Best Practices for Performance Evaluation Reports, PMPF & PMS

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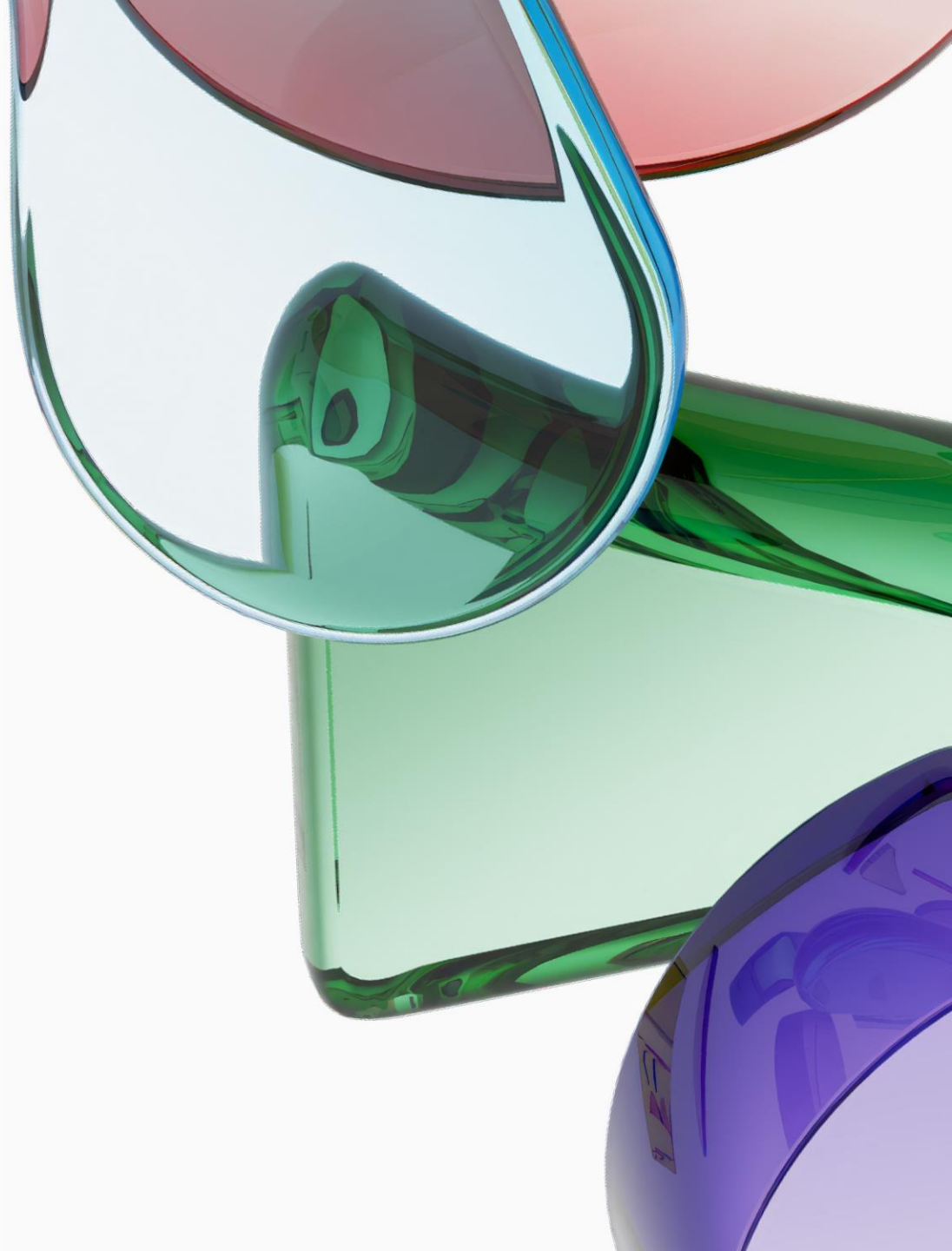

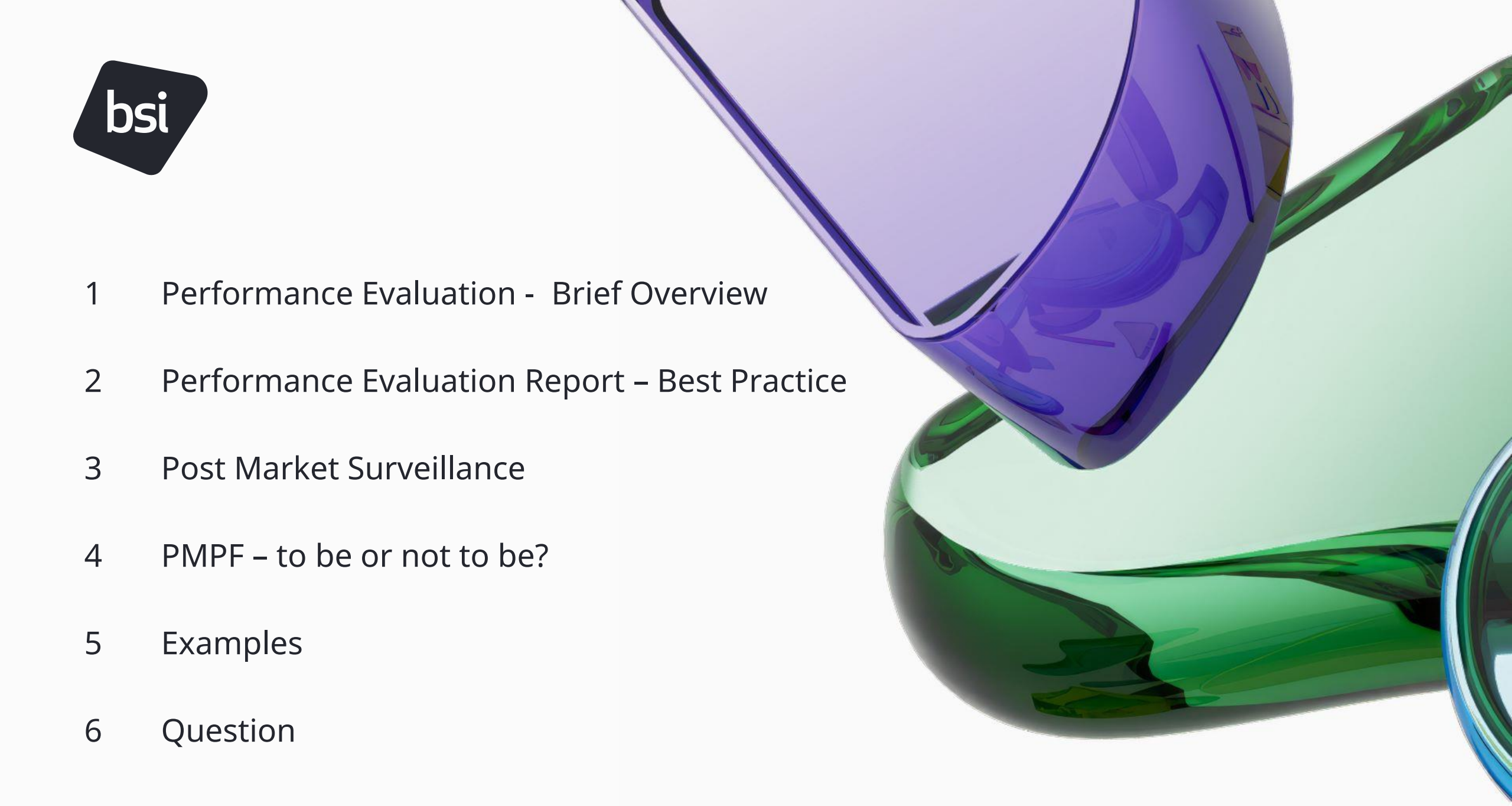

1 Performance Evaluation - Brief Overview

2 Performance Evaluation Report – Best Practice

3 Post Market Surveillance

4 PMPF – to be or not to be?

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Performance Evaluation – Annex XIII

Performance Evaluation is demonstrated via the Requirements of Annex XIII – Part A & Part B

Always Applicable*

- Performance Evaluation Plan (PEP) – 1.1
- Scientific Validity Report (SVR) – 1.2.1
- Analytical Performance Report (APR) – 1.2.2
- Clinical Performance Report (CPR) – 1.2.3
- Performance Evaluation Report (PER) – 1.3

May be Required

- And, as applicable, Clinical Performance studies, Annex XIII, Part A, (2)

and

- Annex XIII Part B – Post Market Performance Follow Up, as applicable.

*Calibrators and Controls may vary

Performance Evaluation – Essentials

Don’t worry if you need a refresher on the essentials!

An Introduction to Performance Evaluation essentials are covered in the below BSI webinars (Season 1 Recap)

Performance Evaluation Under the In Vitro Diagnostic Regulation – Part 1

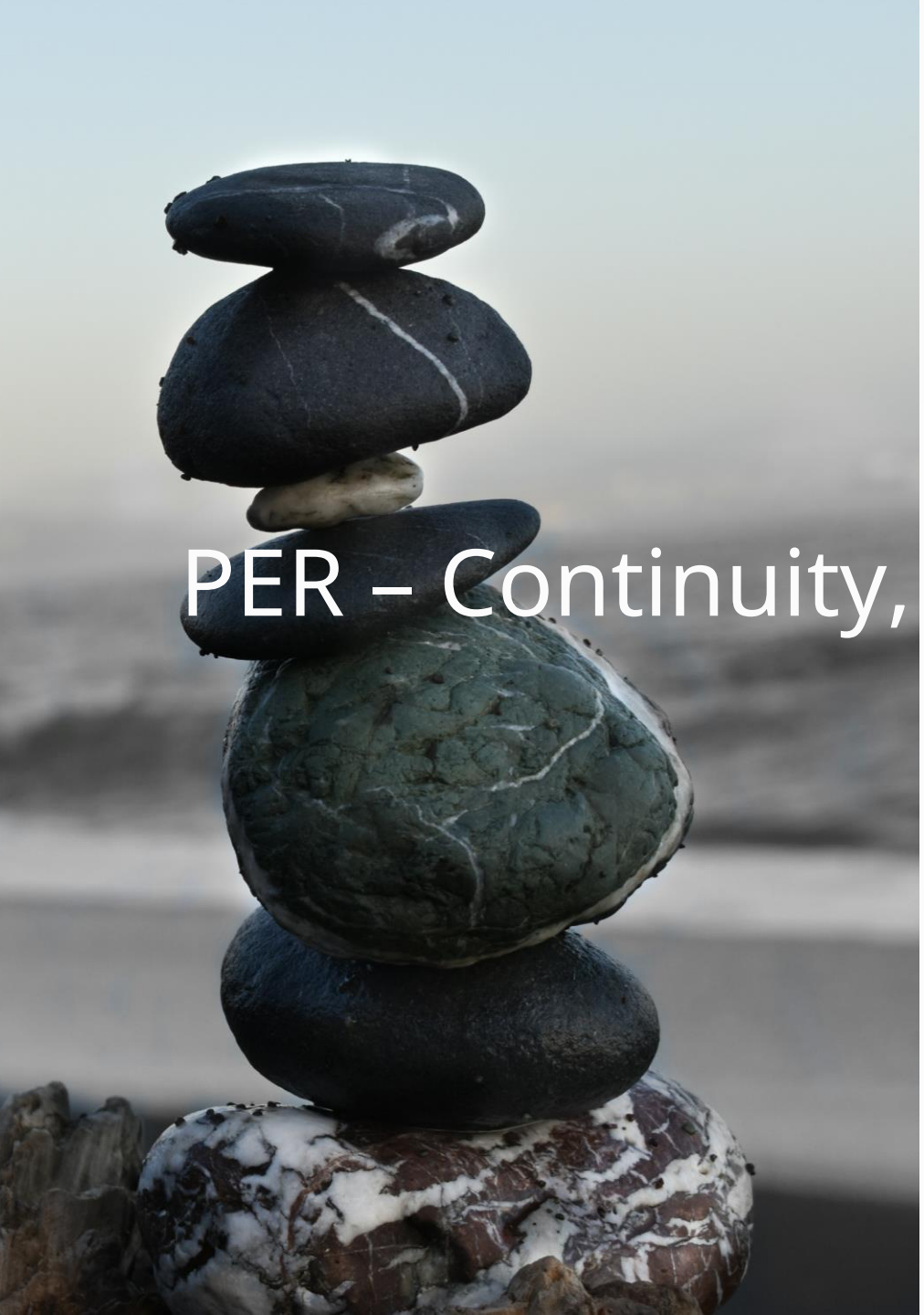
Performance Evaluation Under the In Vitro Diagnostic Regulation – Part 2

Performance Evaluation Report - Contents

The PER requirements are covered in Section 1.3. This is divided into three Sections: **1.3.1, 1.3.2** (consider these in the context of pre-certification), and Section **1.3.3** (post certification and continuous, life cycle).

- Sections 1.3.1 & 1.3.2
- The PER is the culmination of all the objective evidence documented in the SVR, APR & CPR.
- The data and conclusions drawn from this assessment shall constitute the clinical evidence for the device.
- Section 1.3.2 contains 6 indents stipulating contents of the PER – ensure they are addressed with rationales applicable to the device and in line with the clinical evidence generated.

- Section 1.3.3 addresses the life-cycle element of the device – which is objectively assessed via the Performance Evaluation – which is documented by the PER.
- Post certification/PMS activities feed into the continuous appraisal of the PER.
- Data changes – PER is updated.
- Have mechanisms to allow this in a realistic, functional way.
- This is the functional integration of PMPF out puts, but only if PMPF is appropriate/required.



PER – Continuity, Not Conflict

- The PER is generated from the outputs of the SVR, APR and CPR.
- Following the SVR, APR and CPR - the PER should be a cohesive, conclusionary document that clearly demonstrates and consolidates the overall conclusion.

- The information in the PER should NOT conflict or contradict with information or conclusions made elsewhere in the Performance Evaluation (SVR, APR, CPR) or any other element of the Technical Documentation.
- There should not be new information in the PER – if there is new analytical data or conclusions why is this not in the APR?
- This leads to confusion and ambiguity – cannot certify ambiguity.

PER – Format

The format is the at the manufacturer's discretion. There are multiple ways to structure and convey this information.

The PER can be a standalone document.

It can be a large document that contains the PEP, SVR, APR, CPR, PER.

The PER can be a brief document with conclusionary statements with links to the individual SVR, APR, CPR.

However, ensure that:

The conclusions are clear and unambiguous.

All conclusions are traceable and align with the data already provided.

The PER satisfies the requirements of Annex XIII 1.3.

PER – Clear Statements

The conclusions must be clear and robust enough to stand on their own.

Not like an in-person audit where you can ‘talk’ to the evidence and provide context.

Litmus test: read the conclusions documented in the PER – if you need to speak to provide further context then the PER needs to be revised to have those statements documented.

Clinical Performance Studies (CPS)

Requirements are extensively documented in Annex XIII, Part 2.

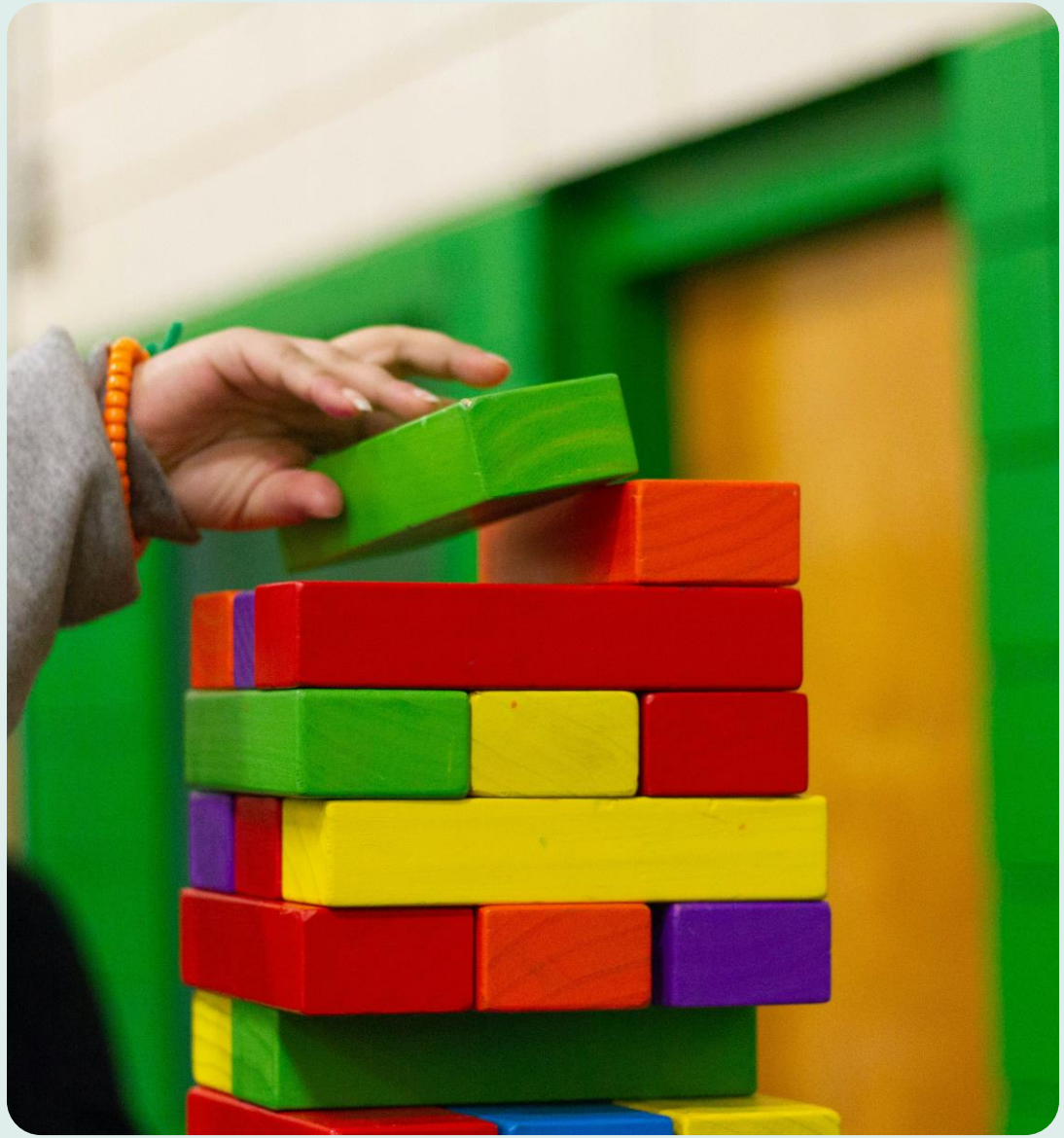
- Plan as per 2.3.2, Report as per 2.3.3. Provide rationales for any deviations.

CPS are not required for all devices but do not be tempted to side-step justifications for why CPS are not conducted – robustly and directly identify what the regulatory and performance strategies were (Annex XIII 1.2.3) and why they are appropriate to satisfy overall requirements with objective evidence.

For new to market devices a CPS would generally be expected as there would not be sufficient evidence in the form of scientific peer-reviewed literature and there would be no routine diagnostic data available.

PMS - The Fundamental Requirements

- Chapter VII and Annex III
- Article 78 – PMS System of the Manufacturer
- Article 79 – The Plan – Links the Annex III
- Article 80 – PMS Report (Class A & B, updated when necessary and made available upon request)
- Article 81 – PSUR (Class C & D, updated at least annually)



Post Market Surveillance

Use Annex III as a scaffold on which to build and optimise your Post Market Surveillance plan.

Ensure the minimum requirements are met.

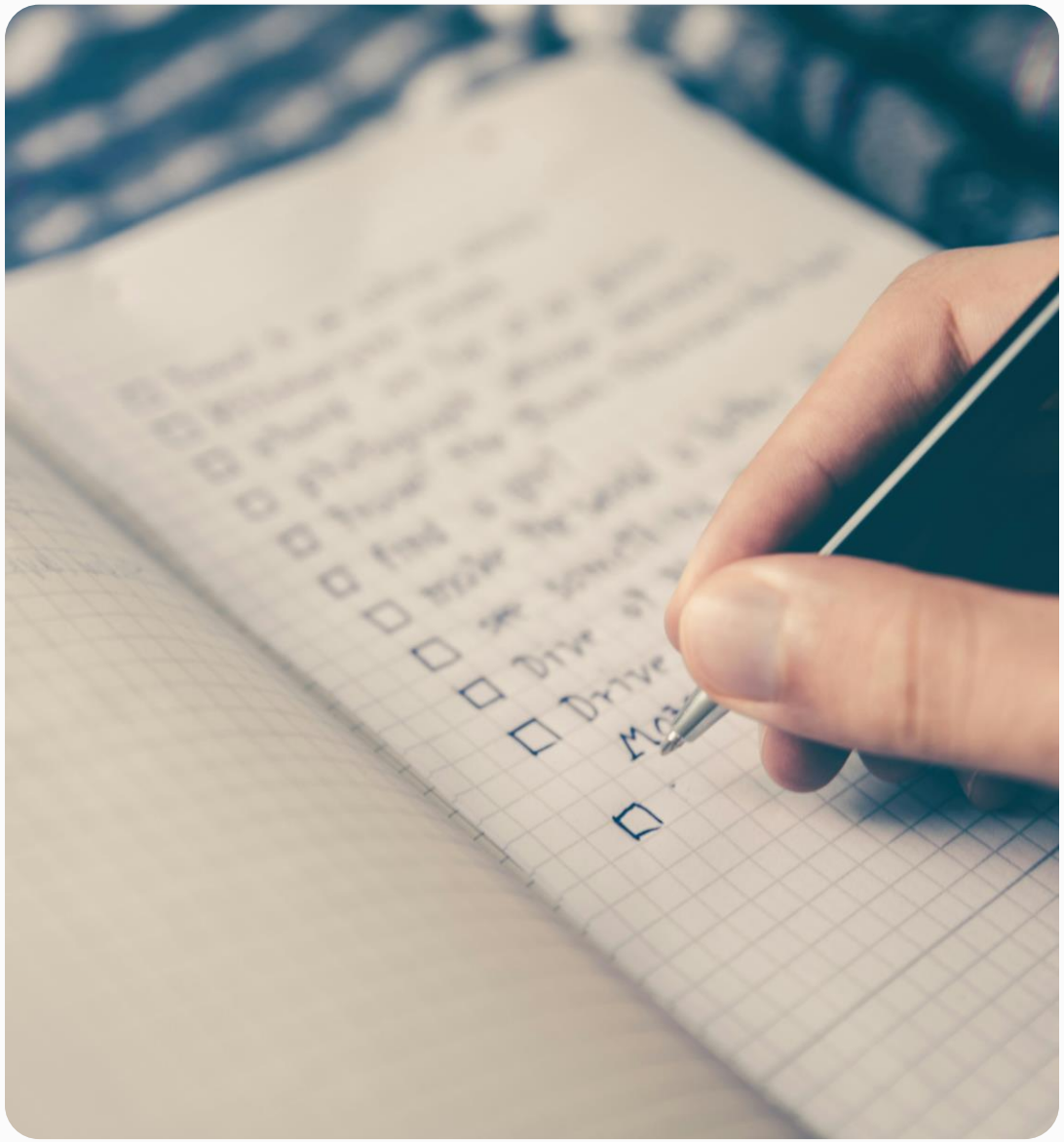
But it is not just a tick box exercise – expand and customise to suit you device, unit numbers, nuances applicable to your device that generate usable data to help drive accurate conclusions relating to safety and performance.

Annex III, 1 (a) states: The post-market surveillance plan shall address the collection and utilisation of available information, **in particular** (6 indents): make sure each are addressed. Expand **as needed**.

Annex III, 1 (b) states: The post-market surveillance plan shall cover **at least** (10 indents): make sure each are addressed. Expand **as needed**.

A Natural Checklist

- Remember that Annex III is a natural Checklist.
- Review your documentation sequentially through Annex III, Parts (a) and (B).
- This is what the Notified Body will do – if you can’t link your documentation to each indent, then neither can we.
- Note – any aspect of the Regulation that is documented as numbered points or indents can be used a checklists to compare against the technical documentation.



Post Market Performance Follow-Up (PMPF)

Important distinctions

- PMPF is **part** of PMS.
- When conducted, PMPF has specific requirements – but it is not a requirement to perform PMPF in all conditions – there should be a rationale for performing PMPF activities.
- PMPF is a PMS tool utilised to support Performance Evaluation when supplementary and supportive data may be required.

Do I Need a PMPF Plan & Study

It depends – but it is always driven by objective data with clear objectives.

- The conclusions of the Performance Evaluation will indicate whether PMPF is required or not.

- The final conclusions of the PER may determine that at present the device meets the performance and safety requirements given the benefit-risk profile of the device. However, there may situations where elements/analytes of the device require monitoring or real-world data to support/amend the performance and safety claims into the future (examples covered in this presentation).

- This is where PMPF is **focal,** whereas PMS overall is **broad.**

Again, be aware of the distinction.

PMPF…

…is not always needed.

But PMPF is *always* considered.

- Annex III, 1, (b), final indent states: a PMPF plan as referred to in Part B of Annex XIII, or a justification as to why a PMPF is not applicable.

- The PMS plan should consider mechanisms where a PMPF may be initiated in the future – adverse events, changing SOTA, complaints etc.

Examples

Health warning.

The following examples are simplified and describe general situations.

They do not represent the full extent of expected Performance Evaluation and PMS/PMPF activities.

Manufacturers responsibility to evaluate the needs and applicability of requirements in the context of their device.

Example 1 – Effective PER

Devices for the aid in diagnosis of an established disease but using a novel marker.

Device used a novel marker and unconventional sample type.

State of the art was demonstrated based on scientific literature and comparison of the performance of the device under review with other markers commonly used for diagnosis.

Analytical data demonstrated concordance with established methods. Clinical Performance demonstrated via Scientific Peer-Reviewed Literature and other Supporting Studies.

The PER had clearly documented the all elements in a cohesive, sequential manner addressing and highlighting novelties and supporting them with objective evidence rather than side-stepping them.

Example 2 – Effective PMPF

IVD - SaMD utilizing Machine Learning.

Manufacturer identifies that this mode of action is susceptible to learning bias.

Performance and Safety claims were demonstrated in the context of the Intended Purpose at time of certification, manufacturer identified device may be susceptible to drift over time due to the bias.

PMPF established in conjunction with other ‘standard’ PMS activities.

A strategy illustrating the understanding that PMS **retroactively** feeds into their PE (wait for data) while the PMPF **proactively** feeds into their PE (seeking possible/expected data).

Example 3 – Effective PMPF Linking Back to PER

Companion Diagnostic (CDx) IVD.

A device to detect multiple mutations; device detects 7 mutations with CDx application/therapies and 5 other less common mutations which might be of interest.

The less common mutations do not have CDx claims but are indicated for patient management.

PMPF established with the focus on the 5 less common mutations.

(1) The 5 less common mutations indicated for patient management had limited Clinical Data due to the low prevalence of these mutations, however they had robust Scientific Validity and Analytical Performance results – function of PMPF was to provide further Clinical Data.

(2) Potential that these less common mutations may in future have a change in SV, and they may become CDx biomarkers in the future. Function of PMPF is to monitor these markers for a change in the scientific validity associated with their indications.

Example 4 – Effective PMPF

Device for a broad panel of markers that has a mixture of both CDx and Tumor Profiling claims.

CDx biomarkers can become associated with more therapies, or new cancer types.

Tumor profiling biomarkers can become associated with new therapies/ cancer types.

PMPF established to monitor these markers in the context of Scientific Validity relating to the causal link to new therapies/cancer types over time.

Thank you – questions?

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