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Medizinische Informatik – Kommunikation von Patientendaten in elektronischer Form – Teil 1: Referenzmodell (ISO 13606-1:2019); Englische Fassung EN ISO 13606-1:2019

Health informatics –
Electronic health record communication –
Part 1: Reference model (ISO 13606-1:2019);
English version EN ISO 13606-1:2019

Informatique de santé –
Communication du dossier de santé informatisé –
Partie 1: Modèle de référence (ISO 13606-1:2019);
Version anglaise EN ISO 13606-1:2019

Gesamtumfang 102 Seiten

DIN-Normenausschuss Medizin (NAMed)

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Nationales Vorwort

Dieses Dokument (EN ISO 13606-1:2019) wurde in der WG 1 „Architecture, Frameworks and Models“ des Technischen Komitees ISO/TC 215 „Health Informatics“ und mit dem Technischen Komitee CEN/TC 251 „Medizinische Informatik“, dessen Sekretariat von NEN (Niederlande) gehalten wird, erarbeitet.

Der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ des DIN-Normenausschusses Medizin (NAMed) hat an der Erarbeitung ebenfalls mitgewirkt.

Dieses Dokument enthält unter Berücksichtigung des Präsidialbeschlusses 1/2004 nur die englische Originalfassung von EN ISO 13606-1:2019.

Für die in diesem Dokument zitierten internationalen Dokumente wird im Folgenden auf die entsprechenden deutschen Dokumente hingewiesen:

ISO 8601:2004	siehe	DIN ISO 8601:2006-09
ISO 13940	siehe	DIN EN ISO 13940
ISO 21090:2011	siehe	DIN EN ISO 21090:2011-06
ISO 22600 (all parts)	siehe	DIN EN ISO 22600 (alle Teile)
ISO 27789:2013	siehe	DIN EN ISO 27789:2013-06

Änderungen

Gegenüber DIN EN ISO 13606-1:2012-12 wurden folgende Änderungen vorgenommen:

a) Übernahme der Internationalen Norm;

b) der Norminhalt wurde mit ISO 13940 *Medizinische Informatik — Begriffssystem zur Unterstützung der Kontinuität der Versorgung* und der Normenreihe ISO 12967 *Medizinische Informatik — Servicearchitektur* harmonisiert;

c) die Teile dieser Normenreihe wurden untereinander harmonisiert.

Frühere Ausgaben

DIN V ENV 13606-1: 2000-09
DIN EN 13606-1: 2007-05
DIN EN ISO 13606-1: 2012-12

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Zusammenfassung

Dieses Dokument legt fest, wie die elektronische Gesundheitsakte (eGA) von einem identifizierten Behandelten oder mehreren identifizierten Behandelten zwischen eGA-Systemen oder zwischen eGA-Systemen und einem zentralen eGA-Repository vollständig oder teilweise übermittelt werden kann.

Sie kann auch verwendet werden für die eGA-Übermittlung zwischen einem eGA-System oder -Repository und klinischen Anwendungen bzw. Middleware-Komponenten (wie z. B. Entscheidungsunterstützungs-komponenten) oder Anwendungen und Geräten für die persönliche Gesundheit, wenn diese Zugriff auf eGA-Daten benötigen oder diese bereitstellen, oder als Darstellung von eGA-Daten innerhalb eines verteilten (föderierten) Datensatzsystems.

Dieses Dokumentwird überwiegend zur Unterstützung der direkten Behandlung von identifizierbaren Personen oder zur Unterstützung von Bevölkerungsüberwachungssystemen wie Krankheitsregistern und der öffentlichen Gesundheitsüberwachung verwendet. Die Verwendung von Gesundheitsakten für andere Zwecke wie Lehre, klinisches Audit, Verwaltung und Berichterstattung, Service-Management, Forschung und Epidemiologie, die oft eine Anonymisierung oder Aggregation einzelner Datensätze erfordern, stehen nicht im Mittelpunkt dieses Dokuments, allerdings könnte dieses Dokument bei solchen sekundären Verwendungen ebenfalls nützlich sein.

Dieser Teil 1 der mehrteiligen Reihe ist eine Datensicht-Spezifikation, wie sie von der Norm *Informationstechnik — Verteilte Verarbeitung in Offenen Systemen — Referenzmodell: Übersicht* (ISO/IEC 10746-1) festgelegt ist. Dieses Dokument hat nicht zum Ziel, die interne Architektur oder das Datenbankdesign von eGA-Systemen zu spezifizieren.

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Nationaler Anhang NA
(informativ)

Begriffe

Die Benummerung der folgenden Begriffe und Abkürzungen sind identisch mit der Benummerung in der englischen Fassung.

3 Begriffe

Für die Anwendung dieses Dokuments gelten die folgenden Begriffe.

ISO und IEC stellen terminologische Datenbanken für die Verwendung in der Normung unter den folgenden Adressen bereit:

— ISO Online Browsing Platform: verfügbar unter http://www.iso.org/obp

— IEC Electropedia: verfügbar unter http://www.electropedia.org/

3.1 Handlungsträger

3.1.1
Attestierer
(en: attester)
Handlungsträger (Person), der die rechtliche Verantwortung für eine bestimmte Informationseinheit zertifiziert und aufzeichnet

3.1.2
Ersteller
(en: committer)
Agent (Partei, Gerät oder Software), dessen direkte Aktivitäten dazu geführt haben, dass Daten in eine elektronische Gesundheitsakte eingestellt wurden

3.1.3
Verfasser
(en: composer)
Handlungsträger, der für die Erstellung, Synthese oder Organisation von Informationen verantwortlich ist, die in eine elektronische Gesundheitsakte eingestellt wurden.

Anmerkung 1 zum Begriff: Dieser Handlungsträger trägt die Verantwortung für die Aufnahme der Informationen in diese elektronische Gesundheitsakte, auch dann, wenn er nicht deren Urheber ist und sogar dann, wenn er nicht der Ersteller dieser Information(en) ist

3.1.4
Anbieter von Auszügen einer elektronischen Gesundheitsakte
(en: electronic health record provider)
Handlungsträger im Gesundheitswesen, der rechtmäßig im Besitz von elektronischen Gesundheitsaktendaten und in der Lage ist, diese an eine andere geeignete Funktionseinheit zu übermitteln

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3.1.5
Anbieter medizinischer Versorgungsleistungen
(en: healthcare provider)
Pflegedienstleister
Gesundheitsversorger
Gesundheitsdienstleister
Dienstleister im Gesundheitswesen
Handlungsträger im Gesundheitswesen, dem ein oder mehrere Pflegezeitmandate zugewiesen werden können

Anmerkung 1 zum Begriff: Das Personal einer *Organisation des Gesundheitswesens*, die *Anbieter medizinischer Versorgungsleistungen* ist, kann sowohl *im Gesundheitswesen tätige, qualifizierte Personen* als auch andere, die an der Bereitstellung von *medizinischen Versorgungsleistungen* teilnehmen, umfassen.

Anmerkung 2 zum Begriff: Dieses Dokument umfasst nur zwei Spezifizierungen von *Anbietern medizinischer Versorgungsleistungen*. Dies soll nicht die Möglichkeit anderer Spezialisierungen ausschließen. In Zuständigkeitsbereichen, in denen andere Arten von *Handlungsträgern im Gesundheitswesen* in das Konzept des *Anbieters medizinischer Versorgungsleistungen* einbezogen sind, können die notwendigen Spezialisierungen hinzugefügt werden.

Anmerkung 3 zum Begriff: Nach dieser Definition sind *Organisationen*, die ausschließlich für die Finanzierung, Bezahlung oder Erstattung von *Gesundheitsleistungen* zuständig sind, keine *Anbieter medizinischer Versorgungsleistungen*; für die Zwecke dieses Dokuments gelten sie als *Dritte im Bereich Gesundheitswesen*.

[QUELLE: ISO 13940:2015]

3.1.6
Rolle
(en: role)
Funktion oder Position

[QUELLE: ISO/HL7 21731:2014]

3.1.7
Behandelter
(en: subject of care)
zu Behandelnder
Patient
Klient
Dienstbenutzer
Handlungsträger im Gesundheitswesen mit der persönlichen Funktion, für den Empfang von Gesundheitsdienstleistungen vorgesehen zu sein, diese zu erhalten oder diese bereits erhalten zu haben

Anmerkung 1 zum Begriff: Ein Fötus kann als *Behandelter* angesehen werden, wenn er *Gesundheitsdienstleistungen* erhält.

BEISPIELE Ein behandelter Patient, ein Klient eines Physiotherapeuten, jedes einzelne Mitglied einer Zielgruppe einer Vorsorgeuntersuchung, jedes einzelne Mitglied einer Gruppe von Diabetikern, die an einer Sitzung zur medizinischen Aufklärung teilnehmen, eine *Person*, die eine Gesundheitsberatung wünscht.

[QUELLE: ISO 13940:2015]

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3.2 Konzepte und Begriffe

3.2.1
generisch
(en: generic)
anwendbar auf Anforderungen oder Informationsmodelle in allen Gesundheitsberufen, Domänen und Ländern

3.3 Informationsmanagement

3.3.1
abstrakte Klasse
(en: abstract class)
eine Klasse, die nicht selbst instanziiert werden kann

[QUELLE: ISO/IEC/IEEE 24765:2017, 3.24]

3.3.2
Archetyp
(en: archetype)
Instanz eines Archetypenmodells, die das klinische Konzept und die wertebezogenen Einschränkungen spezifiziert, die für eine Klasse von Instanzen von Aufzeichnungskomponenten in einem Auszug aus der elektronischen Gesundheitsakte gilt

3.3.3
Archetypenmodell
(en: archetype model)
Informationsmodell der Metadaten zur Darstellung der wertebereichsspezifischen Merkmale von Einträgen in der elektronischen Gesundheitsakte durch Festlegung von Werten oder wertebezogenen Einschränkungen für Klassen und Attribute im Referenzmodell der elektronischen Gesundheitsakte

3.3.4
Daten verwendende Anwendung
(en: client application)
Gesundheitsversorgungsanwendung, die sich im gegebenen Moment wie ein Anforderer von Gesundheitsaktendaten aus einer gemeinsamen elektronischen Gesundheitsakte verhält

3.3.5
Daten
(en: data)
rückübertragbare, formalisierte Darstellung von *Informationen* (3.3.9), die für deren Übermittlung, Auswertung oder Weiterverarbeitung geeignet ist

Anmerkung 1 zum Begriff: Daten werden ohne jeglichen Kontext so definiert, dass man von selbst ihre korrekte Bedeutung nicht erschließen kann, und da wo dies möglich ist, handelt es sich um eine Information.

[QUELLE ISO/IEC 2382-1:2015, 2121272]

3.3.6
Daten-Repository
Datenbehälter
(en: data repository)
identifizierbare Einrichtung zur Speicherung von *Daten* (3.3.5)

Anmerkung 1 zum Begriff: In ISO 10303-22:1998 ist dies die Definition zur englischen Benennung „repository“

[QUELLE: ISO 13940:2015]

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3.3.7
Gesundheitsdaten
(en: healthcare data)
im Rahmen von Gesundheitsdienstleistungen erhobene *Daten* (3.3.5)

[QUELLE: ISO 13940:2015]

3.3.8
Gesundheitsinformationen
(en: healthcare information)
Informationen (3.3.9) über eine Person, die für deren Gesundheitsversorgung von Bedeutung sind

[QUELLE: ISO 13940:2015]

3.3.9
Information
(en: information)
Kenntnisse über Objekte, die in einem gegebenen Zusammenhang eine bestimmte Bedeutung haben

Anmerkung 1 zum Begriff: Sachverhalte, Ereignisse, Gegenstände, Prozesse oder Ideen, einschließlich Konzepten, stellen Beispiele für Objekte dar.

Anmerkung 2 zum Begriff: Information ist etwas, das aussagekräftig ist. Daten können als Information betrachtet werden, sobald ihre Bedeutung zum Vorschein kommt.

[QUELLE ISO 13940:2015]

3.3.10
verteilte Datenverarbeitung
(en: distributed processing)
*Informations*verarbeitung (3.3.9), bei der sich diskrete Komponenten an verschiedenen Orten befinden können oder bei der die Kommunikation zwischen Komponenten verzögert oder unterbrochen sein kann

[QUELLE: ISO/IEC 10746-2:2009]

3.3.11
Gesundheitsakte
(en: health record)
Datenbehälter in Bezug auf die Gesundheit und die *Gesundheitsversorgung* eines *Behandelten*

Anmerkung 1 zum Begriff: Der Begriff *elektronische Gesundheitsakte* kann verwendet werden, wenn alle *Informationen* der *Gesundheitsakte* in elektronischen Medien gespeichert sind. Allerdings ist dieses Konzept in diesem Dokument nicht formal definiert.

Anmerkung 2 zum Begriff: Eine *Gesundheitsakte* kann zum Beispiel medizinische Aufzeichnungen, zahnärztliche Aufzeichnungen und Sozialpflegeaufzeichnungen enthalten.

[QUELLE: ISO 13940:2015]

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3.3.12
Gesundheitsaktenbestandteil
(en: health record component)
Teil einer *Gesundheitsakte* (3.3.11), der für Referenz- und Revisionszwecke identifiziert werden kann

Anmerkung 1 zum Begriff: Dieses Dokument definiert eine Spezialisierung von *Gesundheitsaktenbestandteilen*, der *elektronische Aktenbestandteil*. Da jedoch der Inhalt einer *Gesundheitsakte* nicht auf *Informationen* in elektronischer Form beschränkt ist, kann der Inhalt von *Gesundheitsaktenbestandteilen* auch in anderen als in elektronischen Formaten vorliegen.

Anmerkung 2 zum Begriff: Ein *Gesundheitsaktenbestandteil* kann selbst aus einer Aggregation mehrerer *Gesundheitsaktenbestandteile* resultieren.

[QUELLE: ISO 13940:2015]

3.3.13
elektronische Gesundheitsakte
(en: electronic health record)
Gesundheitsakte (3.3.11), bei der alle Informationen in elektronischen Medien gespeichert sind

3.3.14
elektronisches Gesundheitsaktensystem
(en: electronic health record system)
System zum Aufzeichnen, Abrufen und Handhaben von Informationen in *elektronischen Gesundheitsakten* (3.3.13)

[QUELLE: ISO 18308:2011]

3.3.15
Auszug aus der Gesundheitsakte
(en: health record extract)
Teil- oder Vollauszug aus einer *Gesundheitsakte* (3.3.11) für den Zweck der Übermittlung

[QUELLE: ISO 13940:2015]

3.3.16
Gesundheitsversorgungsanwendung
(en: healthcare application)
System zum Sammeln, Speichern, Aufbereiten und Präsentieren von *Gesundheitsinformationen* (3.3.8) mithilfe eines Computers.

Anmerkung 1 zum Begriff: Diese Definition basiert auf der Definition von „Anwendung“ in ISO/IEC 19770-5:2015.

3.3.17
Informationsarchitektur
(en: information architecture)
strukturelles Design eines Informationsraums zur Erleichterung der Aufgabenvervollständigung und zum intuitiven Zugriff auf Inhalte

3.3.18
Metadaten
(en: metadata)
Daten (3.3.5), die die Objektklasse und die Eigenschaften der erfassten Informationen definieren

[QUELLE: ISO/IEC 11179-3:2013, 3.2.74]

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3.3.19
semantische Interoperabilität
(en: semantic interoperability)
Fähigkeit der von mehreren Systemen gemeinsam genutzten Daten, auf der Ebene vollständig definierter Domain-Begriffe verstanden zu werden

[QUELLE: ISO 18308:2011]

3.3.20
Ansicht
(en: view)
ersatzweise Darstellung von *Daten* (3.3.5) für einen anderen Zweck

3.4 Datenschutz und Sicherheit

3.4.1
Zugriffskontrolle
(en: access control)
Mittel zur Sicherstellung, dass nur autorisierte Entitäten in entsprechend autorisierter Weise Zugriff auf die Ressourcen eines *Daten*verarbeitungssystems (3.3.5) nehmen können

[QUELLE: ISO 17090-1:2013]

3.4.2
Audit-Trail
(en: audit trail)
Sammlung von Auditeinträgen aus einem oder mehreren Auditprotokollen, die sich auf eine bestimmte behandelte Person oder eine bestimmte *elektronische Gesundheitsakte* (3.3.13) beziehen

[QUELLE: ISO 27789:2013]

3.4.3
Authentifizierung
(en: authentication)
Beibringung eines Belegs für die von einer Entität behauptete Identität durch die sichere Verbindung eines Identifikators und seines Authentifikators

[QUELLE: ISO 22600-3:2014]

3.4.4
Autorisierung
(en: authorisation)
Gewährung von Privilegien

[QUELLE: ISO 22600-1:2014]

3.4.5
Vertraulichkeit
(en: confidentiality)
Eigenschaft, dass *Informationen* (3.3.9) für nicht autorisierte Einheiten nicht zugänglich gemacht werden

[QUELLE: ISO 7498-2:1989]

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3.4.6
digitale Signatur
(en: digital signature)
an eine Dateneinheit angefügte *Daten* (3.3.5) oder eine kryptografische Transformation einer Dateneinheit, mit der ein Empfänger der Dateneinheit die Möglichkeit der Überprüfung der Quelle und Integrität der Dateneinheit erhält und die einen Schutz gegen Fälschung z. B durch den Empfänger bietet

[QUELLE: ISO 7498-2:1989]

3.4.7
Datenschutz
(en: privacy)
Verhinderung des Eindringens in das Privatleben oder die Angelegenheiten einer Person, sofern dieses Eindringen aus der unzulässigen oder illegalen Erfassung und Nutzung von *Daten* (3.3.5) über diese Person resultiert

[QUELLE: ISO/IEC 2382-8:2015, 2126263]

3.5 Prozessmanagement

3.5.1
Attestierung
(en: attest)
Aktivität der Zertifizierung und Aufzeichnung der rechtlichen Verantwortung für eine bestimmte *Informations*einheit (3.3.9)

3.5.2
Gesundheitsversorgungsprozess
Versorgungsprozess
(en: healthcare process)
Satz zusammenhängender und sich gegenseitig beeinflussender Gesundheitsdienstleistungen, die Eingaben in Ergebnisse umwandeln

Anmerkung 1 zum Begriff: Der wichtigste Typ eines Gesundheitsprozesses ist der klinische Prozess, der einen Gesundheitszustand als Eingabe und Ergebnis hat und alle Aktivitäten in Bezug auf ein oder mehrere spezifizierte Gesundheitsprobleme umfasst.

Anmerkung 2 zum Begriff: Ein Gesundheitsprozess ist nicht per Definition auf einen Anbieter medizinischer Versorgungsleistungen oder jegliche andere Organisationsgrenzen beschränkt.

[QUELLE: ISO 13940:2015]

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Nationaler Anhang NB
(informativ)

Literaturhinweise

DIN EN ISO 13940, *Medizinische Informatik — Begriffssystem zur Unterstützung der Kontinuität der Versorgung*

DIN EN ISO 21090:2011-06, *Medizinische Informatik — Harmonisierte Datentypen für den Datenaustausch im Gesundheitswesen (ISO 21090:2011); Englische Fassung EN ISO 21090:2011, nur auf CD-ROM*

DIN EN ISO 22600 (alle Teile), *Medizinische Informatik — Privilegienmanagement und Zugriffssteuerung*

DIN EN ISO 27789:2013-06, *Medizinische Informatik — Audit-Trails für elektronische Gesundheitsakten (ISO 27789:2013); Deutsche Fassung EN ISO 27789:2013*

DIN ISO 8601:2006-09, *Datenelemente und Austauschformate — Informationsaustausch — Darstellung von Datum und Uhrzeit (ISO 8601:2004)*

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This European Standard was approved by CEN on 2 July 2019.

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European foreword

This document (EN ISO 13606-1:2019) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2020, and conflicting national standards shall be withdrawn at the latest by January 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 13606-1:2012.

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Endorsement notice

The text of ISO 13606-1:2019 has been approved by CEN as EN ISO 13606-1:2019 without any modification.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 13606-1:2008), which has been technically revised. The main changes compared to the previous edition are summarised in the Introduction.

A list of all parts in the ISO 13606 series can be found on the ISO website.

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

0.1 Preface

The overall goal of this document is to define a rigorous and stable information architecture for communicating part or all of the Electronic Health Record (EHR) of a single subject of care (patient), or for a group of patients whose information might need to be communicated together (for example, a family). This is to support the interoperability of systems (see Annex C). and components that need to communicate (access, transfer, add or modify) EHR data:

— preserving the original clinical meaning intended by the author;

— incorporating the necessary provenance metadata to inform the recipient or receiving system about the context in which the EHR data were obtained and composed;

— observing and communicating the confidentiality of that data as intended by the author and subject of care.

This document considers the EHR to be the persistent longitudinal and potentially multi-organisation or multi-national record of health and care provision, most often relating to a single subject of care (the patient), created and stored in one or more physical systems in order to inform each subject's future healthcare and to provide a medico-legal record of care that has been provided. This corresponds to the definition provided in ISO 18308:2011 (Requirements for an Electronic Health Record Architecture).

This document is not intended to specify the internal architecture or database design of EHR systems or components, nor is it intended to prescribe the kinds of clinical applications that might request or contribute EHR data in particular settings, domains or specialities. For this reason, the information model proposed here is called the EHR Extract, and might be used to define a message, an XML document or schema, or an object interface. These might be used to communicate EHR data between two repositories, to update a centralised regional or national EHR repository, or within a distributed network of EHR components, systems and services. Whilst an EHR service or system will need to interact with many other services or systems providing terminology, medical knowledge, guidelines, workflow, security, persons registries, billing etc. this document has only touched on those areas if some persistent trace of such interactions is required in the EHR itself, and requires specific features in the reference model to allow their communication.

This document may offer a practical and useful contribution to the design of EHR systems but will primarily be realised as a common set of external interfaces or messages built on otherwise heterogeneous clinical systems. The components that might support an interface conforming to this document will be not only electronic health record systems but also other middleware services such as security components, guideline and workflow systems, alerting and decision support services, personal health systems and applications, sensors and wearable devices, and medical knowledge management services. This document might also prove useful for communicating data about individuals between electronic health record systems and population registries, and also for conducting (approved) research using electronic health records.

This document is part of a five-part standard series, published jointly by CEN and ISO through the Vienna Agreement.

In this document dependency upon any of the other parts of this series is explicitly stated where it applies.

0.2 Technical approach

This document is the second version of an original standard which was published in 2007 by CEN, and in 2008 by ISO. This revision has taken into account the experiences gained by EHR system developers and by large scale eHealth programmes from using the original standard. These were ascertained through an international survey, a wide range of 1:1 interviews, a review of the academic literature, and interactions with many experts active in R&D relating to the EHR. It also meets the relevant requirements in ISO 18308:2011 (Requirements for an Electronic Health Record Architecture). The

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revision has taken into account, and aligns as far as possible, with other CEN and ISO Standards and Technical Specifications with which this document might also be used, with international terminology standards and with emerging standards from HL7: Fast Healthcare Interoperability Resources (FHIR). The specifications in this document have drawn from, and align as far as possible with, the reference model specifications published by the openEHR Foundation, and with the archetype models published by the openEHR Foundation and by the Clinical Information Modeling Initiative (CIMI).

The information model in this document is an Information Viewpoint of the ISO Reference Model for Open Distributed Processing (ISO/IEC 10746-1:1998).

Given the diversity of deployed EHR systems, this document has made most features of EHR communication optional rather than mandatory. However, some degree of prescription is required to make EHR Extracts safely processable by an EHR recipient system, which is reflected through mandatory properties within the models in Parts 1, 2, and 4 of this series, and through normative term lists (defined in Part 3 of this series).

0.3 The Dual Model approach

The challenge for EHR interoperability is to devise a generalised approach to representing every conceivable kind of health record data structure in a consistent way. This needs to cater for records arising from any profession, speciality or service, whilst recognising that the healthcare data sets, value sets, templates etc. required by different healthcare domains will be diverse, complex and will change frequently as clinical practice and medical knowledge advance. This requirement is part of the widely acknowledged health informatics challenge of semantic interoperability.

The approach adopted by this standard series distinguishes a Reference Model, defined in this document and used to represent the generic properties of health record information, and Archetypes (conforming to an Archetype Model, defined in Part 2 of this series), which are meta-data used to define patterns for the specific characteristics of the healthcare data that represents the requirements of each particular profession, speciality or service.

The Reference Model represents the global characteristics of health record components, how they are aggregated, and the context information required to meet ethical, legal and provenance requirements. This model defines the set of classes that form the generic building blocks of the EHR. It reflects the stable characteristics of an electronic health record, and would be embedded in a distributed (federated) EHR environment as specific messages or interfaces (as specified in Part 5 of this series).

This generic information model needs to be complemented by a formal method of communicating and sharing the organisational structure of predefined classes of EHR fragment corresponding to sets of record components made in particular clinical situations. These are effectively pre-coordinated combinations of named RECORD_COMPONENT hierarchies that are agreed within a community in order to ensure interoperability, data consistency and data quality.

An Archetype is the formal definition of prescribed combinations of the building-block classes defined in the Reference Model for particular clinical domains or organisations. An archetype is a formal expression of a distinct, domain-level concept, expressed in the form of constraints on data whose instances conform to the reference model. For an EHR_EXTRACT, as defined in this document, an archetype instance specifies (and effectively constrains) a particular hierarchy of RECORD_COMPONENT sub-classes, defining or constraining their names and other relevant attribute values, optionality and multiplicity at any point in the hierarchy, the data types and value ranges that ELEMENT data values may take, and other constraints.

This document recognises that archetypes (or equivalent clinical models) are not always directly incorporated within the present-day architectures of electronic health record systems. This document therefore does not mandate that archetypes are used within such systems. It does, however, require that the clinical information models or equivalents (data items, data item aggregations, data value constraints, terminology bindings, units of measure etc.) that have been used to generate an EHR_EXTRACT are themselves created and communicated, or referenced, within each EHR_EXTRACT. These communicated or referenced archetypes have to conform to Part 2 of this standard series, and maybe communicated through an interface conforming to part 5 of this Standard series.

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0.4 Overview of the EHR_EXTRACT record hierarchy

The information in a health record is inherently hierarchical. Clinical observations, reasoning and intentions can have a simple or a more complex structure. They are generally organised under headings, and contained in "documents" such as consultation notes, letters and reports. These documents are usually filed in folders, and a subject of care may have more than one folder within a healthcare enterprise (e.g. medical, nursing, and obstetric).

The EHR Communications Reference Model needs to reflect this hierarchical structure and organisation, meeting published requirements in order to be faithful to the original clinical context and to ensure meaning is preserved when records are communicated between heterogeneous clinical systems. To do this, the model formally sub-divides the EHR hierarchy into parts that have been found to provide a consistent mapping to the ways which individual EHRs are organised within heterogeneous EHR systems.

These parts are summarised in Table 1 below.

Table 1 — Main hierarchy components of the EHR Extract Reference Model

EHR HIERARCHY COMPONENT	DESCRIPTION	EXAMPLES
EHR_EXTRACT	The top-level container of part or all of the EHR of a single subject of care or for a group of subjects of care (such as a family), for communication between an EHR Provider system and an EHR Recipient.	(Not applicable)
FOLDER	The high level organisation within an EHR, dividing it into compartments relating to care provided to a single subject of care, for a single condition, by a clinical team or institution, or over a fixed time period such as an episode of care.	Diabetes care, Schizophrenia, Cholecystectomy, Paediatrics, St Mungo's Hospital, GP Folder, Episodes 2000-2001.
COMPOSITION	The set of information committed to one EHR by one agent, as a result of a single clinical encounter or record documentation session.	Progress note, Laboratory test result form, Radiology report, Referral letter, Clinic visit, Clinic letter, Discharge summary, Functional health assessment, Diabetes review.
SECTION	EHR data within a COMPOSITION that belongs under one clinical heading, usually reflecting the flow of information gathering during a clinical encounter, or structured for the benefit of future human readership.	Reason for encounter, Past history, Family history, Allergy information, Subjective symptoms, Objective findings, Analysis, Plan, Treatment, Diet, Posture, Abdominal examination, Retinal examination.
ENTRY	The information recorded in an EHR as a result of one clinical action, one observation, one clinical interpretation, or an intention. This is also known as a clinical statement.	A symptom, an observation, one test result, a prescribed drug, an allergy reaction, a diagnosis, a differential diagnosis, a differential white cell count, blood pressure measurement.
CLUSTER	The means of organising nested multi-part data structures such as time series, and to represent the columns of a table.	Audiogram results, electro-encephalogram interpretation, weighted differential diagnoses.
ELEMENT	The leaf node of the EHR hierarchy, containing a single data value.	Systolic blood pressure, heart rate, drug name, symptom, body weight.

An EHR_EXTRACT contains EHR data as COMPOSITIONs, organised in a FOLDER hierarchy.

COMPOSITIONs contain ENTRYs, optionally contained within a SECTION hierarchy.

ENTRYs contain ELEMENTS, optionally contained within a CLUSTER hierarchy.

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Representing participation: The Reference Model in the previous version of this standard provided explicit classes at certain parts of the Record Component hierarchy through which it was possible to represent the identity and roles played by actors contributing to healthcare and to its documentation. In this version of the Reference Model the LINK class is intended to be used to reference demographic entities. The roles played by these entities can be labelled using extended term lists defined in Part 3 of this standard series. This updated mechanism offers greater flexibility than the previous version in where the references to such democratic entities may be represented within the Record Component hierarchy.

Representing context: Any EHR_EXTRACT references any other RECORD_COMPONENTS that are connected to the communicated content, for example via the RECORD_COMPONENT hierarchy and via LINK targets. If the EHR exchange service (e.g. as specified in Part 5) permits access to referenced components, any user would be able to access and review any additional areas of content that were not originally included. (Archetypes bring together the key elements of immediate documentation context.)

Representing authenticity: Every EHR_EXTRACT may contain attested views: these might be PDF or html or other renderings that are the authentic view of what was seen and persisted by the original author. The proof may also optionally be included, which is the evidence of a digital signature.

EHR_EXTRACTS are created for specific purposes, and will not automatically guarantee that these will be fit for other purposes.

0.5 Summary of changes made in this edition of the standard

The scope of all parts remains the same.

The objective of this revision was to:

— obtain implementer feedback on adoption experiences with the published version of the 13606 standard series;

— simplify the reference model by removing properties that have not proved useful to implementers;

— improve the demographics model to support the use of demographic archetypes;

— improve alignment with ISO 13940 System of concepts to support continuity of care (Contsys);

— align the data types with ISO 21090 Harmonized data types for information interchange (see Annex A);

— prepare the ground for alignment with HL7 FHIR;

— update the archetype model to align with the openEHR Archetype Object Model 2.0;

— include reference archetypes for commonly needed information (e.g. demographics);

— update the audit log model to align with ISO 27789 Audit trails for electronic health records, and the ISO 22600 series, Privilege management and access control.

Reference Model changes

Base Component

A class Base Component has been introduced higher in the inheritance hierarchy than Record Component, which has a unique identifier, version history information and attestation information.

This allows all of the structures within an EHR Extract to be version managed and attested, including LINK and demographic information, as well as the original family of Record Components.

Record Component

Several properties that had not proved useful have been removed from Record Component.

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Importantly, the model now semantically labels Record Components through archetype ID, avoiding duplicating and possibly conflicting semantic labels such as name and meaning.

Experience is that these different properties were not differentially well used, and resulted in inconsistent practices.

Consultation with vendors and providers who do not intend to use archetypes has confirmed that they could create a library of archetypes mapping their data structures, should they choose to adopt this standard series.

Properties relating to sensitivity and policy ID have been moved to Composition, to avoid the risk of a Composition containing data of mixed policies and therefore inconsistently complete access by different parties.

Structure Component

A generic parent class Structure Component is now the universal parent class of all Record Components and demographic classes.

All such classes inherit an archetype ID, which now also importantly allows demographic structures to be defined through archetypes, which was a popular change request.

EHR_Extract

Extract Criteria has been removed as implementers did not find it useful.

EHR_EXTRACT may now contain a set of extracted EHR components, and so may contain data on multiple subjects of care.

Folder

The Folder has the property subject of care, which allows an EHR extract potentially to contain information about more than one subject of care, such as a family, which was an important change request we received.

The EHR Extract is a kind of folder, with specific meta data about the extract generation.

Composition, Entry and Cluster

Some unused properties have been removed from Composition, Entry and Cluster.

This includes session_time, obs_time. Such dates and times are better included within relevant archetypes with more precisely specified names and roles.

Element

The Element class, and its counterpart Demographic Element, are more genuinely leaf nodes with fewer inherited properties and fewer inherited associations than in the past.

This is a response to a number of ICT vendors who indicated that the original Element was too property rich, inviting inconsistent adoption practice.

Null flavour is no longer an explicit Reference Model property. Instead a Reference Archetype has been defined in Part 3, to allow null to be asserted not only at Element level but higher up the hierarchy (e.g. that a Cluster or Entry is not present).

Data Value

The data values are now all represented as a constrained subset of the data types in ISO 21090, conforming to its mechanism for profiling (see Annex A).

Demographics

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Rather than being a separate package, demographic entities are represented using classes that inherit many of the same mechanics as Record Components, simplifying adoption.

This is now also means that demographic entries in a demographic extract can be uniquely identified, version managed and attested.

It is now much easier to refer specifically to actors within roles at care settings, in cases where actors play multiple roles and work within different care settings over time, which is relatively common.

Link

The Link class has been simplified, but enriched so that Links have a unique identifier, and can be versioned and attested.

Links can connect any identified components including demographic entities, which is now the way that most participations are represented. This was an important and well supported change request, to correct a less successfully modelled part of the previous standard.

The vocabulary for LINK has been greatly extended within part 3, and where appropriate aligned with Contsys.

LINKS can continue to be used to represent clinically relevant connections between parts of a record, point to point or as a linkage thread.

The former class FUNCTIONAL_ROLE and RELATED_PARTY have been removed, as the connection to demographic entities can now be made through archetyped DEMOGRAPHIC ENTITY instances connected to the relevant RECORD_COMPONENT via LINK.

A new class EXTERNAL_LINK enables references to be included to non-EHR data such as care protocols, safety reports or academic publications.

Audit information

The audit info class now aligns with ISO 27789, as does the corresponding audit model in Part 4 of this standard series.

0.6 Relationship of this standard to other relevant standards

— The data types used in this document are a profile of ISO 21090 Health informatics - Harmonized data types for information interchange.

— Alignment has especially been undertaken with ISO 13940 Health informatics - System of concepts to support continuity of care (Contsys). All of the terms and definitions within the standard series have been harmonised across the five parts, with most of the terms being in Part 1. All of them have been aligned with Contsys.

— An important 13606 FHIR profile project is in progress within HL7 (see Annex B). No challenges have been identified with being able to create such a profile. However there are a few areas of mapping alignment which need further work between ISO 13606 and HL7.

— Parts 1 and 4 align with ISO 27789 Health informatics - Audit trails for electronic health records. Alignment in Part 4 has been maintained with ISO 22600 Health informatics - Privilege management and access control.

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Health informatics — Electronic health record communication —

Part 1: Reference model

1 Scope

This document specifies a means for communicating part or all of the electronic health record (EHR) of one or more identified subjects of care between EHR systems, or between EHR systems and a centralised EHR data repository.

It can also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components), or personal health applications and devices, that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system.

This document will predominantly be used to support the direct care given to identifiable individuals or self-care by individuals themselves, or to support population monitoring systems such as disease registries and public health surveillance. Uses 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 this document but such secondary uses might also find the document useful.

This Part 1 of the multipart series is an Information Viewpoint specification as defined by the Open Distributed Processing – Reference model: Overview (ISO/IEC 10746-1). This document is not intended to specify the internal architecture or database design of EHR systems.

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 21090:2011, *Health informatics — Harmonized data types for information interchange*

3 Terms and definitions

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

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

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

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

3.1 Actors

3.1.1
attester
actor (person) who certifies and records legal responsibility for a particular unit of information

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3.1.2
committer
agent (party, device or software) whose direct actions have resulted in information being committed

3.1.3
composer
healthcare actor responsible for creating, synthesising or organising information that is committed to an electronic health record.

Note 1 to entry: This agent takes responsibility for its inclusion in that electronic health record, even if not the originator of it and even if not the committer of it.

3.1.4
electronic health record provider
healthcare actor in legitimate possession of electronic health record data and in a position to communicate it to another appropriate entity

3.1.5
healthcare provider
care provider
health provider
health service provider
healthcare service provider
healthcare actor that is able to be assigned one or more care period mandates

Note 1 to entry: The personnel of a *healthcare organization* that is a *healthcare provider* may include both *healthcare professionals* and others which participate in the provision of *healthcare*.

Note 2 to entry: This document includes only two specializations of *healthcare provider*. This is not meant to exclude the possibility of other specializations. In jurisdictions where other kinds of *healthcare actors* are included in the concept of *healthcare provider*, the necessary specializations may be added.

Note 3 to entry: According to this definition, *organizations* solely responsible for the funding, payment, or reimbursement of *healthcare* provision are not *healthcare providers*; for the purpose of this document they are considered as *healthcare third parties*.

[SOURCE: ISO 13940:2015]

3.1.6
role
function or position

[SOURCE: ISO/HL7 21731:2014]

3.1.7
subject of care
subject of healthcare
patient, client
service user
healthcare actor with a person role; who seeks to receive, is receiving, or has received healthcare

Note 1 to entry: A fœtus may be considered as a *subject of care* when receiving *healthcare*.

EXAMPLE A treated patient, a client of a physiotherapist, each particular member of a target population for screening, each particular member of a group of diabetic people attending a session of medical education, a *person* seeking health advice.

[SOURCE: ISO 13940:2015]

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3.2 Concepts and terms

3.2.1
generic
applicable to requirements or information models across healthcare professions, domains and countries

3.3 Information management

3.3.1
abstract class
class that cannot be instantiated independently

[SOURCE: ISO/IEC/IEEE 24765:2017, 3.24]

3.3.2
archetype
instance of an archetype model, specifying the clinical concept and the value constraints that apply to one class of Record Component instances in an electronic health record extract

3.3.3
archetype model
information model of the metadata to represent the domain-specific characteristics of electronic health record entries, by specifying values or value constraints for classes and attributes in the electronic health record reference model

3.3.4
client application
healthcare application which is behaving at that moment as a requester of health record data from a shareable electronic health record

3.3.5
data
reinterpretable representation of *information* (3.3.9) in a formalized manner suitable for communication, interpretation or processing

Note 1 to entry: Data are defined without any context in such a way that by itself one cannot tell its correct meaning, where it has meaning this is information.

[SOURCE: ISO/IEC 2382 2015, 2121272]

3.3.6
data repository
an identifiable *data* (3.3.5) storage facility

Note 1 to entry: In ISO 10303 22:1998 this is the definition of repository.

[SOURCE: ISO 13940:2015]

3.3.7
healthcare data
data (3.3.5) produced during healthcare activities

[SOURCE: ISO 13940:2015]

3.3.8
healthcare information
information (3.3.9) about a person, relevant to his or her healthcare

[SOURCE: ISO 13940:2015]

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3.3.9
information
knowledge concerning objects that within a certain context has a particular meaning

Note 1 to entry: Facts, events, things, processes, and ideas, including concepts, are examples of objects.

Note 2 to entry: Information is something that is meaningful. Data might be regarded as information once its meaning is revealed.

[SOURCE: ISO 13940:2015]

3.3.10
distributed processing
information (3.3.9) processing in which discrete components may be located in different places, and where communication between components may suffer delay or may fail

[SOURCE: ISO/IEC 10746-2:2009]

3.3.11
health record
data repository regarding the health and healthcare of a subject of care

Note 1 to entry: The term *electronic health record* may be used for a *health record* where all *information* is stored on electronic media. However, this concept is not formally defined in this document.

Note 2 to entry: A *health record* may include, for example, medical records, dental records, social care records.

[SOURCE: ISO 13940:2015]

3.3.12
health record component
part of a *health record* (3.3.11) that is identifiable for the purposes of referencing and revision

Note 1 to entry: This document defines one *health record component* specialization, the *electronic record component*. However, as the content of a *health record* is not limited to *information* in electronic format, the content of *health record components* may be in formats other than electronic.

Note 2 to entry: A *health record component* may itself result from an aggregation of multiple *health record components*.

[SOURCE: ISO 13940:2015]

3.3.13
electronic health record
health record (3.3.11) where all information is stored on electronic media

3.3.14
electronic health record system
system for recording, retrieving and manipulating information in *electronic health record* (3.3.13)

[SOURCE: ISO 18308:2011]

3.3.15
health record extract
part or all of a *health record* (3.3.11) extracted for the purpose of communication

[SOURCE: ISO 13940:2015]

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3.3.16
healthcare application
system for collecting, saving, processing, and presenting *healthcare information* (3.3.8) by means of a computer.

Note 1 to entry: This definition is based on the definition of application in ISO/IEC 19770-5:2015.

3.3.17
information architecture
structural design of an information space to facilitate task completion and intuitive access to content

3.3.18
metadata
data (3.3.5) that defines and describes other data

[SOURCE: ISO/IEC 11179-3:2013, 3.2.74]

3.3.19
semantic interoperability
ability for data shared by systems to be understood at the level of fully defined domain concepts

[SOURCE: ISO 18308:2011]

3.3.20
view
alternate presentation of *data* (3.3.5) for a different purpose

3.4 Privacy and security

3.4.1
access control
means of ensuring that the resources of a *data* (3.3.5) processing system can be accessed only by authorised entities in authorised ways

[SOURCE: ISO 17090-1:2013]

3.4.2
audit trail
collection of audit records from one or more audit logs relating to a specific subject of care or a specific *electronic health record* (3.3.13)

[SOURCE: ISO 27789:2013]

3.4.3
authentication
provision of assurance of the claimed identity of an entity by securely associating an identifier and its authenticator

[SOURCE: ISO 22600-3:2014]

3.4.4
authorisation
granting of privileges

[SOURCE: ISO 22600-1:2014]

3.4.5
confidentiality
property that *information* (3.3.9) is not made available or disclosed to unauthorised individuals, entities, or processes

[SOURCE: ISO 7498-2:1989]

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3.4.6
digital signature
data (3.3.5) appended to, or a cryptographic transformation of, a data unit that allows a recipient of the data unit to prove the source and integrity of the unit and protect against forgery e.g. by the recipient

[SOURCE: ISO 7498-2:1989]

3.4.7
privacy
freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of *data* (3.3.5) about that individual

[SOURCE: ISO/IEC 2382-8:2015, 2126263]

3.5 Process management

3.5.1
attest
activity of certifying and recording legal responsibility for a particular unit of *information* (3.3.9)

3.5.2
healthcare process
care process
set of interrelated or interacting healthcare activities which transforms inputs into outputs

Note 1 to entry: The main type of healthcare process is the clinical process that has a health state as input and output and includes all activities in relation to one or more specified health issues.

Note 2 to entry: A healthcare process is not by definition restricted to one healthcare provider or any other organizational unit borders.

[SOURCE: ISO 13940:2015]

4 Abbreviations

For the purposes of this document, the following abbreviations apply.

CEN	Comité Européen de Normalisation (European Committee for Standardization, a federation of 28 national standards bodies that are also ISO member bodies)
EHR	Electronic Health Record
EU	European Union
GP	General Practitioner
HL7	Health Level Seven
IANA	Internet Assigned Numbers Authority
IETF	Internet Engineering Task Force
ISO	International Organization for Standardization
OID	Object Identifier
R&D	Research and Development
RFC	Request For Comments

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UCUM	Unified Code for Units of Measure
UML	Unified Modelling Language
XML	Extensible Mark-up Language

5 Overview

5.1 Overview of the reference model

Figure 1 shows the reference model for EHR extracts and demographic extracts.

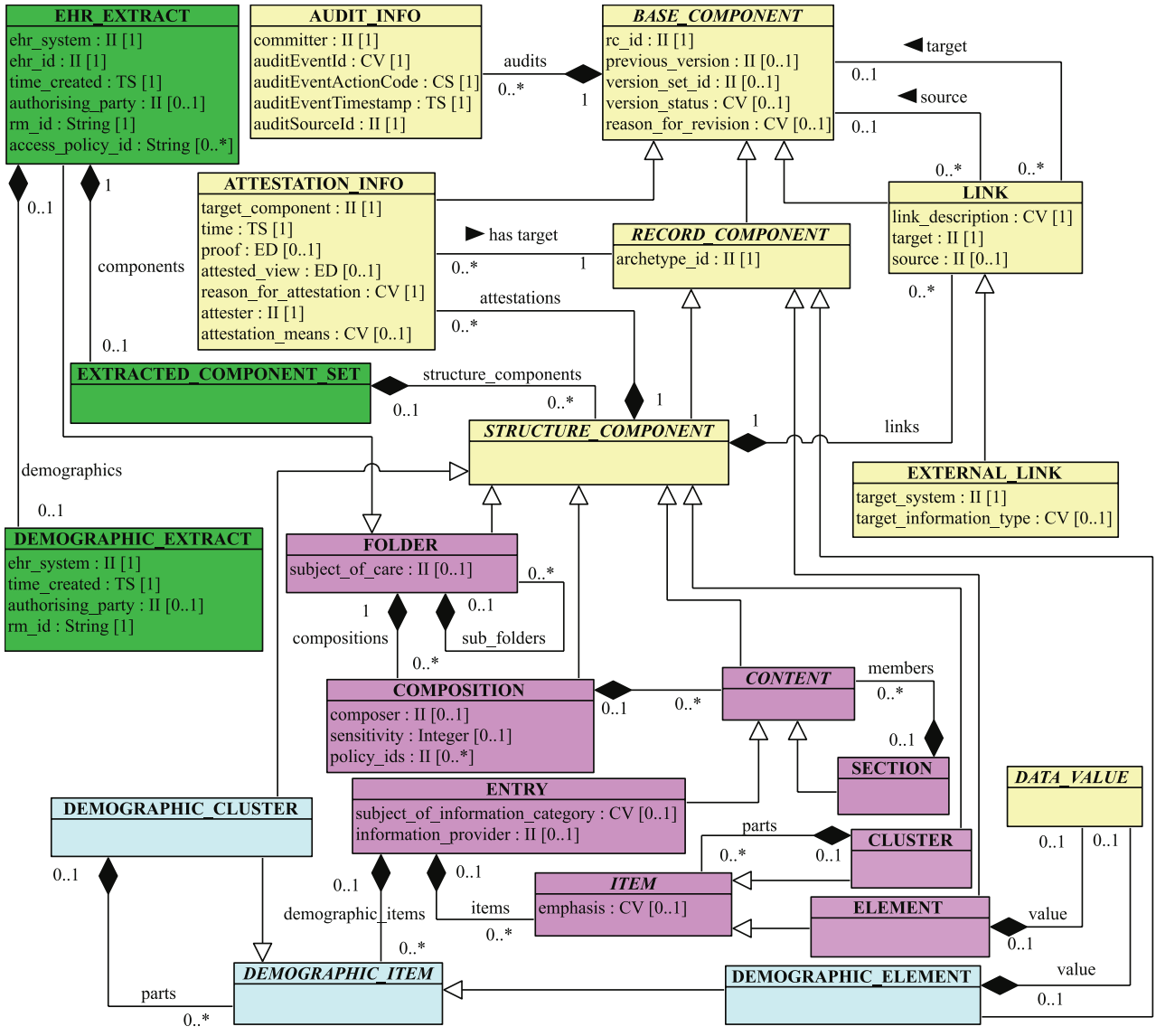

Figure 1 — Reference model for EHR extract and demographics

NOTE The colours in Figure 1, and subsequent diagrams, are offered only as an aid to the reader and have no normative significance. The green coloured classes are the high level containers of the EHR content being communicated. The purple classes represent the main specialisations of RECORD_COMPONENT that provide the main hierarchical organisation of the healthcare information being communicated. The blue classes provide a similar hierarchical organisation to the demographic information being communicated. The cream coloured classes provide additional context to the other classes of the diagram.

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