

Understanding the QMS Requirements under the IVD Regulation

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By Royal Charter

bsi.

Welcome!



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Disclaimer



- Information presented is based on our current understanding of the IVDR
- Subject to change!

Requirements of the Quality Management System

- a. Regulatory Compliance strategy
- b. GSPRs
- c. Management responsibility
- d. Resource management
- e. Risk Management
- f. Performance evaluation
- g. Product realisation
- h. UDI
- i. Post-market surveillance system
- j. Communication with competent authorities
- k. Incident reporting & FSCA
- l. CAPA management
- m. Monitoring & measurement

Art
10(8)

Annex
IX

QMS Assurance conformity assessment process

Quality Management System Assurance under the IVDR




What will be needed...

- Application to a NB
- QMS certification with a scope to cover the processes / technologies / devices
 - QMS assessment by a NB for the purposes of CE marking
 - **ISO 13485 + On-site 'upgrade' to IVDR requirements**
- Submission of technical documentation for review
 - Dependent on the device risk and scope
- Additional processes for Class D devices, Companion diagnostics

QMS Audit

- An on-site audit will be required to certify to IVDR requirements
- The audit scope must cover all devices/device groups that you wish to certify
 - Consider if you are doing your device portfolio 'in stages'
 - **IVDR audit may be done at the time of a routine audit (with additional audit time) or a special audit if not an existing customer**



See BSI
webinar!

QMS Audit



IVDR initial audits, not gap analysis to existing directive

MDCG 2019 – 6: Requirements relating to NBs

IV. PROCESS REQUIREMENTS

IV.1. Do devices certified under the Directives need to be subject to a full conformity assessment under the new Regulations if the manufacturer applies for certification under the MDR / IVDR?

The conformity assessment activities described under Article 52 / Article 48 apply to any certificate issued under the new regulations. As no exceptions were established under the regulations for the migration or transfer of MDD/AIMDD/IVDD certificates to the MDR / IVDR the general provisions should apply. Therefore, all devices to be certified under the MDR / IVDR should be subject to an initial certification according to the applicable annex. **The notified body should ensure that all requirements under the MDR / IVDR are fulfilled. It may not restrict its procedures to gap audits or gap file reviews.**

QMS Audits – You can help us by

PRRC in place – principles in MDCG 2019-7

Procedures /plans/templates in place even if EU Provisions (EUDAMED etc) are not ready

Plans as required by IVDR in place

Provisions for UDI in place

Vigilance/PMS provisions in place

Provisions in place for monitoring the publication of guidance documents and plans in place for implementing them

QMS Audits & COVID-19

MDCG 2020-4

Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions

April 2020



 IAF Mandatory Document

IAF MANDATORY DOCUMENT FOR
THE USE OF INFORMATION AND
COMMUNICATION TECHNOLOGY (ICT)
FOR AUDITING/ASSESSMENT
PURPOSES

Issue 2

(IAF MD 4:2018)



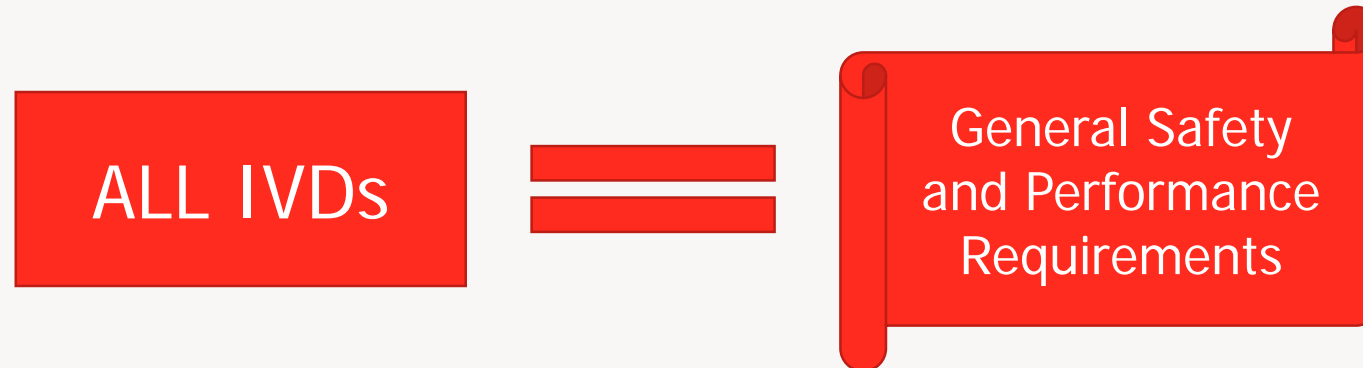
Strategy for Regulatory Compliance

- Article 10 – General obligations of manufacturers
- The quality management system shall address at least the following:
 - (a) a **strategy for regulatory compliance**, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system
- Annex IX Section 2.2 (c):
- The **strategy for regulatory** compliance to include processes for:
 - Identification of relevant legal requirements
 - Qualification
 - Classification
 - Handling of equivalence
 - Choice of and compliance with conformity assessment procedures



General Safety and Performance Requirements

- GSPRs are outlined under Annex I of IVDR
- **ALL IVDs** need to meet the requirements of the GSPRs
 - Devices that are within the scope of the IVDR
 - Including IVDs that have an EU In-house exemption
- For devices that are under performance evaluation, certain requirements of Annex I will still apply



General Safety and Performance Requirements

IVDD Essential Requirements



IVDR General Safety & Performance Requirements



The General Safety and Performance Requirements (Annex I) apply to all IVDs in order to conform and apply the CE mark under the IVDR.

- For devices under performance evaluation certain requirements will still be applicable
- Includes devices that are used in EU Institutions under exemption



Requirements are dependent on the device, therefore, audits will be needed of all existing devices to transition to the IVDR



New IVDs and existing CE-marked IVDs will need to comply with these requirements by 26 May 2022 (end of the transition period)

What we will look for...

- ✓ We will assess against all points under Annex I (GSPRs)
 - ❖ Note specific labelling requirements (chapter III)
 - ❖ Note specific information for the Instructions For Use (IFU, 20.4)
 - 20.4.1 The instructions for use shall contain all of the following particulars...
- ✓ We will assess against all points under Annex II (Technical documentation)
- ✓ We will assess against all points under Annex XIII (Performance Evaluation & Clinical Evidence)

*Make it as easy
as possible for
your Assessor!*

Management Responsibility



5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:

- a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements;
- b) establishing the quality policy;
- c) ensuring that quality objectives are established;
- d) conducting management reviews;
- e) ensuring the availability of resources.

Resource Management



Human Resources

- Competence of personnel
- Training
- Effectiveness evaluation
- Awareness and Contribution to quality objectives
- Records of education, training, skills and experience maintained



Infrastructure

- buildings, workspace and associated utilities
- Process equipment
- Supporting services



Work Environment & Contamination Control

- Health, cleanliness and clothing of personnel
- Competence of staff working temporarily under special environment

Control of Suppliers



Critical Subcontractors and Crucial Suppliers

Regulatory considerations



Risk management

Expectations under the
IVDR



Risk Management Documentation

Required throughout product realization, must be maintained

Specifically required in

- 7.1 Planning of product realization
- 7.2 Customer related processes
- 7.3 Design and development
- 7.4 Purchasing
- 7.5 Production and service provision
- 7.6 Control of monitoring and measuring devices

- Risk management plan
- Risk analysis
- Risk evaluation (as defined in the standard)
- Risk control decision and proposed control measures
- Verification of risk control measures (effectiveness and implementation)
- Assessment of residual risk
- Benefit/Risk analysis and report
- Risk management report
- Results of an nonconformities, investigations, or CAPA activities in manufacturing and/or post marketing that impact product safety and any changes resulting from these activities *

* This section is often missing.
Must be part of the system.

Risk Management

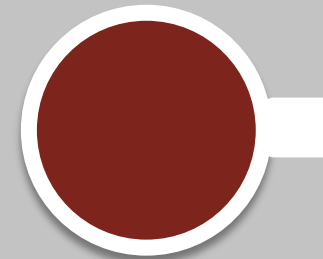
Think of risk management as the pipes connecting different parts of the product lifecycle.

Risk management tools are the taps which adjust how much effort you need to run through the system to address an issue.



Risk Management Report

- Summary of all risk management activities
- Benefit Risk statement is included
- Life cycle activities in place and implemented



Important Aspects of Annex XIII – Performance Evaluation

- Performance evaluation is a **continual** process
- The stated **Intended use/purpose** statement is critical for setting the clinical evidence required
- Driven by a Performance Evaluation **Plan**
 - See Annex XIII!

Including:

- Target population = intended purpose
- Description of state of the art
- Acceptability of risk:benefit

Article 56 –
Performance
evaluation
and clinical
evidence

Annex XIII –
Performance
evaluation,
performance
studies and post-
market
performance
follow-up

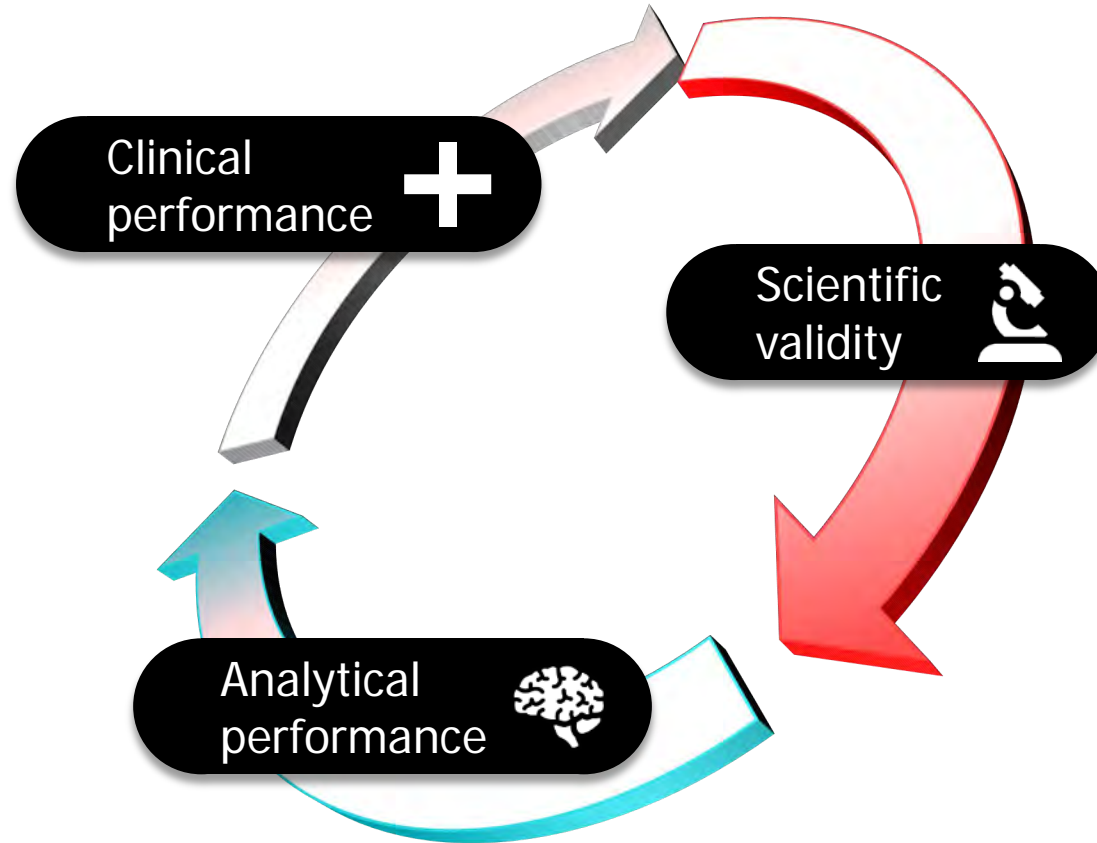
Important Aspects of Annex XIII – Performance Evaluation

- Performance evaluation – thorough and **objective**, considering **both favourable and unfavourable data**.
 - Depth and extent **shall be proportionate** and appropriate to the characteristics of the device including the risks, risk class, performance and its intended purpose.
- Output will lead to **Plan for Post-Market Performance Follow-up (PMPF)**
- ✓ Justify if PMPF is NOT required!

Looking back to Clinical Evidence

Performance evaluation

- Sum total = **Clinical evidence**
 - *Process* of performance evaluation
 - Done according to a **performance evaluation plan**
 - Collated as a **performance evaluation report**
- Continuous during life-time of the device



Clinical Evidence

- The Performance Evaluation will be a critical part of the technical documentation
- ...we will look for:
(reviewed against Annex II, III & XIII)

❖ Performance Evaluation Plan

❖ Performance Evaluation Report

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

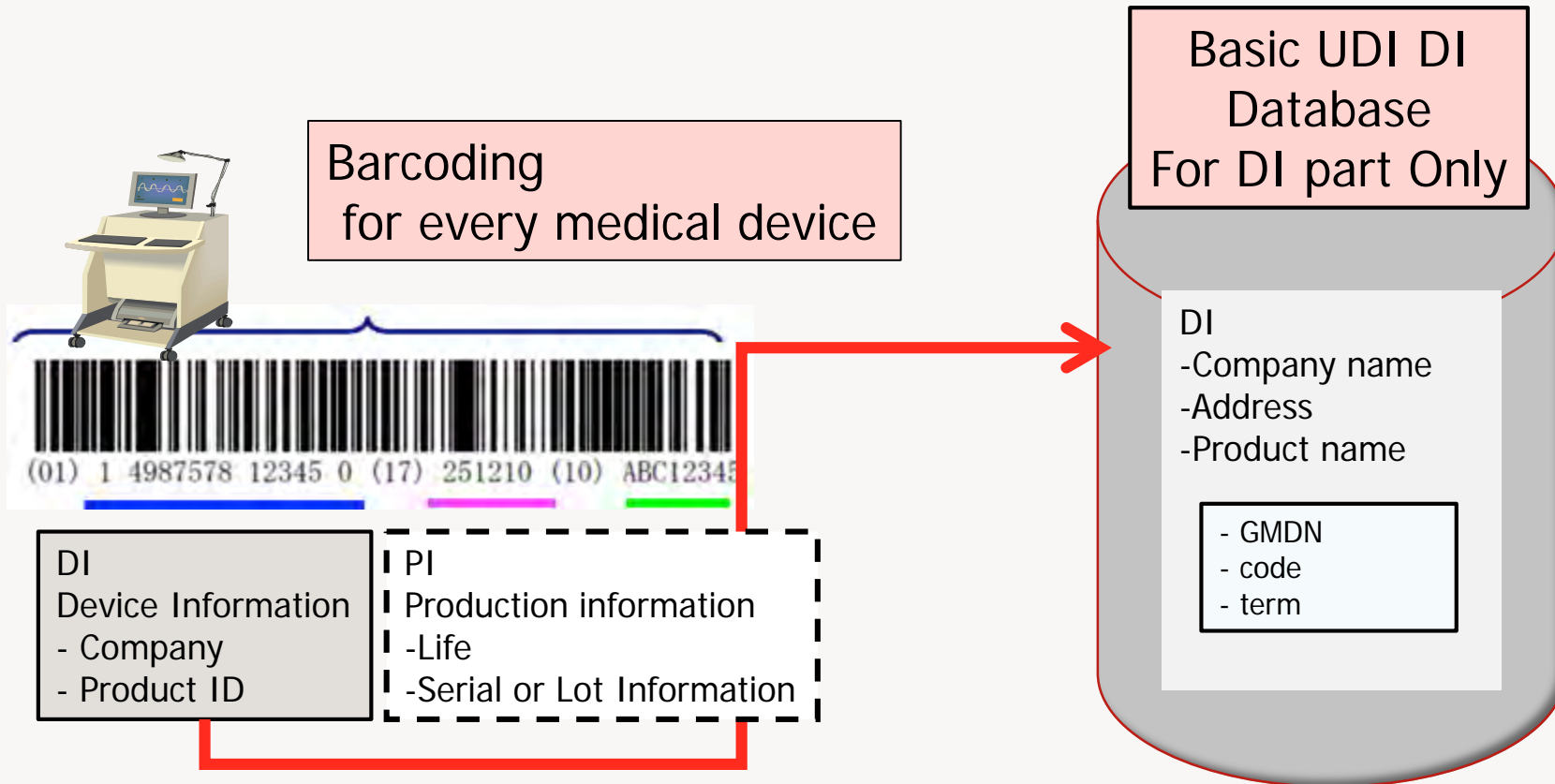
❖ Post Market Performance Follow-up Plan

- 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.)

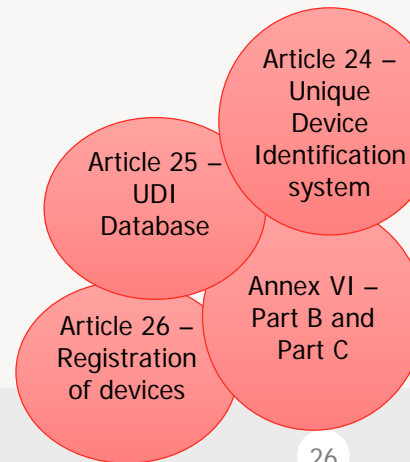
❖ Summary of Safety and Performance

- Class C & D

Unique Device Identifier (UDI)



Manufacturer specific; your NB will expect that you will have this planned for your devices!



Post Market Activities

PMS: Post Market Surveillance

PMPF: Post Market Performance Follow Up

PSUR: Periodic Safety Update Report

PMS



Post Market Plans – IVDR

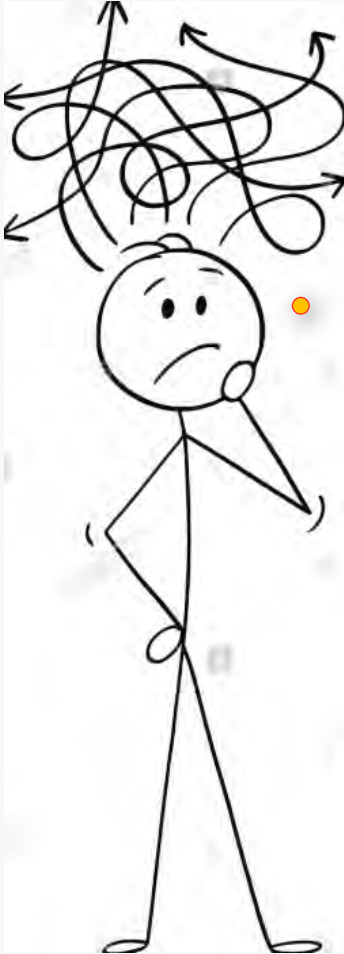
Post Market Surveillance Plan Annex III

- proactive and systematic process
- allow a correct characterisation of the performance of the devices
- allow a comparison to be made between the device and similar products available on the market
- effective and appropriate processes to assess the data, complaints, market-related experience
- suitable indicators and threshold to continuously reassess benefit-risk analysis / risk management
- methods and protocols to manage trend reports, including the methods used to establish any statistically significant increase in the frequency or severity as well as the observation period
- methods and protocols to communicate effectively with CAs, NBs, EOs and users
- reference to procedures to fulfil the manufacturers obligations laid down in Articles 78 (PMS System), 79 (PMS plan) and 81 (PSUR)
- systematic procedures to identify and initiate appropriate measures including corrective actions
- effective tools to trace and identify devices for which corrective actions might be necessary
- **PMPF plan** (Annex XIII Part B), or a justification as to why a PMPF is not applicable.

Post Market Performance Follow-up Plan Annex XIII part B

- (a) the general methods and procedures of the PMPF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data
- (b) the specific methods and procedures of PMPF to be applied (e.g. evaluation of registers or PMPF studies)
- (c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b)
- (d) a reference to the relevant parts of the performance evaluation report referred to in Section 1.3 of Annex XIV and to the risk management referred to in Section 3 of Annex I
- (e) the specific objectives to be addressed by the PMPF
- (f) an evaluation of the clinical data relating to equivalent or similar devices, and the current state of the art
- (g) reference to any relevant CS, harmonised standards when used by MFR, relevant guidance on PMPF
- (h) a detailed and adequately justified time schedule for PMPF activities (e.g. analysis of PMPF data and reporting) to be undertaken by the manufacturer

Communication with Competent Authority



How will the NB/CA interaction work?

Incident Reporting

Manufacturers are required to use MIR form version 7.2 - became mandatory from 1st April 2020 for incident reporting and vigilance incident reports must be submitted via the eVigilance portal.

In May, the EU Commission published an updated version of the form MIR 7.2.1 which becomes mandatory from **January 2021**.

Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD)

Reporting Template Version 7.2.1
European Union Medical Devices Vigilance System

Section 1: Administrative information			
1.1 Corresponding competent authority			
a	Name of receiving national competent authority (NCA)		
b	EUDAMED number of NCA		
c	Reference number assigned by NCA for this incident		
d	Reference number assigned by EUDAMED for this incident		
1.2 Date, type, and classification of incident report			
a	Date of submission <small>(e.g. 2012-10-23)</small>	b	Date of incident <small>(e.g. 2012-10-23)</small> to
c	Manufacturer awareness date <small>(e.g. 2012-10-23)</small>		
d	Type of report <input type="radio"/> Initial <input type="radio"/> Follow up <input type="radio"/> Combined initial and final <input type="radio"/> Final (Reportable incident) <input type="radio"/> Final (Non-reportable incident)		
e	In case of initial and follow-up reports, please indicate the expected date of the next report <small>(e.g. 2012-10-23)</small>		
f	Classification of incident <input type="radio"/> Serious public health threat <input type="radio"/> Death <input type="radio"/> Unanticipated serious deterioration in state of health <input type="radio"/> All other reportable incidents		
1.3 Submitter information			
1.3.1 Submitter of the report			
a	<input type="radio"/> Manufacturer <input type="radio"/> Authorised representative <input type="radio"/> Other, please specify		
b	Manufacturer's reference number for this incident		

New MIR form version 7.2.1



- Changes are minor and mostly address inconsistencies/disparities between the actual validations built into the MIR form version 7.2 vs the guidance provided in the associated XSD files and Helptext.



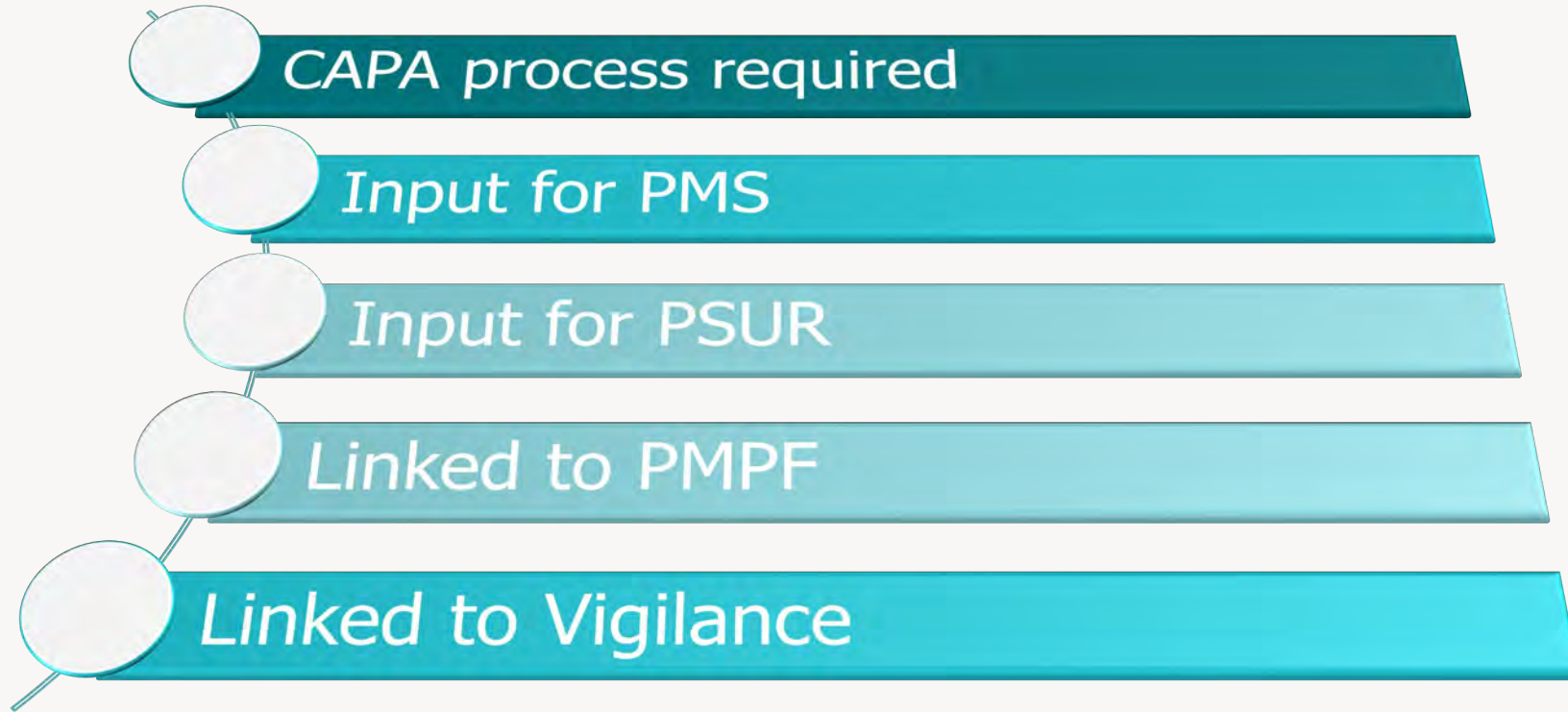
- BSI vigilance portal is in the process of being updated to accept reports using MIR 7.2.1



- In the interim, any reports using version 7.2.1 of the MIR form should be submitted to VigilanceReports@bsigroup.com by the manufacturers (we will accept only MIR 7.2.1 forms into this mailbox)

A notice will be added to the client's vigilance portal interface to reflect this.

CAPA management



IVDR resources

Our website provides a wealth of resources including guidance documents, training courses, webinars and whitepapers

To find out more, visit

bsigroup.com/medicaldevices/IVD

Contact us

Email: eu.medicaldevices@bsigroup.com

Call: +44 345 080 9000



Useful links:

- Official EU website with information for IVD Manufacturers:

https://ec.europa.eu/growth/sectors/medical-devices/getting-ready-new-regulations/manufacturers-ivd_en

- Competent Authorities for Medical Devices FAQs site:

https://www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_IVDR_180117_V1.0-1.pdf

- EU factsheet for IVD manufacturers with details of transitional provisions:

<https://ec.europa.eu/docsroom/documents/33662/attachments/1/translations/en/renditions/native>

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