MDCG 2025-X

Questions and Answers on Trend Reporting as outlined in the Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices

MM 2025

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Introduction

This document aims at explaining and clarifying questions related to Trend reporting as outlined in Article 88 of the Regulation (EU) 2017/745 on medical devices (MDR) and Article 83 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) ("the Regulations"). A common understanding related to Trend reporting is necessary for an effective and harmonised implementation of the Vigilance requirements under the MDR and IVDR. This document is intended for use by Competent Authorities (CAs), economic operators and other relevant parties.

Unless quoted directly from the legal text or otherwise specified, the term 'devices' should be understood to include medical devices, accessories for medical devices, products listed in Annex XVI of the MDR, in vitro diagnostic medical devices and accessories for in vitro medical devices. Furthermore, references to 'the Regulations' should be understood to cover both the MDR and the IVDR. This document is non-exhaustive and should be read in conjunction with the Regulations, relevant standards[1] and MDCG guidance documents[2].

The Trending process is one of the elements of the Vigilance system and is based on risk assessment, the Post-Market Surveillance (PMS) system and the manufacturer's Quality Management System (QMS). In line with the Regulations, manufacturers, are required to implement a PMS system as an integral part of their quality management system[3]. Through the PMS system, manufacturers should systematically collect, record and analyze relevant data on the quality, performance and safety of a device throughout its life cycle and should detect and report trends in accordance with Article 88 MDR and Article 83 IVDR.

The Trend reporting requirements, as defined in Article 88 MDR and in Article 83 IVDR, have become applicable respectively from the 26th May 2021 and 26th May 2022. They are applicable to both MDR devices and MD legacy devices[4] and to IVDR devices and IVD legacy devices[5]. For the trend reporting requirements applicable to "old" devices, please refer to Question 5 of this document.

The trend reporting under the Regulations requires a systematic review of all "incidents", "expected undesirable side effects" (MDR) and "expected erroneous results" (IVDR), apart from "serious incidents".

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[1] For definition of a 'standard' please refer to Article 2(1) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation. A summary list of titles and references of harmonised standards can be found on the European Commission Medical Devices website: Summary list of titles and references of harmonised standards

[2] All MDCG Guidance documents can be found on the European Commission Medical Devices website: Guidance documents

[3] The Post-Market Surveillance guidance is under development at the date of adoption of this guidance and will become available at the following link: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en#guidance

[4] *MDCG 2021-25 Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC*

[5] *MDCG 2022-8 Regulation (EU) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC*

For the purpose of this document, the term "*events*" covers all incidents which are not serious incidents, expected undesirable side-effects and expected erroneous results.

Manufacturers are required to report to the National Competent authorities any statistically significant increase in the frequency or severity of "events" that could have a significant impact on the benefit-risk analysis and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits (MDR) or to the stated performance of the device (IVDR).

Terms and Concepts, useful for Trend reporting, as outlined in Section 2 of Chapter VII of the Regulations are defined on the MDCG 2023-3[6].

1. When is a manufacturer required to submit a trend report to the competent authorities?

The requirements for Trend reporting are outlined in Article 88(1) MDR and Article 83(1) IVDR.

In accordance with the MDR, manufacturers shall report any statistically significant increase in the frequency or severity of incidents that are not serious incidents or expected undesirable side effects that could have a significant impact on the benefit-risk analysis[7] and 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. The "significant increase" shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device or category or group of devices in question during a specific period as specified in the technical documentation and product information.

In accordance with the IVDR, manufacturers shall report any statistically significant increase in the frequency or severity of incidents that are not serious incidents that could have a significant impact on the benefit-risk analysis and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons or any significant increase in the expected erroneous results in comparison to the stated performance of the device as referred to in points (a) and (b) of Section 9.1 of Annex I and specified in the technical documentation and product information.

2. How can manufacturers identify and report a trend to the Competent Authority?

The manufacturer should record incidents and expected undesirable side effects in accordance with Articles 83 - 86 MDR and incidents and expected erroneous results in accordance with Articles 78 - 81 IVDR.

[6] MDCG 2023-3 "*Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 and Regulation (EU) 2017/746*"

[7] Referred to in Sections 1 and 5 of Annex I MDR and IVDR

In accordance with Article 84 MDR and Article 79 IVDR, manufacturers should develop and maintain a PMS Plan which describes the methodology and protocols to manage the collection and use of available information, as specified in section 1 of Annex III of the Regulations.

In accordance with Article 83(2) MDR and Article 78(2) IVDR, manufacturers in their PMS system have to gather, record and analyze in a systematic manner any relevant data on the quality, performance and safety of a device throughout its entire lifetime, in order to be able to draw the necessary conclusions and to determine, implement and monitor any preventive and corrective actions.

As specified in Article 83(3) MDR and Article 78(3) IVDR, data gathered by the manufacturer's PMS system shall, among other things, be used to detect and report trends in accordance with Article 88 MDR and Article 83 IVDR.

Before submitting a trend report, manufacturers, based on the monitoring of the above-mentioned events over time, need to compare the severity and the frequency of the occurrences of these incidents and of expected undesirable side effects / expected erroneous results against the threshold values defined and documented in the technical documentation.

The Regulations include requirements related to risk management to ensure that devices are safe for patients, users and the environment throughout their entire lifecycle. They also require that all risks need to be reduced as far as possible without adversely impacting the benefit-risk analysis.

In that respect although compliance to standards is not mandatory, the harmonized EN ISO 14971:2019[8] defines the requirements and steps in the process of medical device risk management. Risk according to EN ISO 14971:2019 is defined as the combination of the probability of occurrence of harm and the severity of that harm.

Thus, it is implied that while assessing the statistically significant increase in the frequency and severity of events, the risk assessment should be based on quantitative data in adequation with ISO 14971:2019. However, ISO 14971:2019 also allows for qualitative assessment when appropriate, particularly when qualitative data is deemed insufficient.

Further guidance on methods to establish whether an increase is statistically significant is available in ISO/TR 20416 *Medical devices — Post-market surveillance for manufacturers* and in the Global Harmonisation Task Force (GHTF) *Trend Reporting of Adverse Events* document[9]. However, manufacturers should select the statistical techniques which best suits with the data they are analysing[10].

[8] EN ISO 14971:2019 + A11:2021 Medical devices - Application of risk management to medical devices (ISO 14971:2019)

[9] GHTF, Manufacturer's Trend Reporting of Adverse Events: https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n36r7-2003-manufacturer-trend-reporting-adverse-event-030101.pdf

[10] Manufacturers are required to use IMDRF codes when filing a trend report. However, there is no obligation to apply IMDRF coding for trend analysis and detection. Manufacturers should select the statistical techniques (and coding) which best suits the data they are analysing.

3. With reference to the criteria for Trend reporting in Article 88 MDR and Article 83 IVDR, what is meant by a '*significant impact on the benefit-risk analysis*'?

A '*significant impact on the benefit-risk analysis'* is identified when an increase in the frequency or severity of incidents which are not "serious incidents" or which are "expected undesirable side effects" or "expected erroneous results", results in a change of the benefit-risk analysis.

As defined in Article 2(23) MDR and Article 2(16) IVDR, risk is the combination of two elements: (i) the probability of occurrence of harm (frequency) and (ii) the consequences of the harm (severity).

A "*significant increase*" in the risk can be defined as a possible increase of the severity of the harm and/or increase of the probability of occurrence of the harm[11] in such a way that could lead to an unacceptable "residual risk"[12] and to a significant impact on the benefit-risk analysis.

In the context of trending, a "significant increase"should be determined by comparing the foreseeable frequency and/or severity of the incidents with the statistical methodology set out in the technical documentation.

To be able to evaluate the "residual risk", the manufacturer needs to establish and document in its technical documentation, the suitable indicators and threshold values to assess the residual risk as required in Annex III of the Regulations.

Thresholds for frequency and severity of incidents or expected undesirable side effects/expected erroneous results should be taken into account when evaluating the criteria for Trend reporting as defined in Article 2(23) MDR and Article2(16) IVDR.

With regard to IVDs, this can be interpreted for example:

- the expected performance during its clinical use;
- the clinical outcome expected and consequences on clinical decision of the physician;
- factors relevant to the risks and benefits for patients including the implications of errors associated with the device on the physicians' choice of treatment options (including lack of patients' treatment or inadequate treatment).

In line with Article 88 MDR and Article 83 IVDR and with reference to sections 1 and 5 of Annex I / Chapter I (MDR /IVDR), the issuing of a Trend report should be supported by a documented assessment in which the residual risk is weighted against the intended benefits and the threshold values defined in the technical documentation.

[11] Probability of occurrence of harm = the probability of hazard or hazardous situation multiplied by the probability of hazard or hazardous situation causing harm **(**Questions and answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices) MDCG 2023-3 Q&A on Vigilance terms and concepts

[12] Residual Risk = risk remaining after risk control measures have been implemented **(**EN ISO 14971:2019 definition).

4. How should the manufacturer manage a Trend related to "expected undesirable side effects[13]" or "expected erroneous results[14]"?

For the purpose of this guidance, "undesirable side effects" are considered as incidents according to Article 2 MDR. "Expected undesirable side effects" should be clearly documented in the product information and quantified in the manufacturer's technical documentation (Article 87(a) MDR). They should also be acceptable when weighted against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use (Section 8 of Annex I of MDR).

If there is "*any statistically significant increase in expected undesirable side effects that could have a significant impact on the benefit risk analysis, and 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*", they should be reported through a Manufacturer Trend Report (MTR) in accordance to Article 88 MDR.

For IVDs, the "expected erroneous results" are defined by the manufacturer during the development and documented in the product information and technical documentation. Therefore, for the purpose of this guidance, "expected erroneous results" should be subject to Trend reporting and clearly documented in the product information and quantified in the manufacturer's technical documentation (Article 82a IVDR).

The manufacturer has to declare the acceptable performance of the device according to paragraphs (a) and (b) of Section 9.1 of Annex I of the IVDR. When "*any statistically significant increase in expected erroneous results established in comparison to the stated performance of the device*" occurs, it should be reported through Manufacturer Trend Report (MTR) according to Article 83 (IVDR).

5. How to handle the different regulatory statuses of the impacted devices in the Trending report process?

Manufacturers should ensure that their impacted devices are registered in EUDAMED, in compliance with the Regulations, once its use has become mandatory[15].

Manufacturers should in principle apply the same process for identifying trends, regardless of the regulatory status of the devices impacted, in line with the applicable requirements in the Regulations.

[13] See MDCG 2023-3 "*Question and Answer on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 and Regulation (EU) 2017/746*" for the definition of "undesirable side effects".

[14] See MDCG 2023-3 "*Question and Answer on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 and Regulation (EU) 2017/746*" for the definition of "erroneous result".

[15] Q&A document for the transitional provisions and gradual roll-out of Eudamed, in particular Q8, Q12, Q13 and Q14.

For devices[16] which have been placed on the market only before the date(s) of application of the Regulations, so called "old devices[17], the MDR and IVDR requirements related to Trend reporting are not applicable[18]. However, the Trend reporting process (as specified in Question 2) is based on the collection of quantitative and historical data

To facilitate the detection of a Trend, it is recommended to also cover the events related to "old devices" when applicable.

Multiple scenarios are possible:

1) The Trend report covers **legacy and/or MDR/IVDR devices AND old devices**: When the Trend is impacting legacy or MDR/IVDR device(s) which are similar to the corresponding old devices (e.g. implant with same or similar design), it is **recommended** to include the events related to old devices within the same Trend report.

2) The Trend report covers **legacy and/ or MDR/IVDR devices** (**NOT old devices)**: The manufacturer should issue a Trend report covering these types of devices and submit it to EUDAMED once fully operational. Until then, the report shall be submitted to the national vigilance systems.

3) The Trend report covers **ONLY old devices**[19]: In cases where the Trend report covers only events related to old devices, the manufacturer should submit the Trend report according to national vigilance systems.

6. What happens if a new type of incident or unexpected undesirable side effect or unexpected erroneous result is identified?

Unexpected undesirable side-effects and unexpected erroneous results or new incident types are events that have not been considered or addressed by the manufacturer in its risk analysis or risk management file. In those cases, the manufacturer should either:

- report them in accordance with Article 87/82 of the MDR/IVDR through a Manufacturer Incident Report (MIR) in case of a serious incident,
- document and analyze the events when updating the risk analysis and risk management file in case of a new type of incident or unexpected undesirable side-effect or unexpected erroneous result,

[16] For the purpose of Trend reporting, the term "device" relates to a device model and not to an "individual" device, as "individual" devices are placed on the market at different moments during the period covered by the "device" certificate.
[17] The scope of "old devices" covers only devices for which no individual devices have been placed on the market after MDR / IVDR date(s) of application. The scope of "legacy devices" covers all the devices for which at least some individual devices have been placed on the market after MDR /IVDR date(s) of application.
[18] MDR/IVDR requirements that have an impact on the device documentation (the labelling, the technical documentation to be drawn up) or the conditions for the placing the device on the market of the device, do not apply to old devices.
[19] 'Old' devices as described in MDCG 2021-25 and MDCG 2022-8 cannot be registered in the EUDAMED UDI/DEV module.

- conclude whether the residual risk is acceptable or not.

From this point in the process, the previously unknown event becomes expected, should be considered and quantified in technical documentation and used to identify any possible Trend. In addition, technical documentation (including the PMS plan and reports) should be updated when necessary.

For better clarification on significant impact on the benefit-risk analysis and the criteria for Trend reporting, please also refer to Question 3.

7. How is the Trend reporting process linked to the PMS plan?

Taking into account the PMS requirements (MDR and IVDR, Chapter VII: Post-market surveillance, vigilance, and market surveillance), manufacturers do not only need to perform Trend reporting as per Articles 88 MDR and Article 83 IVDR but they should also include in the PMS plan the methods and protocols to manage the events subject to Trend reporting.

This includes the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period (per Annex III, Section 1. B: Technical Documentation on Post-Market Surveillance). The PMS plan[20] should define which type(s) of methods should be used for Trending purposes while an explanation of how they are to be applied may instead be covered by procedures that are referenced in the PMS plan.

As per Article 88(1) MDR and Article 83(1) IVDR, the manufacturer shall specify, in the post-market surveillance plan (PMSP) referred to in Article 84 MDR and Article 79 IVDR:

- how to manage the events subject to the Trend report;
- the methodology used for determining any statistically significant increase in the frequency or severity of such events (or change in performance considering the IVDR);
- the observation period.

For more details about the post-market surveillance please refer also to the MDCG guidance[21] on the Post-Market Surveillance system.

8. How to link the Trend reporting process to the general Quality Management System (QMS)?

The minimum requirements of the quality management system of devices developed by manufacturers are described in Article 10(9) MDR and Article 10(8) IVDR. The implementation of the quality management system must ensure compliance with the Regulations.

[20] See for more details the guidance on the Post-market Surveillance system.

[21] The Post-Market Surveillance guidance is under development at the date of adoption of this guidance and will become available at the following link: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en#guidance

Processes that are compliant with the relevant harmonized standards or the relevant parts of those standards, are presumed to be in conformity with the requirements of the Regulations covered by those standards or parts thereof.

The Trending process is one of the elements of Vigilance, risk management, PMS processes and of the QMS. Manufacturers are required to plan and implement the monitoring, measurement, analysis needed to demonstrate the conformity, the performance, and the safety of their devices and to ensure the effectiveness of the quality management system.

Therefore, according to Article 10(13) MDR and Article 10(12) IVDR, manufacturers should have a system for the recording and reporting of serious incidents and of field safety corrective actions as described in Articles 87 and 88 MDR and Articles 82 and 83 IVDR.

The risk management, the clinical/performance evaluation and PMS process under which the manufacturer operates are essential key elements in Trend reporting and the basis for determining:

- when there is a significant increase of frequency or severity of the events,
- when the acceptable (lowest) risk[22] level might become threatened,
- when the benefit-risk analysis of residual risk indicates that the events have led or may lead to unacceptable risks to health or safety of patients, users and other persons,
- when the residual risk does not constitute an acceptable risk when weighted against the benefits of patients or users,
- when actions are necessary by manufacturers to address unacceptable risks.

9. Which incidents, expected undesirable side-effects, or expected erroneous results have to be included in Trend reporting from a geographic perspective?

The manufacturer should record events in accordance with Articles 83 - 86 MDR and Articles 78 - 81 IVDR requirements for the post-market surveillance.

To have statistically significant data as a basis for a Trend report, the manufacturer should take in account all the events related to a specific Trend and from a geographic perspective should consider all the events that have occurred worldwide. The data collected worldwide by the manufacturer during PMS activity, are all useful to define the statistically significant dataset of events. Therefore, the trend identification is based on the data collected on events occurring in the EU and worldwide.

The identified trend should be notified to the Competent Authorities (CAs) where related events occurred[23]. This reporting should take place in EUDAMED when it has become fully functional.

[22] See Article 2 (23) of the MDR and Article 2 (16) of the IVDR.

[23] The identified trend should be reported to all Competent Authorities where the events occurred, using the same trend report and supporting documentation (unless minor adjustments are needed for country-specific information).

The manufacturer should submit a trend report when the trend refers to events that occurred in the European Economic Area (EEA) + Türkiye (TR) + Northern Ireland (XI) or includes at least one event in that area for trends which already been notified in countries outside that area.

10. How to include additional events occurring in countries that were not included in the initial Manufacturer Trend Report (MTR) form?

If additional events of the same type are detected during the Trend report cycle, in countries (EEA countries, TR and XI) or worldwide and which were not previously included in the initial Manufacturer Trend Report (MTR), the manufacturer has to add the relevant CAs in a follow up Manufacturer Trend Report if foreseen or, at the latest, at the time of the final Manufacturer Trend Report.

11. Could a Trend report include only ONE device or possibly a category or group of devices?

As laid down in Article 88(1) MDR, a Trend report could be performed for a single device type as well as for a category or a group of devices if these devices are impacted by the same (or similar) types of events. This information[24] is provided by the manufacturer in the Section 2 "*Device information*" and in Section 2.1 "*Type of device scope*" of the Manufacturer Trend Report (MTR) form.

In the MTR form, used for submitting at Trend report, the manufacturer should select the type of device scope by choosing between the device category (the first hierarchy level of EMDN), the device group (the second hierarchical level of EMDN) or the device type (Basic UDI-DI(s)/Eudamed DI(s), (master[25]) UDI-DI(s)/Eudamed ID(s) or UDI-PI(s)/Lot/batch number(s).

The "old devices" could be reported only by the device name and reference number and Custom Made Devices (CMD) could be reported by the device name or by the name of the group of devices.

Article 83 (IVDR) does not specify whether a Trend report can apply to a category or group of devices. In the MTR Form the manufacturer can only select the device scope by choosing between Basic UDI-DI/Eudamed DI, UDI-DI/Eudamed ID and UDI-PI(s)/Lot/batch number(s) and for old devices, by the device name and reference number.

For the device(s) impacted by the events reported in the trend report, the manufacturer should provide in that report the list of UDI-DI/or product code(s) as well as the lot(s)/batch(es) impacted.

[24] Only one choice is possible in the "*Type of device scope*" of MTR form.

[25] For the contact lenses category, the UDI-DI is replaced by a Master UDI-DI.

If the affected batches are 5 or less, the data could be entered directly in the MTR on EUDAMED. In case the device scope in trend is the UDI/PI production identifier and covers more than 5 batches, the manufacturer should add a list identifying all the devices covered and the production identifiers (UDI-PI, (LOT/Batch number). This would require to attach a file in csv format into EUDAMED.

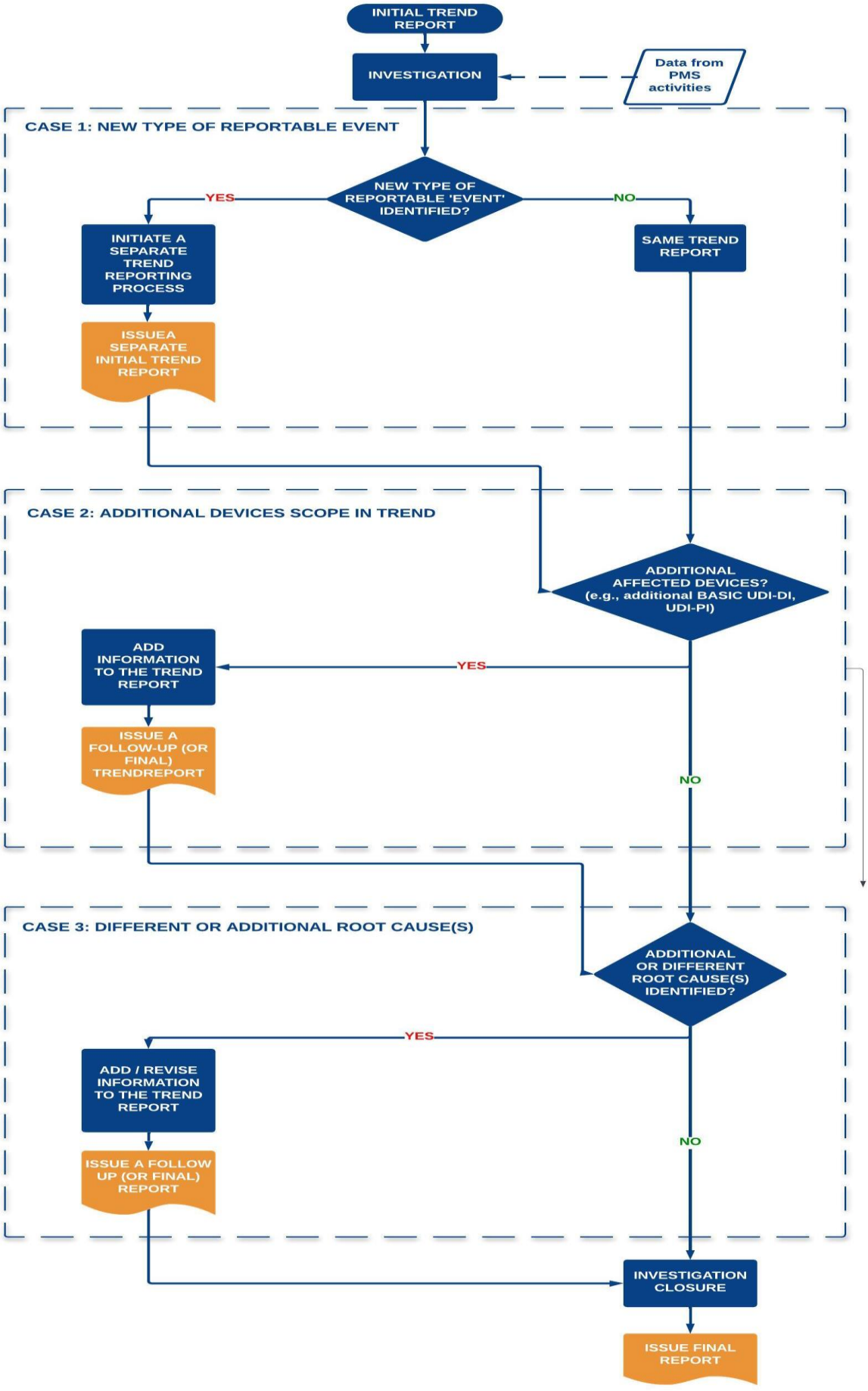
For more details, please refer also to the MTR Helptext[26].

12. Which kind of information can be modified once the initial Trend report has been submitted?

Once a Trend report has been submitted, the type of events triggering the trend reporting obligations should remain consistent throughout the reporting process. However, manufacturers can update the information related to the devices scope in trend and to the root cause if necessary, by providing this updated information in a follow-up or final trend report.

Figure 1 below illustrates different possible scenarios after submission of the initial trend report.

[26] Link to the MTR Helptext ADD LINK


INITIAL TREND REPORT
INVESTIGATION
Data from PMS activities
CASE 1: NEW TYPE OF REPORTABLE EVENT
NEW TYPE OF REPORTABLE 'EVENT' IDENTIFIED?
YES
NO
INITIATE A SEPARATE TREND REPORTING PROCESS
ISSUEA SEPARATE INITIAL TREND REPORT
SAME TREND REPORT
CASE 2: ADDITIONAL DEVICES SCOPE IN TREND
ADDITIONAL AFFECTED DEVICES? (e.g., additional BASIC UDI-DI, UDI-PI)
ADD INFORMATION TO THE TREND REPORT
YES
ISSUE A FOLLOW-UP (OR FINAL) TRENDREPORT
NO
CASE 3: DIFFERENT OR ADDITIONAL ROOT CAUSE(S)
ADDITIONAL OR DIFFERENT ROOT CAUSE(S) IDENTIFIED?
YES
ADD / REVISE INFORMATION TO THE TREND REPORT
ISSUE A FOLLOW UP (OR FINAL) REPORT
NO
INVESTIGATION CLOSURE
ISSUE FINAL REPORT

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a) New type of event

If a new type of event (different from the event identified in the initial report) which is reportable according to the trend report requirements, is identified for the same device/category/group of devices[27] after an initial report has already been issued, it is necessary to create a separate trend report with its own process.

b) Additions of device(s) impacted by the trend

In cases where additional devices/category/group of devices are identified and are linked to the same type of event as initially reported, this information should be incorporated already to the current trend report which needs to be updated accordingly.

If new batches of the same affected device/category/group of devices are placed on the market or put into service, the information related to the new batches should be added to the current trend report when the next trend report (follow-up or final) is issued.

Example

- During the investigation, the root cause of the event is found to be linked to the use of a specific raw material, which is also employed in the manufacturing a different group of devices. The additional group of devices is also linked to the same type of event as originally reported and has itself triggered the reporting obligations laid down in Article 88 MDR or Article 83 IVDR.

c) Change of root cause or addition of another root cause

If during the investigation of a trend either i) a manufacturer identifies that the root cause is different from what was initially determined or ii) discover an additional root cause(s) to that initially reported, it should add this information and update the current trend report.

Examples:

Change of root cause: An emerging pattern is recognized, initially attributed to a particular component malfunction. However, further investigation reveals that the actual root cause of these occurrences is associated with inappropriate storage conditions and not to what was suspected.

Additional root cause: A trend event is identified and reported to be linked to a specific component malfunction: e.g. the legal manufacturer identifies additional data obtained during the investigation which indicate that a different component malfunction also contributes to the events. The manufacturer draws up a follow-up or final trend report to report the information.

13. How can manufacturers submit a Trend report before EUDAMED has become fully functional?

[27] Including MDR / IVDR or legacy devices (see further information in Question 5).

The submission of the Trend report through electronic system (EUDAMED) referred to Article 92 MDR and Article 87 IVDR will apply only when EUDAMED becomes fully functional and will become mandatory 6 months after publication of the notice in the Official Journal of the European Union.

As per Article 92(6) MDR and Article 87(6) IVDR, trend reports (see question 14) shall be automatically transmitted upon receipt via the electronic system to the Competent Authorities of the Member States in which events occurred.

Until EUDAMED has become fully functional, the Trend report requirements set out in the Regulations are applicable and alternative administrative technical solutions have to be adopted as per guidance MDCG 2021-1[28] for MDR and MDCG 2022-12[29] for IVDR for submission of the Trend reports to the National Competent authority(ies). The Trend Report should be submitted using the MTR form[30,31] alongside the Trend Report Document[32,33].

14. Which documents should be submitted for Trend Reporting in EUDAMED?

When submitting a Trend report, the manufacturer has to provide the following information:

- **Manufacturer Trend Report (MTR).** The following information[34] need to be directly entered in EUDAMED: Member States where the events occurred, the administrative information, description of the devices and the detected trend (background, established threshold, methodology, observation period and actions to be taken or already implemented to reduce the risks for the users and other person).

- **Trend Report Document**. The Trend report document is an additional document that includes further information about the affected devices, the methods used to detect the trend, the description of the detected trend, the investigations, conclusions made and information related to the CAPAs (if any). The Trend report document should be uploaded as an attachment into EUDAMED and in a PDF-format. The need for this additional document is related to the reduced amount of information that can be introduced in the Minimum Viable Product (MVP) version of EUDAMED.

15. Which actions are required from a manufacturer when a trend has been identified?

[28] MDCG 2021-1 *"Guidance on harmonized administrative practices and alternative technical solutions until Eudamed is fully functional"*

[29] *MDCG 2022-12 Guidance on harmonized administrative practices and alternative technical solutions until Eudamed is fully functional (for Regulation (EU) 2017/746 on in vitro diagnostic medical devices)*

[30] ADD LINK TO MTR FORM

[31] The MTR Form can be submitted in Word (or manually exported in PDF).

[32] Please refer to Q14 for more information regarding the Trend Report Document.

[33] ADD LINK TO TREND REPORT DOCUMENT

[34] This information corresponds to the content of the former MTR form which was used beforeEUDAMED becomes fully functional

When a trend has been identified, the manufacturer should evaluate and implement appropriate action(s) to mitigate the risks to patients, users or other persons. These actions may include for example Field Safety Corrective Action(s) (FSCAs), other Corrective Action(s) or any other measures as deemed appropriate. They have to be implemented in order to return to the acceptable thresholds in terms of the occurrence or severity of these events, addressing the "unacceptable risk" identified.

These actions should be determined by the manufacturer based on its investigation of the events contributing to the trend. Additionally, an assessment of the trend and its impact on the risk-benefit analysis of the device should be completed.

This assessment is based on evaluating the increased frequency or severity of non-serious incidents which could lead to an unacceptable risks, as well as any new risks identified during the trending period.

Depending on its investigation and possibly of the identified root cause of the events, the manufacturer should initiate the most appropriate action(s) to correct the issue and reduce the risk, which may include for instance FSCAs, other corrective actions, trainings, design changes, labelling updates, improvements in manufacturing or packaging processes. This is part of the risk management system and based on the results of its investigation, the manufacturer should update the risk management files related to the device impacted.

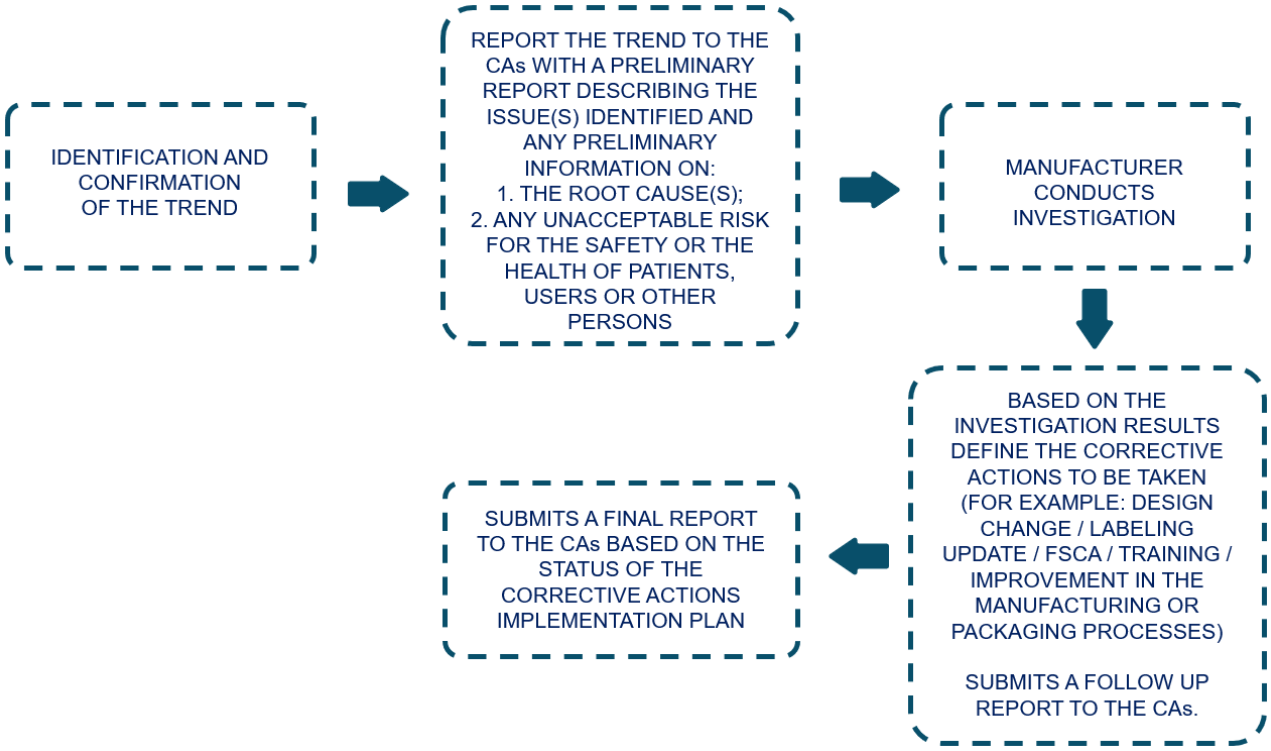

Figure 2: Trend Report Process

The trend report should outline the above mentioned actions if they are known at the time of the initial report; otherwise, they should be included in follow-up or final report(s).

Once a trend has been identified and reported to the Competent Authorities, if the manufacturer determines that a Field Safety Corrective Action (FSCA) is the most appropriate course of action, the Trend report process should be concluded with the submission of a final trend report and the FSCA process should be initiated. It is essential to link both processes by referencing their respective identifiers[35]. In all other cases not involving an FSCA, the manufacturer should notify a final Trend report after the appropriate corrective actions have been implemented. The monitoring of the effectiveness check of the corrective actions needs to be done by the manufacturer though the CAPA process.

For the purpose of the final Trend report, a taken corrective action can be considered as effective for example when the number of events has fallen below the threshold value and when no further events are registered in new countries (no new countries included in the scope of the MTR).

If the evaluating Competent Authority is not satisfied with the action taken by the manufacturer, it can require to adopt appropriate measures to the manufacturer in accordance with the Regulations as for Article 88(2) MDR and Article 83(2) IVDR.

The initial Trend Report should not be filed only by initial observations but should include supporting analysis. The issuance of the initial Trend Report should only occur once the manufacturer has completed a preliminary analysis of the identified trend, including any information on the possible root cause and an assessment of whether the trend represents an unacceptable risk to the safety or health of patients, users, or other persons. This ensures that the report is based on sufficient evidence and that the trend meets the criteria for being reportable.

[35] CAs and manufacturer references of the reports.

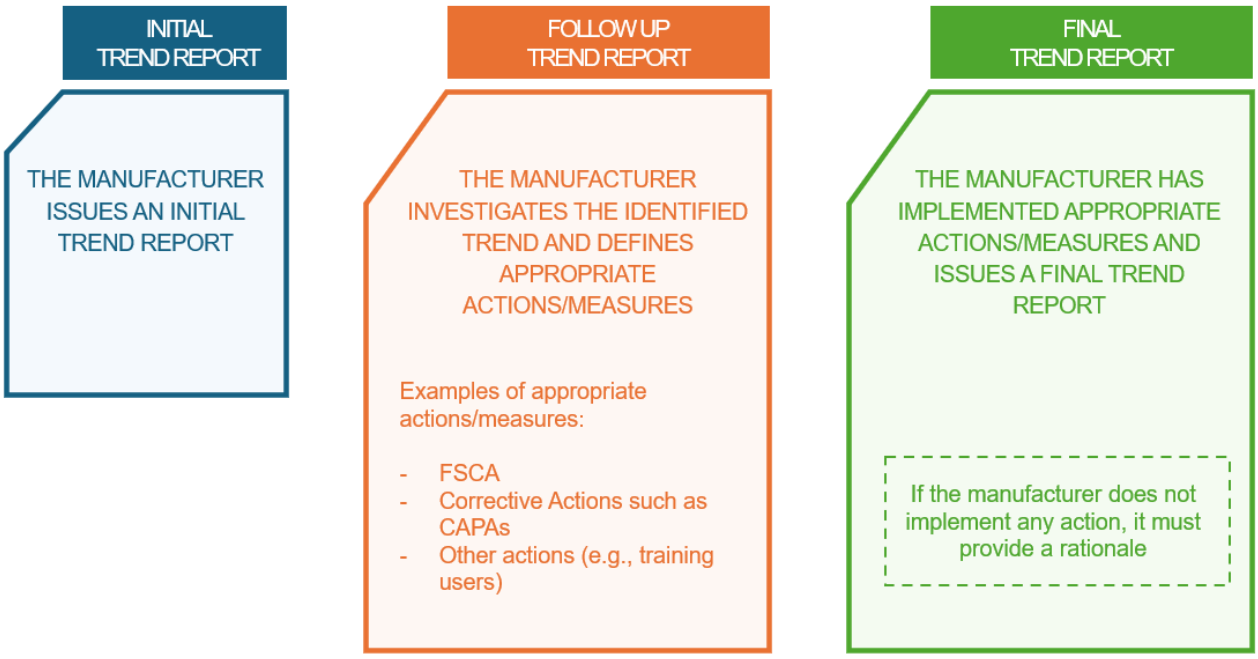

Figure 3: Corrective action process and their identification and report within the trend process

16. What types of requests can a Competent Authority make after the assessment of a Trend report?

The Competent Authority(ies), as specified in Article 88(2) MDR and Article 83(2) IVDR, may conduct their own assessment on a Trend report and require the manufacturer to adopt appropriate measures in accordance with the Regulations in order to ensure the protection of public health and patient safety.

When a Trend report has been notified, the CA which received it should assess it. This assessment could lead to a request of re-evaluation by the manufacturer.

The appropriate measures that a CA may request to a manufacturer can be of various types. For example, it can be asked to issue a corrective/preventive action or any other kind of measure in order to ensure the protection of public health and patient safety.

17. How manufacturers should apply the Trend report requirements to Custom Made Devices?

The same process related to the identification of a Trend also applies to Custom Made Devices (CMDs). With the absence of stated exceptions, manufacturers of CMDs should meet nearly all of the MDR requirements.

As defined also in the guidance MDCG 2021-3[36], the requirements defined in the MDR for risk management, PMS and clinical evaluation life cycle processes as defined by the MDR, should also

[36] Refer also to MDCG 2021 – 3 guidance "*Questions and Answers on Custom-Made Devices*" Question 8 and 9.

apply to groups of devices with the same intended purpose, materials used, process utilized, same principal design etc. and not to each individual CMD. When an issue is identified, for example on components or materials used, the manufacturer should monitor over the time in its PMS activity and verify if a Trend report is required.

As a consequence, the requirements of Article 88 MDR apply to CMD and consequently their registration in EUDAMED according to the guidance MDCG 2021-13[37].

18. Some examples of cases for which a Trend report should be considered

In order to further clarify what could be reported through a Trend report, some examples are provided below:

Examples for MDR:

- A trend of expected undesirable side effects indicates an increasing risk, highlighting the need for reassessment and appropriate mitigation measures in accordance with EN ISO 14971, Medical devices – Application of risk management to medical devices.
- An increase in an incident scenario that does not meet reporting requirements of Article 87 MDR (harm severity: minor) causes a risk management threshold breach and leads to an increase in probability from “remote” to “occasional”.
- A number of similar incidents, according to Article 2(64) MDR, that are not serious incidents reported by different healthcare facilities show a statistically significant increase within the observation period:
  - Skin irritation as a result of device applied with direct dermal contact;
  - Abdominal pain and nausea in the first few weeks after implantation of a contraceptive coil;
  - Paradoxical Hyperplasia after using a cryolipolysis device.

Examples for IVDR:

- An increase in an incident scenario that does not meet reporting requirements of Article 82 (IVDR) leads to threshold breach and to an increase in probability from “remote” to “occasional”.
- The change in upper and/or lower detection limits, which would cause a shift in the benefit-risk analysis of the device, even if detected by controls performance..
- Significant increase in the frequency of a defect in which an analyser dispenses an insufficient amount of test reagent to the reaction due to foaming of the reagent (device malfunction). This causes an erroneous result for the cholesterol test (hazardous situation), and leads to inappropriate medical treatment which is not

[37] MDCG *2021-13 Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorized representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR*

serious in nature but may significantly affect the benefit-risk of the assay if occurrence is frequent.

- The device is showing a lower level of sensitivity or specificity which is different of the one in the technical documentation.
- The repeatability (the deviation of repeated measures of the same sample under identical conditions) is not in line with what the technical documentation describes.
- The Limit of Detection (LoD) is higher than the technical documentation describes.
- A significant increase in the frequency of expected false positive or false negative results from a diagnostic test in comparison to the stated performance of the device in the technical documentation.

19. Examples of rationales for reporting the events

Regulation	Type	Reason for the trend	Possible rationale
MDR	Increase in Frequency	Increase in frequency of skin rashes caused by adhesive patches.	A statistically significant increase in the frequency of non-serious incidents, compared to the stated frequency in the technical documentation, may indicate risks to patient safety that outweigh the intended benefits.
	Increase in Severity	Events of non-serious eye irritations from an ophthalmic device escalating to corneal abrasions.	A significant escalation in the severity of non-serious incidents suggests a deviation from the device's benefit-risk analysis documented in the technical documentation and could result in unacceptable risks for the patient population.
	Increase in Frequency or Severity of Expected Undesirable Side Effects	Events of abdominal pain and nausea events after implantation of a contraceptive coil.	A statistically significant increase in the frequency or severity of expected undesirable side effects, compared to anticipated levels in the technical documentation, results in an unacceptable risk for the intended patient population.
IVDR	Increase in Frequency	Rise in invalid results from a cholesterol assay, where invalid runs exceed 5% of total runs.	A statistically significant increase in invalid results impacts the performance of the device when compared to the documented performance specifications.
	Increase in Severity	False-positive results from a vitamin B12 deficiency test	An increase in the severity of erroneous results affects the benefit-risk analysis, by

		leading to unnecessary injections.	exposing patients to unnecessary interventions.
	Increase in Frequency or Severity of Expected Erroneous Results	Increase in false-negative results from a urine protein test, causing delays in identifying early-stage kidney dysfunction.	A statistically significant increase in the frequency of expected erroneous results when compared to its stated performance, leads to unacceptable risks for the broader patient population.

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