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MDR Compliant
Post-market Surveillance System

2nd Online Conference BIOCOMPATIBILITY TESTING IN MEDICAL DEVICES
12th of May 2021

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Agenda

- About Pulmotree
- Post – Market Surveillance System
  - MDR Timelines / Survey
  - Regulatory requirements
- Scenario Example (Pulmotree)
  - Proactive PMS & PMCF sources

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A Few Words About Us

About Pulmotree

A creative life-sciences family

We are Pulmotree: a young medical technology start-up from Munich. The headquarters in the creative district of Maxvorstadt is where our hearts beat.

- Based in Munich
- Founded in 2018
- Privately owned (100%)
- Sponsored by state of Bavaria and dormant partnership

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Two Business Units – One Pulmotree

Project Management

Product Development

Change Management

Industrialization

Regulatory Affairs

Quality Management

Strategy / Management

Start-Up Support

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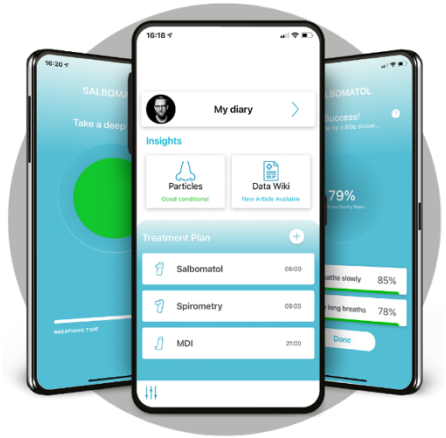

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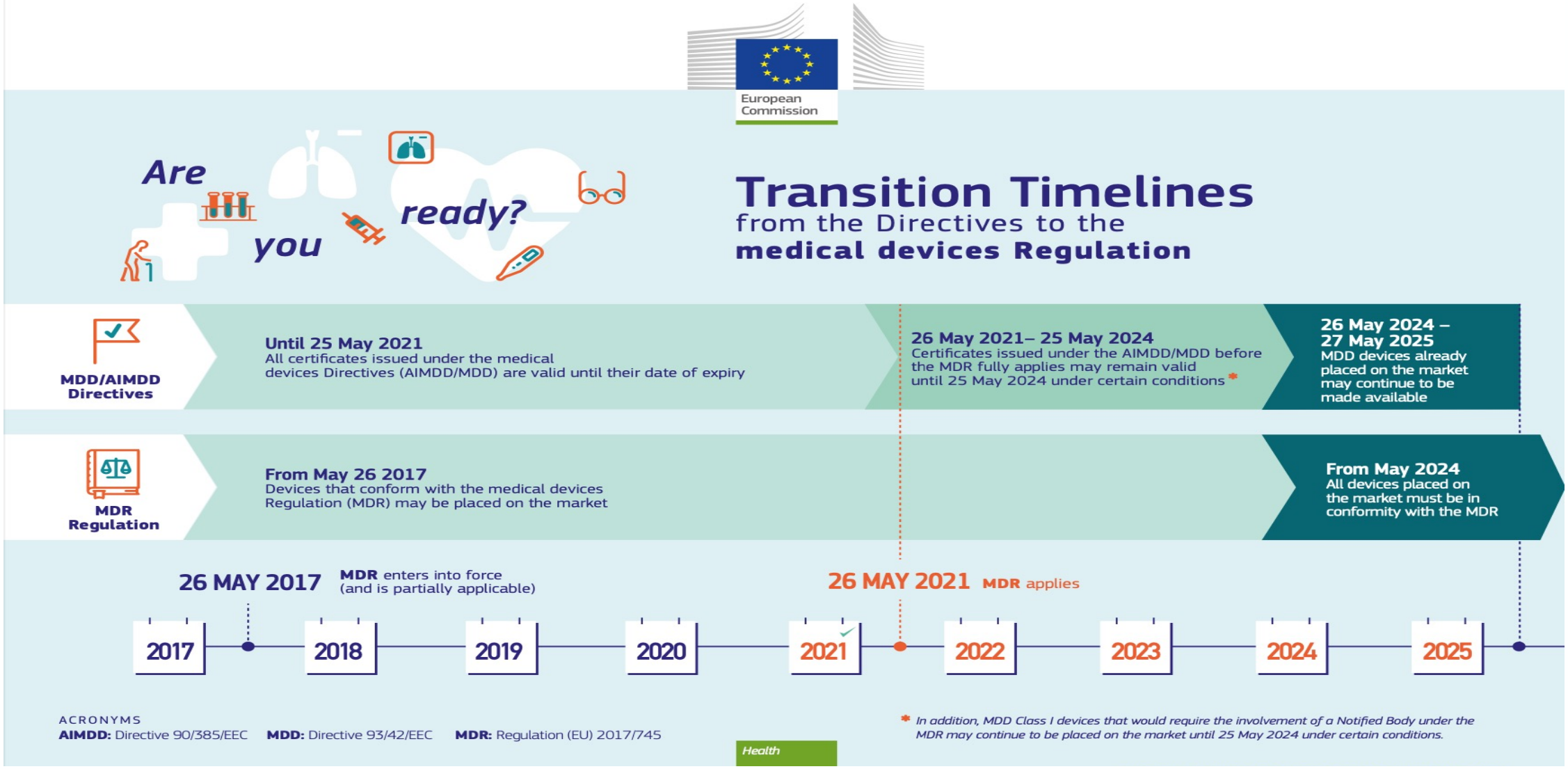
Regulatory Background

MDR (EU) 2017/745

MDR (EU) 2017/745



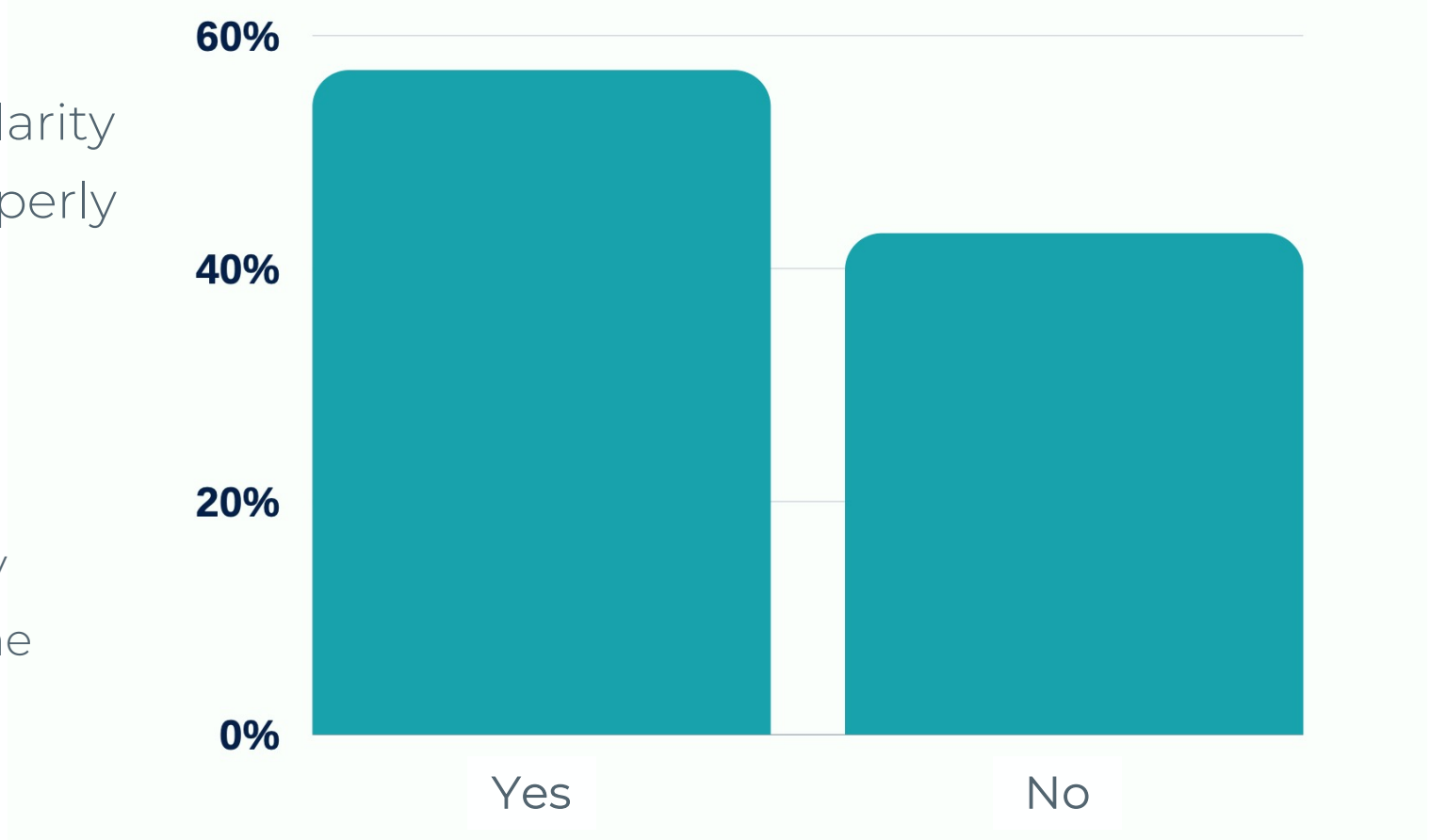
Did MDR Postponement help? (Survey April 2021)

YES

- Appreciated the time for clarity
- Implementation more properly

NO

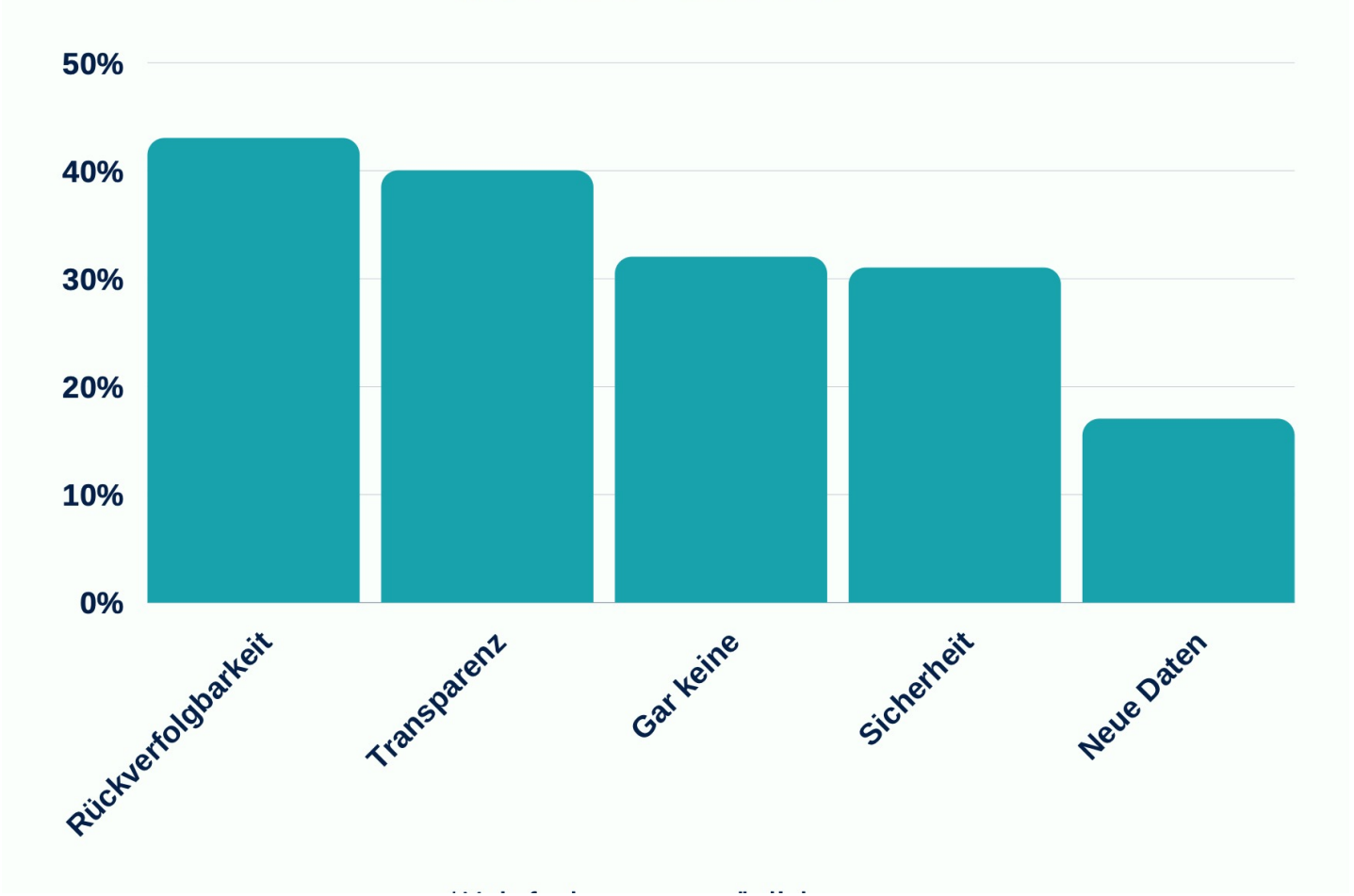
- Was already MDR compliant
- NB was still a bottleneck causing delayed market entry
- Departments sent to part-time or furlough



Source: Climedo – April 2021

Advantages? (Survey)

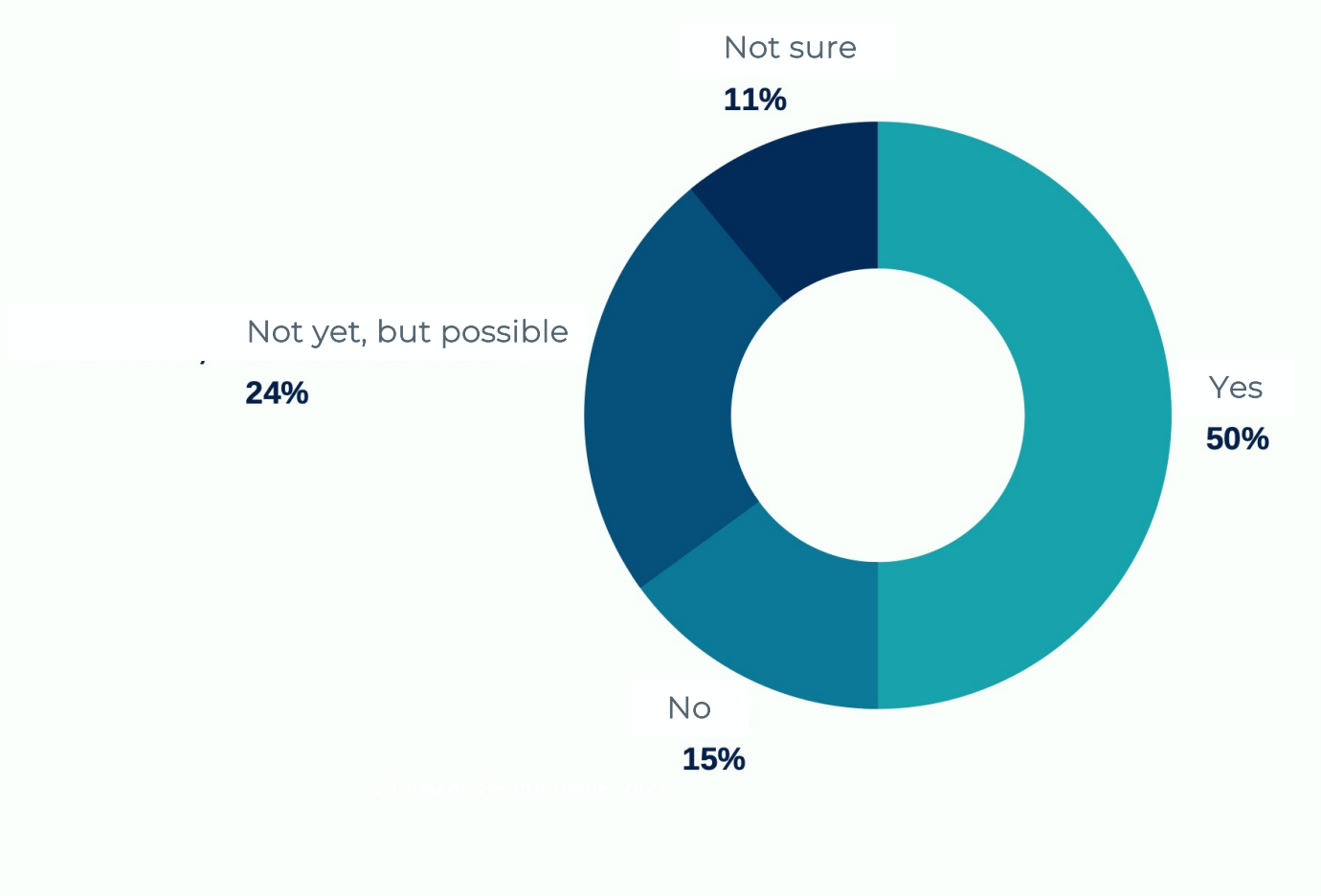
- Tracability
- Transparency
- NOTHING
- Safety
- New Data



Source: Climedo – April 2021

Will you need to conduct PMCF studies? (Survey)

Only 15% are certain not to require PMCF



Source: Climedo – April 2021

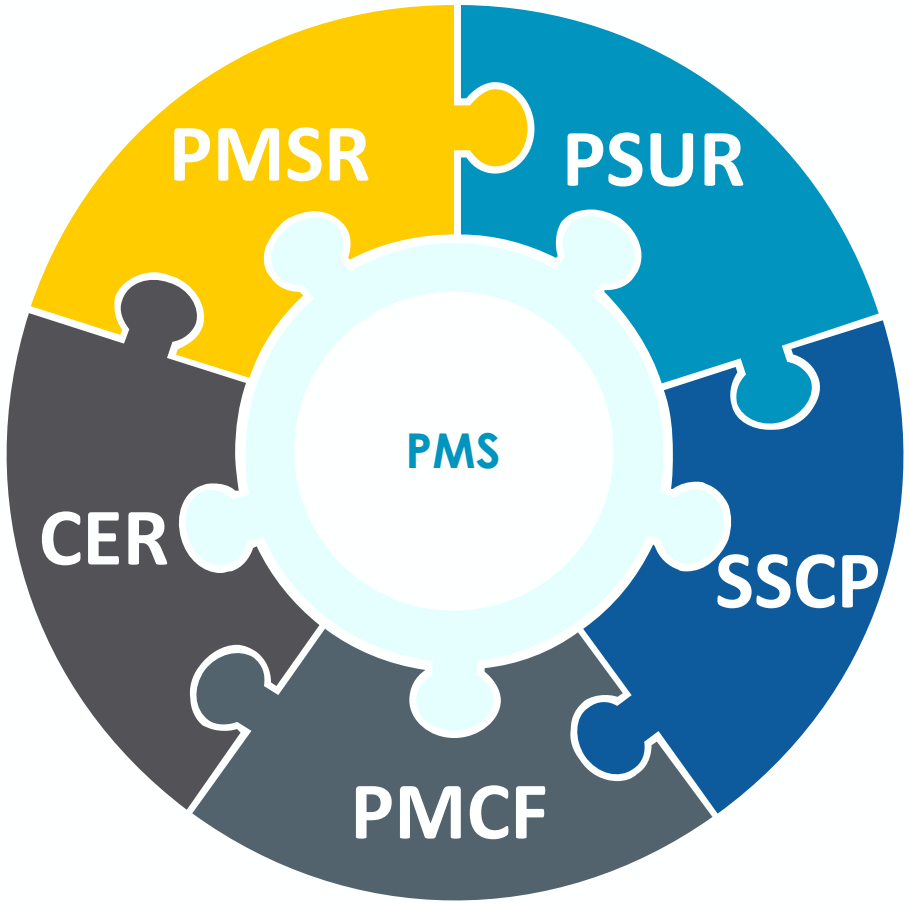
PMS per MDR

What is being understood as Post-Market Surveillance System?

All activities carried out by manufacturers in cooperation with other economic operators to institute and maintain a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market, or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventative action.

CAVE: This is not “Market Surveillance", which is used to describe activities to monitor complaince with regulations by national authorities (not manufacturers!).

PMS Requirements



Part of Manufacturers obligations (MDR, Article 10): "*...shall implement and keep up to date...*"

MDR, **Annex III** - Technical Documentation on Post-Market Surveillance in accordance with **Articles 83-86**

PMSR: Post-Market Surveillance Report
PSUR: Periodic Safety Update Report
CER: Clinical Evaluation Report
SSCP: Summary of Safety and Clinical Performance
PMCF: Post Market Surveillance Follow-Up

PMS Requirements (Article 83)

Comprehensive system to gather experience from the use of devices - in an appropriate manner to the risk class and type of the devices as integral part of manufacturers QMS

→Consistent with ISO 14971 and 13485

Those PMS data to be used for updates of

- Risk Management
- Usability
- Design & Manufacturing information (incl. IFU & Labeling)
- SSCP (per Article 32) –> separate slide
- CAPA / Field Safety Corrective Actions (FSCA)
- Trend Reports

PMS Requirements (Article 84)

Appropriate measures to be in place in order to inform the responsible authorities incl. NB and actions implemented for

- Serious incidents

or

- Field Safety Corrective Actions (FSCA).

PMSR (Article 85) / PSUR (Article 86)

Post-market surveillance report (PMSR) - for class I devices only.
Periodic Safety Update Report (PSUR) for each Class IIa, IIb and III device incl.

- Conclusion on the benefit-risk determination
- Main PMCF findings
- Sales volume incl. usage frequency
- Rationale for any preventive & corrective action

PSUR Update at least annually (class IIb & III) or every two years (class Iia)
PSURs of Class III and Implantables need to submit to EUDAMED system.

SSCP (Article 32)

Summary of Safety and Clinical Performance (SSCP)

- Required for Implantables and Class III
- Written in a *clear and understandable manner* for the intended user and, where relevant, patient
- NB validates and uploads to Eudamed - available to the public

→ MDCG 2019-9

Sources for proactive PMS - PMCF

- Expert User Groups / Focus Groups and Patients / Case Studies
- Surveys
- Device tracking via e.g. Registries
- Focused literature Research – incl. Leverage CER updates

- Post CE-mark studies (PMCF for existing scope, proactive data collection and evaluation on actual device and its use in the market - addressing potential open questions)
  - New claims or indications may have regulatory impact (NB approval, new product certificate, etc)

Feedbacks, complaints, warrantly claims are rather passive…

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Transitional provisions

PMS requirements in the MDR apply to

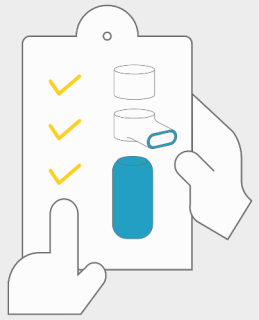
- Devices CE marked under MDR

AND

- Devices CE marked under the MDD

Scenario for Implants, Class III, IIb active devices administering / removing medical substances.

	CER	PSUR	SSCP
Manufacturer (e.g. Pulmotree)	Clinical Evaluation Plan & Report per MDR (annualy) incl. outcome from the PMCF report	Prepares PSUR and uploads to EUDAMED annualy	Prepares & updates SSCP upon PMCF report and PSUR are updated (at least annualy) ensuring alignment of relevant parts of the TD. If needed, translation.



Scenario for Implants, Class III, IIb active devices administering / removing medical substances.

	CEAR	PSUR	SSCP
Notified Body (e.g. mdc)	Prepares a Clinical Evaluation Assessment Report (CEAR) on manufacturers CER. Submits to Commission which may run a consultation procedure per Article 54 Issues Certificate Notifies Competent Authorities.	NB reviews and makes it available for Competent Authorities 	Validates SSCP (in one language) and uploads to Eudamed → Information becomes publicly available!

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REFERENCES

- MDCG 2020-5: Guidance on Clinical Evaluation - Equivalence, April 2020
- MDCG 2020-6: Guidance on Sufficient Clinical Evidence for Legacy Devices, April 2020
- MDCG 2019-3 rev.1: Interpretation of article 54(2)b April 2020
- MDCG 2019-5 Registration of legacy devices in EUDAMED
- MDCG 2020-13: Clinical evaluation assessment report template, July 2020
- MDCG 2020-7: Guidance on PMCF Plan Template, April 2020
- MDCG 2020-8: Post-Market Clinical Follow-up (PMCF) Evaluation Report Template, April 2020
- MDCG 2020-9 Summary of safety and clinical performance
- Regulation (EU) 2017/745 Of the European Parliament and of the Council of 5 April 2017 on medical devices
- MDCG 2019-4: Timelines for registration of device data elements in EUDAMED April 2019
- MDCG 2019-9: Summary of safety and clinical performance - A guide for manufacturers and notified bodies
- IMDRF/UDI WG/N48 FINAL: 2019 Unique Device Identification system (UDI system) Application Guide
- MDCG 2018-3 rev.1: Guidance on UDI for systems and procedure packs, June 2020
- Guide MEDDEV 2.7/1 rev.4: Guidelines on medical devices: Clinical Evaluation -
- Regulation (EU) 2017/745 on medical devices

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