EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medical Device Expert Panels

General overview and main activities

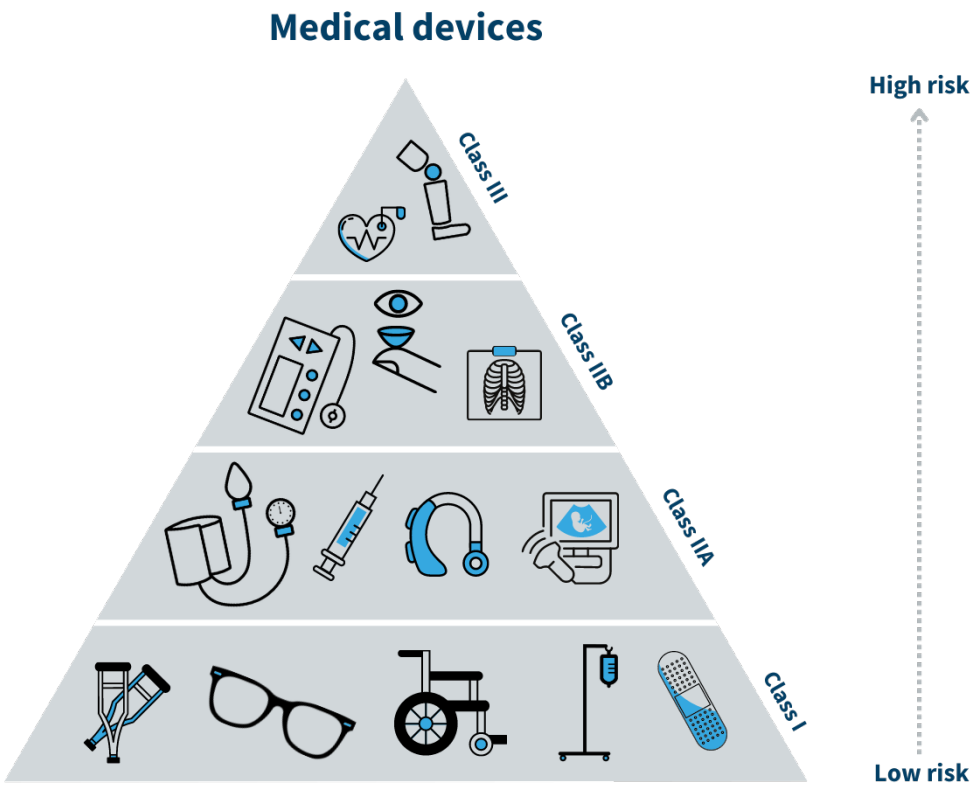
CCEAR Talks - "Painéis de Peritos para Dispositivos Médicos"

Miguel Antunes – Senior Medical Device Specialist in the Panels and Groups Office – EPG / EMA

Outline

- Brief intro on medical devices and *in vitro* diagnostic medical devices (IVD)
- Expert Panels' activities
- Pilot on scientific advice from the Expert Panels to manufacturers

Medical devices



https://laegemiddelstyrelsen.dk/en/devices/

Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for specific medical purposes (…)

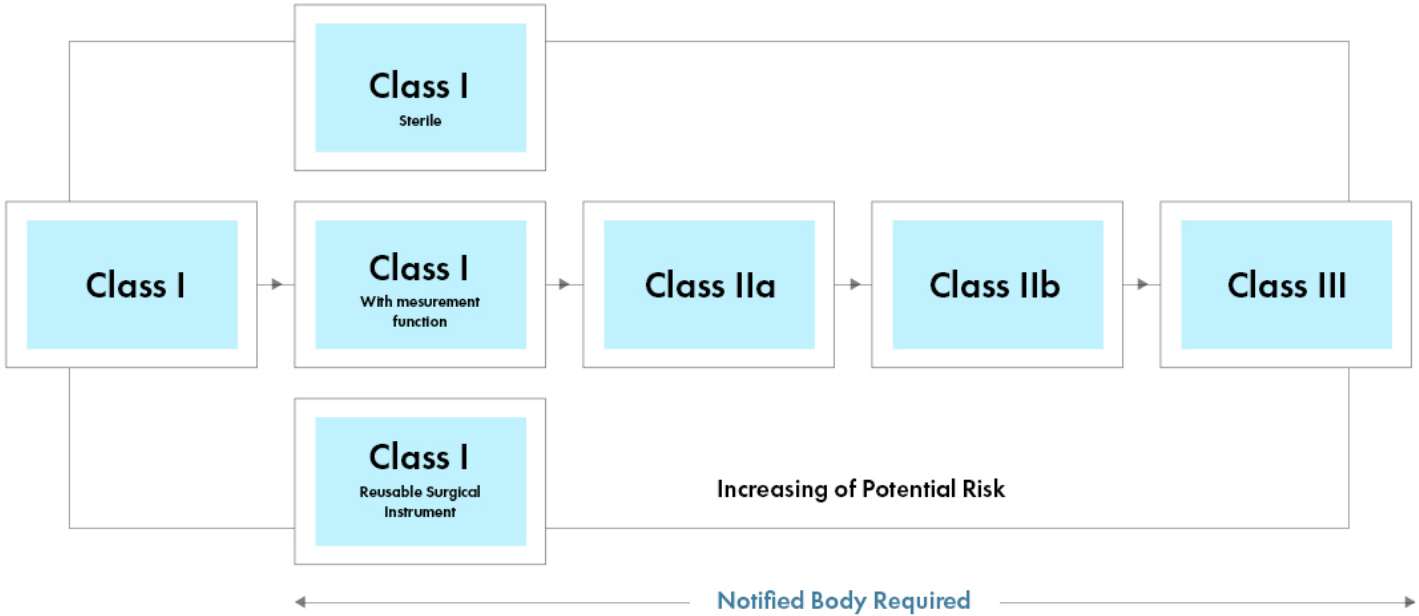
and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Regulation (EU) 2017/745 – MDR

Notified Bodies

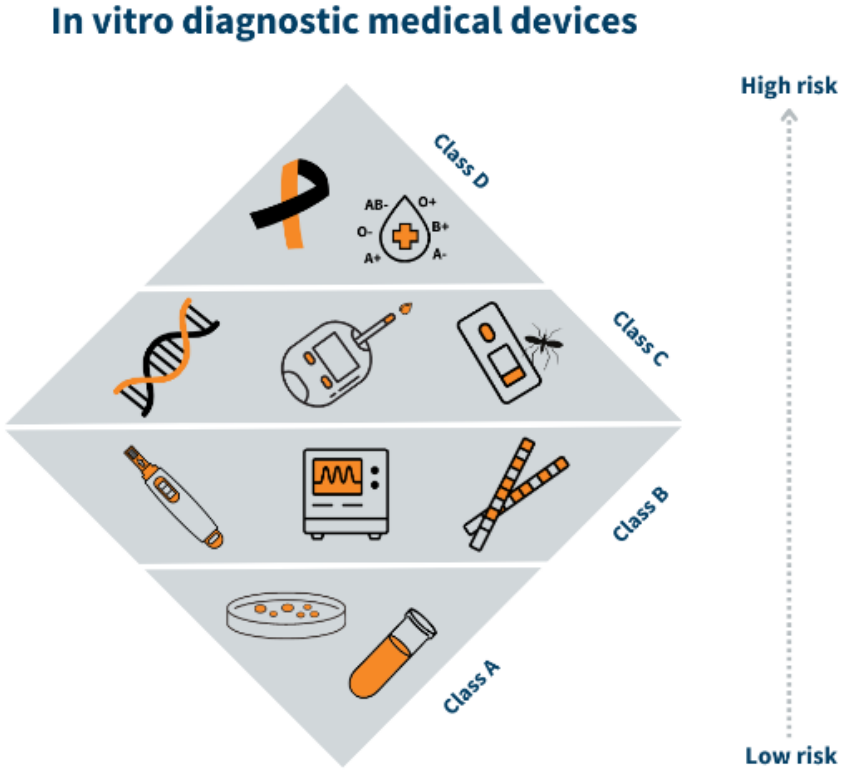
EUROPEAN MEDICINES AGENCY

Notified Bodies are entities, either public or private, performing **third-party conformity assessment activities** including calibration, testing, certification and inspection according to MDR/IVDR.



Freyr. 2022

In vitro diagnostic medical

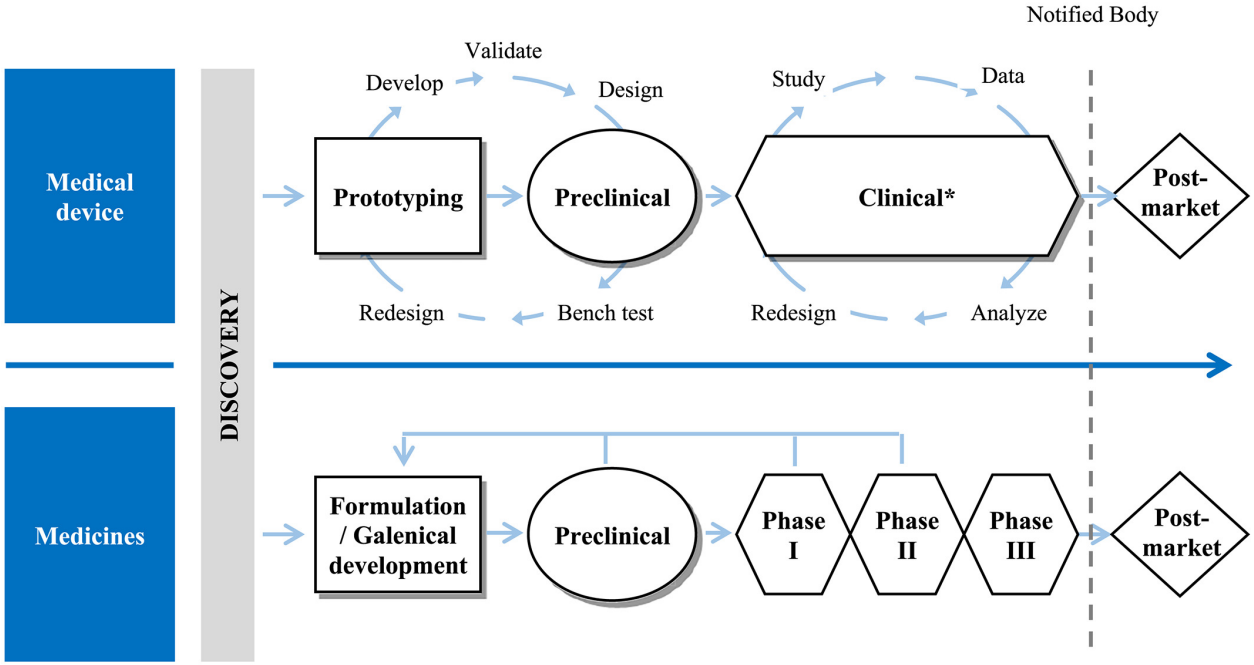


https://laegemiddelstyrelsen.dk/en/devices/

Any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, (…), 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 physiological or pathological process or state, congenital (…), predisposition to (…) condition or a disease, etc.

Regulation (EU) 2017/746 – IVDR

Medicines and the medical device development cycle in the EU



***Not always mandatory**

Note: Some low risk (class I) medical devices may be "self certified" (without requiring a CE certificate from the NB) (25)

Pane, J. 2019

Medical Devices Expert Panels

Expert Panels – What are they and who are the experts

- They were created by the European Commission according to Articles 106 and 48(6) of the Medical Device Regulation (MDR) and the Regulation on *In Vitro* Medical Devices (IVDR) to support the **scientific assessment and advice** in the field of **medical devices** and ***in vitro* diagnostic medical devices**
- Panel members are **experts in their own field** appointed by the European Commission on the basis of their scientific, clinical and technical expertise following a call for expression of interests
- The **Secretariat** for the expert panels has been provided by the EMA (QA-EPG) since **1st March 2022** (before it was the Joint Research Center – JRC)

How are the Expert Panels organised

12 expert panels

1. Screening panel **(≈ 75 experts)**

***Thematic expert panels*: (≈ 100 experts)**

2. Orthopaedics, traumatology, rehabilitation, rheumatology (sub-groups)
3. Circulatory system (sub-groups)
4. Neurology (sub-groups)
5. Respiratory system, anaesthesiology, intensive care
6. Endocrinology and diabetes
7. General and plastic surgery and dentistry (sub-groups)
8. Obstetrics and gynaecology, incl. reproductive medicine
9. Gastroenterology and hepatology
10. Nephrology and urology
11. Ophthalmology

Coordination committee

Chairs & Vice Chairs of 10 MD panels + IVD panel and representatives of screening panel.

Central list of available experts

(≈ 125 experts)

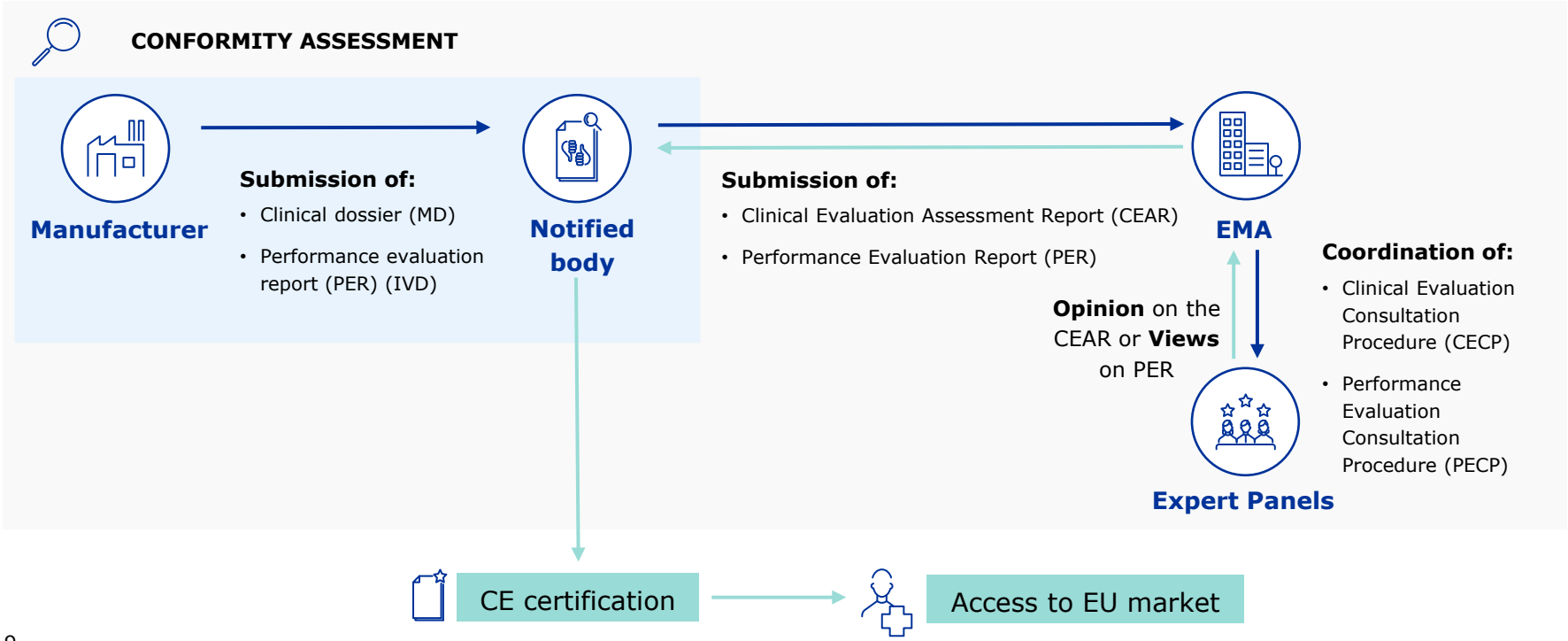
Temporary assignment of experts to panels

Reserve list for appointments

***In vitro* Diagnostics Regulation**

12. *In vitro* diagnostics devices panel: **(≈ 25 experts)**

Expert Panels for medical devices in the context of the conformity assessment process



Provide opinion on notified bodies' assessment of clinical evaluation of certain high-risk medical devices

Consider the legal requirements

Type of device

- For class III implantable e.g. pacemakers, joint replacement devices, breast implants
- For class IIb active intended to administer/ remove medicinal product e.g. infusion pumps, ventilators

Consider exemptions

No Expert Panel if:

- Renewal of certification under MDR
- Same manufacturer/intended purpose and modification does not affect B/R
- CS available for the clinical evaluation of that type of device

Phase I: Screening Panel

Decide on 3 criteria:

- Novel AND major clinical / health impact
- Valid health concerns due to adverse change of benefit-risk profile of the group of devices
- Significant increase of serious incidents

Phase II: Thematic Panel

Provide an Opinion

- Opinion publicly available on EC website
- NB need to give it due consideration

Notified body | **Expert Panel**

Published Opinions and Views

1. Orthopaedics, traumatology, rehabilitation, rheumatology

- 25.08.2022, NB0459, CECP-2022-000232
- 22.10.2021, NB2797, CECP-2021-000205

2. Circulatory system

- 11.11.2022, NB0123, CECP-2022-000235
- 05.07.2022, NB0344, CECP-2022-000225
- 27.06.2022, NB0344, CECP-2022-000216
- 23.05.2022, NB0344, CECP-2022-000213
- 07.12.2021, NB0344, CECP-2021-000207

3. Neurology

- 01.08.2022, NB0344, CECP-2022-000222

4. Respiratory system, anaesthesiology, intensive care

- -

5. Endocrinology and diabetes

- -

6. General and plastic surgery and dentistry

- 06.10.2022, NB2797, CECP-2022-000227
- 15.06.2021, NB0483, CECP-2021-000201

List of opinions provided under the CECP

1. List of views provided under the PECP

This section lists the views provided by the in vitro diagnostics expert panel according to Article 48(6) of Regulation (EU) 2017/746.

- IVD-2021-000001-view
- IVD-2021-000002-view
- IVD-2021-000003-view
- IVD-2021-000004-view
- IVD-2021-000005-view
- IVD-2021-000006-view
- IVD-2021-000007-view
- IVD-2021-000008-view
- IVD-2021-000009-view
- IVD-2021-0000010-view
- IVD-2021-0000011-view
- IVD-2021-0000012-view
- IVD-2021-0000013-view
- IVD-2021-0000014-view
- IVD-2021-0000015-view
- IVD-2022-0000016-view

List of views provided and ongoing consultations under the PECP

Provide a view on the manufacturer's performance evaluation for certain high-risk *in vitro* medical devices

Consider the legal requirements

Type of device

- For Class D

Consider exemptions

No PECP needed if:

- Common Specifications are available for that type of device
- It is the first certification for that type of device

***In vitro* Diagnostic Panel**

Provide a View

- View published on the EC website
- The notified body shall give due consideration to the view

Notified body

Expert Panel

Publication of 1st Group of Common Specifications for IVDs (04.07.2022)

- Blood group antigens in the ABO, Rh, Kell, Duffy and Kidd blood group systems.
- Markers for infection by:
  - human immunodeficiency virus (HIV) or T-cell lymphotropic virus (HTLV).
  - hepatitis C virus (HCV), hepatitis B virus (HBV) infection or hepatitis D virus (HDV).
  - variant Creutzfeldt-Jakob disease (vCJD).
  - Cytomegalovirus (CMV).
  - Epstein-Barr virus (EBV).
  - *Treponema pallidum*.
  - *Trypanosoma cruzi*.
  - Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Medical device Expert Panels opinions and views (CECPs and PECPs)

CECP

- **53 applications** received from notified bodies (NB)
  - **10** decisions of the screening experts that an **opinion** is needed
- Most of the applications were in the **Circulatory system (21)**, followed by **Orthopedics, traumatology, rehabilitation, rheumatology (11), General and plastic surgery and dentistry (7) and Neurology (5)**

PECP

- **16 applications** received from manufacturers (via NBs)
  - **16 views** delivered by the IVD panel
- The greatest number of applications were for devices for **SARS-CoV-2 detection**

Major oversights referred by the expert panels in their opinions

- The CEAR is not usually presented in a well-structured way, what might lead to relevant information being missed (e.g., what is new in the device, why is it (not) novel, what is the clinical data gathered the for the conformity assessment, what is the NB's opinion of that data)
- Data insufficient for one or more of the claimed intended use of the device
- Relevant published information missing from the documentation/CEAR (e.g., published relevant papers): need to ensure the most updated version is presented to the panels
- Some of the literature reviews used are biased and/or incomplete
- Disagreement regarding the design study/level of evidence presented for the conformity assessment
- For some devices, the pre-clinical data is paramount for the clinical assessment. A summary of such assessment would be highly relevant

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Expert panels' areas of agreement

- In general, the expert panels agree with the **proposed PMCF plan** and the relevance of the information provided by it
- The expert panels have mentioned that the **opinion template can be improved** to prevent repetitions and to help focus on the most relevant issues
- The expert panels have also mentioned that they **agree that having a moment of interaction** with the NB before issuing the final opinion might be useful

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European Commission

European Health Union:
Supporting the transition to the new medical device framework

Measures for a successful transition in the longer term

- Pilot project on **scientific advice for clinical development strategies** for high-risk devices
- Targeted **support for SMEs** through the Enterprise Europe Network
- Tailored **solutions for orphan devices**

Orphan devices are crucial for treating relatively small group of patients, especially children.

Small and Medium sized Enterprises (SMEs) represent around **95% of medical device manufacturers** in Europe.

https://health.ec.europa.eu/system/files/2023-01/mdr_proposal_factsheet_0.pdf

Expert Panels – Pilot on advice to manufacturers

Period: February 2023 to Q1 2024

Remit: Class III devices or IIb active devices to administer/remove medicines (MDR Art 61(2))

Area of advice: Clinical only (development of the clinical strategy or proposal for clinical investigation)

Fees: No fees during the pilot phase

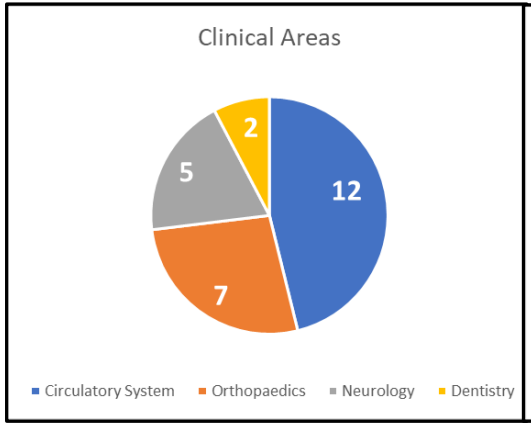
Applicants: manufacturers/authorised representatives established in the EEA (SMEs encouraged to submit)

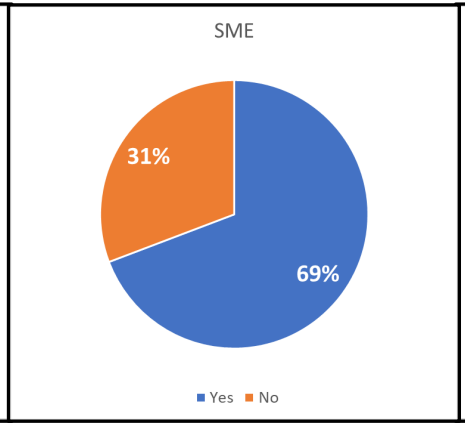
Number of procedures: 10 requests organised in 2 rounds of 5 applications (need to balance with the expert panels' mandatory activities).

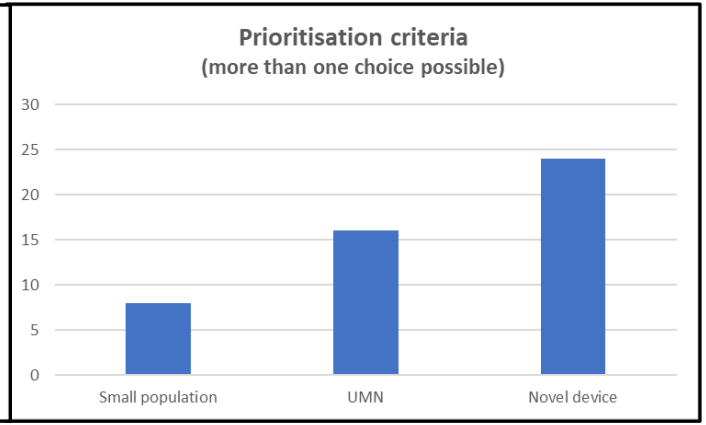
Pilot on advice to manufacturers – selection phase

- **Selection criteria:**
  - ✓ Devices intended to benefit a relatively **small group of patients** in the treatment or diagnosis of a disease or condition (e.g. "orphan devices", devices for paediatric use)
  - ✓ Devices for **unmet medical needs** i.e., medical conditions that are life-threatening or cause permanent impairment of a body function AND for which current medical alternatives are insufficient or carry significant risks ("breakthrough device" - MEDDEV 2.7/1 rev.4, Appendix 8)
  - ✓ **Novel devices** with a possible **major clinical or health impact**
- Ideally, **different clinical areas and types of devices** should be represented
- ***Currently:*** 1st submission phase closed (from 27th Feb to 15th April). Selection ongoing. Decision communicated by 22th May.

Pilot on advice to manufacturers: 26 letters of interest

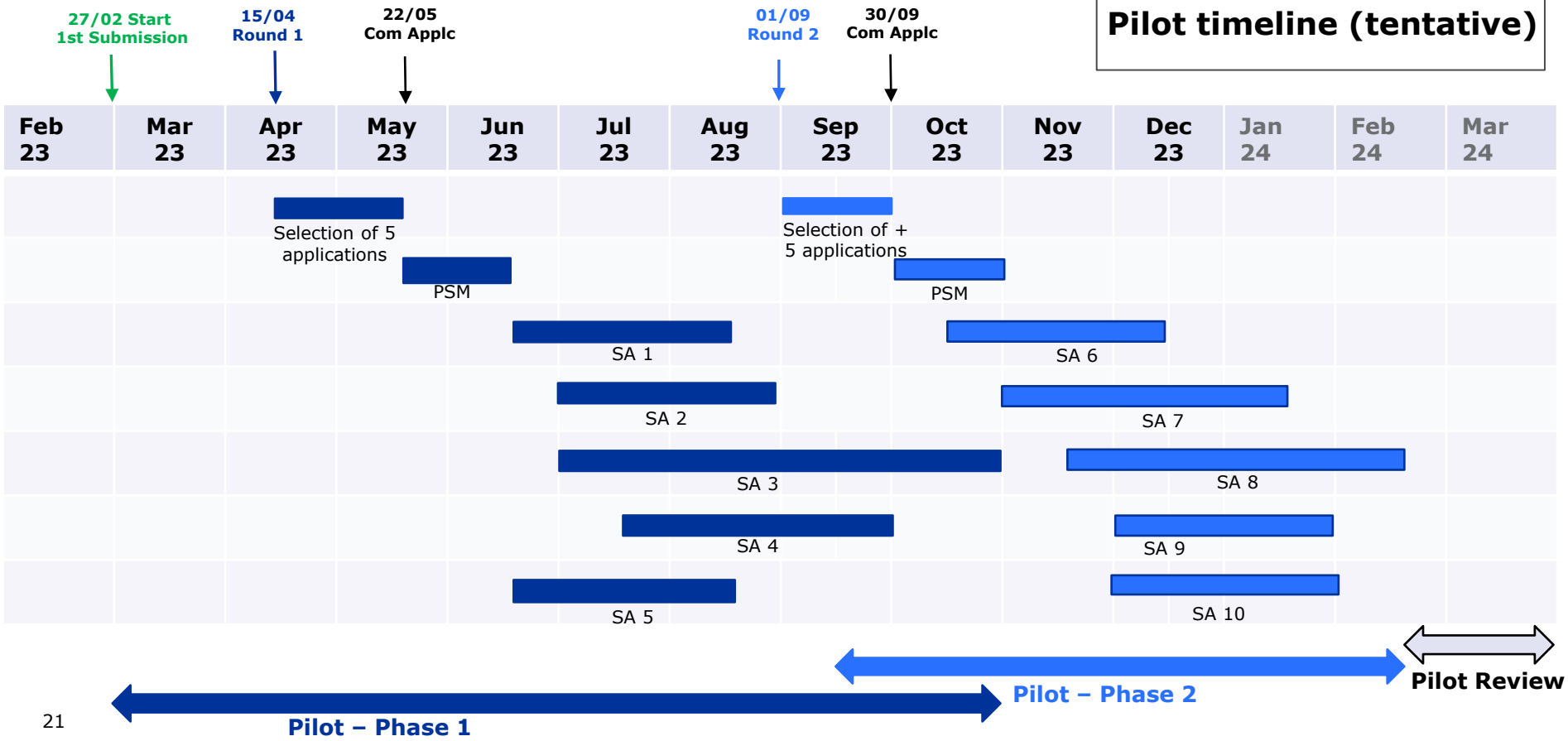






Different phases of development of the device:
• FIH / pilot studies
• Pivotal study
• Full clinical strategy (study designs for approval + PCMF plan (e.g., registry validation)
• Advice on ongoing studies

Pilot timeline (tentative)



Any questions?

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