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

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
- risk management
- data quality
Standards for health software – AI/ML
What are the needs?

Standardization projects need experts from various stakeholder groups, including:

- Healthcare professionals
- Patient advocacy groups
- Industry, incl. SMEs and start-ups
- Notified bodies
- Regulators
- Academia
Standards for health software – AI/ML
What are the needs?

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)

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<tr>
<th>Testing</th>
<th>Usability</th>
<th>Labelling</th>
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<tbody>
<tr>
<td>ISO/IEC 80002-2 Medical devices software – Part 2: Validation of software for regulated processes</td>
<td>ISO 62366-1 Application of usability engineering to medical devices</td>
<td>ISO 20417 Information to be supplied by the manufacturer</td>
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<tr>
<td>ISO/IEC 27001 Information security management systems - Requirements</td>
<td>ISO 15223 Symbols to be used with medical device labels, labelling and information to be supplied</td>
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<th>Clinical and performance evaluation</th>
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<td>EN 13612 Performance evaluation of in vitro diagnostic medical devices</td>
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<td>ISO 14155 Clinical investigation of medical devices for human subjects – Good clinical practice</td>
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<th>Medical device software/Health software</th>
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<td>IEC 62304 Medical device software – Software life cycle process</td>
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<td>IEC 82304-1 Health Software – Part 1: General requirements for product safety</td>
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<td>ISO 81001-1 Health software and health IT systems safety, effectiveness and security – Part 1: Principles and concepts</td>
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<td>IEC 81001-5-1 Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle</td>
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<td>ISO/IEC 27001 Information security management systems - Requirements</td>
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<td>ISO/IEC 27005 Information security risk management</td>
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<td>ISO 14971 Application of risk management to medical devices</td>
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<td>IEC TR 80002-1 Guidance on the application of ISO 14971 to medical device software</td>
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<td>ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes</td>
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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.
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

14
PUBLISHED ISO STANDARDS
under the direct responsibility of ISO/IEC JTC 1/SC 42

25
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”?

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!