Manufacturer Trend Report Document

Guidance on additional information to be provided together with the MTR

Introduction

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 manufacturers shall report to the Competent authority(ies) any statistically significant increase in the frequency or severity of the non-serious incidents and expected undesirable side effects (MDR),or expected erroneous results (IVDR).

This guidance aims at supporting manufacturers to:

- Identify the information to be provided to the competent authority, in addition to the Manufacturer Trend Report (MTR) form submitted in EUDAMED.

- Clarify the minimum information required for the preparation of the Trend Report document.

The information provided in the trend report document together with the MTR form corresponds to the "Trend Report" referred to in Articles 88 (MDR) and 83 (IVDR). Any relevant information which is not submitted via the MTR form or on EUDAMED VIG module and relevant to explain the trend, should be provided in the trend report document.

Trend Reporting

Trend Reporting consist of the submission of the following two documents:

- Manufacturer Trend Report form (MTR): A standalone document submitted through the national vigilance systems.

- Manufacturer Trend Report document: An additional PDF document (as outlined in this guidance), containing further details that cannot be fully entered into the MTR form.

Submission Process

- Before Eudamed Vigilance module becomes mandatory: Until the Eudamed Post-Market Surveillance and Vigilance (VIG) module becomes mandatory, manufacturers must submit trend reporting documents via national vigilance systems.

- After Eudamed Vigilance module becomes mandatory: Once the Eudamed Post-Market Surveillance and Vigilance (VIG) module becomes mandatory, manufacturers must submit the trend report directly through Eudamed.

Please note that the Trend report document is not mandatory for the initial Trend Report submission with the MTR, but is required for follow up and final submissions.

For clarification on terms and concepts used for trend reporting, please consult the MDCG 2023-3 "*Questions and Answers on vigilance terms as outlined in the Regulation (EU) 2017/745 and Regulation (EU) 2017/746*".

Content of the trend report document

The **minimum information** to be provided in the trend report document are as followed:

1. Description of the devices impacted by the trend.

For all types of devices (including MDR, IVDR, Legacy, Custom Made Devices and old devices), the manufacturer needs to provide in this Trend report document the following information:

- Device(s) name(s): when reporting the group or category of the device, list of device(s) name(s) by the reported device group or category.
- Intended purpose, type of device (standalone device, device system, device part of the procedure pack, used with accessories, etc.) by device.
- Patient characteristic or user population.
- The first certification date in the European Economic Area (EEA) + Turkey (TR) + Northern Ireland (XI) and the first date placed on the market or put into service in the world.
- Number of devices placed on the market by Member State[1] (table 1)

In cases the device is not commercialized anymore but the trend reporting is required, it is recommended, when information is available, to indicate the number of devices in use (e.g. Implantable devices) since the device is placed on the market (at least the three last years). If this is not possible, please indicate which data were used for the identification of the trend in accordance with the PMS plan.

Table 1. Devices placed on the market by member state[1] and rest of the world.

	Devices placed on the market in the calendar year the trend was detected	**Devices placed on the market during the last 3 calendar* years****
AT		
BE		
BG		
etc.		
Total in EEA+TR+XI		
Rest of the world		
Total		

*3-year data, the first year is the calendar year before the trend was detected

** Where relevant, it may cover a period of time longer than 3 years (ex of implants)

[1] A country of the EEA+TR+XI

The number or cumulative number of devices on the market is based on:

	Devices placed on the market or put into service
	Units distributed within each time period
	Number of tests performed
	Number of episodes of use (for reusable devices)
	Active installed base
	Units distributed from the date of declaration of conformity/CE mark approval to the end date of each time period
	Number of devices implanted
	Other -describe

2. Description of the trend

In this section provide additional information about the detected trend compared to the information provided in the MTR form.

- Describe the method used to identify the trend, including a justification for the length of the trending period based on the Post market surveillance plan (PMSP).

- Type of the reported trend: if the detected trend was identified and reported previously as a separate trend or if it is newly detected.

- If relevant, (e.g., for implants) trending might also be initiated for clinical findings or other variables such as age, weight and gender of patients, age of the device) and others. When necessary, additional details not provided in the MTR form, about the consequences on the safety or the therapy of the patients or other users can be communicated.

- Provide the number of events[2] and number of devices on the market by country where the event occurred and rest of the world (table 2).
    - The target is to describe the evolution of the reported trend in time. Provide the baseline data before the trend was detected, a "picture" of the trend at the moment of its detection and the changes on the trend after the corrective action(s) has been initiated.
    - The device trending period is defined in the Post Market Surveillance Plan (PMSP) and device technical documentation.

- Indicate whether the number of devices is cumulative or not. The selection should be based on the device type.

[2] The term "event" covers incidents, expected undesirable side effects (MD) and expected erroneous results (IVD)

Table 2. Number of events[2] and total number of devices (including MDR, IVDR, Legacy and old devices) placed on the market in countries where events have taken place by the trending period

	Trending period (N-2) *		Trending period (N-1)**		Trending period N***		Trending period (N+1)****		Trending period (N+2)*****	
Start date										
End date										
	Number of events	**Number of devices on market**	**Number of events**	**Number of devices on market**	**Number of events**	**Number of devices on market**	**Number of events**	**Number of devices on market**	**Number of events**	**Number of devices on market**
Country 1										
Country 2										
Country 3										
Total in *EEA+TR+XI*										
Rest of the world										
Total										

*Two trending periods before the **trend was detected**

** One trending period before the **trend was detected**

*** The trending period when the **trend was detected**

****The following trending period after the trend was detected in cases the final report is not completed

*****Following the previous trending period in cases the final report is not completed

3. Manufacturer's analysis about the reportable trend

❖ **Initial report**

- Preliminary results and conclusions of manufacturer's investigation, including the description of the significant impact on the benefit-risk analysis and which have led or may lead to unacceptable risks.
- Indicate whether the detected trend been found for a specific part/component of the device, category of the devices or for a specific group of patients/users.
  - Describe the further investigations the manufacturer intends to conduct to reach final conclusions.

❖ **Follow-up and final report**

- Describe the investigations conducted and the conclusions reached, and the finalized the actions to be taken
- Use IMDRF codes[3] complemented by a description of the investigation process with the highest reasonable level of detail (refer to table 3)

Table 3. Description of the type of investigation, findings and conclusion by the IMDRF Adverse Event codes

Coding with IMDRF terms	Choice 1 (most relevant)	Choice 2	Choice 3
IMDRF Cause investigation: Type of investigation (Annex B)			
IMDRF Cause investigation: Investigation findings (Annex C)			
IMDRF Cause investigation: Investigation conclusion (Annex D)			

- If the root cause of the trend was not clearly identified after investigation, an assessment of the impact of the trend on the safety and performance of the device need to be provided.
- Describe the assessment of the benefit risk analysis and the estimated impact on the safety and the performance of the affected devices.
- Description of the updates made to the risk analysis including the changes to the thresholds as a result of the trend investigation.
- Justification whether the risk analysis is not updated.

4. Corrective actions

In this section describe the corrective actions, preventive actions, or other measures (if any).

For each corrective or preventive action (CAPA) or other measure, provide the following information:

- **Details of the actions to be taken**: Include the type of action, manufacturer's reference number (if available), issuing date, description of the actions taken, time schedule for the implementation of the different actions, follow-up of the actions taken and the foreseen date for the conclusion of the actions adopted.

[3] 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.

- **Effectiveness check:** Outline measures and timelines to verify whether that corrective action or other measure have effectively addressed the issue. This information should be updated in subsequent follow-up reports and included in the final trend report.

- **Ongoing monitoring:** Specify how the effectiveness of the implemented corrective actions will be monitored over time, including any post-implementation follow-up activities.If the planned schedule for completing the actions is not met, provide a justification and specify the revised timeline for completion.

- **Any additional risk-reduction measures:** Describe any additional corrections implemented to mitigate risks for patients or users, such as updates to labels or Instructions for Use (IFUs) and any training conducted for users.

- **Field safety Corrective Actions (FSCAs)**: If an FSCA is initiated due to identified unacceptable risks, the FSCA process should then be initiated as a separate formal process. The trend report should cross-reference the FSCA report number provided by the competent authorities in EUDAMED or national vigilance databases... An outline of the FSCA actions should be included in the trend report document submitted with the final trend report.

- **Justification for no action**: If no corrective actions, preventive actions, or other measures are taken, provide a justification explaining why no actions are necessary. This should include an assessment of how the risks remain acceptable and why further measures are not required.