**PSUR Template Intro**

This template includes the Annexes from MDCG 2022-21 on Periodic Safety Update Reports (PSURs).

* The guidance document can be found: [**HERE**](https://health.ec.europa.eu/latest-updates/mdcg-2022-21-guidance-periodic-safety-update-report-psur-according-regulation-eu-2017745-december-2022-12-16_en)
* The MDR can be found: [**HERE**](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20200424#tocId141)
* The IMDRF Terminologies for Categorized Adverse Event Reporting (AER) can be found: [**HERE**](https://www.imdrf.org/documents/terminologies-categorized-adverse-event-reporting-aer-terms-terminology-and-codes)
* All MDCG 2022-21 Annexes in word format available: [**HERE**](https://casusconsulting.com/tools-and-templates/)

No text from MDCG 2022-21 was changed. It has simply been moved from PDF to Word and formatted for easier use. However, Casus Consulting has provided some additional context, which is highlighted in blue for transparency.

**Template Instructions:**

1. All text under the section titles should be reviewed and then replaced with your information.
2. Delete the blue highlighting from the final document.

**PSUR Sections:**

1. Cover Page & Table of Contents
2. Executive Summary
3. Description of the devices covered by the PSUR and their intended uses (Article 86.1)
4. Volume of Sales (Article 86.1)
5. Size and other characteristics of the population using the device (Article 86.1)
6. Post-Market Surveillance: Vigilance and CAPA information
7. Post-Market Surveillance: Information including general Post-Market Clinical Follow-up (PMCF) Information (Annex III and Annex XIV, Part B, 6.2(a) and (f) MDR)
8. Specific Post-Market Clinical Follow-up (PMCF) Information (Article 86, MDR Annex XIV, Part B, 6.2(b))
9. Summary of Findings and Conclusions of the PSUR

The template below provides details on how to populate each section.

We recommend reading MDCG 2022-21 Annex III, on how data should be presented. This is available as a separate document in the PSUR template section of our website. However, it is also pasted at the end of this document for ease.

**ANNEX I: Template for the PSUR**

(This is the Template intro text from MDCG 2022-21)

The PSUR should be generated as a stand-alone document that can be assessed independently from the supporting documentation.

The PSUR should provide a general overview of all post-market surveillance activities and the data collected and analyzed based on the PMS plan for the device. Therefore, the aim of the PSUR is not to duplicate all data and reports generated by the PMS Plan but instead to summarize all results and conclusions.

The manufacturer should specify the relevant information and sections of the different reports and provide a summary of the data collected, their assessment and conclusion as well as any actions taken when appropriate. If a manufacturer decides that specific data sets are not used or deemed to be not required, the manufacturer should duly justify the absence of the data sets not included in the relevant sections of the PSUR.

It is recommended to add an executive summary in particular as regards the main relevant information related to benefits and risks and to the changes in the acceptability of the benefit-risk profile.

**Section 1. PSUR cover page**

The PSUR cover page includes the relevant data to allow distinguishing between the various PSUR updates.

For those PSURs submitted to EUDAMED, the PSUR form (EUDAMED Web form, see Annex V) can be considered as a cover page. Until EUDAMED is functional, PSURs should be provided to your Notified Body in the manner they request. For more information, please read: [How do I provide the PSUR until EDUAMED is functional?](https://casusconsulting.com/mdcg-2022-21-psur-periodic-safety-report/#8)

A Table of Contents should also be present for all PSURs.

The cover page should at least include the following information:

* Manufacturer information
* Medical device(s) covered by the PSUR
* Notified body name and organization number;
* PSUR reference number assigned by the manufacturer\*;
* Version number of the PSUR;
* The data collection period covered by the PSUR;
* Table of contents.

\*This asterisk is in MDCG 2022-21 (page 21 of 40); however, there is no corresponding footnote. However, provided here are the definitions for PSUR reference number and version number from the guidance:

**PSUR reference number:** The PSUR reference number is the unique identifier that the manufacturer must assign to a PSUR. It should remain the same during the whole PSUR lifetime.

**PSUR version number:** an incremental number attributed to each update(s) of the PSUR which has been made available by a manufacturer and allowing to identify and trace them.

The **Annex V EUDAMED Web Form** is provided below for ease. Annex V is also available as a separate template in the PSUR Template section of our website

**ANNEX V: PSUR Web Form for Manufacturer**

(This is the Annex V intro text and PSUR Web Form from MDCG 2022-21)

* The PSUR Web form for manufacturer contains all the relevant administrative data necessary for the registration of the PSUR in EUDAMED: certain fields are automatically populated by EUDAMED e.g. Notified Body, Manufacturer, Single Registration Number (SRN) while other data need to be filled up by the manufacturer via EUDAMED Web interface.
* When EUDAMED becomes fully functional, the manufacturer should upload the PSUR in PDF format into EUDAMED for MDR class III devices or implantable devices and provide the information\* of the PSUR Web form directly through the EUDAMED Web interface.
* The manufacturer should create a PSUR reference number which should remain the same for the PSUR updates. In case of grouping of devices within one PSUR, the PSUR reference number relates to the leading device.
* When registering a PSUR in EUDAMED, the manufacturer should capture the Basic UDI-DIs of all the Class III or implantable devices belonging to the group via the web interface.
* For PSURs which are not required in EUDAMED, the PSUR Web form is not applicable. Instead, the manufacturer should fill in the information required in the PSUR cover page (see Annex I of this guidance).

**PSUR Web Form\* for Manufacturer**

|  |  |
| --- | --- |
| 1 | Manufacturer information  |
| A | Manufacturer SRN  |
| B | Manufacturer organisation name  |
| C | Contact’s first name  | D | Contact’s last name  |
| E | Email | F | Phone |
| G | Country |  |  |
| H | Street | I | Street number  |
| J | Address complement  | K | PO Box  |
| L | City name  | M | Postal code  |

|  |  |
| --- | --- |
| 2 | Authorised representative information |
| A | SRN  |
| B | Authorised representative organisation name  |
| C | Contact’s first name | D | Contact’s last name  |
| E | Email | F | Phone |
| G | Country |
| H | Street | I | Street number  |
| J | Address complement  | K | PO Box  |
| L | City name  | M | Postal code  |

|  |  |
| --- | --- |
| 3 | Corresponding Competent Authority  |
| A | Name of National Competent Authority (NCA)  |
| B | EUDAMED number of NCA  |

|  |  |
| --- | --- |
| 4 | Notified Body  |
| A | NB organisation name and number  |
| B | Email |

|  |  |
| --- | --- |
| 5 | Medical Device Information  |
| A | Leading device Basic UDI-DI  |
| B | Other Basic UDI-DI(s) / Eudamed DI(s)-  |
| C | For each Basic UDI-DI / Eudamed DI, NB number and Certificate ID(s) |

|  |  |
| --- | --- |
| 6 | PSUR Submission in Eudamed  |
| A | Date of submissionYYYY MM DD  | Scheduled date YYYY MM DD  | Timeliness Days  |
| B | PSUR Reference number |
| C | Data collection periodYYYY MM DD - YYYY MM DD |
| D | Version Number  |

|  |  |
| --- | --- |
| 7 | Upload the PSUR document  |

\* Only the fields and content of the PSUR Web form need to be considered and not its structure which may be different in the EUDAMED web interface.

**Section 2. Executive summary**

When an executive summary is produced, it should provide a brief overview of the PSUR content and an overall conclusion in relation to the benefit-risk determination.

It should include the following information:

* A brief description and status of actions taken by the manufacturer based on the previous PSUR;
* A brief description and status of actions taken by the Notified Body as part of the review of the previous PSUR;
* In case the data collection period is changed by the manufacturer, a justification should be provided, and a statement should be provided whether the change affects the comparability of the results gained;
* Once the conclusions of the PSUR have been completed, the main results of the current PSUR should include a clear and bold statement declaring whether the benefit-risk profile has been impacted, negatively or positively or remains unchanged, based on the information reported within the current PSUR. The statement could be a simple expression, for example:
	+ “*Based on the analysis of the collected data, it is concluded that the benefit-risk profile of the device(s) has not been (or has been) adversely impacted / remains unchanged*”.

**Section 3. Description of the devices covered by the PSUR and their intended uses (Article 86.1)**

This section is intended to provide an overview of the devices covered by the PSUR and the possible changes to its scope. The added and removed devices should be clearly identified.

The following information should be included for the devices covered by the PSUR:

* Device Classification (risk class of device) in accordance with the applicable classification rules.
* Date from one of the following: first declaration of conformity, first EC / EU Certificate issued, first date device CE-marked, first placed on the market, first put into service, if software, date first made available.
* Status of the device(s): on the market, no longer placed on the market, recalled, field safety corrective action initiated.
* The intended purpose of the device(s) as per the Instructions for Use according to Annex I, Chapter III, 23.4(b) MDR, any indications, contra-indications, and target populations.
* **For MDR Devices**
	+ The information shall be broken down by the Basic UDI-DI(s) and explain any device changes within each Basic UDI-DI compared to the previous PSUR to comprehend possible changes in results compared to the previous PSURs.
	+ Provide device trade name(s) associated to the corresponding Basic DI(s) and the European Medical Device Nomenclature (EMDN).
* **For Legacy Devices**
	+ The information shall be broken down by device group/family of devices.
	+ Provide device trade name(s) (this includes all trade names the device may have on the market in different Member States) and European Medical device Nomenclature (EMDN).
* **For Custom-Made Devices (MDR**)
	+ Provide the required information by device group.

**Grouping of the Devices**

Information regarding the grouping of devices are provided in section 4 of this guidance.

* The manufacturer should justify the grouping of the devices in one PSUR.
* The justification could be based on the benefits to report multiple devices in one PSUR or alternatively the disadvantages to report each device in separate PSURs.
* In case the group of devices is changed, a justification for the change should be provided. The manufacturer should also provide the PSUR reference number of the PSUR where the data of the removed device(s) are reported.
* The manufacturer should define the “leading device” according to which the PSUR schedule is determined.
* The PSUR reference number is attached to the “leading device” and should remain unchanged for the PSUR updates, provided the “leading device” within the grouped devices has remained the same.

MDCG 2022-21 definition

**Leading Device**: The “leading device” in a group of devices covered by the same PSUR corresponds to the highest risk class device. In the case when there are several devices with the same risk classification, the manufacturer should assign a leading device.

**Section 4. Volume of Sales (Article 86.1)**

* The manufacturer should consider all the devices placed on the market. This could be volumes of sales, units shipped, or units implanted or another suitable indicator.
	+ Whichever method is used should be consistent throughout the PSUR in all areas to allow for a comparison of data.
	+ Provide accurate information the number of devices sold. The data should be
* Provide further information on the volume of sales in respect to the various sizes, models and configurations of the device as deemed necessary.
* Indicate to what criteria the number of devices on the market is provided:
	+ Devices placed on the market or put into service;
	+ Units distributed within each time period;
	+ Number of episodes of use (for reusable devices);
	+ Active installed base;
	+ Units distributed from the date of declaration of conformity or EC/EU mark approval to the end date of each time period;
	+ Number of devices implanted;
	+ Other – description/rational should be provided.

Annex I references the tables provided in Annex II throughout. Therefore, the applicable tables have been inserted into this Template for ease. Annex II is also available as a separate template in the PSUR Template section of our website

**Table 1. Volume of sales\* by region over time**

**(Table Source: Annex II, Table 1)**

|  |
| --- |
| Basic UDI-DI/ Legacy device name or model |
|  | Total Number of devices  | Reporting Day+ preceding 12 months (N)  | N – 12 months (N2)  | N2-12 months (N3) |  N3-12 months (N4)  |
| EEA+TR + XI\*\* |  |  |  |  |  |
| Worldwide |  |  |  |  |  |

\*Indicate according to which criteria the number of devices on the market is provided (Annex II, 4.1)

 \*\*EEA: European Economic Area, TR: Turkey, XI: Northern Ireland.

**Section 5. Size and other characteristics of the population using the device (Article 86.1)**

* Evaluate how many patients have been exposed to the device and the characteristics of the exposed patient group(s).
* Estimate the number of patients exposed, as the sales numbers alone do not necessarily reflect the number of uses of the device (usage frequency). There are different scenarios as:
	+ Active devices may have a lifetime of several years with multiple uses each day, resulting in high number of patients exposed to the device (e.g. CTs).
	+ In case of implants, multiple devices may be used in one patient, e.g. several bone screws in one surgery.
	+ For other devices, the sales numbers directly correlate with the patient number exposed to the device.
* Describe the usage of the device in different patient populations and when available compare it to the expected usage and identify the possible over-represented or under-represented patient groups if clinically relevant and known by the manufacturer.
* When possible, consideration should be given to patient demographic aspects.
* When applicable, evaluate the effect of the detected changes to findings obtained previously and in the current PSUR.

**Table 2. Estimated size of the population using the device\* over time**

**(Table Source: Annex II, Table 2)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Estimated size of population using the device Reporting Day+ preceding 12 months (N) | Estimated size of population using the device N – 12 months (N2)  | Estimated size of population using the device N2-12 months (N3)  | Estimated size of population using the device N3-12 months (N4) |
| EEA+TR + XI\*\* |  |  |  |  |
| Worldwide |  |  |  |  |

\*When clinically relevant and known by the manufacturer

\*\*EEA: European Economic Area, TR: Turkey, XI: Northern Ireland.

**Table 3. Characteristics of the population using the device\* over time**

**(Table Source: Annex II, Table 3)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Characteristic X of population using the device Reporting Day+ preceding 12 months (N) | Characteristic X of population using the device N – 12 months (N2)  | Characteristic X of population using the device N2-12 months (N3)  | Characteristic X of population using the device N3-12 months (N4)  |
| EEA+TR + XI\*\* |  |  |  |  |
| Worldwide |  |  |  |  |

\*Characteristics of the population using the device is defined by the manufacture based on the usage of device

\*\*EEA: European Economic Area, TR: Turkey, XI: Northern Ireland.

**Section 6. Post-Market Surveillance: Vigilance and CAPA information**

Background information should be gathered prior to the current PSUR and may include, for example, the achieved safety and performance of the device, information related to intended benefits achieved or not and description of new risks or emerging trends reported in earlier PSURs.

Vigilance data consist of information concerning serious incidents, field safety corrective actions (FSCAs) and trend reports. The data could be presented in tables, figures and/or in text format.

The aim of the data presentation is to provide an accurate summary and appraisal of the Vigilance data (Article 87 and Article 88 MDR) and CAPA data (Article 83(4) and Article 86 MDR) for the reported data collection period and to compare with the same types of data from the previous PSURs.

The data should be presented by the device (Basic UDI-DI), device group (CMD) or device group/family level (legacy devices).

When justified, the data can be presented for combinations of devices, for example, a device and its accessory.

1. **Information concerning Serious Incidents (Article 87, Annex III MDR)**
* The aim is to present the serious incidents and their impact on the overall device safety. This section should characterize the data from at least three different perspectives: the device problems, the root cause and the health effects on the person(s) affected.
	+ In addition to the data, provide a summary text regarding any new types of serious incidents which have occurred since the last report.
* Data regarding serious incidents should be reported using the IMDRF Adverse Event Terminology (AET) (link to [IMDRF](https://www.imdrf.org/documents/terminologies-categorized-adverse-event-reporting-aer-terms-terminology-and-codes) website), when available. With regard to the historical data, the usage of the IMDRF Adverse Event Terminology is not required.
	+ The usages of the Level 2 terms/codes are considered sufficient to enable the grouping of the serious incidents;
	+ Report both the codes and the terms.
* When applicable report both absolute figures and rate of the serious incidents and split the data by region (EEA+TR+XI) and worldwide. EEA = European Economic Area / TR = Turkey / XI = Northern Ireland
* Examples of the data presentation are shared in Annex II of this guidance.
* The most frequent medical device problems by IMDRF Adverse Event Terminology Annex A – “Medical Device Problem”, by year to year- (see Annex II, Table 4).
* The most common investigation findings as part of the completed “cause investigation” of the serious incidents by IMDRF Adverse Event Terminology Annex C – “Investigation Findings”, (see Annex II, Table 5).
* The health impacts on the person affected as a consequence of the medical device serious incident by IMDRF Adverse Event Terminology Annex F – “Health Impact”, including the term and code. It could also be used for the 4-year summary data (starting as of the device MDR certification date or the MDR date of application for legacy devices) and split the data by the IMDRF Adverse Event Terminology Annex D – “Investigation Conclusion” (including term and code).
	+ Use only the most relevant investigation conclusion terms/codes which are related to the detected health impacts.
	+ Report the most common health impacts as well as any cases resulting into death, regardless if they are included in the most common health impacts.
	+ In addition, split the data by region (see Annex II, Table 6).
1. **Information from Trend Reporting (Article 88, Annex III MDR, non-serious incidents and expected undesirable side effects)**

The data related to the trend reports will be detailed after the adoption of the MDCG guidance on trend reporting.

1. **Information from Field Safety Corrective Actions (FSCA) (Article 87, Annex II MDR)**
* Provide a summary of the FSCAs for the period of the PSUR and compare with the information from the previous PSURs.
* The summary should include the following information\*:
	+ types of actions.
	+ issuing date,
	+ scope of the FSCA,
	+ status of the FSCA at the time of the PSUR,
	+ manufacturer’s reference number,
	+ a brief description of the reason for action and description of action and impacted regions.

An example of the data presentation is presented in Annex II of this guidance (table 7).

\*When EUDAMED will become fully functional, the information that need to be collected may change and the information presented in this section should be updated accordingly.

1. **Preventive and / or Corrective Actions (CAPA) (Article 83.4 and Article 86 MDR)**
* Provide a list of all preventive and / or corrective actions (CAPA) according to Article 83(4) and to Article 86.
* The following information should be provided for each CAPA:
	+ the type of action,
	+ initiation date,
	+ scope of the CAPA,
	+ status of the action,
	+ manufacturer’s reference number,
	+ CAPA description,
	+ the root cause (internal codes with the explanation, IMDRF terms/codes or free text),
	+ effectiveness of the CAPA

An example of the data presentation is presented in Annex II of this guidance (table 8).

**Table 4. Total number (N) and rate (%)\*of the serious incidents by IMDRF Adverse Event Terminology (AET) Annex A – Medical Device Problem by time and region over time**

(Table Source: Annex II, Table 4 /Link to IMDRF Annexes available: [here](https://www.imdrf.org/documents/terminologies-categorized-adverse-event-reporting-aer-terms-terminology-and-codes))

|  |
| --- |
| Basic UDI-DI/Legacy Device name or model |
| IMDRF Adverse Event Medical Device Problem code (Annex A) and term by region  | Reporting Day+ preceding 12 months (N) | N – 12 months (N2) |  N2-12 (N3) months  | N3-12 (N4) months  |
| N | % | N | % | N | % | N | % |
| EEA+TR + XI\*\* |  |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |  |
| EEA+TR + XI\*\* |  |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |  |

\*The denominator is compatible to the number of devices in table 1 or based on manufacturer’s reasoning e.g. reusable instruments

\*\*EEA: European Economic Area, TR: Turkey, XI: Northern Ireland.

**Table 5. Total number (N) and rate (%)\* and of the serious incidents by IMDRF AET Annex C - Cause Investigation-Investigation Findings by time and region over time**

(Table Source: Annex II, Table 5)

|  |
| --- |
| Basic UDI-DI/Legacy Device name or model |
| IMDRF Adverse Event Investigation Findings (Annex C) code and term by region  | Reporting Day+ preceding 12 months (N) | N – 12 months (N2) | N2-12 months (N3) | N3-12 months (N4)  |
| N | % | N | % | N | % | N | % |
| EEA+TR +XI\*\* |  |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |  |
| EEA+TR + XI\*\* |  |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |  |

\* The denominator is compatible to the number of devices in table 1

\*\*EEA: European Economic Area, TR: Turkey, XI: Northern Ireland.

**Table 6. IMDRF AET Annex F - Health Effects-Health Impact code of the serious incidents by IMDRF Adverse Event Terminology Annex D - Investigation Conclusion in last 4 years**

(Table Source: Annex II, Table 6)

|  |
| --- |
| BASIC UDI-DI/Legacy Device name or model |
| IMDRF Adverse Event Health Impact (Annex F) code and term by region  | Number of serious incidents  | Investigation conclusion code+ term1 %  | Investigation conclusion code+ term2 %  | Investigation conclusion code + term3 %  | Investigation conclusion code + term4 %  |
| EEA+TR +XI\* |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |
| EEA+TR + XI\* |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |

\*EEA: European Economic Area, TR: Turkey, XI: Northern Ireland.

**Table 7. FSCA initiated in current reporting period and open FSCAs\***

(Table Source: Annex II, Table 7)

|  |
| --- |
| BASIC UDI-DI/Legacy Device name or model |
| Type of action  | Issuing date  | Scope of the FSCA  | Status of the FSCA\*\* | Manufacturer Reference number  | Rationale and description of action taken | Impacted regions  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

\*Will be further developed when the new FSCA form is in use

\*\*Follow-up, final at the time the data collection time ended

**Table 8. CAPA initiated in current reporting period and open CAPA**

(Table Source: Annex II, Table 8)

|  |
| --- |
| BASIC UDI-DI/Legacy Device name or model |
| Type of action  | Initiation Date | Scope of the CAPA | Status of the CAPA | Manufacturer Reference number | CAPA description | Root cause\*  | Effectiveness of the CAPA if closed\*\*  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

\*Internal codes with the explanation, IMDRF codes or free text

\*\*If CAPA is still open then this is not applicable, if CAPA is closed comment on whether it is resolved, not resolved or comment if additional CAPA has been opened.

**Section 7. Post-Market Surveillance: information including general Post-Market Clinical Follow-up (PMCF) information (Annex III and Annex XIV, Part B, 6.2(a) and (f) MDR)**

The data that should be reported in this section consist of other PMS datasets not referred to above and are generated by general methods and procedures of PMCF (Annexes III, Annex XIV Part B, 6.2 (a) and (f) MDR).

The sections below should be completed in alignment with the PMS and PMCF plans.

A list of collected data from other sources of clinical data in the post-market phase should be provided.

Safety and performance data generated from these activities should be used also for comparison to other similar devices with the same intended purpose.

1. **Feedbacks and complaints from users, distributors and importers**
* All feedback from users, distributors, and importers and complaints not reported in the Vigilance section above should be considered in this section. The most common complaints should be presented within this section of the PSUR with the following considerations:
	+ Grouping of complaints by [IMDRF](https://www.imdrf.org/documents/terminologies-categorized-adverse-event-reporting-aer-terms-terminology-and-codes) Adverse Event Terminology Annex A – “Medical Device Problem” (including the term and code) or internal event codes including term;
	+ Occurrence rate (including reference chosen);
	+ Justification for inclusion of these groups of complaints and exclusion of those not presented;
	+ Information whether the presented complaints have led to initiation of preventive and / or corrective actions (CAPA).
1. **Scientific Literature Review of relevant specialist or technical literature**
* For detailed information about literature searches conducted and results generated, the manufacturer may refer to the technical documentation.
1. **Public Databases and /or Registry Data**
* Provide a list of all registries reviewed including the following information: the name or registry reference, type of registry (Prospective or Retrospective data collection);
* Provide a list of findings in comparison to the devices with same intended use and justify any identified differences.
	+ Provide information about any new risks identified from this data set.
1. **Publicly Available Information about Similar Medical Devices**
* Additional publicly available information may include information gathered from other manufacturers of similar medical devices, (e.g. results of a manufacturer’s specific PMCF study made publicly available in the manufacturer’s Summary of Safety and Clinical Performance (SSCP), Cochrane Library or other libraries);
* The type and location of this information should be provided, and when possible a comparison of the devices with same intended purpose should be evaluated with any possible differences in safety and performance reported.
1. **Other Data Sources**
* The other used data sources could be for example real-world data from electronic health records and digital health-monitoring devices;
* Provide a list of the used data sources and findings with specific reference to safety and performance of the device.

**Section 8. Specific Post-Market Clinical Follow-up (PMCF) Information (Article 86, MDR Annex XIV, Part B, 6.2(b))**

This section should include a summary of the findings generated from the analysis of specific PMCF activities performed by the manufacturer as defined in Annex XIV, Part B, 6.2(b).

This section is not limited to PMCF studies and should include other specific PMCF activities conducted by the manufacturer.

For this section, the manufacturer should refer to the main findings of the PMCF and, when available, to the conclusions documented in the PMCF Evaluation Report to allow for a comprehensive assessment of the specific PMCF activities it has performed.

**Section 9. Summary of Findings and Conclusions of the PSUR**

In this section of the PSUR, the manufacturer should consider the validity of the collected data taking into consideration any deficiencies or bias, and provide a conclusion on the benefits and risks of the device from the gathered data.

In the case when these data have had any impact on the overall benefit-risk determination, this should be described.

The manufacturer should also outline all actions that have been taken as a result of the analysis of data collected since the last PSUR.

1. **Validity of the collected data**
* The manufacturer should identify any limitations to the data that have been collected, this could include for example reduced sales or usage of the device, known bias from feedback obtained or enrolment into a PMCF study.
* The manufacturer should consider whether these limitations impact the ability to formulate meaningful conclusions and whether an impact assessment of the overall benefit-risk profile is still possible.
1. **Overall conclusions from the analysis of the collected data**
* The manufacturer should outline any new or emerging risks identified or when common occurrences of poor performance or claimed benefits have not been achieved within the current reporting period.
	+ When there are new or emerging risks that have been identified, the manufacturer should consider any specific patient groups, device models, accessories used, geographical regions impacted, duration of risk etc.
	+ Specific information should be provided on the seriousness and the full potential clinical impact of these risks.
* The manufacturer may also describe any new benefits that have been identified from the reporting period.
* The manufacturer should formulate evidence-based conclusions to determine whether the benefit-risk profile of the device has changed or not.
* Finally, within the conclusion, the manufacturer should declare whether there has been an adverse impact on the benefit-risk profile of the device or the benefit-risk profile remains unchanged.
1. **Actions taken by the manufacturer**
* The manufacturer should describe any specific actions that have been taken to address any newly identified or emerging risks and occurrences of poor performance.
* The manufacturer should identify all actions initiated during the data collection period as described in Article 83(3).

Annex III is a separate Annex within MDCG 2022-21. It is provided here as it provides relevant guidance on how to assess and present the data in the PSUR. It is also available as a separate document in the PSUR template section of our website.

**ANNEX III: General Information Related to the Presentation and Assessment of the Collected Data by the Manufacturer**

**1. How Data Should be presented**

* Each dataset specified in the PMS Plan should be presented and analysed individually. A summary providing the used datasets including the PMCF data should highlight the limitations related to the collected data.
* Datasets should be split by Basic UDI-DI or model of the device if the Basic UDI-DI does not exist.
* If the group of devices or the devices within a Basic UDI-DI(s) have changed then it is necessary to report separately the data with former and later combination of devices.
* The data should be split by region, when applicable. The used regions are EEA, TR, XI and worldwide. Worldwide data include data from EEA, TR and XI.
* Each PSUR should contain data from the data collection period of this PSUR compared with the same types of data from the previous PSUR periods (see tables 2 to 5 of Annex II of this guidance).
* The first PSUR data collection is not retrospective (does not go before the date of application of the MDR) except when no PSUR has been issued for the corresponding MDD compliant device: it is then recommended that the “historical data” collected before the MDR DoA be considered for the first PSUR of the MDR compliant device (see section 5.2.2.1).
* Data should be reported by year to year
	+ Class III and Class IIb: Reporting Day+ preceding 12 months (N); N – 12 months (N2); N2-12 months (N3); N3-12 months (N4)
	+ Class IIa: Reporting Day+ preceding 24 months (N); N – 24 months (N2)
* The manufacturer should present the data utilizing the International Medical Device Regulators Forum (IMDRF) Adverse Event Terminology when the content of the data facilitates it.
* The following IMDRF Adverse Event Terminologies, terms and codes should at least be utilized:
	+ - Annex A: Medical Device Problem
		- Annex C: Cause Investigation - Investigation Findings
		- Annex D: Cause Investigation - Investigation Conclusion
		- Annex F: Health Effects - Health Impact
	+ Level 2 terms are satisfactory to enable the grouping of cases.
	+ When the Level 2 terms are not available, manufacturers can use Level 1 terms/codes.

**2. How Data Should be assessed by the manufacturer**

* Findings from all datasets should be considered and evaluated by comparing data from the various sources and identifying possible conflicting results.
* The manufacturer should assess the results considering the different patient populations, sizes and models of the device, device combination or variants. When applicable, the manufacturer should evaluate the findings in relation to the state of the art.
* The manufacturer should assess the data in relation to the thresholds concerning known risks and side effects and benefits intended to be gained.
* The manufacturer should identify factors that support or refute previously identified safety and performance concerns as well as evidence relating to new safety signals or emerging risks.
* The manufacturer may also describe any new benefits that have been identified from the reporting period and benefits not achieved as intended.
* When applicable, the IMDRF Terminologies for Categorized Adverse Event Reporting should be used in the analysis.
* If the device is used in a combination of devices, the analysis should identify the role of each device in comparison to other devices or accessories used together.
* The performance and safety of the device should be compared to other devices with the same intended use.