Post Market Surveillance – Requirements

MDD & AIMDD

- MDD – conformity annexes (II, III, VII)
- AIMDD – conformity annexes (2 and 3)
- MedDev 2.12/1 (rev 8) – Guidelines on a Medical Devices Vigilance System
- MedDev 2.12/2 (rev 2) – Post Market Clinical Follow Up Studies: A Guide for Manufacturers and Notified Bodies

MDR

- Chapter VII: Post-Market Surveillance, Vigilance and Market Surveillance
- Annex III: Technical Documentation on Post-Market Surveillance
- Annex XIV (Part B): Post Market Clinical Follow Up

Article 2(44):

Clinical evaluation: a systematic and planned process to **continuously** generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.

Article 83

*"For each device, manufacturers shall plan, establish, document, implement, maintain and update a **post-market surveillance system** in a manner that is proportionate to the risk class and appropriate for the type of device."*

Annex III 1.1b says PMS should include:
*"a **PMCF** plan as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable."*

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PMS – What's changing from MDD/AIMDD to MDR?

Requirements are more explicit and prescriptive with respect to:

1

What data should be gathered

PMS - Annex III (1a):

- Serious incidents, FSCA, information from PSURs
- Non-serious incidents and data on any undesirable side-effects
- Sales, complaints and trend reporting
- Data from literature, databases and/or registers
- Other market feedback (eg provided by users, distributors and importers)
- Publicly available information on similar medical devices

PMCF - Annex XIV Part B:

- Safety and performance throughout device lifetime
- Side-effects and contraindications, including previously unknown side-effects
- Emergent risks
- Information on possible systematic misuse or off-label use

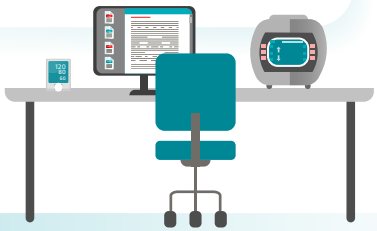
How it should be gathered

PMS - Annex III (1b):

- Proactive and systematic
- Enable comparison with similar devices on the market
- Methods to assess the data, including indicators and threshold values
- Statistical methods for trending and monitoring increases in frequency or severity of incidents
- Protocols for communication with CA, NB, EO & users
- Procedures for corrective actions

PMCF - Annex XIV Part B:

- Clinical data from use in / on humans on the device
- Within its intended purpose as referred to in the relevant conformity assessment procedure
- Specific methods and procedures, including rationale for appropriateness
- Specific objectives
- Reference to CS, harmonised standards and relevant guidance
- Comparison to equivalent or similar devices
- Detailed and adequately justified time schedule



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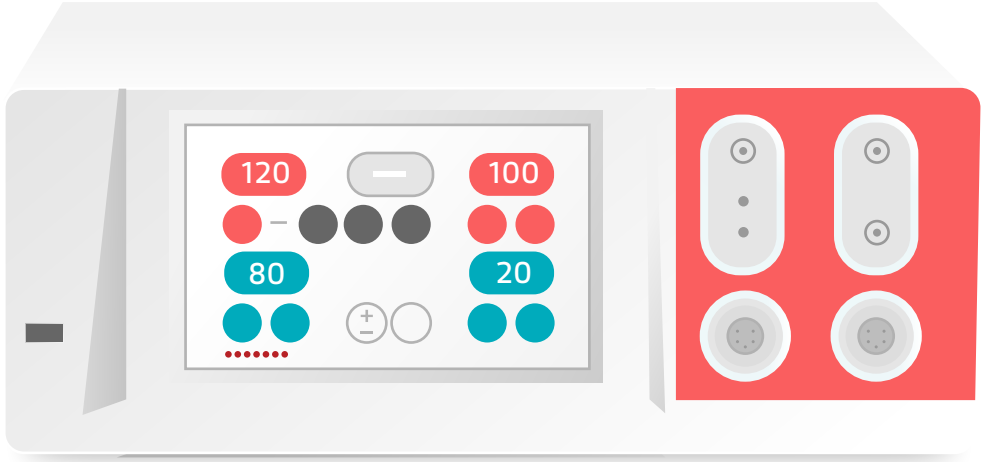
Timescales for updates, review and validation

PMS is linked to PSUR (Article 86) and SSCP (Article 32)

- PSUR updated annually for Class III and IIb, every two years for Class IIa
- SSCP updated if outputs of PMS impact on it
- For Class III and implantable devices, NB must validate these documents and upload to EUDAMED

- For Class III and implantable devices, **PMCF** report is updated at least annually (Article 61(11))



How it should be used

PMS - Article 83(3):

PMS data shall be used to:

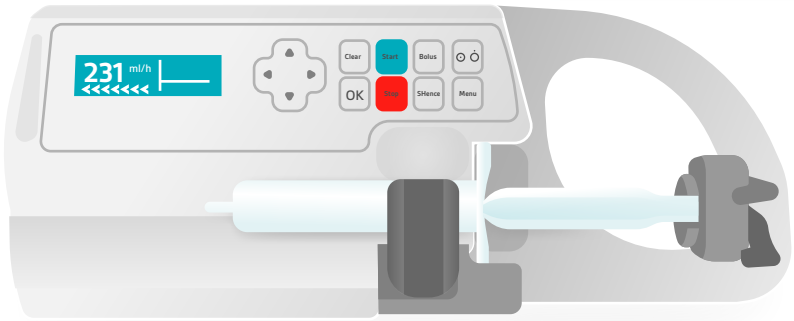
- Update the benefit-risk determination, technical documentation, IFU, labelling, clinical evaluation, SSCP
- Improve risk management
- Identify needs for CAPAs or FSCA
- Identify options to improve the usability, performance and safety of the device
- Contribute to the post-market surveillance of other devices (where relevant)
- Detect and report trends

PMCF - Annex XIV Part B:

- Confirm safety, performance and benefit-risk throughout device lifetime
- Identify requirements for corrective action

Article 61(11):

- Update clinical evaluation, PSUR and **(if indicated)** SSCP



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New requirements for publicly available information and sharing of information across Member States

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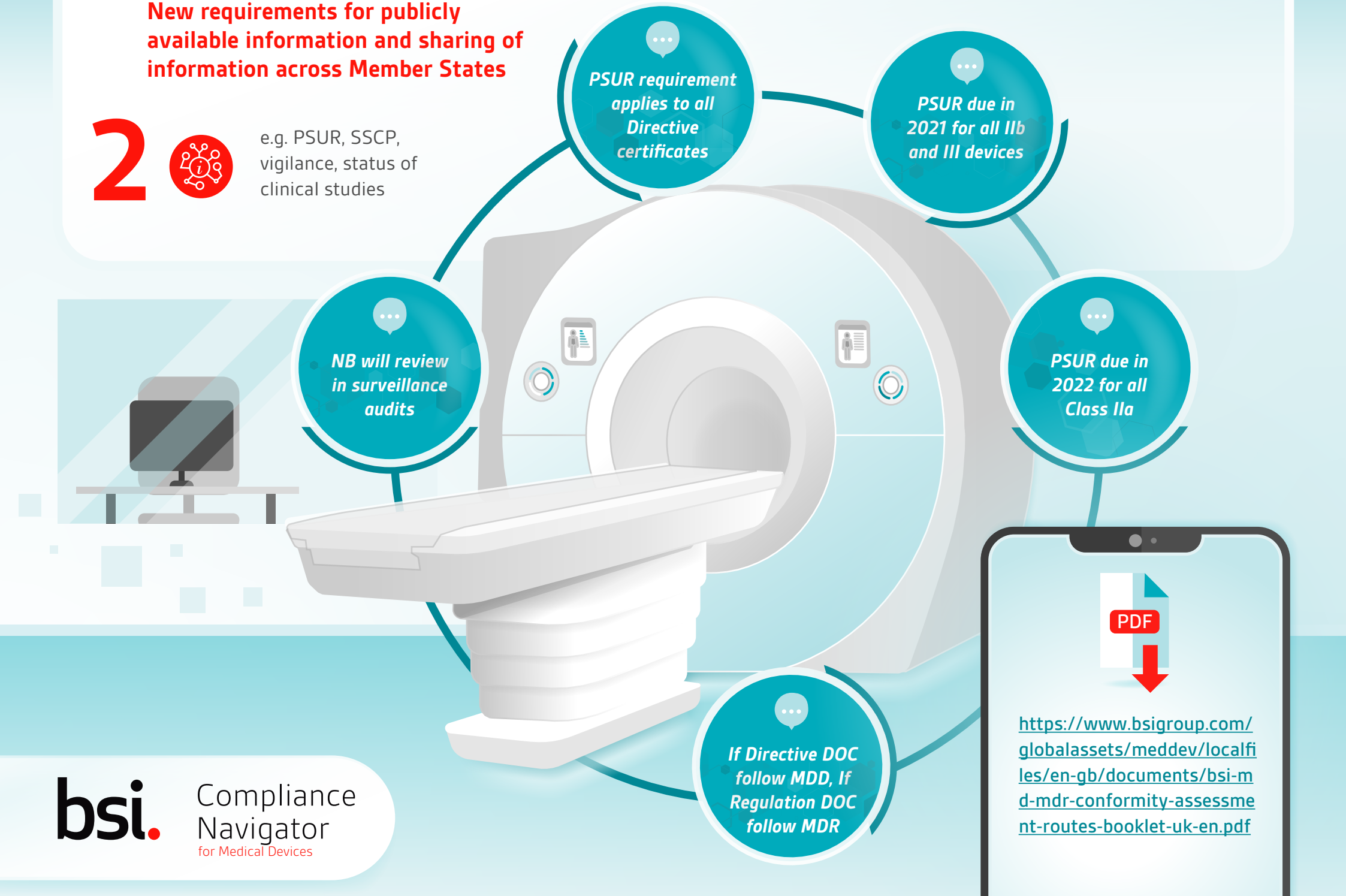
e.g. PSUR, SSCP, vigilance, status of clinical studies



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