Getting ready for In Vitro Diagnostic Regulation (IVDR)

Meet our speakers

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GENOMIC ANALYSIS BY LGC

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The importance of Intended Purpose and the IVDR

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Definition IVD

- *in vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:
  - (a) concerning a physiological or pathological process or state;
  - (b) concerning congenital physical or mental impairments;
  - (c) concerning the predisposition to a medical condition or a disease;
  - (d) to determine the safety and compatibility with potential recipients;
  - (e) to predict treatment response or reactions;
  - (f) to define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be *in vitro* diagnostic medical devices;

You have to justify why your product is an IVD and relate it back to the definition in your Technical File

Research use only, General Lab Use, and devices invasive in a body orifice are NOT IVDs

Intended purpose

'Intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the performance evaluation.

- The requirement is now much more prescriptive and may drive the need to update the intended purpose stated in the IFU.
- Annex II, 1.1c the intended purpose should detail:
  - What is being detected/measured
  - Intended function (e.g., screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, or companion diagnostic)
  - Specific disorder, condition, or risk factor the test is intended to detect, define, or differentiate
  - Whether or not the test is automated
  - Whether test is qualitative, semi-quantitative, or quantitative
  - Who is the intended user?
  - Intended population if applicable
  - Specimen type
- **Data is needed to support each intended use**

Claims

New requirement – must have data to support each claim

- **Article 7 Claims**
  In the labelling, instructions for use, making available, putting into service and advertising of devices, it is prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

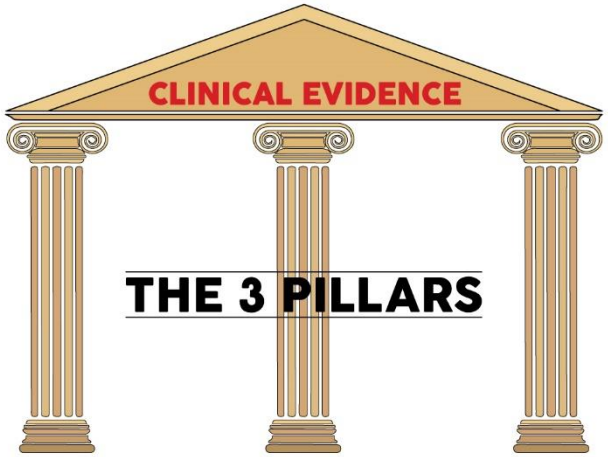
  (a) ascribing functions and properties to the product which the product does not have;

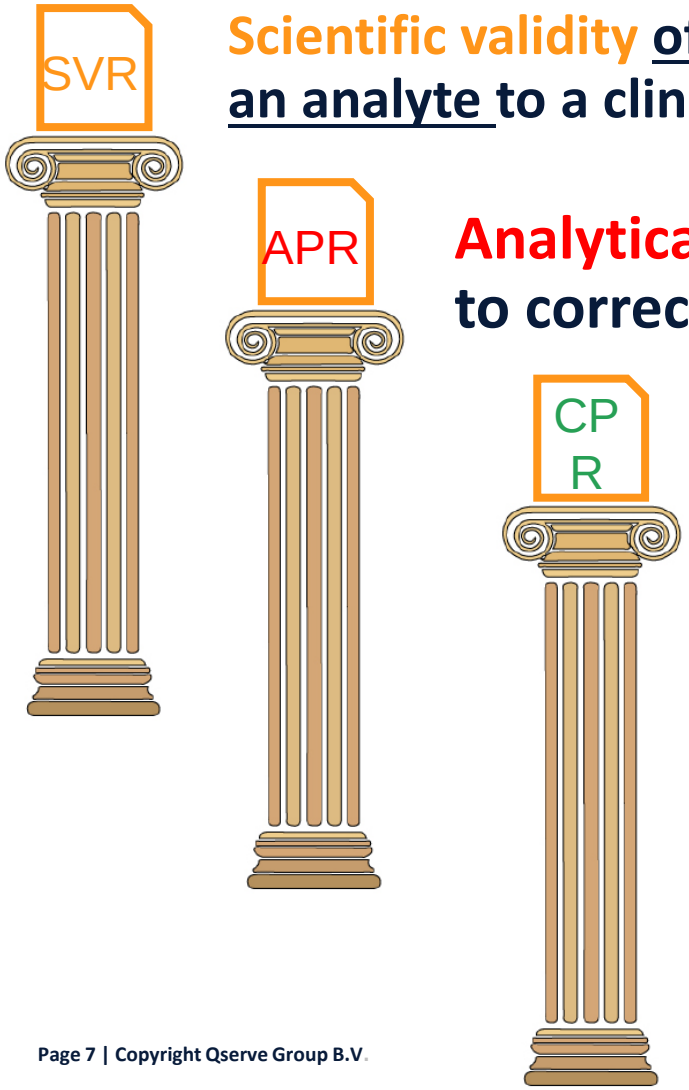
  (b) creating a false impression regarding treatment or diagnosis, functions or properties which the product does not have;

  (c) failing to inform of a likely risk associated with the use of the product in line with its intended purpose;

  (d) suggesting uses of the product other than those declared in the intended purpose when the conformity assessment was carried out.

Performance Evaluation



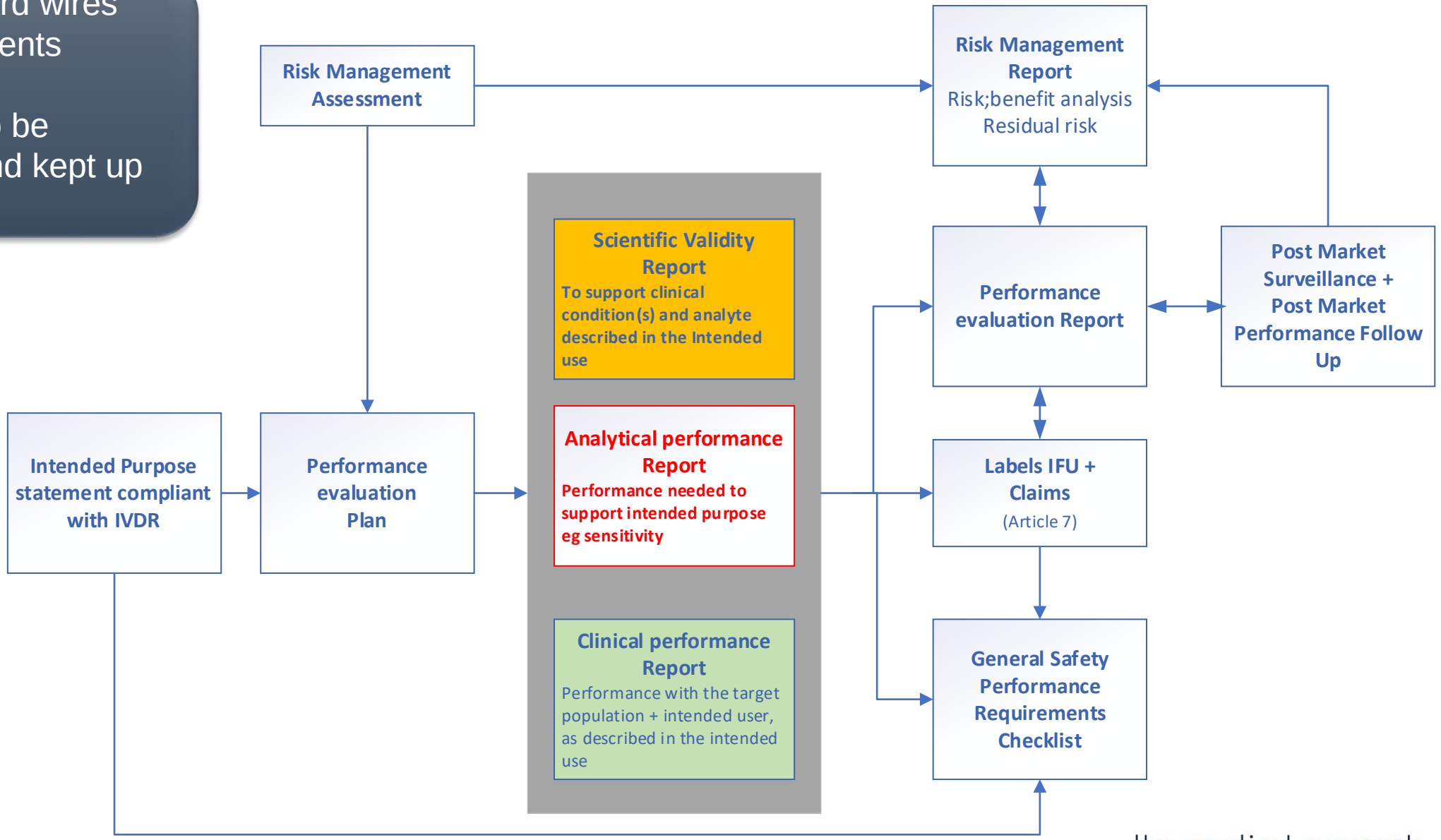


Scientific validity of an analyte means the association of an analyte to a clinical condition or a physiological state;

Analytical performance means the ability of a device to correctly detect or measure a particular analyte

Clinical performance means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user

- The IVDR hard wires these documents together
- They need to be consistent and kept up to date



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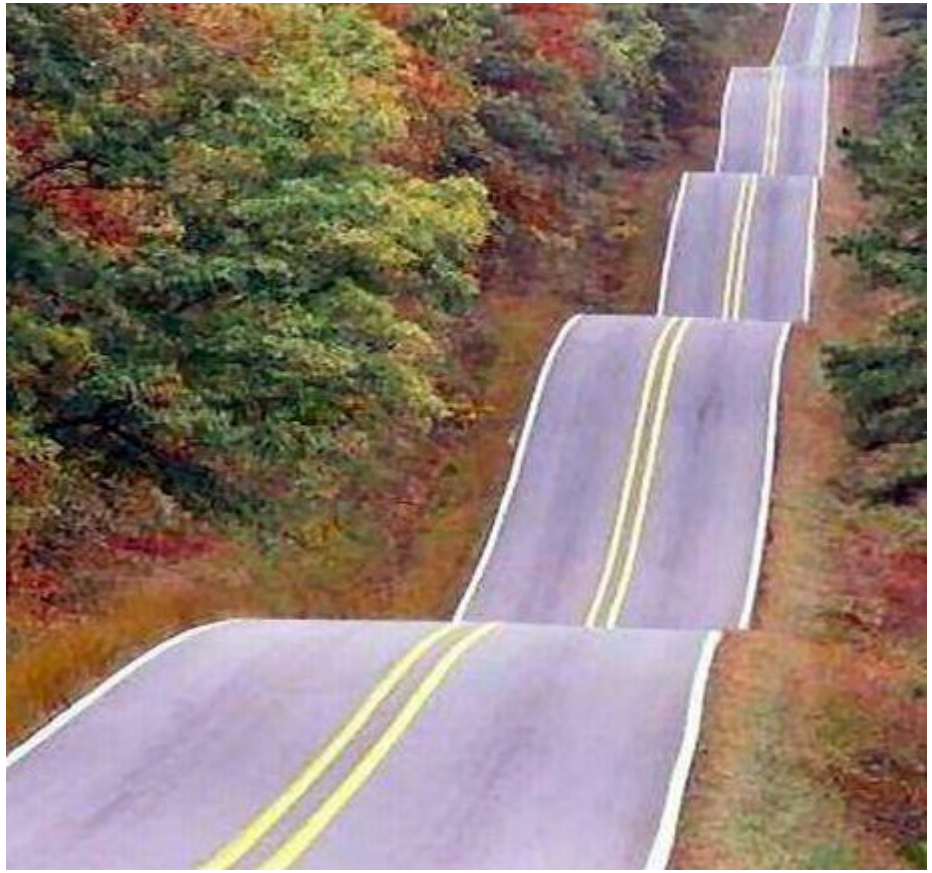
Map to the Intended Purpose

i. what is to be detected and/or measured;
ii. its function such as screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic;
iii. the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;
iv. whether it is automated or not;
v. whether it is qualitative, semi-quantitative or quantitative;
vi. the type of specimen(s) required;
vii. where applicable, the testing population;
viii. the intended user;
ix. in addition, for companion diagnostics, the relevant target population and the associated medicinal product(s).

Finally

- Implementing the IVDR will be a bumpy ride
- To start your journey make sure you have defined an intended purpose that meets the IVDR before you start to create your technical documentation
- Next understand the requirements before implementing



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Thank you for your attention

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Responsibilities of the manufacturer

- “When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.” (article 10 (1) IVDR)

BUT

- What if I don’t make the product?
- How do broader marketing claims impact my certification and liability?

What if I don’t make the product?

- Article 16 IVDR – anyone third party becomes manufacturer if he does any of the following:

  a) makes available on the market a device under its own name, registered trade name or registered trade mark (except where he has an agreement with the manufacturer that manufacturer remains responsible and is on the label);
  b) changes the intended purpose of a device already placed on the market or put into service;
  c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected

    - Unless this concerns repacking or translation in accordance with IVDR procedures in article 16 (2) – (4) IVDR

- Another typical situation:

    - Non-CE marked medical device is added to a kit (and the kit is not CE marked as a device in itself)

Claims under IVDR

Article 7 IVDR:

In the labelling, instructions for use, making available, putting into service **and** advertising of devices, it is **prohibited** to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

(a) ascribing functions and properties to the product which the product does not have;
(b) creating a false impression regarding treatment or diagnosis, functions or properties which the product does not have;
(c) failing to inform of a likely risk associated with the use of the product in line with its intended purpose;
(d) suggesting uses of the product other than those declared in the intended purpose when the conformity assessment was carried out.

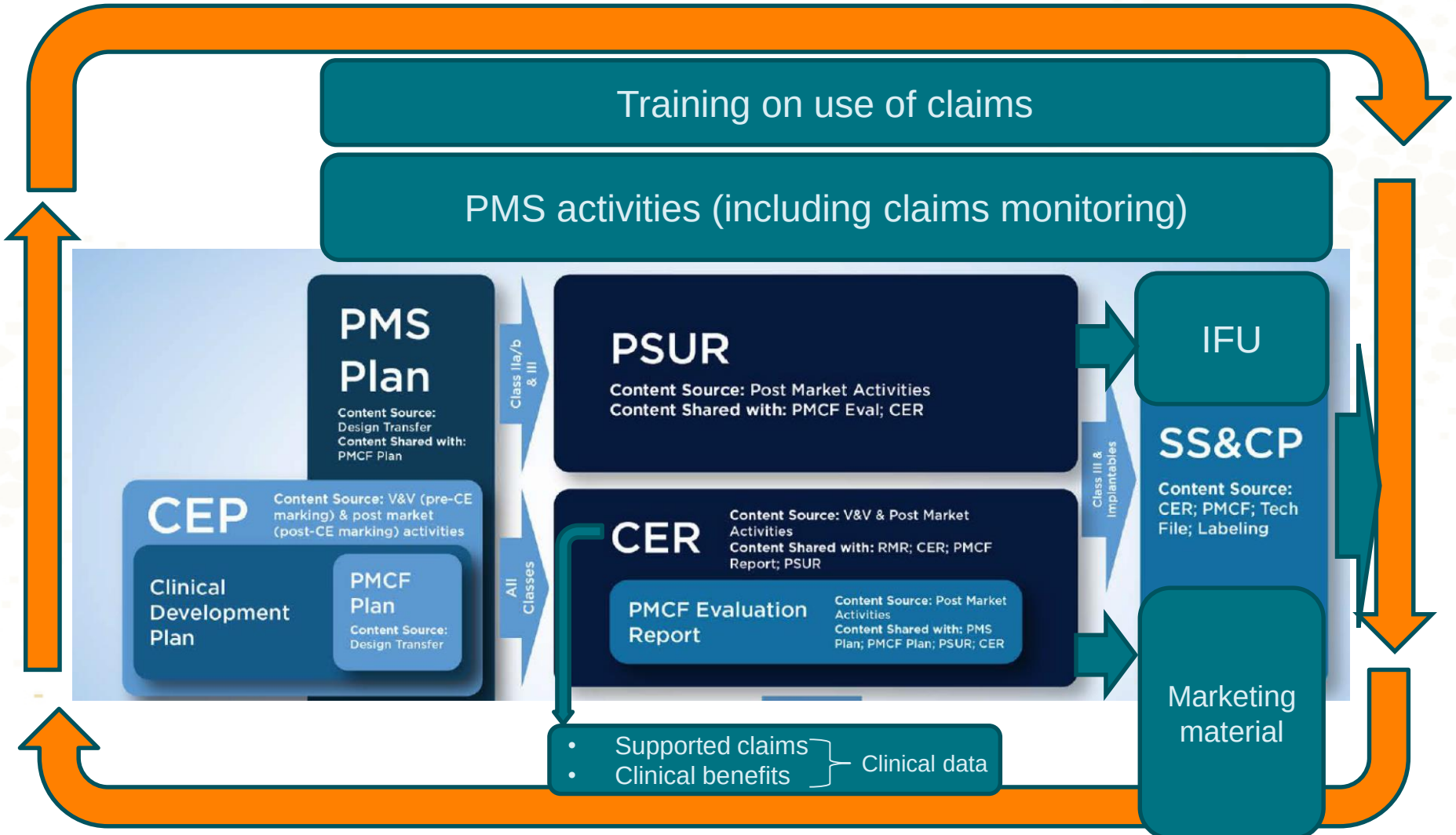
Claims: connected everything

Connected Everything follows from how documents in the technical documentation are linked:

- Clinical benefits and performance parameters are set out in the IFU, as well as specifications for correct and safe use;
- Consistency with the summary of safety and performance (“SSP”) for class C and D IVDR devices, which is based on PER and sets out clinical benefits and any residual risks and any undesirable effects, warnings and precautions (which is a clear link to art. 7 (c)) and links to the IFU;
- Although PMPF does not necessarily require an active process for each claim, there should at least be a general procedure for amending claims based on PMPF findings, because these findings may require the PER to be amended, as these are explicitly continuous lifecycle processes under the IVDR

Golden rule: everything is connected

- Because everything is connected in terms of shared content, everything must be consistent to avoid issues



Thanks for your attention!

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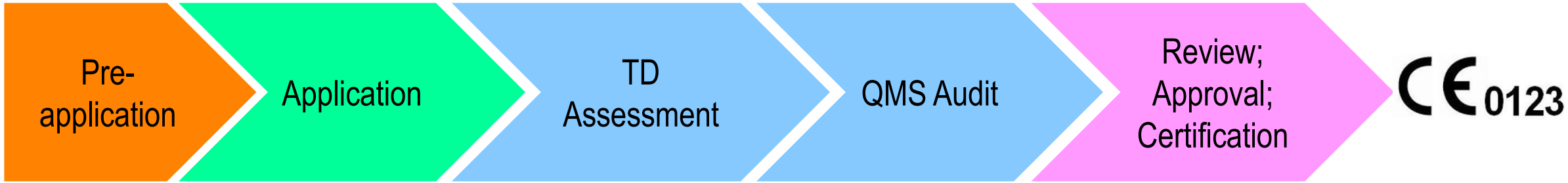
Choose certainty.
Add value.

The Notify Body Application Process

Julien Senac, Ph.D.

Journey to CE certification



Pre-Application

- Why do we introduce a pre-application phase?
  - A requirement of Annex VII 4.2 (d)
  - Manufacturer cannot lodge application in parallel with another notified body for the same conformity assessment procedure.
  - A notified body shall inform the other notified bodies of any manufacturer that withdraws its application prior to the notified body's decision regarding the conformity assessment.
  - Allow notified body to provide non-binding quotes for services
  - Allow manufactures to evaluate the most suitable notified body for its portfolio

Pre-Application

- What is requested during the pre-application phase?

  - Information related to the manufacturer (Legal entity)

  - Sites covered by the QMS within the scope of certification
    - Address(es)
    - Main contact per locations
    - Number of employees
    - Shifts
    - Products manufactured

- Processes and subsystem per locations
  - Top Management / QM / Admin
  - Regulatory Affairs
  - Design and Development
  - Production and Process Controls
  - Product Documentation
  - Purchasing Controls, incl. Verification of Purchased Devices
  - Corrective and Preventive Actions, incl. Post-Market Surveillance
  - Post-Market Performance Follow-up (PMPF)
  - Others (Finance, IT, etc…)

Pre-Application

- What is requested during the pre-application phase?
  - Requested service and assessment route
    - Annex IX
    - Annex X and XI
  - Details on suppliers and subcontractors that significantly influence product conformity
    - Name and Address
    - Product, component, process or service provided
    - QMS certification (if any)
    - Control in place by the manufacturer
  - Details on the products
    - Device Name
    - Basic UDI-DI
    - Class (As, B, C, or D)
    - Rule (1-7)
    - Device Type (ST, NPT, CDx, Professional use)
    - EMDN code (W----)
    - IVP code (most appropriate)
    - IVR codes (Device category)
    - Other codes (IVS, IVD, IVT, IVP)
    - Device specifics (Software, kit, reagent, system…)
    - Intended purpose of the device
    - Readiness

Application

- A formal application is signed by the manufacturer or the authorized representative
- A written contract with clear terms and conditions between the NB and the manufacturer
- Documents to provide with the application for Annex IX (section 2.1):
  - Draft of an EU declaration of conformity for the device model covered by the conformity assessment procedure
  - The documentation on the manufacturer's quality management system
  - A documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under the Regulation and the undertaking by the manufacturer in question to apply those procedures
  - A description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures
  - The documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMPF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance
  - A description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMPF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance, as well as the undertaking by the manufacturer to apply those procedures
  - Documentation on the performance evaluation plan
  - A description of the procedures in place to keep up to date the performance evaluation plan, taking into account the state of the art

Application

- Documents to provide with the application for Annex IX (continued):

  - **For Class B, C (including CDx), and D**:
    i. Description of the design, manufacture and performance of the device in question
    ii. Technical documentation as referred to in Annexes II and III

  - **For Class B, C, and D for self-test and near-patient testing**:
    i. Description of the design characteristics and performance(s)
    ii. Technical documentation as referred to in Annexes II and III
    iii. Test reports, including results of studies carried out with intended users
    iv. Where practicable, an example of the device; if required, the device shall be returned on completion of the technical documentation assessment
    v. Data showing the suitability of the device in view of its intended purpose for self-testing or near patient-testing
    vi. Information to be provided with the device on its label and its instructions for use

Application

- Documents to provide with the application for Annex X:
  - The technical documentation referred to in Annexes II and III
  - A representative sample of the device production envisaged ('type') including information about the representative sample made available to the notify body.
  - **Additionally, in the case of devices for self-testing or near-patient testing**:
    i. test reports, including results of studies carried out with intended users, and data showing the handling suitability/suitability of the device in relation to its intended purpose for self-testing or near patient-testing
    ii. the information to be provided with the device on its label and its instructions for use

- Documents to provide with the application for Annex XI
  - Same documents required for Annex IX (Section 2.1)
  - The technical documentation referred to in Annexes II and III for types approved
  - a copy of the EU type-examination certificates referred to in Section 4 of Annex X; if the EU type-examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and its updates and the certificates issued shall also be included in the application

? QUESTIONS ?

спасибо
GRACIAS 谢谢
THANK YOU
ありがとうございました MERCI
DANKE धन्यवाद
شُكراً OBRIGADO
Gracie
감사합니다

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Questions and answers

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