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# Post-Market Surveillance

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PlantVision do not claim to present complete requirements and do not take responsibility for any deviations in this presentation from official legislations, directives, regulations, standards or guidelines.



## Regulatory requirements and guidance documents

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**Regulation**

Medical Device Regulation

Chapter VII, Article 83-86, 88 and Annex III

**Commission Guidance**

MDCG 2020-7 Guidance on PMCF plan template

MDCG 2020-8 Guidance on PMCF evaluation report template

**Planned guidances**

| 4. Post-Market Surveillance and Vigilance (PMSV) | | | | |
|---|---|---|---|---|
| MDR + IVDR | *Guidance on Periodic Safety Update Report requirements* | | Q4 2021 | PSUR for MDR to be later adapted for IVDR |
| MDR + IVDR | *Guidance on Post-Market Surveillance requirements* | MS | Q2 2022 | Work to be coordinated with the Market Surveillance WG |

**Other Guidance**

ISO/TR 20416:2020 Medical devices — Post-market surveillance for manufacturers

MDR, Article 83

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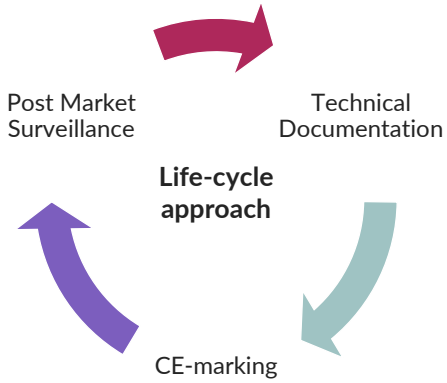
# Post-market surveillance system

”The post-market surveillance system shall be suited to **actively and systematically gathering**, **recording** and **analysing relevant data** on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to **determining, implementing and monitoring any preventive and corrective actions**”




**Part of company QMS**



MDR, Article 83

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# For which devices?

Post-market surveillance;

- is relevant for all medical devices, regardless of risk class
- is relevant for both devices fulfilling MDR **as well as** legacy devices (fulfilling MDD)
- shall be proportionate to the risk class and appropriate for the type of device

MDR, Article 83, Article 13-14

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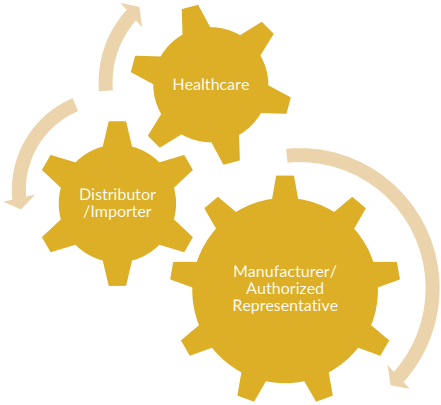
# Who shall collect data?

- Responsibility of the legal manufacturer of a medical device
- Input needed from healthcare and other economic operators such as distributors and importers hence close collaboration is needed.
  - Requirements for economic operators are listed in Article 13 and 14






MDR, Article 83, 85 and 86

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# When to collect data?

Throughout the life-cycle of the device.

Timeline for when to compile reports for post-market surveillance is based on risk class of the device;

- Class I- when necessary
- Class IIa- at least every two years
- Class IIb and class III- at least annually

*Same timelines applicable for legacy devices*

MDR, Article 84-86, Annex III

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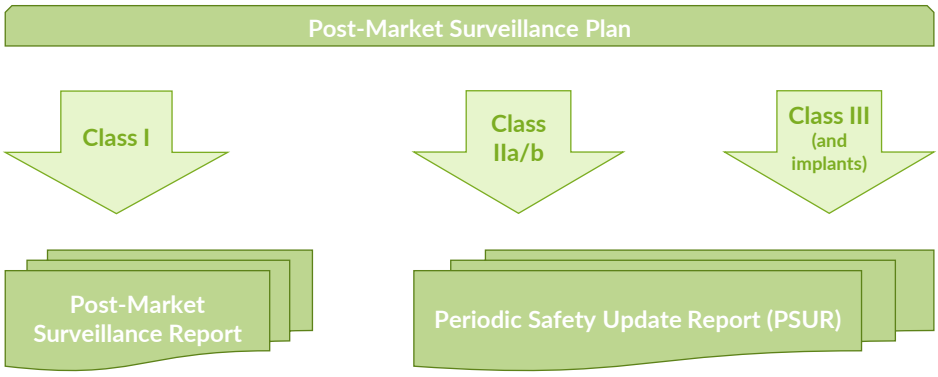
# What documentation is needed?




*For description of content, see MDR and ISO/TR 2416*



MDR, Article 85-86

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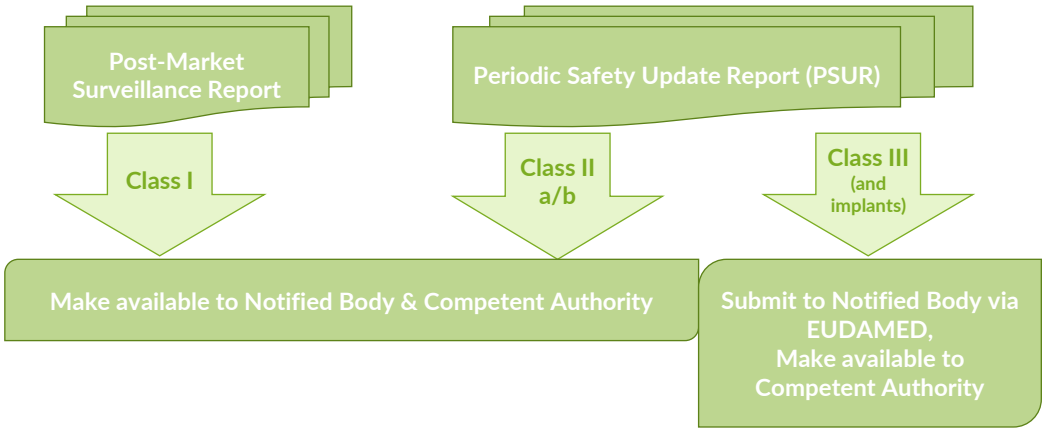
# What documentation to report externally?



MDR, Annex III

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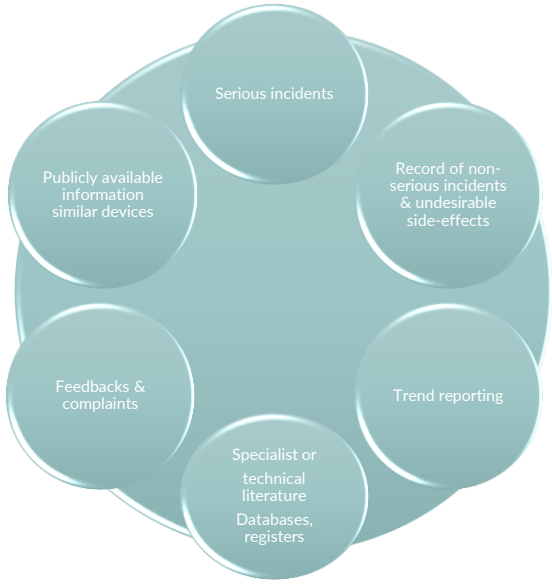
# What to collect?

In particular, the following data shall be addressed

Ensure data is reliable- consider data quality and integrity!

ISO/TR 20416 recommends an appraisal of data






MDR, Annex III and ISO/TR 20416:2020

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# How to collect?

## Proactive

- Collect info via a survey, ask users
- Literature search
- Search in registries, MAUDE database
- Post-market clinical follow-up studies
- Information from regulatory agencies, for example on recalls

## Reactive

- Review of incoming complaint/incidents
- Review of incoming "casual" information/observations by user, healthcare or sales team
- Review of service/maintenance reports
- Review of regulatory compliance notifications

MDR, Annex III and ISO/TR 20416:2020 Medical devices

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## What needs to be defined before collection can start?

| | |
|---|---|
| Objective | What is the objective with the collection?<br>Relate to risk class, device type och device history |
| Data Source | What source to use? |
| Data Collection method | How to collect the data? |
| Data Analysis | How to analyse the data? |



Example on data collection

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| | |
|---|---|
| Objective | Continued safe use |
| Data Source | Incidents (serious and non-serious) |
| Data Collection method | Compile number of incidents per quarter in relation to installed base (or sold units for single use devices) |
| Data Analysis | Quantitative. Perform trend analysis by plotting number of incidents per quarter in relation to installed base.<br>If the data shows an increasing trend, perform analysis on reason to the incident |
| Examples on action | Introduce a change on the device to lower the maximum possible temperature<br>Update risk analysis with the increased probability for a specific risk |

## Example on data collection

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| | |
|---|---|
| Objective | Maintain currency of the manufacturing process |
| Data Source | Test records from final release |
| Data Collection method | Compile the yield for each month |
| Data Analysis | Quantitaive. Perform trend analysis of the yield, by plotting the yield versus month for the last two years. If an increasing trend is found, evaluate the reason for the increase by reviewing the final release test records. |
| Examples on action | Update manufacturing instruction<br>Introduce a new calibration tool with narrow tolerances |



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| | |
|---|---|
| Objective | Continued safe use, long-term safety |
| Data Source | Post-Market Clinical Follow-Up (PMCF) studies |
| Data Collection method | Compile the conclusions from PMCF studies |
| Data Analysis | Qualitative. Summarize the results from the PMCF studies, compare to known clinical benefit, claims, side effects |
| Examples on action | Update benefit-risk profile<br>Update marketing material |

ISO/TR 20416:2020

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# Interface with other processes

- Design and Development
- Risk management
- Clinical evaluation
- Regulatory reporting
- Marketing and sales
- Change management


## Example on data collection

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| | |
|---|---|
| Objective | Monitor continued satisfaction of the users |
| Data Source | Customer surveys |
| Data Collection method | Perform a customer survey on usability. Summarize the result. |
| Data Analysis | Quantitative and qualitative. Plot data where applicable. If possible, identify the reason for low usability.<br>Evaluate all additional information added by the user. |
| Examples on action | Update the GUI to enhance usability |

## Example on data collection

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| | |
|---|---|
| Objective | Improve interaction with other medical devices |
| Data Source | Installation records |
| Data Collection method | Review all installation records, look for unforeseen situations or hazardous conditions |
| Data Analysis | Qualitative. Perform analysis of the records that have any unforeseen situations/hazardous conditions. |
| Examples on action | Update installation instruction |



## Example on data collection

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| | |
|---|---|
| Objective | Continued safe use |
| Data Source | Complaints |
| Data Collection method | Categorize the type of complaints received |
| Data Analysis | Quantitative. Plot the categories using Pareto diagram to find the most common complaints.<br>Ensure there are actions implemented or ongoing for the most common complaints |
| Examples on action | Update the training program for the device<br>Perform a supplier evaluation to further identify the reason to the increasing number of complaints |

## Example on data collection

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| | |
|---|---|
| Objective | Continued safe use |
| Data Source | Adverse event databases |
| Data Collection method | Search for adverse event with the keywords stated in the Clinical Evaluation Plan. |
| Data Analysis | Qualitative. Evaluate each adverse event found. Any new risks relevant for our device? |
| Examples on action | Update risk analysis with the new risk and identify the need for a risk control Measure<br>Increase the frequence of post-market surveillance |



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# Thank you for listening!

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