A Review of AI Life Cycle-related Standards to Address AI-enabled Medical Device Development

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Abstract. The integration of Artificial Intelligence (AI) in Medical Device Software (MDSW) can bring opportunities to enhance clinical workflow. However, this has also brought challenges to manufacturers, of which additional considerations during the development process must be contemplated. As an initial step to address the development of AI-enabled Medical Device (AIeMD), this review paper aims to identify relevant AI Standards for an initial understanding and propose an alignment of the development life cycle (DLC) of MDSW and AI systems. Standards are resources to harmonise best practices, some of which are also accepted to address aspects of MDSW. In the AI domain, standardisation work is a key ongoing process to ensure the responsible development of AI systems. ISO/IEC 5338 provides a life cycle framework for AI systems; however, identifying related standards is essential to consider consistent use of processes, stages, activities, and terminologies. As numerous AI Standards have been published in recent years, the most relevant AI Life Cycle-related standards are identified through the AI Standards Hub (AIHub). A set of criteria is established to select standards that cover the DLC of AI systems, including standards associated with the data management life cycle. The search on AIHub brought 33 AI-specific standards, most of which were issued by ISO/IEC. After cross-validation, the standards were inspected to identify additional standards not included in the AI-Hub results, resulting in four more being added to the list. After data selection, eleven AI life cycle-related standards were chosen towards implementing a framework for the DLC of AIeMD.

Keywords: Standards, Medical Device Software, Artificial Intelligence Systems, Development, Life Cycle

1 Introduction

The field of health software is rapidly changing with the introduction of new technologies. Artificial Intelligence (AI) in healthcare can transform the sector to benefit people's health, improving the delivery of medical services. AI models can enhance the performance of Medical Device Software (MDSW), boosting medical staff's workflow and patient care delivery [1, 2]. When a Medical Device (MD) uses AI models to

achieve a medical purpose, they are referred to as an AI-enabled Medical Device (AIeMD) [3]. Examples of AIeMDs include those that enhance medical imaging to support, e.g., radiologists reading images more quickly and accurately, improving the diagnosis of diseases [4]. Nevertheless, alongside these benefits, considerations during the development process of MDSW must be contemplated to preserve the safety and performance of the devices. This is particularly important for safety-critical domains such as MDSW, given that there could be severe consequences if a software system fails [5]. With the adoption of AIeMDs in the healthcare sector, these consequences may be magnified if there is no control during the development process.

The adoption of AI models into MDSW can bring diverse challenges to manufacturers, including the different development processes of MDSW and AI systems [6]. Even with the existence of data-driven development life cycle (DLC) models for AI systems [7], these may not be suitable for the development of AIeMD due to the lack of alignment of activities and regulatory considerations [8]. Other factors that may impact the development process of AIeMD are the tendency among data scientists not to follow an explicit development process, or the absence of documentation control [8, 9]. To this end, as an initial step to propose a framework for the development of AIeMD, this review paper aims to identify relevant AI life cycle-related standards to subsequently propose an alignment of MDSW and AI DLC processes. There is a broad number of published standards by Standard Development Organisations (SDOs) such as ISO, IEC, and IEEE. Therefore, it is critical to inspect and select relevant standards to propose a DLC process for AIeMD.

The structure of the paper is as follows: Section 2 discusses standards related to software development of MDs; Section 3 introduces the landscape of AI standards; Section 4 describes the methodology and data selection protocol established; Section 5 shows the results and selected standards; Section 6 presents a discussion on these standards; and, Section 7 concludes the review paper and describes future work.

2 Medical Device Standards for Software Development

A solid framework exists for the design, development, and regulation of health technologies [10]. However, embedding AI technologies in MDSW will adjust the development process with additional activities and tasks that should be considered. Standards are important to promote robust use of globally agreed rules and practices for products and services. Some regulatory bodies from the MD industry, such as the FDA, support the use of standards [11, 12]. Even though standards are not legally mandatory, these are essential resources that provide guidance to reach a certain level of product quality and safety, facilitating proof of adequate implementation [13]. In Europe, harmonised standards are voluntary European Standards that can be utilised to demonstrate compliance with specific regulatory requirements from a given legislation [12].

In the MDSW industry, there is a range of published standards. Manufacturers may consider some standards, including ISO 14971 for Risk Management, ISO 13485 for Quality Management, IEC 82304-1 for general requirements for product safety, and IEC 62304 for Software Life Cycle Process.

IEC 62304 is an international standard for the MDSW life cycle process. It establishes a common framework to assist manufacturers in the development and maintenance of software that is itself an MD or embedded or integral part of an MD [14]. As the standard is designed to encompass common activities and tasks based on software safety classification, it does not imply or mandate a specific software DLC model [15, 16], but shall be specified during Software Planning (IEC 62304, Clause 5.1). IEC 62304 is considered the most widely adopted standard in the MD industry [14]. The FDA recognises IEC 62304 as a consensus standard for software development [17]. In Europe, IEC 62304 is a harmonised standard for the Medical Device Directive, and it is expected to become harmonised to the Medical Device Regulation by May 2028 [18, 19]. Besides IEC 62304, there are two other software life cycle standards: TIR45 and IEC/TR 80002-3. The former covers the development of MDSW using Agile practices, considering activities described in IEC 62304 [20]. The latter provides a process reference model of MDSW life cycle processes, directly derived from IEC 62304 [21].

The existing work of MDSW provides a good foundation for proposing new approaches to AI in the MD industry [10] and thus serves as a starting point to define a DLC process for AIeMD. IEC 62304 is considered a pivotal standard to propose an AIeMD DLC, whereas TIR45 and IEC/TR 80002-3 are left as secondary references for future work. Subsequently, the inspection of standards related to the DLC of AI systems should also be considered.

3 Artificial Intelligence Standardisation Work

Standard Development Organisations (SDOs), such as ISO, IEC, and IEEE, are working on AI standards to promote and foster the development of responsible AI systems across various industries [22]. These standards include areas such as trustworthiness, bias, transparency, data quality, and performance evaluation [23].

ISO and IEC are jointly developing AI standards through the SC 42, which plays a critical role in the development of comprehensive horizontal standards [24]. Some ISO/IEC standards published include ISO/IEC 22989 for concepts and terminologies, ISO/IEC 42001 for AI management systems, ISO/IEC 23894 for guidance on risk management, ISO/IEC 38507 for governance implications, ISO/IEC 23053 for using Machine Learning (ML), and ISO/IEC 5338 for AI system life cycle processes [25]. Some other standards under development, including ISO/IEC DIS 5259-6 for data quality for analytics and ML, ISO/IEC AWI 23282 for evaluation methods for accurate Natural Language Processing systems, and ISO/IEC AWI 24029-3 for assessment of the robustness of neural networks [26]. There is another set of AI Standards for MDs under development that is carried out by the IEC/TC 62 (Medical equipment, software, and systems), including IEC 63450 for methods for technical verification and validation, ISO/CD TS 24971-2 for guidance on the application of ISO 14971 (risk management for MDs) for ML and AI technologies, IEC 63521 for Performance Evaluation Process, IEC PAS 63621 Data Management for AI enabled MD, and IEC TS 62366-3 for guidance on the application of usability engineering for AI and ML technologies [27–30].

Even though it is expected that most of the AI standardisation work will be carried out by ISO and IEC, other standard organisations are also performing similar work, including IEEE SA [31]. IEEE SA offers globally recognised standards in ethics and system engineering. This includes published standards from the IEEE 7000 series, for example, IEEE 7000 Standard model Process for Addressing Ethical Concerns during System Design, IEEE 7001 Standard for Transparency of Autonomous Systems, and IEEE 7003 for Algorithmic Bias Considerations.

One year before the EU AI Act (AIA) entered into force, the EC adopted a standardisation request which was accepted by European Standards Organisations (ESOs) to develop necessary Harmonised Standards to provide a presumption of conformity with the regulation [32–34]. To ensure global consistency, some Harmonised Standards can be derived from international standardisation activities [34]. However, some factors unique to the AIA are not captured in these activities [23], which remaining gaps are expected to be addressed by ESOs [35]. A list of preliminary standardisation work for the AIA is available on [35, 36]. Even though ISO/IEC 5338 is not in this preliminary list, this document provides an AI life cycle framework that can be used to propose an AIeMD DLC in conjunction with the MDSW DLC. However, it is hypothesised that this is not the only AI life cycle-related standard. Therefore, an examination of published AI standards is needed to select those that are relevant to propose an AIeMD DLC.

4 Methodology

4.1 Introduction

A review of standards related to the AI life cycle development process is conducted. Information from standards is initially extracted on the AI Standards Hub (AIHub), a platform that offers access to a Standards Database covering more than 400 documents. This database includes a filtering tool to identify relevant standards based on, e.g., domain, scope, and topic. The three major steps to collect and review AI-related life cycle standards are as follows:

1. Search for AI life cycle-related standard titles on AIHub:
   a. Review and select fields to filter the Standards Database on AIHub
   b. Define values for each field selected to filter the Standards Database on AIHub
   c. Perform research based on filters established
2. Collect relevant information from AIHub:
   a. Inspect information related to the standards
   b. Download and store data in an Excel file
   c. Cross-validate the stage of development of the standard on SDO's website
   d. Validate access to standard documents for the selection protocol
3. Standard selection:
   a. Define a set of criteria to select relevant standards
   b. Download standard documents (depending on the researcher's accessibility)
   c. Select relevant standards based on a set of criteria

4. Present and discuss the results.

4.2 Data Collection

The data source to retrieve relevant information from AI standards is gathered from AIHub, an initiative from the National AI Strategy of the United Kingdom (UK) and supported by the UK Government through the Department for Science, Innovation, and Technology [37]. This initiative aims to inform the direction of the work in the AI field based on a collaborative community. AIHub also provides public access to a Standards Database to find relevant information on AI standards [37].

The AIHub Database is used to inspect information from standards related to the AI system life cycle. The tool to filter the database contains the following fields: Domain, Scope, Topic, Stage of Development, Issuing Body, and Type of Standard. These fields and respective values are shown in Table 1. The main topic is "system lifecycle", expecting to find standards related to design and development processes for AI systems. Additionally, as data management encompasses processes to collect, prepare, and check the quality of the data [38], it is expected to find data life cycle-related standards by including the "data management" topic. The database is filtered on "horizontal" and "healthcare and medicine" domains, and stage of development as "published" standards. The scope field has two options: AI-specific (standards explicitly designed for AI) and AI-enabling (standards adjusted for AI). For this research paper, standards specifically designed for AI are reviewed.

Table 1. List of fields and values selected to filter the AIHub Database.

Field	Meaning	Value
Domain	The industry or sector that the standard covers.	Horizontal, Healthcare and medicine
Scope	Whether the standard is focused entirely on AI or is adjacent to AI.	AI-specific
Topic	The theme, principle, or area covered by the standard.	System life cycle, Data management
Stage of Development	If the standard is pre-draft, draft, or published.	All values available
Issuing Body	The standards body or organisation that issued the standard.	All values available
Type of Standard	Whether the standard covers terminology, processes, performance requirements, or measurement requirements.	All values available

It is important to note that the AIHub does not provide access to standard documents. To inspect content from each standard, the accessibility of the documents is validated on other platforms. Our Institution provides access to different databases, including the British Standards Online (BSOL) and IEEE Standards Association. The BSOL tool offers access to European and International Standards, including BS, ISO, EN, and IEC standards. These platforms are used to download standard documents to run the data selection protocol.

4.3 Data Selection Protocol

After gathering the relevant data from the AIHub Database, AI-specific standards are selected based on a set of criteria. These are established to select standards that will support the design of a framework for AIeMD development. As the integration process of MDSW DLC (IEC 62304) and the AI DLC is proposed, the criteria for selecting standards for integration purposes in detail are based on the processes, activities, and level of detail of the life cycle of each standard. The standards are selected to identify the following objectives: (1) what standards will serve to *build* an initial DLC process for AIeMD (referred to *baseline*) and (2) what standards to *support* the baseline. The baseline refers to the first form of the DLC framework for AIeMD, which will include stages, processes, activities, and tasks in a high-level approach. Therefore, for (1), the criteria from [C1] to [C5] are established to find standards that describe the AI DLC, including stages, processes, activities, and tasks. For (2), criterion [C6] is established to find standards that provide detailed specifications, which will serve to enhance the baseline. The criteria, conditions, and objectives are shown in Table 2, from which each standard is assigned one point, a half point, or no point.

Table 2. The set of criteria to filter Standards from the AIHub Database.

Ref.	Criteria	Conditions	Obj.
[C1]	Does the standard *introduce* the AI DLC?	OP: The document introduces the development of AI models. HP: It introduces the data life cycle, part of the AI DLC. NP: It does not introduce the development of AI models.	BL
[C2]	Is the AI DLC the *core* theme of the document?	OP: The document is particularly designed to describe the AI DLC. HP: It is designed to describe its core theme based on the AI DLC, or it includes the data life cycle as the core theme. NP: It just mentioned the life cycle of AI systems.	BL
[C3]	Is the AI DLC described *in detail*?	OP: The document describes each activity within the AI DLC. HP: It partially describes the activities within the AI DLC. NP: It does not describe the activities within the AI DLC.	BL
[C4]	Is the AI DLC outlined *beyond* data collection, data preparation, model training, and model evaluation activities?	OP: The document introduces activities beyond data acquisition, data preparation, model training, and model evaluation. HP: The document includes some activities beyond data collection, data preparation, model training, and model evaluation. NP: The document does not include other activities beyond data engineering and model engineering.	BL
[C5]	Does the document describe the AI DLC in a way that it is *possible to align* terminologies with IEC 62304?	FP: The document describes the AI DLC with terminology possible to align with IEC 62304, including process constructs as Process, Activity, and Task. HP: The document includes some terminology possible to align with IEC 62304. EP: The document does not describe the AI DLC with terminology possible to align with IEC 62304.	BL
[C6]	Does the standard include *specifications* for designing and developing AI systems?	OP: The document includes specifications on AI tasks that will support the baseline. HP: The document includes some specifications on AI tasks that will support the baseline. EP: The document does not include specifications beyond the definitions of stages and processes.	SP

Ref. = Reference, Obj. = Objective, OP = One Point, HP = Half Point, EP = Empty Point, BL = Baseline, SP = Support

5 Results

The search on AIHub brought a list of 33 AI-specific standards[1], conducted in November 2024 and revisited in March 2025. For standards with "stage of development" as draft and pre-draft were cross-validated with their respective SDO's website. For Standards that belong to the "system lifecycle" topic, it was found that six standards were still under development. For the "data management" topic, two standards were recently published in February 2025. Moreover, the accessibility of the standard documents was verified, from which 12 standards were available via institutional subscription and eight were open access. All standards that were still under development (draft or pre-draft) or inaccessible were removed from the review process. Table 3 presents the final list of standards for data selection protocol, with ten documents in the "system lifecycle" topic, nine in the "data management" topic, and one in both topics.

Table 3. List of published AI-specific Standards found on the AIHub Database.

Standard	Title	Description	Topic	Domain
ISO/IEC 22989	AI concepts and terminology	This standard establishes vocabulary related to AI. It also includes a description of the AI system life cycle. The life cycle described in this document is mapped to the OECD's AI system life cycle.	SLC	HL
ISO/IEC 5338	AI system life cycle processes	This standard contains and describes the life cycle processes of AI systems. The life cycle process is based on two other standards: ISO/IEC/IEEE 12207 and ISO/IEC/IEEE 15288.	SLC	HL
ISO/IEC TR 24714-1	Biometrics — Cross-jurisdictional and societal aspects of biometrics — General guidance	This standard provides general guidance for the life cycle of systems using biometric and related elements. It includes a brief description of the ML workflow life cycle.	SLC	HL
ISO/IEC TR 24027	Bias in AI systems and AI-aided decision making	This document addresses bias, including measurement techniques and methods, and its scope within the life cycle of AI systems. The life cycle of AI systems is presented based on the stages described in ISO/IEC 22989.	SLC	HL
ISO/IEC 8183	Data life cycle framework	This document defines data-related stages through the data management life cycle process, including tasks on AI model development.	SLC DM	HL
ISO/IEC 5259-3	DQ for analytics and ML — Part 3: DQ management requirements and guidelines	This document is part of the ISO/IEC 5259 series. It includes requirements and guidelines for implementing DQ for ML. It takes the data life cycle process from ISO/IEC 5259-1, which is based on ISO/IEC 8183.	DM	HL
ISO/IEC 5259-4	DQ for analytics and ML	This document is part of the ISO/IEC 5259 series. It outlines guidelines on DQ for training ML. It takes the data life cycle process from ISO/IEC 5259-1, which is based on ISO/IEC 8183.	DM	HL
ISO/IEC 5259-5	AI — DQ for analytics and ML — Part 5: DQ governance	This document is part of the ISO/IEC 5259 series. It provides a governance framework that can be applied to Data Analytics or ML to oversee the DQ through its life cycle.	DM	HL

SLC = System Life Cycle, DM = Data Management, HL = Horizontal, HM = Healthcare and medicine, DQ = Data Quality

[1] Results are available as supplementary material https://github.com/karla-cepeda/AIeMD-DLC-Project/tree/main/Standards%20Review.

Table 3. *(continue)*

Standard	Title	Description	Topic	Domain
ISO/IEC TR 29119-11	Software and systems engineering – Software testing – Part 11: Guidelines on the testing of AI-based systems	This document introduces AI systems, challenges of testing these systems, and covers testing of these systems across their life cycle. There is an introduction of the AI life cycle referenced from another standard.	SLC	HL
IEEE 3652.1-2020	IEEE Guide for Architectural Framework and Application of Federated ML	This document defines architectural requirements and specifications for federated ML, including terminologies and categories. No life cycle introduced or described.	DM	HL
IEEE 2801-2022	IEEE Recommended Practice for the Quality Management of Datasets for Medical AI	This document identifies best practices for establishing a quality management system for data sets used for AI in MDs, covering the life cycle of data set management. The life cycle is introduced, and best practices are included.	DM	HM
IEEE Std 7010-2020	IEEE Recommended Practice for Assessing the Impact of Autonomous and Intelligent Systems on Human Well-Being	This document provides recommended practices on well-being metrics to facilitate human well-being impact assessment. The document includes a brief introduction to the ML workflow. The life cycle is not referenced in another document.	SLC	HL
NIST AI RMF 1.0	AI Risk Management Framework 1.0	This document supports the responsible design and development of AI systems, with risk management as the core component of the framework. The document additionally includes a discussion on the life cycle of AI systems based on work done by the OECD.	SLC	HL
ETSI GR SAI 002 V 1.1.1	Securing Artificial Intelligence – Data Supply Chain Security	This standard document focuses on the security of data, including mechanisms to preserve the integrity of data and cybersecurity practices. The document includes a general discussion on the AI life cycle.	DM	HL
ETSI GR SAI 004 V 1.1.1	Securing AI – Problem Statement	This document is related to challenges in securing AI-based systems. This work includes an ML workflow from data acquisition to deployment.	SLC	HL
DIN SPEC 92001-1	Life Cycle Processes and Quality Requirements – Part 1: Quality Meta Model	This document deals with the quality characteristics of AI systems and includes an AI system life cycle process based on ISO/IEC/IEEE 12207.	SLC	HL
DIN SPEC 92001-2	Life Cycle Processes and Quality Requirements – Part 2: Robustness	This work deals with safe and transparent development and use of AI models, applying to all stages of the AI system life cycle. The life cycle is based on DIN SPEC 92001-1 and the ISO/IEC/IEEE 12207.	SLC	HL
ITU-T F.748.13	Technical framework for the shared machine learning system	This document describes architectural design and processes to implement shared ML models in centralised and decentralised modes. Data management processes are described based on shared ML models.	DM	HL
ITU-T Y.3531	Cloud computing – Functional requirements for machine learning as a service	This document describes the functional requirements of cloud services for provisioning and using a set of ML functions. It describes a generic ML process but does not provide further information.	DM	HL
ANSI/ CTA 2107-A	The Use of AI in Health Care: Managing, Characterising, and Safeguarding Data	This document identifies recommended data practices for the development of AI-based applications in healthcare. The data life cycle is presented, and recommendations are provided based on the life cycle.	DM	HM

SLC = System Life Cycle, DM = Data Management, HL = Horizontal, HM = Healthcare and medicine, DQ = Data Quality

Before performing the data selection protocol, each standard gathered from the AI-Hub was reviewed to include other relevant standards, including any relevant normative references. Four AI-specific standards were found (see Table 4), which are ISO/IEC 5259-1, ISO/IEC 5259-2, ISO/IEC 23053, and ANSI/CTA 2090. Another non-AI standard found was ISO/IEC/IEEE 12207, which describes a generic life cycle framework for software systems [39]. Besides the five standards, a sixth document by the Organisation for Economic Co-operation and Development's (OECD) Expert Group on Artificial Intelligence was also found, which defines the AI life cycle [40]. The AI-specific standards were included in the data selection protocol, excluding the OECD document and the ISO/IEC/IEEE 12207 standard.

Table 4. List of additional standards found.

Standard	Title	Description
ISO/IEC 5259-1	Data quality for analytics and ML Part 1: Overview, terminology, and examples	This document is part of the ISO/IEC 5259 series. It presents the conceptual foundations of data quality for ML and the ML life cycle based on ISO/IEC 8183.
ISO/IEC 5259-2	Data quality for analytics and ML Part 2: Data quality measures	This document is part of the ISO/IEC 5259 series and presents data quality metrics and reporting guidelines. It also presents the data life cycle to support expanding the data quality management process.
ISO/IEC 23053	Framework for AI Systems Using ML	This document establishes a generic framework for AI and ML technologies, including a description of elements of the AI ecosystem and ML pipelines based on IEC 22989.
ANSI/CTA-2090	The Use of AI in Health Care: Trustworthiness	This document identifies the core requirements and baseline for AI solutions in health care to be deemed trustworthy. The AI life cycle is mentioned but not detailed.

Each standard was inspected to identify its relationship with other relevant standards. The process was performed by inspecting normative references and, when applicable, references to other documents, particularly for those sections addressing the life cycle of AI systems. This was primarily conducted to find other relevant standards; however, it was also insightful to examine the relationship among standards. The purple area has standards that belong to the "system life cycle" topic, whereas the yellow one for the "data management" topic. The lines connect standards, from which solid ones connect standards to normative references, whereas dashed lines connect standards to other relevant documents. The green lines (either solid or dashed) represent standards that cite/use the AI life cycle from another one. The standards outside these areas are additional documents identified.

The content of each standard was evaluated against the criteria outlined in Table 2. Points were added up, and standards that scored more than half of the total were selected. The standard ISO/IEC 5259-2 was removed from the data selection process as BSOL provided a draft version. As it is likely that the published and the draft versions have different content, this standard was removed. Table 5 shows the standards selected, which are marked with a (✓) symbol, whereas those rejected are marked with a (✗) symbol. In total, eleven standards were selected: two for the baseline, six for detailed support to the baseline, and three for both the baseline and support.

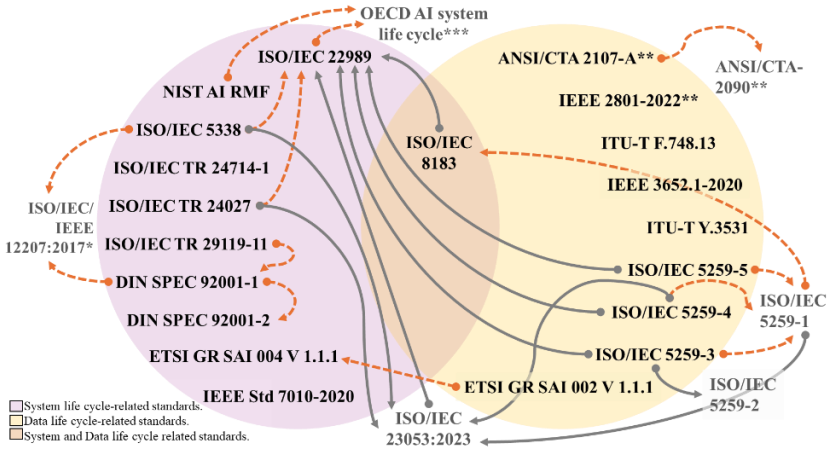

Fig. 1. Relationship between standards based on relevant normative references (solid lines) or citation on the life cycle of another standard (dashed lines).

Table 5. List of selected standards based on the established criteria in Table 2.

Standards	[C1]	[C2]	[C3]	[C4]	[C5]	BL Score	BL [C1-5]	SP [C6]
ISO/IEC 22989	●	◑	●	◑	◑	3.5/5	✓	✗
ISO/IEC 23053	●	◑	◑	●	○	3/5	✓	✓
ISO/IEC 5338	●	●	◑	●	◑	4/5	✓	✓
ISO/IEC 8183	◑	◑	●	◑	◑	3/5	✓	✓
ISO/IEC 5259-1	●	◑	◑	◑	◑	3/5	✓	✗
ISO/IEC 5259-3	◑	◑	◑	○	○	1.5/5	✗	✓
ISO/IEC 5259-4	◑	◑	◑	○	○	1.5/5	✗	✓
ISO/IEC 5259-5	●	○	○	○	○	1/5	✗	✗
ISO/IEC TR 29119-11	●	◑	○	◑	○	2/5	✗	✗
ISO/IEC TR 24714-1	◑	◑	◑	○	○	1.5/5	✗	✗
ISO/IEC TR 24027	◑	◑	○	○	○	1/5	✗	✓
AI RMF 1.0	●	○	◑	◑	○	2/5	✗	✗
DIN SPEC 92001-1	●	◑	○	◑	○	2/5	✗	✗
DIN SPEC 92001-2	◑	◑	○	◑	○	1.5/5	✗	✗
ETSI GR SAI 004	◑	◑	○	○	○	1/5	✗	✗
IEEE 3652.1-2020	◑	○	○	○	○	0.5/5	✗	✗
IEEE 2801-2022**	◑	◑	◑	◑	○	2/5	✗	✓
IEEE Std 7010-2020	◑	○	○	○	○	0.5/5	✗	✗
ITU-T F.748.13	◑	○	○	○	○	0.5/5	✗	✗
ITU-T Y.3531	●	◑	◑	○	○	2/5	✗	✗
ETSI GR SAI 002	●	◑	◑	○	○	2/5	✗	✗
ANSI/CTA-2017-A**	◑	◑	◑	○	○	1.5/5	✗	✓
ANSI/CTA-2090**	◑	○	○	○	○	0.5/5	✗	✓

BL = Baseline, SP = Support, D = Documentation, ● = One point, ◑ = Half Point, ○ = No Point,
✓ = Standard Selected, ✗ = Standard not Selected, ** = Healthcare and Medical

6 Discussion

A total of 33 standard titles were retrieved from the AIHub Database, and after cross-validation, 20 standards remain for the data selection process. Among these standards collected, the SDO that had the largest number of standards published is ISO/IEC. Regarding the selected topics, the number of AI-specific standards in the "horizontal" domain exceeded those in "healthcare and medicine". Nevertheless, this does not mean there are no AI standards for healthcare. When inspecting the "healthcare and medicine" domain across all topics on AIHub, there were around eleven AI-specific standards, including safety, quality, and privacy topics. Additionally, there are more AI standards under development for MDs under the IEC TC 62 [27–30]. Therefore, there is a standardisation effort to gradually integrate AI in the healthcare sector.

This review paper is the first step to propose a DLC for AIeMD, to identify standards for two objectives: (1) to build an initial DLC (referred to as *baseline*), and (2) to provide additional *support* to (1). After performing data selection to identify relevant standards, eleven standards were selected. Based on the criteria established in Table 2. , the horizontal AI-specific standards selected for (1) are ISO/IEC 22989, ISO/IEC 5338, ISO/IEC 8183, and ISO/IEC 5259-1. For (2), horizontal AI-specific standards selected are ISO/IEC 5259-3, ISO/IEC 5259-4, ISO/IEC 23053, and ISO/IEC 24027. Moreover, ISO 5338, ISO 23053, and ISO 8183, already part of (1), were found relevant for (2). Even though the standards under the "healthcare and medicine" domain were not selected for (1), these were included for (2), which included ANSI/CAT 2107, ANSI/CAT-2090, and IEEE 2801-2022.

Besides the AI-specific standards found, IEC 62304 and ISO/IEC/IEEE 12207 were included for (1). It was interesting to observe that ISO/IEC 5338 had a normative reference to ISO/IEC 12207, which was used to extend the generic life cycle process to AI systems [41]. IEC 62304 was derived from ISO/IEC/IEEE 12207 to tailor the generic DLC to MDSW needs [42]. These documents may provide useful insights in the next stage of the research; therefore, these are added for (1). Fig. 2 shows the final list of standards, where white boxes are AI-specific standards, grey boxes are non-AI standards, and bold text highlights standards under the "healthcare and medicine" topic. All these standards are expected to give an initial shape to the DLC process for AIeMD.

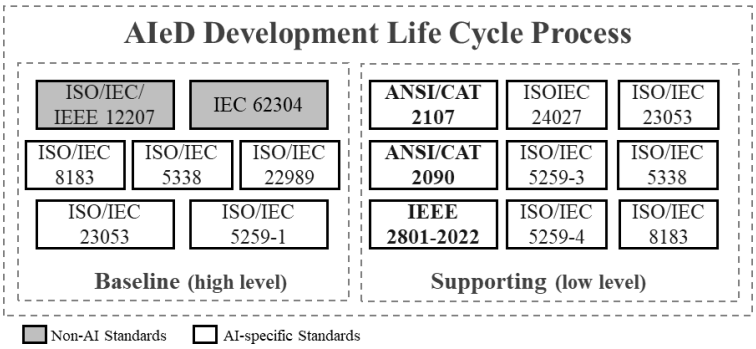

Fig. 2. Standards that will be used to create an initial version of an AIeMD DLC.

A preliminary mapping among the standard documents for (1) is shown in Fig. 3. The most referenced document within the standards collected is ISO/IEC 22989 (see Fig. 1). This standard is taken as the root for the description of the AI system life cycle, which is represented in bold text in Fig. 3. AI standards for (1) are colour coded based on the topics used to filter the AIHub Database. The standard ISO/IEC 8183 is categorised in both topics, but it is exclusively moved to data management. Some parts of this standard describe the activities of the development of AI models, but it seems its content is substantially towards the data life cycle process. Therefore, ISO/IEC 8183 and ISO/IEC 5259-1 are in the "data management" region (yellow rectangles) in Fig. 3, whereas ISO/IEC 22989, ISO/IEC 23053, and ISO/IEC 5338 are in the "system life cycle" region (purple rectangles). The arrows included represent the relationship and direction among standards, as illustrated in Fig. 1.

IEC 62304 and ISO/IEC 5338 are also included in Fig. 3. These standards have a standard in common, ISO/IEC/IEEE 12207. This might suggest an indirect connection between IEC 62304 and ISO/IEC 5338 that could serve as a basis for initial considerations and integration. Therefore, it is hypothesised that a mapping process can be performed by bridging ISO/IEC/IEEE 12207 towards both the IEC 62304 and ISO/IEC 5338 standards. Nevertheless, as ISO/IEC 5338 and ISO/IEC/IEEE 12207 relate to the DLC process in a general context, it is important to consider specific factors for AIeMD when drafting the DLC framework. Once this is done, the other standards ISO/IEC 22989, ISO/IEC 8183, and ISO/IEC 5259-1 can also be integrated. However, the standards for (1) should be further investigated to propose formal integration, including how to integrate relevant elements from the standards for (2). As IEC 62304 and ISO/IEC 5338 refer to different versions of the ISO/IEC/IEEE 12207, the ISO/IEC/IEEE 12207-2 standard that provides the mapping between these two versions is considered [43].

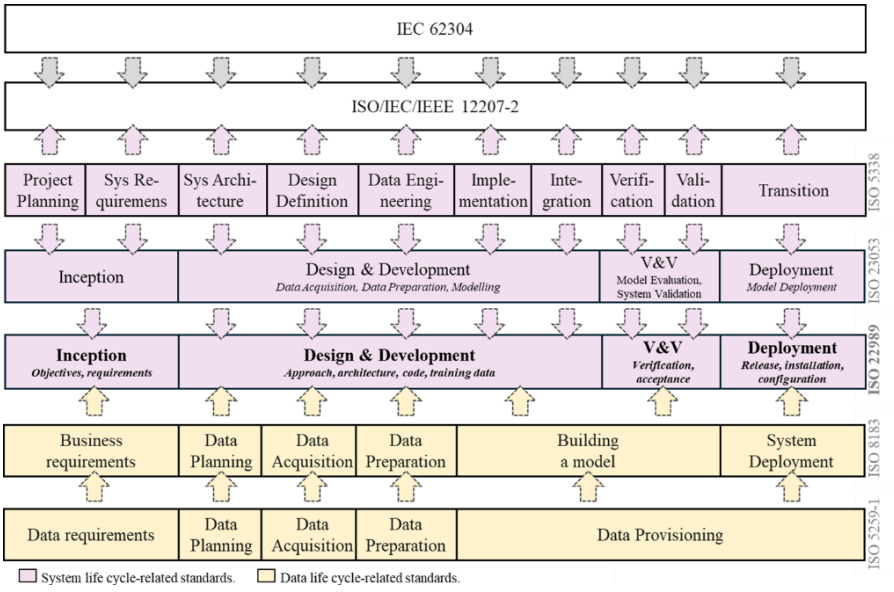

Fig. 3. Initial mapping process to build a baseline for the DLC process of AIeMD.

In addition to the standards, the AI System life cycle by the OECD is also identified as relevant work. This document is referenced in ISO/IEC 22989, where the AI life cycle definition is aligned with the OECD one. The "AI System lifecycle" is a Recommendation released in May 2019 by the OECD that defines key terminologies, including "AI system lifecycle" and its typical phases. Therefore, this document is also considered for the proposal of a DLC of AIeMD.

7 Conclusions

There is a standardisation effort for AI to support the harmonisation of best practices and recommendations for the responsible development of AI systems. In the MD domain, recognised standards are relevant documents part of the pre-marketing assessment process. There is an ongoing development of AI standards to support healthcare and MD domains, and it is expected that these standards, mostly from ISO/IEC, may also become recognised for pre-marketing assessment purposes at some point. However, in the meantime, it is also important to consider the existing work by SDOs when proposing a life cycle process to support manufacturers during the AIeMD development. This work is the first step in proposing a DLC framework for AIeMD. Eleven AI-specific standards were found, of which three are from the healthcare domain and the rest are horizontal. The next stage of the research will focus on analysing each standard identified in this review to propose a formal integration process. The analysis will include a focus on IEC 62304 and ISO 5338, as both reference ISO/IEC/IEEE 12207. It is hypothesised that these indirect connections could serve as the starting point to build the initial AIeMD DLC. For future work, it is also expected to integrate documentation control, considering ISO 13485 and ISO/IEC 42001 and technical documentation requirements from the AIA. The standards found in this review are expected to contribute to the basis for addressing the development life cycle of AIeMD by establishing procedures at both a high and low level.

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