



HEALTH INFORMATICS



- International level -



ISO/TC 215 – Health informatics

Scope	Standardization in the field of health informatics, to facilitate capture, interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system.	
Committee information	Published standards	248
	Standards under development	69
	National delegates	3

Major “ISO/TC 215 ” standards

Published standards	<u>ISO 16527:2023</u>	Health informatics — HL7 Personal Health Record System Functional Model, Release 2 (PHR-S FM)
	<u>ISO 10781:2023</u>	Health informatics — HL7 Electronic Health Record-System Functional Model, Release 2.1 (EHR FM)
	<u>ISO 13606 series</u>	Health informatics — Electronic health record communication
	<u>ISO/TR 4419:2026</u>	Health informatics — Pathways for human-computer interaction in electronic health information record systems to reduce clinician burden
	<u>ISO 5477:2023</u>	Health informatics — Interoperability of public health emergency preparedness and response information systems
	<u>ISO/TS 5777:2024</u>	Health informatics — The architecture of internet healthcare service network
	<u>ISO/TS 5788:2024</u>	Health informatics — Internet healthcare service pattern
	<u>ISO/TS 6201:2025</u>	Health informatics — Personalized digital health framework
	<u>ISO/TS 6268 series</u>	Health informatics — Cybersecurity framework for telehealth environments
	<u>ISO 12967 series</u>	Health informatics — Service architecture (HISA)
	<u>ISO/TS 9321:2024</u>	Health informatics — General requirements of multi-centre medical data collaborative analysis
	<u>ISO/IEEE 11073-10201:2020</u>	Health informatics — Device interoperability — Part 10201: Point-of-care medical device communication — Domain information model
	<u>ISO/IEEE 11073-10207:2019</u>	Health informatics — Personal health device communication — Part 10207: Domain information and service model for service-oriented point-of-care medical device communication
	<u>ISO 11615:2017</u>	Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information
	<u>ISO 13119:2022</u>	Health informatics — Clinical knowledge resources — Metadata
	<u>ISO 21090:2011</u>	Health informatics — Harmonized data types for information interchange
Standards under development	<u>ISO/CD TS 16599-1</u>	Health informatics — Data Governance and Quality — Part 1: Foundations
	<u>ISO/AWI TS 16599-2</u>	Health informatics — Health data and governance — Part 2: Data design (DataQual2)
	<u>ISO/DIS 18308</u>	Health informatics — Requirements for an electronic health record architecture
	<u>ISO/CD 13101</u>	Health informatics — Telehealth services — Quality planning guidelines
	<u>ISO/DTS 19844 series</u>	Health informatics — Identification of medicinal products (IDMP)
	<u>ISO/CD 21089</u>	Health informatics — Trusted end-to-end information flows
	<u>ISO/CD TS 22039</u>	Health informatics — Generic model for bridging healthcare and prescribed care processes
	<u>ISO/AWI 22857</u>	Health informatics — Guidelines on data protection to facilitate trans-border flows of personal health data
	<u>ISO/DIS 27789</u>	Health informatics — Audit trails for electronic health records
	<u>ISO/AWI 25979</u>	Health informatics — Semantic Machine-Readable Data Standards for Clinical Trial Business and Operations

- European level -



CEN/TC 251 – Health informatics

Scope	Standardization in the field of Health Information and Communications Technology (ICT) to achieve compatibility and interoperability between independent systems and to enable modularity. This includes requirements on health information structure to support clinical and administrative procedures, technical methods to support interoperable systems as well as requirements regarding safety, security and quality.	
Committee information	Published standards	113
	Standards under development	29
Major “CEN/TC 251” standards		
Published standards	<u>CEN ISO/TS 14265:2024</u>	Health informatics - Classification of purposes for processing personal health information
	<u>CEN ISO/TS 17251:2023</u>	Health informatics - Business requirements for a syntax to exchange structured dose information for medicinal products
	<u>CEN/TR 15212:2006</u>	Health informatics - Vocabulary - Maintenance procedure for a web-based terms and concepts database
	<u>CEN/TR 15253:2005</u>	Health informatics - Quality of service requirements for health information interchange
	<u>CEN/TR 15300:2006</u>	Health informatics - Framework for formal modelling of healthcare security policies
	<u>CEN/TR 15872:2014</u>	Health informatics - Guidance on patient identification and cross-referencing of identities
	<u>CEN/TS 17288:2020</u>	Health informatics - The International Patient Summary - Guideline for European Implementation
	<u>EN 14484:2003</u>	Health informatics - International transfer of personal health data covered by the EU data protection directive - High level security policy
Standards under development	<u>EN 14822 series</u>	Health informatics - General purpose information components
	<u>FprCEN ISO/TS 20443</u>	Health informatics - Identification of medicinal products - Implementation for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information
	<u>prEN ISO 13606-1</u>	Health informatics - Electronic health record communication - Part 1: Reference model
	<u>prEN ISO 20737</u>	Health informatics - Interoperability of personal health decision support services
	<u>prEN ISO 24973</u>	Digital Therapeutics - Product Requirements

ETSI/TC eHEALTH

Scope	TC eHEALTH is committed to the creation of a standards-based market for ICT enabled health. The standards and reports produced by the committee promote a climate of innovation, where the content of the technical standards underpin assurance of interoperability, efficiency, security, privacy and safety in the provision of health services worldwide.	
	Global health care can be improved by the practical application of technology, and particularly of communications technology. Innovation through standardisation is essential in bringing stakeholders together to achieve consensual access to this market by both existing stakeholders and new developers.	
Committee information	Technical standards offer an effective way to ensure levels of excellence that are expected in a new age of patient-centric medical care.	
Committee information	Published standards	7
	Standards under development	1
Major “ETSI/TC eHEALTH” standards		
Published standards	<u>ETSI TR 103 477 V1.3.1 (2023-01)</u>	eHEALTH; Standardization use cases for eHealth
	<u>ETSI SR 003 809 V1.1.2 (2021-12)</u>	eHEALTH; The role of ICT to enable Health crisis management and recovery; Responding to the 2019 SARS-CoV-2 Pandemic
	<u>ETSI TR 102 764 V1.1.1 (2009-02)</u>	eHEALTH; Architecture; Analysis of user service models, technologies and applications supporting eHealth