Some of the EU & global organisations preparing regulatory guidance for AIMDs

- Definitions
- Standards
- Expert recommendations
- Regulatory initiatives

Fraser AG et al, Exp Rev Med Dev. 2023; 20: 467–491

State of health-care situation or condition	Significance of information provided by the AI system to the health-care decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

World Health Organization, 2023

Regulatory considerations on artificial intelligence for health.

(after IMDRF 2017)

- Function of the MDSW – informs / drives / treats
- Stage of the clinical condition – non-serious / serious / critical
- Potential impact – none / low / medium / high / catastrophic

the CORE–MD AI Risk Score adds:

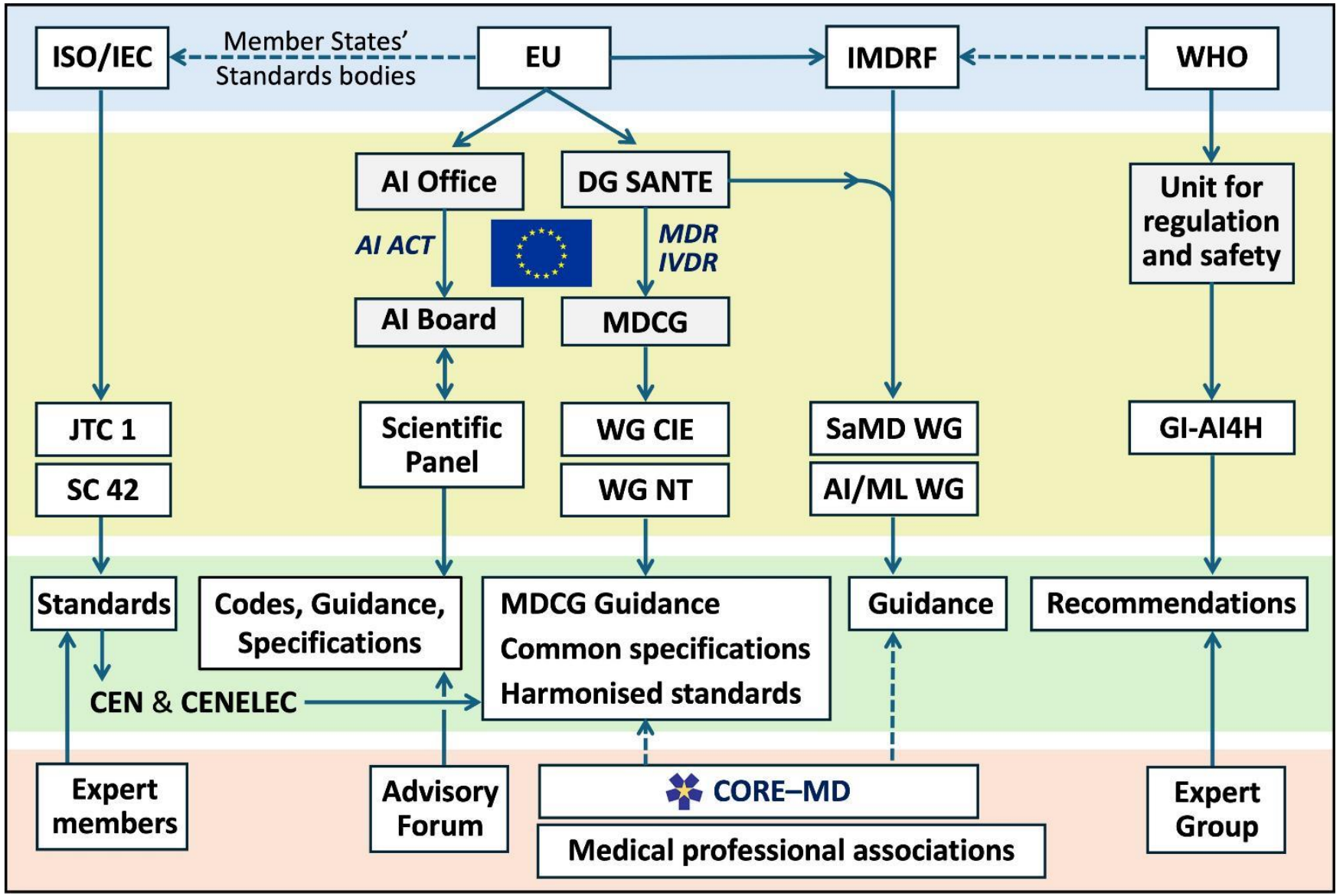
- Technical Performance – performance, validation
- Clinical association – transparency, oversight, impact

Rademakers F et al,

npj Digital Medicine 2024 (resubmitted)

Rademakers F et al,

npj Digital Medicine 2024 (resubmitted)



CORE–MD

Coordinating Research and Evidence for Medical Devices

REPORTING GUIDELINES

equator network

Enhancing the QUAlity and Transparency Of health Research

SPIRIT-AI Extension	**Protocol** – **clinical trial** involving AI
CONSORT-AI Extension	**Report** – **clinical trial** involving AI
TRIPOD-AI	**Prediction model** using AI
PROBAST-AI	**Risk of bias tool** for AI prediction model
DECIDE-AI	Early evaluation of AI **decision support**
CLEAR	Evaluation of **radiomics**
CLAIM	AI in **medical imaging**
PRIME	**Cardiovascular imaging** using AI

CORE-MD

Coordinating Research and Evidence for Medical Devices

Some priorities for ESC regulatory advocacy concerning AI-ML-MD

- Identify and engage (cardiovascular) experts in new advisory structures
- Participate in drafting of guidance for AI and ML in medicine (especially in EU):
  - AI Act ↔ MDR / interactions with GDPR ?
  - Any conflicting or unnecessary requirements? Appropriate use.
  - Circumstances requiring disclosure? Advice via EU Expert Panels.
- Unmet need – how to conduct post-market surveillance / clinical follow-up ?
- Unmet need – how to manage self-learning algorithms ? 'Change protocols' ?
- Unanswered question – legal personality, responsibility, reporting of harms ..
- Global regulatory convergence .. including ISO/IEC, and IMDRF working groups

Other ideas from this discussion ..

- Educational tools – when is software / AI & ML a medical device?
- Identification of clinical needs / what targets for new tools?
    - including advice to start-ups?
- Inclusion of AI tools in Clinical practice guidelines, when there is evidence
- How to influence speed of regulatory responsiveness?
- “Implementation science” ..

Comments from Ruben Casado follow:

What are the boundaries and limitations for artificial intelligence successful implementation from the regulatory point of view?

1. Data Privacy and Protection

- Regulation: GDPR
- AI developers must ensure that data used for training models is obtained ethically and with informed consent. Data anonymization and secure storage are also necessary to comply with these regulations.

2. Bias and Fairness

- Regulation: EU's AI Act and the Equal Employment Opportunity laws in various countries, demand that AI systems are fair, transparent.
- Limitations: AI systems must be regularly audited and tested. This poses challenges in highly complex, data-driven systems.

3. Accountability and Liability

- Regulation: In the event of harm or errors caused by AI systems, who is liable?
- Limitations: Current laws may not have clear provisions for AI-driven decisions, leading to uncertainty in legal liability.

4. Transparency and Explainability

- Regulation: GDPR require AI systems to be transparent in their operations. How is this possible?
- Limitations: The "black-box" nature of many AI software...

5. Safety and Risk Management

- Regulation: GDPR and EU AI Act categorizes AI applications into high-risk and low-risk categories, with more stringent requirements for high-risk applications.
- Limitations: The complexity of AI introduces challenges in predicting and mitigating all possible risks.

6. Ethical Standards

- Regulation: the OECD Principles on Artificial Intelligence and the EU's Ethical Guidelines for Trustworthy AI emphasize the need for AI to be developed and used in ways that respect human rights.
- Limitations: Defining and adhering to ethical standards can be subjective and vary across different countries.

7. International Regulations and Standards

- Regulation: International organizations like the UN, OECD, and ISO are working to create harmonized standards for AI governance. However, different countries have different approaches to AI regulation.
- Limitations: The lack of global consistency in AI regulation poses challenges for multinational companies and cross-border AI development. Companies must navigate a patchwork of legal frameworks, which could increase the complexity and cost of AI deployment.

8. Surveillance and Privacy Concerns

- Regulation: AI is often used in surveillance systems (e.g., facial recognition, predictive policing), leading to concerns about privacy violations and human rights.
- Limitations: In regions with strict privacy laws, the use of AI for surveillance is highly regulated or prohibited..

9. Intellectual Property and Innovation

- Regulation: AI-driven innovation can lead to questions about intellectual property (IP) ownership, especially when AI autonomously creates inventions or content in healthcare.
- Limitations: In the future AI systems that autonomously generate in healthcare content may face regulatory barriers in determining the ownership and rights associated with that content.

10. AI in Employment and Labor Markets

- Regulation: The rise of AI has raised concerns about its impact on healthcare jobs and the labor market.
- Limitations: There are increasing calls for regulating the impact of AI on employment.

Conclusion:

1. Regulatory frameworks often struggle to keep pace with the rapid development of AI technology, creating challenges for both developers and regulators.
2. As AI continues to evolve, so too will the regulatory landscape, striving for a balance between encouraging innovation and mitigating risks to society.