IVDR Breakout
IVDR Clinical evidence and performance evaluation
IVDR – Performance Evaluation
Clinical Evidence

• New requirement for Clinical Evidence

• *Clinical evidence* = *clinical data and performance evaluation results, pertaining to a device of sufficient amount and quality to allow a qualified assessment of whether the device achieves the intended clinical benefit and safety, when used as intended by the manufacturer*

• Based on harmonised guidance

• **GHTF documents** (IMDRF archive):
  - Clinical Performance Studies for In Vitro Diagnostic Medical Devices
  - Clinical Evidence for IVD Medical Devices – Key Definitions and Concepts
  - Clinical Evidence for IVD Medical Devices – Scientific Validity Determination and Performance Evaluation
Clinical Evidence

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‘Clinical benefit’ consideration

Clinical benefit of an IVD = Accurate medical information ≠ Final clinical outcome
Performance Evaluation

**Process** of obtaining clinical evidence = Performance Evaluation

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

- Collated as a **Performance Evaluation Report**

- Continuous during life-time of the device
Clinical Performance

Ability to yield results that relate to a particular clinical condition or physiological state for the intended use and in accordance with target population, and where applicable to the intended user.

Data to support diagnostic accuracy compared to reference test; information related to expected values.

Scientific Validity

Refers to the association of an analyte to a clinical condition or physiological state.

For established analytes, this may be from literature; but for novel analytes or companion diagnostics this would need to be established.

Analytical Performance

Refers to the ability of an IVD medical device to correctly detect and measure a particular analyte.

Performance requirements similar to IVD Directive essential requirements.
Expectations for Performance

**Performance Evaluation Plan**, as well as a file of **Clinical Evidence** will form part of the Technical Documentation, as a **Performance Evaluation Report**

- **Clinical Performance studies** may be required, unless justified

**Interventional performance studies** – new requirements

- In line with clinical trial expectations for clinical trials of medicinal products

**Clinical Evidence** will need to be updated

- Consolidated text states if there has been a ‘trigger’, then the PE Report will need updating

**Post-market Surveillance** and **Post-market Performance Follow-up (PMPF)**
6. Scrutiny
Additional scrutiny of High Risk devices
So you have your CE certification…
Maintaining your certification

• **Vigilance requirements**
  - Incident Reporting
  - Trending

• **Post-market Surveillance Plan & Post-market Surveillance**
  - Reviewed as part of Surveillance visits
  - Post-market surveillance Report (Class A & B); or
  - Periodic Safety Update Reports (Class C & D)

• Maintaining **Clinical Evidence**

• **Post-market Performance Follow-up (PMPF)**

• For **Class C & D devices**, updates to the **Summary of Safety and Performance**, at least annually
  - Will be publicly available
QMS as part of the conformity assessment process

Certificates issued under Annex IX - *surveillance*

**Class C**

1. **EU Quality Management System certificate** (Annex IX, I & III)
   - Substantial changes
     - Potential audit or assessment
     - Supplement to EU QMS certificate
   - Annual surveillance audits
     - Inc Post-market Surveillance Plan
   - Unannounced on-site audits, at least every 5 years
   - Sampling of technical documentation

**Class D & Others specified**

1. **EU Quality Management System certificate** (Annex IX, I & III)
   - Surveillance as per C (without sampling)
2. **EU Technical Documentation Assessment certificate** (Annex IX, II)
   - Significant device changes
     - Potential conformity assessment or supplement to EU Tech Doc Assessment certificate
     - Possible Ref Lab consultation if changes impact compliance with the Common Specification (Class D)
   - On-going verification of manufactured batches (Class D)

*Self-test and near patient tests, Classed B-D; Companion Diagnostics*
Where can I find full details of the changes?

bsigroup.com/MDR-revision
bsigroup.com/IVDR-revision

Webinars: bsigroup.com/webinars
Whitepapers: bsigroup.com/whitepapers

Please ask if you want any extra information from BSI.
Questions & Answers
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