CORE-MD

Coordinating Research and Evidence for Medical Devices

Global regulatory convergence

Priorities for development

A national Competent Authority perspective

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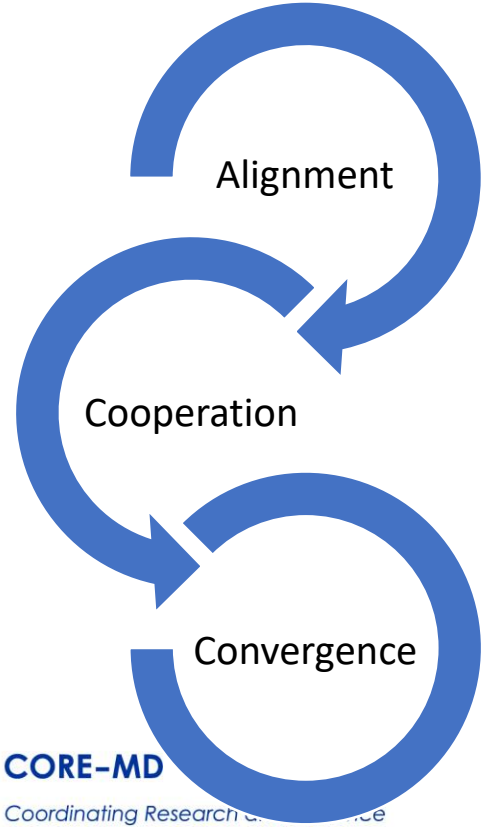
IMDRF overview



	Membership	Official observers	
	Australia	Argentina	
	Brazil	Switzerland	
	Canada	World Health Organisation	
	China	**Affiliate organisations**	
	Europe	South Africa	Israel
	Japan	Taiwan	Montenegro
	Singapore	Cuba	Chile
	South Korea	Egypt	
	United Kingdom	**RHIs**	
	United States of America	PAHO, GHWP, APEC, AMDF	

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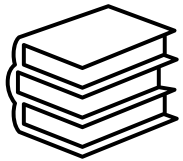
IMDRF – previous & future work

GHTF

Foundational guidelines
Pre-market evaluation
Post-market surveillance/vigilance
Quality systems
Auditing
Clinical safety/performance



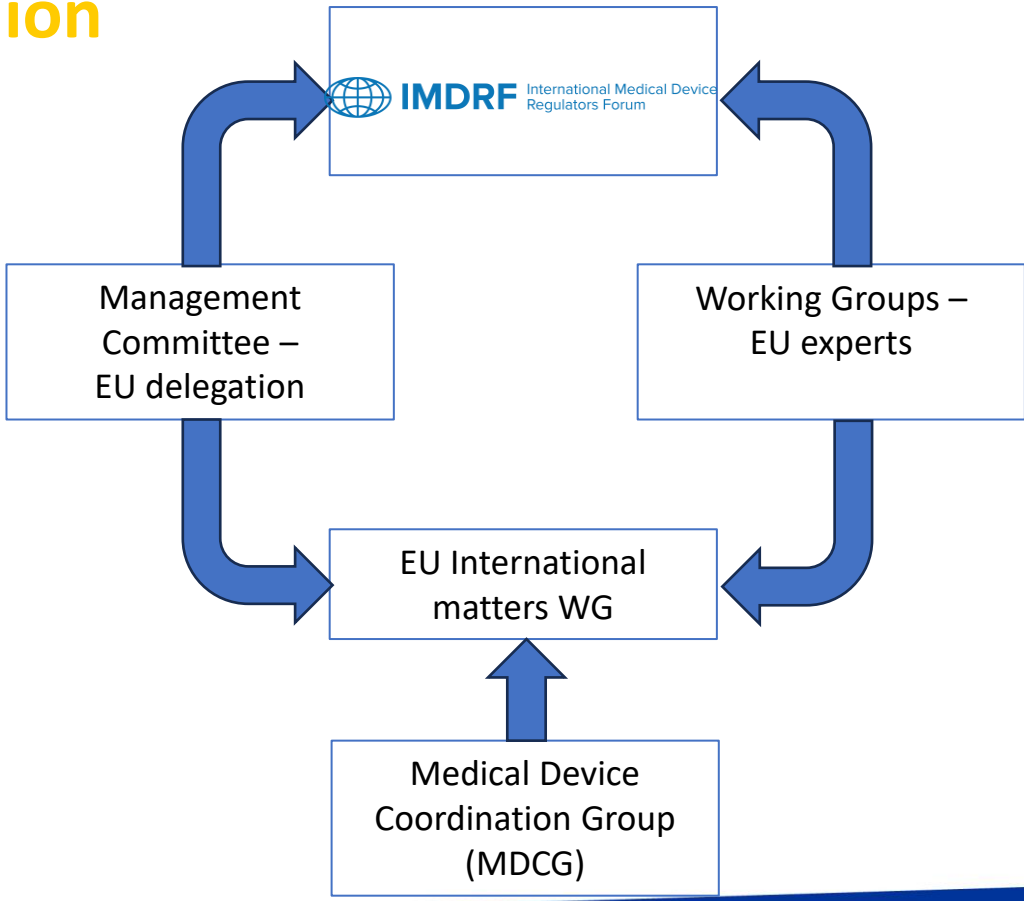
IMDRF work

Operational
UDI guidelines
NCAR exchange
MDSAP
Registries

IMDRF current/planned

Good regulatory review practice
AE terminology
Personalised medical devices
AI/ML devices
Quality management systems
SAMD
Regulated product submission

IMDRF – European Union



Benefits of convergence

- Harmonisation of requirements and regulatory approaches
- Inspiration for guidance, policy and legislation at national level
- Collaboration and cooperation between regulatory authorities internationally
- Common expectations for safety, performance and innovation of high-risk medical devices and new technologies
- Clarity and consistency for manufacturers and other stakeholders

Needs for convergence

- Stable, consistent and mature regulatory system
- Transparency, clear requirements and procedures at regional level
- Effective governance and scientific infrastructure to support defining criteria, requirements and systems at regional level
- Legal framework amenable to international initiatives & collaboration
- Reliability of regulatory system, confidence building and trust internationally

Priorities for development

- Clear purpose, objectives and overall international strategy
- Explore potential increased participation in reliance schemes – such as MDSAP
- Increase EU emphasis on developing governance and scientific infrastructure
- Build confidence and trust with other regulatory regions through effective application of EU regulatory system and engagement in collaborative initiatives

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.

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

ESC
EFORT
Biomedical Alliance in Europe
European Academy of Paediatrics
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
University of Gothenburg
Politecnico Milano 1863
HPRA
LÆGEMIDDELSTYRELSEN Danish Medicines Agency
National Institute for Public Health and the Environment Ministry of Health, Welfare and Sport
Istituto Superiore di Sanità
ainta HTA Austria Austrian Institute for Health Technology Assessment GmbH
AETSA
TEAM NB

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