

### ISO 13606-1:2008

Здравна информатика -- ЕЗД комуникация -- Част 1: Референтен модел

ISO 13606-1:2008 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.

ISO 13606-1:2008 will predominantly be used to support the direct care given to identifiable individuals, or to support population monitoring systems such as disease registries and public health surveillance. Use of health records for other purposes such as teaching, clinical audit, administration and reporting, service management, research and epidemiology, which often require anonymization or aggregation of individual records, are not the focus of ISO 13606-1:2008 but such secondary uses might also find this document useful.

### ISO 13606-2:2008

Здравна информатика -- ЕЗД комуникация -- Част 2: Спецификация за обмен на архетипите

ISO 13606-2:2008 specifies the information architecture required for interoperable communications between systems and services that need or provide EHR data. ISO 13606-2:2008 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 ISO 13606-2:2008 but such secondary uses could also find this document useful.

ISO 13606-2:2008 defines an archetype model to be used to represent archetypes when communicated between repositories, and between archetype services. It defines an optional serialized representation, which may be used as an exchange format for communicating individual archetypes. Such communication might, for example, be between archetype libraries or between an archetype service and an EHR

persistence or validation service.

### [ISO 13606-3:2009](#)

Здравна информатика -- ЕЗД комуникация -- Част 3: Референтни архетипи и терминологични списъци

ISO 13606-3:2009 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 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.

ISO 13606-3:2009 defines term lists that each specify the set of values that particular attributes of the Reference Model defined in ISO 13606-1 may take. It also defines informative Reference Archetypes that correspond to ENTRY-level compound data structures within the Reference Models of openEHR and HL7 Version 3, to enable those instances to be represented within a consistent structure when communicated using ISO 13606-3:2009.

### [ISO/TS 13606-4:2009](#)

Здравна информатика -- ЕЗД комуникация -- Част 4: Сигурност

ISO/TS 13606-4:2009 describes a methodology for specifying the privileges necessary to access EHR data. This methodology forms part of the overall EHR communications architecture defined in ISO 13606-1.

ISO/TS 13606-4:2009 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.

### [ISO 13606-5:2010](#)

Здравна информатика -- ЕЗД комуникация -- Част 5: Спецификация на интерфейса

ISO 13606-5:2010 specifies the information architecture required for interoperable communications between systems and services that need

or provide EHR data.

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.

ISO 13606-5:2010 defines a set of interfaces to request and provide:

an EHR\_EXTRACT for a given subject of care as defined in ISO 13606-1;

one or more ARCHETYPE(s) as defined in ISO 13606-2;

an EHR\_AUDIT\_LOG\_EXTRACT for a given subject of care as defined in ISO/TS 13606-4.

ISO 13606-5:2010 defines the set of interactions for requesting each of these artefacts, and for providing the data to the requesting party or declining the request. An interface to query an EHR or populations of EHRs, for example for clinical audit or research, are beyond its scope, although provision is made for certain selection criteria to be specified when requesting an EHR\_EXTRACT which might also serve for population queries.

ISO 13606-5:2010 defines the Computational Viewpoint for each interface, without specifying or restricting particular engineering approaches to implementing these as messages or as service interfaces.

ISO 13606-5:2010 effectively defines the payload to be communicated at each interface. It does not specify the particular information that different transport protocols will additionally require, nor the security or authentication procedures that might be agreed between the communicating parties or required by different jurisdictions.

### **ISO 18308:2011**

Здравна информатика – Изисквания за архитектурата на електронното здравно досие

ISO 18308:2011 defines the set of requirements for the architecture of a system that processes, manages and communicates electronic health record (EHR) information: an EHR architecture. The requirements are formulated to ensure that these EHRs are faithful to the needs of healthcare delivery, are clinically valid and reliable, are ethically sound, meet prevailing legal requirements, support good clinical practice and facilitate data analysis for a multitude of purposes.

ISO 18308:2011 does not specify the full set of requirements that need to be met by an EHR system for direct patient care or for other use

cases, but the requirements defined by ISO 18308:2011 do contribute to the governance of EHR information within such systems.

### [ISO/TR 20514:2005](#)

Здравна информатика – Електронно здравно досие -- Определение, обхват и контекст

ISO/TR 20514:2005 describes a pragmatic classification of electronic health records, provides simple definitions for the main categories of EHR and provides supporting descriptions of the characteristics of electronic health records and record systems.

### [ISO/TS 21547:2010](#)

Здравна информатика -- Изисквания за сигурност при архивиране на ЕЗД – Принципи

The purpose of ISO/TS 21547:2010 is to define the basic principles needed to securely preserve health records in any format for the long term. It concentrates on previously documented healthcare specific archiving problems. It also gives a brief introduction to the general archiving principles. Unlike the traditional approach to standardization work, where the perspective is that of modelling, code sets and messages, this Technical Specification looks at archiving from the angle of document management and related privacy protection.

In ISO/TS 21547:2010 archiving is understood to be a wider process than just the permanent preservation of selected records.

ISO/TS 21547:2010 defines architecture and technology-independent security requirements for long-term preservation of EHRs having fixed content.

ISO/TS 21547:2010 and a complementary Technical Report, ISO 21548, concentrate on the security requirements (integrity, confidentiality, availability and accountability) necessary for ensuring adequate protection of health information in long-term digital preservation. This Technical Specification will also address privacy protection requirements for both the EHR and eArchiving systems used in the healthcare environment.

ISO/TS 21547:2010 defines functional security requirements for long term archiving of EHRs, but the practical archiving models and technology required are outside the concept of this Technical Specification.

### [ISO/TR 21548:2010](#)

Здравна информатика -- Изисквания за сигурност при архивиране на ЕЗД – Насоки

ISO/TR 21548:2010 is an implementation guide for ISO/TS 21547. ISO/TR 21548:2010 will provide a methodology that will facilitate the implementation of ISO/TS 21547 in all organizations that have the responsibility to securely archive electronic health records for the long term.

ISO/TR 21548:2010 gives an overview of processes and factors to consider in organizations wishing to fulfil requirements set by ISO/TS 21547.

### [ISO/FDIS 27789](#)

Здравна информатика – Системен лог за ЕЗД