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Artificial intelligence enabled medical devices - Data management

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Artificial intelligence enabled medical devices - Data management

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The text of this Publicly Available Specification is based on the following documents:

Draft	Report on voting
62/559/DPAS	62/579/RVDPAS

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs . The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

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INTRODUCTION

Ensuring the safety and effectiveness of a medical device that incorporates AI involves several steps. These steps include establishing data requirements, data planning and data acquisition, managing data throughout its life cycle, and demonstrating that the device meets its intended purpose without posing unacceptable risks.

This document outlines requirements for data management lifecycle cycle processes, detailing the activities and tasks essential for managing data used by medical devices incorporating AI. It specifies requirements for each stage of the data life cycle.

The data management process consists of a number of activities. These activities are shown in Figure 1 below.

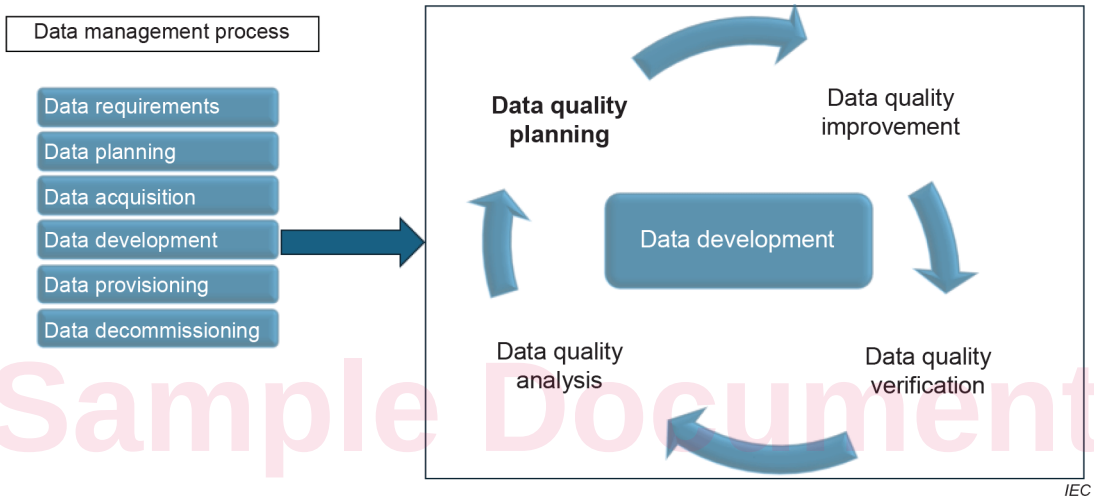

Figure 1 – Data management process

Data management process: Data management is a lifecycle activity that continues throughout the full device lifecycle. This includes adjustments to improve the data quality in case data characteristics no longer meet the requirements defined in data planning.

This document does not specify an organizational structure for the manufacturer or which part of the organization is to perform which process, activity, or task.

This document does not specify the name, format, or detailed content of the required documentation. While this document provides requirements about the documentation of tasks, it leaves the choice of how to organize and present this documentation up to the user.

Annex A provides further information about how the clauses of this document should be seen in relation to the quality management system.

This document assumes that the manufacturer has a quality management system in place which is appropriate for medical device development.

For the purposes of this document:

– "shall" means that conformance with a requirement is mandatory for conformance with this document;
– "should" means that conformance with a recommendation but is not mandatory for conformance with this document;

– "may" is used to describe a permissible way to achieve conformance with a requirement;
– "establish" means to define, document, and implement; and
– where this document uses the term "as appropriate" in conjunction with a required process, activity, task or output, the intention is that the manufacturer shall use the process, activity, task or output unless the manufacturer can document a justification for not so doing.

1 Scope

This document provides a framework for the data life cycle processes for management of data used to train, test or validate an AI model that is part of a medical device.

For data acquisition and management lifecycle the following considerations apply, amongst others: data suitability, data quality and integrity insurance, data privacy and security, data governance and documentation, data sampling and bias mitigation, data versioning and traceability, data storage and infrastructure, data access and sharing, and data labelling and annotation.

This document outlines the requirements for the data lifecycle, covering stages from planning and acquisition to usage and decommissioning. It emphasizes maintaining data quality, including aspects such as dataset classification, data annotations, traceability, metadata comprehensiveness, representativeness, and validity periods.

The scope is limited to the high-level process concepts applicable across medical specialties and device types and does not include specific requirements that can be covered by modality- or device-specific standards documents.

This document outlines the additional requirements for AI data management for data management, where an organization demonstrates its capability to manage data in accordance with applicable medical device guidance and standards. Organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing and maintenance of a medical device that incorporates AI. This document can also be used by suppliers or external parties that provide data, including quality management system-related services to such organizations.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

– IEC Electropedia: available at https://www.electropedia.org/
– ISO Online browsing platform: available at https://www.iso.org/obp

3.1
manufacturer
natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)

Note 1 to entry: "Design and/or manufacture", as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

Note 2 to entry: The manufacturer's responsibilities are described in other GHTF or IMDRF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 3 to entry: This "natural or legal person" has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

Note 4 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.

Note 5 to entry: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

Note 6 to entry: An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.

Note 7 to entry: To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

[SOURCE: ISO 13485:2016 [1], 3.10, modified – Reordering of notes to entry; addition of "or IMDRF guidance documents" in Note 2 to entry.]

3.2
data
re-interpretable representation of information in a formalized manner suitable for communication, interpretation, or processing

Note 1 to entry: Data can be processed by humans or by automatic means.

[SOURCE: ISO/IEC 2382:2015 [2], 2121272, modified – Deletion of Note 2 to entry and Note 3 to entry.]

3.3
data annotation
process of attaching a set of descriptive information to data without any change to that data

Note 1 to entry: The descriptive information can take the form of metadata, labels and anchors.

[SOURCE: ISO/IEC 22989:2022 [3], 3.2.1]

3.4
dataset
data set
collection of data with a shared format

EXAMPLE 1 Micro-blogging posts from June 2020 associated with hashtags #rugby and #football

EXAMPLE 2 Macro photographs of flowers in 256x256 pixels.

Note 1 to entry: Datasets can be used for validating or testing an AI model. In a machine learning context, datasets can also be used to train a machine learning algorithm.

[SOURCE: ISO/IEC 22989:2022 [3], 3.2.5, modified – Addition of the synonym "data set".]

3.5
data management
encompassing processes and tools for dataset acquisition, construction, storage, governance, privacy, security, integrity, provision, use and decommissioning

[SOURCE: ISO/IEC 22989:2022 [3], 6.1, modified – Addition of "construction, storage, governance, privacy, security, integrity, provision, use and decommissioning".]

3.6
data quality
ability of data that the data meets the manufacturer's requirements for a specified context

3.7
data quality management
coordinated activities to direct and control an organization with regard to data quality

[SOURCE: ISO 8000-2:2020 [4], 3.8.2]

3.8
data quality model
defined set of characteristics which provides a framework for specifying data quality requirements and evaluating data quality

[SOURCE: ISO/IEC 25012:2008 [5], 4.6]

3.9
data quality verification
activity that ensures that data is accurate, consistent, and meets established requirements and acceptance criteria as defined by the manufacturer

Note 1 to entry: This involves assessing dataset descriptions, evaluating quality characteristics, and analyzing dataset risk to confirm that the data is fit for its intended purpose and meets required standards and documenting the validation.

3.10
data quality analysis
activity that looks at data development cycle to determine if the reason for the failure of the data quality verification is the data itself or the process for the data improvement

3.11
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of

– diagnosis, prevention, monitoring, treatment or alleviation of disease,
– diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
– investigation, replacement, modification, or support of the anatomy or of a physiological process,
– supporting or sustaining life,
– control of conception,
– disinfection of medical devices,
– providing information by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but can be assisted in its function by such means

Note 1 to entry: Products which can be considered to be medical devices in some jurisdictions but not in others include:

– disinfection substances;
– aids for persons with disabilities;
– devices incorporating animal and/or human tissues;
– devices for in vitro fertilization or assisted reproduction technologies.

[SOURCE: ISO/IEC Guide 63:2019 [6], 3.7]