Solutions to Your Pressing MDR Challenges

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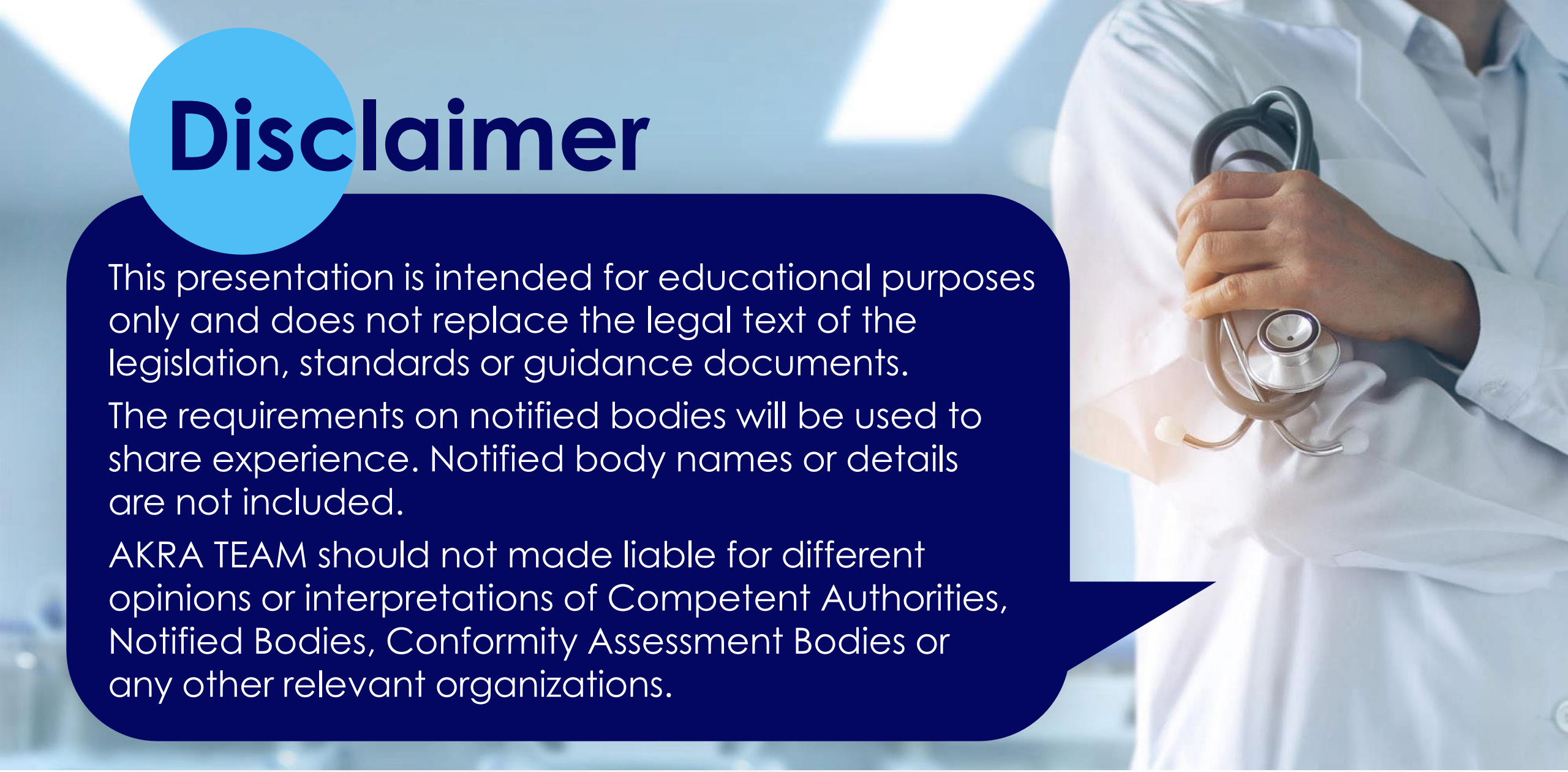

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The requirements on notified bodies will be used to share experience. Notified body names or details are not included.

AKRA TEAM should not made liable for different opinions or interpretations of Competent Authorities, Notified Bodies, Conformity Assessment Bodies or any other relevant organizations.

Implementation of the MDR

Extension of Transition Provisions per MDR Art. 120

Regulation 2023/607 15 March 2023

Applies only to devices that

- do not present any unacceptable risk to health and safety
- have not undergone significant changes in design or intended purpose AND
- for which the manufacturers have already undertaken the necessary steps to launch the certification process under the MDR
  - Adaptation of QMS to MDR
  - Application for conformity assessment by a NB before a certain deadline

Extension of the transitional period in Art. 120 (3)

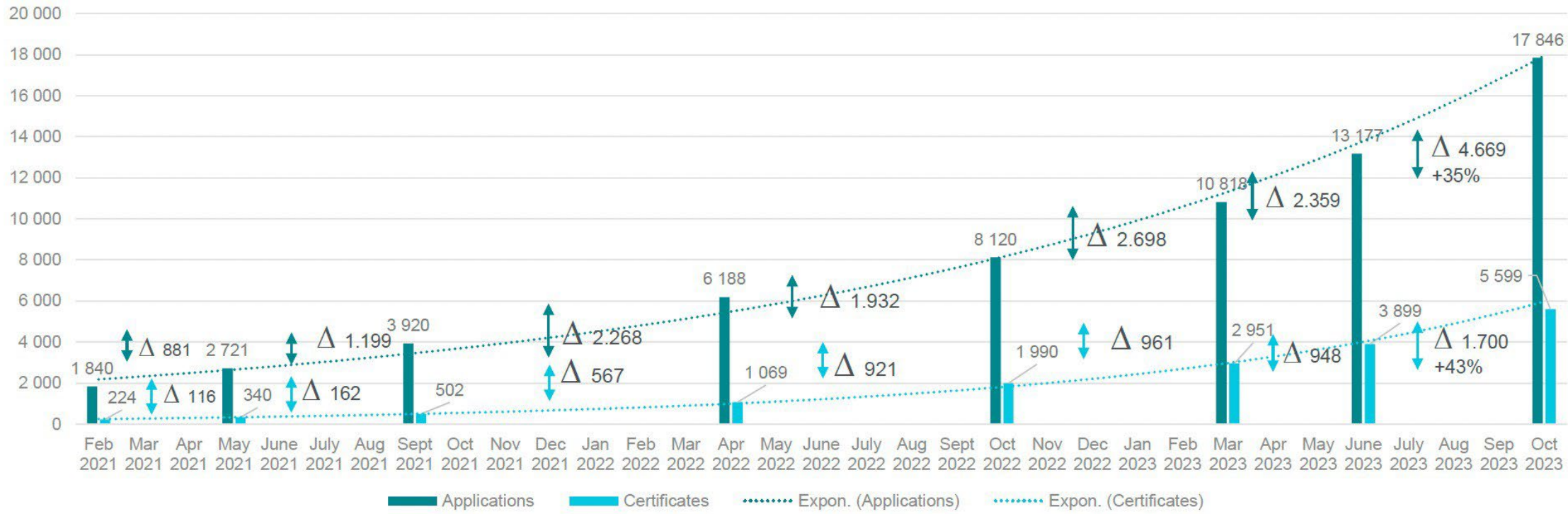
- 2027 for class III and class IIb
- 2028 for class IIa and class I devices

Extension of the validity of certificates issued under MDD /AIMDD,

if needed for legal or practical reasons (e.g., third country markets access)

Removal of the "sell off" provision in MDR and IVDR

6th Notified Bodies survey with data up to 31st October, 2023

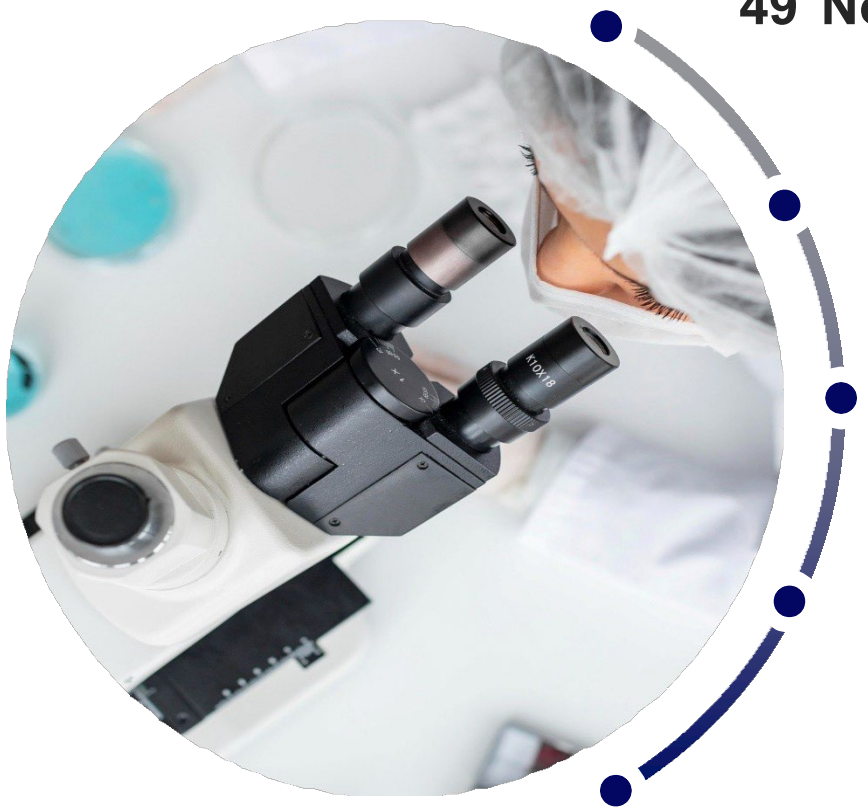


Notes: October 2023: Designated NBs for MD: 39; NBs that included Annex XVI products in the numbers provided: 15

* The data shown comes from the medium data set Ⓜ – except for 2 NBs where the total number of applications filed was derived from the small data set Ⓢ since they could not provide the data per Annex.

- Δ (Delta) = Difference in MDR Applications / MDR Certificates from one survey to the next one
- **Applications filed**: This number includes **all applications filed (syn. lodged) so far** according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publicatic in the Single Market Compliance Space to the date of the survey up to 31/10/2023), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- **Certificates issued:** This number includes **certificates issued so far** (from designation up to 31/10/2023) under the MDR.

Biggest Challenges for Clinical Evidence



49 Notified Bodies and 27 National Competent Authorities

> 100 MDCG Guidance Documents

Learning Curve (NB and Manufacturer)

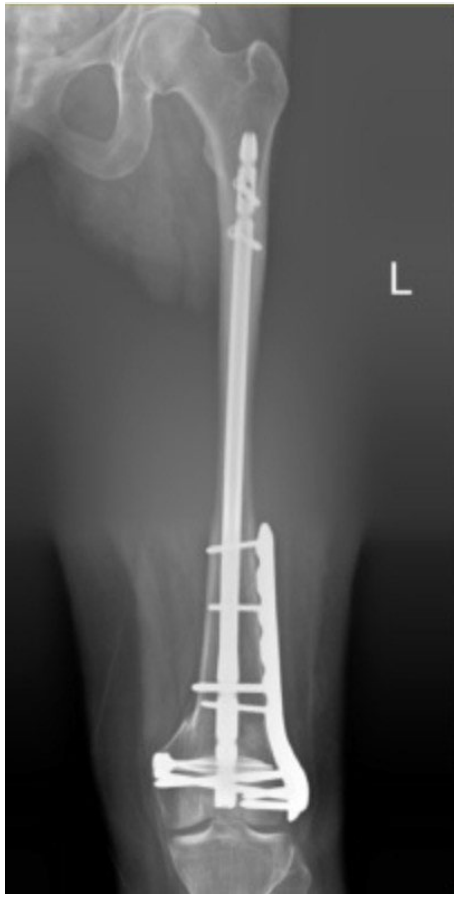
Insufficient clinical data for legacy devices

Expectations on clinical evidence differ between NBs

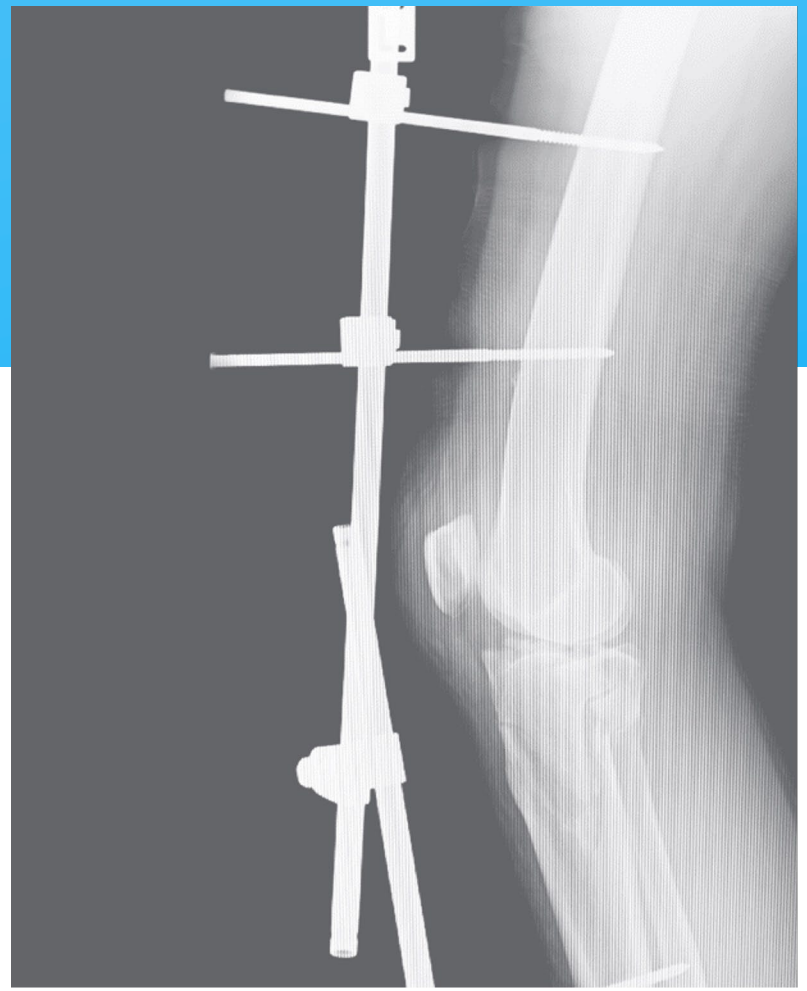
Device Lifetime and how to address in the PMCF

GSPR 6 requires safety and performance over the lifetime of the device

- **Definition of Lifetime**
- We have seen NB requests to collect **specific PMCF data over the full lifetime**
- **Real-World Evidence and Registries** do not always include all **relevant safety and performance endpoints**
- Team-NB and BSI have published position papers



WHAT COULD BE FUTURE DATA SOURCES



- More National Registries
- More (implantable) devices included in Registries
- Increasing interest in different Member States on device safety

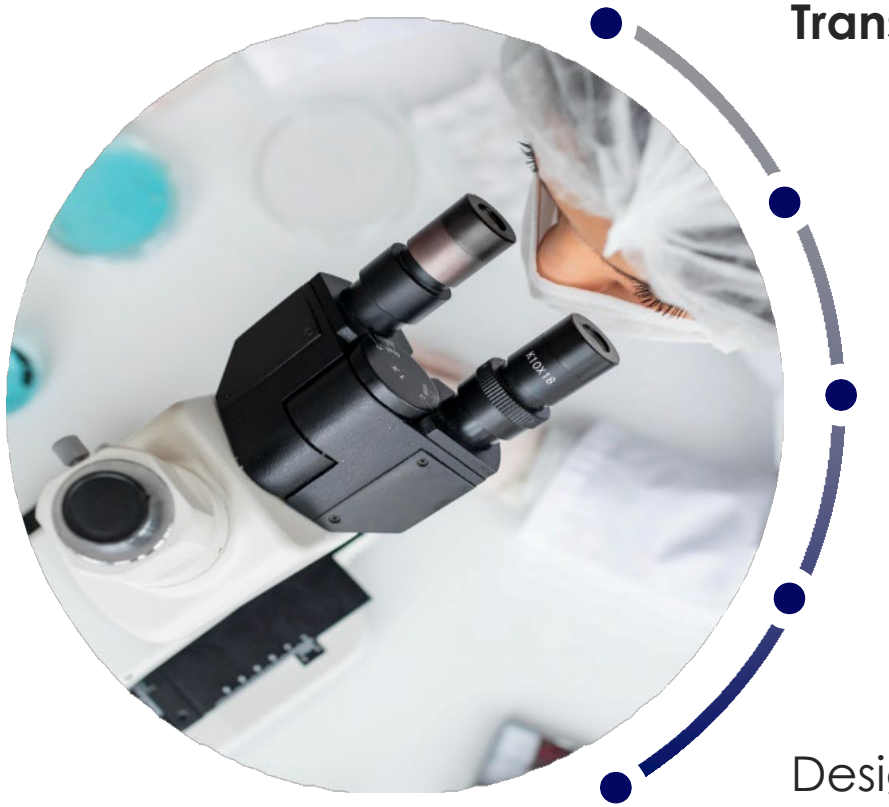
- Common Specifications
- Core-MD
- EUDAMED

- Smart Devices
- Artificial Intelligence
- In Silico Clinical Trials

Notable Statements from the Scientific Opinions

Published Scientific Opinions

https://health.ec.europa.eu/medical-devices-expert-panels/experts/list-opinions-provided-under-cecp_en



Transferability of clinical data between different indications

Could **not follow the benefit/risk conclusion** of the NB

Quality of the literature search
EP cited literature not disclosed by manufacturer

Generic device group still considered SOTA
(Metal-back Glenoid)

Design and number of patients included in **PMCF studies**

UPDATE OF MEDDEV 2.7/1, Rev. 4 – 2 Steps

- 2 Steps in 2024
- Proof of Sufficient clinical evidence
- Evaluation of WET per article 6.6(b)
- Use of Clinical Data coming from Clinical Investigations outside the EU
- Clarifications on PMCF, e.g. when a PMCF study is required
- Hierarchy of Clinical Evidence (Core-MD)

Questions?

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