



BSI Standards Publication

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

National foreword

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collaboratives multicentriques de données médicales*

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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Symbols and abbreviate terms	2
5 General requirements	2
5.1 General	2
5.2 Data isolation	2
5.3 Terminology standardization	2
5.4 Data standardization	2
5.5 Data incremental expansion	2
5.6 Distributed network framework	3
5.7 Network scalability	3
5.8 System modularization	3
5.9 Security	3
6 Architecture and workflow	3
6.1 Architecture	3
6.2 Workflow	5
6.2.1 Multi-centre collaborative research initiation workflow	5
6.2.2 Multi-centre collaborative research implementation workflow	6
7 Functional framework and requirements	7
7.1 Functional framework	7
7.1.1 General	7
7.1.2 User layer	8
7.1.3 Service layer	8
7.1.4 Resource layer	8
7.1.5 System security	8
7.2 Functional requirements	9
7.2.1 General	9
7.2.2 User layer functional requirements	9
7.2.3 Service layer functional requirements	10
7.2.4 Resource layer functional requirements	12
7.2.5 System security functional requirements	13
Annex A (informative) Examples of multi-centre medical data collaborative analysis networks	14
Annex B (informative) Reference implementations	15
Bibliography	18

Foreword

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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.

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.

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*

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:

- 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]