IMDRF/DITTA Joint Virtual Workshop

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Standards for health software – AI/ML Can "one size" fit all?

Needs and challenges - industry perspective

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**Standards for health software – AI/ML
Can "one size" fit all?
Needs and challenges - industry perspective**

Agenda

- Standards for health software – AI/ML: What are the needs?

- Current situation and resulting challenges

- Summary

We need a common understanding between affected stakeholders on topics such as:

bias

transparency

human oversight

performance evaluation

explainability

risk management

pre-determined changes/continuous learning

data quality

good data management practices

Standardization projects need experts from various stakeholder groups, including:

Healthcare professionals

Patient advocacy groups

Industry, incl. SMEs and start-ups

Notified bodies

Regulators

Academia

We need relevant standards "in time" to:

enable innovation

demonstrate compliance with legal requirements

define the state of the art

Current situation and resulting challenges:
The existing health software standards landscape
(not complete, focus on international standards)

Testing

ISO/IEC 80002-2 Medical devices software – Part 2: Validation of software for regulated processes

Usability

IEC 62366-1 Application of usability engineering to medical devices

Labelling

ISO 20417 Information to be supplied by the manufacturer
ISO 15223 Symbols to be used with medical device labels, labelling and information to be supplied

Clinical and performance evaluation

EN 13612 Performance evaluation of in vitro diagnostic medical devices

ISO 14155 Clinical investigation of medical devices for human subjects – Good clinical practice

Medical device software/Health software

IEC 62304 Medical device software – Software life cycle process
IEC 82304-1 Health Software – Part 1: General requirements for product safety
ISO 81001-1 Health software and health IT systems safety, effectiveness and security – Part 1: Principles and concepts
IEC 81001-5-1 Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle

Security

ISO/IEC 27001 Information security management systems - Requirements
ISO/IEC 27005 Information security risk management

Risk management

ISO 14971 Application of risk management to medical devices
IEC TR 80002-1 Guidance on the application of ISO 14971 to medical device software

Challenge: identifying gaps related to AI/ML and establishing common understanding of what those gaps are and how to address them without changing established concepts.

Quality Management System

ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes

**Current situation and resulting challenges:
Usefulness of horizontal standards and
need for vertical standards**

The majority of AI-related standardization projects so far are horizontal

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PUBLISHED ISO STANDARDS *
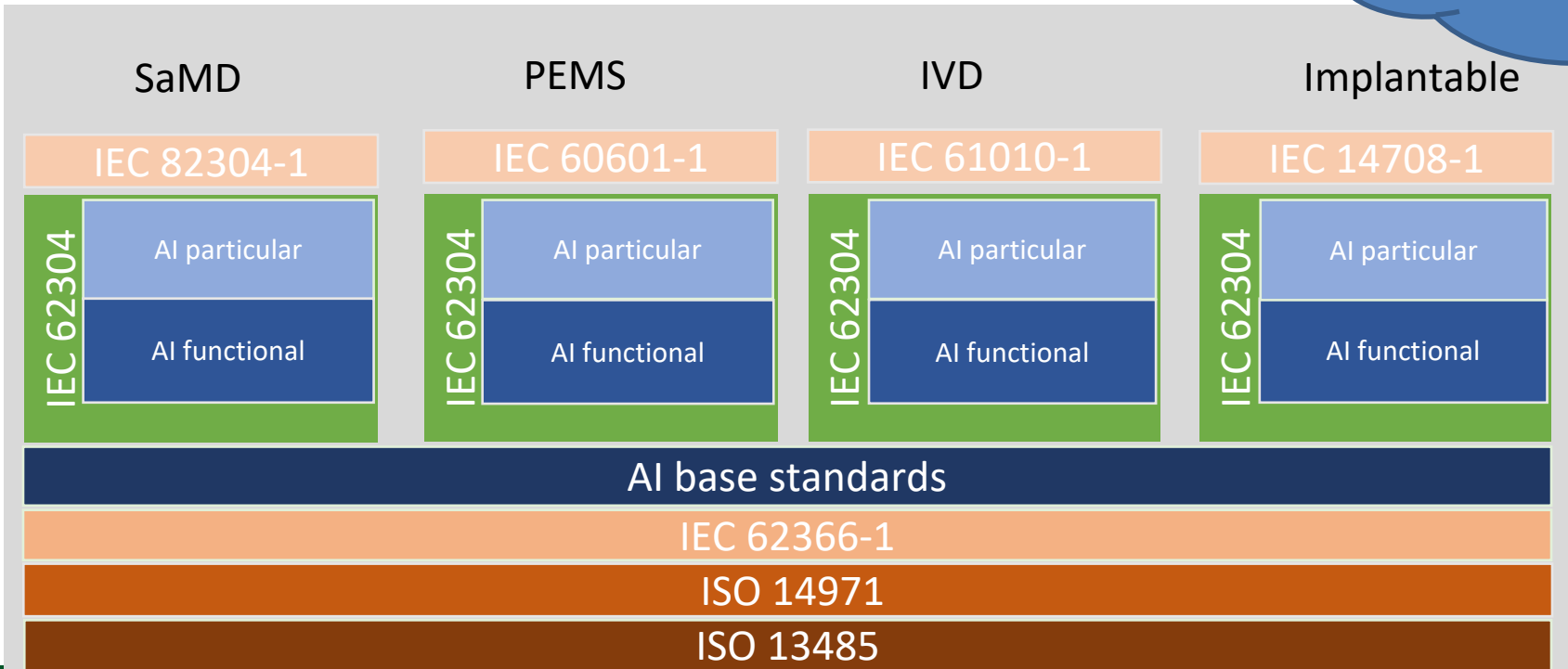under the direct responsibility of ISO/IEC JTC 1/SC 42

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ISO STANDARDS UNDER DEVELOPMENT *
under the direct responsibility of ISO/IEC JTC 1/SC 42

Challenge to identify which horizontal standards can be used – directly or as a basis – in the healthcare sector

Current situation and resulting challenges: Developing the 'right' standards in healthcare-specific standardization committees

Challenge: which standards should be written first, and how to make them fit into the "big picture"?

SaMD	PEMS	IVD	Implantable
IEC 82304-1	IEC 60601-1	IEC 61010-1	IEC 14708-1

IEC 62304 — AI particular / AI functional (SaMD)
IEC 62304 — AI particular / AI functional (PEMS)
IEC 62304 — AI particular / AI functional (IVD)
IEC 62304 — AI particular / AI functional (Implantable)

AI base standards

IEC 62366-1

ISO 14971

ISO 13485

The standardization architecture shown on this slide is a proposal by IEC TC 62

Summary
Standards for health software – AI/ML
Needs and challenges - industry perspective

Needs:
- We need a common understanding between affected stakeholders on key topics related to AI/ML
- Standardization projects need experts from various stakeholder groups, including regulators
- We need relevant standards in time

Challenges:
- Identifying gaps related to AI/ML in existing health software standards landscape
- identifying which horizontal standards can be used in the healthcare sector
- In healthcare-specific standardization committees, which standards should be written first, and how to make them fit into the "big picture"?

Thank you!