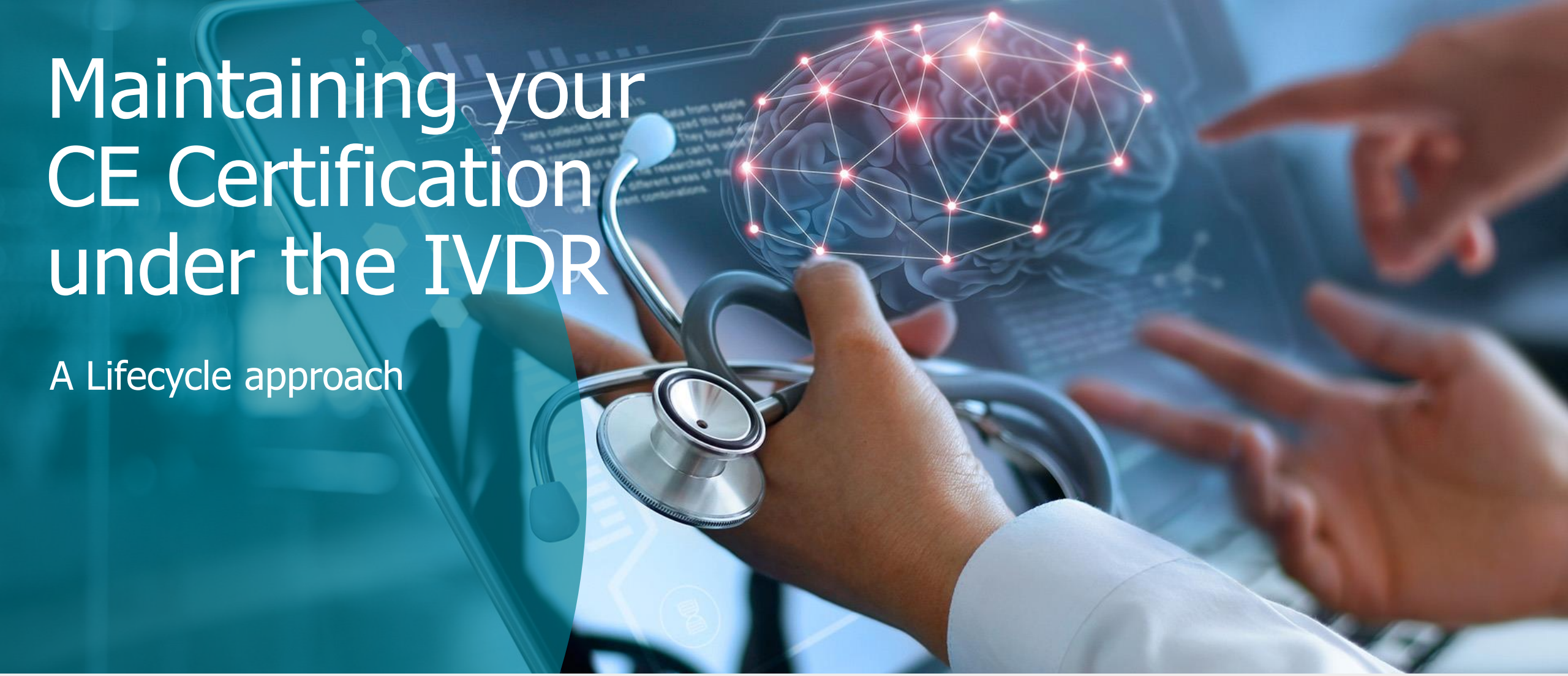
Maintaining your CE Certification under the IVDR

A Lifecycle approach



Dr Heike Möhlig-Zuttermeister
Technical Team Manager - IVD

28 Oct 2020

By Royal Charter

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Series of webinars available

- QMS Requirements under IVDR
- Performance Evaluation Part 1
  - Introduction to Performance Evaluation
  - Performance Evaluation Plan
  - Scientific Validity
  - Link to PE Report & conclusion
- Performance Evaluation Part 2
  - Clinical Performance as part of the PER
  - **Link to PMPF**

Performance Evaluation under the In Vitro Diagnostic Regulation (IVDR) – Part 1

Download the presentation >

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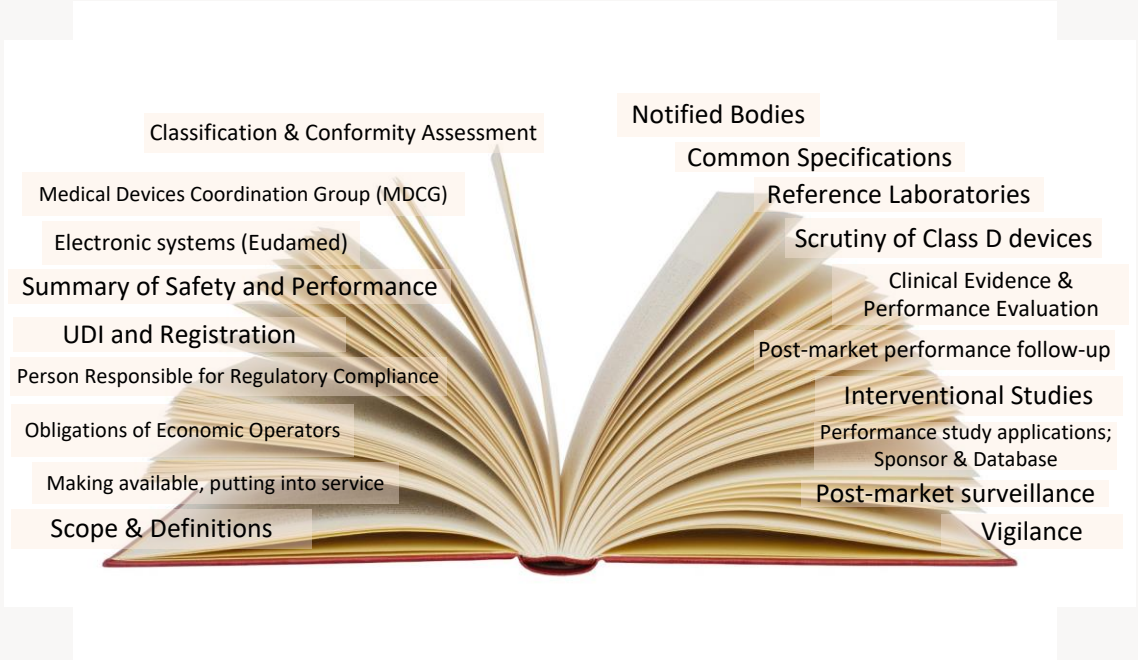
www.bsigroup.com/IVDR

Agenda

- Introduction to Post-market Surveillance
- Difference between PMS & PMPF
- PMS – some Details
- PMPF – some Details
- Surveillance Audits
- Summary



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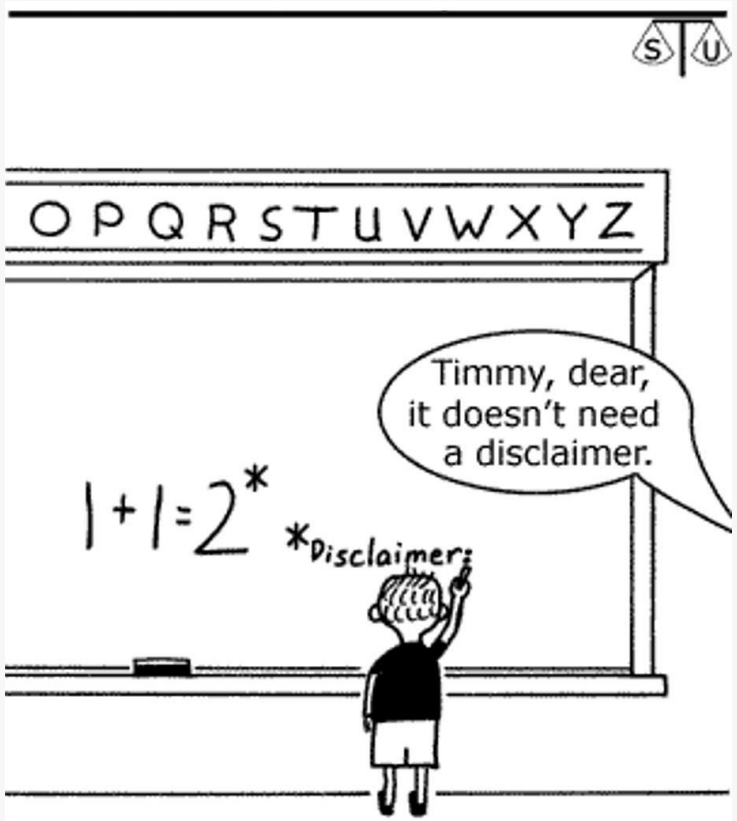
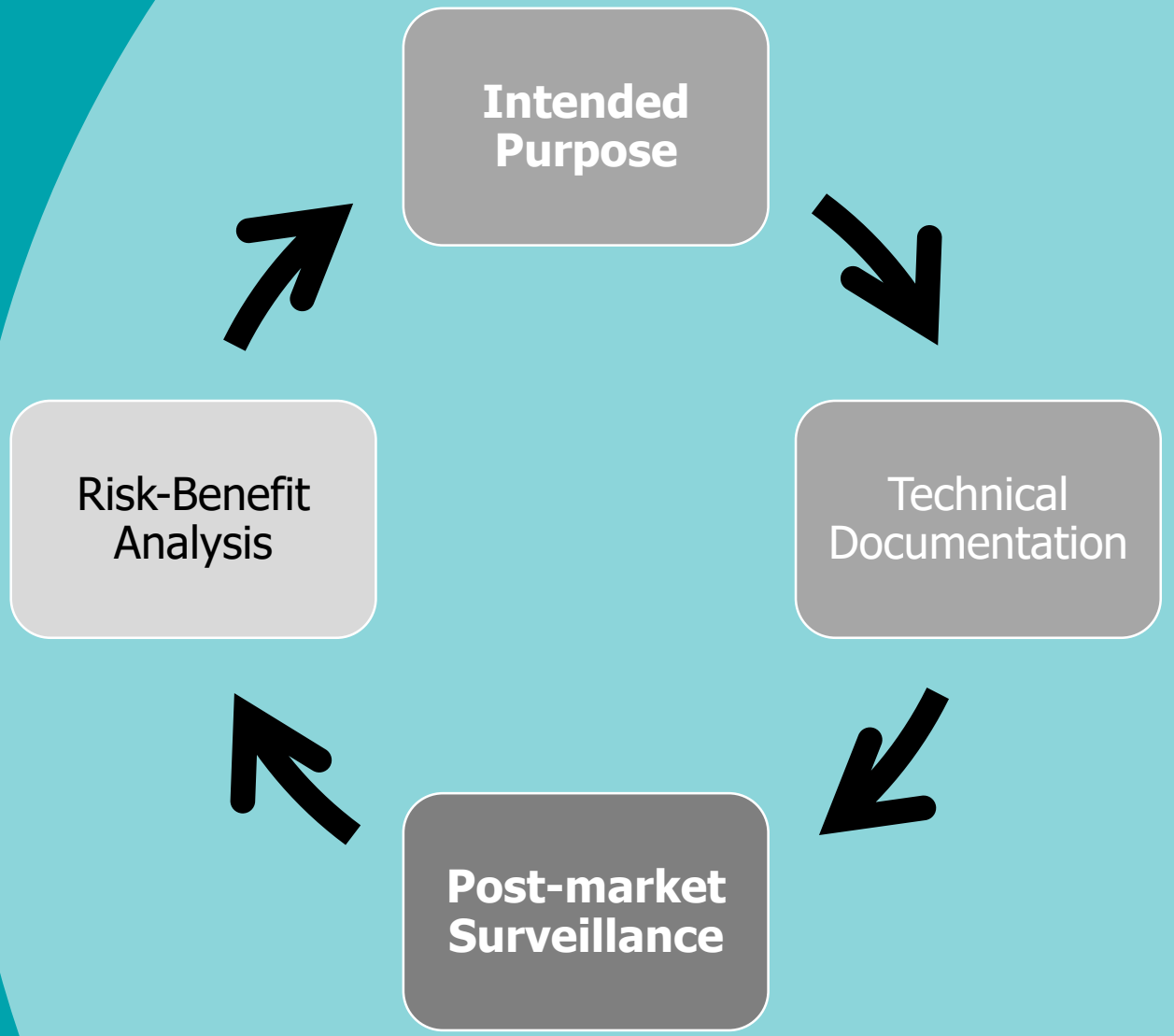


- Information presented within this webinar is based on our current understanding of the IVDR
- Subject to change

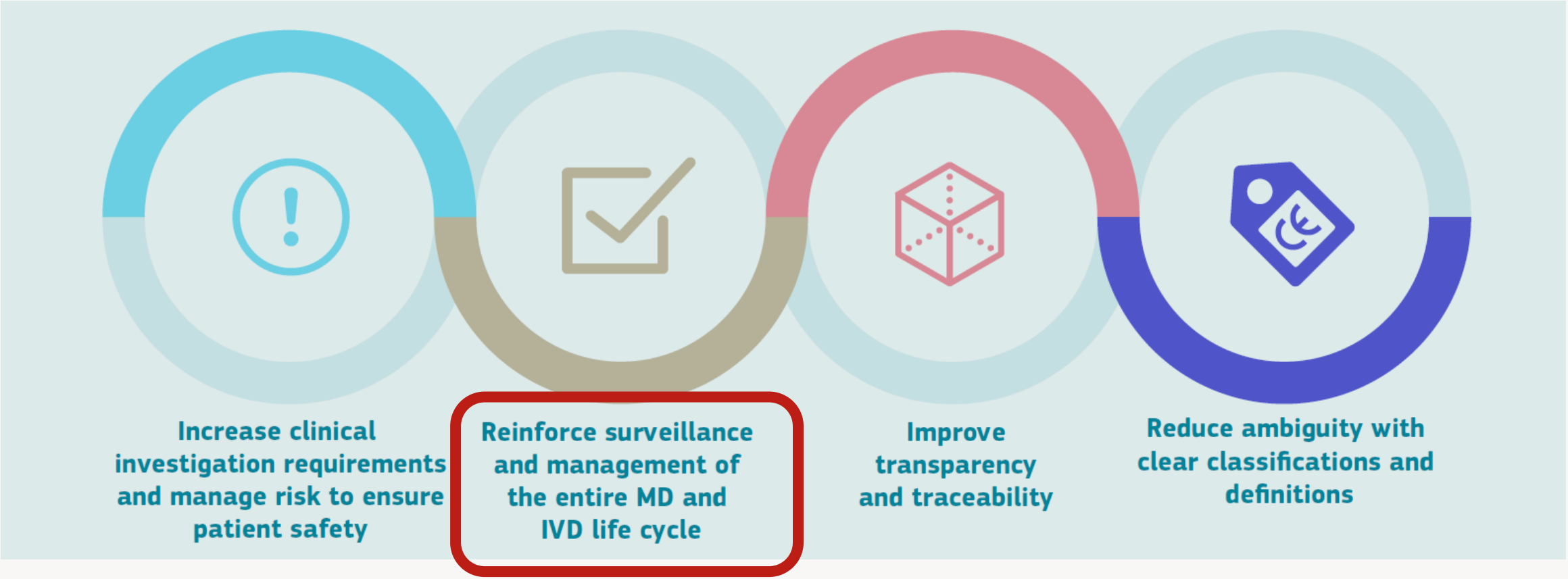
Introduction

- Post-market Surveillance under the IVDR



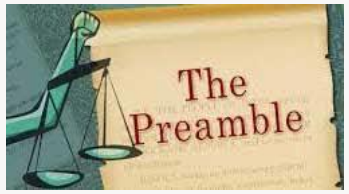
Post-market Surveillance

Key Elements



Source: „MDR-IVDR infographic on https://ec.europa.eu/docsroom

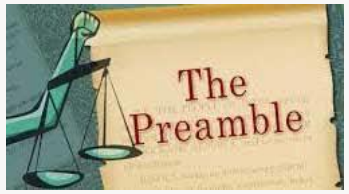
Post-market Surveillance – Key Elements



Laid out in the Preamble

(4) **Key elements** of the existing regulatory approach, such as the supervision of notified bodies, risk classification, conformity assessment procedures, performance evaluation and performance studies, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding *in vitro* diagnostic medical devices should be introduced, to improve health and safety.

Post-market Surveillance – Key Elements



Laid out in the Preamble

- (31) should be proportionate to the risk class …. In addition, in order to minimize risks or prevent incidents related to devices, manufacturers should establish a system for risk management and a system for reporting incidents and field safety corrective actions
- (75) Manufacturer should play active role during the post-market phase by systematically and actively gathering information from post-market experience with their devices in order to update their technical documentation and cooperate with the national competent authorities in charge of vigilance and market surveillance activities.

Key Elements feeds into PMS definition

Article 2 (63)

'post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date 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 preventive actions;

✓thorough tool for the benefit-risk evaluation and continuous risk acceptability
Reference GSPR 3

Article 78 – Post-market Surveillance

1. 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.

- ✓ Part of the manufacturer's quality management system referred to in Article 10(8).
- ✓ PRRC responsible for keeping up to date the PMS, in accordance with Article 78.

2. 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.

✓Key in the establishment of a new framework for **proactive** safety & performance evaluation during lifetime - **PMPF**

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Article 78.3 – PMS covered in the QMS + TD

Data gathered by the manufacturer's PMS shall in particular be used:

(a) to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I;

(b) to update the design and manufacturing information, the instructions for use and the labelling;

(c) to update the performance evaluation

(d) to update the summary of safety and performance referred to in Article 29;

(e) for the identification of needs for preventive, corrective or field safety corrective action;

(f) for the identification of options to improve the usability, performance and safety of the device;

(g) when relevant, to contribute to the post-market surveillance of other devices; and

(h) to detect and report trends in accordance with Article 83.

✓The technical documentation shall be updated accordingly.

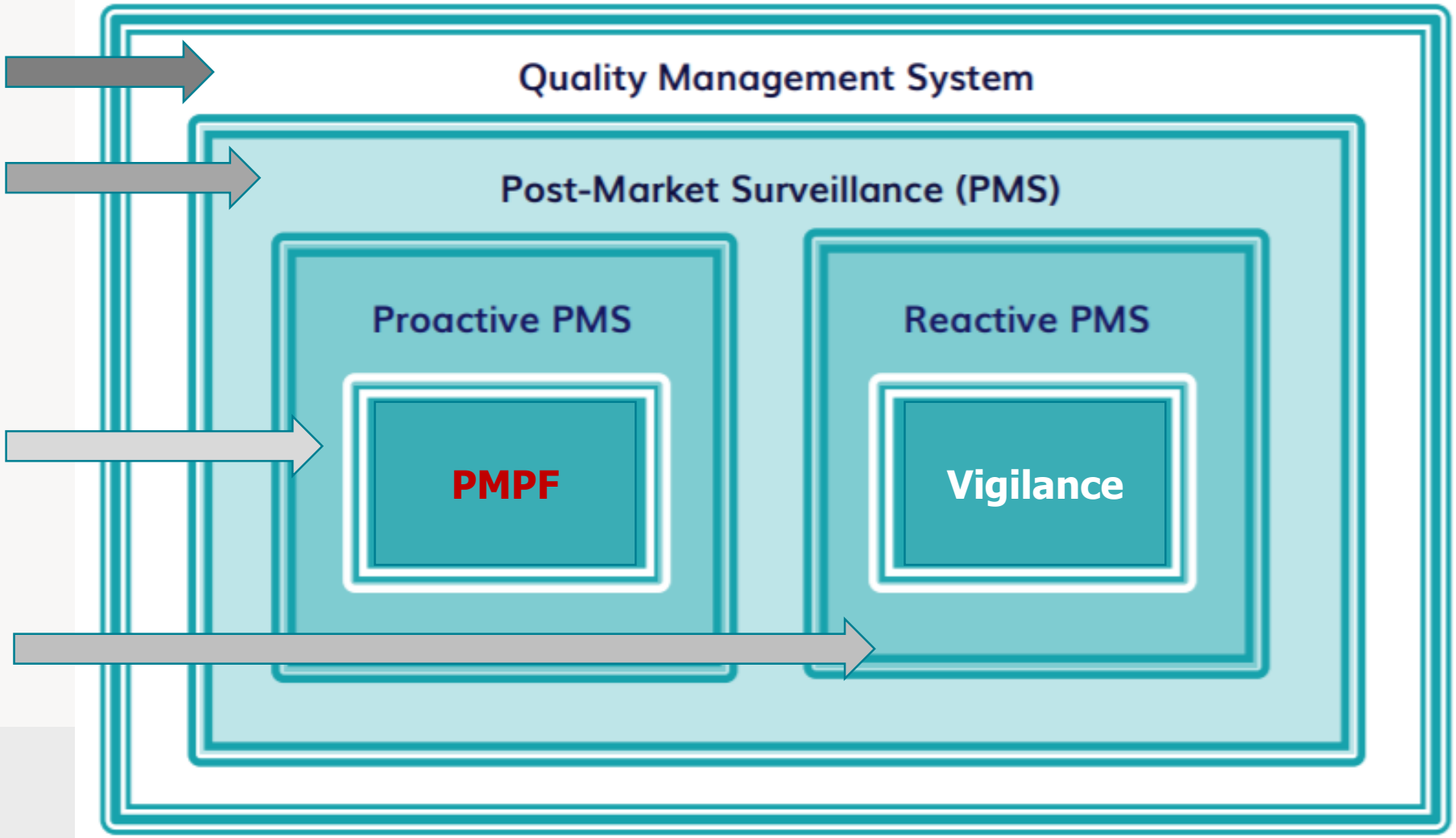
Article 78.3 - Linkage to PMPF

Annex IX Chapter I

Article 78
Article 80
Article 81
- Annex III

Proactive PMS
Article 56(6)
- Part B Annex XIII

Reactive PMS
Article 82
Aticle 83
Article 84
Article 85



PMPF is a subset of PMS

Your PMS plan must include at least (Annex III):

- Your methods and procedures for:
  - Proactively collecting information, including characterizing device performance and comparing it to similar competing devices
  - Assessing the collected data
  - Investigating complaint and market-related experience
  - Tracking the frequency and severity increase of incidents
  - Communicating with authorities or Notified Bodies
  - Fulfilling manufacturer obligations for a PMS system, PMS plan and PSUR (article 81)
  - Identifying and initiating appropriate measures (incl. corrective actions)
- **Indicators** and values to reassess the benefit-risk analysis & risk management
- Tools for tracing and identifying which corrective actions may be necessary
- A **PMPF plan** or justification if PMPF is not applicable

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PMPF is a subset of PMS

Your PMPF plan must include at least:

- PMPF objectives
- Methods and procedures for:
  - Gathering clinical experience, user feedback, literature screening, other sources of clinical data
  - Applying PMPF (evaluating registers or PMPF studies)
- A rationale of the used methods' appropriateness
- An evaluation of clinical data on equivalent or similar devices & current state of the art
- A reference to
  - Any relevant CS, harmonized standards used and guidance on PMPF
  - **Relevant parts of performance evaluation report** and risk management

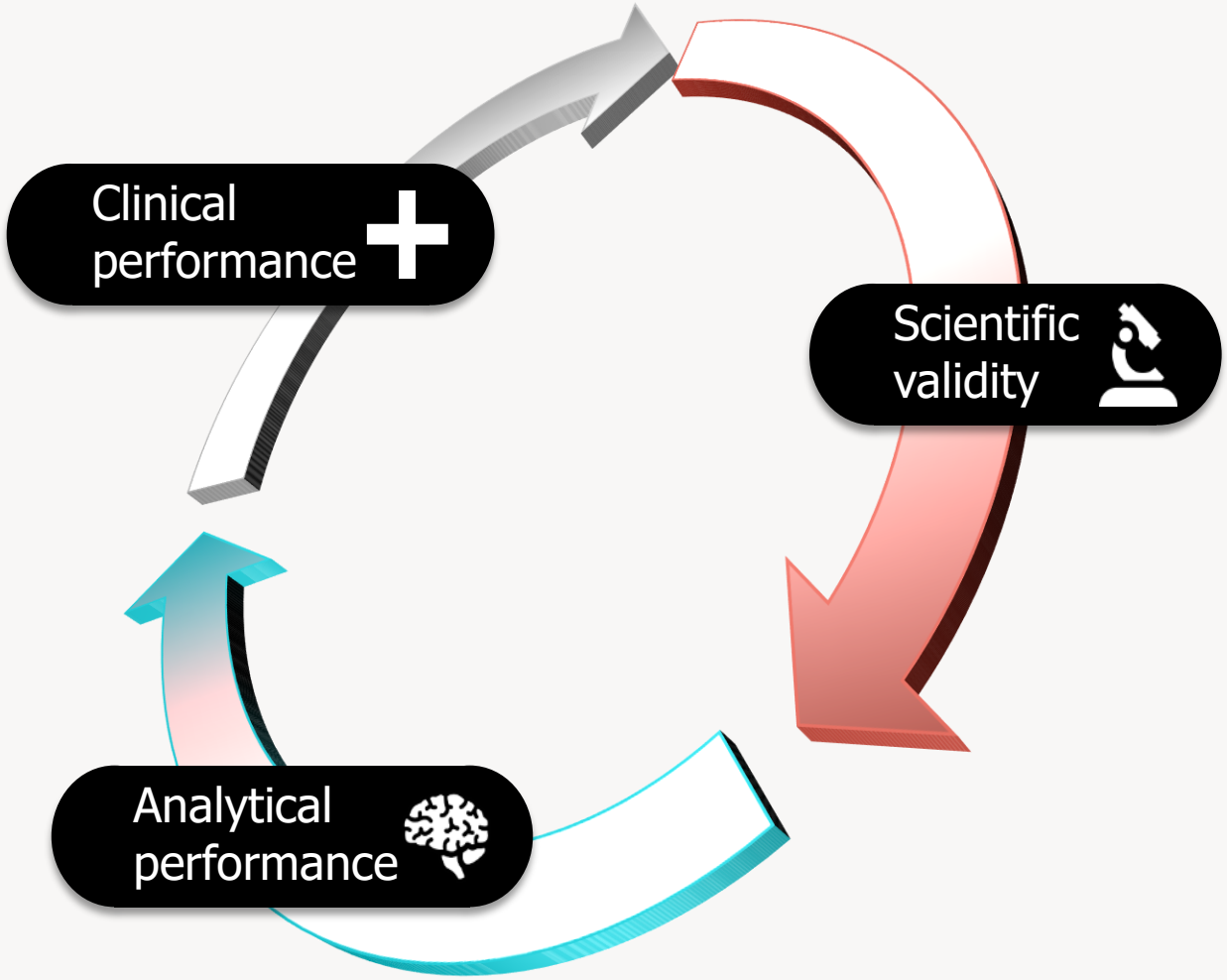
Looking back to Performance Evaluation

- ***Process*** of Performance Evaluation
- Ref Annex II & **Annex XIII**

- Done according to a **Performance Evaluation Plan**

- Collated as a **Performance Evaluation Report**

- *Continuous during life-time of the device*



Performance Evaluation Report

- Reference Annex II sec 6.2

- The Performance Evaluation Report is a *critical* part of the technical documentation

…we will review against all specified requirements

❖**Performance Evaluation Plan**

❖**Performance Evaluation Report**

- ❖- Scientific Validity Report
- ❖- Analytical Performance Report
- ❖- Clinical Performance Report
- ❖- & *Conclusion (see An XIII, 1.3.2)*

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Performance Evaluation Report

- Reference Annex II sec 6.2

- The Performance Evaluation Report is a *critical* part of the technical documentation

…we will review against all specified requirements

❖**Performance Evaluation Plan**

❖**Performance Evaluation Report**

… linked to:

➢**Post Market Performance Follow-up Plan**

- ❖- Annex XIII part B
- ❖- Linked to conclusion of PER
- ❖- **PMPF evaluation report shall update the PER**
- ❖- If deemed not appropriate, then justification to be given in the PER (An XIII, 8.)

➢**Summary of Safety and Performance**

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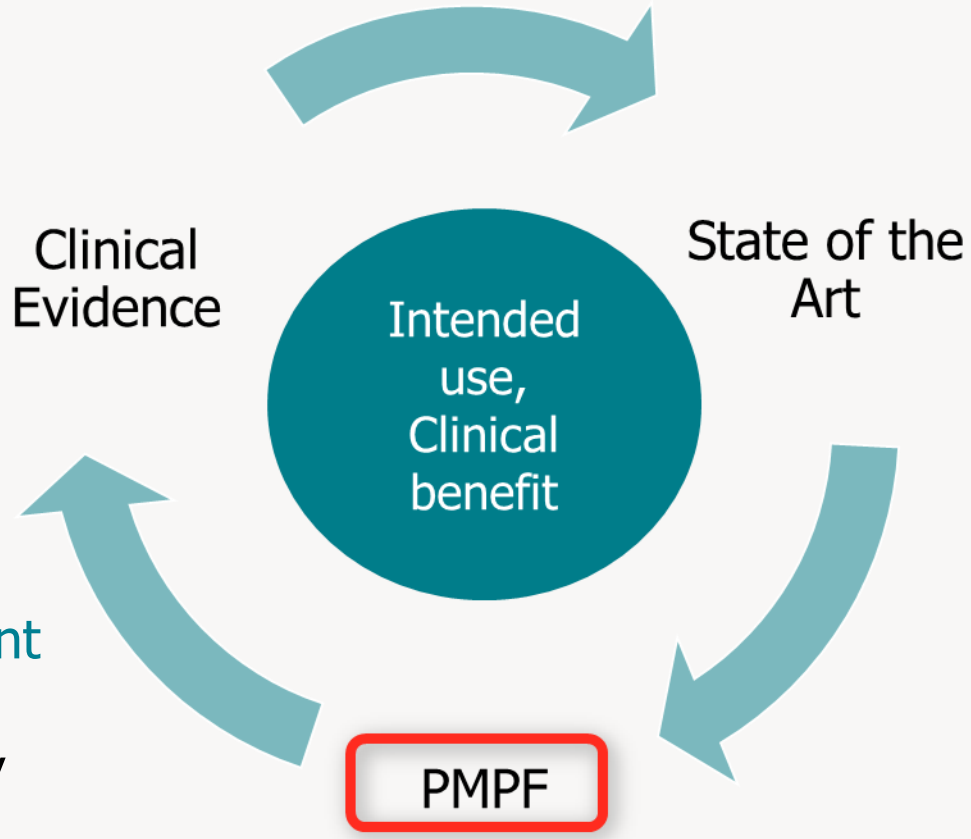
Post-Market Performance Follow Up - PMPF

- PMPF shall be:
  - A continuous process to update the performance evaluation
  - specifically addressed in the PMS plan

- PMPF shall be conducted:
  - proactively collect and evaluate performance and relevant scientific data from use as per intended purpose
  - confirming the safety, performance and scientific validity throughout the expected lifetime of the device,
  - Ensuring continued acceptability of the benefit-risk ratio
  - Identifying previous unknown risks and/or emerging risks
  - Identifying possible systematic misuse



Post-Market Performance Follow-up - PMPF

- Is PMPF always needed?

➢As PMPF is used to confirm the safety and validity of the device on the market - **if it is already confirmed** during Performance Evaluation and Risk Management that the device is safe, then PMPF studies are not required to *further confirm*, unless issues are **flagged by Post-Market Surveillance**

✓**PMPF is about confirming benefit-risk ratio when you have outstanding residual risks**

✓**PMPF is not deemed appropriate, then justification shall be provided in the PE Report** (Ref: Annex XIII Part B sec 8)

✓**Triggers for PMPF should be addressed in the PMS Plan.**

Post-Market Requirements - PMS

All Classes

- **PMS plan – Annex III, Article 78**
  - The PMS system referred to in Article 78 shall be based on a PMS plan, the requirements for which are set out in Section 1 of Annex III.

The PMS plan shall be part of the technical documentation specified in Annex II

Class A & B

- **PMS report – Annex III, Article 80**
  - Manufacturers of class A and B devices shall prepare a PMS report summarizing the results and conclusions of the analyses of the PMS data gathered as a result of the PMS plan referred to in Article 79 together with a rationale and description of any preventive and corrective actions taken.

The report shall be updated when necessary and made available to the NB and the competent authority upon request.

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Post-Market Requirements - PMS

Class C & D

Periodic safety update report (PSUR) – Annex III, Article 81

- Manufacturers shall prepare a PSUR for each device (or category/group of devices) summarizing the results and conclusions of the analyses of PMS data gathered
- update at least annually.
- **For Class C devices**, manufacturers shall make PSURs available to the NB involved in the conformity assessment and, upon request, to CAs.
- **For class D devices** shall submit PSUR by means of EUDAMED to the NB (Art 81).

As per PMS plan (Article 79) together with a rationale and description of any preventive and corrective actions taken

PSUR shall be part of the technical documentation (as per Annexes II and III)

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Post-Market Requirements - PMS

Class C & D

Periodic safety update report (PSUR) – Annex III, Article 81

(a)The conclusions of the benefit-risk determination

(b)The main findings of the PMPF

(c)The volume of sales of the device and an estimate of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

Maintained throughout the lifetime of the device

Post-launch Requirements - PMS

Additional Guidance: MEDDEV 2.12-1 rev. 8
May 2019

Vigilance – Article 82 (Reporting)

- Manufacturers shall report to the relevant CAs the following:
  - Any serious incident involving devices made available on the EU market
  - Any field safety corrective action in respect of devices made available on the EU market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the EU market
- Reporting timelines:
  - Serious incident: Immediately on establishing a causal relationship, **no more than 15 days**
  - Serious public health threat: Immediately upon awareness, no more than 2 days
  - Death or serious deterioration in state of health: Immediately on establishing a causal relationship, no more than 10 days

Don’t forget you are now also communicating with your NB!

Post-launch Requirements - PMS

Put Procedures in place to ensure compliance with IVDR vigilance requirements

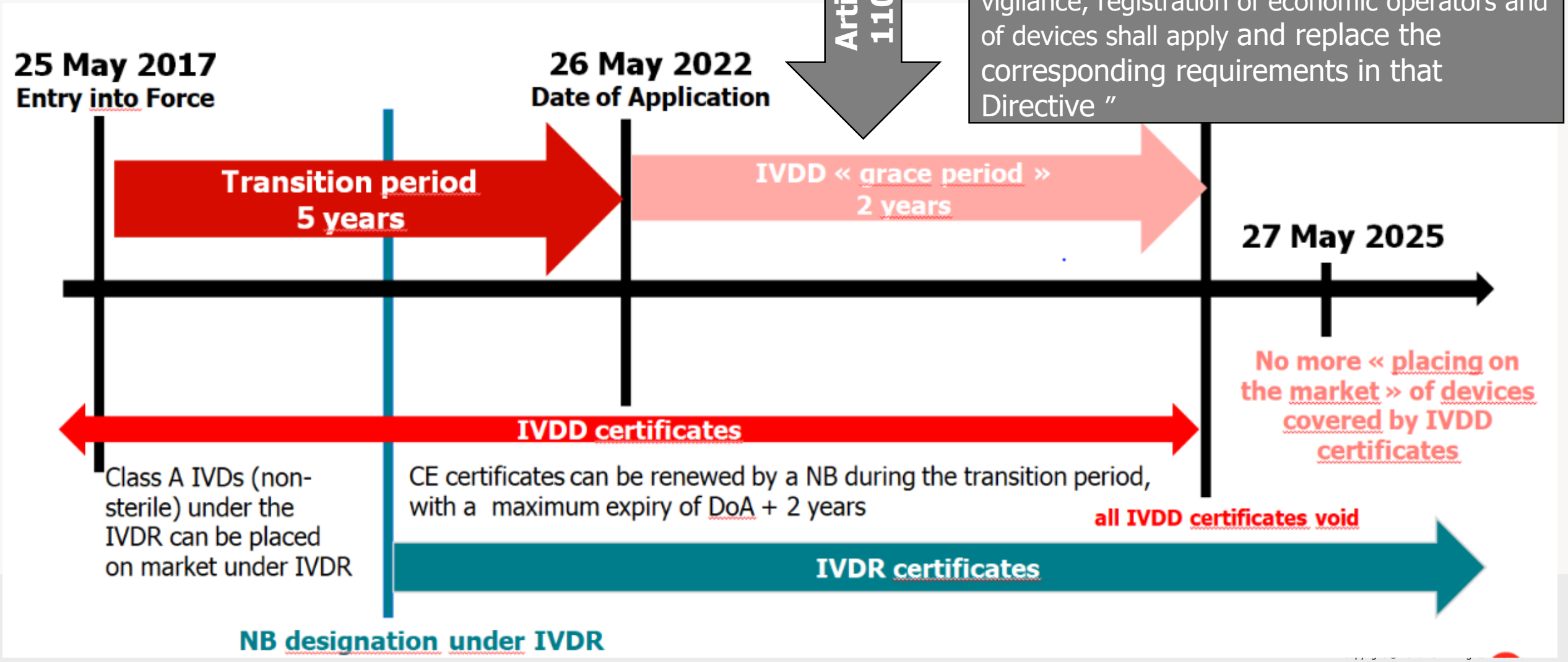
Vigilance – Article 83, 84 & 85

- Trend reporting
  - Manufacturers shall report any statistically significant increase in the frequency or severity of incidents.

- Analysis of incidents
  - Following the reporting of a serious incident, the manufacturer shall, without delay, perform the necessary investigations This shall include risk assessment of the incident and field safety corrective action.
  - The competent authority shall investigate reports and monitor manufacturer's investigation of a serious incident.

Transitional arrangements for IVDR

Article 110.3 "…it continues to comply with that Directive, and provided there are no significant changes in the design and intended purpose…
…the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply and replace the corresponding requirements in that Directive "



Surveillance Audits

- QMS
- Unannounced Audits
- Technical Documentation

QMS Audits

QMS audits will take place annually

- IVDR checklist will be part of ISO 13485 surveillance audits if BSI is your certification body
- include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors.

See BSI webinar!

NB Requirements – Annex VII 4.5.1 & 4.10

"conduct surveillance audits of the manufacturer on at least an annual basis which shall be planned and conducted in line with the relevant requirements in Section 4.5"

✓ The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations arising from the approved quality management system (Annex IX)

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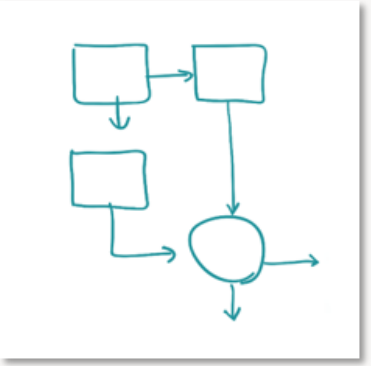
Unanounced Audits

Unannounced audits will take place randomly at least once every five years

- UA audit will be delivered by a team (QMS auditor + Technical Expert) if BSI is your certification body
- Will be on the site of the manufacturer and, where appropriate, the site of the manufacturer's suppliers and/or subcontractors
- To test an adequate sample of the devices produced or an adequate sample from the manufacturing process to verify that the manufactured device is in conformity with the technical documentation

NB Requirements – Annex VII 4.5.1; Annex IX 3.4

Surveillance of Technical Documentation



Technical Documentation Assessment

- Sampling of Technical documentation will occur every year during the certificate cycle
- Applicable to Class B categories and Class C generic device groups

➢ at least one device file *per group* for initial certification and at least another file in every group over the certificate cycle

➢ where there are fewer groups, this may mean more technical audits of that group over the certificate cycle if there are still devices to be reviewed

NB Requirements – Annex VII VII 4.5.1 & 4.5.2(a); Annex IX 3.5

✓ NB Obligation for technical file sampling
✓ Creation of a Sampling Plan at the time of initial certification

Device Grouping – Guidance MDCG 2019-13

Class B – Grouping by **Subcategory** of device

MDCG 2019-13: based on **IVR** codes*

Class C – Grouping by **Generic** device groups

MDCG 2019-13: **3rd level EMDN code** (one letter + 4 digits) + **IVP** code*
(most appropriate IVP code)

OR: 4th level EMDN codes (one letter + 6 digits) + **IVP** code

✓ MDCG 2019-13 allows us to go down to the 4th level if the 3rd level is not sufficiently specific to satisfy the definition of generic device group

*Codes according to (EU) 2017/2185: *The list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies*

Sampling Plans - Guidance MDCG 2019-13

NB Obligations for technical file sampling

- 15 % of devices of **each generic Class C group** and/or **each category Class B group** will be reviewed under surveillance under the certificate scope

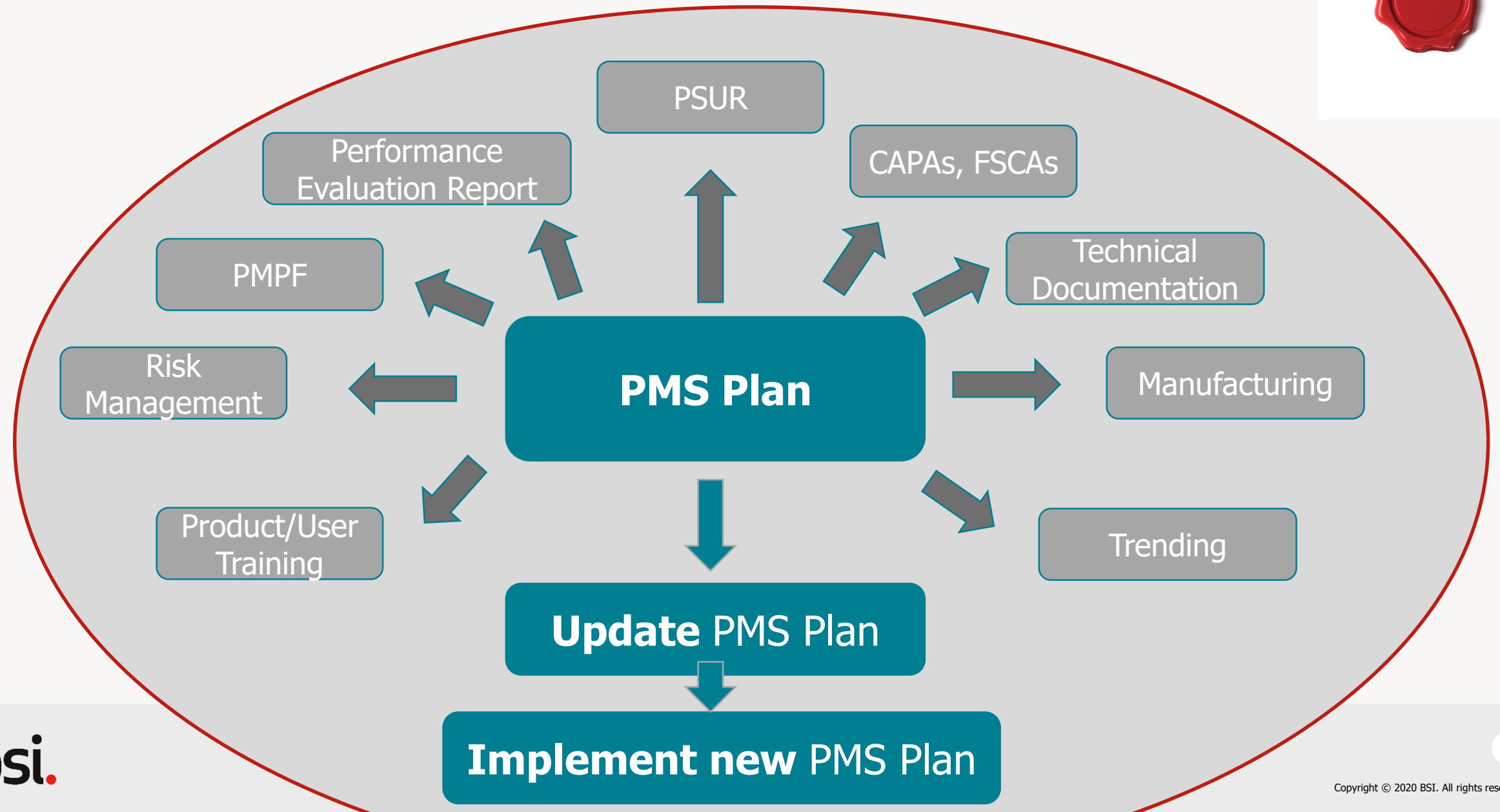
- May be reduced to a minimum of 5% in the first certification cycle

✓ Technical file sampling include SSPs & PSURs!

Summary

- Maintaining certification

Summary – Output of PMS Plan



Summary

- PMS includes PMPF as a subset
- Post-market obligations are during life time of the device
- PMS needs to be systematic & proactive
- Thorough tool for continuous benefit-risk evaluation
- Key in establishment a framework for proactive safety evaluation

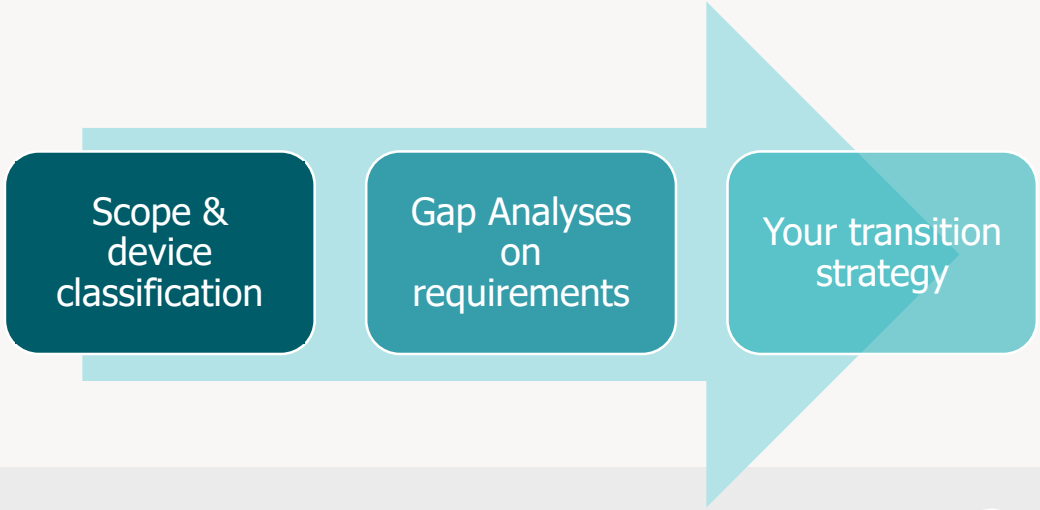
Gathered PMS output requests you to

- Reassess the device PMS plan
- Reassess the Risk Management
- Reassess the device Performance

✓ **Update Procedures as applicable!**
✓ **Update the Technical Documentation as applicable!**

Make your application/s as soon as possible!

- Time until 26 May 2022 is running out!
  - For self-declared devices, you will need your certification by this date
  - You need to allow time for the QMS Audit/s and Technical documentation review/s
    - ➢ At least 6, 7, 8 months or longer?
    - ❖ Timelines will extend as NBs get busier!
- Plan your strategy – but please start!



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