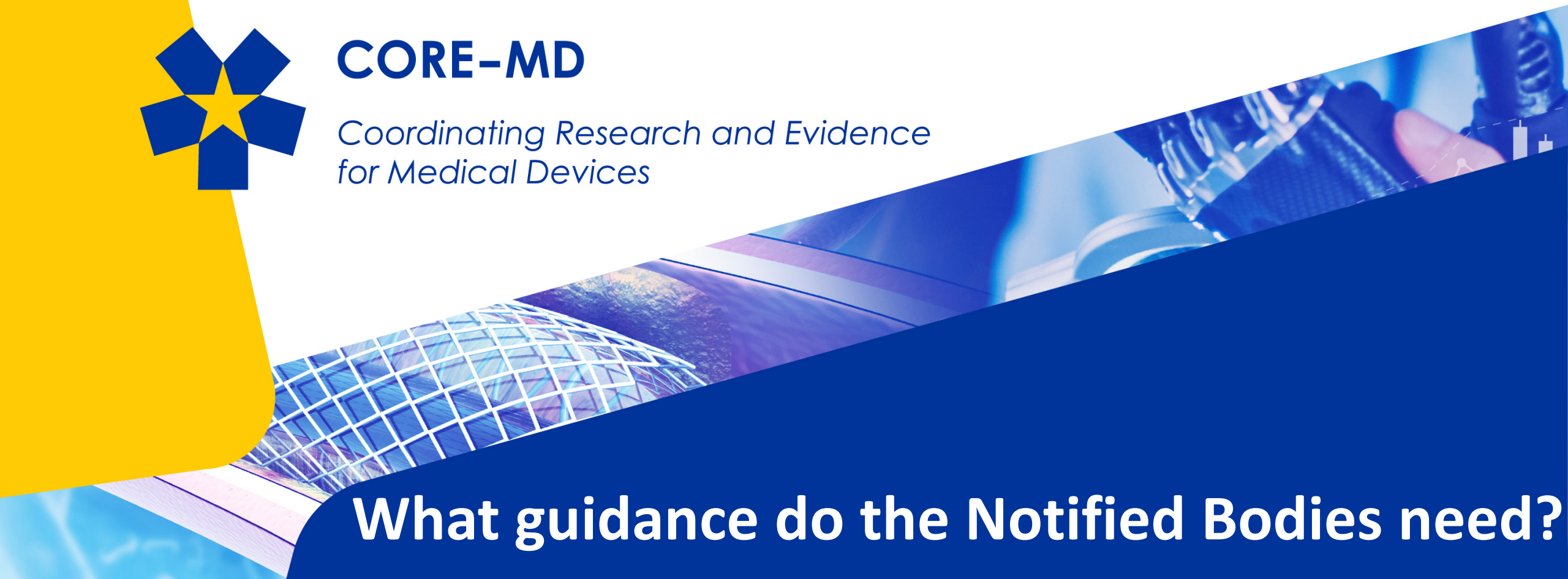
CORE-MD

Coordinating Research and Evidence for Medical Devices



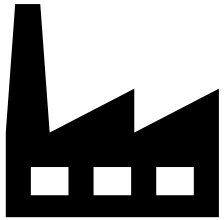
What guidance do the Notified Bodies need?

Richard Holborow, Head of Clinical Compliance BSI Group & Team NB

27 November, 2023

Medical Device Regulation (MDR 2017/745)

Council Directive 90/385/EEC (3) and Council Directive 93/42/EEC (4) constitute the Union regulatory framework for medical devices, other than in vitro diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a ***robust, transparent, predictable and sustainable regulatory framework for medical devices*** *which ensures a high level of safety and health whilst supporting innovation. (Opening Statement)*



The manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

…. shall be based on *clinical data providing sufficient clinical evidence*,

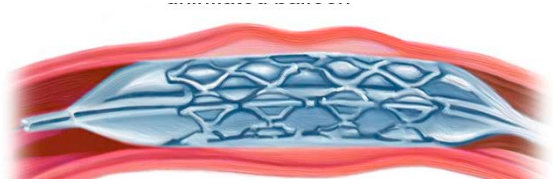
(Article 61(1))

The notified body shall have permanent availability of personnel with relevant clinical expertise and where possible such personnel shall be employed by the notified body itself. Such personnel shall be integrated throughout the notified body's assessment and decision-making process in order to be able to make an assessment of the manufacturer's clinical evaluation.

(Annex VII Section 3.2.4)

Challenges

The term *'sufficient'* is interpreted to mean '*quantity and quality*' of clinical data



Different regulatory scenarios may present different interpretations of what is sufficient…

Claims of Equivalence

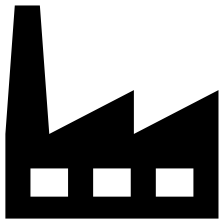
Devices previously marketed

Novelty

Device Lifetime

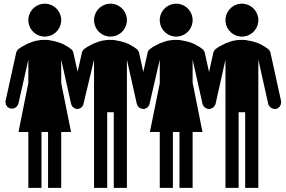
Challenges

When this is a lack of clear guidance on the interpretation of sufficiency for these forementioned scenarios, this leads to individual interpretation and does not provide a ***predictable*** outcome for manufacturers.



Manufacturers interpretation of sufficiency

Notified body clinician expectations on sufficiency



European expert panels expectations of sufficiency

Competent authority expectations of notified body interpretation of sufficiency

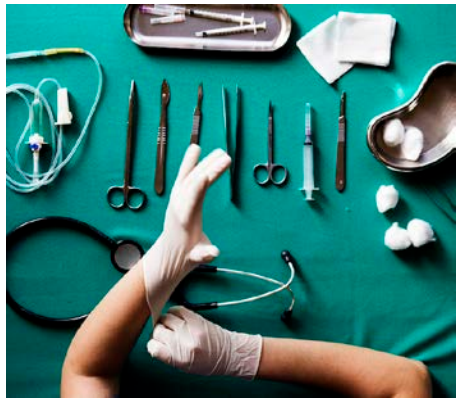
When there is a lack of consensus on the interpretation of sufficiency of data, this will lead to all actors having a different opinion.

Solutions needed

What guidance do ~~the Notified Bodies~~ *all actors in the regulatory* system need?

Guidance on what is *state of the art* * in the area of medicine

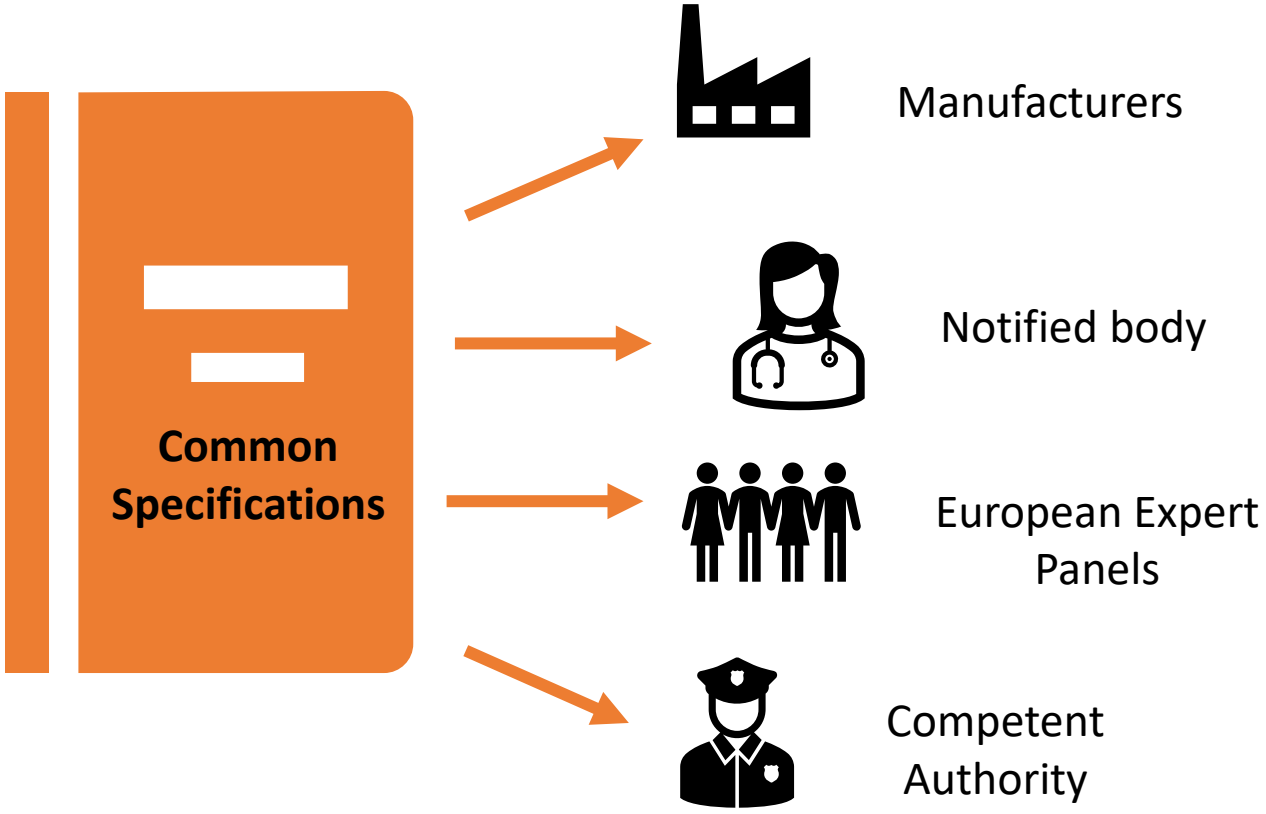
Guidance that guarantees sufficient clinical data from clinical investigations



Guidance that defines expectations on post market clinical follow up (PMCF)

*'**state of the art**': IMDRF/GRRP WG/N47 provides the following definition: *Developed stage of **current technical capability** and/or **accepted clinical practice** in regard to products, processes and patient management, based on the relevant consolidated findings of science, technology and experience.*

Common Specifications



- The Medical Device Regulation 2017/745 does mention the role of common specifications.

- When agreement can be achieved between all actors on the sufficiency of clinical data, then this will provide the harmonisation of interpretation for all actors involved helping to achieve the aim of the MDR to provide a robust, transparent, predictable and sustainable regulatory framework.

CORE-MD, Coordinating Research and Evidence for Medical Devices, aims to translate expert scientific and clinical evidence on study designs for evaluating high-risk medical devices into advice for EU regulators.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 945260

For more information, visit: www.core-md.eu

ESC
EFORT – JOINT EFFORTS
Biomedical Alliance in Europe
EAP European Academy of Paediatrics Paediatric Section of U.E.M.S
EPF European Patients Forum
LUMC Leiden University Medical Center
University of Oxford
Region Uppsala
RCSI University of Medicine and Health Sciences
INSELSPITAL Universitätsspital Bern Hôpital universitaire de Berne
KU LEUVEN
UMIT TIROL The Tyrolean Private University
University of Gothenburg
Politecnico Milano 1863
HPRA An tÚdarás Rialála Táirgí Sláinte Health Products Regulatory Authority
LÆGEMIDDELSTYRELSEN Danish Medicines Agency
National Institute for Public Health and the Environment Ministry of Health, Welfare and Sport
Istituto Superiore di Sanità
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TEAM NB