for these kinds of devices, the benefit is that they perform their intended function (with the implication being that there is a clinical benefit to doing so). Similarly, it would not be beneficial to list out every procedure in which a scalpel, needle or syringe could be used, or to define the clinical benefits of these procedures.	A determination of the level of clinical evidence required to demonstrate an indirect clinical benefit should be made on the basis of a thorough risk assessment and evaluation of short-, medium- and long-term clinical risks (for example, a guidewire, although used transiently, may have long term clinical risks if it leads to vessel dissection). Although direct clinical benefits should be supported by clinical data, indirect clinical benefits may be demonstrable by other evidence such as: • pre-clinical and bench test data (e.g. compliance to product standards or common specifications); • real world data such as registries, information deriving from insurance database records, etc.; • data from another device that is used with the subject device which does have direct clinical data (e.g., data from a stent used to justify safety and performance of a guidewire) (based on MDCG 2020-6). 2. Elaboration of a guidance document by MDCG regarding devices with a broad or generic intended use for which it is not practical or beneficial to define the clinical benefits associated with them and to define measurable endpoints.
8. MD specific: Realistic expectations needed for PMCF surveys from Notified Bodies	Currently some Notified Bodies expect PMCF surveys at the level of Good Clinical Practice, which is burdensome, difficult to put in practice and drives the cost higher to be similar with a PMCF investigation. This is not the purpose of the PMCF survey which is a PMCF activity and should not be confused with PMCF investigation. The user feedback structured surveys are not Good clinical practice (GCP) studies, and there should not be any such expectations for their design. However, they should be acceptable when it comes to devices with indirect clinical benefits. These types of surveys are especially	**Long-term measure** **Eliminate unnecessary requirements** Clearly distinguish through a legal amendment of the MDR between PMCF investigations and other PMCF activities such as a survey. This should be implemented by Notified Bodies.

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	helpful for MDD devices being transitioned to MDR and/or WET devices and are associated with acceptable cost.	
9. MD specific: Article 61 (10): non-clinical data	Clarification for MDR Article 61 (10) is missing. This creates uncertainty especially for medical devices falling into the low to moderate risk class (Class IIa) and in the moderate to high (class IIb) risk class, where the requirement to perform a clinical investigation for the demonstration of conformity with the general safety and performance requirements (GSPR) is not imposed by the legislation. With the current advances in technology, medical device testing environments are expanding. Considering this, digital twinning, curative databases, computer modelling, use of physical or digital phantoms, generation of artificial patients or use of retrospective patient data may provide controlled and scientifically valid concepts to be utilized as non-clinical data within the device's clinical evaluation. The focus on the assessment within the clinical evaluation should be on scientific validity of the testing methodology, test case design and the output, whether the data can be extrapolated to the expected clinical use of the device and in the intended clinical use environment, and whether the non-clinical data solely or in addition to clinical data is sufficient to cover all clinically relevant characteristics and claims made on the device by the manufacturer, and thus demonstrate the conformity of the device with the applicable GSPRs.	**Short-term measure** **Provide guidance** Elaboration of MDCG guidance regarding the use of non-clinical data to demonstrate conformity with the applicable GSPRs (e.g. could be included in the MDCG clinical evaluation draft).
Clinical Investigations		
TOP 1 MD specific: Article 74: **a. Art 74 not regulating PMCF clinical investigations without additional**	a) Article 74(1) MDR explicitly regulates only PMCF clinical investigations if the subjects are submitted to invasive or burdensome procedures in addition to the normal conditions of use of the device. PMCF clinical investigations without such additional invasive or burdensome procedures are not explicitly regulated in Article 74. This leads to confusion, differences in interpretation, expectations and	**Long-term measure** **Eliminate unnecessary requirements** a) Clarification of the legal classification of post-market clinical investigations of a device **within the scope of its intended purpose**, in which subjects are NOT submitted to additional invasive or burdensome procedures compared to the normal conditions of use of the device ("Non-notifiable PMCF investigations").

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procedures to those performed under the normal conditions of use of the device, or where additional procedures are not invasive or not burdensome	divergent practices among Member States and Ethical Committees (ECs) as some classify such PMCF clinical investigations as other clinical investigations per Article 82 MDR.	**Targeted changes to the MDR legal text art 74:** 1. Where a clinical investigation is to be conducted to further assess, within the scope of its intended purpose, a device which already bears the CE marking in accordance with Article 20(1), ('PMCF ***clinical*** investigation'), and where the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic system referred to in Article 73. ~~*The sponsor shall include the documentation referred to in Chapter II of Annex XV as part of the notification.*~~ Points (b) to (k) and (m) of Article 62(4), Article 75, Article 76, Article 77, Article 80(5) ~~and (6)~~, and the relevant provisions of Annex XV shall apply ***to PMCF clinical investigations referred to in the first sentence.*** Proposal Art 74(3) *(new):* "*The provisions of Articles 62 to 82 and Annex XV shall not apply to PMCF clinical investigations in which subjects are not submitted to procedures additional to those performed under the normal conditions of use of the device, or where subjects are submitted to additional procedures but those additional procedures are not invasive or not burdensome*"
b. PMCF clinical investigations treated as Article 82 studies by some Member States, creating discrepancies in	b) There is confusion, differences in interpretation, expectations and divergent practices among all stakeholders (EU Member States, ECs, Sponsors and Investigators) on which clinical investigations fall within the scope of Article 82. Once a Sponsor has determined that a post-market clinical investigation falls within MDR Article 82, the Sponsor shall meet national legislation and submit/notify (if applicable) the clinical investigation to the relevant ECs and Competent Authorities	b) Targeted change to Article 82: add to paragraph 1: *Clinical investigations, not performed pursuant to any of the purposes listed in Article 62(1)* ***or Article 74(1) (i.e. PMCF clinical investigations),*** *shall comply with the provisions of Article 62 (2) and (3), points (b), (c), (d), (f), (h), and (l) of Article 62(4) and Article 62(6).*

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requirements and divergent practice	(CAs) in each of the EU Member States where the investigation is planned to be conducted. Example: due to the divergence of harmonization/interpretation of MDR Article 82, the Sponsor received feedback from ECs and/or CAs that the study was either not a clinical investigation at all or that it shall rather fall within Article 74(1). This triggered a significant burden for the Sponsor to justify. Ultimately, if after further discussion, the Sponsor's rationale is not accepted by the EC and/or the CA, the Sponsor may have to withdraw participation of a given country given that the same clinical investigation cannot be conducted under different MDR regulatory pathways in different EU Members.	Targeted change to Article 82: add to paragraph 2: *"In order to protect the rights, safety, dignity and well-being of subjects and the scientific and ethical integrity of clinical investigations not performed for any of the purposes listed in Article 62(1)* ***or Article 74(1) (i.e. PMCF clinical investigations****), each Member State shall define any additional requirements for such investigations, as appropriate for each Member State concerned. "*
c. Clarification on documentation needed for PMCF clinical investigations falling within the scope of MDR Article 74(1)	c) **Another example of burden**: expectation from some CAs (e.g. Czech Republic, Sweden, Finland) to develop an **Investigator's Brochure containing similar information as required for clinical investigations conducted with a non-CE marked medical device**. These investigations must be notified to EU Member States with the **complete documentation per Annex XV MDR** required for the CA notification. Annex XV does currently not differentiate between documentation requirements for clinical investigations subject to authorisation and clinical investigations subject to notification. This is only justified for devices without CE marking, as the conformity assessment procedure has not yet been completed, and the authorities must assess safety and performance. However, if a clinical investigation uses a CE-marked device within its intended purpose there is no reason to (re)request the technical documentation and summarise it in an investigator's brochure as required for clinical investigations conducted with non-CE marked devices, since the safety and performance of the device have already been demonstrated in the conformity assessment (plus CIP and IFU).	c) Targeted changes to the MDR legal text art 74 (and related articles accordingly): Clarifications of the content of the documents to be submitted for post-market clinical investigations of a device within the scope of its intended purpose, in the context of which subjects are submitted to additional invasive or burdensome procedures compared to the normal conditions of use of the device ('Notifiable PMCF investigations'). **Targeted changes to legal text Annex XV: Chapter IV Requirements for PMCF investigations in accordance with Article 74(1) MDR.** 1. For PMCF investigations referred to in Article 74(1), only the following sections of this Annex shall apply: • Chapter I Sections 1. to 2.4., 2.7. sentences 2 and 3 and 2.8. • Chapter II Sections 1. to 1.14. and 1.16., 3. to 3.17. and 3.19. and 4.2. to 4.5. • Chapter III Sections 4. to 7.

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	Examples of countries requiring full dossier for post-market studies (Art. 74.1): PL, CZ (requiring IB).	2. The documentation mentioned in this Annex shall be kept for a period of at least 10 years after the clinical investigation with the device in question has ended. In the case of implantable devices, the period shall be at least 15 years. Each Member State shall require that this documentation is kept at the disposal of the competent authorities for the period referred to in the first subparagraph in case the sponsor, or its contact person or legal representative as referred to in Article 62(2) established within its territory, goes bankrupt or ceases its activity prior to the end of this period
TOP 2 MD specific: Coordinated assessment start date is too late – bring it forward (Art.78)	Current submissions per Member State are cumbersome with Member States creating their own additional requests and sponsors have to deal with lots of discrepancies and manage different processes at the same time. Coordinated assessment is foreseen in the MDR. However, the legal due date/date when it becomes binding is only in 2033 as currently foreseen due to the delay of EUDAMED. A pilot coordinated assessment is about to be launched for medical devices but this will not be legally binding, and the sponsors participating in the pilot may have to repeat the process at national level. Even if the national level process gets expediated it still remains burdensome as opposed to having one coordinated assessment.	**Long-term measure Applying 'Once only' principle (OOP) (EU added value)** Bring forward the legal start date for using coordinated assessment as the only way to assess applications, e.g. 2028 to align with the launch of the CIPS module and applications going through the pilot coordinated assessment process before 2028 should be deemed assessed without having to apply again at national level.
TOP 3 MD specific: Duplication of reporting of adverse events that occur during clinical investigations	Clinical Investigations within the scope of MDR Articles 62 or 74: Some EU Member States impose additional reporting requirements to provisions of MDCG 2020-10/1 & /2. Additionally, once the investigational device gets CE marking during the course of the investigation, safety reporting requirements still apply until the end of the investigation whereas provisions of vigilance laid down in Articles 87-90 also apply, leading to duplication of reporting. Clinical Investigations currently within the scope of MDR Articles 82: Even if the device in the clinical investigation is CE marked, used within its intended purpose and subjects are submitted to additional non-	**Long-term measure Eliminate unnecessary requirements, Applying 'Once only' principle (OOP) (EU added value)** There shall be no additional reporting requirements expected by all EU Member States than provisions outlined in MDCG 2020-10/1 & /2. Once a non-CE marked investigational device gets CE marking while a clinical investigation has not yet ended, only apply Vigilance requirements laid down in Articles 87-90. In PMCF clinical investigations involving CE marked devices used within their intended purpose per normal conditions of

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	burdensome/non-invasive procedures, some EU Member States require additional reporting of events to provisions of vigilance laid down in Articles 87-90, or some even apply reporting requirements outlined in MDR Article 80(2). This requires sponsors to develop specific databases and systems for the collection, assessment and reporting of events which represent significant administrative burden and costs. Examples of EU Member States requirements in addition to provisions outlined in MDCG 2020-10/1 & /2 reporting for MDR Art 62/74.2 and 74.1 studies: • *Germany*: BfArM requires individual reporting for reportable events occurring in Germany using a 5-page reporting form and quarterly safety reporting using specific templates where information is required to be provided in an evaluation report which needs to be accompanied by a complication rate table. • *Czech Republic*: The Sponsor is required to provide an annual safety report including an evaluation of the safety of the clinical investigation, which shall be provided no later than 31 January of the following year. • *Denmark:* An annual safety report to be submitted once a year throughout the duration of the clinical investigation. The annual safety report must contain a list of all serious adverse events that have occurred during the clinical investigation in Denmark and abroad, as well as an assessment of the risks and benefits of the investigational device (risk-benefit) and a conclusion regarding the safety of the subjects. Clinical Investigations within the scope of MDR Articles 82: • *Finland* requires reporting according to MDR Art 80(2) as for clinical investigations conducted with non-CE marked devices, according to the provisions outlined in MDCG 2020-10/ 1 & 2.	use of the device, only Vigilance reporting requirements per Articles 87-90 shall apply. Delete Art. 80(6).

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	• *France* requires reporting of events with causality established with the preceding investigational procedure (index procedure and any non-standard of care procedures which is not invasive and/or not burdensome) according to the provisions outlined in MDCG 2020-10/ 1 & 2.	
TOP 4 MD specific: Requirement to notify CA's of substantial modifications within 1 week (Art. 75)	The requirement to notify substantial amendments within 1 week when the last affected and relevant document is issued creates unnecessary administrative burden since the date of issue will need to be tracked in order to meet this MDR requirement. However, there is no added value or risk since substantial modifications can only be implemented when the deadline in Art. 75 has expired or an authorisation letter is issued by the CA and/or EC (according to national provisions). The Sponsor should be responsible to decide on the timeline for notifying substantial changes. It is challenging to meet this MDR requirement to notify within one week after the last relevant document is issued due to other factors, such as waiting for EC approval in countries with a sequential process, or studies with multiple countries where submissions are often staggered.	**Long-term measure Changing frequency/timing** Revise Art. 75 (and related MDCG guidance 2021-6) to remove the "within one week" requirement for notifying substantial changes.
5. MD specific: Correction regarding corrective measures taken by Member States	Not all clinical investigations need an authorisation, some only need to be notified. The current MDR wording, the revocation of an authorisation as a corrective measure is only valid in the case of a clinical investigation requiring authorisation.	**Long-term measure Eliminate unnecessary requirements** Targeted wording change in Article 76 paragraph 1 a) revoke the authorisation for the clinical investigation **requiring authorisation.**
6. MD specific: Correction regarding Information from the sponsor at the end of	For clinical investigations of devices with CE marking, the reference to Article 77(7) currently only makes sense for the first sentence. The subsequent text is only applicable to devices that are not yet registered.	**Long-term measure Eliminate unnecessary requirements** Article 77(7): The summary and the clinical investigation report referred to in paragraph 5 of this Article shall become publicly accessible through the electronic system referred to in Article 73. **For devices that have not yet been registered, this shall be done**

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a clinical investigation		**at the latest** when the device is registered in accordance with Article 29 and before it is placed on the market.
7. MD specific: Lack of harmonization on (process and timelines) across EU Member States (MS) for non-substantial amendments of clinical investigations	Non-substantial modifications of clinical investigations are not regulated in the MDR. MDCG 2021-6 does not provide further clarity despite its Annex II, it only states "once EUDAMED is available, sponsors are expected to keep the information in the database up to date in accordance with MDR Article 70(2). However, in the absence of EUDAMED Member States have not yet harmonised their approach, and it is thus necessary to check the national requirements." Some EU Member States (MS) implement national provisions and/or provide guidance through other sources (e.g. website, guidance documents, etc.) while some EU Member States do not provide any guidance/clarification. Timelines differ, some EU Member States require a notification immediately after implementation vs. other EU Member States within one year of implementation or at the end of a clinical investigation. Sponsors have to find out and/or closely monitor different sources from all EU MS to understand if and when to report non-substantial modifications to national Competent Authorities (CA). This is a time consuming and administrative burden to identify the requirements/expectations and to implement different process to fulfil each EU MS expectation. Sponsors need to keep internal track records to submit non-substantial modifications per the timelines set out by the national CA. In addition, the clinical investigation documentation available at investigational sites may differ from the documentation the CA may have in their systems. This increases the risk of questions during site audits from authorities.	Short-term measure **Providing guidance** Update MDCG 2021-6 to harmonise EU MS expectations for the management of non-substantial modifications of clinical investigations in terms of timelines and clear criteria of what is considered non-substantial.
8. MD specific: Correction of	In the case of an early termination, a lot of preparatory activities are not possible: In these cases, the clinical investigation is still ongoing, and some non-monitored data are available at the study sites, queries	Long-term measure **Changing frequency/timing & eliminate unnecessary requirements**

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timelines for submission of the final report according to Art. 77(5)	are open, Serious Adverse Events (SAE) status is not conclusively known, and in blinded study arms, the assignment is not yet known. In case of a temporary halt, priority must be given to whether and under what changed conditions this clinical investigation can be resumed, and a substantial amendment must usually also be submitted with appropriate measures to ensure the safety of the investigation subjects. Root cause analysis, determination of corrective actions and adaptation of documents, and submission pending approval of a significant change are the essential steps in this situation.	Targeted change to the MDR legal text art 77(5): It is proposed that the deadline for prematurely terminated clinical investigations should also be set at 12 months and that no final report should be required for temporarily halted clinical investigations, as these clinical investigations have not yet been terminated by definition. Proposal Art 77(5) subparagraph 1: "*(5) Irrespective of the outcome of the clinical investigation, within one year of the end of the clinical investigation ~~or within three months~~ of the early termination ~~or temporary halt~~, the sponsor shall submit to the Member States in which a clinical investigation was conducted a clinical investigation report as referred to in Section 2.8 of Chapter I and Section 7 of Chapter III of Annex XV.*"
9. MD specific: Correction of application for extension of the deadline of the final report according to Art 77 (5) subparagraph 3	The requirement stated in subparagraph 3 of Article 77 (5) MDR is hardly feasible, because it requires that the scientific justification for exceeding the deadline of one year after completion should already be stated **in the clinical investigation plan**. Experience of sponsors or their contract data processors shows that the scientific reasons why the final report cannot be completed on time only emerge during the evaluation and reporting phase.	**Long-term measure Eliminate unnecessary requirements** Targeted change to the MDR legal text art 77(5) subparagraph 3: a possibility should be provided to grant the sponsor an extension of the deadline upon request. Proposal Art 77(5) subparagraph 3: "*Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year of the end of the investigation, it shall be submitted as soon as it is available. In such case, ~~the clinical investigation plan referred to in Section 3 of Chapter II of Annex XV~~ the sponsor submits an application for an extension of the deadline to the Member States no later than 3 months before the due date of the final report. This application shall specify when the results of the clinical investigation are going to be available, together with a justification*."

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10. MD specific: Additional documentation and duplication of documentation referred to in Chapter II of Annex XV MDR	MDR Art 70 (1) states "The sponsor of a clinical investigation shall submit an application to the Member State(s) in which the clinical investigation is to be conducted (referred to for the purposes of this Article as 'Member State concerned') accompanied by the documentation referred to in Chapter II of Annex XV." In addition, MDCG 2021-8 provides application/notification documents that have been created to support clinical investigation procedures with respect to MDR. However, neither the MDR Art 70 (1) nor MDCG 2021-8 provide clarity on naming convention of documentation referred to in Chapter II of Annex XV nor on the folder structure for submitting the application dossier to competent authorities in EU Member States. National CAs have set out their individual requirements for providing the clinical investigation dossier, such as naming convention, folder structure and additional documentation to those referred to in Chapter II of Annex XV. If a Sponsor submits a clinical investigation to multiple EU Member States, the Sponsor has to duplicate the documentation per Chapter II of Annex XV and needs to adapt naming convention and filling structure according to national provisions and needs to add additional documentation. **Examples:** • Examples of countries with specific naming convention and folder structure: France, Portugal, Sweden, Spain • Examples of countries with additional documentation per national provisions: Spain: States for sponsors and investigators • Italy: Statements from legal manufacturer • Belgium: Site suitability statement.	Short-term measure **Provide guidance / Applying 'Once only' principle (OOP)** To avoid unnecessary administrative burden, naming convention and folder structure of submission dossiers should be clearly stated in the MDCG 2021-8 and additional clinical investigation deliverables should be eliminated.
11. MD specific: Lack of reliance on	Some MDCG guidance documents, notably MDCG 2024-3 (CIP), 2024-5 (IB) use substantial input from ISO 14155 while not being aligned with it, which creates burden and discrepancy. The	Short-term measure **Remove duplicating requirements**

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international standards	purpose of these documents is unclear since, as mentioned, these topics are substantially covered by ISO 14155. Since they use the text from ISO but repeat it in a different manner, this creates additional burdens for sponsors. It should be noted that sponsors often operate in international environment and guidance documents should strive for alignment with international practice.	Alignment with international standards should be ensured, the best practice is to consider **referring to existing international standards** rather than re-writing local guidance with modifications.
12. MD specific: Signatures of the principal investigators from each investigational site on the clinical investigation report according to Annex XV, Chapter III (7)	In big multicentre clinical investigations, the time between the site-individual site closure and the availability of the clinical investigation report can range over years. Principle Investigators (PI) change relatively frequently. Therefore, only the signature of the last active PI can be collected. But then, however, the PI can hardly have been involved in patient treatment during the whole study period at the site. In addition, the results cannot be verified by the PIs. The Coordinating Investigator is responsible for the clinical conclusions. Provision of the report to each investigational site is mandatory. But the signature of the report by the PI does not really confirm the reading of it. Often it will not be read, especially if the results had already been provided months or years ago in papers and congresses. Furthermore, ISO14155:2020 only requires signatures of the Coordinating Investigators (PI signature only required in case no Coordinating Investigator is appointed).	**Long-term measure** **Eliminate unnecessary requirements** Targeted change to the MDR legal text Annex XV, Chapter III (7): *The Sponsor shall prepare a clinical investigation report which includes at least the following:* *— Cover/introductory page or pages indicating the title of the investigation, the investigational device, the single identification number, the CIP number ~~and the details with signatures of the coordinating investigators and the principal investigators from each investigational site~~.*

Notified Body Assessment

The administrative burden arising from the Notified Body practices ranges from certification timelines and the unpredictability of the procedures, to the vast variability in how Notified Bodies interpret the regulatory requirements. This includes differing methodologies and approaches to conformity assessment. In this chapter, we focus on the interpretations, procedures, and limitations currently present in the system that add little or no value in safety to the final device.

What?	Why?	How & When?
TOP 1 Limited validity of certificates (recertification)	**Main source of admin burden:** Requirement in regulation legal text. Recertification every 5 years represents a high bureaucratic effort and re-investment burden without clear safety benefits. The Notified Body is required to repeatedly and continually assess devices and quality systems after their certification (including change control, review of reports on serious incidents, Periodic Safety Update Reports (PSUR) and Summaries of Safety and (Clinical) Performance (even if unchanged), conducting both annual and unannounced surveillance audits, sampling of products, etc.), which, to our knowledge, already ensures the highest level of oversight of devices on the market in the world. Some manufacturers have reported re-certification fees which are higher than initial certification fees (albeit it is worthwhile noting that this information comes from >15 respondents, therefore the data must be treated with caution). Re-certification costs after 5-years have been reported to be on average ~55% higher for QMS assessment and ~94% higher for Technical Documentation assessment than initial certification fees. Based on a very rough estimate, on average, the Notified Body fees for re-certification of one QMS certificate may cost ~212K € for MD sector and ~168K € for IVD sector, while re-certification of one Technical Documentation assessment certificate for MD sector may cost ~342K € and IVD sector ~124K €. These re-certification costs do not include internal manufacturer's costs (e.g. employee costs, which can be substantially higher as reflected in internal costs reported in MedTech Europe survey for initial certification) and come on top of maintenance costs, which, per one device only, on average, can round up to ~498K € for MD sector and ~309K € for IVD sector after 5-years (excluding internal costs)[11].	**Short-term measure/Mid-term measure Eliminating unnecessary requirements** In the shorter term, it is important to extend the validity of certificates by at least one cycle, to avoid bottlenecks in Notified Body activity, which is especially the case for MDR transitional deadlines in 2027-2028. In the foreseen implementing act for application of uniform rules for Notified Body requirements providing detailed specifications for the recertification process under Annex VII 4.11 could aim to streamline the process by emphasizing a life cycle approach. It could eliminate the need for full assessments of technical documentation. A subset of documentation could be reviewed instead of fully reviewing everything through certification, such as: • PSURs, which should be filled on time, with no increased risk/change in risk-benefit; • ISO/QMS audits; • PM(P)CF. **Long-term measure Eliminating unnecessary requirements** In a revision of IVDR/MDR, certification validity should be adapted to follow the device lifetime instead of setting an arbitrary end of validity every 5 years. This can be achieved by removing the maximum duration limit of 5 years for IVD/MD certificates. Many safe and performing technologies already in use by patients and their care teams in Europe will be able to stay on the market by removing the unnecessary and high

[11] MedTech Europe 2024 Regulatory Survey: Key Findings and Insights (Lifecycle costs section). Please note, that the internal (e.g. manufacturer's employee costs) and external (e.g. costs paid by the manufacturer to Notified Bodies) costs that have been taken into account for these numbers vary significantly.

What?	Why?	How & When?
	For medical device sector, there is a strong concern about the bottlenecks possibly arriving at the end of 2027-2028 as Notified Bodies process first-time MDR certificates simultaneously with processing recertification for early adopters. Similar pattern might follow later in the IVD sector. Recertification is not sustainable from a burden and cost point of view. Many companies, especially SMEs, struggle with the initial certification cost and resource burden. Repeating a certification exercise every 5 years is not sustainable for many manufacturers, leading to decisions not to re-certify or not to certify the devices in the first place. Many manufacturers are no longer prioritising the EU as a preferred geography and stopping or planning to stop the supply of their devices to the EU market, in part due to high regulatory costs[12,13]. It also can divert resources away from research and development (R&D) or other activities (particularly for SMEs, who have less resources to spare).	bureaucratic hurdles of re-certification every 5 years, which provides little additional safety benefit, yet it causes a high burden. The risk of bottlenecks will be reduced and resources of Notified Bodies freed up to focus on certification, change control and post-market surveillance activities for safe and performing devices. Notified Bodies should proactively withdraw their certification for devices whenever there is demonstrable justification for doing so. Notified Bodies are currently able to make this assessment, considering that they are continuously assessing and auditing: the Quality Management System, device post-market system, safety and incident reporting, and change notification along with other post-market activity evaluations for the devices under the certificates which they issue.
TOP 2 **Long and unpredictable Notified Body initial conformity assessment timelines**	**Main source of admin burden:** Notified Body practice The time it takes from application to certification can vary greatly: • The total average time for both SMEs and large companies to complete either the quality management system (QMS) or Technical Documentation assessment certification is around 18 months for each[14]. • Based on GÖG survey results, certification timelines can take anywhere between 6 months to 24 months or more[15]. Based on MedTech Europe survey the IVDR/MDR conformity assessment timelines can vary between 3 months and 15 months. In addition,	**Short-term measures**/**Mid-term measures**: **Change frequency/timing and eliminate unnecessary requirements** 1. **Short-term measure** Require Notified Bodies to offer dialogues in pre-application and during conformity assessment to set out evidence and timeline expectations for the submission and conformity assessment with the manufacturer, with the outcome described in a formal binding statement. There is an urgent need to allow a clearly defined and minuted discussion on clinical strategy between manufacturer and

[12] MedTech Europe 2024 Regulatory Survey: Key Findings and Insights (IVD and MD Innovation section)
[13] Based on the Gesundheit Österreich GmbH (GÖG) survey on the monitoring of the availability of devices, which was commissioned by the European Commission, 3 out of 5 main reasons for IVD manufacturers having stopped or planning to stop production/marketing/supply of some IVDs to the EU market are related to costs (i.e. products with low sales volumes, product revenue does not justify cost to reapprove device under the IVDR, products with low profitability)
[14] MedTech Europe 2024 Regulatory Survey: Key Findings and Insights (IVD and MD: Access to a Notified Body section)
[15] Based on the Gesundheit Österreich GmbH (GÖG) survey on the monitoring of the availability of devices

What?	Why?	How & When?
	the time spent in different phases (pre-review, review and certificate issuance), as well as the differences between and within the SMES and large manufacturers show outstanding variations[14]. • The Notified Body spends >55% of the total time from application to certificate issuance of the QMS outside of the review phase (pre-review + issuance)[14]. While the certification phase at the certification body is a major process, activities other than the actual review phase take at least half of the total time from the manufacturer sending their submission to receiving their certification. When certification takes longer than 12 months, this can strongly impact the ability of the manufacturer to produce the device for which they were seeking regulatory approval. For example, components may no longer be available, trained operators may have left the company or moved to another function, the machinery has been exchanged or the software has changed. In some cases, the Notified Body may even ask the manufacturer to update the Technical Documentation in the application they had submitted if many months have passed before they start reviewing it. When experienced, these issues present even greater challenges for SMEs due to their resource's constraints. Long and unpredictable timelines have especially high impact on SMEs. There are more than 37,000 medical technology companies in Europe, and 90% of them are Small and Medium-Sized Enterprises (SMEs)[16] for whom lengthy and unpredictable conformity assessment procedures of either MDR or IVDR can have a devastating impact on their ability to resource and finance those procedures. This may contribute to decisions to discontinue devices, product lines or even	Notified Body to take place before submission of the application for conformity assessment. **Update wording to this effect in the revision of MDCG 2019-6, which currently states this should take place "after submission of application"**[19]. 2. **Short-term measure**/**Mid-term measure** Require each Notified Body to make publicly available, in the form of ex-post reports, current certification timelines and fees per Notified Body per device type. Notified Bodies should exceed the planned budget by a certain level only if duly justified. Suggestions for reducing initial assessment timelines and increasing predictability are listed below. If the use of an implementing act is not possible for the below approaches and amendment to the legal text is needed, it would make sense to include a new implementing act which can set the appropriate timelines and mechanisms, to ensure that these can be updated as needed and taking into account technological progress. 3. **Mid-term measure** The following approaches could be adopted for reducing assessment timelines and increasing predictability: Set maximum timelines for Conformity Assessment: • Pre- and post-review timelines should be set to maximum of 20 working days each; • For the review phase, based both on the Notified Body ex post reporting on timelines and the application (its complexity or other considerations), the manufacturer and Notified Body agree on maximum number of review

[16] MedTech Europe 2024 Regulatory Survey: Key Findings and Insights (Certification costs section)
[19] See more in MedTech Europe position paper 'Urgent call for clarity on clinical strategy discussions'

What?	Why?	How & When?
	complete product ranges[17]. Long certification timelines, next to low product revenue, is one of the most important reasons why manufacturers do not transition their devices to IVDR/MDR[18] or decide to launch new devices first outside of Europe.	days and mechanisms such as clock stops and extended time. The aim should be to arrive at a reasonable timeline which does not exceed a review time of 120 working days for QMS Certification and 60 days for Technical Documentation A Certification; where applicable, a timeline which combines both certifications may be considered.
TOP 3 Notified Body (pre)review practices	MDCG encourages Notified Bodies and manufacturers to engage in a structured dialogue before the initial conformity assessment submission to enhance the efficiency and predictability of the review process[20]. However, currently there is a lack of effective implementation and harmonisation of structured dialogue before the start of initial IVDR/MDR certification, which, in addition, are not offered by some Notified Bodies. Administrative burden and inefficiencies are created on both the side of the manufacturer and Notified Body if non-conformities need to be addressed at the application stage. Also, the MDCG guidance that has been developed after an application has been submitted, should not be retroactively applied to the application unless specifically required by MDCG.	**Short-term measure Providing guidance** A more effective structured dialogue and harmonization of Notified Body review practices would enhance predictability, reduce feedback rounds due to unexpected findings and increase first time right number of applications. Consistency between reviewers within and between different Notified Bodies is of paramount importance for the manufacturers to be able to learn from their application process and predict what is expected. Inconsistencies, such as the lack of agreement between reviewers on what had been agreed as an interpretation or on number of questions per product, could be addressed by harmonized and well documented review process applicable to all reviewers. Effective structured dialogue is essential to improve completeness of applications by, for example, implementing: • Pre-agreed questions: formal written request should be made in writing to Notified Body with a meeting request, if needed, and specific questions prepared regarding their

[17] In over 50% of product portfolios: individual products, sometimes entire product lines and complete product ranges are being withdrawn from the market. In almost 20% of cases, there are no equivalent alternatives on the market. See survey report by the German Chamber of Commerce and Industry (DIHK), the MedicalMountains cluster initiative, and the German industry association SPECTARIS '*Current assessment of the German medical device manufacturers on the effects of the EU MDR*', December 2023

[18] Based on the Gesundheit Österreich GmbH (GÖG) survey on the monitoring of the availability of devices

[20] MDCG 2022-14 Position Paper Transition to the MDR and IVDR Notified Body capacity and availability of medical devices and IVDs

What?	Why?	How & When?
		submission and/or product development to review during the meeting. The request should include questions that help guide product development and/or submission preparation. • Documented meeting minutes: all discussion that occurs during the meeting should be documented in meeting minutes that are drafted by the submitter and submitted for Notified Body review. • Well-reasoned feedback: Notified Body should develop feedback by considering relevant scientific and regulatory approaches consistent with GSPR. • Some reviewers within the Notified Body expect a consolidated file (i.e., finalized documents in the QMS) with each round, while others are fine with receiving a draft document highlighting the changes. It would help reduce the administrative burden if the consolidated file with all changes were only required at the end of the review process.
TOP 4 Quality Management System auditing duplication	The IVDR/MDR Quality Management System (QMS) requirements are overlapping with those in other jurisdictions (e.g. overlapping requirements listed in MDCG 2020-14 Guidance[21]). When a manufacturer chooses to undergo Medical Device Single Audit Program (MDSAP) they already possess MDSAP audit report which covers many similar or equivalent IVDR/MDR requirements. If MDSAP audit results are not utilised in IVDR/MDR QMS audits (when available), manufacturer's QMS is being audited twice for QMS requirements under IVDR/MDR which have already been audited with MDSAP. If the MDSAP and MDR/IVDR audits are not combined, an	**Mid-term measure Applying 'Once only' principle (OOP) (EU added value)** Until the EU fully joins the MDSAP program, the QMS review should be optimised through reliance on a wider level by enabling the usability of MDSAP for IVDR/MDR QMS auditing. The option to use MDSAP for EU Certification process should be choice-based so both larger and smaller manufacturers could be accommodated (not all manufacturers are part of MDSAP). This would also mean that the certificate timeline would be affected since MDSAP is issued every 3 years.

[21] MDCG 2020-14 Guidance for notified bodies on the use of MDSAP audit reports in the context of surveillance audits carried out under the Medical Devices Regulation (MDR)/In Vitro Diagnostic medical devices Regulation (IVDR) August 2020

What?	Why?	How & When?
	unnecessary auditing duplication may be created for manufacturers that are part of the MDSAP.	
TOP 5 Submission review rounds	**Main source of admin burden**: Unpredictable review rounds The number of review rounds allowed during IVDR/MDR conformity assessment submissions varies across different Notified Bodies. For example, one Notified Body does not limit the number of review rounds, while others permit a maximum of three rounds. If this limit is exceeded, the review process is halted, necessitating a restart or resubmission, which creates the burden of going through the same process again. There is currently a lack of transparency regarding the number of review rounds a manufacturer should expect and the process to follow. The communication is important from both the Notified Body and manufacturer's side. However, it is manufacturer's expectation that the list of findings is as complete as possible right at the first round. The rounds of review built up, if the questions are not clear, the expectations are not expressed, and new findings occur with each new round. In addition to the review rounds, every submission requires documentation in a specific form, which is burdensome due to the sheer volume of information requested and the inconsistent process of updating these forms. During deficiency rounds, numerous questions arise surrounding the forms and reworking them consumes a significant amount of time. The timing and transparency of submission reviews, compounded by these challenges, pose a considerable hurdle for many MD and IVD manufacturers. This is particularly evident when compared to other regulatory frameworks with clearly defined consultation processes, where the entire procedure and timelines are transparently outlined.	Short-term measure **Provide guidance** Communication between Notified Body and manufacturer is key. It is up to the manufacturer to present its devices or QMS in the documentation well-organized and structured, well-written and understandable which is why the structured dialogue is important before and during the review. Transparency on how the review process works must be improved through improved communication between Notified Body and manufacturer, by, for example, agreeing on the most suitable review timelines before the start of the review. Improved transparency would help manufacturers to plan for the review and know what to expect. Grouped submissions or family files should be encouraged, as this will streamline the documentation management and reduce the administrative burden. See other measures proposed under Long and unpredictable Notified Body initial conformity assessment timelines. Measures proposed there would address some of the issues around number of review rounds.

What?	Why?	How & When?
6. Inconsistent interpretation regarding labelling requirements	**Main source of admin burden**: Requirement in regulation legal text, guidance or other interpretation of regulation legal text, Notified Body practice and Lack of optimisation (considering the state of the art). manufacturers are facing challenges to comply with the various international standards and requirements in their information provided by the manufacturer while keeping a common labelling as much as possible for all countries. Inconsistent interpretation of requirements across and within the Notified Bodies is contributing considerably to the burden of maintaining the labelling. Based on manufacturers experience, Notified Bodies are not fully aligned on labelling requirements because of different interpretation of the requirements and lack of standardization of Notified Body practices. **Examples:** • Some Notified Bodies wish to keep an up-to-date copy of the technical documentation they have reviewed initially, including any modified label and IFU to be provided before implementation. • Some Notified Bodies require on the label a symbol for the substances which are carcinogenic, mutagenic or toxic for reproduction (CMR) while other Notified Bodies do not have such an expectation. • The interpretation of what is a significant change that requires notification may differ substantially across Notified Bodies. For example after acquiring a company the eIFU website was transitioned to the new company's website which was considered a significant change for one Notified Body while for another it was not a significant change. Also, some manufacturers report that they have been asked to send all changes made to the instructions for use (IFU) for approval before implementing them, even if those are minor changes. Thus, some Notified Bodies consider any and all changes in IFU as significant.	**Short-term measure** **Provide guidance** Guidance is needed which could clearly differentiate between significant changes that require notification and Notified Body approval before implementation and not significant changes which could be reviewed as part of the annual surveillance audit. Stronger coordination between Notified Bodies should be established. Requirements, especially those related to translation, should be standardised among and within different Notified Bodies. Guidance should be provided.

What?	Why?	How & When?
	Inconsistent interpretation by Notified Bodies regarding labelling requirements can lead manufacturers to (amongst other): • to destroy or to retreat stock of labels or devices; • different interpretation of symbols and regulation by different Notified Body and by different reviewers within one NB, causing misalignment across products. • make notifications of changes to international regulators across the globe which in turn lead to significant resources needed to manage these notifications; • have loss of visibility of critical information for the user with the multiplication of symbol / text and difficulties to answer the request for small devices with small labels. This increases cost and causes delay to provide the devices to the end-users and adds to administrative burden for manufacturers and Notified Bodies' impact which add little (or not at all) to safety and performances of the device.	
7. Short-term contracts with Notified Bodies	**Main source of admin burden**: Notified Body practice For manufacturers, the Notified Body is a critical supplier and their market access depends heavily on them. Maintaining contracts with Notified Bodies are a purely administrative task which can take time and resources for manufacturers. Currently, the length of Notified Bodies' contracts with many manufacturers is relatively short and can vary from 1 to 3 years. Such short contracts create unnecessary (in some cases yearly) contracts renewal burden for manufacturers, a burden that is purely administrative. In addition, short contracts are a source of uncertainty on whether and under which conditions those contracts will be renewed. This is especially burdensome given that devices are regulated by regulations according to a 5-year re-certification cycle (and the manufacturer's QMS undergoes a 3-year ISO 13485 accreditation cycle).	**Short-term measure** **Changing frequency/timing** Increase the length of Notified Body contracts to at least 5 years to align with the certification cycle and reduce uncertainty and administrative burden related to frequent contract renewals.

What?	Why?	How & When?
8. IVD specific Notified Body designation process	**Main source of admin burden**: Requirement in IVDR legal text and guidance or other interpretation of regulation legal text (Implementing Regulation 2017/2185/EU). The Notified Body designation process and the complexity of the scope designation codes is a problem for manufacturers because the Notified Bodies struggle to get the right experts to audit manufacturers. Notified Bodies also may need to hire, maintain and train more experts to match the number of codes within their scope – and will pass those costs and training days onto manufacturers. A significant source of burden are the number and level of detail of codes/competences needed. These codes/competences and therefore control needed should be proportionate to the diversity and size of the sector: • Annex I provides 71 competency codes across 3 tables for the MD sector, which is a greatly diverse sector made up of circa 500,000 devices; • Annex II provides 101 competency codes across 5 tables for the IVD sector, which is a relatively homogenous sector made up of circa 40,000 devices. The implementing regulation should not require 30% more competence and personnel to assess the IVD sector than for the MD sector, considering the relative homogeneity of the IVD sector. In fact, the IVD sector should have far less codes considering its relatively small size and diversity compared with the MD sector.	**Mid-term measure Eliminating unnecessary requirements** Review the level of granularity needed for scope designation codes for the IVD sector (Annex II), taking comparison with the MD sector (Annex I). This should result in far less codes for the IVD sector vs the MD sector, which in turn should reduce burden and cost on the IVD sector and on IVD Notified Bodies.

Post-Market Surveillance

Based on MedTech Europe IVDR and MDR survey results[22], post-market surveillance costs under the regulations as compared to the directives have increased up to 49% and, in some cases, doubled. Total average IVDR yearly maintenance costs can reach up to 61,907 € per device and under MDR – 99,648 € per device. Maintenance costs, accumulated over the course of a device's lifecycle, may outweigh the initial Notified Body certification fees. By the end of the five-year certification cycle, IVD manufacturers are likely to spend approximately 70% more, while MD manufacturers 50% more on maintenance and re-certification as compared to initial IVDR/MDR QMS and Technical Documentation certification costs (excluding internal costs, such as full-time equivalent (FTE) costs). The below list of administrative burden, at least partially, explains the increased financial burden on manufacturers to maintain medical devices and IVDs on the EU market.

What?	Why?	How & When?
TOP 1 Change notification process	**Main source of admin burden:** Guidance or other interpretation of regulation legal text together with Notified Body practice. The current change notification process under IVDR/MDR is unpredictable and heavy on manufacturers. This is an issue for health systems which rely on having best in class devices. The three main issues are: 1. **Double and excessive reporting**: Currently, there is no guidance as to which changes the manufacturers have to notify, and which changes can be reviewed during annual surveillance audit. This creates uncertainty and double reporting, which is unproportionally burdensome for manufacturer, especially for IVD sector due to changes in classification under IVDR (the number of IVDs under Notified Body review has increased up to 80% under the IVDR as compared to the directive). **Example**: Not every substantial change to Safety and Performance or to Intended Purpose is equal. Consider: Modifying a device to keep it going as intended (not to be used below -10C) versus expanding intended purpose of a device (new indication, new target population etc.).	**Short-term measure Changing frequency/timing** Change notification should not take longer than 1 month in most cases. Individual change notifications can be reduced by focussing on notification of only those changes which are substantial. Individual change notifications should be reduced and made more efficient through mechanisms such as predetermined change controls. **Short-term measure Eliminating duplication/unnecessary requirements** Make the change notification process more efficient by differentiating between which substantial changes that need to be assessed and allowed immediately by the Notified Body and which substantial changes could be assessed once per year. a) A change which is substantial but which nonetheless does not adversely affect the safety, performance or usability and does not negatively affect the risk/benefit ratio of the device:

[22] MedTech Europe 2024 Regulatory Survey: Key Findings and Insights (Changes in costs under the regulations as compared to the directives section & Maintenance costs section)

What?	Why?	How & When?
	2. **Unpredictable timelines**: There is no timeline when an Notified Body will finalize the assessment and provide approval which result in significant delays of assessing and implementing changes. Example 2: While waiting for Notified Body approval of a minor change concerning a new model number, the annual report concerning the same device group had to be submitted. Change notification approval was mixed with annual report review and this review significantly delayed the change approval due to unclear sequence of reviews by the NB. In addition, numerous studies show that the Notified Bodytimelines are lacking predictability in both pre and post market activities (e.g. GÖG survey[23] and MedTech Europe Survey[14]) and change notification does not seem to be an exception. **Examples** of change notification timelines: • For some manufacturers, substantial change (i.e. addition of new indication, based on available published clinical data) for a class III MDR device took almost two years • For some manufacturers, a change notice approval can take a year which can cause product shortages. • Some Notified Bodies have introduced standard, dedicated and interactive dedicated change notification approval path. A dedicated path is more costly but doesn't always get approved in a shorter amount of time. Furthermore, the interactive dedicated should take even less time but it can still take 4-6 months.	review together once a year. See MDCG 2020-3 and 2022-6 for examples. b) A change with a potential negative impact on safety & performance, or usability or which adversely affects the risk/benefit ratio of the device: review immediately **Short-term measure** **Provide guidance** • Support grouping of changes and introduction of predetermined change control plans whereby changes which will be carried out, are agreed upfront and can be enacted by the manufacturer. • Establish a clear guidance on requirements related to change notification (e.g. substantial change definition/changes that need to be reported). For example, an update to NBOG 2014-3[24]. • In addition, change notification forms should be simplified. **Mid-term measure** / **Long-term measure** Measures enacting the above proposals also could be included in the MDR and IVDR through implementing acts or legal amendment in the future.

[23] Per Gesundheit Österreich GmbH / Austrian National Public Health Institute (GÖG) Survey results time to reach/issue IVDR/MDR NB certification vary from less than 6 months to more than 24 months. Per MedTech Europe IVDR and MDR survey, the IDVR/MDR NB certification timelines vary between less than 3 months to more than 15 months. Also, the costs paid to NB for the assessment of PMS reports vary significantly which shows the lack of alignment of current NB fees and practices for evaluating these reports

[24] NBOG 2014-3 Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System

What?	Why?	How & When?
	3. **Complex forms**: The forms that manufacturers need to fill in for change notification can be burdensome which delays change implementation process. For example, the content of some Notified Body forms is very detailed and complex to navigate, and their format is updated frequently. Thus, it cost a lot of time for manufacturers when they do the annual check or add new product codes.	
TOP 2 **Periodic Safety Update Report (PSUR) frequency of update**	**Main source of admin burden:** Requirement in regulation legal text. Updating the PSUR[25] data yearly if there is no change in the benefit-risk profile of the device creates unnecessary duplication of work with little added value to patient safety. The PSURs will be reviewed during the annual surveillance audits, meaning that the same content will be reviewed with annual PSUR updates, annual surveillance audits and recertification. Yearly update puts a lot of strain on manufacturers and Notified Bodies because, if this requirement is strictly interpreted, PSUR must be updated and renewed within one year, which means that the date of approval of the document is earlier each year. Based on manufacturers' experience, the cost can be as high as 320 hours of work to update Class III PSUR and on average, can reach 6,427 € per PSUR evaluation report. In addition, PSUR evaluation fees range from less than 1,000 € to more than 5,000 €. This variability shows the lack of alignment of current Notified Body fees and practices for evaluating these reports[26].	**Long-term measure** **Changing frequency/timing for PSUR reports** Annual updates should not be required for devices with PSUR data that has been stable for a reasonable period after it was placed on the EU market (both MDR/IVDR certified devices, as well as (AI)MDD/IVDD legacy devices). The PSUR updates should rather be based on the risk and novelty of the medical device and IVD. The surveillance audits are enough to regularly review the PSURs for devices with stable PMS data. In addition, for novel devices that require annual PSUR update, the PSUR report should be allowed to be sent within one year after the last report was sent. The free termination within this year timeframe would support manufacturers to adapt their schedule of PSUR, like reports for several jurisdictions, which would decrease administrative burden by having the possibility to re-use dataset created.

[25] As per regulations, the PSUR must be updated annually for higher class devices (class IIb and class III devices under MDR Article 86(1), class C and D devices under IVDR Article 81(1)), which helps the Notified Bodies and Competent Authorities to monitor and evaluate device performance on the EU market.
[26] MedTech Europe 2024 Regulatory Survey: Key Findings and Insights (Maintenance costs section)

What?	Why?	How & When?
	Such practice is in contrast to the Pharmacovigilance, where the PSUR for medicines timeline was adjusted based on international birth date for the compound, meaning "old" drugs have very long PSUR periods as no new safety issues are expected[27]. **Examples**: • If the device has demonstrated few or no incidents (field safety corrective action (FSCA) initiated) for several years in a row (e.g. 5 years for highest risk Class III and Class D devices; 3 years for other implantable Class IIb/IIa and Class C devices) and the PSUR data have been stable, there is little to no added value for patient safety to provide PSUR yearly, while there is a significant use of Notified Body and manufacturer resources. • Some Notified Bodies require PSUR (as well as SS(C)P) to be submitted for evaluation within ~4 months of the end of the reporting period, while for some products it can take 6 months to analyse all the clinical and PMS data to complete these documents. In addition, it is expected that the time periods covered by PSUR and SS(C)P match, and synchronising clinical and PMS activities requires additional work that overlaps.	
TOP 3 **Vigilance data review by Notified Bodies**	**Main source of admin burden:** Requirement in the legal text and Notified Body practice (interpretation of MDR and IVDR Annex VII section. 4.10, third indent). According to MDR and IVDR[28], the Notified Bodies are required to review vigilance data to assess its impact on the existing certificates. In practice, some Notified Bodies interpret that to comply with this requirement, they must assess every serious	**Short-term measure** **Eliminating duplication** Notified Bodies do not serve as primary operational actors in the vigilance system established by the regulations; instead, they play a supportive role. The primary responsibility for reporting and evaluating serious incident reports lies with manufacturers and competent authorities. The Notified Bodies should not duplicate the work of competent

[27] See Periodic safety update reports (PSURs) rules for medicines in EMA website (link)
[28] Annex VII section 4.10, third indent NBs are required "*The Notified Body shall have documented procedures: <...> to review vigilance data to which they have access under [Article 92(2) in MDR] / [Article 87 in IVDR] in order to estimate its impact, if any, on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented.*"

What?	Why?	How & When?
	incident report a Manufacturer submits. While this interpretation may be connected to the fact that Notified Bodies will be notified of individual serious incidents submitted in EUDAMED, it should be noted that this requirement is not stated in the MDR and IVDR Annex VII section 4.10. Serious incident review is the responsibility of Competent Authorities as per Art 89 MDR/Art 84 IVDR while Notified Bodies are responsible for reviewing vigilance data which may have the impact on certification as part of their audits as per Annex VII section 4.10. There is no safety gap being fulfilled with current Notified Body practices of additional serious incidents review; this critical safety requirement is a full responsibility of experts from Competent Authorities. The current practice of individual serious incident review by Notified Bodies is an unnecessary duplication which creates burden and unpredictable expenses for the manufacturers (given that serious incidents are not to be planned for) and might even create a disincentive for reporting. Duplicate vigilance case reviews are significantly contributing to high regulatory costs: additional (unpredictable) serious incident review by Notified Bodies can cost to manufacturers, on average, 285 € per one report and yearly costs could pile up to 600 000 € or more (depending on a Notified Body)[26].	authorities, especially as the regulations do not require their assessment of single vigilance reports. In addition, a holistic Post-Market Surveillance and Vigilance system under the regulations creates a well-grounded process to ensure the safety of medical devices and IVDs for public health. Duplicate vigilance case review has little benefit to fulfilling this objective, instead it creates a profound administrative burden. Single serious incident review by Notified Bodies should be avoided entirely. Notified Bodies ought to review vigilance data that may have impact on certification during their annual surveillance audit. To read more on MedTech Europe's proposal for the change in the current practice of vigilance data review by Notified Bodies see our position paper on Submission of vigilance reports to Notified Bodies under EU MDR & IVDR.
TOP 4 **Vigilance reporting of low value events**	**Main source of admin burden**: Competent Authority practice. There is lack of understanding of what low value events (incidents other than expected side-effects or erroneous results) are not expected to be reported to Competent Authorities as serious incidents. This often leads to an inevitable increase in the need to submit serious incident reports (individual Manufacturer Incident Reporting forms) for low value scenarios, i.e. cases in which the event does not qualify as a serious incident and could otherwise	**Short-term measure** **Eliminating unnecessary requirements by providing guidance** Low value vigilance events should be out of scope for serious incident reporting. A more viable solution would be to consider these low value scenarios not fitting the serious incident definition, and therefore, be out of scope of individual serious incident reporting and subjecting them to trend reporting instead, provided that these reporting

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	be reported with trend reporting and other applicable PMS reports, such as PSUR. While it is understood that low value events are part of the vigilance dataset and relevant for the device benefit-risk assessment, individual reporting of events that do not have to be notified as serious incidents, increases the burden for both the submitter and the reviewing Competent Authority while adding little to the protection of patient safety. In fact, such reporting may create distraction and 'noise' away from genuinely needed reporting. Based on some manufacturers experience, of total individual incident reports per year, up to 50% may fall under incidents that can be considered 'low value events' **Examples** of low value scenarios when the incidents should not be considered serious incidents: • Deficiency of a device found by the user prior to its use • Event caused by patient conditions • Service life or shelf-life of the medical device exceeded • Protection against a fault functioned correctly • Expected and foreseeable side effect • Negligible likelihood of occurrence of death or serious deterioration in state of health.	modalities offer added value as opposed to submitting individual MIR forms.
TOP 5 IVD specific: Sampling of class B and class C devices	**Main source of admin burden:** Guidance or other interpretation of regulation legal text. Based on the current MDCG 2019-13 REV. 1 guidance, technical documentation of class B and class C devices needs to be sampled and reviewed based on 15% sampling criteria which may be decreased to a minimum of 5%. The assessment of the technical documentation requires significant resources for the Notified Bodies and, therefore, implies significant costs for the manufacturers, especially SMEs. The overall post-market surveillance costs have doubled since the	**Short-term measure Eliminating duplication and applying risk-based approach & considerations for SMEs** While the recent update to MDCG 2019-13 rev 1, which has introduced the possibility of 5% sampling beyond the first certification cycle, has partially relieved the burden on the IVD sector, this is a temporary revision until the overall ongoing revision of this guidance document will be published and we argue that a more risk-proportionate approach should be considered.

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	IVDR, with the current criteria for sampling being a major contributor, which is especially burdensome for SMEs. The average sampling costs per one technical file assessment during initial certification audit can round up to 38K €, which constitutes approximately 2.4% of total Notified Body fees for one QMS certification. If that cost is applied for and SME organisation, the proportion of financial burden is a lot higher than for a large manufacturer. In addition, the average number of samples taken for technical file assessment is higher under IVDR (5.2) as compared to MDR (2.5) which is likely to result from the current sampling criteria, more extensive Notified Body scope designation codes for IVDs than medical devices and more grouping categories for IVDs[29]. Most important, according to the GÖG survey, the spike in costs is one of the most important reasons for IVD manufacturers having stopped or planning to stop production, marketing, and supply of some IVDs to the EU market[30]. If the average cost from MedTech Europe survey is considered a representative average amount charged by the Notified Bodies per one technical documentation review (~38K €)[31], based on the total number of IVDs on the EU market from GÖG survey, the total costs for sampling for the whole IVD sector could amount to[32]: • **Class B**: 6.1mln € based on 5% sampling and 18.4mln based on 15% sampling;	Sampling needs to be reduced at least for class B and class C devices that have been long on the EU market with stable PMSV data. To introduce a more risk-based approach and cut the sampling costs for IVD manufacturers up to 70% we suggest: • After the first certification cycle, automatic technical documentation sampling should be removed for class B devices, with sampling instead initiated by the Notified Body based on increased risk (the IVD sector could save between ~6.1mln € and ~18.4mln €). • For class C devices, sampling should be set to 5% (the IVD sector could save up ~5mln €). • For device groups with few or very similar devices which already have been sampled, no further sampling should take place – even during annual surveillance visits – unless triggered by a concern arising from PMSV data. • A higher sampling proportion should only be done if it adds meaningful value for safety and performance (e.g. new, innovative devices and devices with unstable PMSV data). These changes could be done by updating MDCG 2019-13 guidance or through implementing acts.

[29] MedTech Europe 2024 Regulatory Survey: Key Findings and Insights (Certification costs section)
[30] Based on the Gesundheit Österreich GmbH (GÖG) survey on the monitoring of the availability of devices, which was commissioned by the European Commission, 3 out of 5 main reasons for IVD manufacturers having stopped or planning to stop production/marketing/supply of some IVDs to the EU market are related to costs (i.e. products with low sales volumes, product revenue does not justify cost to reapprove device under the IVDR, products with low profitability)
[31] Please, note the estimation provided here is a very rough estimate based on average costs collected with MedTech Europe IVDR/MDR survey (the actual cost may be lower or higher, depending on Notified Body).
[32] Even though the total absolute number of devices in the GÖG survey data does not represent the whole IVD market, the distribution percentage by classes reflects the IVD market with class B devices constituting over a half and class C devices a third of the IVD market in the EU (class A sterile: 113 (3%); class B: 3256 (66%); class C: 1293 (26%); class D: 260 (5%)). Note that the actual numbers can be bigger than those represented in the GÖG survey.

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	• **Class C:** 2.4mln € based on 5 % sampling and 7.3mln based on 15% sampling; • **Class B:** 9.8mln € for full technical file review (see annex IV for graphical representation of these estimations). These numbers, even though they are a simulation, still represent a rough estimate of the burden on the IVD sector which is nor risk-proportionate (i.e. the lower the class – the more time the Notified Body spends on sampling activities). This is even more difficult for device groups with few or very similar devices which already have been sampled and continue to be sampled repeatedly, as well as for SMEs, for whom the proportion of costs based on their revenue is much more considerable than for large manufacturers.[33]	Reduced burden on sampling would make the requirements under IVDR more proportionate for lower risk-class devices as well as for SMEs. These changes would especially serve the SMEs who are affected unproportionally and who are struggling to keep the devices on the EU market under the IVDR. For Notified Bodies it would mean that they could dedicate more time and resources on PMSV areas that add more value to ensuring safety of devices, such as timely assessment of changes. If the actual implementation of such change is to be done by updating MDCG 2019-13 guidance, it would not require legislative change and it would prove to be an effective way to immediately reduce unnecessary administrative burden on manufacturers and Notified Bodies without significant effort, which is perfectly feasible within the current regulatory framework. Please, note that MedTech Europe is finalising a reflection paper on the topic of sampling under IVDR which will be shared with the European Commission once finished to provide more details on our analysis on sampling in the IVD sector, as well as proposal to improve it.
6. Inconsistent PSUR review by Notified Bodies	**Main source of admin burden**: Notified Body practice The review practices of PMS documents vary significantly between Notified Bodies. By applying different criteria and standards to the review of documents, a manufacturer must anticipate multiple levels of detail and timelines for approval based on the Notified Body. This leads to more complex documents, since one format	**Short-term measure** **Eliminating unnecessary requirements** Notified Body practices need to be aligned on PSUR requirements by, for example creating guidance for Notified Bodies on:

[33] Please, note MedTech Europe is preparing a separate position paper on the topic of sampling in the IVD sector which will be shared with the European Commission once available.

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	must meet the requirements of all Notified Bodies, and creates inconsistencies in schedules, which must be absorbed by the manufacturer. Lack of understanding of expectation as to what is required by which Notified Body results in overly burdensome PSURs being developed by the manufacturers. The longer and more complicated the PSUR, the more time and costs are needed to evaluate it (i.e. manufacturers are mostly charged per hour). It is worthwhile noting that the initial idea of PSUR was (and still is) a summary report[34]. Such inconsistencies result is significant variability in resources needed for PSUR. The current costs for PSUR vary significantly: the costs range from less than 1,000 € to more than 5,000 € (in some cases significantly more than 5,000 €), which shows the lack of alignment of current Notified Body fees and practices for evaluating these reports[26]. **Examples**: • A manufacturer has a PSUR that is covering devices which are listed under multiple certificates. Their Notified Body has reviewed the PSURs per different certificates and, therefore, they have reviewed the same PSUR several times. In addition, the manufacturer was charged per several reviews of the same PSUR around a dozen euros. • Notified Body A reviews the PSUR and may ask a few questions via email. The Notified Body then either approves or rejects the PSUR and provides recommendations for the next submission of updated PSUR. Notified Body B conducts an annual review of all PMS documents. The documents are	• Clarifying that PSUR is a summary report and providing principles for a least-burdensome approach to drafting and reviewing PSUR • clarifying what issues must be addressed before a PSUR can be approved, and which types of issues can be addressed in a subsequent PSUR; • acceptable timelines for the approval/rejection of a PSUR.

[34] MDCG 2022-21 GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR) ACCORDING TO REGULATION (EU) 2017/745 (MDR) December 2022: "*The main objective of a PSUR is to present a summary of the results and conclusions of the analyses of post-market surveillance data relating to a device or a device group, thus allowing the reporting of any possible changes to the benefit-risk profile of the medical device(s), considering new or emerging information in the context of cumulative information on benefits and risks.*"

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	subject to multiple rounds of review for clarification, to correct typographical errors, and ensure consistency across all documents. Only after all documents have been reviewed and updated does the Notified Body approve the PSUR. Since everything has been updated, there no recommendations remain to address in the next PSUR. • A section in the PSUR is required to summarize literature reviews in the past year. Some Notified Bodies are expecting that it is necessary to describe the fact that a literature search was conducted in conjunction with the Clinical Evaluation Report (CER) and no new harms were identified, while others may expect search terms presented, discussions of particular papers, specifics surrounding off-label use and other elements running several pages. • Some Notified Bodies expect short product description in PSUR, such as "Device XYZ is an implantable device for the treatment of ABC.", others expect several pages of product descriptions and drawings. • Some Notified Bodies requires the PSUR to be submitted three months after the data collection period and expects manufacturers to respond to any questions within two weeks. Some, require PSUR with sufficient information aligned with MDCG 2022-21 to be submitted within 90 days. If not done timely (or correctly) a reminder for further 30 days will be sent to the manufacturer; if not fulfilled – the certificate will be suspended and eventually cancelled. It is ought to be noted that the timeframe within which the PSUR needs to be submitted is not mentioned in the regulation. • Many Notified Bodies require the SS(C)P to be submitted simultaneously with the PSUR, creating a challenge since updating the SS(C)P depends on the conclusions of the PSUR. As a result, the PSUR submission is consistently delayed.	

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	• In addition to requests to submit SSCP together with PSUR, some Notified Bodies require to submit Post-Market Surveillance Plan, Post-Market Clinical Follow-Up (PMCF) plan, and PMCF report (for which the manufacturers are charged more, in some cases half more than just PSUR and SSP review). • Based on some manufacturers' experience, each additional PSUR deficiency round may cost 1,000 €. • Some Notified Bodies issue deficiencies that are not related to PSUR content. For example, a deficiency was issued because the "PSUR Cover Page" did not match the EUDAMED "Web form" that is the non-mandatory and is not yet in EUDAMED production system.	
7. One manufacturer serious incident report per one device	**Main source of admin burden**: guidance or other interpretation of legal text. Currently, the vigilance reports have to be submitted per devices, without the possibility of having several devices per one report even when the number of devices implicated in the same incident constitute very large quantity (e.g. 1000 devices in which case the manufacturer has to submit 1000 MIR forms for the same incident). Thus far, the rule is quite strict: one report per device. In practice, however, some Competent Authorities are making exemptions in cases where large quantities of devices are affected by the same incident simply because the sheer volume is unmanageable. In addition, such strict rule of 1 report per 1 device is not justified for effect it brings for patient safety (the same impact can be achieved with one report listing all implicated devices in one case). **Examples**: • Pain on Knee Implant equals one report versus one report for each CE marked device that makes up the need.	Short-term measure **Eliminate duplication** There should be more flexibility allowed with reporting per device, especially in case of large volumes. For example: a. Allowing one MIR form for medical device systems, rather than a MIR for each CE marked device that may have contributed to the event. b. Allowing one MIR form for high volume medical devices and IVDs by batch. c. Another section could be added to the MIR form, similarly to what is done for Sec 3.2(b) for "number of patients involved" could be used for quantifying the devices (same could be applied with EUDAMED).

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	• Suture, where the UDI-DI[35] and potential UDI-PI[35] would be the same (e.g. 4 sutures broke from lot ABC. Current expectations require 4 MIR forms which are essentially the same, while one MIR with quantity of devices impacted would suffice). • The hospital opens 10 boxes containing 100 each of the same devices and reports that there is a defect. There are 3 batch numbers between the 10 boxes. Manufacturer should submit 1,000 reports for the failure, but 1 MIR for each batch with the same alleged failure would be sufficient as long as implicated devices are reported in that one MIR). • Some manufacturers reported needing to submit more than 1,000 reports for one event. • The patient used 2 devices with the failure but returned 200 devices. All had the same batch number. The manufacturer should submit 200 reports for the same reported failure while only 2 catheters were used with the reported outcome. The rest of the catheters were returned by the user as they did not want to use them.	
8. Reporting time frame of 15 days for incidents classified as "Other" - lowest risk class	**Main source of admin burden**: requirement in regulation legal text. IVDR Art 82/MDR Art 87 defines incident reporting time frame depending on the risk of the incident: • Public health threat: 2 days • Death/ unanticipated serious deterioration in a person's state of health: 10 days • All other: 15 day.	**Long-term measure** **Change frequency/timing** Change the serious incident reporting timeframe for "All other" to 30 days. This would significantly reduce the number of initial/final not reportable incidents and would also align with the reporting time frames for medical devices in other jurisdiction: reporting “All other” in the US, Canada, India, Japan is 30 days; guidance from World Health Organisation

[35] Unique Device Identifier (UDI): device identifier (UDI-DI); production identifier (UDI-PI)

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	The lowest risk category for reporting is 15 days, which is a very short timeframe for all the tasks (collecting detailed information on the incident, translation, first investigation etc), which need to be performed until a manufacturer incident report (MIR) can be sent to the respective authority. The time frame encourages unnecessary reporting, which in the end are reported as "Final-non reportable"[36]. The required resources at manufacturer and/or Authorised Representative dedicated to meeting a strict time frame of 15 days for lower risk scenarios ("All other" cases) is unreasonably challenging. Based on some manufacturers' experience, the final-non-reportable incidents could mount up to 20-30%. It is ought to be noted that determining the root cause of an incident often takes more than 15 days as the investigation has to take into consideration different processes (not all of which are in the hands of the manufacturer) and variety of root causes. For example, the root causes that need to be analysed the IVD sector: • Pre-analytical (e.g., blood collection) (around 60-70% of root causes are typically related to pre-analytical issues). • Analytical (i.e., testing process) • Post-analytical (e.g., data transmission, result interpretation by the doctor). While the exact numbers may be difficult to tell, several manufacturers reported that the share of final-non reportable	(WHO), ASEAN[37] and IMDRF[38] foresee the timeframes of 30 days for these cases. Also, based on MEDDEV 2.12-1[39] (guidance document for previous EU directives for medical devices and IVDs) for lower-risk cases was 30 days. Additionally, for pharmaceuticals, which can have severe side effects for the patient, the following reporting requirements apply in EU: Non-Serious Adverse Drug Reactions (ADR) require 90 calendar days and Serious ADRs require 15 day[40].

[36] As per MDCG 2023-3, 'Final, (Non-reportable incident)' for cases where the manufacturer has submitted a MIR for potentially serious incident within the timeframe outlined in the regulations to the relevant competent authority but later establishes through its investigation that the criteria for a serious incident were not met.
[37] ASEAN – Association of Southeast Asian Nations
[38] IMDRF - International Medical Device Regulatory Forum
[39] Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev. 8
[40] EudraVigilance: electronic reporting

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	incidents has increased significantly under the regulations as compared to the directives.	
9. The value of Trend Reporting	**Main source of admin burden**: guidance or other interpretation of legal text. Under Article 88 of MDR / Article 83 of IVDR on Trend Reporting, manufacturers are required to report any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects (MDR) or expected erroneous results (IVDR) that could have a significant impact on the benefit-risk analysis which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits. There are several reasons why Trend Reporting under IVDR/MDR is duplicating other reporting requirements rather than adding additional value for ensuring patient safety: • **Duplicating requirements established under Article 82 (IVDR) and Article 87 (MDR):** While the trend reporting requirement is still in the early stages of implementation, in practice, manufacturers and Competent Authorities find it difficult to identify examples when the trend is not a serious incident, yet it may cause an unacceptable risk to patients. Technically, when the risk to patient safety is unacceptable it likely falls under serious incidents as per Article 82 (IVDR) and Article 87 (MDR) "*any serious incident involving devices made available on the Union market, except expected erroneous results [expected side-effects under MDR]*" and require initiation of field safety corrective action (FSCA). This raises questions regarding the possible duplication between trend reporting and serious incident reporting.	**Short-term measure Eliminating duplication** The duplicative reporting between Trend Reporting and reporting of serious incidents at the same time should be avoided by providing guidance that a Trend Report should not be required if an FSCA has already been submitted. **Long-term measure Eliminating duplication** Trend Reporting data could be made a part of PSUR and PMSR only rather than a separate reporting requirement. Trending data pertaining to "*statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects [or expected erroneous result] that could have a significant impact on the benefit-risk analysis which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits*" and their related actions could be presented and discussed within the PSUR/PMSR rather than reported in a separate Trend Report.

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	The highest risk trends will be likely identified from aggregate review of serious incidents and not the non-serious ones. Even when it is a significant increase in expected undesirable side-effects or expected erroneous results causing harm to patients above expected threshold – it may be considered a serious incident for which a FSCA must be initiated. The decision to submit a serious incident is at a complaint level, not at trend level, which makes the trend reporting requirement difficult to implement in practice. • **Duplicating requirements established under periodic safety update report (PSUR; Article 81 IVDR and Article 86 MDR) and post-market surveillance report (PMSR; Article 80 IVDR and Article 85 MDR):** The review and evaluation of reportable and non-reportable complaints is already part of PSUR and PMSR[41]. These reports must summarise the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken, including CAPA and/or field safety corrective actions related to serious and non-serious incidents, as well as information from trend reporting.	
10. PSUR data presentation in prescribed formats	**Main source of admin burden**: guidance or other interpretation of legal text. MCDG Guidance 2022-21 for PSURs presents formats for the presentation of data in relation to IMDRF codes. While these formats are identified as example-only, in practice they can be and	Short-term measure **Eliminating unnecessary requirements** Allow for flexibility in the presentation of data, perhaps by • Removing examples

[41] See MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) According to Regulation (EU) 2017/745 (MDR) December 2022 (link). Please, note while the current version of PSUR guidance is only dedicated to MDR it is also applicable to IVDR. The European Commission is currently working on updating the PSUR guidance to IVDR. In addition, while PSUR guidance aims to support the implementation of Article 81 IVDR and Article 86 MDR, this guidance although not covering PMSR, may provide useful suggestions on how information can be presented.

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	have been treated as a requirement. These formats are not necessarily consistent with how the manufacturer reviews data internally and must be generated specifically for the PSUR. This creates tables that cannot be readily compared with internal analysis, as well as effort and time manufacturers have to spend in developing and updating these reports. Based on MedTech Europe recent survey[8], for both MD and IVD sectors, 70% of manufacturers report needing up to 4 months to update their PMS reports and for some (~30%) it may take up to 12 months and, in some cases, 20 months or more. **Examples**: • Several tables mentioned in MDCG 2022-21 set out the calculation of percentages for serious incidents for different IMDRF codes and for 12 rolling months for 4 years. The tables are difficult to read and analyse. This amount of information is not required in the regulation. The manufacturer should be free to identify the best way to present data. • The guidance tables call for the separation of serious and non-serious events in the PSUR. Risk management practices, however, analyse the rates of all severities of events combined. Thresholds of acceptable performance based on risk management acceptability cannot therefore be readily applied to PSUR data. • Data tables in MDCG 2022-21 separate performance in the EU and Worldwide line-by-line; each IMDRF code is presented in two rows, one for EU, one worldwide. This has been interpreted as requirement and doesn't allow for the presentation of data in a more natural form: separate tables for EU and for Worldwide performance. While generating a separate EU table is relatively easy, combining it row-by-row with worldwide data is much more difficult. Also, the manufacturer does not typically examine the performance in	• Specifying which information is strictly required according to the legal text and which information is optional • Alternatively, providing multiple acceptable formats for the presentation of data.

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	the EU in isolation from other regions, so these tables do not readily align with the rest of PMS activities.	
11. Reporting under periodic summary reports	**Main source of admin burden**: Competent Authority practice. MDR Article 87 / IVDR Article 82 allows the reporting of common and well-documented incidents under a periodic summary report (PSR) instead of submitting individual Manufacturer Incident Reporting (MIR) forms, if criteria are established by the Coordinating Competent Authority, in consultation with the other Competent Authorities, on the format, content and frequency of the PSR. In practice, however, there is no practical solution to this requirement that alleviates reporting pressure for Manufacturers. Currently, creating a number of MIR forms for bulk submission is foreseen to be implemented in EUDAMED for PSR instead of allowing an aggregate report (e.g., in a form of a well-structured listing). This increases the administrative burden on manufacturers instead of providing a viable alternative to the multiplication of individual MIR submissions which that are submitted over a certain period.	**Short-term measure** **Eliminate duplication** Provide guidance to ensure effective use of PSR for manufacturers and Competent Authorities. Allow for aggregated reporting to avoid multiplication of MIR submissions. The solution would be a summary report produced at a given frequency in replacement of individual serious incidents (MIR) forms.
12. Unflexible PSUR data collection start date	**Main source of admin burden**: guidance or other interpretation of legal text. While the Regulation does not specify the PSUR data collection starting date, MDCG 2022-21[42] indicates that the data collection period for new devices first time launched under MDR should start at the device MDR certification date, which, while not mentioned – is also applicable to IVDR. There seems to be little added value for patient safety to start PSUR data collection period before the new device is released to the EU market and it has not yet reached the customer. However, for the manufacturers which do not place	**Short-term measure** **Changing frequency/timing** Allow more flexibility to discuss with Notified Bodies on PSUR data collection start date. MedTech Europe suggests aligning PSUR data collection start date with IVDR/MDR which would allow manufacturers to choose not to start data collection period right after CE mark has been obtained but, for example, at the EU Declaration of Conformity date or from the moment when the first device is placed on the EU market.

[42] MDCG 2022-21 GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR) ACCORDING TO REGULATION (EU) 2017/745 (MDR) December 2022

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	a new device on the EU market immediately after certification date it means an early start of data collection period while technically no data can be generated. Based on some manufacturers' experience, it seems that different Notified Bodies approach this differently: some are allowing for more flexibility with PSUR data collection start date, while others – not.	
13. Notifying Competent Authorities of preventive or corrective actions (CAPA)	**Main source of admin burden**: requirement in regulation legal text According to Art. 83(4) MDR and Art. 78(4) IVDR[43] manufacturers have "*to inform competent authority on the need of preventive or corrective action*", corrective actions other than those mentioned under Art. 87 MDR and Art. 82 IVDR "*Reporting of serious incidents and field safety corrective actions*". There is little clarity as to which CAPAs exactly need to be notified to competent authorities, given that those related to serious incidents are being reported according to Art. 87 MDR and Art. 82 IVDR. Moreover, some competent authorities expressed that they do not want to be notified of all CAPAs in addition to those related to serious incidents. This has led to a discussion in the MDCG PMSV Task Force for MDCG 2022-21 guidance on PSUR when it has been drafted initially and the addition on Art. 83(4) MDR and Art. 78(4) IVDR to this guidance. The MDCG task force tried to palliate this situation by adding "*The PSUR may also be the tool to provide information about Corrective Action(s) or Preventive Action(s) (CAPA) which are covered by [Art. 83(4) MDR and Art. 78(4) IVDR] first sentence and for which the information of the competent*	**Long-term measure** **Eliminate unnecessary requirements** The most important is that a manufacturer is implementing the appropriate preventive or corrective action to ensure that identified problems do not arise again. Where a serious incident is identified or a field safety corrective action is implemented, it is already reported to respective authorities according to vigilance requirements (Art. 87 MDR and Art. 82 IVDR). Therefore, eliminating the requirement to report CAPAs other than those mentioned under vigilance requirements would reduce bureaucratic burden without compromising safety related information being reported to authorities. Update MDR/IVDR legislation text by e.g. removing the respective sentence part from Art. 83(4) MDR and Art. 78(4) IVDR: "*If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures ~~and inform the competent authorities concerned and, where~~*

[43] Art. 83(4) MDR and Art. 78(4) IVDR: "*If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with [Article 87 MDR / Article 82 IVDR].*"

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	authorities and, when applicable, the Notified Body about these CAPAs and their implementation is required." However, it is important to note that PSURs are not sent to the competent authorities, they are subject to the Notified Body review, so this information will not be reviewed by Competent Authorities (especially for the reports that will not be uploaded to EUDAMED). There is thus no form, no indication on how to perform this notification and it will not be part of EUDAMED. The industry does not have adequate tools and guidance for how to comply with this requirement. Further, manufacturers need to review all CAPAs to identify which of them are PMS related and which of them have not yet been notified as part of Art. 87 MDR and Art. 82 IVDR, which creates additional layer of admin burden with little added value. In addition, there is little safety related basis for reporting all CAPAs to competent authorities, given that some of the CAPAs are related to negligible level of risk (or no risk) to patient safety and are of preventive or cosmetic nature (e.g. cosmetic defects).	~~*applicable, the Notified Body*~~." A requirement could be included to provide the necessary information to the Competent Authority upon request, or this information can also be provided with PMSR/PSUR which are already required to be made available upon request.

Economic Operators Requirements

Challenges with regards to Economic Operators requirements are mostly linked to the verifications required by MDR/IVDR that have to be performed by both importer and distributor, resulting in significant duplication. Also, the duplication between information included in national databases and EUDAMED is of significant concern.

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1. Economic Operators	The same product undergoes the same verification multiple times in the supply chain, creating repetitive actions and duplication of work.	Long-term measure **Eliminating unnecessary requirements**

What?	Why?	How & When?
verifications (13.3 and 14.2) & importer details (Art.13.3)	Also, in Art 14.2 (a), (b) and (d) sampling method can be applied, while not for 14.2c) (importer details 13.3.). This has to be checked on every single item. Wording adjustment of the IVDR/MDR is proposed to allow sampling method in the same way as for the other Art 14.2 subpoints. Importer details themselves (art 13.3.) are causing high administrative burden as economic operators have to re-label, issue specific leaflets or stickers with the importer information to make sure this will remain with the product until it reaches the end user. This information will be available in EUDAMED and it can be easily made available through digital label (please see more on digital label in the Digitalisaiton section below). Note that importer and distributor are not able to do the following: • Assess whether the label provided by the manufacturer includes all the information of Annex I.23.2 and 23.3 MDR/ 20.2 IVDR since the importer (unless they are part of the manufacturer's organisation) does not have the knowledge of the device to the same level of detail as the manufacturer and will not have access to relevant documentation such as Technical File/Documentation, which is the sole property of the manufacturer. • Visually check the instructions for use which physically accompanies the device in the package for the reasons stated above (plus should not be expected to open the package). In addition, the importer cannot: • Verify that the UDI has been assigned in accordance with MDR Art. 27/IVDR Art. 24 since the importer does not have the qualifications to assess the complexity of the UDI process. The importer can, however, verify that the UDI-DI has been assigned.	We propose a concrete wording suggestion for update of IVDR/MDR Art 13.2: "*In order to place a device on the market, importers shall verify that:* […] *b) a manufacturer and an Authorised representative, if applicable, is identified ~~and that an authorised representative in accordance with Article 11 has been designated by the manufacturer~~;* *c) the device is accompanied by label and ~~labelled in accordance with this Regulation~~ ~~and accompanied by the required~~ instructions for use;* (*d*) ***where applicable,*** *a UDI has been assigned by the manufacturer ~~in accordance with Article 27.~~*" Update Art 13.3 MDR/IVDR as follows: *~~Importers shall indicate on the device or on its packaging or in a document accompanying the device their~~* ***The importer*** *name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established,* ***shall be made available through EUDAMED and/or through digital label.*** *~~They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer~~* Update IVDR/MDR Art 14.2 as follows: "*Before making a device available on the market, distributors shall verify that all of the following requirements are met:* *[…]* *(b) the device is accompanied by label and instructions for use~~the information to be supplied by the manufacturer in accordance with Article 10(11);~~*

What?	Why?	How & When?
		(c) for imported devices, the importer has been assigned ~~complied with the requirements set out in Article 13(3);~~ *(d) that, **where applicable,** a UDI has been assigned by the manufacturer."* *In order to meet the requirements ~~referred to in points (a), (b) and (d) of the first subparagraph~~ the distributor may apply a sampling method that is representative of the devices supplied by that distributor."*
2. EUDAMED delay impact on EcoOps and verification process design, Art 13.4	Delay in EUDAMED implementation and guidance leads to Economic Operators having to update their internal processes again. Guidance given impacts IT System & Solutions and Business Processes that enable DTX-change with EUDAMED. Processes need to be re-assessed, amended and re-validated to incorporate new expectations. Registration in EUDAMED is part of Manufacturer QMS processes and therefore a risk-based approach would be more valuable than systematic verification by the importer prior to placing on the market (delays market access, cause financial loss). This will be checked by the authorised representative in case the legal manufacturer is based outside of the EU.	**Short-term measure** **Provide guidance** • Stable environment needed. Guidance needs to be published timely with clear instructions, economic operators should not have to re-do their processes. • Guidance with a risk-based approach to verification per Art.13.4.
3. Double registrations in EUDAMED and in national databases	**Main source of admin burden**: Competent Authority practice Once EUDAMED respective modules become mandatory for use, there will no longer be a legal requirement to register economic operators (except for distributors if required by national law) and devices in national databases and send new serious incident, post-market surveillance and serious adverse event reports, as well as clinical/performance study applications etc. via national processes. MedTech Europe would like to bring to the European Commission's attention to the fact that the national registration (notification) requirements for medical devices and IVDs is additional to EUDAMED registration is very burdensome for placing devices on the EU market	**Short-term measure** **Eliminate duplication & apply 'Once only' principle (EU added value)** Country requirements that duplicate EUDAMED device registration should be eliminated once the EUDAMED UDI and Device module is made mandatory (foreseen in January 2026). Instead of duplicating, Competent Authorities could ask for a minimum data (e.g. the Unique Device Identifier UDI-DI or Basic UDI-DI) that allows the identification of the particular device in the central database for data download.

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	and duplicates much information already found in EUDAMED. A patchwork of different requirements exists in different Member States. MedTech Europe has an overview of national practices, which it could share with the European Commission to substantiate this point, if of interest. Requiring device data at national level other than a list of distributed UDI-DIs can be regarded as a measure having equivalent effect, given that data on devices would be required to be registered in EUDAMED. The implementation of UDI as a means to identify devices is expected to provide more accurate and reliable information compared to the current fragmented data found in national databases and other registries. Device information in national distributor databases should not replicate device information already found in EUDAMED (speaking about device not the distributor details as there is no distributor registration in EUDAMED). **Example case study**: Time and Workload Implications regarding the registration process in one of the national databases: • If all required information is readily available, completing a registration takes approximately 15 minutes per product reference. If information is missing or requires retrieval from manufacturers, the process can take significantly longer. • Keeping records up to date is also time-consuming. Whenever a manufacturer modifies any of the registered data fields, companies must manually update each affected reference, which can take approximately 5 minutes per change, even for simple modifications such as a brand name update. • Label and IFU updates require uploading new files into the database.	It is critical already today, that Member States, the European Commission and stakeholders work to ensure that the necessary information can be downloaded from EUDAMED and interact with existing national databases (which may be based on different platforms). Information/data attributes on devices distributed nationally should be aligned with that from the single source of truth in EUDAMED. To avoid creating double formalities, we urge Member States to leverage reliable and quality device data referencing or synchronizing data from the unique central source of truth, which is EUDAMED. Existing distributor databases and other national registries should rely on device information contained in EUDAMED for a more effective use of available resources.

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	• In many cases, distributors are not proactively informed of changes by manufacturers. Instead, they detect modifications when receiving stock and must request the updated information, leading to delays. • The overall administrative burden depends on the company's portfolio size. A distributor handling a large, multi-brand portfolio may need one or two full-time employees dedicated solely to registrations and updates.	

EUDAMED

The European central database for medical devices (EUDAMED) is a critical infrastructure for IVDR and MDR. Industry users are the main contributors of data to be present in the central database therefore its success depends on its technical useability (device registration and lifecycle management) for manufacturers and on the rules that are required to apply to transition to mandatory use. The smooth implementation with efficiency and time gains could be achieved by using the central database via enhanced data input methods, by providing reliable timelines and pragmatic transition rules, by harmonising member states' information needs channelled through EUDAMED – read MedTech Europe position paper on Smooth transition to the mandatory use of EUDAMED.

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TOP 1 EUDAMED readiness and implementation	**Main source of admin burden**: changing roadmap and lack of technical documentation, lack of transition guidance to the mandatory use of Vigilance and Clinical modules The official launch of EDAMED has been postponed several times in the past few years. It had an impact on companies' resourcing their EUDAMED IT transformation projects. Since EUDAMED has been launched for voluntary use, it has been updated several times and often with changes that required revision and updates to data. Accordingly, preparation of M2M interface has	Short-term measure **Providing guidance** (roadmap and final technical documentation), transition guidance and regulatory guidance to the mandatory use of Vigilance and Clinical modules. It is crucial that the European Commission provides and keeps reliable timelines and a realistic transition period which enables users to build up resources, tools and infrastructures (set up a team of experts, establish a budget and a project plan) to execute a large-scale IT project to align internal systems and to enable technical interfaces with EUDAMED. Industry uses GxP validated systems that require time to modify: the development, validation, implementation (etc.) of IT solutions is a multi-step process which

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	been delayed leading to a delay in populating the required product specific data. Awaiting a functional UDI/Device module has (and still does) lead to extra administration for organizing and reorganising required data in internal data management systems for easy and correct M2M upload when EUDAMED becomes available. Currently there is a high uncertainty of the system specifications (technical documents with the necessary IT details are not 100% matching the functionalities implemented in the database) which makes difficult for manufacturers, Notified Bodies and other actors to plan ahead and leverage efficiencies.	takes several months. It requires intensive resource and budget commitments. The initial readiness for EUDAMED requires a lot of upfront work in creating the DTX system (for automated submission: bulk XML upload or machine-to-machine communication) to integrate with the EUDAMED database for which precise technical documentation is needed. It is important that the European Commission publishes final technical documentation for each module (data dictionaries, business rules, entity diagrams, XSDs etc.) that are fully aligned with the modules. We welcome attention to ensuring accessibility to the playground (both via manual and automated input) as it is crucial for manufacturers to familiarise with the system, prepare, align in order to comply on time. Where the implementation of technical functionalities is not viable, provide transition guidance (practical details of how to transition to mandatory use) and regulatory guidance (helptext how to fill the various forms) to ensure smooth transition from national to central mandatory use of Vigilance and Clinical modules.

TOP 2 **Efficiency and accessibility of EUDAMED for users**	**Main source of admin burden**: Lack of optimisation (considering the state of the art), Lack of functionality in EUDAMED, Applying 'Once only' principle
	
	MedTech Europe collected input from its members who participate in the testing of EUDAMED modules. They were asked to compare their activities via the current national vs. the anticipated future practices in EUDAMED. Most responders do not anticipate that using the central database will improve time nor efficiency for the forms submitted through the Vigilance and Clinical modules.
	
	Possible resource savings through EUDAMED (automated acknowledgement / confirmation, one streamlined process to
		Mid-term measure **Change frequency/timing, introduce digitalisation, eliminate duplication, streamline Competent Authority practice**
		
		• Make sure that EUDAMED readily useable / workable for all economic operators
		• Efficiency and time gains would be achieved by enabling use of the central database via enhanced data input methods by:
		  ○ prioritising the implementation of automated input and download methods,
		  ○ ensuring inter-module data consistency with auto-population of data from source module,
		  ○ avoiding multiplication of the same data input,

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	follow) need to be put in context of the significant investments required by the manufacturer for updating and validating internal IT software to enable M2M capabilities. Also, a much longer data set is requested for EUDAMED submission compared to what was previously required using national processes: EUDAMED requires 128 device data elements, 50% of which is not updatable, FSCA and FSN module demands approximately 65% additional information related to field actions. **Examples of efficiency drains with EUDAMED:** The national competent authorities' additional inquiries and variances are considered as being the biggest efficiency drains which if they continue also after EUDAMED mandatory use will necessitate use of two systems in parallel (central submission + email follow-ups referencing submissions in EUDAMED). EUDAMED should achieve a standard process without the Member States' variances. Compliance with CIPS module is foreseen to be resource intense, as its use will be 100% manual for Sponsors when it is launched as Minimum Viable Product (MVP). Also, the CIPS coordinated assessment procedure is not binding for Competent Authorities until 2033, therefore the submissions are foreseen to continue per country, etc.	○ reducing the number of non-updatable data fields by enabling flexibility in updating data, ○ increasing the number of validation rules, ○ harmonising member states' information needs channelled through EUDAMED. • Duplicative work and administrative burden should be identified and addressed throughout the system. Examples of efficiency gains with EUDAMED: • The overall aim is the reduction in the administrative burden associated with data submission and maintenance in individual member state databases through their convergence with EUDAMED. • The submission of ongoing clinical investigations and performance studies should not be required: studies already have started, or which already received authorisation when the CIPS becomes mandatory for use as Sponsors will already have completed their legal requirement to report such information by submitting it per country at national level. • The M2M and XML functionalities for upload and download of Serious Adverse Events should be prioritised and implemented before the notice confirming the functionality of the CIPS module will be published in the OJEU. • Download functionality for Vigilance reports for reporter (manufacturer or Authorised Representative) should be enabled. • Provide VGL and CIPS transition guidance to explain the regulatory requirements for the different upload scenarios in EUDAMED to ensure a smooth transition from national to central EUDAMED processes. **For a more detailed description of these aspects, please read the** MedTech Europe position paper Smooth transition to the mandatory use of EUDAMED and the MedTech Europe position

What?	Why?	How & When?
		paper Ensuring a smooth implementation and use of the EUDAMED Clinical Investigation and Performance Studies module. Please note that MedTech Europe's position paper for the EUDAMED Vigilance module is being developed for more detailed suggestions. It will be shared publicly and with the European Commission once ready.
TOP 3 **Inconsistent information across modules**	**Main source of admin burden**: Lack of optimisation (considering the state of the art), eliminating duplication, lack of functionality in EUDAMED At present, EUDAMED is not structured as an integrated system. The modules and forms are being built separately without synergy on the data attributes definition. When it relates to the device data, it should be a harmonized naming of the data and its legal definition. Until this is addressed, a lack of integration in the system considerably will impact the consistency and usability of data. The current design of PMSV forms requires the company vigilance expert to replicate information that is already available within other modules of EUDAMED (Actor, Device, Certificates) and which likely would have been submitted/maintained by a different colleague possibly in another team. Conflicting data can be inputted into different modules of EUDAMED for a single device without any controls or error messages being generated. It is crucial that the system autopopulates key information from its source module and makes the user unable to input inconsistent and conflicting information in different modules or at least provides an alert when this is attempted. **Example**: In the device registration module, the Notified Body ID and Certificate number associated with this UDI is entered; this module should be considered as the source of truth. In the MIR the user is	**Short-term measure** **Introduce digitalisation** Enable autopopulation of data fields which repeat information already registered in the source modules, as essential for establishing a single source of truth, lowering admin burden and ensuring alignment across interconnected EUDAMED modules. Inter-module data consistency has utmost importance for ensuring data quality in EUDAMED. Further reduction in admin burden should be gained by only requiring a limited data set when submitting a vigilance or post-market surveillance report in EUDAMED (e.g. populating UDI information should address all the "static information"): only the incident information and event coding should be added.

What?	Why?	How & When?
	asked to submit the same information (which is duplicative) and this information can be entered with errors or entirely conflict with what is in the device registration module. Despite that conflict in critical information, the form can successfully be submitted without an error message being generated. The certificate number as entered/modified by the Notified Body in the NB/Certs module should be considered the source of truth when used in any other module.	
4. EUDAMED Vigilance module	**Main source of admin burden**: Lack of optimisation (considering the state of the art), lack of coordination between policy and IT requirements, duplication of work (database development) EUDAMED architecture should follow comparable quality standards as those which medical device / IVD manufacturers need to follow for their software systems (Validation, Change documentation, Traceability etc). As the IVDR/MDR legal texts do not contain much detail on software development requirements, this missing focus on quality standards in the database is leading to higher administrative burden at the industry user side. Detailed technical requirements are needed to carry out the transformation of the internal IT systems to match the data structure/expected content/validation rules of the EUDAMED forms. Currently, there is a concern that the updated Manufacturer Incident Reporting (MIR) programmed PDF form and its generated XML (required to be implemented despite the fact that it will not be EUDAMED compatible) will delay the EUDAMED transition projects for companies and will need to divert resources for establishing a temporary process.	**Short-term measure Introduce digitalisation & Provide guidance** The MIR PDF (and generated XML) should have a 100% match in its content and validation rules with the XSD files and User Interface to be later implemented in EUDAMED for bulk/M2M upload. If the developed MIR PDF 7.3.1 is not compatible, then the form should not be published and new fully EUDAMED-compatible MIR form could be designed based on EUDAMED rules (EUDAMED compatible XML) for XML upload to EUDAMED or to send to the Competent Authority before EUDAMED. The two projects (to implement MIR 7.3.1 PDF/XML/XSD files before EUDAMED and to prepare for EUDAMED) must be combined into one for the best use of resources. Industry users should not expect any future change in the validation rules and content of the VIG data once transition from PDF to XML and finally to XSD files received by EUDAMED.
5. Vigilance reporting for	**Main source of admin burden**: Lack of optimisation (considering the state of the art), Lack of functionality in EUDAMED, Applying 'Once only' principle	**Mid-term measure Eliminate duplication** Avoid duplicate registration: Registering a non-registered (NRD) or the legacy device (which is the same as the already registered Regulation device) in the case of a Vigilance case does not bring

What?	Why?	How & When?
legacy and old devices	Based on current EUDAMED functionality, an 'Old' device must be registered as a devices not for registration (NRD) prior to submission of an Initial Manufacturer Incident Reporting form (MIR). This requirement is in conflict with MDR/IVDR that state that old and custom-made devices are legally not required to be registered in EUDAMED. NRD devices are old and therefore to look for device data is not always straightforward, and the Vigilance teams will have to dedicate lots of energy on this activity. The EUDAMED gradual roll-out Q&A requires the registration of legacy devices despite the general rule (which is also present in the amending Regulation (EU) 2024/1860) that states if the same Regulation device is registered, the legacy device registration is not required. This means that Vigilance experts need to develop competencies in an area that was not considered necessary under the medical devices directives: ensure registration of old/ legacy devices. A consequence is removing focus from the patient and the device vigilance assessment. This process is expected both to be confusing and burdensome since registering such an old/legacy device duplicates the registration already in place for their counterpart Regulation device. Additionally, the reports for unknown actor or unknown devices, where at the moment, EUDAMED does not allow the submission of incidents of this nature. This is part of a day-to-day business and there is no guidance on how to handle them in or outside EUDAMED.	value and loses overall visibility to the incident/ Vigilance case that occurred. A more flexible approach to reporting Serious Incidents on 'Old' devices would be welcome. Manual entry of known data attributes at all stages of the report life cycle should be permitted, even in the event where the device is not registered. Validation to submit the Final report in the absence of data attributes listed above should be removed, as data attributes required are embedded in the MIR.
6. Upload of Summaries of Safety and (Clinical)	**Main source of admin burden**: Lack of optimisation (considering the state of the art), lack of functionality in EUDAMED The supply of devices to patients should not be dependent on the upload of SS(C)P by Notified Bodies. Most SS(C)Ps are expected to be	**Short-term measure Eliminate administrative burden of Notified Bodies, Introduce digitalisation**

What?	Why?	How & When?
Performance (SS(C)Ps) to EUDAMED	uploaded during the first registration wave of devices; therefore, this functionality is crucial when starting the UDID mandatory use.	Transfer the functionality to manufacturers for **uploading non-validated and translated Summaries of Safety and (Clinical) Performance (SS(C)Ps) to EUDAMED**. In alignment with the UDI/Device registration module mandatory usage timeline, it is essential to prolong the measures of MDCG 2021-1 Rev. 1 and MDCG 2022-12 for the making available of the SS(C)P by manufacturers, to ensure manufacturers can continue to place product on the market compliantly.
7. Only manual entry allowed to Clinical Investigation and Performance Evaluation by Sponsors, no download of Vigilance reports	**Main source of admin burden**: Lack of optimisation (considering the state of the art), lack of functionality in EUDAMED Compliance with Clinical Investigation and Performance Evaluation (CIPS) module is foreseen to be resource intense for Sponsors who are the main contributor of data in this module as all forms are foreseen to be 100% manual in the Minimum Viable Product (MVP) version of EUDAMED. The DTX download of vigilance reports is not planned to be implemented in MVP.	**Short-term measure** **Introduce digitalisation** Prioritise automated data submission and download methods for efficient use: implement M2M/XML data upload and download capabilities for Serious Adverse Event reports, for download of Manufacturer Incident Reporting / FSCA forms.
8. Processes of using EUDAMED Access Point (also via 3rd party organisation)	**Main source of admin burden**: lack of guidance It is not officially confirmed how to group proof of testing for several actors who use the same access point. **Proof of testing**: guidance on how to update the "first access point" for 3rd party providers, in case the original access point is deleted or the relation between manufacturer and 3rd party provider is no longer active • **Business justification**: ○ Current template makes manufacturers sign that they have "... a database that needs to be interoperable with EUDAMED".	**Short-term measure** **Introduce digitalisation** Explain methods how several actors can leverage one consistent process for managing data through the same access point (i.e. proof of testing can be demonstrated with one SRN - from a group of actors that belong to the same organisation – per actor type such as EU MNF, non-EU MNF, S/PP).

What?	Why?	How & When?
	This is not accurate for AP using a 3rd party provider and causes issues in collecting signatures. ○ No confirmation on the number of items and frequency that serves as a threshold to get an AP approved or denied. This leaves manufacturers with the pressure to include a difficult to calculate high number otherwise their request could be denied. Mention of Single Registration Numbers (SRN) in Production and Playground: is this mention linked in any way to the Proof of Testing? Can different Playground accounts be mentioned in this document?	
9. No EUDAMED playground exists that mirrors the production environment	**Main source of admin burden**: Lack of optimisation (considering the state of the art), lack of functionality in EUDAMED Commission encourages **early compliance for actor and UDI/device registrations**. For that the **discrepancy between the UDID module's Production and Playground environments should be eliminated** as it causes GAMP5 validation concerns for companies who are ready to go-live for device registration. Often, the Playground environment is not aligned to the Production causing several issues for not knowing what is causing issues for launching data in production. EUDAMED implementing act is expected to regulate the sequence and harmonization of playground and production environment - applicable from mandatory use of the system so from Jan 2026.	**Short-term measure Introduce digitalisation** Once EUDAMED is mandatory to use, 2 playgrounds are needed: one QA environment that is a copy of the Production environment for Industry to use before going into the production and another where the upcoming new functionalities and updates could be tested.
10. Automated M2M return message	**Main source of admin burden**: Lack of optimisation (considering the state of the art), lack of functionality in EUDAMED Currently, there are no **automated technical return messages** to confirm electronic transactions have been successfully completed or not (*certain technical responses are received from EUDAMED access point with timestamps*)	**Short-term measure Introduce digitalisation** Improve **automated technical return messages** to confirm electronic transactions have been successfully completed or not.

European Medical Device Nomenclature

The benefit of the European Medical Device Nomenclature can only be achieved if it is used in an aligned way: in the identification of analogous or similar devices in the EUDAMED database, on certificates, in sampling but also in national databases (distributor database, reimbursement, procurement). The education and awareness raising of all EMDN users should continue to achieve this.

What?	Why?	How & When?
TOP 1 Maintenance of EMDN codes in EUDAMED and in related regulatory documents after yearly update	**Main source of admin burden**: Lack of optimisation (considering the state of the art), lack of functionality in EUDAMED Each year in January when the outcome of the annual EMDN update will be published, users of the codes should carry out an impact assessment of already assigned EMDN codes to check for necessary changes. This manual maintenance of changes and comparison of EMDN codes in an Excel file is expected to be time consuming (significant non-value added manual comparison of versions, source of human error). As per EMDN FAQ MDCG 2021-12 rev.1, it is a new responsibility for manufacturers to set up a standard practice to assess each annual publication of EMDN for any changes which may impact devices in their product portfolio and to notify the relevant Notified Body about EMDN changes impacting their portfolio. The updating timeline is also in the discretion of the Notified Body (should be done: "In a timely manner and reasonable manner, and at the latest prior to the next annual surveillance audit following the finalisation of the annual EMDN update cycle") and can be burdensome depending the impact of EMDN changes on the device portfolio.	**Short-term measure Introducing digitalisation** An automated notification from EUDAMED should be implemented to inform the users of the codes (manufacturers who register the devices in EUDAMED) that are impacted by the annual EMDN revision. Users should then assess and update their code assignment where necessary. A broad communication should be launched for all EMDN users (especially to the users of codes 90 and 99) to bring to their attention the list of newly created codes – for ensuring an easier assessment if any changes need to be implemented. Notified Bodies and Competent Authorities should receive the same communication. Also, it should be clearly communicated to both manufacturers and to Competent Authorities how the yearly update will be implemented and manged in EUDAMED (e.g. how changing of the codes will impact the grouping of devices in EUDAMED).
TOP 2 Lack of harmonised nomenclatures	**Main source of admin burden**: lack of harmonisation among Member States Local Authorities not adopting EMDN in their local databases and in local processes (distributor database, reimbursement, procurement) will create the need to maintain several nomenclatures by the	**Short-term measure Eliminating duplication** Local authorities should adopt EMDN by aligning the national processes and databases with EUDAMED (including EMDN).

What?	Why?	How & When?
among Member States	manufacturer and the local nomenclatures will never be up to date to the EMDN changes.	
TOP 3 Non-harmonised Notified Body practices in using EMDN and challenging EMDN assignment to devices by manufacturers	**Main source of admin burden**: lack of harmonisation among Notified Bodies Lack of harmonization between Notified Bodies' conformity assessment application templates, where some of them ask for the terminal (most granular) level of EMDN on and others requests the level 3 or 4 needed for the sampling process (and include them to the certificates). This potentially leads to unnecessary updates of certificates. There is also a misunderstanding of the "most granular" which previously was the "most granular applicable" use of EMDN. This will trigger a documentation update with no value to the patient and risk of supply chain disruption (e.g. due to delayed or changing certification) and increase of the certification review cost. If a Notified Body uses EMDN code and term on the certificate to indicate the device type, if that level of EMDN is changing it leads to an updated certificate and therefore to an update to all international registrations that leverage CE marking.	Short-term measure **Provide guidance** Notified Bodies should align their practices in using EMDN e.g. on certificates. The different uses of EMDN by manufacturers (in regulatory documents, in technical documentation, in master data management, etc.) and the reasons for changing it should be explained to Notified Bodies. EUDAMED only accepts the registration of the most granular EMDN code that should be assigned to all devices at UDI-DI level. Notified Bodies who ask for level 3/4 code should be aware of EMDN structure and assignment principles.
TOP 4 Challenging Basic UDI-DI grouping by Notified Bodies	**Main source of admin burden**: lack of guidance The relationship of EMDN and Basic UDI-DI goes beyond EUDAMED database, it should be clearly explained from a policy perspective. Notified Bodies asking to change Basic UDI-DI late in the process leads to a burdensome update of numerous documents.	Short-term measure **Provide guidance** The FAQ on EMDN must be clear on the relationship between the EMDN and Basic UDI-DI to avoid misuse and misunderstanding of the EMDN. The sampling plan of Notified Bodies rely on number of Basic UDI-DIs within a manufacturer portfolio and the selection criteria are arising from the MDCG 2019-13 Sampling guidance that is based on level 3 (for Class C IVDs) and 4 (for Class IIb MDs) EMDN codes.

What?	Why?	How & When?
TOP 5 Lack of EMDN definitions and procedural guidance describing the principles of EMDN updates	**Main source of admin burden**: Lack of EMDN definitions and procedural guidance document on the update rules of EMDN EMDN is a new nomenclature being implemented to support MDR and IVDR, in particular the registration of devices in EUDAMED. Users (manufacturers, Notified Bodies, Competent Authorities etc) need education to ensure the appropriate allocation of EMDN to devices and its use for sampling, on certificates, in national databases and registries etc. Currently EMDN definitions are not provided for users, neither the translations of the EMND terms are available in most official EU languages. Clarity is needed to all users of EMDN about the rules that are applied to update the nomenclature (rules of creating new codes, editing or splitting codes, retiring – never deleting – existing codes, moving codes etc). Any change to the EMDN -especially after the mandatory use of the EUDAMED UDI/Device registration module will start where EMDN most granular code is registered as part of the device information - creates a burdensome update process to all users of the codes. The long-term stability of EMDN should be ensured.	Short-term measure **Provide guidance** It is important that the same EMDN code/term is assigned to devices that have the same functional and structural characteristics to enable competent authorities to carry out their market surveillance activities based on vigilance and device data submitted to EUDAMED. The attribution of the appropriate EMDN code to each UDI-DI thus becomes a fundamental step to ensure the correctness of these activities: to evaluate devices in a homogeneous way. Description and the translation of the EMDN codes are needed that will aid users to select and assign the appropriate EMDN codes to devices. The relative stability of EMDN ensures that Competent Authorities can carry out their market surveillance activities using this tool in EUDAMED (e.g. generating reports by the grouping criteria of EMDN levels). The stability would ensure that the users of the codes should make updates only on a well-reasoned ground. A procedural guidance describing the principles of EMDN updates would bring trust to the stability of EMDN and would ensure that its update is carried out from a regulatory perspective. Suggest turning the types of updates described on the EMDN submission planform (https://webgate.ec.europa.eu/dyna2/emdn/) into a guidance document.

Unique Device Identification (UDI)

To achieve a single, globally harmonised positive identification of medical devices, the EU should adopt the principles established by the International Medical Device Regulators Forum (UDI-DI triggers/non-updatable fields programmed into local databases). In this context the local legislator should not change rules, idents or regulatory concepts which make such local rules incompatible with the global framework of UDI. Incompatibilities lead to local differentiation of one and

the same device and identifying them with a variety of UDI-DIs. Assigning a different UDI-DI per jurisdiction for the same device creates more complex supply chain management with bigger ecological footprint and leads to loos of oversight of identity of devices and their safety and vigilance information worldwide.

There is no clarity for users about the expected content of the UDI information to be registered in EUDAMED due to the lack of related regulatory guidance. There are extra administrative burden arising from local legislation to receive traceability information in other means than from the label. The benefit of the single device identification should be further leveraged by health systems, national databases and device registries.

What?	Why?	How & When?
TOP 1 Proliferation of UDI-DIs	**Main source of admin burden**: lack of guidance or other interpretation of the legal text, Changing frequency/timing, EUDAMED database design The EUDAMED database design does not allow to change or update content of a high number of data fields. Changes which concern data fields which are not updateable are considered „Trigger fields" where a change results in the assignment of a new UDI-DI. This is followed by entry of a new device into EUDAMED and thus the proliferation of Identifiers for the same device. The EUDAMED database design forces the change of the device identifier, UDI-DI compared to MDR/IVDR requirements and compared to those listed by International Medical Device Regulators Forum (IMDRF/UDIWG/N7 10.7 UDI Guidance: Unique Device Identification (UDI) of Medical Devices, 2013). A high number of device registration elements (34 of 49 BUDI and 26 of 79 UDI-DI, in total 60 out of 128 device data elements!) are not updatable in EUDAMED forcing the creation of a new UDI-DI and registration of a 'new' device should a data error be identified or a valid business event such as changing a Notified Body occur. The UDI-DI triggers implemented in EUDAMED go beyond the UDI-DI changing rules legally required by MDR and IVDR but arising from the database design and from related MDCG 2018-1 rev.4 guidance. To correct existing UDID records (the non-updatable fields) is either difficult or not possible: The correction feature does not exist via M2M, only manual discard with resubmission as an alternative. Discard is only possible in the	**Short-term measure Eliminating duplication, Change frequency / timing, Provide guidance** Reduce the number of non-updatable fields in EUDAMED UDI/Device registration module to prevent the proliferation of unique device identifiers and supply chain disruption as well as to ensure data quality, allow editability of data fields. Cautiously choose which data elements' change represents a new device and prioritise the versioning option over to UDI-DI trigger option in EUDAMED whenever the change of data does not affect the identification, traceability or the safety and performance of the device. • keeping the EU-only UDI-DI triggers to the **minimum**, • keeping UDI-DI triggers **internationally aligned according to the IMDRF guidelines**, • having an **EU UDI-DI trigger list transparently available** *Flexibility in updating data elements would be crucial especially at the start of the mandatory use to ensure good data quality.* During the transition, there should be a grace period where users can correct mistakes, meaning all fields can be edited for a specified period without triggering the registration of a new record. Users need a transparent communication in a form of a guidance to understand what combination of legal requirements and database field editing rules will necessitate the creation of a new UDI-DI.

What?	Why?	How & When?
	manual interface when the device record is not yet linked to certificates or any vigilance / PMS reports. Once UDID record is linked to certificates or any vigilance / PMS reports, no option remains to update non-updatable information in EUDAMED but to create a new record with a new UDI-DI which has far-reaching consequences: relabelling, re-registration of the product worldwide, updating UDI-DI information throughout the supply chain etc. When manufacturers add or change certain device information in EUDAMED, this triggers the need to issue a new Device Identifier for that essentially the **same** device of the data field is not updatable. This has a significant impact for all stakeholders as it: • leads to regional Europe-only UDI-DI (it prevents the single, globally harmonised positive identification of medical devices i.e. National Competent Authority Report (NCAR) exchange program and early detection of issues at international level) and disconnects the Vigilance history of the device for **authorities,** • has a consequence throughout the **supply chain and for end users**: hospitals are not equipped to be able to identify clinically equivalent devices that have been assigned different UDI-DIs, it leads to scanning errors, manual data capture, which is causing confusion, inefficiencies and increasing risk for patients, • necessitates a labelling update of the device and eventually a re-registration in EUDAMED and worldwide by **manufacturers**, • and related certificates should be revised (in case a non-updatable Basic UDI-DI data element is changing) by **Notified Bodies**. This results in additional non-value-added activity within manufacturers and Notified Bodies organisations, multiplicate	Users, authorities and manufacturers need stable UDI-DI for a device to support patient safety, early signal detection, traceability, trending and overview of historical vigilance data.

What?	Why?	How & When?
	records in EUDAMED and in potentially jeopardized traceability in case of a vigilance event. The collateral effect of a newly assigned UDI-DI arising from the European database design is the wave of the word-wide re-registration if company uses global label. The requirement by national law (e.g. in Spain, in Portugal) to submit images of labels for distribution notifications means that any UDI modification necessitates updates in national systems, adding complexity to compliance and traceability efforts.	
TOP 2 **UDI-DI data elements' definitions / descriptions missing**	**Main source of admin burden**: lack of guidance or other interpretation of the legal text The EUDAMED database design goes beyond the legal requirements and requests for a much longer dataset to be registered in the central database than the list of data elements in Annex VI of MDR and IVDR. There is no existing guidance document that would help users to describe the expected content of the various UDI-DI data elements to be submitted to EUDAMED. The previous guidance document on the same subject "**UDIWG 2018-1 'UDI database. Definitions, descriptions and formats of the UDI core elements'**" has been removed therefore is no longer visible at the European Commission website. The EUDAMED UDI/Device data dictionary is not a guidance document for regulatory purposes (it is strictly to be used only for EUDAMED Data Exchange purposes, however it contains a Field Description / Notes column where misleading/inaccurate descriptions are displayed). For example, we seek clarification for the data elements on animal/human/microbial cells/tissues and to critical warnings if those are changing due to environmental legislation and not due to change in the composition of the device, that should not lead to the change in the Basic UDI-DI/UDI-DI information.	**Short-term measure** **Provide guidance** There is a need for an MDCG / European Commission document to describe the expected content of various data elements to be registered in the UDID module, which is essential to ensure that comparable and quality device data is submitted upon device registration into EUDAMED. Quality data in EUDAMED is essential for ensuring that Competent Authorities are able to carry out their market surveillance activities and it is also crucial to build an electronic system trusted by all stakeholders (hospitals, laboratories, healthcare professionals, Notified Bodies, manufacturers and other economic operators etc. Having a common data attribute definition is also essential to ensure intermodular data consistency (to avoid entering the same data elements in different modules via ensuring data autopopulation from source module) – for that mapping and linking the same data attributes throughout the different modules (Actor, UDI, CERT, VGL, MSU, CIPS) are required.

What?	Why?	How & When?
TOP 3 Mergers and acquisitions impact on traceability and vigilance history	**Main source of admin burden**: lack of functionality in EUDAMED, lack of guidance, Applying 'Once only' principle Current technical limitations (non-updatable fields) implemented in EUDAMED and lack of guidance make the management of mergers and acquisitions difficult to process in EUDAMED. Changes in UDI due to company mergers or acquisitions significantly impact regulatory records: when the Single Registration Number associated with the device is changing, a new Basic UDI-DI and UDI-DI needs to be assigned which affects the entire device portfolio or a product line. This leads to complex changes of certificate, label and device & actor registration, furthermore, has an impact on Declaration of Conformity, technical documentation and Certificate of Free Sale where the previous SRN is included. Eventually, changing ownership leads to the loss of traceability and vigilance history of the same device. Regulatory and technical rules are missing to enable keeping the same device identification of device by transferring device information from one Actor to another one in EUDAMED.	**Short-term measure Eliminating duplication, Introduce digitalisation, Provide guidance** Develop rules to enable linking of devices across Actors / Single Registration Numbers (e.g. in case of mergers & acquisitions) to maintain traceability and vigilance history of the devices for signal detection and trending of the same device. Guidance should be provided for maintaining the same BUDI/UDI-DI of devices under certain conditions following mergers or acquisitions. (i.e. enabling the transfer of the same BUDI and UDI-DI of the device under a different legal manufacturer / different SRN.) Enable data accessibility and retrieval by different economic operators, where an accepted use case exists, throughout the product lifecycle. **Mid-term measure Amend** the existing EUDAMED Implementing Regulation 2021/2078 (based on MDR Article 33(8): it could be amended to regulate the maintenance of the UDI/Device registration information in case of merger and acquisitions.
4. Users' requests to receive traceability information	**Main source of admin burden**: Applying 'Once only' principle MDR Article 27.9 requires the storage of UDI preferably by electronic means for health institution, of Class III implantable devices. The requirement covers both UDI-DI and UDI-PI information as clarified by the European Commission. Furthermore, some national law has a broader scope than MDR/IVDR requesting users (hospitals / healthcare professionals and laboratories) to keep and store UDI-DI and –PI information. (e.g. Italy: MDR Class III + all implantable MDs and Class D IVDs; Belgium: all implantable MDs and all classes of IVDs). These obligations are aimed at the institutions and healthcare professionals, however, they are transferred to manufacturers and distributors who therefore face extra obligations. Users started	**Short-term measure Eliminating duplication, Introduce digitalisation, Provide guidance** Manufacturers comply with the legal requirements when providing UDI-DI and PI on the labels (quality-controlled way to establish traceability). Member States should encourage users / hospitals to set up their system to be able to scan the UDI information of the devices they receive. Recording device identification from shipping documents or invoices instead from the device and its label does not lead to the traceability needed. It is prone to erroneous data capture and therefore failure to establish traceability to the patient. Such shortcuts jeopardize the efforts industry has invested into the UDI-system. Users should be provided with the capability of mass information download from EUDAMED to leverage device data from the

What?	Why?	How & When?
	asking UDI-DI and -PI via other means (e.g. in shipping docs) from manufacturers as they are not equipped for automatic data capture at delivery. These are non-validated ways to retrieve UDI information: the AIDC (machine readable) or HRI (human readable) UDI information is provided from the UDI system on labelling. Due to the delay of EUDAMED, users do not have access to reliable and up-to-date device information from the central source of truth.	central system to reduce administrative burden for healthcare professionals, hospitals, non-EU countries relying on the CE marking, manufacturers, distributors etc. Download functionality from the public site would be an efficiency gain as the hospitals are looking for device data access, many times of data that will be in EUDAMED but because they have only view-access and they cannot mass download the data, the request comes to the manufacturer to provide this data to many hospitals.
5. Challenging Basic UDI-DI grouping by Notified Bodies	**Main source of admin burden**: lack of harmonisation among Notified Bodies Assignment of Basic UDI-DI is a requirement for all products before placing a device on the market and the Basic UDI-DI is the main key in all relevant regulatory documentation and in EUDAMED. When the grouping of Basic UDI-DI is challenged by Notified Bodies after the conformity assessment has been carried out or even after the certificate has already been issued, it leads to burdensome update of regulatory documents to reference the new Basic UDI. Furthermore, the technical documentation should be rearranged to follow the new Basic UDI-DI grouping logic. If the device has already been registered, such change leads to a new registration in EUDAMED (consequently to the assignment of a new UDI-DI and relabelling). When Notified Bodies challenge the Basic UDI-DI grouping of the manufacturer, it leads to burdensome reassignment, reorganisation, and revision of impacted regulatory documents referring the Basic UDI-DI.	Short-term measure **Provide guidance** Provide guidance for Notified Bodies that they should only challenge the Basic UDI-DI grouping during the conformity assessment and only if there is a clear misalignment to the definition of a Basic UDI-DI. Explain the linkage of Basic UDI-DI grouping with the technical documentation and other regulatory documents and reports. Make clearance of such assignment to become part of the application review to avoid surprises late in the conformity assessment or even after certification. Allow Notified Bodies to follow manufacturers' proposal for an appropriate concept instead of judging a concept to the letters of the law. For major difficulties to apply the UDI assignment rules: allow COM to adopt exceptions and alternate concepts for specific cases.

Digitalisation

This section includes challenges in various digital areas, which include (but are not limited to) digitalisation of labelling and technical documentation, where MedTech Europe believes that digitalisation can provide a quick, efficient and safe solution. Both medical devices and IVDs are covered, unless stated otherwise.

What?	Why?	How & When?
TOP 1 Paper Instructions for Use (IFU)	**Main source of admin burden**: Lack of optimisation (considering the state of the art) Paper IFU currently is required to accompany most medical devices as well as near-patient and self-testing IVDs. The acceptance of electronic information has increased greatly in the EU, and most healthcare professionals would prefer using eIFU. By contrast, the production and shipping (by the manufacturer) and storage and management of paper IFUs (by the user) can cause significant cost and administrative burden on all actors as well as environmental burden from paper IFU waste. Moreover, frequent changes which has increased with IVDR/MDR (see *Post-Market Surveillance -> Change notification process* discussed earlier in this paper) has increased the time and resources needed to manage the IFUs. Other EU legislation impacting on devices also may require updates to information in the IFU (a recent example may be information on microplastics[44]). Also, a key issue is that devices already in distribution may reach users with outdated IFUs, which becomes critical in cases where updates involve corrective actions or market withdrawals. Expanding the scope of eIFUs would mitigate these risks and streamline regulatory compliance. See below specific IVD and MD subpoints for more detail, data and examples.	Short-term measure/Long-term measure **Introducing digitalisation** Expanding and promoting the use of Electronic Instructions for Use (eIFUs) for all types of medical devices and IVDs in principle, would help to reduce the environmental burden and costs for all actors in the medical device and IVD sectors, while also helping to increase device usability and IFU readability as well as improve the tracking of the most recent version of IFU.
• **IVD specific: Expanding eIFU scope for IVD near-patient testing devices**	The IVDR allows for IFU in non-electronic format to accompany all professional use IVDs but prohibits IFU from accompanying devices intended for near-patient testing (NPT) and self-testing in electronic format only. • **Near-patient testing IFUs:** Article 2 (6) defines NPT devices as "*… any device that is not intended for self-testing but is intended to*	Long-term measure **Amend legal text** MedTech Europe calls for expanding use of eIFU use to all professional use IVDs, including devices intended for near-patient testing. Amendment of the IVDR is needed (there is no implementing act as exists under

[44] Commission Regulation (EU) 2023/2055 of 25 September 2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles

What?	Why?	How & When?
	perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional" (emphasis added). The IVDR distinguishes in its definition of NPT only between the different environments of use, not between different health professional users. In addition, IVDR demands that NPTs are accompanied by the instructions where the manufacturer should make clear the level of training, qualifications and/or experience required by the user. Therefore, it is not clear as to why this regulation mandates paper IFUs only for the NPT when that device can only be used by healthcare professionals whereas other professional use IVDs are permitted to be accompanied by eIFU. Also, data has emerged showing clear preferences on the part of healthcare professionals towards use of eIFU (see data on healthcare professionals for use of MDs, below under the following MD section) and at the time of writing the European Commission is considering an implementing act expanding the scope of eIFU for all medical devices used by health care professionals. By analogy the same conditions should apply for healthcare professionals using the IVD. The exclusion of eIFUs for NPTs is burdensome on IVD manufacturers because the IVD packaging is generally smaller in size therefore the IFUs are smaller in size, which accounts for a smaller footprint of IFU with an increased number of pages. manufacturers spend a lot of time on trying to find ways to increase sizing of paper IFUs to account for the additional languages needed for IVDR, which increased costs for packaging material, resources for projects allocation, and costs for IFU material. • **IFUs for self-testing**: while IVDR does not permit self-testing IVDs to be accompanied solely by eIFU, the Heads of Medicines Agencies, the European Commission and EMA are moving fast towards expanding the use of electronic product information	MDR which permits a flexible and science-based approach taking into account the state of the art). In the longer term, the expansion of the possibility for eIFUs for IVDs should cover all IVDs, including lay users for self-testing devices, based on a risk assessment by the manufacturer. Minimal information on paper should be provided where needed to use the device safely and as intended. Lay users who do not have internet access or are not confident using digital information should be able to access a paper version of the IFU free of charge and within a certain timeframe. An ISO standard is under development to support safe and effective use of eIFU for IVDs. Harmonisation of the standard against IVDR should be considered if IVDR is amended to support eIFU for more IVD categories or for all IVDs.

What?	Why?	How & When?
	(ePI) to human medicines for HCP and patients/ consumer in the EU as part of EU4Health initiative, together with EU ePI Common Standard adopted by the European medicines regulatory network[45]. There are numerous benefits of expanding electronic instructions for use for patients (lay users) that have been supported by the ePI initiative[46]. Thus, eIFU for self-testing devices is an area of improvement in the IVD sector that seems to be lagging the current ePI developments in the pharma sector.	
• **MD specific: Expanding eIFU to all medical devices and accessories**	Regulation (EU) 2021/2226 (eIFU Regulation) no longer reflects the generally acknowledged state of the art as called out in the MDR; Annex I General Requirements, Art. 1 of the eIFU Regulation, even though recently published, only allows for a limited extension of the original legislation EU 207/2012 in terms of scope. It falls short of the needed legislation for a digital era tha allows for the use of electronic format Instructions for Use (eIFU) for all professional use medical devices. MedTech Europe conducted a data collection survey among healthcare professionals and staff working in hospitals, from which clear messages emerged regarding the healthcare sector's preference for an electronic format IFU[47]. A similar survey has been conducted by the European Commission (published results pending). eIFUs contribute to paper reduction and reduction in use of Ethylene Oxide, it has always up to date information, it is more searchable, adaptable, more user friendly, and readily available in all languages. Other jurisdictions (such as the US and Canada, Japan, South Korea etc) already allow eIFUs for all professional use medical devices[47]. Regarding lay use eIFU, these are allowed in Vietnam, India, Thailand, South Korea (see reference).	MedTech Europe welcomes the proposed scope expansion of the regulation EU 2021/2226 to all professional use Medical Devices. This is a positive step towards a more digitalised medtech sector. However, there are more areas where MDR and IVDR could be made more future-proof. **Mid-term measure Consider also electronic IFU for all devices, particularly medical devices for lay use where the user is trained by a professional** (on how to use the device, since these devices are for recurrent use by patient). Manufacturer can always provide paper IFU upon request as is current practice. Additionally, the extension to all professional use devices can be achieved without change in the MDR legal text - by a quick targeted update of EU reg 2021/2226 – we are pleased to see this initiative is already on the Have your say portal and await opening of the public consultation.

[45] First electronic product information (ePI) published for selected human medicines
[46] See Electronic product information for human medicines in the EU: key principles A joint EMA–HMA–EC collaboration
[47] For more information, see MedTech Europe position paper on Electronic Instructions for Use for all professional use Medical Devices: MedTech Europe calls for scope expansion of EU 2021/2226 & MedTech Europe position paper from 2021 in Annex II.

What?	Why?	How & When?
	In addition, the Australian government_currently considers eIFU expansion to lay use based on recent TGA survey results.	
TOP 2 **High number of requirements to be implemented on the device label, which also require translations**	**Main source of admin burden**: Requirement in regulation legal text and guidance or other interpretation of regulation legal text. Regulatory requirements which are not linked to device safety and handling – such as for additional product compliance markings and documents – are growing. With the addition of each new information requirement crowding the label, users can find it more difficult to locate or focus on information which is essential for device safety and handling. Also, this growth in label requirements which are not strictly related to device safety and handling, means manufacturers must update the entire physical label; in consequence they must either relabel or destroy stock with the now outdated labelling. Such label changes have an impact on environment, product availability, they cause inefficiencies and ultimately raise cost; also, international registrations can be impacted. Local requirements for the label regarding device disposal are increasing and lead to increased amount of packaging (and therefore later increased amount of waste). **Examples**: • In case of change of importer(where manufacturer includes importer details on the label) / Authorised Representative this creates administrative burden for the supply chain and labelling change management, since 1/ AR/IMP are available in EUDAMED and 2/ providing such information through other means such as a digital label would allow the user to obtain on time information (as opposed to lengthy implementation change into a physical labelling).	**Mid-term measure** **Introducing digitalisation and Eliminating unnecessary requirements** Overcrowded labels are an area of administrative burden which could be easily improved by implementing **digital label,** which would avoid frequent updating of paper labels for manufacturers, reduce environmental footprint, streamline supply chain and improve user experience. Please note the current call 10 IHI project proposal on digital label[48]: Digital label is a label carrier affixed on the physical label which connects directly to the needed information online. Digital label should store primarily non-essential regulatory information to which is not directly related to device safety or its use such as Authorised Representative, Importer information, disposal instructions etc. Currently ongoing initiatives on digital label internationally: • Canada: initiative aimed to allow electronic format for low risk over the counter (lay use) healthcare products (including MDs) • Belgium: new government has included 'partial digital labelling' in their government agreement, to be transposed into law. In additional, for IVDs, clarification would be helpful when the information can be added on which types of labelling (e.g. other than label and IFU such as safety data sheet, packaging insert).

[48] For more information please see the IHI project proposal Draft Topic DigitalLabelling_v171024.pdf

What?	Why?	How & When?
TOP 3 Translations of all labelling documents into many EU languages	**Main source of admin burden**: Requirement in IVDR and MDR legal texts and Notified Body practice. Translations of all labelling documents into many EU languages are requested by Notified Bodies and these consume a lot of time and resources, often needing to be managed within very short deadlines. Some documents are between 30 and 50 pages long and are updated every year. Printed documents represent an even greater burden to manage, with the verification of the proof as well as the physical documents once received, inventory management, etc. The burden related to translations represents practically a full-time job in some companies (includes Summary of Safety and (Clinical) Performance translations). One company reports that translation costs can reach >€80,000 since the switch to the regulations for only half of one product portfolio. In addition, while manufacturers aim to minimise label content through harmonised symbols, additional text elements often require translation.	Digital label implementation should help streamline the processes of translation of labelling documents[48]. **Mid-term measure Introducing digitalisation** Implementation of eIFU would also help streamline these processes. **Short-term measure Providing guidance** It should also be considered that documents be translated upon request rather than upfront.
4. Worldwide registrations	**Main source of admin burden**: Requirement in regulation legal text There is a lot of extra information in the information accompanying the device required by IVDR/MDR, which triggers re-registration in countries outside Europe. Usually, when the label is changed the manufacturer needs to re-register the devices in all applicable outside EU countries (this may include any updates such as e.g., changed class, changed intended purpose, economic operator details, etc). Current IVDR/MDR change notification process is particularly burdensome as changes are triggering a lot of re-registrations internationally (in addition to those that manufacturers have to do in the EU). Frequent labelling changes (especially those that require Notified Body approval as they may take long with no predictable timelines) are causing supply chain issues, especially with directive	**Mid-term measure Introducing digitalisation** Implementation of the digital label could solve many issues and label updates would be easier to manage (e.g. no need to change packaging label hence smoother supply chain processes)[48]. **Short-term measure Changing frequency/timing and eliminating duplication/unnecessary requirements** Improvements to the IVDR/MDR change notification processes would bring a significant relief to manufacturers in managing labelling updates. Shorter and more predictable approval of changes by Notified Bodies, as well as removal of pre-approval for minor (non-significant) changes would bring considerable reduction in administrative burden associated with the management of labelling updates (see *Post-Market Surveillance -> Change notification process* discussed earlier in this paper).

What?	Why?	How & When?
	and regulation products being on the market at the same time during the transition period. The re-registrations have been additionally burdened with the IVDR/MDR amendments and long-lasting transition problems (e.g. lack of EUDAMED).	
5. Digital and electronic signature recognition	**Main source of admin burden**: Lack of optimisation (considering the state of the art). Digital and electronic signatures (e-signatures) can significantly reduce administrative burden by saving time, cutting costs, improving accuracy, enhancing security, and simplifying document management processes. While a lot has been done in the past years to increase the usability of digital and e-signatures, many gaps remain in implementing and accepting e-signatures across various parts of regulatory reporting and documentation in the medtech sector. **Examples**: • While most of the Competent Authorities in the EU accept digitally signed MDR/IVDR Declaration of Conformity, based on manufacturers' experience, there are still a few EU Countries which do not recognise electronic/digital signatures, for example, Croatia. • Based on manufacturers' experience, for Clinical Investigation Plan (CIP), Statement of Conformity investigational device (for investigational devices covered under MDR Art. 62)., e-signatures are not accepting in Poland and Slovenia. A similar situation exists for IVDs. The wet signature requirement creates a significant administrative burden for the manufacturers as it not only consumes time but also prolongs product approval processes. In addition, it is confusing and burdensome that some countries accept e-signatures and others accept wet signatures only for the same essential paperwork which can cover multi-country investigations or studies.	Long-term measure **Introducing digitalisation** A Europe-wide acceptance of electronic or digital signatures is needed.

What?	Why?	How & When?
6. MD specific: Implant card Provision	**Main source of admin burden**: Lack of optimisation (considering the state of the art). Currently, the implant card is provided to the patient in paper format. Digital provision of the implant card would better allow for meeting the requirements in article 18 (1) and (2) MDR, as: • This would ensure that the implant card data in article 18 (1) are always available to the patient "by any means that allow rapid access to that information and possibly others (e.g. HCPs) regardless of whether the patient is in possession of the physical implant card. • It would make the link between implant card and implanted devices more direct. Health institutions no longer would need to match the device and the implant card information physically. • It also would mitigate the risks related to the filling in of the physical implant card by the HCP (see section 7 of MDCG 2019-8 Rev 2). The HCP could be assisted by electronic means, or the digital implant card could automatically be populated thus mitigating risks of human error. • Electronic implant cards better could accommodate for situations where revisions of (components of) implantable devices (see MDCG 2019-8 Rev 2 section 8) are needed by updating the electronic implant card. • Electronic implant cards are more durable and issues with wear and tear or readability of a physical card (as can be the case with handwritten implant cards) could be avoided. • Electronic implant cards could be provided in a format that can reside in or be linked to the patient's health records.	**Short-term measure** **Provide guidance** Article 18 MDR states that the implant card must be 'provided' but does not exclude that this happens via electronic means. In fact, article 18 (1) states that it can be provided "by any means that allow rapid access to that information". Change MDCG 2019-8 Rev 2 (and possibly MDCG 2021-11) to explicitly clarify that the implant card may be provided by digital means. MDCG 2019-8 Rev 2 states that "Ways could be explored by relevant stakeholders to develop common rules on how the necessary information to be placed on the System IC is delivered with the replaceable component and how health professionals could ensure that the System IC is appropriately updated, when necessary." This and other ways to harmonise the technical format of the digital implant card should be addressed in a revised version of the MDCG guidance after stakeholder consultation. **Long-term measure** **Provide clarification in the legal text** Update the EU MDR art 18 text with possibility to provide an e-implant card. Art 18.1 last paragraph: ' In addition.....*either on an implant card or an e-implant card* and delete: delivered with the device.
7. Digitalisation of technical documentation	The Regulations introduced a fundamental shift by explicitly requiring that risk, benefit, and performance assessments be continually updated using data collected during the post-market phase. This means that the deliverables described above are subject to very frequent changes, as are the common components within them. As a result, manufacturers are faced with the continuous task of compiling	**Long-term measure** **Introducing digitalisation** In the future, a more efficient approach to managing technical documentation would involve handling it at the data or item level, with version control applied to common data artifacts. These items could then be exchanged and assembled as needed for specific deliverables, like PSURs, SS(C)Ps, or electronic

What?	Why?	How & When?
	and recompiling a very large and ever-shifting dataset into multiple fixed but overlapping reports for the purposes of audit by Notified Bodies and Competent Authorities. Likewise, Notified Bodies are tasked with reviewing these deliverables in many different formats from multiple manufacturers whilst maintaining track of changes that may occur in the documentation during the course of the review. This is clearly highly inefficient and given the number of devices on the EU market, not desirable nor sustainable in the long term. These challenges are intensified when the manufacturer collaborates with two or more Notified Bodies (sometimes even between different reviewers within the same Notified Body), each with its own reviewers who follow different approaches to documentation structures and assessment procedures.	labelling. This requires standardised formats and nomenclature to ensure system compatibility. MedTech Europe suggests exploring a transition to a harmonised model, separating content from form, allowing documents to be broken down into discrete, version-controlled items, such as the Intended Purpose and then assembled into standardised deliverables. Developing a standardised nomenclature and framework is essential for secure and efficient data exchange with multiple stakeholders, especially with Notified Bodies. This framework should be system-agnostic to ensure compatibility with the various IT tools used by the stakeholders involved. For more information see MedTech Europe position paper on Digitalisation of Technical Documentation[49].

Other

What?	Why?	How & When?
1. MD specific: Medicinal Agency Review	**Main source of admin burden**: Requirement in regulation legal text and Competent Authority practice. Review times by some medicinal agencies for drug consultations (per Annex IX 5.2) are exceeding the 210-day timeline mentioned in the MDR. With only a limited number of agencies offering this service to support MDR certification, their capacity for new reviews is constrained. This necessitates planning well in advance, which can pose challenges for post-approval changes.	Short-term measure **Provide guidance** Annex IX 5.2 “Procedure in the case of devices incorporating a medicinal substance” 210-day timeline mentioned in the MDR should be adhered to.

[49] See MedTech Europe position paper on Digitalisation of Technical Documentation

What?	Why?	How & When?
	Example: Review by Competent Authority was done within the 210 day period, but they informed that they could only start the review 1 year after the submission. Thus, 210 days only started counting after 1 year.	
2. MD specific: Classification of accessories Rule 8	**Main source of admin burden**: Requirement in regulation legal text, guidance or other interpretation of regulation legal text and Notified Body practice. Accessories to active implantable devices comprise very broad range of devices, including helping tools such as torque wrenches or cables connecting external devices. Unless the accessories are implantable or long-term surgically invasive devices themselves, they should not be treated as Class III and should not require the same level of clinical evidence. However, MDCG 2021-24 and consequently Notified Bodies interpret classification rule 8 in a way that "also non-implantable and non-active accessories to AIMDs should be classified as Class III". As per Art. 61(4), clinical investigations are required for all class III devices, independent of their actual intended purpose. For such accessories a clinical investigation can be costly, challenging, impractical, or not feasible at all.	Long-term measure **Apply risk-based approach and eliminate unnecessary burden, targeted change in the legal text** Clarify in the MDR text (Annex VIII, Chapter 3, Classification rules, Rule 8, 6th indent) that rule 8 refers only to "*implantable devices and long-term surgically invasive devices*". — are active implantable devices or their accessories (***in case these accessories are also implantable or long-term surgically invasive***), in which cases they are classified as class III;"

Annex I

Examples for burdensome, non-harmonised and costly IVDR authorization and notification process for performance studies

Lack of coordination & harmonization within the countries (ECs):

- Different level of flexibility between ECs (e.g. MPDG certificate for clinical PIs in Germany)

Lack of coordination & harmonization between the countries:

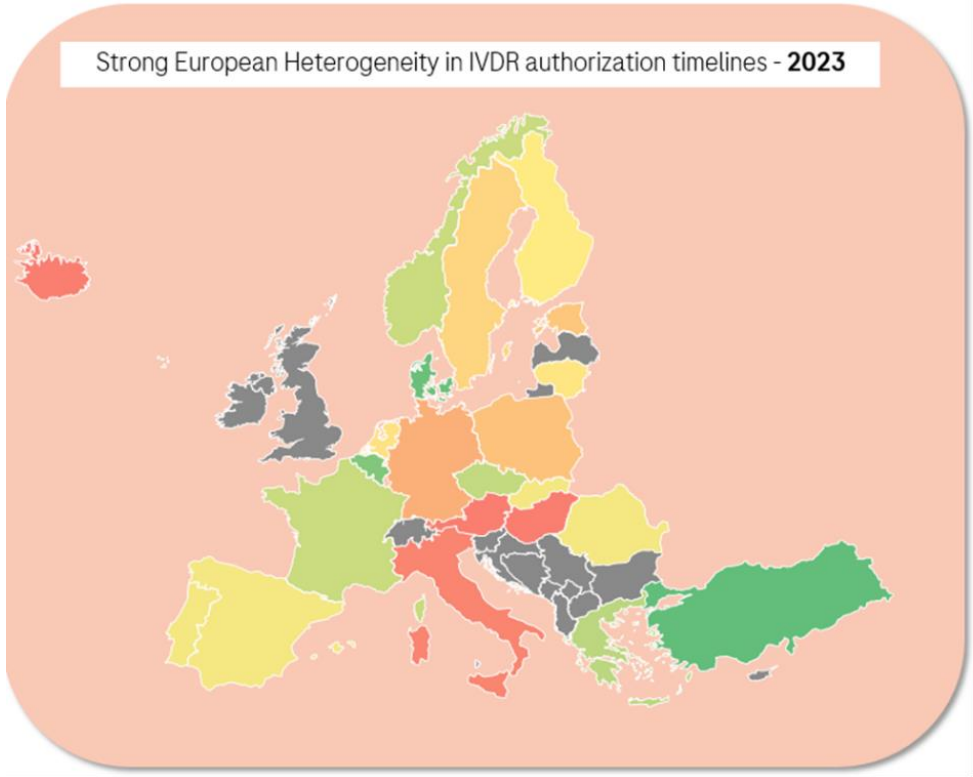
- Costs vary (several 100 to several 1000)
- Amendment processes are very different
- Amount of document and translation requirement vary

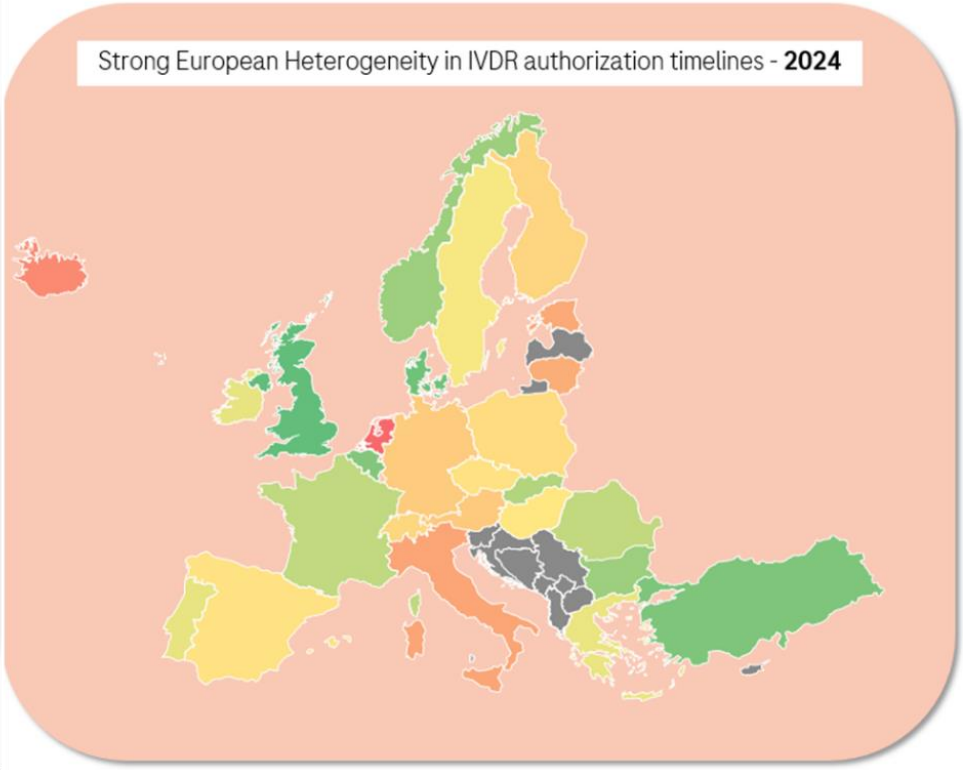
Changing processes: This might improve over time!

- Lead EC approved study per initial information by the CA -> ad hoc request that approval by all local ECs needed
- Submission to local ECs changed to submission to regional ECs
- Outdated forms and portals

Cumbersome and time-consuming processes:

- Some countries request wet signatures
- Signatures have to be provided in “blue” but this information was not provided
- Lead-Pi has to go to coordinating EC and give a talks about performance study (native speakers and training required)
- Electronic portals do not display electronic signatures correctly (memo required to confirm that signatures are valid)
- Only citizens are able to submit electronically, others have to send USB sticks or hard copy documents
- Country specific templates, some have to be notarized


Strong European Heterogeneity in IVDR authorization timelines - **2023**


Strong European Heterogeneity in IVDR authorization timelines - **2024**

		Mar-23	Dec-24
Country	**Submission process (EC/NCA)**	**Total submission time in days (CA and EC)**	**Total submission time in days (CA and EC)**
Austria	Sequential	267.5	167
Belgium	Parellel	61.67	68
Bulgaria	Parellel		83
Croatia			
Republic of Cyprus			
Czech Republic	Sequential	95.6	146
Denmark	Parellel	49.75	57
Estonia	Sequential	165.5	195
Finland	Sequential	127	158
France	Parellel	98.75	103
Germany	Sequential	190.67	166
Greece	Semi-Parallel	91.4	127
Hungary	Sequential	244.44	142
Iceland	Parellel	246	223
Ireland	Parellel		125
Italy	Sequential	237.83	199
Latvia			
Lithuania	Semi-Parallel	132	192
Luxembourg			
Malta			
Netherlands	Semi-Parallel	136	252
Poland	Sequential	169.83	152
Portugal	Parellel	121	125
Romania	Sequential	118.56	104
Slovakia	Sequential	113.64	95
Slovenia			
Spain	Sequential	124.95	146
Sweden	Semi-Parallel	150	134
Liechtenstein			
Norway	Parellel	98.5	83
Switzerland	Parellel		156
Turkey	Sequential	45	65
UK	Parellel		49

Annex II

Why should all professional use instructions for all professional use medical devices benefit from electronic format? (September 2021)

MedTech Europe proposes an extension of scope of the EU draft Implementing Act on Electronic Instructions for Use (formerly Regulation EU No 207/2012) to all the professional use instructions for all professional use medical devices (covered by the EU Regulation 2017/745),[50] regardless of risk class or type. The benefits of such extension are outlined in the present summary for the attention of the regulators.

In addition, we support the use of e-IFU for certain medical devices for lay (patient) use which would benefit from electronic IFU, such as: software and contact lenses, for which we refer to the work of other stakeholders. We consider apps downloaded and used by consumers as already falling under the scope of the draft Implementing Act on e-IFU, Art.3.4 and therefore, being eligible for e-IFU.

Why should the professional (non-lay user) receive electronic IFUs?

1. Professional users are expected to have access to internet, given its widespread use by businesses of all kinds.
2. Professional users have specific training in their medical discipline as a foundation to the use of medical devices.
3. Use of e-IFU has been a practice in the US (since 20 years) and other major markets with a broader scope of medical devices using e-IFU. No new risk or issues have emerged challenging the e-IFU success.
4. Use of e-IFU is a practice in the last 11 years in the EU for high-risk devices under the scope of 207/2012[51] regulation.

Benefits for Users

- UP-TO-DATE INFORMATION
  - e-IFUs provided on the internet are always the most current.
  - A paper IFU originally received with the device may be superseded by a new version which may not reach the customer unless a new device is ordered.

[50] The scope of this paper is medical devices only. IVD medical devices per EU regulation 2017/746 are not covered here.
[51] Revised in 2021 and superseded by EU regulation 2021/2226

- INCREASED AVAILABILITY
  - e-IFUs on the internet are available whenever the user needs them, and they will enable easy handling and opening, especially in hospitals were paper IFUs are likely to be disposed of, get lost or become outdated.
  - e-IFUs can be read prior to procedures and preparation of surgery rather than waiting for them to be delivered with the device.

- INCREASED UTILITY
  - e-IFUs are searchable, which reduces the time to find specific information.
  - They create *user specific views* in different formats such as the possibility of embedded illustrations, multimedia (videos) or possibility to project the information from the e-IFUs.
  - They allow for easy handling and storage, unlike paper IFU that may get lost, disposed of or outdated.
  - legibility where users can resize the text as they find it more comfortable on their device.

- ENHANCED ACCESSIBILITY
  - Their digital nature provides users with more language options
  - e-IFUs can be updated easily, which will ensure the users' instant access to the most up to date version.

- REDUCE CARBON FOOTPRINT
  - eliminating paper IFUs from each sales package both reduces paper waste from the IFU and at the same time reduces the shipping weight for each product.
  - They are likely to encourage manufacturers to use smaller sales package sizes, further reducing waste and allowing more storage space in the hospitals.
  - They facilitate compliance with the EU waste directive 2008/98/CE.

Example: Table below covers Europe in a year to illustrate the paper waste savings (put together based on feedback from several MedTech Europe members)

POTENTIAL COST & PAPER WASTE SAVING

Implantable Device Group	Units	Print Costs €	Paper Savings Kg
Pacemakers, ICDs	450,000	€ 3,200,000	135,000
Neuro Stim/Drug Pumps		€ 625,000	35,000
Stents	1,150,000	€ 3,000,000	270,000
Heart valves	90,000	€ 820,000	60,000
Ventilation Tubes, Middle Ear Prostheses	330,000	€ 180,000	30,000
Spinal Implants *	3,700,000	€ 1,000,000	115,000
Hip / Knee Prostheses etc.**		€ 3,200,000	71,000
Implant Lenses		€1,150,000.00	310,000
Total	**5,720,000**	**13,175,000 €**	**1,026,000**

- PORTABILITY
  - Some e-IFUs support mobile platforms; these e-IFUs are portable and can be accessed from any connected mobile device wherever the user is.

Example

Spanish doctors working in Belgium can search for their native language instead of requesting a paper version in the official languages of Belgium. Providing rapid access to the desired language e-IFU will enhance the ease of understanding in case of complex medical systems, availability and accessibility of information.

Electronic IFU for professional use are already allowed in the following jurisdictions:

Numerous countries allow for e-IFU to be utilized for professional use, such as, but not limited to, Australia, USA, Canada, Saudi Arabia, Brazil, Serbia. Detailed quotes can be found in Annex 1.

Example:

FDA based its rationale for allowing e-IFU on the profile of the targeted user (professional or lay) rather than on risk class or type of medical device.

In fact, the risk class or type are not part of this distinction, only the expected access to internet of the intended user. Professional users are expected to have access to the internet, due to its widespread use by businesses of all kinds. On top of that, professional users in hospitals and clinics have a training in their medical discipline.

EU-MDR compliance: Streamlining of regulatory procedures

- Member State Authorities will have direct access to e-IFU during the review of Vigilance cases and FSCA notifications in their territory.
- FSNs that include labelling updates as a corrective action can be immediately distributed to professional users in the field electronically, rather than waiting for physical delivery to reach the final user at their hospital or clinic.
- Efficient fulfilment of MDR requirements for importers and distributors to verify the IFU – no need to open a validated package.
- Timely compliance with MDR 23.1 of keeping information supplied by the manufacturers available and up to date on the manufacturer's website.

e-IFU extension: Should not present new risks

- For any device that is currently eligible under the 207/2012 regulation to use electronic IFUs, its manufacturer is required to complete a risk analysis which is currently part of the conformity assessment by the Notified Body (NB).
- Extending the scope of the regulation to all professional use devices does not create any new risks as the manufacturer's risk analysis would be assessed during the Notified Body QMS audits.
- Paper copies are made available free of charge at any time in line with the regulation 207/2012/, when requested.
- Professional users rely on their overall and specialty medical training to deal with any emergency situations during a surgical or clinical procedure.

Missed opportunities if continuing with paper IFU:

1. Hindrance to innovation and to free circulation of goods and people throughout the EU.
2. Alignment of the European practice with other jurisdictions around the world.
3. Facilitation of the work of users, authorities, manufacturers and other economic operators – at no additional risk.
4. Environmental considerations, such as Ethylene Oxide emissions[52], and paper waste.
5. Delays in making the most current version available to the user (internal procedures - inventory in the field depletion, implementing new IFUs on the manufacturing line to be packaged with the device…).

We encourage the regulators to support making medical product information available in a way that allows healthcare professionals better serve patients.

Extending the e-IFU scope will ensure that Europe keeps up with the pace of innovation seen in other jurisdictions of the world and will ensure that European healthcare professionals benefit from a rapid access to information that is appropriate, up to date, available and accessible.

Annex III

Overview of documents which may be required to be produced by the Manufacturer under Medical Devices Regulation (EU) 2017/745

Category	Document
General	Technical documentation
	Risk management plan
	Instructions for use
	Label
	EU declaration of conformity
	Summary of safety and clinical performance (SSCP)
	Clinical investigation plan (CIP)

[52] For more information on EO emission reductions initiatives, please see: https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions and here: https://www.fda.gov/news-events/press-announcements/statement-new-steps-advance-innovation-medical-device-sterilization-ethylene-oxide ; the FDA encourages MD manufacturers to move to electronic materials

Documents related to clinical investigations	Clinical investigation report
	Application form *(for investigational devices covered by article 62 MDR)*
	Investigator's brochure (IB) (*for investigational devices covered by article 62 MDR)*
	Informed consent forms
	Other information (*for investigational devices covered by article 62 MDR)*
Documents related to clinical evaluation	Clinical evaluation plan
	Clinical evaluation report
	Post-Market clinical follow-up plan (PMCFP)
	Post-Market clinical follow-up evaluation report (PMCFER)
Documents related to Post -Market Surveillance (PMS)	Post-Market Surveillance Plan (PMSP)
	Periodic safety update report (PSUR)
	Post-Market Surveillance Report (PMSR)
	Manufacturer Incident Reporting (MIR)
	Manufacturer Trend Report (MTR)
	Periodic Summary Report (PSR)
	Field Safety Corrective Action (FSCA)
	Field Safety Notice (FSN)

Overview of documents which may be required to be produced by the Manufacturer under IVD Regulation 2017/746 EU

Category	**Document**
General	Technical documentation
	Risk management plan
	Instructions for use
	Label
	EU declaration of conformity
	Summary of safety and performance
Documents related to performance studies	Clinical performance study plan (CPSP)
	Clinical performance study report
	'Other performance study' plans and reports
	Informed consent forms
	Application form *(for interventional clinical performance studies and other studies involving risks)*
	Investigator's brochure (IB) *(for interventional clinical performance studies and other studies involving risks)*

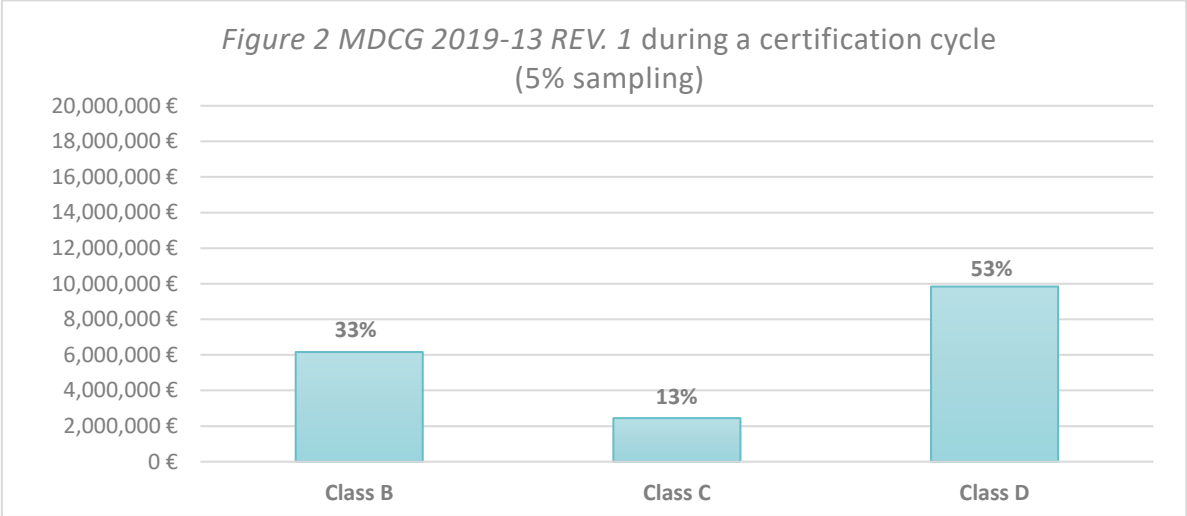
	Other information *(for interventional clinical performance studies and other studies involving risks)*
Documents related to performance evaluation	Performance evaluation plan
	Scientific validity report
	Analytical performance report
	Clinical performance report
	Performance evaluation report
	Post-market performance follow-up plan (PMPFP)
	Post-market performance follow-up evaluation report (PMPFER)
Documents related to Post-Market Surveillance (PMS)	Post-Market Surveillance Plan (PMSP)
	Periodic safety update report (PSUR)
	Post-Market Surveillance Report (PMSR)
	Manufacturer Incident Reporting (MIR)
	Manufacturer Trend Report (MTR)
	Periodic Summary Report (PSR)
	Field Safety Corrective Action (FSCA)
	Field Safety Notice (FSN)

Annex IV

The impact of CURRENT % for technical documentation sampling under IVDR (simulation)

Table 1 Current costs for 1st certification cycle: sampling of 5% for class B and class C devices

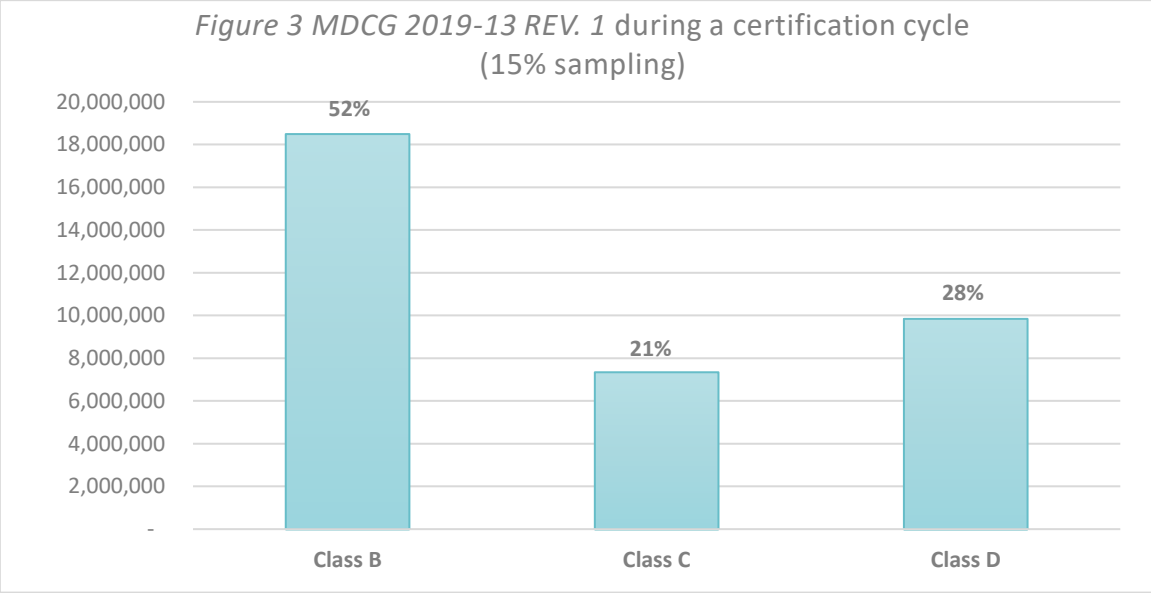
Class	Cost per Technical Documentation review by Notified Body[53]	Sampling criteria (%)	# of IVDs on EU market[54]	# of Technical Documentation s auto-reviewed by Notified Bodies	Investment for Technical Documentation review	Investment %
Class B	37,853 €	5%	3,256	163	6,162,468 €	33%
Class C	37,853 €	5%	1,293	65	2,447,196 €	13%
Class D	37,853 €	100%	260	260	9,841,780 €	53%
			Total:	**487**	**18,451,445 €**	**100%**



[53] MedTech Europe 2024 Regulatory Survey: key findings and insights
[54] Based on the Gesundheit Österreich GmbH (GÖG) survey on the monitoring of the availability of devices, which was commissioned by the European Commission

Table 2 Current costs during a certification cycle: sampling of 15% for class B and class C devices

Class	Cost per Technical Documentation review by NB[53]	Sampling criteria (%)	# of IVDs on EU market[54]	# of Technical Documentation s auto-reviewed by Notified Bodies	Investment for Technical Documentation review	Investment %
Class B	37,853 €	15%	3,256	488	18,487,405 €	52%
Class C	37,853 €	15%	1,293	194	7,341,589 €	21%
Class D	37,853 €	100%	260	260	9,841,780 €	28%
			Total:	**942**	**35,670,775 €**	**100%**



MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

References

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[iv] EUROPEAN COMMISSION, Action Programme for Reducing Administrative Burdens in the EU, Office for Official Publications of the European Communities, Luxembourg 2010.

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[vi] NIFO - National Interoperability Framework Observatory, Glossary - Administrative simplification

[vii] European Commission: Have your say - Public Consultations and Feedback, Published initiatives, Administrative burden – rationalisation of reporting requirements