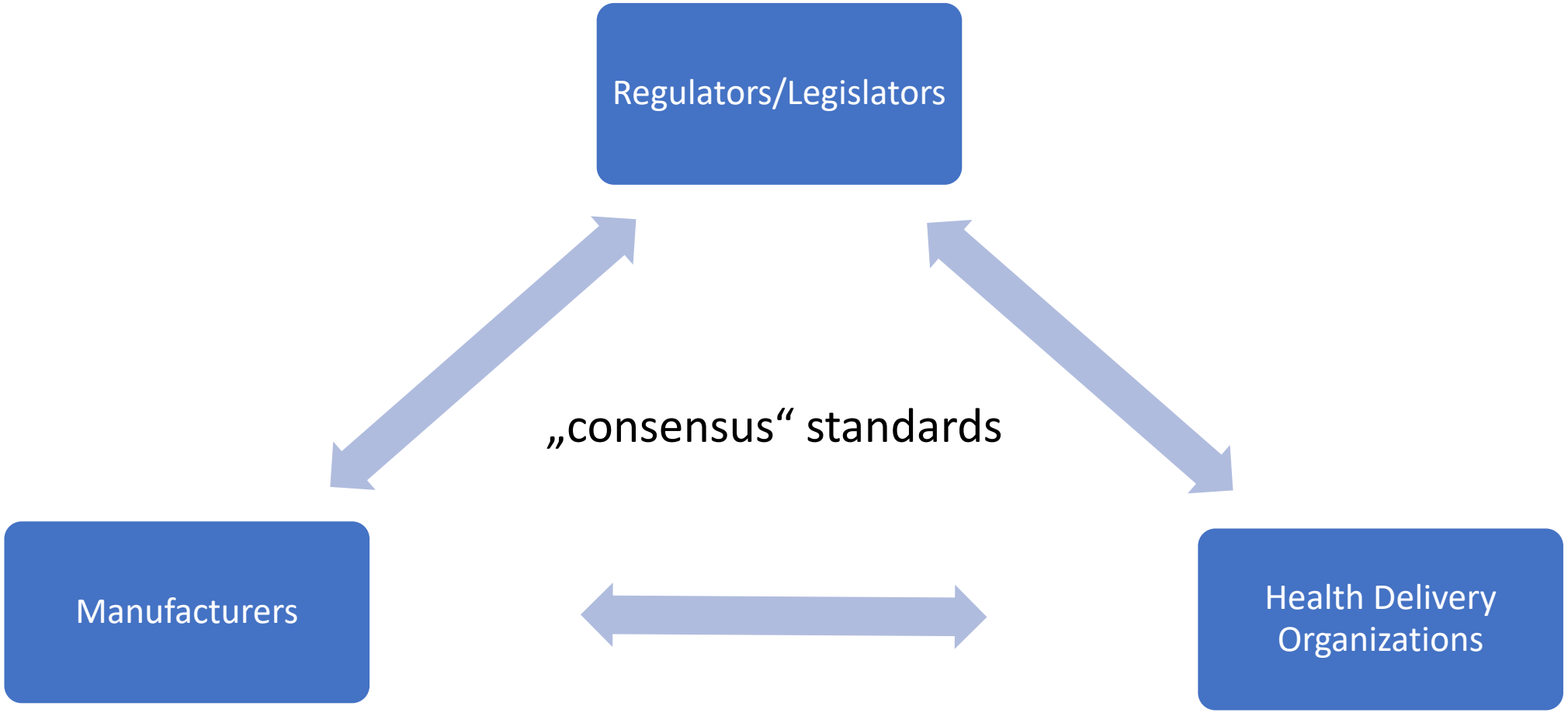
Medical Device Standards

Focus: AI/ML enabled medical devices

Role of standards for medical devices



Base „consensus“ standards for active medical devices *

Main objective derived from the legislation is to ensure that the benefit for end-users outweighs their residual risk in a traceable way

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

ISO 14971 Medical devices — Application of risk management to medical devices

IEC 62304 Medical device software – Software life cycle processes

IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices

All standards for specific devices and device groups (several hundreds) in the area refer to the principles laid down in these base standard

*active medical device: Supply of non-biological power is needed, includes software

Implications for AI Standards

All AI Standards for medical devices shall follow the established concepts for standards in this regulated area and use the principles laid down by the applicable legislation.

Terms, definitions and concepts shall be known and aligned with the legislation and the existing standards

The market access of the AI/ML enabled devices is jeopardized, if this alignment doesn’t happen

Proposed AI/ML standards architecture for MEE/MES

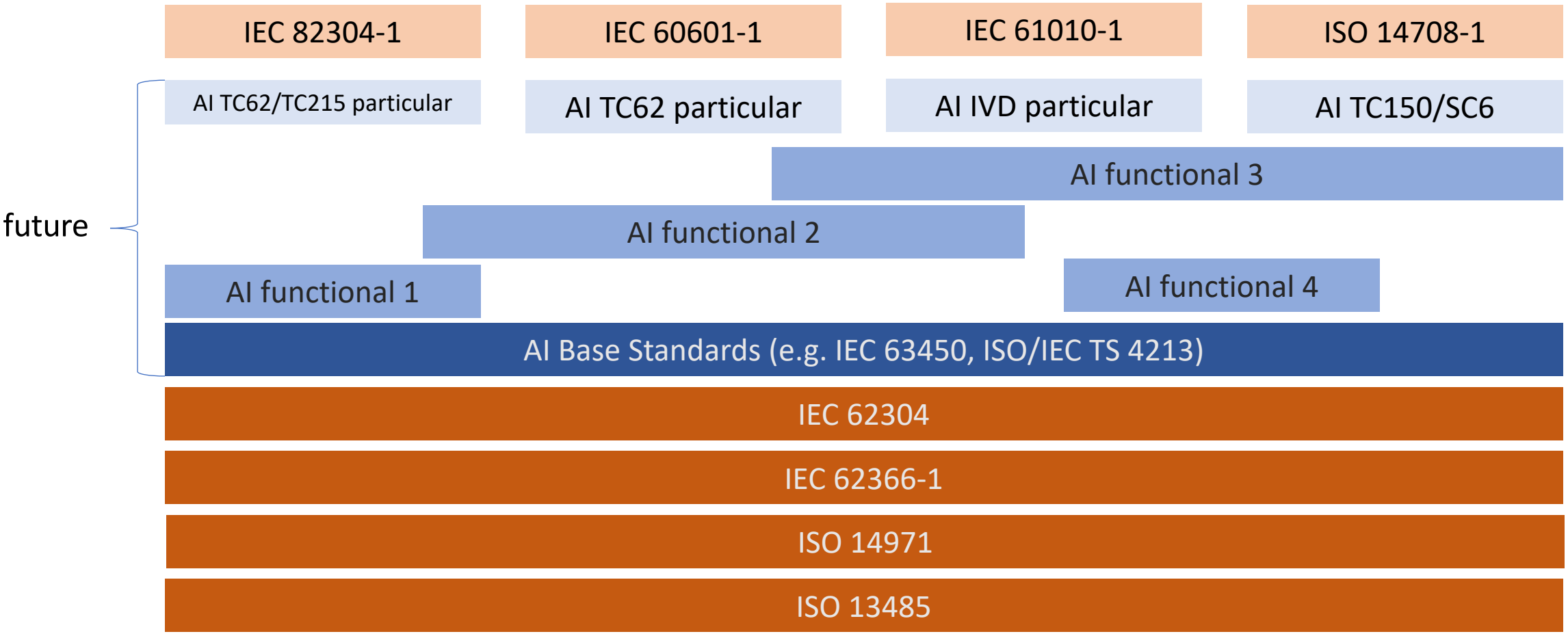


Figure 1 in the 4th SNAIG Report (62/432/INF)

„Roadmap“

Overview			
Existing standards sufficient; some additions for the application to AI-MD software different partners			
(all sorts of MD) QMS, RMS, PMS, Security, Privacy	Clarification where additional factors are to be considered - basic standards are basically sufficient		Impact of patient as operator in the private space and cloud are hardly considered at present
Traditional ME (Hardware + non AI Software)	covered		
SAMD	Extension/addition to 62304 for ML	clinical validation for SAMD	
New standards are necessary; IEC TC62 is in the lead or works in a JWG with partners			
(ML – MD, maybe AI - MD in general) Logic component	Quality metrics for external data component	clinical validation (data aspects, statistical effectiveness)	Techno-Vigilance necessary
	Quality criteria and docu req. for „logic“ component		Clinical utility (effective benefit at the site)
	Methods for building test sets		Transparency in Usage and operation
(AI – MD) Bias (Ethics?)	Overarching process standard and consideration in all columns for symbolic AI + ML		
New standards are necessary; ISO TC215 is in the lead or works in JWGs; IEC TC 62 contributes			
(ML – MD) Data component	Data Lifecycle process standard (incl. Selection, collection, vetting, documentation etc.)		
	Quality standards in design and development		Including changes based on PMS data or continuous learning
	Quality assurance methods and quality metrics		
	Methods for validation		

Thank you for listening

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