

**JOINT INITIATIVE ON SDO GLOBAL HEALTH INFORMATICS STANDARDIZATION**  
**JOINT SDO WORK PROGRAM INVENTORY**  
Version 1.2, 24 February 2008

Name	Number	Stage ⇒ Prelim ⇒ New ⇒ Active ⇒ Ballot 1 ⇒ Ballot 2 ⇒ Ballot n ⇒ Ballot Fin. ⇒ Published	Description	Status ⇒ Unique ⇒ Common (Dev. or Adopt) ⇒ Joint	Comments
Health informatics - Electronic health record communication - Part 1: Reference model	IS 13606-01	Published (CEN) Ballot FDIS (ISO)	Part 1 of this multipart standard on Electronic Health Record Communication specifies the communication of part or all of the electronic health record (EHR) of a single identified subject of care between EHR systems, or between EHR systems and a centralized EHR data repository. It may also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components) that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system.	Joint	Joint Initiative Joint Working Group Work Program
Health informatics - Electronic health record communication - Part 2: Archetype interchange specification	IS 13606-02	Published (CEN) Ballot DIS (ISO)	Part 2 of this multipart standard on Electronic Health Record Communication specifies the information architecture required for interoperable communications between systems and services that need or provide EHR data. This is not intended to specify the internal architecture or database design of such systems.	Joint	Joint Initiative Joint Working Group Work Program
Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists	prEN IS 13606-03	Ballot Final (CEN) Ballot DIS (ISO)	Part 3 of this multipart standard on Electronic Health Record Communication is for the communication of part or all of the electronic health record (EHR) of a single identified subject of care between EHR systems, or between EHR systems and a centralised EHR data repository. It may also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components) that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system.	Joint	Joint Initiative Joint Working Group Work Program
Health informatics - Electronic health record communication - Part 4: Security	TS 13606-4	Published (CEN) Active (ISO)	Part 4 of this multipart standard on Electronic Health Record Communication describes a methodology for specifying the privileges necessary to access EHR data. This methodology forms part of the overall EHR communications architecture defined in Part 1 of this standard. This standard seeks to address those requirements uniquely pertaining to EHR communications and to represent and communicate EHR-specific information that will inform an access decision. It also refers to general security requirements that apply to EHR communications and points at technical solutions and standards that specify details on services meeting these security needs.	Joint	Joint Initiative Joint Working Group Work Program

Health informatics - Electronic health record communication - Part 5: Interface specification	prEN IS 13606-5	Active (CEN) Active (ISO)	Part 5 of this multipart standard on Electronic Health Record Communication specifies the information architecture required for interoperable communications between systems and services that need or provide EHR data. This standard is not intended to specify the internal architecture or database design of such systems. The subject of the record or record extract to be communicated is an individual person, and the scope of the communication is predominantly with respect to that person's care. Uses of healthcare records for other purposes such as administration, management, research and epidemiology, which require aggregations of individual people's records, are not the focus of this standard but such secondary uses could also find the standard useful. Part 5 of this standard defines a set of interfaces to request and provide: an EHR_EXTRACT for a given subject of care as defined in Part 1 of this standard; one or more ARCHETYPE(s) as defined in Part 2 of this standard; an EHR_AUDIT_LOG_EXTRACT for a given subject of care as defined in Part 4 of this standard. Part 5 defines the set of interactions to request each of these artefacts	Joint	Joint Initiative Joint Working Group Work Program VA CEN
Health informatics - Patient healthcard data - Part 5: Identification data	prEN ISO 21549-5	Ballot Final (CEN) Ballot FDIS (ISO)	Part 5 establishes a common framework for the content and the structure of identification data held on healthcare data cards. Specifies the basic structure of the data, but does not specify particular data-sets for storage on devices.	Common	VA ISO
Health informatics - Patient healthcard data - Part 6: Administrative data	prEN ISO 21549-6	Ballot Final (CEN) Ballot FDIS (ISO)	Part 6 specifies the basic structure of the data contained within the data object administrative data, but does not specify or mandate particular data sets for storage on devices.	Common	VA ISO
Health informatics - Patient healthcard data - Part 7: Electronic prescription (medication data)	prEN ISO 21549-7	Ballot Final (CEN)	Part 7 specifies the basic structure of the data contained within the medication data object, but does not specify or mandate particular data-sets for storage on devices.	Common	VA ISO
Health informatics - Patient healthcard data - Part 8: Linkage and reference data	prEN ISO 21549-8	Active (CEN) Active (ISO)	Part 8 defines a method which facilitates access to distributed patient records using health cards. It defines the structure and elements of "links" typically stored in health cards and representing references to individual patients' records as well as to subcomponents of them. It is outside the scope of this work item to include access control data or mechanisms to ensure security and privacy.	Common	VA ISO Lead
Health informatics - HL7 Electronic health record system functional model	prEN ISO 10781	Active (CEN) Active (ISO)	The HL7 EHR System Functional Model provides a reference list of functions that may be present in an Electronic Health Record System (EHRS). The function list is described from a user perspective with the intent to enable consistent expression of system functionality. This EHRS Functional Model, through the creation of Functional Profiles for care settings and realms, enables a standardized description and common understanding of functions sought or available in a given setting (e.g., intensive care, cardiology, office practice in one country and primary care in another country).	Common	VA ISO
Health informatics - Service architecture - Part 1: Enterprise viewpoint	IS 12967-1	Published (CEN) Active (ISO)	This standard provides guidance for the description, planning and development of new systems as well as for the integration of existing information systems, both within one enterprise and across different healthcare organisations through an architecture integrating the common data and business logic into a specific architectural layer (i.e. the middleware), distinct from individual applications and accessible throughout the whole information system through services.	Common	

Health informatics - Service architecture - Part 2: Information viewpoint	IS 12967-2	Published (CEN) Active (ISO)	This document represents the second part of EN 12967, a multi-part standard that provides guidance for the description, planning and development of new systems as well as for the integration of existing information systems, both within one enterprise and across different healthcare organisations through an architecture integrating the common data and business logic into a specific architectural layer (i.e. the middleware), distinct from individual applications and accessible throughout the whole information system through services.	Common	
Health informatics - Service architecture - Part 3: Computational viewpoint	IS 12967-3	Published (CEN) Active (ISO)	This document represents the third part of EN 12967, a multi-part standard that provides guidance for the description, planning and development of new systems as well as for the integration of existing information systems, both within one enterprise and across different healthcare organisations through an architecture integrating the common data and business logic into a specific architectural layer (i.e. the middleware), distinct from individual applications and accessible throughout the whole information system through services.	Common	
Health informatics - Data types for use in health care interchange	prEN ISO 21090	Active (CEN) Active (ISO)	To provide a globally harmonized (ISO/CEN/HL7) set of representations for data used in the presentation and communication of health care information. This standardized set will be an internationally agreed upon, proper sub-set of data types currently adopted by national and trans-national health care standards development organizations.	Joint	Joint Initiative Joint Working Group Work Program VA ISO Note ISO title: Harmonized Data Types for Information Interchange
Health informatics -Pharmacovigilance - Test names and units for reporting laboratory results	prEN ISO 11595	Active (CEN) Active (ISO)	The project will investigate existing relevant available standards and terminology resources and establish a single standardized subset of unit terms and codes that can be used to capture laboratory test units of measurement for pharmacovigilance reporting purposes. The project will need to take into account that there is a constant need for updates and maintenance of resources that list all relevant terms and will specify how the updated controlled vocabulary can be communicated to the reporting and receiving systems.	Joint	Joint Initiative Joint Working Group Work Program VA ISO
Health informatics - Identification of Medicinal Products - Data Elements and Structure for the Exchange of Product Information for Drug Dictionaries	prEN ISO 11615	Active (CEN) Active (ISO)	This project will adapt and adopt, or if necessary develop a single structure for the data elements required for the exchange of information that uniquely and and certainly identifies a medicinal product, wherever authorised for marketing. The project will further provide references to other standards and external terminological resources required to populate the data elements defined in this standard.	Joint	Joint Initiative Joint Working Group Work Program VA ISO
Health informatics - Identification of Medicinal Products - Pharmaceutical Product Identifiers	prEN ISO 11616	Active (CEN) Active (ISO)	The project will develop one or more structures (as few as practicable) to make available a set of PhPID Controlled Vocabularies that is related to the core elements of one or more medicinal products (see also ISO-Form_04-NP_MPID.doc). The PhPID Controlled Vocabulary set is further linked to the Controlled Vocabulary for Ingredients (See also ISO Form 4 - NWIP for Ingredients), the Controlled Vocabulary for Pharmaceutical Dose Forms (ISO-Form_04-NP_PhD-RA-CVs) and the Controlled Vocabulary for Units and Measurements (ISO-Form_04-NP_UM). Aspects related to version control and terminology maintenance must be taken into account when developing one or more structures for the PhPID Controlled Vocabulary set.	Joint	Joint Initiative Joint Working Group Work Program VA ISO

Health informatics - Identification of Medicinal Products - Structures and Controlled Vocabularies for Ingredients	prEN ISO 11238	Active (CEN) Active (ISO)	The project will adapt and adopt, or if necessary, develop structures and content of controlled vocabularies for ingredients that are used worldwide in medicinal products. Each ingredient will be defined at the molecular level and then assigned a randomly generated unique identifier. When an ingredient cannot be defined at the molecular level because of insufficient molecular information (e.g., polymers and botanicals), then it will be defined at the non-molecular level by a set of criteria that is deemed by experts to be sufficient. Ingredients include, but are not necessarily limited to, chemicals, biologics (including vaccines, allergenic extracts, and botanicals), and select foods that are known to interact with drugs. Ingredients will include both the active ingredients and the inactive ingredients (excipients).	Joint	Joint Initiative Joint Working Group Work Program VA ISO
Health informatics - Identification of Medicinal Products - Structures and Controlled Vocabularies for Pharmaceutical Dose Form, Units of Presentation and Routes of Administration	prEN ISO 11239	Active (CEN) Active (ISO)	The project will adapt and adopt, or if necessary, develop one or more structures (as few as practicable) to make available controlled vocabularies for Pharmaceutical Dose Forms, Units of Presentation and Routes of Administration that are related to the core data elements for medicinal products (see also ISO-Form_04-NP_MPID.doc). The Pharmaceutical Dose Forms Controlled Vocabulary, is also the basis for a vocabulary for the Units of Presentation that is used to express the unit of strength of a medicinal product i.e. the expression of the strength of the drug substance(s) per unit of presentation such as 250 mg per one tablet. The Pharmaceutical Dose Form and Routes of Administration Controlled Vocabularies are further linked to the PhPID Controlled Vocabulary (see also ISO-Form_04-NP_PhPID-CVs.doc). Aspects related to version control and terminology maintenance must be taken into account when developing one or more structures for the Controlled Vocabularies for Pharmaceutical Dose Forms, Units of Presentation and Routes of Administration.	Joint	Joint Initiative Joint Working Group Work Program VA ISO
Health informatics - Identification of Medicinal Products - Structures and Controlled Vocabularies for Units of Measurement	prEN ISO 11240	Active (CEN) Active (ISO)	The project will adapt and adopt, or if necessary develop structures and content for an international reference source of controlled vocabulary terms and codes for medication dosing information. The scope of this work includes: 1) Standardized terms and codes for medication dose units of measurement and 2) Standardized terms and codes for specifying medication dosing intervals.	Joint	Joint Initiative Joint Working Group Work Program VA ISO
Health informatics -Pharmacovigilance - Structure and data elements for individual case safety reports	prEN ISO 27953	Active (CEN) Active (ISO)	The project will develop a standardised specification of the data elements for transmission of Individual Case Safety Reports of adverse events/reactions that may occur upon the administration of one or more medicinal products to a patient, regardless of source and destination.	Joint	Joint Initiative Joint Working Group Work Program VA ISO

Health informatics - Clinical knowledge resources - Metadata (MetaKnow)	prCEN/TS 15699	Active (CEN)	This Technical Specification defines a number of metadata elements that describe documents containing medical knowledge, primarily digital documents provided as web resources, accessible from databases or via file transfer, but can be applicable also to paper documents, e.g. articles in the medical literature. The metadata should: <ul style="list-style-type: none"> <li>• support unambiguous and international understanding of important aspects to describe a document, e.g. purpose, issuer, intended audience, legal status and scientific background;</li> <li>• be applicable to different kinds of digital documents e.g. recommendation from consensus of a professional group, regulation by a governmental authority, clinical trial protocol from a pharmaceutical company, scientific manuscript from a research group, advice to patients with a specific disease, review article;</li> <li>• be possible to present to human readers including health professionals as well as citizens/patients</li> <li>• be potentially usable for automatic processing e.g. to support search engines to restrict matches to documents of a certain type or quality level.</li> </ul> The metadata here described is not intended to: <ul style="list-style-type: none"> <li>• describe documents about a single patient, such as medical records</li> <li>• describe details of the medical content of the document (but some information can be described via keywords or codes);</li> <li>• prescribe criteria for the quality of the document content.</li> </ul>	Unique	
Health informatics - Categorical structure of systems of concepts -Medical devices	prEN 12611 rev	Active (CEN)	Currently deleted from work program. Scope: Specifies the necessary requirements for the categorial structure of systems of concepts for medical groups.	Unique	
Health informatics - Categorical structure for classifications and coding systems of surgical procedures	prEN 1828 rev	Active (CEN)	To define the characteristics of the categorial structure required to synthetically describe the organisation and content of surgical procedure terminological systems, in order to support the exchange of meaningful surgical procedure information between different terminological systems using different national languages within Europe. The proposed European Standard is primarily intended for use with computer-based applications such as clinical electronic health records, international and national coding systems, decision support and for various bio-medical research purposes. The proposed European standard itself is not suitable for or intended for use by, the individual clinician or hospital administrator.	Unique	
Health informatics - Security management in health using ISO/IEC 17799	prEN ISO/IEC 27799	Ballot Final (CEN)	This standard defines guidelines to support the interpretation and implementation in health informatics of ISO/IEC 17799 (Information Technology - Code of practice for information security management) and is a companion to that standard. It specifies a set of detailed controls for managing health information security and provides health information security best practice guidelines.	Common	VA ISO

Health informatics - Audit trails for electronic health records	prEN ISO 27789	Active (CEN) Active (ISO)	<p>Electronic health records on an individual may reside in many different information systems within and across organisational or national boundaries. To keep track of all actions that involve records on an individual a common framework for audit trails is a prerequisite.</p> <p>ISO 27799 requires information systems containing personal health information to create a secure audit record each time a user accesses, creates, updates, or archives personal health information via the system. This audit log will at minimum uniquely identify the user, uniquely identify the data subject (i.e., the patient), identify the function performed by the user (record creation, access, update, etc.), and its point in time. However, ISO 27799 does not specify the format and processes for these.</p> <p>Audit trails on electronic health records across different systems need a comprehensive common framework to keep the complete set of personal health information auditable. This project will specify the minimum requirements in terms of audit trigger events and audit data. Minimum requirements for audit log management (e.g. retention) Examples will be given of services for audit log management based on</p>	Common	VA ISO
Health informatics - Application of clinical risk management to manufacture of health software	prCEN ISO/TS 29321	Active (CEN) Active (ISO)	<p>This Technical Specification describes the risk management processes required to ensure patient safety in respect to the manufacture of health software products. It does not apply to software which is:</p> <ul style="list-style-type: none"> <li>necessary for the proper application of a medical device or which is an accessory to a medical device or</li> <li>which is a medical device in its own right.</li> </ul> <p>This standard applies to any health software product whether or not it is placed on the market as an off the shelf or configurable product and whether or not it is for sale or free of charge. It is addressed to all manufacturers of health software products.</p> <p>This standard does not cover the manufacture of COTS products such as operating systems e.g. UNIX (Windows), DBMS However where a COTS product is incorporated by a manufacturer into a health software product, this standard shall apply to the totality of that engineered product and include the COTS product on which it is based.</p>	Common	VA CEN
Health informatics - Guidance on risk evaluation and management in the deployment and use of health software (GREMIDUHS)	prEN ISO/NP TR 29322	Active (CEN) Active (ISO)	<p>This document considers the risk management processes required to ensure patient safety in respect to the deployment and use of health software products either as new systems within a health organisation, as changes to an existing systems environment, including the interfacing of systems to each other, or in creating clinical safety case evidence to share with others. It does not apply to software which is in the process of being manufactured, which is covered in ISO TS 29231, or to the manufacture of medical devices, that is covered in ISO/IEC 14971. Indeed, health organisations are encouraged to apply the guidance contained in this document to the deployment and use of heterogeneous systems i.e. those containing medical devices and/or health software.</p> <p>This document applies to any health software product whether or not it is offered for sale or free of charge. It is addressed to all users of health software products. Whilst it is therefore principally addressed to healthcare organisations, it will also prove useful reference to those involved in the manufacture of health software products</p> <ul style="list-style-type: none"> <li>the 'localisation' of manufactured health software;</li> <li>the construction of interfaces between health software components</li> <li>the local development of applications.</li> </ul>	Common	<p>Note ISO title: Health Informatics: Guidance on the management of risk to ensure the patient safety of health software systems in deployment and use.</p> <p>VA CEN Lead</p>

Health informatics - Guidance on Patient identification and Cross-referencing of identities	PrCEN/TR	Active (CEN)	<p>This technical report will provide the principles determining patient identification and cross-referencing of identities. It is provided to the healthcare organizations to help them develop and implement an identification and cross-referencing policy, and to standards makers and system suppliers to give them an analysis of the possible development solutions.</p> <p>The report will propose definitions of the basic concepts used for person identification. The patient identity management processes will be described with analysis of risky actions, generation of errors, the ways of detecting and correcting them. The same will apply for the cross-referencing management process with a description of the different models and model implementations, analysis of risky actions and errors generation and propagation within the cross-referenced domains.</p> <p>This work item will propose solutions to improve interoperability between health information systems and thereby enhancing the continuity of care for patients who move within the European Union and particularly for trans-borders patients.</p>	Unique	
Health informatics - Point of care medical device communication - Part 20301: Application profile -Optional package, remote control	ISO/NP 11073-20301	Active (CEN) Active (ISO)	<p>This International Standard is designed to confirm the identities of both the healthcare application provider and the healthcard holder in order that information may be exchanged by using cards issued for healthcare service. This International Standard focuses on the machine-readable cards of ID-1 type defined in ISO/IEC 7810 that are issued for healthcare services provided in a service area that crosses the national borders of two or more countries/areas.</p> <p>This International Standard applies to healthcare data cards where the issuer and the application provider are the same party.</p> <p>This International Standard applies directly or refers to existing ISO standards for the physical characteristics and recording techniques. Security issues should follow the requirements of each healthcare data card system. In addition, this International Standard regulates the visual information written on the healthcare data card.</p>	Common	VA ISO Lead
Health informatics - Point of care medical device communication - Part 00000: Framework and overview	prEN ISO 11073-00000	Active (CEN) Active (ISO)	<p>The scope of the ISO Health informatics - Point-of-care medical device communication set of standards is to provide for plug and play interoperability in healthcare applications between point-of-care medical devices and patient care information systems in a manner that is compatible with the range of point-of-care environments. The scope of this standard is to provide the overall definition of the set of standards. It does so by defining a conceptual model, an information model, and a communications model for medical device communications and specifies constraints for conforming to the set of standards.</p> <p>The purpose of this standard is to define the overall architecture for communications between point-of-care medical devices and patient care information systems and to provide a roadmap to the overall set of standards. This standard therefore provides an introduction to point-of-care medical device communication for end-users, specifiers, medical engineers, informaticians and medical device manufacturers.</p> <p>This standard defines certain logical and functional entities, and as such no particular implementation is implied by this standard.</p> <p>It is important to note that this standard defines certain services that are not part of the Health Informatics Framework.</p> <p>The scope of this standard does not preclude the use of the Health Informatics Framework.</p>	Common	VA ISO Lead

Health informatics - Point of care medical device communication - Part 20202: Application profile -Baseline	prEN ISO 11073-20202	Active (CEN) Active (ISO)	This standard defines the service and dynamic models for medical devices that communicate using an event-driven type of protocol, where data updates are communicated automatically by the device when they are available. This standard builds upon the definitions provided in the Base MDAP standard (ISO/IEEE 11073-20101), and defines the method for retrieving application-specific data formatted in accordance with the ISO/IEEE 11073-1xxx set of standards. It is intended for use by the majority of medical device specializations and is titled "asynchronous" because it enables devices to send information either periodically or episodically as needed and without a manager system first issuing a request. It does not define application-specific message content.	Common	VA ISO Lead
Health informatics - Point of care medical device communication - Part 20201: Application profile-Polling mode	ISO/NP 11073-20201	Active (CEN) Active (ISO)	This standard defines the service and dynamic models for medical devices that communicate using a polling-type of protocol. This standard builds upon the definitions provided in the Base MDAP standard (ISO/IEEE 11073-20101), and defines the method for retrieving application-specific data formatted in accordance with the ISO/IEEE 11073-1xxx set of standards. It does not define application-specific message content.	Common	VA ISO Lead
Health informatics - Point-of-care medical device communication - Part 90201: Medical waveform format - Encoding rules	prEN ISO/TS 11073-90201	Active (CEN)	This technical specification specifies how medical waveforms, such as Electrocardiogram, Electroencephalogram, Spirometry waveform etc., are described for interoperable among healthcare information systems. This technical specification may be used with other relevant protocols such as HL7, DICOM, ISO/IEEE11073, and database management systems for each purpose.	Unique	VA ISO Lead
Health informatics: Point-of-care Medical Device Communication - Application gateway, HL7 (v2) observation reporting interface	DIS 11073-60101	Active (ISO)	This standard specifies how medical devices that use ISO/IEEE 11073 protocols and systems that use Health Level 7 (HL7) protocols may interoperate to communicate vital signs observations and general medical device information. This is an Application Gateway standard, meaning that there will be no particular transport requirements specified beyond those which already identified for use by the ISO/IEEE 11073 set of standards and within HL7, though some informative examples are included in annexes. This standard specifies how ISO/IEEE 11073 data model components or objects and nomenclature terms shall be expressed using HL7 protocols, using both HL7 (positional) Encoding Rules and XML formats. It uses related conventions for the communication of medical device data (e.g., the NCCLS point-of-care test device ORI standard - POCT-1A), and specifies multiple versions of HL7 as necessary, with usage constraints and guidelines for each.	Unique	
Health informatics: Point-of-Care Medical Device Communication - Nomenclature Annotated ECG	IS 11073-10102	Active ISO)	This standard extends the base ISO/IEEE 1073-10101 Nomenclature to provide support for ECG annotation terminology. It may be used either in conjunction with other IEEE 1073 standards (e.g., ISO/IEEE 1073-10201 Domain information model) or independently. Major subject areas addressed by the nomenclature include ECG beat annotations, wave component annotations, rhythm annotations, and noise annotations.	Unique	
Health informatics: Point-of-care Medical Device Communication - Nomenclature, Implantable Device, Cardiac	IS 11073-10103	Active (ISO)	This project extends the base nomenclature provided in ISO/IEEE 1073-10101 to support terminology for implantable cardiac devices (IDC) (e.g., pacemakers). Its primary focus is semantics included in IDC program configuration reports, namely between the IDC programmer and other enterprise-based applications, not between the programmer and the actual implanted device. The nomenclature extensions may be used in conjunction with other ISO/IEEE 11073 standard components (e.g., ISO/IEEE 11073-10201 Domain Information Model) or with other standards, such as HL7.	Unique	

Health infodevice communication - Application profiles MIB Elements	IS11073-20102	Active (ISO)	The scope of this standard is specification of the elements of Medical Device Communication (MDC) Management Information Bases (MIB). Definition of the object-oriented abstractions supporting MDC MIBs is not within the scope of this document and can be found in ISO/IEEE 11073-10102, Domain Information Model (DIM).	Unique	
Health informatics: Point-of-care Medical Device Communication - Application profile, Association Control Function	IS 11073-20200	Active (ISO)	This standard defines a profile for utilizing ISO Open Systems Interconnection (OSI) service for an Association Control Service Element (ACSE) in point-of-care medical device communication within the framework of the ISO/IEEE 11073 standards. This service provides for the establishment, release and aborting of an association between a medical device agent and another system acting as a manager. Service establishment includes dynamic negotiation of presentation layer functions such as message encoding and abstract syntax, as well as application layer services to be used.	Unique	
CEN en1064:2007, ISO 11073-91064 - Health informatics - Standard communications protocol	IS 11073-91064	Published (CEN) Active (ISO)	This document specifies the common conventions required for the cart-to-host as well as cart-to-cart interchange of specific patient data (demographic, recording, ...), ECG signal data, ECG measurement and ECG interpretation results. This document specifies the content and structure of the information which is to be interchanged between digital ECG carts and computer ECG management systems, as well as other computer systems where ECGdata can be stored.	Common	
Deployment of a Clinical Data Warehouse	TS 29585	Active (ISO)	This new Technical Specification furthers the work of ISO TR 22221, Principles and Practices for a Clinical Data Warehouse, by providing implementation guidance for a clinical data warehouse and describing: general considerations of development and deployment, issues and applications of data aggregation and data modelling, and architecture and analytical approaches. The first section guides the establishment and deployment of a clinical data warehouse. The second section specifies different categories and approaches for common types of data aggregation including health indicators. The third section specifies architectural issues and analytical approaches that support effective use of a clinical data warehouse.	Unique	
Health informatics: Provider Identification	TS 27527	Ballot DTS (ISO)	This will be a Technical Specification for uniquely identifying Health Service Providers in the context of shared EHR implementations. This project will leverage the work being done in Canada and Australia on their representative National Level Provider Registry programs. This work item will be developed in liaison with WG4 due to the substantive work on Directory Services for Provider Identification and corresponding definition of role-based access and privilege management. It is anticipated that as part of the data modeling that certain terminologies will be required to deal with typing of providers, roles, etc.. WG1 will work closely with WG3 as these elements are identified. The scope of work will include data modeling of the representation of Providers, focusing on the delineation between use of identifiers use for: electronic systems access, accreditation, and health service delivery purposes.	Unique	
Health informatics: Identification of Subjects of Health Care	ISO/TS 22220	Published (ISO)	This Technical Specification identifies the data elements and structure suited to the identification of individuals in health care and gives guidelines for improving the positive identification of subjects of care within and between health care organizations. It defines demographic and other identifying data elements suited to capture and use for identification in health care settings; provides guidance on their application in the manual and the computer environment; and makes recommendations about the nature and form of health care identifiers; and the management organisation to oversee subject of care identification. The TechnicalSpecification provides a generic set of identifying information, which is application independent.	Unique	

Document Registry Framework	TS 27790	Active (ISO)	This Technical Specification is applicable to focus on presenting further development of Document Registry Framework for transmitting, storing, and utilizing documents (e.g. CDA, DICOM, etc.) in the clinical environment based on the ebXML Registry Framework. This document is to specify the general document registry and associated repository framework by specialization of ISO 15000 (ebXML registry standards). This Technical Specification defines a specific use of the ebXML Registry Standard for the sharing of documents of any standardized content in the context of healthcare. It does not require the development of new health informatics standards. It describes the means to locate and access documents among a diverse set of health organizations.	Unique	
Messages and Communication - Web Access Reference Manifest	IS 10159	Active (ISO)	This standard specifies the format of a manifest of web access reference pointers, information object identifiers, information object filenames and associated information which is required by a recipient IT system to enable local web access to the referenced information objects when a document that references the information objects is sent together with the objects, stored in files, to a domain within which the server references are different from those used in the domain within which the document was created. The technologies used for data storage and communication are outside the scope.	Unique	
IHE Global Standards Adoption Part 1 - Process	DTR 28380-1	Active (ISO)	This Technical Report describes how the IHE process specifies and facilitates profiles of selected standards to support carefully defined healthcare tasks that depend on electronic information exchange. It accelerates the worldwide adoption of standards targeted at achieving interoperability between software applications within healthcare enterprises and across healthcare settings. The Integration and Content Profiles are specified in Part 2 of this two part ISO Technical Report.	Unique	
HL7 Version 2.5 messaging standard	IS 27931	Ballot DIS (ISO)	Contains the specifications for Version 2.5 of the Health Level Seven (HL7) Standard for electronic data exchange in all healthcare environments, with special emphasis on inpatient acute care facilities (i.e., hospitals).	Common	
Clinical Document Architecture (Release 2)	IS 27932	Ballot DIS (ISO)	Specifies the structure and semantics of "clinical documents" for the purpose of exchange.	Common	
Genomic sequence variation Markup Language	IS 25720	Ballot DIS (ISO)	The purpose of this International Standard is to provide the standardized data exchanging format for genomic sequence variation data. The genomic sequence Variation Markup Language (GSVML) intends to provide the standardized data exchanging format for genomic sequence variation data in human health. This document tries to provide the GSVML specification mainly for the case of SNP and STRP.	Unique	
Exchange of Information between Healthcare Information Systems -Development of Messages	IS 17113	Ballot 2 <sup>nd</sup> DIS (ISO)	This standard defines a general methodology suitable for developing messaging standards for the exchange of information between healthcare information systems.	Unique	
Common Terminology Services (Release 1)	IS 27951	Active (ISO)	An international standard for a set of application programmer interface (API) calls to support generisized access to terminologies for runtime binding or browsing. The exact scope is identical with the ANSI HL7 Common Terminology Services specification.	Unique	

Common Glossary for ISO/TC 215	TS 28379	Active (ISO)	The proposed work item will be a Technical Specification to define the terms used in health informatics standards to support harmonisation of standards and to improve their clarity and consistency. The report will identify terms, their definitions and where appropriate the rationale for variations in terms in different contexts. It is intended that this work will simplify the development of consistent standards in the health informatics domain. The scope of work will include a review of existing standards, including, but not limited to those produced by TC215, collect the definitions of terms used, details of the context in which the term is used in the in the standard/s in which it currently appears and determine a consistent defintion appropriate to context, or where appropriate clearly identify contextual differences and guidelines for use. The specification will also identify processes for inclusion of additional terms and contextual variations into the specification.	Unique	
Health informatics: Conceptual Framework for patient findings anfd problems in terminologies	TS/ISO 22789	Active (ISO)		Unique	
Health informatics: Criteria for the Categorization and Evaluation of Terminological Systems	TS (Revision of ISO/TS 17117)	Active (ISO)		Unique	
Health informatics - Dynamic on -demand virtual private network for health infromation infrastructure	TR 11636	Active (ISO)	This TR intends to introduce examples of security measures taken with dynamic on-demand VPN for exchange of medical information and does not intend to specify dynamic on-demand VPN. These examples provide network solutions to potential risks for such user enviroment. Examples include use cases of regional healthcare cooperation and remote medical care (teleradiology,telepathology),remote maintenance, and so on. Necessities, usefulness and security advantages of dynamic on-demand VPN in health field are described in this TR. This TR also explains "network requirements in healthcare field", "Network security of open network for healthcare field" and "• Minimum guidelines for security management of health information exchange including personal data between external institutions".	Unique	
Health informatics - The Information Security Management Guidelines for Remote Maintenance Services for Medical Devices and Health Information Systems	TR 11633	Active (ISO)		Unique	
Health informatics: Secure Archiving of electronic health records Part 1: Principles and Requirements	TS 21547-1	Active (ISO)	Part I will define the functional requirements of security services for long term digital archiving of health records. By elaborating on existing standards, it defines: 1. security requirements for data to be archived; 2. security requirements archiving and recovery of the data; 3. security requirements and features for metafile data linked to any stored data object and to patient records; 4. security requirements for metadata required for long-term digital archiving; 5. access conditions and possible methods for access, including the express consent by the data subject; 6. associated issues relating to auditing access and to audit logs 7. data migration policy needed to fulfill various national legislation and to meet other business objectives; and 8. methods for managing transfer of stored records to new media and operating system conditions during the archival time.	Unique	

Health informatics: Secure Archiving of electronic health records Part 2: Guidelines	TS 21547-2	Active (ISO)	<p>Part II will provide guidance on how to apply the requirements for secure, long- term archiving of electronic health records set out in the related work item Health Informatics – Secure archiving, Part I: principles and requirements. Health care specific issues are discussed, such as patient consent management during long archival periods, purpose-based access, overriding conditions for access, and management of anonymisation and pseudonymisation within the archives.</p> <p>Part II gives guidance on implementation of security services for long term digital archiving of health records specified in Part I. By elaborating on existing standards, it provides guidance on how best to implement:</p> <ol style="list-style-type: none"> <li>1. security requirements for data to be archived;</li> <li>2. security requirements archiving and recovery of the data;</li> <li>3. security requirements and features for metafile data linked to any stored data object and to patient records;</li> <li>4. security requirements for metadata required for long-term digital archiving;</li> <li>5. access conditions and possible methods for access, including the express consent by the data subject;</li> <li>6. associated issues relating to auditing access and to audit logs</li> <li>7. data migration policy needed to fulfill various national legislation and</li> <li>8. methods for managing transfer of stored records to new media and</li> </ol> <p>This technical report will additionally provide informative examples of</p>	Unique	
HC Information Privilege Management & Access Control Part 3: Access Control Management	TS 22600-3	Active (ISO)	<p>This multi-part technical specification shall define privilege management and access control services required for communication and use of distributed health information. It introduces principles and specifies services needed for managing privileges and access control using the framework of ISO/IEC 10181-3. (Access control framework for open systems). This Technical Specification will use existing architectural and security standards for platform independent solutions and describe possible solutions. "Part 1: Overview and policy management" and "Part 2: Formal models" have already been approved for publication.</p>	Unique	
Pseudonymisation	TS 25237	Active (ISO)	<p>This technical specification contains principles and requirements for privacy protection using pseudonymisation services for the protection of personal health information.</p> <p>The technical specification:</p> <ul style="list-style-type: none"> <li>- Defines basic concepts for identification and pseudonymisation</li> <li>- Gives an overview of different use cases for pseudonymisation that can be both reversible and irreversible</li> <li>- Defines at least one methodology for pseudonymisation services including organizational as well as technical aspects</li> <li>- Gives a guide to risk assessment for re-identification</li> <li>- Specifies a policy framework and minimal requirements for trustworthy practices for the operations of a pseudonymisation service</li> <li>- Specify a policy framework and minimal requirements for controlled re-identification</li> <li>- Specifies the interoperability of services interfaces</li> </ul>	Unique	

Health informatics: Functional and Structural Roles	TS 21298	Active (ISO)	This technical specification defines a model for expressing functional and structural roles and populates it with a basic set of roles for international use in health applications. Roles are generally assigned to entities that are actors. This will focus on roles of persons (i.e., the roles of health professionals and healthcare consumers/clients/patients). Roles can be structural (e.g.: licensed general practitioner, non-licensed transcriptionist, patient/consumer, next-of-kin, etc.) or functional (e.g.: a provider who is a member of a therapeutic team, an attending physician, etc). Structural roles are relatively static, often lasting for many years. They deal with relationships between entities expressed at a level of complex concepts. Functional roles are bound to the realisation of actions and are highly dynamic. They are normally expressed at a decomposed level of fine-grained concepts.	Unique	
Electronic reporting of adverse drug reactions	TS 22224	Active (ISO)	This international standard encompasses the electronic reporting of adverse reactions caused by drugs for human uses. Thus, other businesses relating to adverse events caused by blood transfusion, medical devices and veterinary drugs are excluded from the scope of this standard. Since ICH guidelines (E2B Data Elements for Transmission of Individual Case Safety Reports and other revised documents) were well developed and are being adopted in EU, US, Japan and other countries, there may be no need to develop the ISO guidelines independently from ICH. Since ICH guidelines have been developed for electronic transmissions of individual case safety information between pharmaceutical companies and regulatory bodies in ICH member countries, these do not fully reflect the needs of other non-member countries and also do not contain consumer perspectives in reporting process. In this point of view, ISO working group has studied on the ICH guidelines and developed the international standards for electronic reporting of adverse drugreactions by modifying the existing ICH guidelines which all the member countries can use for implementing electronic reporting system for ADRs.	Unique	
Business requirements for the Reporting of Pharmacist Services	TR 10895	Active (ISO)	To identify and document the business requirements for messaging standards that enable the participating systems in pharmacist supplied professional services to communicate with each other interoperably. This BR will identify the components and processes that are common to all professional services and consequently supply information on the unique elements for each service.	Unique	
ISO/IEC 80001 Part 1: Application of Risk Management for IT - Networks incorporating medical devices	ISO/IEC 80001	Active (ISO)		Common	
Requirements for EHR reference architecture	ISO 18308 rev	Active (ISO)		Unique	
Health informatics: Requirements and specifications of common essential information for health summary records	TR	DTR Ballot (ISO)		Unique	
Health informatics: EHR standards Map		Active (ISO)		Unique	Potential Joint Initiative
EHR Blueprint Definition		Preliminary (ISO)		Unique	
Identity Management Framework Task Group		Preliminary (ISO)		Unique	
Semantic linkages between Information Models and Terminologies		Preliminary (ISO)		Unique	
Health Summary Record - Minimum Data Set		Preliminary (ISO)		Unique	
Health Informatics: Telehealth Systems - Teleradiology Interoperability		Preliminary (ISO)		Unique	
Trusted end- to- end information flows	DTS 21089	Preliminary (ISO)		Unique	
IHE Global Standards Adoption Part 2 - Integration and Content Profiles	TR 28380-2	Preliminary (ISO)		Unique	

Health informatics: The categorization and nomenclature of medical devices - Requirements and analysis		Preliminary (ISO) + prCEN/TR	<p>Many systems exist for the categorization and nomenclature of medical devices but these systems serve different purposes and are incompatible.</p> <p>More recently, the development of electronic health record systems introduce requirements to reference and include details of medical devices at a wide range of levels of abstraction e.g. bone screw at the more abstract to orthopaedic bone screw, cannulated, lag, titanium, gauge 2.3mm, length 12mm. In addition the health record will be required to record information about 'actual' devices, devices as supplied by a particular manufacturer.</p> <p>These ehr requirements cut across the existing nomenclatures which were primarily designed for product regulation and supply. The purpose of this task is to analyse the existing systems in order to:</p> <ul style="list-style-type: none"> <li>• capture and document naming conventions, clinical and commercial requirements and processes</li> <li>• provide an analysis of requirements</li> <li>• create a framework/reference architecture for a harmonized medical devices reference source</li> </ul>	Unique	
Health informatics: Mapping of terminologies to classifications		Preliminary (ISO)		Unique	
EHR Glossary				Unique	
Health informatics: Principles and guidelines for the maintenance of terminological systems		Preliminary (ISO)		Unique	
Health informatics: Principles and guidelines for the measurement of conformance in the implementation of terminological systems		Preliminary (ISO)		Unique	
Health informatics: Transforming clinical descriptions into higher level classification: Principles and issues		Preliminary (ISO)		Unique	
Health informatics: Harmonisation: Traditional medicine (TrM) terminologies		Preliminary (ISO)		Unique	
Cross terminology referencing, including drug references in laboratory testing		Preliminary (ISO)		Unique	
Health informatics: Guide for international healthcare terminology standard development		Preliminary (ISO)		Unique	
Semantic harmonization across Information Models and Terminologies		Preliminary (ISO)		Unique	
Health informatics: Guidelines on data protection to facilitate trans-border flows of personal health information		Preliminary (ISO)		Unique	
Health informatics: Guidance on the application of risk analysis and management across the health informatics domain	IS 21091 (Revision of TS 21091)	Preliminary (ISO)		Unique	
Health informatics: Directory Services for healthcare providers, subjects of care and other entities		Preliminary (ISO)		Unique	
Study for the use of cards and other technologies in the health care area, not specified as patient data cards	TR	Preliminary (ISO)		Unique	

Overview of National Healthcare Professional Card Projects and/or Plans	TR	Preliminary (CEN) Preliminary (ISO)	The work item prENV 13729:2000 "Health informatics - Secure user identification - Strong authentication using microprocessor cards" is currently undergoing revision. Add EU official scope concerning mandation / legalization of HPC interoperability Due to broad range of interoperability issues foreseeable in this context because of national healthcare responsibilities and differing (or even yet non-existent) technical frameworks it has been deemed necessary to gather an up-to-date and encompassing overview of salient information regarding national activities for healthcare professional cards in the member states of the EC. The following aspects are to be covered: 1) Identify institutions responsible for national healthcare professional cards (planning and rollout) 2) Identify / enumerate involved healthcare professions x) Identify industrial solution and product providers 3) Document status of current plans and development 4) Identify (technical) correspondents for HPC queries 5) Collect design frameworks and/or guides of national HPC's.	Common	CEN title: Health informatics-overview of national health professional cards in the CEN member countries
Business requirements for an International Coding System for Medicinal products	TR 25257	Preliminary (ISO)	This Technical Report specifies the business requirements for an international coding system for medicinal products by: - Analyzing the most significant coding system in use with an international standing in the context of the objectives they were designed to serve and assesses their potential for fulfilling all the identified business requirements of an international coding system. - Considering the issues involved in the creation of an international coding system which will meet all business requirements. - Making recommendations for next steps.	Unique	
Health informatics - Medical waveform format - Encoding rules, Reporting with HL7 clinical document architecture (CDA)	NP/TS 11073-92205	Preliminary (ISO)		Unique	
Health informatics - Medical waveform format - Encoding rules, SCP-ECG	NP/TS 11073-92206	Preliminary (ISO)		Unique	
Health informatics - Medical waveform format - Encoding rules, 12-lead ECG	NP/TS 11073-92301	Preliminary (ISO)		Unique	
Health informatics - Personal health device communication - Device specialization - Common framework	NP/IS 11073-10400	Preliminary (ISO)		Unique	
Health informatics - Personal health device communication - Device specialization - Pulse oximeter	NP/IS 11073-10404	Preliminary (ISO)		Unique	
Health informatics - Personal health device communication - Device specialization - Heart rate monitor	NP/IS 11073-10406	Preliminary (ISO)		Unique	
Health informatics - Personal health device communication - Device specialization - Blood pressure monitor	NP/IS 11073-10407	Preliminary (ISO)		Unique	
Health informatics - Personal health device communication - Device specialization - Thermometer	NP/IS 11073-10408	Preliminary (ISO)		Unique	
Health informatics - Personal health device communication - Device specialization - Weighing scale	NP/IS 11073-10415	Preliminary (ISO)		Unique	
Health informatics - Personal health device communication - Device specialization - Glucose meter	NP/IS 11073-10417	Preliminary (ISO)		Unique	
Health informatics - Point-of-care medical device communication - Application profile - Common networking infrastructure	NP/IS 11073-20401	Preliminary (ISO)		Unique	
Health informatics - Personal health device communication - Application profile - Optimized exchange protocol	NP/IS 11073-20601	Preliminary (ISO)		Unique	
Health informatics - Point-of-care medical device communication - Transport profile - Inter-LAN	NP/IS 11073-30400	Preliminary (ISO)		Unique	

Health informatics - Point-of-care medical device communication - Transport profile - RF wireless - Local area network (wLAN)	NP/IS 11073-30503	Preliminary (ISO)		Unique	
Health informatics: Point-of-care medical device communication - Technical report - Guidelines for the use of RF wireless technology	pNWIP/11073-00101	Preliminary (ISO)		Unique	
Health informatics: Point-of-care medical device communication - Device specialization - Dialysis device	pNWIP/11073-10316:	Preliminary (ISO)		Unique	
Health informatics - Security of concepts to support continuity of care - Part 2: Workflow	prEN 13940-2	Preliminary (CEN)	The aim of this Standard is to describe a system of concepts focused on the health care process, supporting its continuity. This is an extension of EN 13940-1:2007 using a process modelling technique to identify the links between activities, sub-processes, and refinement objects. It also takes into consideration the responsibilities of health care providers and means for patients' participation. The purpose of this European Standard is to enable communication at the semantic level between information systems in health care. It provides terminology for planning, delivery and follow-up of the activities as well as of the overall process.	Unique	