# Questions and Answers on Trend reporting as outlined in the Regulation (EU) 2017/745 on medical devices (MDR) and in the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) (March 2024)

## 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). A common understanding related to Trend reporting is deemed essential for an effective and harmonised implementation of the Vigilance requirements under the MDR and IVDR. To that end, this document is intended as a supporting tool for use by competent authorities (CAs), economic operators and other relevant parties and to be read in conjunction with the MDR and IVDR (the Regulations) and other MDCG guidance documents[1].

The Trend reporting requirements, as defined in Article 88 of the MDR and in Article 83 of the 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[2] and to IVDR devices and IVD legacy devices[3]. 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". 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.

It allows the national competent authorities to be notified by manufacturers or their authorized representatives of 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).

The Trending process is one of the elements of the Vigilance system and is based on risk assessment, Post-Market Surveillance (PMS) processes and the manufacturer's Quality Management System (QMS). The manufacturers, according to the Regulations, have to establish a PMS system as an integral part of the manufacturer's quality management system. Through the PMS system, manufacturers actively and systematically collect, record and analyze relevant data on the quality,

[1] All MDCG guidance documents can be found on the European Commission Medical Devices website: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

[2] *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*

[3] *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*

performance and safety of a device throughout its life cycle and can detect and report trends in accordance with Article(s) 88/83 of the MDR/IVDR.

For the purpose of this guidance, the term "*device*" covers medical devices, accessories for medical devices, products listed in Annex XVI of the MDR, in vitro diagnostic medical devices and accessories for in vitro diagnostic medical devices.

The Terms and Concepts, useful for Trend Reporting, as outlined in Section 2 of Chapter VII of the Regulation (EU) 2017/745 on medical devices, are defined on the MDCG 2023-3 "*Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices"*[4].

## 1. When shall a manufacturer submit a Trend Report?

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

In accordance to 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[5] 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 to 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 can 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 of the MDR and incidents and expected erroneous results in accordance with Articles 78-81 of the IVDR for PMS requirements. In particular, in accordance with Article 84 of the MDR and

[4] MDCG 2023-3 'Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices' (link https://health.ec.europa.eu/system/files/2023-02/mdcg_2023-3_en_0.pdf). MDCG 2023-3 guidance is under revision to include IVDR aspects. Please refer to the updated version when available at the following link: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en#guidance

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

Article 79 of the IVDR, the PMS Plan should describe the methodology and protocols to manage the collection and use of available information, as specified in the Annex III of the MDR and IVDR.

In accordance to 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 also 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).

In view of a possible issuing of a trend report, the manufacturer, based on the monitoring of the above-mentioned events over time, needs to compare the severity and the frequency of the occurrences of these incidents and of expected undesirable side effects / expected erroneous results with the corresponding threshold values defined and documented in the risk analysis.

Both MDR and IVDR include requirements related to risk management to ensure that devices are safe for patients, users and the environment throughout their entire lifecycle. They further stipulate that all risks need to be reduced as far as possible without adversely affecting the benefit-risk analysis.

In that respect although compliance to standards is not mandatory, the harmonized EN ISO 14971:2019[6] 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 must be based on quantitative data in adequation with ISO 14971:2019.

**3. With reference to the criteria for trend reporting (Article 88 of the MDR and Article 83 of the IVDR), what is meant by a '*significant impact on t*he 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 categorized as serious incidents or which are expected undesirable side effects or expected erroneous results, results in a change in the benefit-risk analysis.

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

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

A significant increase in the risk can be defined as possible increase of the severity of the harm and/or increase of the probability of occurrence of the harm[7] in such a way that could lead to unacceptable residual risk[8] and to a significant impact on the benefit-risk analysis.

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 MDR / IVDR.

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

With particular regard to IVDs, that can be read for example as :

- the expected performance during its clinical use;
- the clinical outcome expected from this service and consequences on clinical decision of the physician;
- factors relevant to the risks and benefits of other treatment options (including lack of treatment or inadequate treatment).

In line with Article 88 of the MDR and Article 83 of the IVDR and with reference to sections 1 and 5 of Annex I / Chapter I, the issuing of a Trend report is 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.

## 4. How manufacturers should manage a Trend related to “expected undesirable side effects” or “expected erroneous results”?

For the purpose of this guidance, “undesirable side effects” are considered as incidents under Article 2 (MDR). “Expected undesirable side effects” must be clearly documented in the product information and quantified in the manufacturer’s technical documentation (Article 87(a) MDR). They must 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 in accordance to Article 88 of the MDR.

[7] 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

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

The "expected erroneous results" are defined by the legal 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 must be clearly documented in the product information and quantified in the manufacturer's technical documentation (IVDR, Art.82 a).

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 of the IVDR.

For further clarification on "expected side effects" (MDR) and "expected erroneous results" (IVDR), please refer to MDCG 2023-3 "*Question and Answer on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices*".

**5. How to handle "old devices" in the trending report process?**

For devices[9] which have been placed on the market only before the date(s) of application of the Regulations, so called "old devices[10], the MDR and IVDR requirements related to Trend reporting are not applicable[11].

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 **only 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 when it becomes fully available and to national vigilance systems in the meantime.

[9] 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.

[10] 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.

11 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.

3) The Trend report covers **ONLY old devices**: In cases where the Trend report covers only events related to old devices, the manufacturer should submit its 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 MIR) in case of serious incident, or
- 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.
- 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, the product information and the PMS plan 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 the Trend reporting process is 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 for MDR and Article 83 for 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[12]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);

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

- the observation period.

For more details about the post-market surveillance please refer also to the EU guidance[13] 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.

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 of the MDR and Articles 82 and 83 of the 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[14] 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 to patient,
- when actions are necessary by manufacturers to address unacceptable risks.

**9. Which incidents, expected undesirable side-effects, 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

[13] 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

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

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 CAs where related events occurred. This reporting should take place in EUDAMED when it has become fully functional.

The manufacturer should submit a trend report based on the MDR/IVDR 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 same type of events are detected during the trend report cycle, in countries (EEA countries, TR or 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[15] 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[16]) 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 the 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.

[15] Only one choice is possible in the "Type of device scope" of MTR form.
[16] For the contact lenses category, the UDI - DI is replaced by a Master UDI-DI.

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.

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 a separate file in csv format to be uploaded into EUDAMED. If the affected batches are 5 or less, the data could be entered directly in EUDAMED when compiling the MTR form.

For more details, please refer also to the MTR Helptext[17].

**12. Which kind of information can be modified once the initial trend report has been sent?**

When a trend report was already submitted, the type of events which triggered 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 needed, by providing this information through a follow-up or final trend report.

**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[18] 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

[17] Link to the MTR Helptext

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

reported and has itself triggered the reporting obligations laid down in Art 88 MDR or Art 83 IVDR.

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

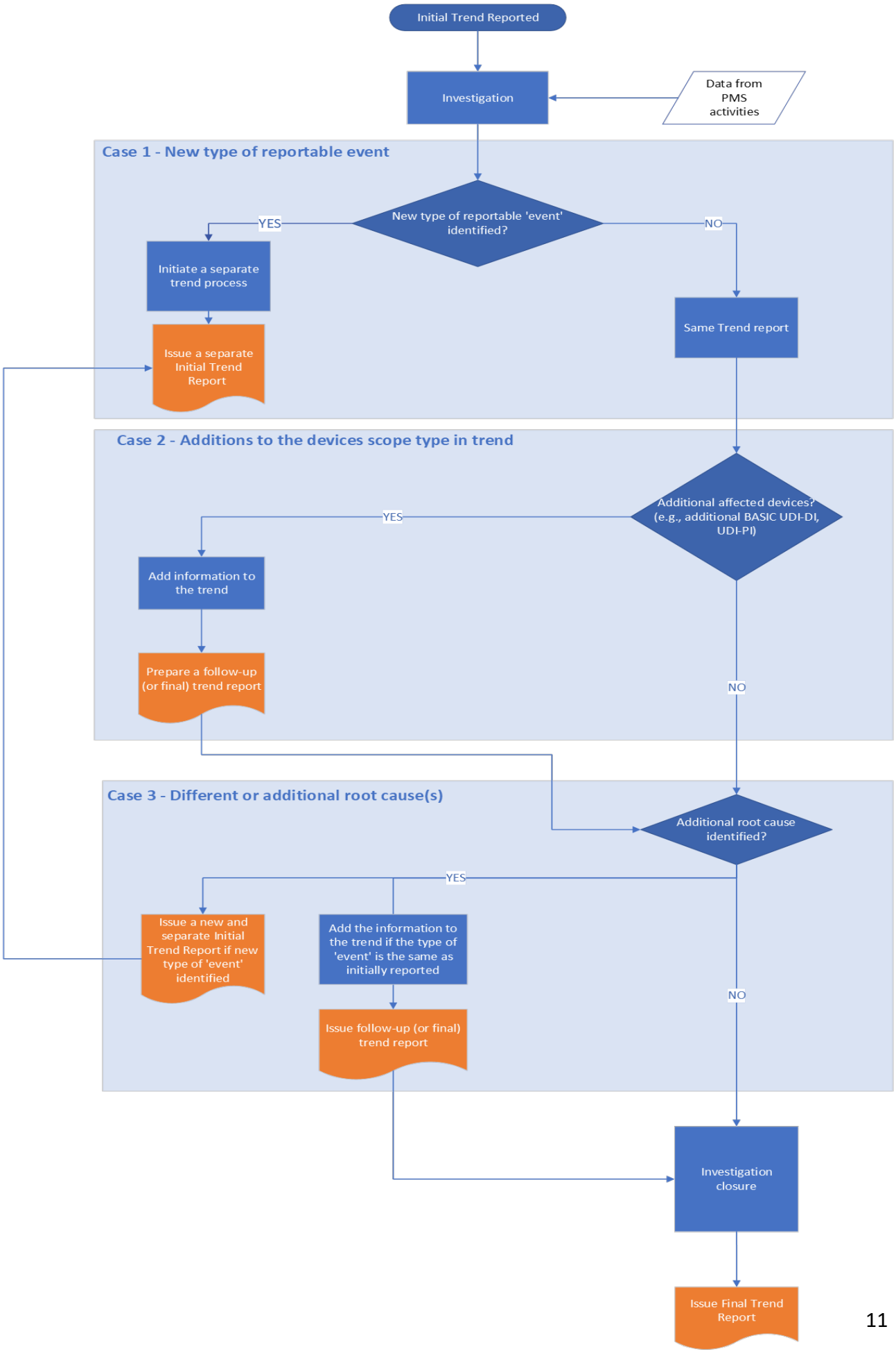
If during the investigation of a trend either i) a manufacturer identifies that the root cause is actually different from what was initially determined or ii) discover an additional root cause(s) to that initially reported, it should add this information and update the current trend report.

Examples:

i. 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.

ii. 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.

Fig 1 – *Information which can be modified once the initial trend report has been sent*


Initial Trend Reported
Investigation
Data from PMS activities
Case 1 - New type of reportable event
New type of reportable 'event' identified?
YES
NO
Initiate a separate trend process
Issue a separate Initial Trend Report
Same Trend report
Case 2 - Additions to the devices scope type in trend
Additional affected devices? (e.g., additional BASIC UDI-DI, UDI-PI)
YES
Add information to the trend
Prepare a follow-up (or final) trend report
NO
Case 3 - Different or additional root cause(s)
Additional root cause identified?
YES
Issue a new and separate Initial Trend Report if new type of 'event' identified
Add the information to the trend if the type of 'event' is the same as initially reported
Issue follow-up (or final) trend report
NO
Investigation closure
Issue Final Trend Report

**13. Can the Manufacturer Trend Report (MTR) form be used before EUDAMED becomes fully functional?**

The submission of a Trend report through electronic system (EUDAMED) referred to Article 92 ( MDR) and Article 87 (IVDR) using the MTR Form 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 CAs of the Member States in which events occurred.

EUDAMED will send a notification of the trend report also to the National Competent Authority (NCA) where the manufacturer, or its authorized representative (AR), has his registered place of business.

In the meantime, until EUDAMED becomes fully functional, the MDR/IVDR Trend report requirements are applicable and alternative administrative technical solutions have to be adopted as per guidance MDCG 2021-1[19] for MDR and MDCG 2022-12[20] for IVDR for submission of the Trend reports to the national competent authority(ies).

**14. Which documents are required when submitting a Trend Report in EUDAMED?**

When the manufacturer issues a Trend Report, he has to draw up 2 documents:

- **Manufacturer Trend Report (MTR) Form.** The data of the MTR form need to be directly entered in EUDAMED including the following information: 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, its investigations, conclusions made and information related to the CAPAs. The trend report document should be uploaded as an attachment into EUDAMED and in a PDF-format. The Trend report document is not mandatory with the initial MTR form, but it is expected with the follow-up and final MTR form.

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

[20] *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)*

The need for two separate documents (MTR Form and trend report document) is related to the reduced amount of information that can be introduced in the Minimum Viable Product (MVP) version of EUDAMED. As mentioned above, the MTR Form (and its related MTR Helptext) will be applicable only when EUDAMED becomes fully functional.

In the meantime, until EUDAMED becomes fully functional, the trend report (document) needs to be submitted at least to the competent authority(ies) (CA) of the Member State(s) where the events occurred.

**15. Can a Trend Report lead to corrective action(s) /preventive action(s)?**

Following the assessment of the trend report data, the manufacturer can issue corrective action(s) including a field safety corrective action or preventive action to reduce or prevent the risk for patients, users or other persons of the device. In this context the manufacturer should initiate an appropriate action (e.g. FSCA, CAPA, update of labeling, training).

The manufacturer should notify a final trend report when the effectiveness of the taken corrective action is confirmed. For the purpose of the final trend report, a taken corrective action can be considered effective when the number of events has lowered below the threshold value and when no further events are registered in new countries (no new country included in the scope of the MTR).

As specified in the Regulations (Annex I MDR 2017/745 and IVDR 2017/746), a manufacturer in its own risk management system should implement all actions to reduce the risk.

If a manufacturer does not implement any action or any measure in order to reduce the risk, he should provide a substantiated justification or a rationale about it to the CA.

If the evaluating CA is not satisfied with the action taken by the manufacturer, it can require additional corrective actions as appropriate, according to Article 88 (2) MDR and Article 83 (2) IVDR.

**16. What types of request can a Competent Authority make after the assessment of a trend report?**

The Competent Authority(ies) (CA), 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 MDR/IVDR 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[21], the requirements defined in the MDR for risk management, PMS and clinical evaluation life cycle processes as defined by the MDR, should also 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 rev.1[22].

## 18. Some examples of cases for which a Trend Report is considered necessary

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

Examples for MDR:

- A trend of expected undesirable side effects causes a risk zone change from low to medium, or an increase from medium to high, within the risk matrix as suggested 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 of the 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 sickness 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 (harm severity: minor) causes a risk management threshold breach and leads to an increase in probability from “remote” to “occasional”.

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

[22] MDCG *2021-13 rev.1 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*

- The change in upper and lower detection limits.
- Significant increased occurrence of the defect in which an analyser dispenses too small amount of test reagent to the reaction due to foaming of the reagent (device defect, an incident) causing to a wrong result from the cholesterol test (hazardous situation). And leading to inappropriate medical treatment which is not serious in nature but may significantly affect to benefit-risk of the assay if occurrence is too frequent.
- The device is claiming a certain % of sensitivity/specificity in the technical documentation but later PMS studies/other PMS data show that the actual % is lower
- The repeatability (the deviation of repeated measures of the same sample under identical conditions) is less good than the technical documentation describes.
- The Limit of Detection (LoD) is higher than the technical documentation describes.