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Horizon Standardisation Booster

AI Standards in Healthcare: The Sustainable Formula Includes: Body, Mind, Technology and Standards

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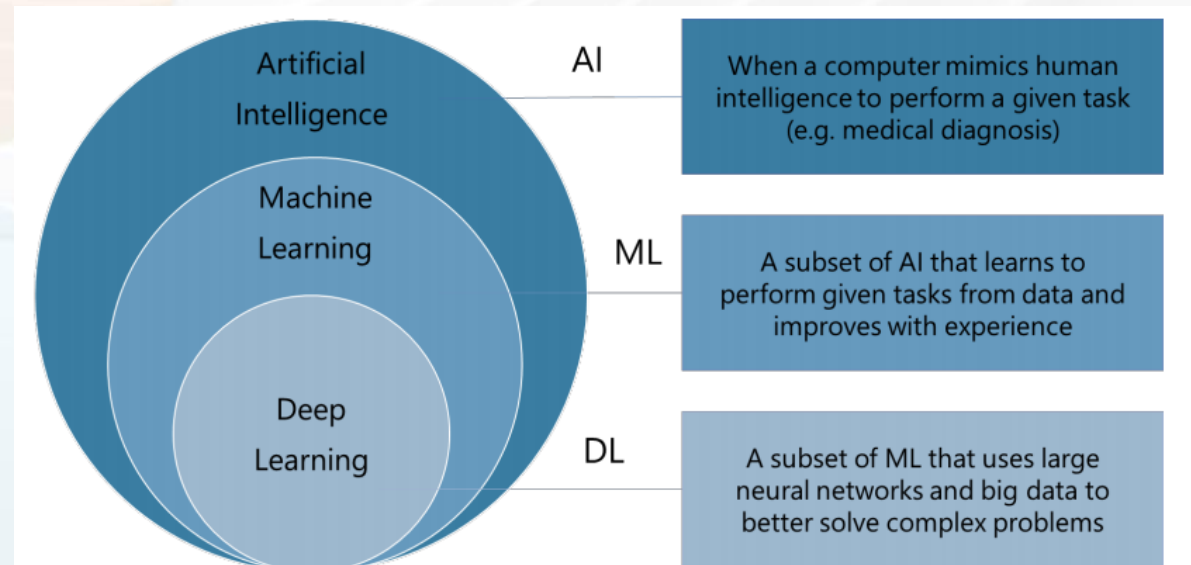
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Overview

1. The AI Space and Sub-Spaces
 2. Healthcare Status and AI
 3. Deployment of AI in healthcare
 4. Main application domains for AI in healthcare
 5. Risks of AI in Healthcare
 6. AI Standardisation in Healthcare
-

The AI Space and Sub-Spaces

- AI Space:
 - Definition (ISO/IEC 22989:2021): “AI - the capability to acquire, process, create and apply knowledge, held in the form of a model, to conduct one or more given tasks”
 - Umbrella covering:
 - Machine Learning (ML): Standards and regulations
 - currently cover a large part
 - of the applications.
 - Deep Learning

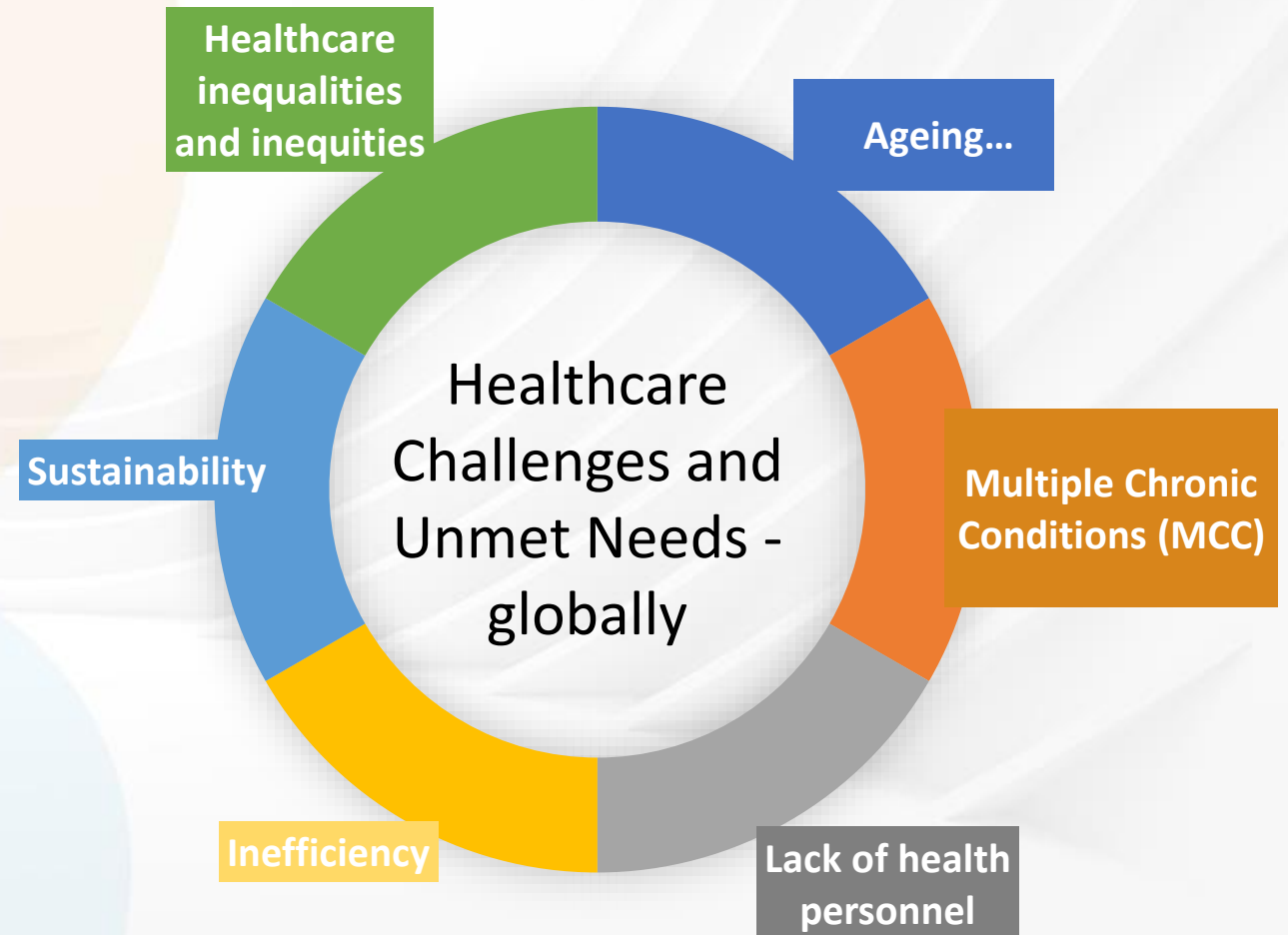


Healthcare Status and AI

AI deployment within healthcare* can address pressing issues:

- The rise of chronic diseases
- Lack of healthcare workforce
- Inefficiency of health systems
- Need for sustainability
- The Ageing population, with increasing multiple chronic conditions
- Health inequalities and inequities

* Healthcare includes also medical care in most contexts in this presentation

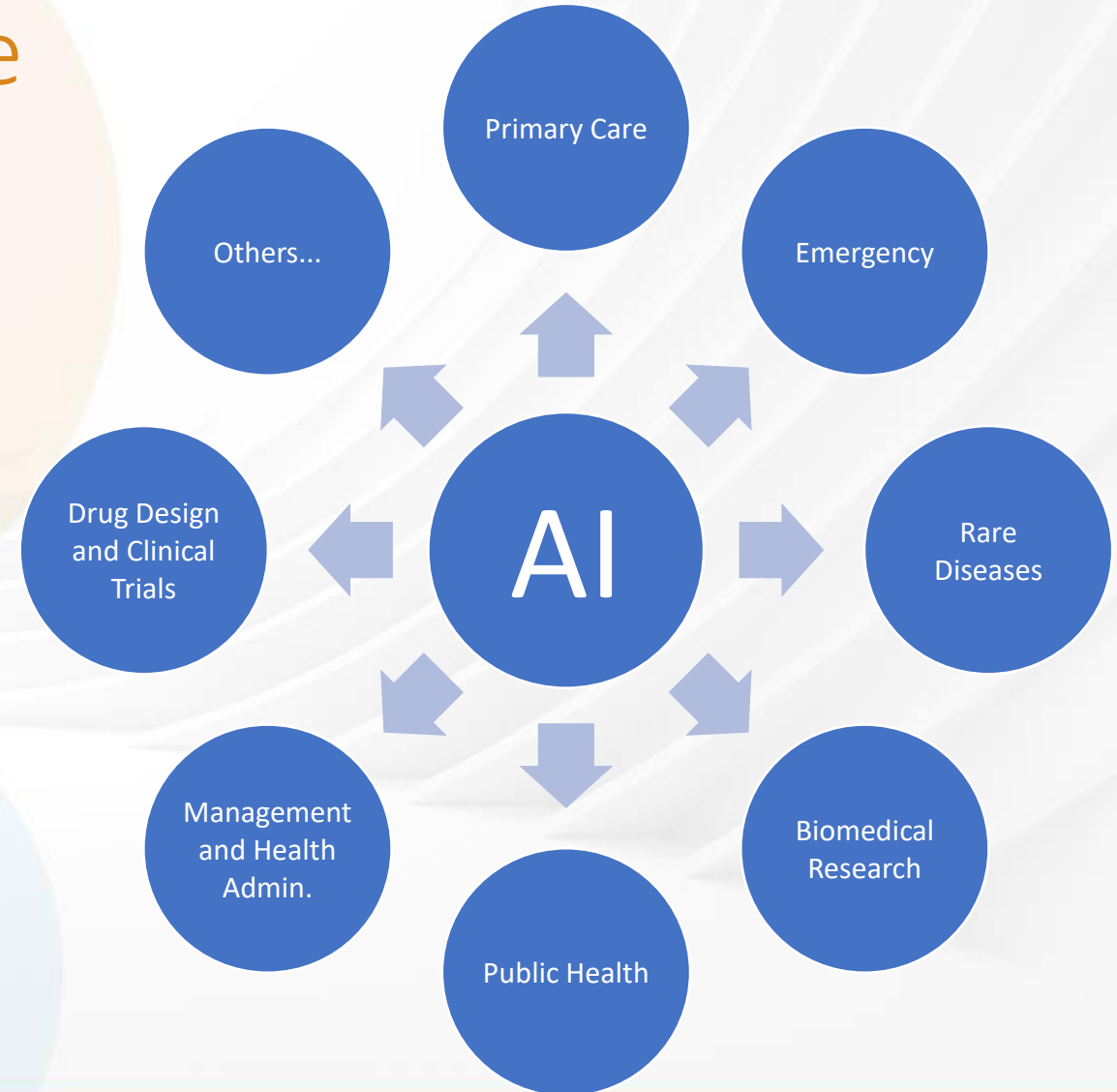


EU Healthcare Aims

- Reducing levels of healthcare inequities and inequalities among the member states and their populations
 - The right of every EU citizen to timely access to affordable, preventive care
 - High quality curative care: a key principle of the European Pillar of Social Rights
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AI Applications within Healthcare

- AI has progressively covered more areas of health- and medical care, and more to come
- Pressing issues within healthcare can be supported by AI tools



Potential of AI in Healthcare?

- Enormous, IF done 'correctly'
 - Some benefits include:
 - Increase efficiency of clinicians
 - Improve medical diagnosis and treatment (precision, early detection, modalities, therapies etc.)
 - Optimise allocation of human and technical resources
 - Improved preventive care and patient prioritisation
 - Support remote monitoring and virtual care
-

Some Specific Uses of AI within Healthcare

- Wide range, and more to come:
 - automation of diagnostic processes
 - therapeutic decision making
 - clinical research
 - image analysis and interpretation (e.g. radiology, ophthalmology, dermatology.)
 - signal processing (e.g. electrocardiogram, audiology, and electroencephalography) etc..

 - Clinical workflows
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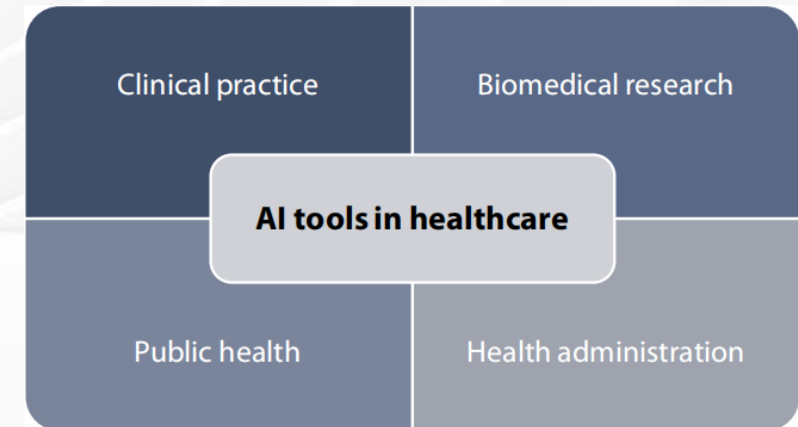
Categorising Healthcare AI tools

AI tools used in healthcare can be classified based on:

1) Stakeholder user groups: Patients and citizen, Clinicians and caregivers, Healthcare administrators, Public health professionals and policy makers

2) Usage: Clinical settings (hospitals, primary care centres, emergency care centres etc.), Clinical and managing settings (laboratory, pharmacy, radiology, etc), Administrative settings.

3) Settings*: Clinical, Research, Public health, Administrative



* Per EC report: "Artificial intelligence in healthcare - Applications, risks, and ethical and societal impacts"

Risks of AI in healthcare

- Risk areas and levels:
 - Clinical
 - Technical
 - Socio-ethical

 - Reduced level of trust in AI tools and systems:
 - Clinicians
 - Society at large (include patients)
-

Risk Assessment of AI uses in healthcare

➤ VITAL:

Risk assessment, classification and management must be integrated into all processes at different levels, including:

- Design and Development of AI models and tools
 - Evaluation of AI tools both in simulated and real-world settings
 - Deployment and uses by all relevant stakeholders (clinicians, patients, admins etc.)
 - Post-market surveillance and re-evaluations
-

Specific Risks of AI in healthcare

Specific risks of AI in medicine and healthcare, include:

- Patient harm due to AI errors
 - The misuse of medical AI tools
 - Increasing Bias and the continuation, including exacerbation, of existing inequities
 - Lack of transparency
 - Privacy and security issues
 - Gaps in accountability
 - Obstacles in implementation
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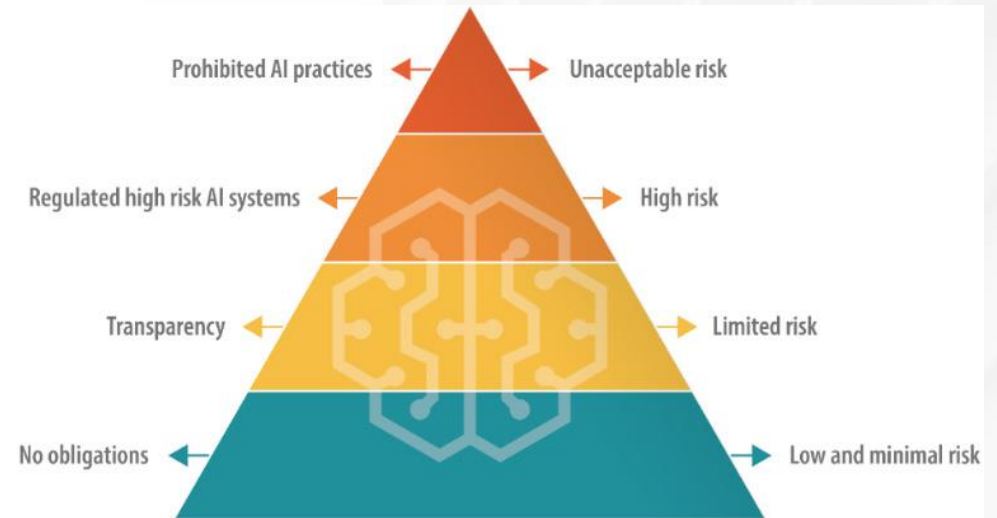
Specific risks of AI tools in the Clinic

Three major sources of errors for AI in clinical practice, include:

1. Predictions by AI:
impacted by noisy input data (during usage)
 2. Misclassification:
due to dataset shift, hospital-specific biases, machines from different manufacturers etc..
 3. Unforeseen large gaps between controlled settings and real-world settings
due to difficulties of AI algorithms to adapt to unexpected changes in the environment and context in which they are applied
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EU AIA Risk Categories (Jun 2023)

- Risk-based approach
- A Pyramid of risk levels
- Categories:
 - **Unacceptable risk:** Prohibited AI practices - banned “harmful AI practices that are considered to be a clear threat to people's safety, livelihoods and rights” (eg. social scoring purposes, real-time biometric identification)
 - **High risk:** Regulated high-risk AI systems - “adverse impact on people's safety or their fundamental rights” (eg .management and operation of critical infrastructure, Law enforcement)
 - **Limited risk:** Transparency obligations (eg. chatbots, emotion recognition systems)
 - **Low or minimal risk:** No obligations - All other AI systems presenting only low or minimal risk



NOTE: Generative AI (eg.ChatGPT):

- Must comply with transparency requirements:
 - Disclosing that the content was generated by AI
 - Designing the model to prevent it from generating illegal content
 - Publishing summaries of copyrighted data used for training

AI Standardisation in Healthcare

AI-related standards that can support aspects of healthcare, include:

- Risk management
- Data and data governance
- Record keeping
- Transparency and information provision
- Human oversight
- Accuracy and specifications for AI systems and tools
- Cyber security specifications
- Quality management systems
- Conformity assessment

Standardisation in Healthcare, cont.

- Mitigation measures and policy options to minimise risks
 - Maximise benefits of medical/healthcare AI, e.g.. increased interoperability
 - Increased transparency and traceability
 - In-depth clinical validation of AI tools
 - Training and education of clinicians and citizens on AI
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Development of Standards and Regulations for AI in Healthcare

1. Standardisation:

- AI standards and/or material supporting the development of standards, under development at various organizations (ISO, HL7, HIMMS, ANSI, CEN/CENELEC, WHO, IEEE etc..)
- Some degree of overlaps exists

2. Regulation of AI:

- For healthcare (and in general) is developing in several regions around the world: EU (AIA), USA (FDA), China etc..



Standards Related to AI in Healthcare*

1) ISO/IEC 23053 - Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML)

Establishes an Artificial Intelligence (AI) and Machine Learning (ML) framework for describing a generic AI system using ML technology. The framework describes the system components and their functions in the AI ecosystem. This document is applicable to all types and sizes of organizations, including public and private companies, government entities, and not-for-profit organizations, that are implementing or using AI systems.

2) ISO/IEC 20546:2019 - Information technology — Big data — Overview and vocabulary

Provides a set of terms and definitions needed to promote improved communication and understanding. It provides a terminological foundation for big data-related standards. It provides a conceptual overview of the field of big data, its relationship to other technical areas and standards efforts, and the concepts ascribed to big data that are not new to big data.

* Non-exhaustive

Standards Related to AI in Healthcare, cont.

3) ISO/IEC TR 20547-1:2020 - Information technology — Big data reference architecture — Part 1: Framework and application process

This document describes the framework of the big data reference architecture and the process for how a user of the document can apply it to their particular problem domain.

4) ISO/IEC TR 24027:2021 - Information technology — Artificial intelligence (AI) — Bias in AI systems and AI aided decision making

This document addresses bias in relation to AI systems, especially with regards to AI-aided decision-making. Measurement techniques and methods for assessing bias are described, with the aim to address and treat bias-related vulnerabilities. All AI system lifecycle phases are in scope, including but not limited to data collection, training, continual learning, design, testing, evaluation and use.

Standards Related to AI in Healthcare, cont.

5) ISO/IEC TR 24028:2020 - Information technology — Artificial intelligence — Overview of trustworthiness in artificial intelligence

This document surveys topics related to trustworthiness in AI systems, including the following:

- approaches to establish trust in AI systems through transparency, explainability, controllability, etc.;
- engineering pitfalls and typical associated threats and risks to AI systems, along with possible mitigation techniques and methods; and
- approaches to assess and achieve availability, resiliency, reliability, accuracy, safety, security and privacy of AI systems.

The specification of levels of trustworthiness for AI systems is out of the scope of this document.

Standards Related to AI in Healthcare, cont.

6) ISO/IEC 24029-2:2023 - Artificial intelligence (AI) — Assessment of the robustness of neural networks — Part 2: Methodology for the use of formal methods

This document provides methodology for the use of formal methods to assess robustness properties of neural networks. The document focuses on how to select, apply and manage formal methods to prove robustness properties.

7) ISO/IEC TR 24030:2021 - Information technology — Artificial intelligence (AI) — Use cases

This document provides a collection of representative use cases of AI applications in a variety of domains.

Standards Related to AI in Healthcare, cont.

8) ISO/IEC TR 24372:2021 - Information technology — Artificial intelligence (AI) — Overview of computational approaches for AI systems

This document provides an overview of the state of the art of computational approaches for AI systems, by describing: a) main computational characteristics of AI systems; b) main algorithms and approaches used in AI systems, referencing use cases contained in ISO/IEC TR 24030.

Standards Related to AI in Healthcare, cont.

9) ISO/IEC 38507:2022 - Information technology — Governance of IT — Governance implications of the use of artificial intelligence by organizations

This document provides guidance for members of the governing body of an organization to enable and govern the use of Artificial Intelligence (AI), in order to ensure its effective, efficient and acceptable use within the organization.

This document also provides guidance to a wider community, including:

executive managers; external businesses or technical specialists, public authorities and policy-makers; internal and external service providers (including consultants); assessors and auditors.

It is applicable to the governance of current and future uses of AI as well as the implications of such use for the organization itself. It is applicable to all organizations, including public and private companies, government entities and not-for-profit organizations; of any size irrespective of their dependence on data or information technologies.

Standards Related to AI in Healthcare, cont.

10) ISO/IEC TS 4213:2022 - Information technology — Artificial intelligence — Assessment of machine learning classification performance

This document specifies methodologies for measuring classification performance of machine learning models, systems and algorithms.

Standards Related to AI in Healthcare, cont.

11) ISO/IEC DIS 5259-1 - Artificial intelligence — Data quality for analytics and machine learning (ML) — Part 1: Overview, terminology, and examples

Status

: Under development

Standards Related to AI in Healthcare, cont.

12) ISO/IEC DIS 5259-2 - Artificial intelligence — Data quality for analytics and machine learning (ML) — Part 2: Data quality measures

Status

: Under development

Standards Related to AI in Healthcare, cont.

13) ISO/IEC DIS 5259-3 - Artificial intelligence — Data quality for analytics and machine learning (ML) — Part 3: Data quality management requirements and guidelines

Status

: Under development

Standards Related to AI in Healthcare, cont.

14) ISO/IEC DIS 5259-4 - Artificial intelligence — Data quality for analytics and machine learning (ML) — Part 4: Data quality process framework

Status

: Under development

Standards Related to AI in Healthcare, cont.

15) ISO/IEC CD 5259-5 - Artificial intelligence — Data quality for analytics and machine learning (ML) — Part 5: Data quality governance

This document provides a data quality governance framework for analytics and machine learning to enable governing bodies of organizations to direct and oversee the implementation and operation of data quality measures, management, and related processes with adequate controls throughout the data life cycle. This document can be applied to any analytics and machine learning. This document does not define specific management requirements or process requirements specified in 5259-3 and 5259-4 respectively.

Standards Related to AI in Healthcare, cont.

16) ISO/IEC FDIS 5338 - Information technology — Artificial intelligence — AI system life cycle processes

Status

: Under development

Standards Related to AI in Healthcare, cont.

17) ISO/IEC FDIS 5339 - Information technology — Artificial intelligence — Guidance for AI applications

Status

: Under development

Standards Related to AI in Healthcare, cont.

18) ISO/IEC DIS 5392 - Information technology — Artificial intelligence — Reference architecture of knowledge engineering

Status

: Under development

Standards Related to AI in Healthcare, cont.

19) ISO/IEC DTR 5469 - Artificial intelligence — Functional safety and AI systems

Status

: Under development

Standards Related to AI in Healthcare, cont.

20) ISO/IEC DTS 25058 - Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Guidance for quality evaluation of artificial intelligence (AI) systems

Status

: Under development

Standards Related to AI in Healthcare, cont.

21) ISO/IEC NP TS 5471 Artificial intelligence -- Quality evaluation guidelines for AI systems

This document provides guidelines for evaluation of AI systems using an AI system quality model.

The document is applicable to all types of organizations engaged in the development and the use of artificial intelligence.

Standards Related to AI in Healthcare, cont.

22) ISO/IEC CD TS 6254 - Information technology — Artificial intelligence — Objectives and approaches for explainability of ML models and AI systems

This document describes approaches and methods that can be used to achieve explainability objectives of stakeholders with regards to ML models and AI systems' behaviours, outputs, and results. Stakeholders include but are not limited to, academia, industry, policy makers, and end users. It provides guidance concerning the applicability of the described approaches and methods to the identified objectives throughout the AI system's life cycle, as defined in ISO/IEC 22989.

Status

: Under development

Standards Related to AI in Healthcare, cont.

23) ISO/IEC 8183:2023 - Information technology — Artificial intelligence — Data life cycle framework

This document defines the stages and identifies associated actions for data processing throughout the artificial intelligence (AI) system life cycle, including acquisition, creation, development, deployment, maintenance and decommissioning. This document does not define specific services, platforms or tools. This document is applicable to all organizations, regardless of type, size or nature, that use data in the development and use of AI systems.

Standards Related to AI in Healthcare, cont.

23) ISO/IEC CD TS 8200 - Information technology — Artificial intelligence — Controllability of automated artificial intelligence systems

This document defines a basic framework with principles, characteristics and approaches for the realization and enhancement for automated artificial intelligence (AI) systems' controllability. The following areas are covered: — State observability and state transition — Control transfer process and cost — Reaction to uncertainty during control transfer — Verification and validation approaches
This document is applicable to all types of organizations (e.g. commercial enterprises, government agencies, not-for-profit organizations) developing and using AI systems during their whole life cycle.

Status

: Under development

Standards Related to AI in Healthcare, cont.

24) ISO/IEC DTS 12791 - Information technology — Artificial intelligence — Treatment of unwanted bias in classification and regression machine learning tasks

This document provides mitigation techniques that can be applied throughout the AI system life cycle in order to treat unwanted bias. This document describes how to address unwanted bias in AI systems that use machine learning to conduct classification and regression tasks. This document is applicable to all types and sizes of organization.

Status

: Under development

Standards Related to AI in Healthcare, cont.

25) ISO/IEC CD 12792 - Information technology — Artificial intelligence — Transparency taxonomy of AI systems

This document defines a taxonomy of information elements to assist AI stakeholders with identifying and addressing the needs for transparency of AI systems. The document describes the semantics of the information elements and their relevance to the various objectives of different AI stakeholders. This document uses a horizontal approach and is applicable to any kind of organization and application involving AI. V02/

Status

: Under development

Standards Related to AI in Healthcare, cont.

26) ISO/IEC CD TR 17903 - Information technology — Artificial intelligence — Overview of machine learning computing devices

Status

: Under development

Standards Related to AI in Healthcare, cont.

27) ISO/IEC 22989:2022 - Information technology — Artificial intelligence — Artificial intelligence concepts and terminology

This document establishes terminology for AI and describes concepts in the field of AI.

This document can be used in the development of other standards and in support of communications among diverse, interested parties or stakeholders.

This document is applicable to all types of organizations (e.g. commercial enterprises, government agencies, not-for-profit organizations).

Standards Related to AI in Healthcare, cont.

28) ISO/IEC 23053:2022 - Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML)

This document establishes an Artificial Intelligence (AI) and Machine Learning (ML) framework for describing a generic AI system using ML technology. The framework describes the system components and their functions in the AI ecosystem. This document is applicable to all types and sizes of organizations, including public and private companies, government entities, and not-for-profit organizations, that are implementing or using AI systems.

Standards Related to AI in Healthcare, cont.

29) ISO/IEC 23894:2023 - Information technology — Artificial intelligence — Guidance on risk management

This document provides guidance on how organizations that develop, produce, deploy or use products, systems and services that utilize artificial intelligence (AI) can manage risk specifically related to AI. The guidance also aims to assist organizations to integrate risk management into their AI-related activities and functions. It moreover describes processes for the effective implementation and integration of AI risk management.

The application of this guidance can be customized to any organization and its context.

Standards Related to AI in Healthcare, cont.

30) ISO/IEC 24029-2:2023 - Artificial intelligence (AI) — Assessment of the robustness of neural networks — Part 2: Methodology for the use of formal methods

This document provides methodology for the use of formal methods to assess robustness properties of neural networks. The document focuses on how to select, apply and manage formal methods to prove robustness properties.

Standards Related to AI in Healthcare, cont.

31) ISO/IEC TR 24030:2021 - Information technology — Artificial intelligence (AI) — Use cases

This document provides a collection of representative use cases of AI applications in a variety of domains.

Standards Related to AI in Healthcare, cont.

32) ISO/IEC TR 24368:2022 - Information technology — Artificial intelligence — Overview of ethical and societal concerns

This document provides a high-level overview of AI ethical and societal concerns.

In addition, this document:

- provides information in relation to principles, processes and methods in this area;
- is intended for technologists, regulators, interest groups, and society at large;
- is not intended to advocate for any specific set of values (value systems).

This document includes an overview of International Standards that address issues arising from AI ethical and societal concerns.

Standards Related to AI in Healthcare, cont.

33) ISO/IEC 24668:2022 - Information technology — Artificial intelligence — Process management framework for big data analytics

This document provides a framework for developing processes to effectively leverage big data analytics across the organization irrespective of the industries or sectors.

This document specifies process management for big data analytics with its various process categories taken into account along with their interconnectivities. These process categories are organization stakeholder processes, competency development processes, data management processes, analytics development processes and technology integration processes. This document describes processes to acquire, describe, store and process data at an organization level which provides big data analytics services.

Standards Related to AI in Healthcare, cont.

34) ISO/IEC 25059:2023 - Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Quality model for AI systems

This document outlines a quality model for AI systems and is an application-specific extension to the standards on SQuaRE. The characteristics and sub-characteristics detailed in the model provide consistent terminology for specifying, measuring and evaluating AI system quality. The characteristics and sub-characteristics detailed in the model also provide a set of quality characteristics against which stated quality requirements can be compared for completeness.

Standards Related to AI in Healthcare, cont.

35) ISO/IEC TR 29119-11:2020 - Software and systems engineering — Software testing — Part 11: Guidelines on the testing of AI-based systems

This document provides an introduction to AI-based systems. These systems are typically complex (e.g. deep neural nets), are sometimes based on big data, can be poorly specified and can be non-deterministic, which creates new challenges and opportunities for testing them. This document explains those characteristics which are specific to AI-based systems and explains the corresponding difficulties of specifying the acceptance criteria for such systems. This document presents the challenges of testing AI-based systems, the main challenge being the test oracle problem, whereby testers find it difficult to determine expected results for testing and therefore whether tests have passed or failed. It covers testing of these systems across the life cycle and gives guidelines on how AI-based systems in general can be tested using black-box approaches and introduces white-box testing specifically for neural networks. It describes options for the test environments and test scenarios used for testing AI-based systems. In this document an AI-based system is a system that includes at least one AI component.

Standards Related to AI in Healthcare, cont.

35) ISO/IEC FDIS 42001 - Information technology — Artificial intelligence — Management system

Status

: Under development

Standards Related to AI in Healthcare, cont.

ISO 13606-1:2019 - Health informatics — Electronic health record communication — Part 1: Reference model

This document specifies a means for communicating part or all of the electronic health record (EHR) of one or more identified subjects of care between EHR systems, or between EHR systems and a centralised EHR data repository. It can also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components), or personal health applications and devices, that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system. This document will predominantly be used to support the direct care given to identifiable individuals or self-care by individuals themselves, or to support population monitoring systems such as disease registries and public health surveillance. Uses of health records for other purposes such as teaching, clinical audit, administration and reporting, service management, research and epidemiology, which often require anonymization or aggregation of individual records, are not the focus of this document but such secondary uses might also find the document useful. This Part 1 of the multipart series is an Information Viewpoint specification as defined by the Open Distributed Processing ? Reference model: Overview (ISO/IEC 10746-1). This document is not intended to specify the internal architecture or database design of EHR systems.

Standards Related to AI in Healthcare, cont.

ISO 12967-2:2020 - Health informatics — Service architecture (HISA) — Part 2: Information viewpoint

This document specifies the fundamental characteristics of the information model implemented by a specific architectural layer (i.e. the service architecture) of the information system to provide a comprehensive and integrated storage of the common enterprise data and to support the fundamental business processes of the healthcare organization, as defined in ISO 12967-1. The information model is specified in this document without any explicit or implicit assumption on the physical technologies, tools or solutions to adopt for its physical implementation in the various target scenarios. The specification is nevertheless formal, complete and non-ambiguous enough to allow implementers to derive an efficient design of the system in the specific technological environment that will be selected for the physical implementation. This document does not aim at representing a fixed, complete, specification of all possible data that can be necessary for any requirement of any healthcare enterprise. It specifies only a set of characteristics, in terms of overall organization and individual information objects, identified as fundamental and common to all healthcare organizations, and that is satisfied by the information model implemented by the service architecture. Preserving consistency with the provisions of this document, physical implementations are allowed extensions to the standard information model in order to support additional and local requirements. Extensions include both the definition of additional attributes in the objects of the standard model, and the implementation of entirely new objects. Also, this document specification is extensible over time according to the evolution of the applicable standardization initiatives.

The specification of extensions is carried out according to the methodology defined in ISO 12967-1:2020, Clause 7.

Standards Related to AI in Healthcare, cont.

ISO 13940:2015 - Health informatics — System of concepts to support continuity of care

ISO 13940:2015 defines a system of concepts for different aspects of the provision of healthcare. The core business in healthcare is the interaction between subjects of care and healthcare professionals. Such interactions occur in healthcare/clinical processes and are the justification for the process approach of ISO 13940:2015. To be able to represent both clinical content and clinical context, ISO 13940:2015 is related to a generic healthcare/clinical process model as well as comprehensive concept definitions and concept models for the clinical, management and resource aspects of healthcare services. In practice ISO 13940:2015 covers the concept definitions needed whenever structured information in healthcare is specified as a requirement. The definitions are intended to refer to the conceptual level only and not to details of implementation. ISO 13940:2015 will cover all levels of specifications in the development of logical reference models within the information viewpoint as a common basis for semantic interoperability on international, national or local levels, information systems, and information for specified types of clinical processes.

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THANKS!

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