Technical Specification

ISO/TS 9321

Health informatics — General requirements of multi-centre medical data collaborative analysis

Informatique de santé — Exigences générales des analyses collaboratives multicentriques de données médicales

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Medical data collaborative analysis across multiple medical centres plays an important role in enabling extensive and universally applicable outcomes in medical research. The establishment of multi-centre medical data collaborative analysis systems aims to enable researchers to securely and efficiently utilize medical data among medical centres.

This document introduces an architecture for multi-centre medical data collaborative analysis, which differs from the conventional centralized data analysis approach. Its purpose is to address various challenges encountered in current practices. These challenges include:

— ensuring that data analysis is performed under robust safety and privacy measures;

— handling data heterogeneity;

— maintaining consistency of research findings;

— implementing effective authority controls;

— meeting general service requirements.

The ultimate objective of this document is to foster trust among researchers and medical centres by implementing regulated data protections and standardized research processes. It aims to expedite the results obtained from collaborative analysis efforts of large-scale medical data.

ISO 29585[10] provides a framework for healthcare and data reporting, addressing both the opportunities and the responsibilities of the handling of the data, emphasizing the framework for data governance, privacy, security, acquisition, processing, loading and reporting. This document, on the other hand, places greater emphasis on the collaborative analysis of healthcare data and other requirements in multi-centre scenarios.

Specifically, this document presents a detailed scope, elucidates key concepts, outlines the resulting architecture, and provides comprehensive and standardized instructions to assist medical centres in establishing or participating in a robust and cohesive multi-centre medical data collaborative analysis system.

This document holds various potential applications, including:

— guiding developers to establish new medical data collaborative analysis systems;

— aiding technicians to seamlessly and securely integrate local medical resources into collaborative analysis systems;

— supporting supervisors to effectively manage the research processes;

— enabling physicians and medical researchers to conduct multi-centre medical data collaborative analysis;

— providing a fundamental set of functional requirements to ensure the essential functionality and security, while allowing for gradual enrichment of system features.

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Health informatics — General requirements of multi-centre medical data collaborative analysis

1 Scope

This document outlines the general requirements for conducting a multi-centre medical data collaborative analysis, covering various aspects such as system architecture, data storage, data standardization, collaborative research management and security. The data considered in this standard primarily encompasses electronic health record data for multi-centre collaborative researches, including structured data, medical text data, image data, etc.

This standard is applicable to a wide range of individuals and institutions, including developers, maintainers, management personnel, researchers, and data-owning organizations.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 27799, *Health informatics — Information security management in health using ISO/IEC 27002*

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3 Terms and definitions

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

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

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— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
multi-centre
consortium of at least two medical centres

3.2
terminology base
collection of formally structured concepts and relationships serving as standardized expressions for specific entities with the capability to manage and maintain this collection for collaborative research

3.3
multi-centre medical data standardization
protocols and capabilities implemented across multiple centres to ensure the integrity and consistency of medical data

3.4
interoperability
ability of two or more systems or components to exchange information and use the information that has been exchanged

[SOURCE: ISO/TS 27790:2009, 3.39]

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3.5
cohort
in observational studies, a group of individuals who share a common set of characteristics, such as age, sex, ethnicity

3.6
common data model
CDM
standardized, systematic approach to structuring and organizing data, ensuring that data from different sources or systems can be easily integrated, compared and analysed in a consistent manner

4 Symbols and abbreviate terms

CDM common data model

ETL extract-transform-load

API application programming interface

5 General requirements

5.1 General

Participants can conduct medical data collaborative analysis across multiple medical centres while preserving data privacy. Secure multi-party computing and federated learning methods can be employed to acquire statistical and meta-analysis results across multiple medical centres, as well as for model developments and applications.

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The multi-centre medical data collaborative analysis system shall incorporate a collaboration network, function modules, and system security modules to facilitate diverse multi-centre collaborative researches. The original medical data shall remain within medical centres, adhering to ethical and legal considerations. The system shall provide robust security, strict confidentiality and exceptional reliability to researchers. It shall also aim to reduce the cost of medical data collaborative analysis and enhance the quality of research outcomes. Some existing systems are listed in Annex A. The general requirements are as detailed in 5.2 to 5.9.

5.2 Data isolation

The original medical data of each medical centre shall be stored securely within its internal database, ensuring it remains within local medical centre and shall not be transferred outside of local centres. Data isolation shall adhere to ISO 27799. Country-specific legal requirements can apply.

5.3 Terminology standardization

The medical centres shall use standard health terminology for local medical data. Detailed requirements regarding terminology are listed in 7.2.3.1. The medical centres shall have the capability to standardize their health terminology to ensure terminology consistency between medical centres.

5.4 Data standardization

The transformed data shall meet the requirements of format consistency, structural consistency and semantic consistency and be stored in a CDM.

5.5 Data incremental expansion

The transformed database of medical centres shall have the capability to automatically and incrementally import and store clinical data. The newly imported data shall not impact or conflict with the existing data.

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5.6 Distributed network framework

All service modules associated with the original medical data shall be built within the local networks of each centre. The local medical centre can communicate with the coordination centre and other centres.

5.7 Network scalability

The network framework shall support the enrolment and withdrawal of new medical centres. The access of additional medical centres shall not impact or conflict with existing network connections.

5.8 System modularization

The system should be decomposed into multiple independent logical entities.

5.9 Security

The system shall implement robust security controls to ensure the reliability of confidentiality and integrity for medical data, encryption keys, intermediate and final results. The system's security requirements should align with ISO/IEC 27001[9], while the data security protection requirements should adhere to ISO 22857[6]. The utilization of anonymized data follows the classification outlined in ISO/TS 14265[2] for effective data consistency management.

6 Architecture and workflow

6.1 Architecture

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Figure 1 presents a detailed architecture of multi-centre medical data collaborative analysis, specifically focusing on scenarios where the original medical data cannot leave the respective medical centres. The key components depicted in the figure are as follows.

— ETL: this module is responsible for transforming original medical data into the transformed database utilizing a CDM.

— Trusted logging tools: these tools record all operations conducted within the system to ensure the integrity of the records and prevent tampering.

— Health terminology base: the health terminology base manages terminology standardization of the local medical centres. Functionally, it standardizes the locally-used medical concepts to the global standard health terminology and stores them to ensure consistency of the terminology across multiple centres.

— Analysis tools: these tools are utilized for conducting multi-centre medical data collaborative analysis and managing the process of multi-centre collaborative researches.

— Coordination centre: the coordination centre serves as a central hub to facilitate collaborations among multiple centres. Collaborations between the medical centres and the coordination centre enable the secure transmission of essential non-original data for collaborative analysis services and applications.

— Terminology management: the terminology management provides protocols and methods for medical centres and the coordination centre to manage the terminology and maintain terminology consistency, including standardization, extension and quality control of health terminology.

— Multi-centre medical data standardization: the data standardization provides protocols and methods for medical centres to perform data cleaning, data standardization, and quality control to ensure integrity and consistency of medical data for collaborative analysis.

These components collectively enable efficient medical data collaborative analysis while preserving privacy and data integrity of the original medical data within the respective medical centres.

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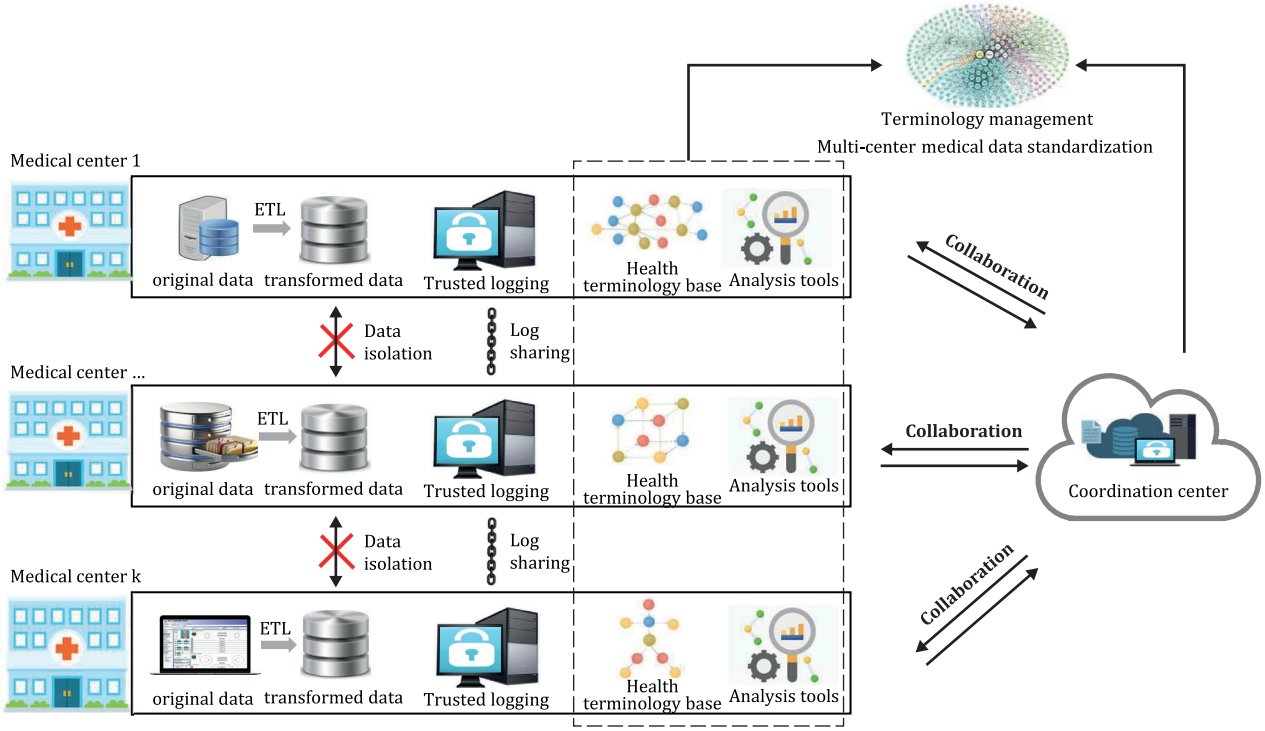

Figure 1 — Architecture of multi-centre medical data collaborative analysis

With stringent requirements for data isolation, security, and privacy in the use of medical data, collaborative analysis procedures shall adhere to a general standardized process, as illustrated in Figure 2. “Member grouping” involves collaborative research centres forming a research team and defining their respective research tasks. “Review & adjusting” entails conducting research ethics reviews and assigning data access rights by the medical centre. While “Member grouping”, “Result reporting”, and “Review & adjusting” are best discussed and determined within a centralized environment, “Data gathering” and analysis based on original data shall only be conducted in a distributed environment.

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