भारतीय मानक

Indian Standard

IS 18878 : 2024
ISO 10781 : 2023

(*Superseding IS/ISO 10781 : 2015*)

स्वास्थ्य सूचना विज्ञान — एच एल 7 इलेक्ट्रॉनिक स्वास्थ्य रिकार्ड-प्रणाली कार्यात्मक मॉडल, रिलीज़ 2.1 (ईएचआर एफएम)

Health Informatics — HL7 Electronic Health Record-System Functional Model, Release 2.1 (EHR FM)

ICS 35.240.80

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NATIONAL FOREWORD

This Indian Standard which is identical to ISO 10781 : 2023 'Health informatics — HL7 electronic health record-system functional model, release 2.1 (EHR FM)' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Health Informatics Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard supersedes IS/ISO 10781 : 2015 'Health informatics — HL7 electronic health record-system functional model, release 2 (EHR FM)'.

The text of ISO standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 13606-1 Health informatics — Electronic health record communication — Part 1: Reference model	IS 18301 (Part 1) : 2023/ ISO 13606- 1 : 2019 Health informatics — Electronic health record communication: Part 1 Reference model	Identical
ISO 13606-2 Health informatics — Electronic health record communication — Part 2: Archetype interchange specification	IS 18301 (Part 2) : 2023/ISO 13606-2 : 2019 Health informatics — Electronic health record communication: Part 2 Archetype interchange specification	Identical
ISO 13606-3 Health informatics — Electronic health record communication — Part 3: Reference archetypes and term lists	IS 18301 (Part 3) : 2023/ ISO 13606- 3 : 2019 Health informatics — Electronic health record communication: Part 3 Reference archetypes and term lists	Identical
ISO 13606-4 Health informatics — Electronic health record communication — Part 4: Security	IS 18301 (Part 4) : 2023/ ISO 13606- 4 : 2019 Health informatics — Electronic health record communication: Part 4 Security	Identical
ISO 13606-5 Health informatics — Electronic health record communication — Part 5: Interface specification	IS 18301 (Part 5) : 2023/ ISO 13606- 5 : 2019 Health informatics — Electronic health record communication: Part 5 Interface specification	Identical

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0 Introduction

0.1 Notes to Readers

Electronic Health Record (EHR) System Functional Model Release 2.1 is based on a series of predecessors, starting in 2004 with the release of the first consensus Draft Standard, followed in 2007 by Release 1, followed in 2009 with Release 1.1 (jointly balloted with ISO TC215 and CEN TC251), followed in 2014 with Release 2.0 (jointly balloted with ISO TC215, CEN TC251, DICOM, SNOMED (IHTSDO), CDISC and GS1). HL7 also published Release 2.01 as an unballoted errata version in 2017.

0.2 Changes from Previous Release

The HL7 EHR-System Functional Model Release 2.1 had its first normative ballot in December 2019. Following are key changes from Release 2.0:

- Includes updates from HL7 errata Release 2.01;
- Record Infrastructure Section is updated to include three new Record Lifecycle Events: verify, encrypt and decrypt. There are now a total of 27 Record Lifecycle Events, describing how an Electronic Health Record System manages health record entries their lifespan, from first point of entry origination/retention to last point of entry deletion or destruction. The 27 Record Lifecycle Events match those specified in ISO 21089-2018, Health Informatics – Trusted end-to-end information flow and HL7 Fast Health Interoperable Resources (FHIR) Record Lifecycle Event Implementation Guide, published a spart of FHIR Core STU-3 (March 2017) and now part of FHIR Core R4 (in ballot, September 2018).
- The 27 Record Lifeycle Event definitions/descriptions are updated according to agreements of the HL7 Vocabulary Alignment project (in joint collaboration of the HL7 EHR and Security Work Groups). The Glossary Section also includes those definitions/descriptions.
- The Conformance Clause is updated to include a definition/description of a new type of EHR-S FM Functional Profile (FP): Derived Companion FP.
- Trust Infrastructure is updated to include functions and conformance criteria to support ISO/HL7 Detailed Clinical Models (DCMs).

0.3 Background

0.3.1 What are Electronic Health Record Systems?

The effective use of information technology is a key focal point for improving healthcare in terms of patient safety, quality outcomes, and economic efficiency. A series of reports from the U.S. Institute of Medicine (IOM) identifies a crisis of "system" failure and calls for "system" transformation enabled by the use of information technology. Such a change is possible by "an infrastructure that permits fully interconnected, universal, secure network of systems that can deliver information for patient care anytime, anywhere."

In developing this EHR-S Functional Model, HL7 relied on three well-accepted definitions: two provided by the U.S. Institute of Medicine and one developed by the European Committee for Standardization/ Comité Européen de Normalisation (CEN). This Functional Model leverages these existing EHR-S definitions and does not attempt to create a redundant definition of an EHR-S.

0.3.2 How were the Functions Identified and Developed?

To achieve healthcare community consensus at the outset, the functions are described at a conceptual level, providing a robust foundation for a more detailed work. Functions were included if considered essential in at least one care setting. Written in user-oriented language, the document is intended for a broad readership.

Functional Granularity is a term used to describe the level of abstraction at which a function is represented. Functions that are commonly grouped together in practice or by major systems have been consolidated where appropriate; functions requiring extra or separate language or involving different workflows have been kept separate where appropriate. For example, decision support is maintained as a separate section, but mapped to other key sections, to indicate the "smart" function behind an action. All of the functions can be expanded into more granular elements but a balance between a usable document and an unwieldy list of functions has been agreed upon. The goal of determining an appropriate level of functional granularity at this time is to present functions that can be easily selected and used by readers of this standard, but that are not so abstract that readers would need to create a large number of additional functions within each function.

Although the determination of functional granularity is a relatively subjective task, systematic evaluation of each function by diverse groups of industry professionals has resulted in a level of granularity appropriate for this EHR-S Functional Model. Every attempt has been made to provide supporting information in the functional descriptions to illustrate the more granular aspects of functions that may have been consolidated for usability purposes.

Keeping with the intent of this EHR-S Functional Model to be independent with regard to technology or implementation strategy, no specific technology has been included in the functions, but may be used in the examples to illustrate the functions. Inclusion of specific technologies in the examples does not endorse or support the use of those technologies as implementation strategies.

The EHR-S Functional Model and specific functions have been widely reviewed by healthcare providers, vendors, public health agencies, regulatory and accreditation bodies, professional societies, trade associations, researchers and other stakeholders. This Standard reflects input from all these reviewers.

Indian Standard

HEALTH INFORMATICS — HL7 ELECTRONIC HEALTH RECORD-SYSTEM FUNCTIONAL MODEL, RELEASE 2.1 (EHR FM)

1 Scope

1.1 EHR-S Functional Model Scope

The HL7 EHR System Functional Model provides a reference list of functions that may be present in an Electronic Health Record System (EHR-S). The function list is described from a user perspective with the intent to enable consistent expression of system functionality. This EHR-S Functional Model, through the creation of Functional Profiles for care settings, realms, services and specialties, 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 or primary care in another country).

The HL7 EHR-S Functional Model defines a standardized model of the functions that may be present in EHR Systems. From the outset, a clear distinction between the EHR as a singular entity and systems that operate on the EHR – i.e., EHR Systems is critical. This Standard makes no distinction regarding implementation - the EHR-S described in a Functional Profile may be a single system or a system of systems. Within the normative sections of the Functional Model, the term “system” is used generically to cover the continuum of implementation options. This includes “core” healthcare functionality, typically provided by healthcare-specific applications that manage electronic healthcare information. It also includes associated generic application-level capabilities that are typically provided by middleware or other infrastructure components. The latter includes interoperability and integration capabilities such as location discovery and such areas as cross application workflow. Interoperability is considered both from semantic (clear, consistent and persistent communication of meaning) and technical (format, syntax and physical connectivity) viewpoints. Further, the functions make no statement about which technology is used, or about the content of the electronic health record. The specifics of 'how' EHR systems are developed or implemented is not considered to be within the scope of this model now or in the future. This EHR-S Functional Model does not address or endorse implementations or technology, nor does it include the data content of the electronic health record.

Finally, the EHR-S Functional Model supports research needs by ensuring that the data available to researchers follow the required protocols for privacy, confidentiality, and security. The diversity of research needs precludes the specific listing of functions that are potentially useful for research.

This Functional Model is not:

- a messaging specification
- an implementation specification
- a conformance specification
- an EHR specification
- a conformance or conformance testing metric
- an exercise in creating a definition for an EHR or EHR-S

It is important to note that the EHR-S Function Model does not include a discussion of clinical processes or the interaction of the healthcare actors. However, ISO 13940 Health Informatics – System of Concepts to Support Continuity of Care, is an international standard that does outline key principles and processes in the provision of healthcare. It is recommended that users of the EHR-S FM refer to this standard for clinical processes that EHR systems support.

This EHR-S Functional Model package includes both Reference and Normative sections. Table 1 explains the differences between Reference and Normative sections.

Status	Description
Reference	Content of the EHR-S Functional Model Package that contains information which clarifies concepts or otherwise provides additional information to aid understanding and comprehension. Reference material is not balloted as part of the standard.

Normative	Content that is part of the EHR-S Functional Model which HL7 committee members and interested industry participants have formally reviewed and balloted following the HL7 procedures for Balloting Normative Documents. This HL7 developed Functional Model document has been successfully balloted as a normative standard by the HL7 organization.

Table 1: Normative Status Types

Each section within this document is clearly labeled "Normative" if it is normative. For example, in section 5 (Overview) section 5.3 is normative. In section 7, Conformance Clause; sections 7.1 through 7.6 are normative.

In the external Annex A, Function List, the Function ID, Function Name, Function Statement, and Conformance Criteria components are Normative in this Functional Model.

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.ASTM E1769:1995, Standard guide for properties of electronic health records and record systems

HL7 Fast Health Interoperable Resources (FHIR), Release 4, January 2019

HL7 FHIR Record Lifecycle Event Implementation Guide, part of FHIR Core Release 4, January 2019

ISO 13606:2018, Health Informatics – Electronic health record communication, Parts 1-5

ISO 13940:2015, Health Informatics – System of concepts to support continuity of care

ISO 20514:2005, Health Informatics – Electronic health record – definition, scope and context

ISO 21089:2018, Health Informatics – Trusted End-to-End Information Flows

3 Terms and Definitions

For the purposes of this document, the following terms and definitions apply.
ISO and IEC maintain terminology databases for use in standardization at the following addresses:
— ISO Online browsing platform: available at https://www.iso.org/obp
— IEC Electropedia: available at https://www.electropedia.org/

3.1
access control
means of ensuring that the resources of a data processing system can be accessed only by authorized entities in authorized ways

3.2
base functional profile
existing domain or companion functional profile from which new functional profiles are created/derived

3.3
conformance
fulfillment of a product, process, or service of specified requirements

3.4
conformance criteria
requirements indicating the behavior, action, capability that constitutes implementation of the function

3.5
conformance clause
section of a specification that defines the requirements, criteria, or conditions to be satisfied in order to claim conformance

3.6
conformance statement
description of the function in an EHR system that have been implemented. It reflects the degree to which an EHR system has met the functionality has met the functional profile's requirements and may include optional functions and information

3.7
derived functional profile
functional domain or companion profile that is created from a base functional profile, (i.e., child functional domain profile to children's hospital domain profile)

3.8
extension
ability for an EHR-S to incorporate additional functionality beyond what is defined in the Functional Profile

3.9
functional profile
subset of the Functional Model, in which functions have been designated (sometimes in varying degrees) for certain EHR systems or healthcare delivery settings or narrow operation requirements

3.10
informative functional profile
registered functional profile that has successfully completed formal public scrutiny via the HL7 consensus process

3.11
inherited criterion
all the conformance criteria listed in a parent function will be inherited by all its children functions

3.12
registered functional profile
functional profile that has successfully completed HL7 EHR Work Group registration process and review

3.13
situational criterion
criterion that is required if the circumstances given are applicable (IF/Then or Dependent SHALL)

4 Overview and Definition of the Functional Model (Normative)

The EHR-S Functional Model is composed of a list of functions, known as the Function List, which is divided into seven sections: Overarching, Care Provision, Care Provision Support, Population Health Support, Administrative Support, Record Infrastructure and Trust Infrastructure as show in Figure 1.

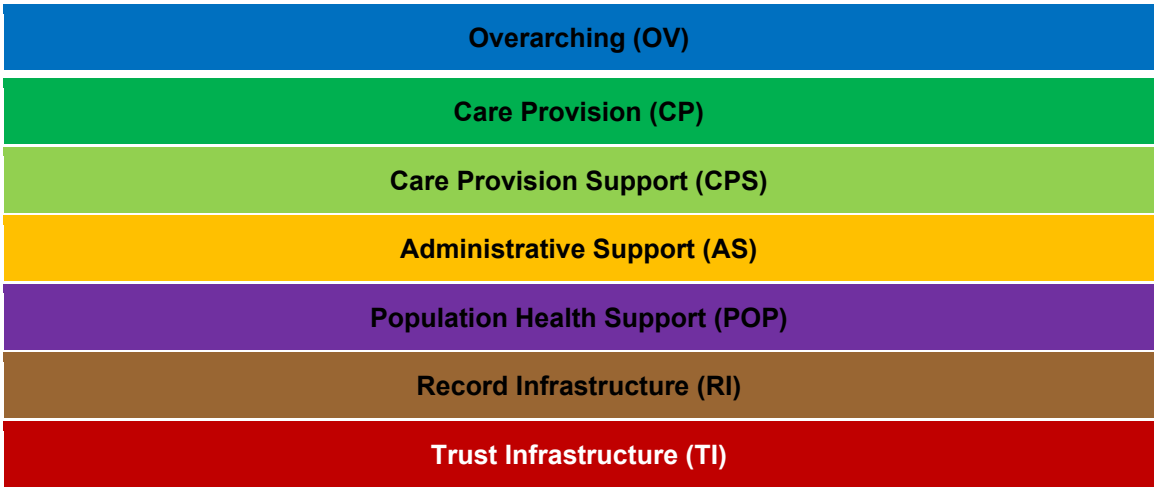

Figure 1: Function List Sections

Within the seven Sections of the Functional List the functions are grouped under header functions which each have one or more sub-functions in a hierarchical structure.

4.1 Sections of the Function List

Below is a summary description of each of the seven sections:

- Overarching: The Overarching Section contains functions and conformance criteria that apply to complete EHR Systems and which are typically included in all EHR-S FM compliant profiles.
- Care Provision: The Care Provision Section contains those functions and conformance criteria that enable direct care to a specific patient and facilitate hands-on delivery of healthcare. The functions are general and are not limited to a specific care setting and may be applied as part of an Electronic Health Record supporting healthcare clinics, hospitals, services, specialties, acute, post-acute and long-term care settings.
- Care Provision Support: The Care Provision Support Section focuses on functions and conformance criteria supporting the provision of care. This section is organized generally in alignment with Care Provision Section. For example, CP.4 (Manage Orders) is supported directly by CPS.4 (Support Orders).
- Population Health Support: The Population Health Support Section focuses on functions and conformance criteria supporting the prevention and control of disease among a group of people (as opposed to the direct care of a single patient). This section includes functions to support input to systems that perform medical research, promote public health and improve the quality of care to a population.
- Administrative Support: The Administrative Support Section focuses on functions and conformance criteria enabling the management of clinical practice and facilitating administrative and financial operations. This includes management of resources, workflow and communication with patients and providers as well as the management of non-clinical administrative information on patients and providers.
- Record Infrastructure: The Record Infrastructure Section consists of functions and conformance criteria describing how an EHR system manages an EHR record, particularly those functions vital to managing the lifecycle of EHR record entries (such as origination/retention, attestation, amendment/update, access/use, translation/transformation, transmittal/disclosure, receipt, de-identification, archive…) and record entry lifespan (persistence, indelibility, continuity, audit, encryption). RI functions are core and foundational to all other functions of the EHR-S FM (CP, CPS, POP, AS).
- Trust Infrastructure: The Trust Infrastructure Section consists of functions and conformance criteria common to an EHR System infrastructure, particularly those functions foundational to system operations, security, efficiency and data integrity assurance, safeguards for privacy and confidentiality, and interoperability with other systems. TI functions are core and foundational to all other functions of the EHR-S FM (CP, CPS, POP, AS and RI).

4.2 Functional Profiles

While the Functional Model contains all reasonably anticipated EHR-S functions, it is not itself intended as a list of all functions to be found in a specific EHR-S or implementation thereof. Functional Profiles offer a method to constrain EHR-S FM functions and conformance criteria to an intended use.

In the aggregate, the EHR-S FM is intended to include the superset of functions from which a profile subset can be generated. This subset illustrates what is needed within an EHR-S. Only a subset of all EHR-S FM functions will apply to any particular EHR-S Functional Profile (FP).

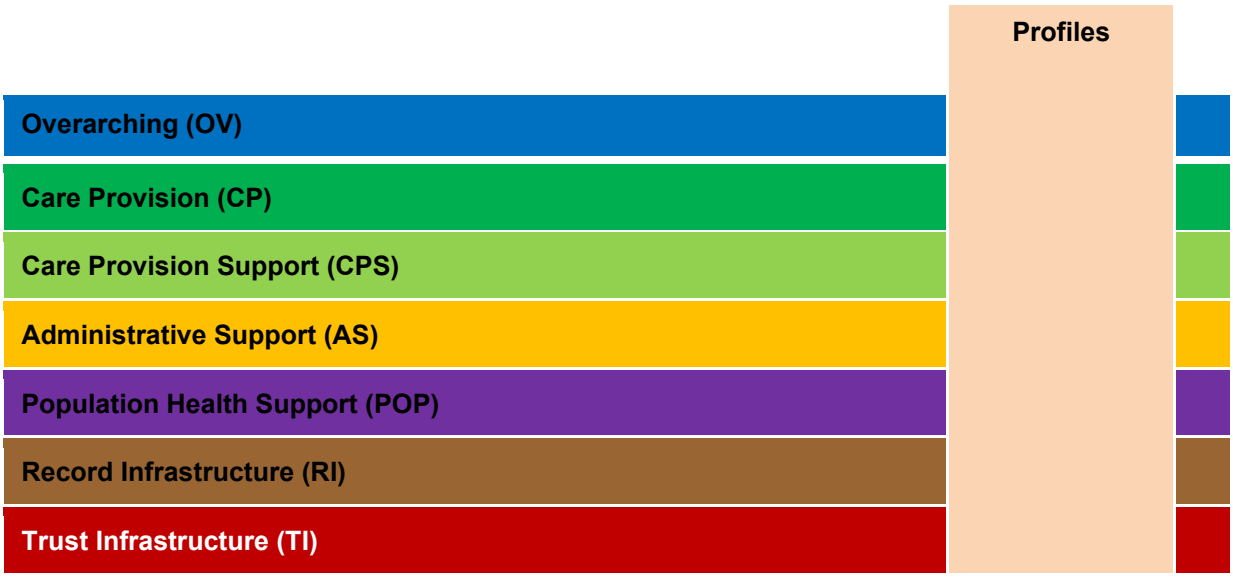

Figure 2. Profiling from the EHR-S FM.

Figure 2 shows that a profile would include all 7 sections of the Functional Model, however it may not be necessary to include all the functions and criteria within each section. A profile may include additional functions and criteria to meet the requirements of the particular profile domain or subject area.

The Conformance Clause is a high-level description of what is required of profiles and implementations. It, in turn, refers to other parts of the standard for details. The Conformance Clause describes concepts critical to the understanding and implementation of the Functional Model, such as: '*What is a profile? What are Conformance Criteria? Or how do you know what is mandatory versus optional*? A Conformance Clause can also provide a communication between the implementers (producers) and users (buyers) as to what is required, and gives meaning to the phrases, "conforming profile" and "conforming EHR system". Additionally, it serves as the basis for inspection, testing and/or certification activities which may be performed by organizations external to HL7.

Refer to the Conformance Clause, section 7, for additional information related to the rules for selecting and adding Conformance Criteria in the development of a Functional Profile.

4.3 EHR-S Function List Components

The EHR-S Function List is a list (superset) of functions organized into discrete sections. Functions describe the behavior of a system in user-oriented language so as to be recognizable to the key stakeholders of an EHR-S.

EHR-S functions can be used to:

- Describe end user defined benefits such as patient safety, quality outcomes and cost efficiencies in terms of standard EHR-S functions.
- Promote a common understanding of EHR system functions upon which developers, vendors, users and other interested parties can plan and evaluate EHR system designs and implementations.
- Provide the necessary framework to drive the requirements and applications of next level standards, such as EHR content, coding, information models, constructs and interoperability for information portability between sub-systems of an EHR system and across EHR systems.
- Establish a standards-based method by which each realm (country) can apply these EHR system functions to care settings, services, specialties, other uses and priorities.

- Inform those concerned with supporting subsequent use of data initially collected for the purpose of care (also known as “secondary use”) on what functions can be expected in an EHR system.
- Inform those concerned with supporting realm-specific health information infrastructure on what functions can be expected in an EHR Systems.

Each function in the HL7 EHR-S Functional Model is identified and described using a set of elements or components as detailed in Table 2.

ID	Type	Name	Statement	Description	Conformance Criteria
CP.1	H	Manage Clinical History	Manage the patient's clinical history lists used to present summary or detailed information on patient health history.	Patient Clinical History lists are used to present succinct “snapshots” of critical health information including patient history; allergy intolerance and adverse reactions; medications; problems; strengths; immunizations; medical equipment/ devices; and patient and family preferences.	
CP.1.4	F	Manage Problem List	Create and maintain patient-specific problem lists.	A problem list may include, but is not limited to chronic conditions, diagnoses, or symptoms, injury/poisoning (both intentional and unintentional), adverse effects of medical care (e.g., drugs, surgical), functional limitations, visit or stay-specific conditions, diagnoses, or symptoms…	
CP.1.4	C				1. The system SHALL provide the ability to manage, as discrete data, all active problems associated with a patient.
CP.1.4	C				2. The system SHALL capture and render a history of all problems associated with a patient.
CP.1.4	C				3. The system SHALL provide the ability to manage relevant dates including the onset date and resolution date of problem.

Table 2: Function List Example

4.3.1 Function ID (Normative)

This is the unique identifier of a function in the Function List (e.g., CP.1.1) and uniquely identifies the function. The Function ID also serves to identify the section within which the function exists (CP = Care Provision Section) and the hierarchy or relationship between functions (CP.1.1 is at the same level as CP.1.2, CP.1.1 is also a parent of CP.1.1.1 and child of CP.1. In many cases the parent is fully expressed by the children. NOTE: For a detailed discussion and graphic of the parent and child relationship, see 6.6.1 Hierarchical Structure in Chapter 6, Conformance Clause.)

4.3.2 Function Type (Reference)

This is an indication of the line item as being a Header (H), Function (F) or Conformance Criteria (C). The Tag (T) is used to identify a new section in the spreadsheet and its related functions in the spreadsheet. A Tag has no directly associated Functions or Criteria.

4.3.3 Function Name (Normative)

This is the name of the Function and while expected to be unique within the Function List; it is not recommended to be used to identify the Function without being accompanied by the Function ID.

Example: Manage Medication List

4.3.4 Function Statement (Normative)

This is a brief statement of the purpose of this function. While not restricted to the use of structured language that is used in the Conformance Criteria (see below); the Statement identifies the purpose and scope of the function.

Example: Create and maintain patient-specific medication lists.

4.3.5 Description (Reference)

This is a more detailed description of the function, including examples if needed.

Sample Description: Medication lists are managed over time, whether over the course of a visit or stay, or the lifetime of a patient. All pertinent dates, including medication start, modification, and end dates are stored. The entire medication history for any medication, including alternative supplements and herbal medications, is viewable. Medication lists are not limited to medication orders recorded by providers, but may include, for example, pharmacy dispense/supply records, patient-reported medications and additional information such as age specific dosage.

4.3.6 Conformance Criteria (Normative)

Each function in the Function List includes one or more Conformance Criteria. Conformance Criteria, which exist as normative language in this standard, define the requirements for conforming to the function. The language used to express a conformance criterion is highly structured with standardized components with set meanings. The structured language used to define Conformance Criteria in the Function List are further specified in the Conformance Section 7 and Glossary Section 8.

5 Anticipated Uses (Reference)

The HL7 International community supports development of Functional Profiles (FPs), which may be realm (country) specific specifications (i.e., tailored functional requirements) built off the base EHR-S FM Standard. There are a range of FPs developed and balloted by HL7 International or its national affiliates. These FPs designate a subset of functions from the base EHR-S FM for use in specific care settings (e.g., Ambulatory Care), services or specialties (e.g. Behavioral Health) or specify cross-cutting characteristics of EHR systems and/or records (e.g. the Records Management and Evidentiary Support). Balloted, approved and published FPs, based on the EHR-S FM, are available in the HL7 International library of Standards.

5.1 Development Approach: Functional Profiles

A “Functional Profile" is a selected set of functions applicable for a particular purpose, realm (country), domain, care setting, service or specialty.

It is not anticipated that any system or implementation will conform to all functions and conformance criteria set forth in the base EHR-S FM. Rather EHR systems or implementations may conform to one or more Functional Profiles.

For more information about creating, registering, and balloting Functional Profiles, see Conformance Section 7.

One may create a Functional Profile to support a business case for EHR-S use by selecting an applicable subset of functions from the based EHR-S FM list of functions, in effect constraining the model to meet specific requirements. For example, a Functional Profile may be created by a purchaser, to specify requirements; by a vendor, to specify capabilities of a system design; or by any person/entity wishing to stipulate a desired subset of functions for a particular purpose, for example, functions to support a care setting within a particular realm.

Readers may wish to focus on sections of the FM that are most relevant for their purpose of EHR-S use. For example, a clinician may read the Care Provision and Care Provision Support sections very closely, while technical specialists may focus especially on Record and Trust Infrastructure sections. Within an organization, it may be helpful to designate responsibility for reviewing different FM sections among staff with different responsibilities and expertise for use and support of the EHR system

Three vignettes are included here to help readers in different positions or organizations envision how they would study, and ultimately utilize the EHR-S Functional Model.

5.1.1 Scenario 1 – Group Practice

Dr. Smith is part of a 50-person group practice. The practice currently has a clinical information system that provides billing, scheduling, and other administrative support. For several reasons, it will need to be upgraded or replaced within 2 years. It does not include electronic health records. Dr. Smith and interested colleagues review an Ambulatory Care registered profile to see how the use, setting and scenario illustrate the EHR functions related to their practice; they look at the Ambulatory Care prioritization of the individual functions that a group of experts working with HL7 have identified. With a good understanding of what the EHR functions would mean for their practice, Dr. Smith and several other providers then focus on the Care Provision and Care Provision Support sections, while clinic administration staff look at the Administrative Support section, while the technical support staff look at the Record and Trust Infrastructure sections. They all meet to discuss their conclusions. They plan to use the list of functions in discussions with vendors about their next EHR system, recognizing that some functions may not yet be available.

5.1.2 Scenario 2 - Hospital

Mr. Jones is the Chief Informatics Officer in a large hospital organization Their IT system was installed two years ago and includes patient tracking and ordering components; it was upgraded for compliance with United States HIPAA (Health Insurance Portability and Accountability Act). It does not include clinical decision support, performance monitoring, or public health reporting. Mr. Jones asks the Chief Medical Officer to organize a review of the HL7 EHR-S FM while his team also reviews it. They both begin by looking at an Acute Care Functional Profile to see how a group of experts working with HL7 have identified how an EHR-S can be used within a hospital. The scenario and prioritization of the individual functions is helpful. The CMO and several doctors and senior nurses review the Care Provision and Care Provision Support sections of the EHR-S Functional Model Acute Care profile; the CIO and his team focus on the Record and Trust Infrastructure sections but also look at the Care Provision and Care Provision Support sections. A small team of providers and IT staff meet to discuss their conclusions. They plan to use the list of functions in discussions with vendors about adding decision support, performance monitoring, and public health reporting to their existing system, recognizing that their budget will only allow very limited expansion in the near term.

5.1.3 Scenario 3 - IT Vendor

Ms. Green is the head of the clinical systems division of a large health IT company. Their product line includes both dedicated EHR systems and integrated systems that include an EHR. Their EHR and integrated systems have some decision support for medication ordering, but no performance monitoring/reporting functions. While most of their clients are larger provider organizations and hospitals, they are planning to expand into the small practice and home health markets with a simple, less expensive clinical system. In anticipation of HHS's implementation of the Merit-Based Incentive Payment System (MIPS), which provides financial incentives for providers who use IT to track patients, the company wants to add a range of functionality to its products that would meet or exceed these requirements. Ms. Green asks her staff to review the entire HL7 EHR-S FM package, and also review applicable care setting Functional Profiles. Based on these examples, they determine that they can add a relatively small number of functions to various products to be able to offer superior products for current and future clients. They see value in the EHR-S FM for their discussions with their clients about upgrades or new purchases.

5.2 Examples of Current Use

5.2.1 Functional Profile for Clinical Research based on the EHR-S FM

Below is the text of a November 2009 HL7 Press Release demonstrating industry use:

> Ann Arbor, Michigan, U.S.A.–November 5, 2009– Health Level Seven International® (HL7®), the global authority for interoperability and standards in healthcare information technology with members in 57 countries, today announced it has published the healthcare industry's first ANSI (American National Standards Institute)-approved standard that specifies the functional requirements for regulated clinical research in an electronic health record system (EHR-S). The HL7 EHR Clinical Research Functional Profile for EHR systems is based upon the HL7 EHR Work Group's EHR System Functional Model Release 1, which is also an ANSI-approved American National Standard.

The EHR Clinical Research Functional Profile defines high-level requirements critical for using electronic health record data for regulated clinical research, and provides a roadmap for integrating the information environment that must support both the patient care and the downstream clinical research processes. According to Donald Mon, PhD, co-chair of the HL7 EHR Work Group and member of the HL7 Board of Directors, "This profile is an excellent demonstration of how important functional requirements for secondary data use, such as clinical research, can be integrated into the patient care work flow and documented in EHR systems." Pharmaceutical, biotechnology, clinical research technology vendor, healthcare technology vendor, and federal regulatory stakeholders from the United States and the European Union collaborated for two years to identify and address a broad list of data protection, regulatory and ethical research requirements. The EHR Clinical Research Functional Profile is also a resource for the Certification Commission for Healthcare Information Technology (CCHIT) Clinical Research Work Group as they define new clinical research certification criteria for EHR systems. This functional profile will be complemented by the EHR-Clinical Research interoperability specification, currently being developed by the Health Information Technology Standards Panel (HITSP). Additionally, Dr. Rebecca Kush, President and CEO of the Clinical Data Interchange Standards Consortium (CDISC), commented that "CDISC is pleased to be a collaborator and to contribute clinical research standards and eSource Data Interchange concepts towards these initiatives. The ultimate goal is to accelerate the pace at which research informs healthcare for the benefit of patients and this functional profile contributes to the achievement of that goal."

5.2.2 AHRQ adopts Health Level Seven International (HL7) Child Health Functional Profile Specification, Release 1 and incorporates key functionalities in the Children's Electronic Health Record Format

Below is an excerpt from AHRQ's Children's Electronic Health Record Format - https://healthit.ahrq.gov/health-it-tools-and-resources/pediatric-resources/childrens-electronic-health-record-ehr-format

"The Children's Electronic Health Record (EHR) Format was developed to bridge the gap between the functionality present in most EHRs currently available and the functionality that would more optimally support the care of children. Specifically, the Format provides information to EHR system developers and others about critical functionality, data elements, and other requirements that need to be present in an EHR system to address health care needs specific to the care of children, especially those enrolled in Medicaid or the Children's Health Insurance Program (CHIP). To address these needs, the Format includes a minimum set of data elements and applicable data standards that can be used as a starting point or checklist for EHR developers seeking to create a product that can capture the types of health care components most relevant for children….The Children's EHR Format contains portions of the Health Level Seven International (HL7®) Child Health Functional Profile Specification, Release 1, and modifications thereof, developed by HL7, the copyright of which is owned by HL7. Portions of the Format that contain excerpts from the HL7 Child Health Functional Profile are identified in the Provenance Field…"

5.2.3 Linking clinical content descriptions to the EHR-S FM (Reference)

HL7 has ongoing initiatives to link clinical content descriptions to functions and criteria in the EHR-S FM. This clinical content linkage can be helpful input to developers of EHR-systems. Examples of these clinical content descriptions include the Domain Analysis Models (DAMs) and Detailed Clinical Models (DCMs). Each of these examples can be linked to applicable sections of the EHR-S FM. For example, a Care Plan DAM which can be linked to a care planning functions in the Care Provision and Care Provision Support sections in the EHR-S FM.

At a more detailed level, the DCMs can be linked to specific functions in the EHR-S FM or EHR-S Functional Profiles. For example, a DCM for the Apgar score can be linked to CP.3.1 Conduct Assessments and CPS 3.1 Support for Standard Assessments. Another example is using the DCM for blood pressure with CP.3.2 Manage Patient Clinical Measurements.

On the level of data elements, which can be specified in a DCM, or in a data table, the linkage to EHR-S FM is usually through an individual criterion. For example, CP.3.2 Manage Patient Clinical Measurements, for example criterion 'The system SHALL provide the ability to capture patient vital signs including blood pressure, temperature, heart rate, and respiratory rate, as discrete elements of structured or unstructured data.'

Finally, similar to EHR-S FM Function TI.4 Standard Terminology and Terminology Services, a Function is created for Clinical Models and Clinical Models Services. The function name is 'TI.10 Standard or Preferred Clinical Models and Clinical Model Services'. There are three child functions:

- TI.10.1 Standard or Preferred Clinical Models. The statement is; Employ approved standard or Preferred Clinical Models to ensure structured data correctness and to enable semantic interoperability (both within an enterprise and externally). Support a standard or Preferred Clinical Model.

- TI.10.2 Maintenance and Versioning of Standard or Preferred Clinical Models. The statement is; Enable version control according to scope of practice, organizational policy, and/or jurisdictional law to ensure maintenance of utilized standard or preferred clinical models. This includes the ability to accommodate changes to clinical models as the source clinical model undergoes its update process. Such changes need to be cascaded to clinical content embedded in templates, custom formularies, etc., as determined by existing policy.
- TI.10.3 Clinical Model Mapping; The statement is; Map or translate one clinical model to another as needed by local, regional, national, or international interoperability requirements.

6 Conformance Clause

6.1 Introduction (Reference)

Sections 6.2 through 6.7 are the HL7 EHR Work Group approved Conformance Clauses. As important background on conformance, please note the following:

1. This Conformance Clause defines what it means to conform to the EHR-S Functional Model.
2. Conformance to the Functional Model is defined for functional domain profiles, and for functional companion profiles. An EHR system does not directly conform to the Functional Model, rather it conforms to one or more Functional Profiles.
3. Conformance criteria are associated with functions in the EHR-S Functional Model.
4. This Conformance Clause does not specify inspection, testing or validation procedures to determine whether an EHR system conforms to an EHR-S Functional Profile or whether a Functional Profile conforms to the EHR-S Functional Model.

6.2 Scope and Field of Application (Normative)

This *Conformance Clause* defines the minimum requirements for *Functional Profiles* claiming conformance to the EHR System Functional Model. It also identifies how EHR systems achieve conformance to the Functional Model, which is via the system's conformance to a particular functional domain profile, multiple Functional Profiles, or combination of domain and companion profiles. This clause specifies:

1. The purpose, structure, and use of conformance criteria that are to be included in the Functional Model and conforming Functional Profiles,
2. The rules for defining conforming Functional Profiles of the Functional Model,
3. The relationship between Functional Profiles and EHR systems,
4. Sample Conformance Clauses and use case scenarios,
5. Guidance on the conformance requirements that a Functional Profile may levy on EHR systems,
6. Guidance on the purpose and use of an EHR system Conformance Statement.

While the conformance requirements for Functional Profiles can be found in this clause, they necessarily reference the Functional Model and other sources.

This Conformance Clause does not specify inspection, testing or validation procedures to assess a Functional Profile's conformance to the Functional Model. It also does not specify inspection, testing or validation procedures to determine whether an EHR system conforms to a Functional Profile or matches the EHR System Conformance Statement.

6.3 Concepts (Normative)

6.3.1 Functional Profiles

Creating a Functional Profile is a method for defining subsets of the Functional Model. A Functional Profile is a specification which uses the Functional Model to indicate which functions are required, desired, or implemented for certain EHR systems, healthcare delivery settings, or for other purposes (e.g., the functional profile for Records Management and Evidentiary Support).

Functional Profiles can be created by healthcare community stakeholders with interest in using and/or providing a Functional Profile for an EHR system. Functional Profiles can represent the functionality required and desired for a realm (country/region), domain, care setting or service/specialty, or reflect the functionality incorporated in a vendor's EHR system.

(NOTE: During the process of creating a Functional Profile, it may be important to discuss clinical processes, work flows and/or interaction(s) of the healthcare actors. The international standard 'ISO 13940 System of Concepts to Support Continuity of Care' provides an outline of key principles and processes in the provision of healthcare. We would highly recommend reviewing this standard as part of your work.)

There are two types of Functional Profiles. The Functional Domain Profile is the common type of profile used to describe an EHR system for use in one or more care settings, or to describe an EHR system for use in a selected realm (country/region) to meet the rules, regulations and standards applicable for that realm, to describe an EHR system for use by a particular service or specialty, etc. The Functional Companion Profile is a type of profile that must be paired with one or more Domain Profiles. The purpose of a Companion Profile is to add unique features to an EHR System, such as for research or for evidentiary support. For example, many EHR systems in a clinic environment do not need to support clinical research. But for a clinic that was supporting advanced research, they may want an EHR system that was both capable of all of the expected functions for routine clinic patient care activities, but also had unique features to support the needs for research reporting and clinical trials.

Once a Functional Profile is defined its functions (complying with conformance criteria) can be implemented within EHR systems or it may trigger the creation of derived Functional Profiles. A *derived Functional Profile* is a Functional Profile that is created from an existing Functional Profile, inheriting FP functions and conformance criteria. There are two types of derived Functional Profiles: Derived Domain FP and Derived Companion FP.

There are two types of mandatory inheritance in the EHR-S FM. All Functional Domain Profiles will inherit the full set of functions in the EHR-S FM Overarching section and their related “SHALL” criteria. All criterion listed in a parent function will be applicable to all the children of that parent function.

A formal HL7 process exists for registering and balloting Functional Profiles. Functional Profiles that are submitted to the HL7 EHR WG with an attestation of conformance to Section 7: Conformance Clause of the HL7 EHR-S Standard and successfully complete review by the WG are designated as “*Registered Functional Profiles*”. Registered Functional Profiles that undergo formal public scrutiny via the HL7 consensus process as an Informative EHR TC ballot at the committee level will be designated as *HL7 functional domain or companion profiles*. HL7 Functional Profiles are eligible to undergo full membership ballot via the HL7 consensus process.

6.3.2 Conformance Model

Conformance to the Functional Model is defined for Functional Profiles. A functional domain profile conforms either (1) directly to the base EHR-S FM or (2) to another conforming functional domain profile. NOTE: All functional domain profiles must include all the functions and “SHALL” criteria of the Overarching Chapter. An EHR system does not conform directly to the Functional Model; rather, it conforms to a functional domain profile, or to a domain profile in combination with selected companion profile(s). Thus, Functional Profiles claim conformance to the Functional Model and EHR systems claim conformance to one or more conforming domain Functional Profiles. An EHR system can also claim conformance to a domain Functional Profile, in combination with one of more companion profiles. An EHR system cannot claim conformance to only a companion profile. Figure 3 (below) illustrates this relationship.

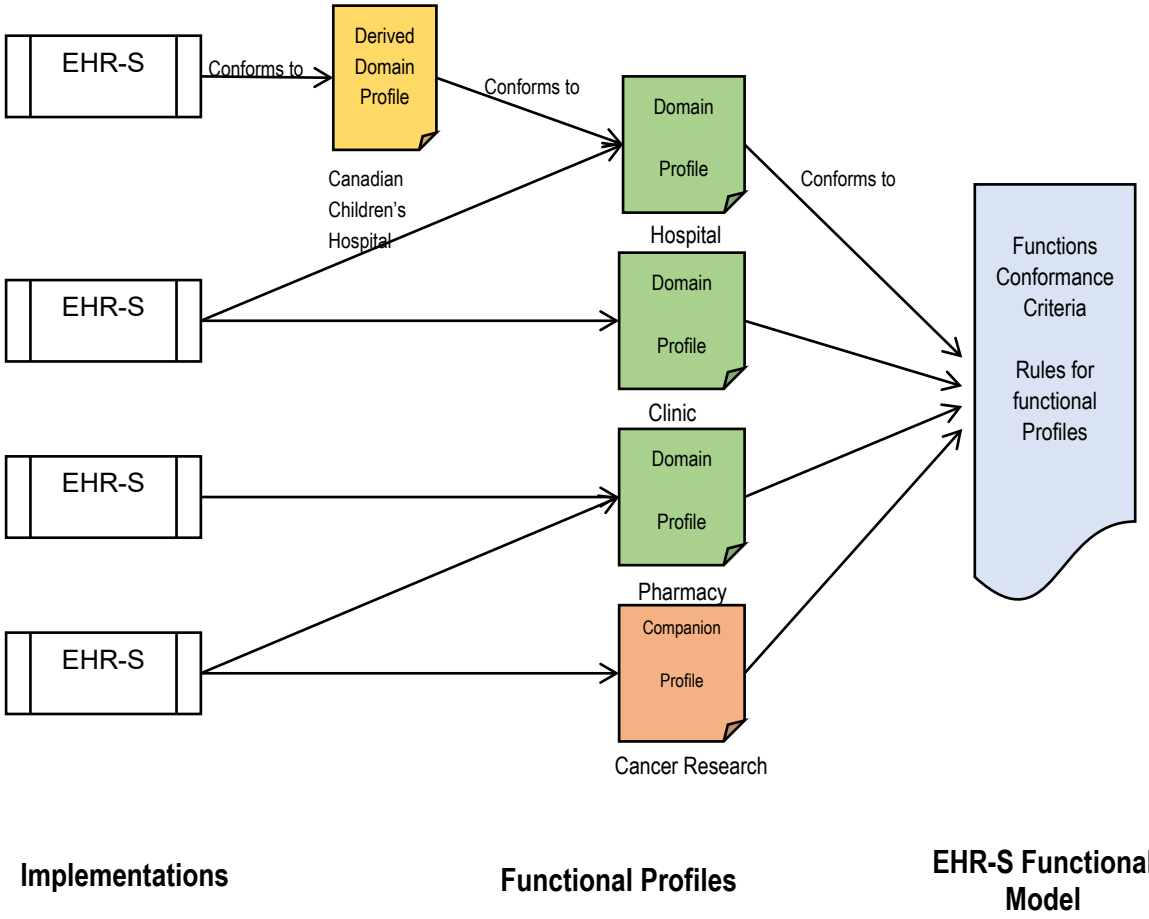

Figure 3 Conformance Relationships

6.3.3 Profile Traceability

Functional Profiles allow for added specificity and extensibility to the Functional Model with changes allowed to the base FM functions and criteria. However, Section 6.6 (following) defines rules for these changes. It is also required that any changes and additions be tracked. Two added columns in profiles accomplish this. One column will document the unique source FM row number for each item in the new profile (or source profile for a derived profile). The second column will provide codes for the type of changes from the source FM (or source profile). Together, these two traceability columns will keep track of the origins of the functions or criteria – and whether it is modified or unchanged from that within the FM or the source profile. This may be important when questions arise as to where did it come from, why was it chosen or modified, etc. It can also be helpful to have traceability back to the FM functions and criteria if and when revisions to a profile or for derived profile are needed to reflect care setting, regulatory, technology changes – or a future new release of the base EHR-S FM.

6.4 Normative Language (Normative)

The EHR-S Functional Model (i.e., all chapters) contains normative, informative, and reference sections. In this Conformance Clause section, the normative content defines how a Functional Profile achieves conformance to the Functional Model.

The following keywords (i.e., normative verbs) **SHALL** be used to convey conformance requirements:

- SHALL – to indicate a mandatory requirement to be followed (implemented) in order to conform. Synonymous with 'is required to'.
- SHALL NOT – to indicate a prohibited action. Synonymous with 'prohibited'.
- SHOULD – to indicate an optional recommended action, one that is particularly suitable, without mentioning or excluding others. Synonymous with 'is permitted and recommended'.
- MAY – to indicate an optional, permissible action. Synonymous with 'is permitted'.

6.5 Conformance Criteria (Normative)

Every function in the Functional Model is associated with a set of conformance criteria. These *conformance criteria* form the basis for determining whether the function has been implemented.

6.5.1 Criteria in the Functional Profile

Functional Profiles also have conformance criteria associated with functions in the Functional Profile. The Functional Profile's criteria are either (1) adapted from the Functional Model conformance criteria with requirements or language specific to the purpose, care-setting, realm (country/region), domain, service or specialty focus of the Functional Profile; or otherwise (2) inherited directly from Functional Model. Functional domain and companion profiles **MAY** change Functional Model criteria to match the needs and priorities of the Functional Profile's constituency, e.g., by making it more specific, or changing it from 'may' or 'should' to 'shall'. Functional Profiles **MAY** change the criteria of a function to allow for alignment to realm specific nomenclature, including language distinctions and implication of non-english translations. In these cases, the International Organization for Standardization (ISO) country code (ISO 3166 Country Codes) **SHALL** be appended to the function ID in the Functional Profile.

The functional domain profile **SHALL NOT** be made less restrictive than the Functional Model by changing 'shall' criteria to 'may' or 'should' criteria (The functional companion profile **MAY** be less restrictive that the FM by ignoring 'shall' criterion). Functional domain and companion profiles **MAY** also add additional criteria.

6.5.2 'Dependent SHALL' Criteria

Conformance criteria that contain the keyword 'shall' **and** a dependency on situational conditions are called 'dependent shall' criteria. The 'dependent shall' **SHALL** contain the phrase "in accordance with scope of practice, organizational policy, or jurisdictional law" or other appropriate grammatical tie-in words (e.g., 'based on' rather than 'in accordance'). A 'dependent shall' criteria is used to highlight only these (i.e., scope of practice, organizational policy or jurisdictional law) conditions. A 'dependent shall' criterion is a mandatory criterion for Functional Profiles and situational for EHR systems. Specifically,

- All functional domain profiles SHALL inherit the criterion if the function appears in the Functional Profile.
- An EHR system is required to implement the Dependent SHALL criterion only if the criterion is applicable per the stated dependency in the Functional Model. (If the Dependent SHALL criterion is not applicable to the profile, the developer of the profile may still use the criterion if desired.)

6.5.3 Referencing Other Criteria or Functions

There is often a link between functions and their criteria with other functions and criteria. For example, a given function may depend on another function or on a specific criterion associated with another function.

A criterion in the Functional Profile that references another function in the Functional Profile **SHALL** reference that function by indicating its name and ID, as "X.n.n (Name)". If the referenced function is required to be implemented, then all the 'shall' criteria of this referenced function apply. If the referenced function is a parent with children, the reference must be explicit on whether the children are included in the reference, all or selected ones. See the examples below:

- The system SHALL/SHOULD/MAY conform to TI.1.1 (Entity Authorization).
- The system SHALL/SHOULD/MAY conform to TI.2 (Audit) and all child functions.
- The system SHALL conform to CPS.4 Support Orders, and separate function(s) The systems SHALL conform to CPS.4.3 Non-medication Orders. The systems SHALL conform to CPS.4.6 Support for Referrals and all children functions.

A criterion in the Functional Profile that references a specific criterion in another function **SHALL** reference that function by rewriting the referenced criterion as one of its own and indicating the function and criterion number from where it came (e.g. F#, CC3).

6.6 Functional Model Structure and Extensibility (Normative)

6.6.1 Hierarchical Structure

Functions **MAY** be contained (i.e., nested) within other functions. A nested function is a 'child' to its 'parent' (i.e., the function that contains it). A child **SHALL** always have a parent. A function that is not a parent to another function is considered a 'leaf'. Figure 4 illustrates this hierarchical structure.

The Functional Model is represented as a hierarchical list of functions, consisting of functional header parents, functional header children and functional leaf functions. Headers include an ID, Name and "H" in the column labeled "Type". Parent and Child Headers **MAY** contain conformance criteria only if the criteria apply to all its

descendent functions (i.e., children, grandchildren, and leafs). Parent, Child and Leaf functions contain at a minimum the following: ID, Name, Statement, Description, and Conformance Criteria and have a “F” in the “Type” column. Conformance criteria listed in a parent function **SHALL** be inherited by all its child functions. Conformance Criteria have a “C” in the “Type” column.

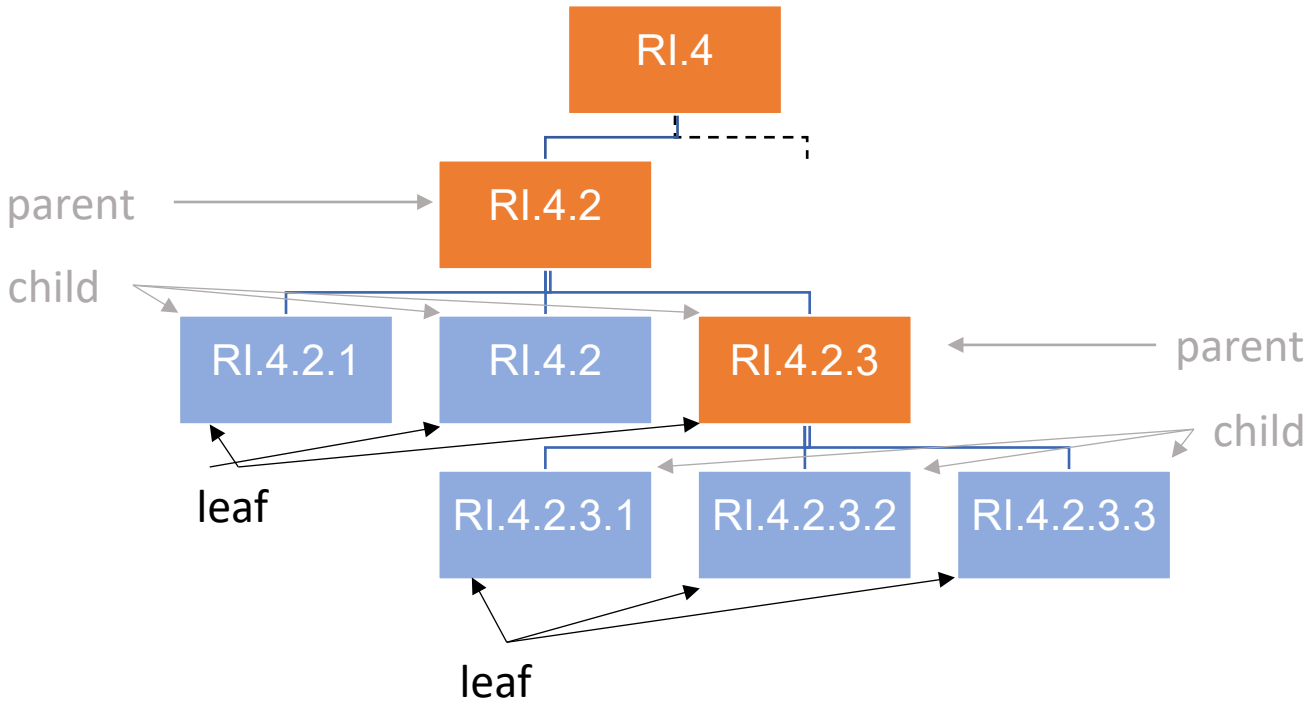

Figure 4 Portion of the Functional Model hierarchical structure

(Note: The numbering schema above reflects functions in the Record Infrastructure (RI) chapter.)

Functional Profiles either:

- Select functions from the Functional Model for inclusion in the Functional Profile,
- Deem a function in the Functional Model as not applicable, thus do not select it for inclusion in the Functional Profile, or,
- Add a new child function when it has been determined that there is no applicable function in the Functional Model to represent a functional need in the Functional Profile.

6.6.2 Naming Convention

Functional Profiles **SHALL NOT** change the name or statement of a function except to allow for alignment to realm specific nomenclature, including language distinctions and implication of non-english translations. In these cases, the International Organization for Standardization (ISO) country code (ISO 3166 Country Codes) **SHALL** be appended to the function ID in the Functional Profile. It is recommended that the HL7 Affiliate for the respective realm coordinate with the profile development process to maintain a mapping of the Functional Model function name and/or statement and the realm-adjusted name and/or statement.

6.6.3 Priorities

Functional Profiles indicate the importance and/or immediacy of a Functional Profile by associating a priority with a function. Three priorities have been defined, Essential Now, Essential Future, and Optional:

- Essential Now indicates that the implementation of the function is mandatory, as of the profile issuance date.
- Essential Future indicates that the implementation of the function is currently optional but will be mandatory at some future time, which is specified by the Functional Profile
- Optional indicates that the implementation of the function is optional.

Any or all of these priorities **SHALL** be used in a Functional Profile. If the Essential Future priority is used, then Functional Profiles are required to define the timeframe associated with implementing functions. A timeframe **MAY** be a date, time allotment (e.g., year 2014 or 4 months after Functional Profile publication), or event (e.g., republication of this Functional Profile). A Functional Profile **MAY** define multiple timeframes for the Essential

Future priority. If multiple timeframes are defined, then the timeframe **SHALL** be used to qualify each occurrence of the Essential Future priority (e.g., EF-2015, EF-2016).

6.6.4 Extensibility

To accommodate changes in technology as well as Functional Profiles' needs, the Functional Model is designed for extensibility, for functions and their related criteria. Incorporation of additional functions in the Functional Profile beyond what is defined in the Functional Model is accommodated through a set of rules for adding new functions as defined in Section 6.7.2.

Incorporation of additional criterion, changing the sequence of criterion and providing greater profile-specific detail, beyond what is defined in the Functional Model, is accommodated through a set of rules for adding new criterion or changing existing criterion as defined in Section 6.7.2.

6.7 Functional Profile Conformance (Normative)

A Functional Profile claiming conformance to the Functional Model **SHALL** meet all requirements specified in the 6.7.1 Rules for Functional Domain Profiles or in the 6.7.5 Rules for Functional Companion Profiles.

6.7.1 Rules for Functional Domain Profiles

Functional Domain Profiles **SHALL** claim conformance to the version of the EHR-S Functional Model from which it was derived.

Functional Profiles claiming Functional Model conformance SHALL:

1. Identify the Functional Model with version/date, from which the Functional Profile is derived,
2. Include a description, version and issuance date of the Functional Profile,
3. Contain a Conformance Clause which:
   a) Defines the requirements that EHR systems must satisfy in order to claim conformance to the Functional Profile,
   b) Defines the requirements that Functional Profiles derived from the Functional Profile (i.e., derived Functional Profiles) must satisfy in order to claim conformance to the Functional Profile.
   c) Specifies that functions designated with the priority 'Essential Now' SHALL be implemented by conformant EHR systems.
   d) Specifies that functions designated with the priority 'Essential Now' SHALL be included in any derived Functional Profiles.
   e) If Essential Future is used, defines the meaning of 'Essential Future', including specifying the timeframe for when these functions are required to be implemented.
   f) Requires that at least one function, regardless of its priority, be implemented in order for an EHR system to claim conformance to the profile.
4. Include all functions in the Overarching section of Function List as Essential Now and identify functions from other sections of Function List of the Functional Model that are applicable to the functional domain profile. For each identified function, indicate its priority (i.e., Essential Now, Essential Future or Optional).
5. For each function, derive conformance criteria based on the Functional Model's conformance criteria:
   a) In the Functional Profile, there SHALL be at least one criterion for each function that is mandatory (a 'shall' criterion).
   b) If there are 'shall' criteria (for the function in the Functional Model), then those criteria SHALL also exist for the function (in the Functional Profile). Additionally, if the function is split (in the Functional Profile), then the parent's 'shall' criteria SHALL appear in at least one child of that function.
   c) If, as yet there is no 'shall' criterion (for the function in the Functional Model), then at least one of the 'should' or 'may' criterion SHALL be made mandatory, i.e., a 'shall' criterion.
   d) Adhere to the rules for referencing functions or criteria in Section 6.5.3.
6. For any function in the Functional Model where one or more criteria are 'dependent shall' criteria, the Functional Profile for that function SHALL
   a) Replicate verbatim each 'dependent shall' in the Functional Profile, regardless of whether the dependent situation applies or not.
   b) When the dependent situation applies, create 'shall' criteria that apply the dependency to the 'dependent shall' criterion, resulting in one or more new, constrained versions of the 'dependent shall' criterion.
   c) State the specific scope of practice, organizational policy, and/or jurisdictional law which applies or state why these dependencies do not apply.
7. Adhere to the rules for creating new functions in Functional Profiles in Section 6.7.2.
8. Adhere to the rules for creating and changing conformance criteria in Section 6.5.

9. Complete the two traceability columns, see Section 6.3.3, for any changes to functions or criteria, and include the following codes for type of change: (N/C for no change; A for added; M for modified.).
10. Be structured in accordance with the structural requirements defined for the Functional Model in Section 6.6.1.
11. Use the Glossary Action verbs for modifying or creating new conformance criterion.

Functional domain profiles claiming conformance to the Functional Model MAY:

1. Create additional functions according to the rules specified in Section 6.7.2.
2. Contain conformance criteria more specific and limited in scope than those of the Functional Model.
3. Replace the text 'standard(s)-based' found in some criteria with specific standards and/or specifications named at the most discrete level of designation.
4. Change a 'should' criterion to a 'shall' or a 'may' criterion.
5. Change a 'may' criterion to a 'shall' or a 'should' criterion.
6. Ignore a 'should' or 'may' criterion in the Functional Model (i.e., not include it in the Functional Profile).
7. Add additional conformance criteria beyond those in the Functional Model.
8. Make the order of the conformance criteria significant (e.g., put all 'shall' criteria first).
9. Enforce common resolution of ambiguous semantics of the Functional Model.
10. Make the Functional Profile public (e.g., published on a web site) so interested parties can see/use it.
11. Submit the Functional Profile for registration review by the HL7 EHR Work Group.

Functional domain profiles claiming conformance to the Functional Model SHALL NOT:

1. Specify any requirements that would contradict or cause non-conformance to the Functional Model.
2. Modify the name or statement of any function in the Functional Model, except to allow for alignment with realm specific nomenclature as specified in Section 6.6.2.
3. Change a mandatory conformance criteria to an optional criteria (i.e., replace the 'shall' within the criteria to 'should' or 'may') of any function in the Functional Model.
4. Modify any requirements of a function not selected for the Functional Profile (i.e., all unselected functions default to the Functional Model's criteria. If a profiling group wants to change something, they SHALL promote it into their Functional Profile).

6.7.2 Rules for Creating New Functions in Functional Profiles

If a function is not adequately specified for a Functional Profile or does not exist, the Functional Profile **SHALL** only create new children, the new children can be parents or leafs. Figure 5 illustrates the addition of a new child function.

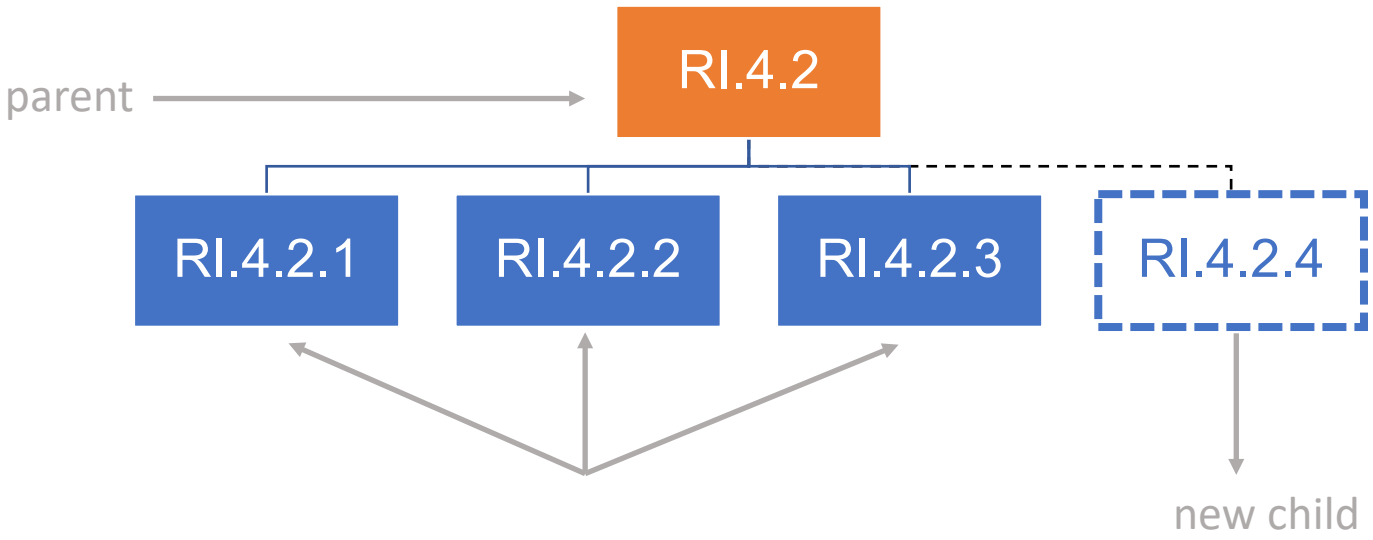

Figure 5 Creating a new function

The following rules specify the method for creating new functions:

1. Whenever possible, conformance criteria SHOULD be used to avoid creating a new function. This may be done, for example, in cases where the original function's conformance criteria are too broad: divide the Functional Model's or base Functional Profile's inherited conformance criteria into two criteria in the

Functional Profile, one being mandatory and the other optional. If this is not possible, the creation of a new child function and associated criteria is allowed if necessary to clearly define the profile requirements.

2. When a 'leaf' function exists (a child that is not a parent) but is too broadly specified in the Functional Model or base Functional Profile for conformance criteria to adequately constrain it, then the function MAY be split as follows:
3. The original 'leaf' function is retained as the parent of its newly created children functions, or
4. The original 'leaf' function's conformance criteria SHALL be distributed among its children functions.
5. When no candidate function exists to express the requirements of a Functional Profile, a new child function MAY be created (e.g., adding a new kind of summary list under the summary list's parent).
6. 'Parent functions SHALL NOT be split. This preserves the structure of the underlying Functional Model in the Functional Profiles.

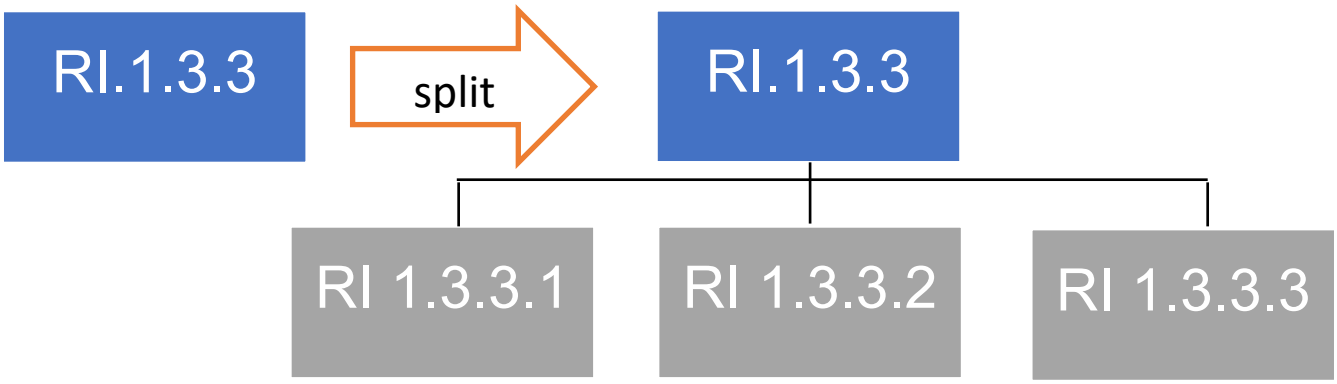

Figure 6 Splitting a function

If new children functions are created by a Functional Profile that is balloted or registered, these new functions will be captured by the HL7 EHR WG and tracked for review as show in Figure 6. The EHR TC WILL use these new functions and related criterion as input and candidates for changes to the Functional Model (e.g., inclusion, relaxation of conformance criteria). The EHR WG MAY maintain a file of functions and criterion reviewed and rejected for inclusion in a future version of the FM.

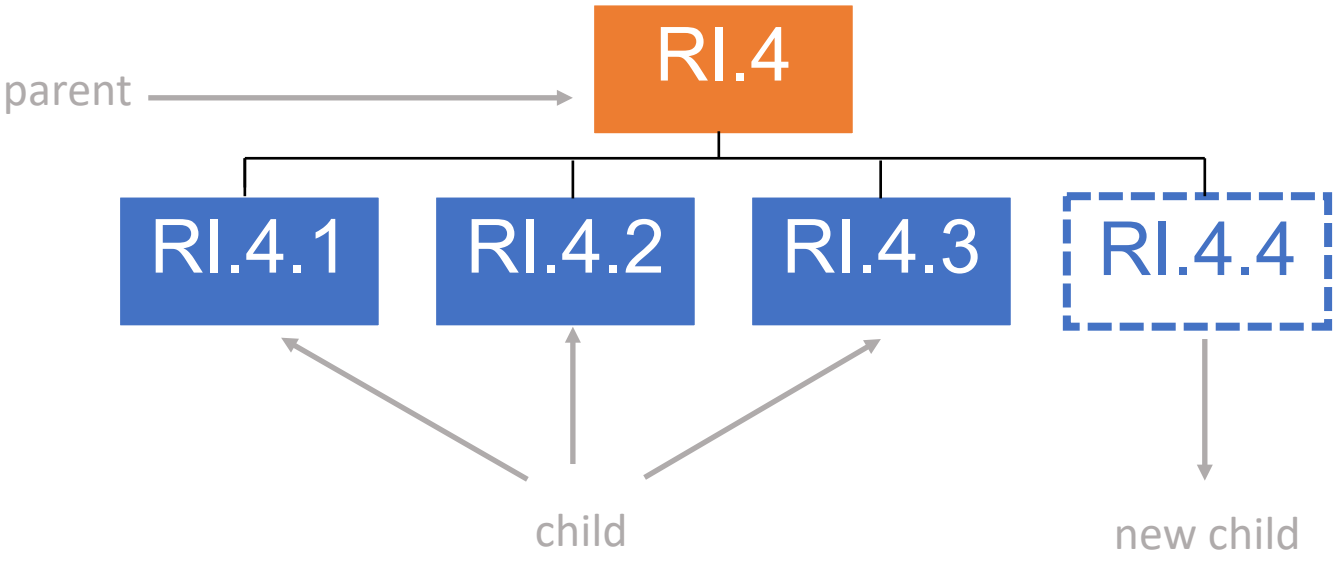

Figure 7 Adding a new child function

Figure 7 depicts function RI.4.4 is added as a new child which is a sibling to RI.4.1, RI.4.2, and RI.4.3.

6.7.3 Rules for Derived Functional Profiles

Derived functional domain profiles claiming conformance to one or more base functional domain profiles SHALL:

1. Adhere to all the rules for Functional Domain Profiles as specified in Section 6.7.1.
2. Adhere to the rules for creating new functions as specified in Section 6.7.2, if not prohibited by the base Functional Profile.
3. Identify the base Functional Profiles from which it is derived.
4. For each function inherited from a base Functional Profile, retain and not change mandatory conformance criteria to optional conformance criteria.

6.7.4 Conformance Statement

Functional Profiles **MAY** want to require that a conformance statement be produced for systems claiming conformance to the profile. A *Conformance Statement* provides information about an EHR system, by presenting in a uniform manner the functions that have been implemented by the EHR system. A blank (i.e., yet to be completed) Conformance Statement typically takes the form of a questionnaire or checklist, to be completed for each EHR system.

A Conformance Statement provides a concise summary of a Functional Profile. It follows a standard layout, thus providing EHR system vendors and users a quick overview of the Functional Profile's functions. Moreover, it can also be used to highlight optional functions and capabilities supported by the EHR systems as well as document any extensions (i.e., additional functionality beyond what is in the Functional Profile) or specializations that have been made. An EHR system's Conformance Statement provides information that can be used in assessing the EHR system's conformance to a specific Functional Profile. Additionally, organizations wishing to acquire an EHR system **MAY** produce a Conformance Statement to indicate the functions that are required and/or desired in an EHR system

Functional Profiles **MAY** want to include a blank, to be completed, sample Conformance Statement in order to promote consistency among completed Conformance Statements. Conformance Statements can be useful in determining the chances of interoperability between two EHR systems, by comparing the functions supported by each EHR system. Additionally, for conformance testing purposes, it can be used to facilitate the selection of tests that would be applicable to a particular EHR system being tested. For example, if an EHR system did not implement functions designated as 'Essential Future', this would be evident in the Conformance Statement and the tests for these functions (which are unimplemented) would not be performed.

6.7.5 Rules for Functional Companion Profiles

Functional Domain Profiles **SHALL** claim conformance to the version of the EHR-S Functional Model from which it was derived. Functional Companion Profiles will follow the section 6.7.1 Rules for Functional Domain Profiles and the section 6.7.3. Rules for Derived Functional Profiles, except for the exceptions and addition described below.

Functional companion profiles claiming Functional Model conformance SHALL:

1. Adhere to section 6.7.2 for adding new functions,
2. Contain a Conformance Clause which:
   a) Defines at least one functional domain profiles for which the companion profile can be linked that EHR systems must satisfy in order to claim conformance, or state any specific domain profiles that can or cannot be link to the companion profile,
   b) Defines the requirement(s) that companion profiles derived from the base functional companion profile (i.e., derived Functional Profiles) must satisfy in order to claim conformance to the functional companion profile.
3. Include **only functions being modified** from the Overarching section of Function List as Essential Now and identify functions from other section of Function List of the Functional Model that are applicable to the functional companion profile. For each identified function, indicate its priority (i.e., Essential Now, Essential Future or Optional).
4. For each function, derive conformance criteria based on the Functional Model's conformance criteria:
   a) In the Functional Profile, there **SHALL** be at least one criterion for each function that is mandatory (a 'shall' criterion).
   b) If there are 'shall' criteria (for the function in the Functional Model), then those criteria **MAY** also exist for the function (in the functional companion profile) if changes. Additionally, if the function is split (in the Functional Profile), then the parent's 'shall' criteria **MAY** appear in at least one child of that function.

5. For any function in the Functional Model where one or more criteria are ‘dependent shall’ criteria, the functional companion profile may elect to ignore the criterion, but **if selected** for that function **SHALL** follow the rules of section 6.7.1.

Functional companion profiles claiming conformance to the Functional Model MAY:

1. Ignore a ‘shall’, ‘‘should’ or ‘may’ criterion in the Functional Model (i.e., not include it in the Functional Profile).

There are no exceptions to section 6.7.5. for Derived Functional Companion Profiles

6.8 Use Cases and Samples (Reference)

6.8.1 Functional Profile Use Cases

Care setting

It is determined that a new care setting functional domain profile is needed to reflect the care setting specific requirements. To help ensure widespread use and uniformity, the Functional Profile authors elect to undergo the registration review followed by the HL7 consensus process (i.e., submitting the registered Functional Profile for an “Informative” committee level ballot). If successful, the result will be designated a HL7 Informative Functional Profile.

After looking at current list of HL7 informative Functional Profiles, the decision to create a new Functional Profile is made. Each function in the EHR System Functional Model is examined and those that are relevant to the care setting are chosen. From these functions, a small set of ‘core’ functions are selected as being essential and mandatory. For each function, conformance criteria is developed either adapting the Functional Model conformance criteria or in a few cases, using the Functional Model criteria as is. To complete the Functional Profile, a description of the Functional Profile, including its intended use and audience as well as a Conformance Clause is written. The Functional Profile is made public by publishing it on various web sites. Additionally, the Functional Profile is submitted to HL7’s EHR Work Group for registration review, comment and ballot.

Community of interest derived functional domain and companion profiles

A community of interest (e.g., regional health information exchange network) wants a functional domain profile to reflect their specific needs, and the needs of one of their members to support clinic research.

The Community of Interest doesn’t want to create a new Functional Profile from scratch. After looking at the list of Registered Functional Profiles, they find an existing Functional Profile that is very close to what they want. Using this Functional Profile as the base, they accept all the functions designated as ‘Essential Now’, reject functions designated as ‘Future’ and add several more functions. For each function, they review the conformance criteria and adapt the criteria to reflect their situational information.

For the one member of the community that needs to support research, a functional companion profile is created. The Functional Profile is only needed to address the narrow areas of operation that are specific to research. So, the group finds an existing companion profile for clinical research and modifies it to reflect the functions needed for the specific disease state implications for the research activities of their member. Now the Community of Reference can seek a vendor that can meet the needs of both the domain profile for the group and the companion profile for the unique member.

Vendor functional domain profile and overarching conformance

A vendor with an EHR system wants to claim conformance to the EHR System Functional Model.

The vendor identifies and lists all the functions that are in his product. The vendor adds a description and a Conformance Clause (see samples in section 7.2). This is the vendor’s functional domain profile. If the vendor has actually implemented all the functions listed, then this is equivalent to ‘Essential Now’ and these functions are mandatory. If functions that are currently implemented and those that will be implemented in the future are listed, then the Functional Profile is comprised of ‘Essential Now’ and ‘Essential Future’ and/or optional functionality. Finally, the vendor adds conformance criteria for each function, inheriting some criteria directly (without change) from in the Functional Model. But can also add new criterion to reflect added system features. If all children of a function have the same new criterion, that criterion would be moved to the parent function as overarching, and applicable to all the children. This is appealing in that, the vendor has the opportunity to list all the current functionality and if desired, indicate future plans. In essence, this is similar to a vendor Conformance Statement (a concept most vendors are already familiar with). A vendor may create multiple Functional Profiles.

6.8.2 Sample Functional Domain Profile Conformance Clauses

To aid Functional Profile developers in developing a Conformance Clause for their Functional Profile, as required by Section 6.1 rule #3, the following examples are offered. Note: in these examples, the keywords 'shall', 'should', and 'may' are capitalized and bold. This is a convention to draw attention to the keywords.

Conformance Clause for a care-setting functional domain profile

This functional domain profile defines the conformance requirements for EHR systems and derived functional domain profiles. To conform to this Functional Profile, all 'Essential Now' functions **SHALL** be implemented. 'Essential Now' functions are considered mandatory functions. An EHR system is conforming if it implements all the functions designated as 'Essential Now' and the mandatory conformance criteria associated with that function. A derived functional domain profile is conforming if it follows the Rules for Functional Profiles.

Mandatory conformance criteria are indicated by the keyword 'shall**'**. Optional conformance criteria are indicated by the keywords 'should' or **'**may'.

EHR systems **SHALL** provide a Conformance Statement structured according to the rules and policies defined in this Functional Profile.

Conformance Clause for an application

E-Application is an application that if included in a care-setting specific system **SHALL** conform to this Functional Profile. E-Application is an application that has a defined set of attributes of which a minimum set of functions is required of any system claiming this e-Application functionality. Two levels of conformance are designated:

- Core Conformance is comprised of the functions in the minimal set of functions that are designated as 'Essential Now'.
- Advanced Conformance comprises the entire minimal set of functions (i.e., all 'Essential Now' as well as those designated 'Essential Future' functions).

A system **MAY** claim conformance to either the Core or Advanced Conformance levels, if it implements all the mandatory criteria for the functions at the conformance level for which the claim is being made.

Functions designated with the priority 'Essential Now' indicate core functionality. These functions are required to be implemented in order to claim conformance to E-Application, regardless of the level of conformance (i.e., core or advanced) to which the claim is made.

Functions designated with the priority 'Essential Future' indicate advanced functionality. These functions are required to be implemented in order to claim advanced level conformance. 'Essential Future' functions become mandatory 18 months after publication of this Functional Profile and thus, required for immediate implementation in order to claim conformance at either the core or advanced levels.

Conformance Clause for a vendor system functional domain profile

Conformance is defined for My-EHRsystem. All functions in this Functional Profile are mandatory, are deemed as 'essential now', and **SHALL** be implemented in order to conform to this Functional Profile.

Conformance Clause for a community of interest functional companion profile

Conformance is defined for BuyMyDiabetesEHR. To conform to this functional companion profile, all functions labeled as 'essential now' **SHALL** be available and have been implemented, and all functions labeled 'essential now' in the Long Term Care or Ambulatory domain profile must also be available and implemented. Functions labeled 'essential future' are optional, in that they are present for informational purposes only and **MAY** be implemented in future functional companion profiles.

6.8.3 Interpreting and Applying a Conditional 'SHALL' (Reference)

Conformance criteria in the FM and those created can be structured in the simple format an Actor followed by normative verb followed by action or property. For example: The system **SHALL** capture demographic information as part of the patient record.

However, there are two conditional forms for which if the condition is true, then the following text must apply. One is If/Then. If condition, then Actor followed by normative verb followed by action. If the condition is not met (i.e., false) then ignore the rest of the sentence. For example, IF data is exchanged with internal or external systems, THEN the system **SHALL** conform to function IN 5.1 (Interchange Standards)

The other is a ‘Dependent Shall’ format. Actor followed by normative verb followed by action/interaction followed by ‘according to scope of practice, organizational policy or jurisdictional law’. For example, "The system **SHALL** enable EHR-S security administrators to grant authorizations to principals according to scope of practice, organizational policy, or jurisdictional law."

The following example of a Functional Model ‘dependent shall’ criterion will be used to illustrate conditional concepts throughout this section.

> Functional Model criterion: The system SHALL enable EHR-S security administrators to grant authorizations to principals according to scope of practice, organizational policy, or jurisdictional laws.

6.8.4 General Concepts

The purpose of the ‘dependent shall’ is to allow Functional Profiles to constrain a Functional Model ‘shall’ criteria based on situational conditions such as policy and legal implications. Specifically, the ‘dependent shall’ criteria in the Functional Model are ‘shall’ criteria + a dependency, where the dependency is defined by:

- Scope of practice which applies to the EHRs user’s scope of practice and refers to best practices within the user’s discipline – which may be care setting specific or not.
- Organizational policy which refers to a plan or course of action intended to influence and determine decisions, actions, and other matters of a group of persons organized for a particular purpose within an association and structure through which individuals cooperate systematically to conduct business.
- Jurisdictional law which refers to the territorial range of authority or control with the power, right, or authority to interpret, apply, and declare the body of rules and principles governing the affairs of a community and enforced by a political authority; a legal system.

The structure of the ‘dependent shall’ criteria in the Functional Model is the same as the ‘shall’ criteria except with the addition of the phrase “in accordance with scope of practice, organizational policy or jurisdictional law” or other appropriate grammatical tie-in words (e.g., based on rather than in accordance). Note that all three dependencies are present in the Functional Model ‘dependent shall’ criteria. It is the Functional Profile that narrows it to any one dependency or any combination of the three. Moreover, in the Functional Profile, the specific scope of practice, organizational policy, and/or jurisdictional law which necessitates evoking the ‘dependent shall’ is explicitly identified.

For example: (derived from the Functional Model criterion above)

> Functional Model criterion: The system SHALL enable EHR-S security administrators to grant authorizations in accordance with HIPAA.

The difference between a ‘shall’ criterion and a ‘dependent shall’ criterion is shown in Table 3 below.

	‘SHALL’ Criterion	**‘Dependent SHALL’ Criterion**
Be present in the Functional Profile	Yes, either verbatim or modified (e.g., constrained or refined)	Yes, verbatim. If dependency exists, add additional criteria reflecting the dependency.
Implemented by EHR systems	Yes.	Situational - only implement if the dependency exists. Specifically, EHR system does not implement the ‘dependent shall’ criterion (as copied from the FM), but does implement additional ‘shall’ criteria created to reflect the dependency.

Table 3: Differences between 'shall' and 'dependent shall'

6.8.5 Rationale for ‘Dependent SHALL’

The reason for using a ‘dependent shall’ in the Functional Model is to highlight these criteria and bring them to the attention of the reader – both developers of Functional Profiles as well as other users. These criteria are considered to be special cases, where there are one or more dependencies that affect these criteria, across multiple care settings. Using the ‘dependent shall’ ensures that developers of all Functional Profiles address the criterion and consciously decide whether the criterion in question is applicable, based on the stated dependency.

Regardless of whether a dependency exists or not, the ‘dependent shall’ is copied verbatim into the Functional Profile. The reasons for this are:

- Adherence to the rule that a ‘shall’ criterion is always inherited by the Functional Profile.

- Consistency with handling the ‘dependent shall’ under all conditions (i.e., when there are dependencies and when there are not.
- Retention of the ‘dependent shall’ so that it is present for derived profiles.
- Retention of the ‘dependent shall’ so that it remains effective for this profile if future requirements change (i.e., the dependency may not be applicable at this present time, but may be applicable in the future due to changes in scope of practice, organizational policy or jurisdictional law.

6.8.6 How to Apply the ‘Dependent SHALL’

The way to interpret and apply a ‘dependent shall’ criterion in a functional domain profile is as follows:

- Copy the criterion into the Functional Profile.
- Review the criterion and determine if any of the dependencies are applicable to the Functional Profile.
- Dependency exists

  If one or more dependencies are applicable to the Functional Profile (e.g., there are jurisdictional legal requirements), add one or more ‘shall’ criteria that refine and further constrain the ‘dependent shall’ with respect to the dependencies.

  For the new criteria, add an explanation and/or citing for the dependency. For example, jurisdictional legal requirements for this Functional Profile are defined by Federal Regulations (see 45 CFR Parts 160, 162 and 164 – The HIPAA Security Rule. The explanation or citing may be in an appendix. It is likely that multiple criteria will reference the same explanation or citing.

  Examples:

  Functional Profile criteria

  1. The system SHALL enable EHR-S security administrators to grant authorizations to principles in accordance with HIPAA*.

  2. The system SHALL enable EHR-S security administrators to grant authorizations for roles in accordance with 42 CFR Part 2*.

  Dependency Explanation

  *For a U.S. realm Functional Profile, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as well as other jurisdictional legal requirements or other more stringent requirements would be applied to ‘dependent shall’ criteria in the Functional Profile as shown in Table 4.

FM	Dependency Applicable?	Applicability	Functional Profile
Dependent SHALL	Yes	Mandatory	Copy SHALL from FM
		Mandatory	Add additional criteria to reflect the dependencies. Use ‘shall’.
		Mandatory	Add explanation or citing
		Optional	Add additional criteria derived from ‘dependent shall’. Use ‘shall’, ‘should’ or ‘may’.

Table 4: Summary of actions when dependency exists

No Dependency exists

If no dependency is applicable to the functional domain profile (i.e., there are no scope of practice, organizational policies or jurisdictional legal requirements that apply), then document the rationale for deciding that no dependencies apply as shown in Table 5. This explanation may be in an appendix. It is likely that this explanation will apply to multiple ‘dependent shall’ criteria.

FM	Dependency Applicable?	Applicability	Functional Profile
Dependent SHALL	No	Mandatory	Copy SHALL from FM
		Mandatory	Add explanation
		Optional	Add additional criteria derived from 'dependent shall'. Use 'shall', 'should' or 'may'.

Table 5: Summary of actions for when no dependencies

Add additional criteria – regardless of whether a dependency exists or not.

It is always permissible for a Functional Profile to add new criteria. Add new criteria that are derived from the 'dependent shall'. Use any keyword: 'shall', 'should' or 'may' (see Section 3) in these new criteria.

Examples:

*1. The system **SHOULD** enable EHR-S security administrators to grant authorizations to principals.*

*2. The system **MAY** enable EHR-S security administrators to grant authorizations for roles.*

*3. The system **SHOULD** enable EHR-S security administrators to grant authorizations within contexts.*

*4. The system **SHALL** enable EHR-S security administrators to grant authorizations for roles for organizations with 10 employees or more.*

7 EHR System Conformance Claim via Self-Attestion

Claiming Conformance to a Functional Profile

When a software vendor/developer wishes to claim (for their product) conformance to a version of an EHR Functional Profile the document claiming conformance should include the following information:

- The Name and Version of the standard that the software product is conformant with
- A full listing of the functions and conformance criteria that the software product is conformant with

In this manner any individual/organization evaluating the software product may easily determine its claimed functionality.

The documentation detailing the process of determining conformance using a tool (for example, the software was tested using the widget tool for specific conformance criteria) shall include the name of the tool, the version of the tool and the date(s) of testing.

The process of claiming conformance to one or more Functional Profiles shall not be construed as creating a new Functional Profile.

Should an end user (provider) find that a particular EHR-S product is not in compliance with a conformance criterion claimed in the software statement of conformance, the end user (provider) should first address the issue with the software developer. The end user (provider) may also communicate their findings with the HL7 EHR Work Group. The EHR WG shall not be responsible for validation of any statement of conformance or for intervening with a software vendor/developer when a discrepancy is reported by an end user but may at its discretion reach out to the EHR-S vendor/developer to discuss the identified issues.

8 Glossary

8.1 Preface (Reference)

Portions of this Glossary Clause are classified as NORMATIVE, including the Action-Verb Structure Section (8.4). See section by section labels. The Glossary is provided as guidance for preparing and interpreting HL7 Electronic Health Record and Personal Health Record System Functional Models (EHR-S FM and PHR-S FM respectively) and Functional Profile (FP) specifications and conformance statements. The goal is to promote clarity and consistency when interpreting and applying language of the FMs.

This Glossary is intended to be international in application. However, each realm may want to adjust terms to their own language.

8.2 Introduction (Normative)

The Health Level Seven International (HL7) EHR-S and PHR-S FM Glossary is an HL7 reference document that provides a set of definitions and guidelines in order to ensure clarity and consistency in the terms used throughout the FMs and in related FPs. The Glossary includes the definition of important terms used in the expression of EHR and PHR system functionalities, and comprises a consensus-based list of Action-Verbs and specific guidelines for constructing conformance criteria (CC).

Action-Verbs play a critical role in phrasing conformance criteria. Extensive efforts were made to categorize and normalize Action-Verbs and to develop guidelines for creating clear and consistent CCs throughout the FMs and in related FPs. Continuity with previous FM versions is provided by including Glossary terms that have been deprecated, accompanied by suggestions for preferred replacement terms. Vigorous efforts were deployed to reduce the ambiguities inherent in the use of human language; care was used to respect the fundamental meaning of words and to avoid domain specific usage of terms.

8.3 Overview (Reference)

HL7's EHR Work Group has unified glossaries for both the EHR-S and PHR-S FMs to ensure consistency. Each FM has a unique focus and coverage in the health information domain with specific system functional requirements, yet readers are often the same people. It is expected that FPs created within the context of either FM will align with this Glossary. However, this Glossary will not provide definitions for all the terms used in FPs. FPs will typically use context-specific, realm-specific, or specialized terms associated with their area of focus, and may need to incorporate a complementary glossary for these special terms.

In the case where FPs are merged, care should be exercised to ensure that the same Action-Verbs are used with the same meaning, and that identical meanings are conveyed with the same Action-Verb. It is recommended that existing FPs be re-examined and updated to closely align with the current set of Action-Verbs.

Some common terms and Action-Verbs have not been included in this Glossary. For example, terms like 'computer', 'keyboard', 'archive' and 'compact' are considered general computer field terms that do not need to be defined here. Some other terms reflect functionalities inherent in any computer system and are not defined here, e.g. compute. Readers who desire definitions of terms not covered in the Glossary are invited to consult trusted dictionaries or encyclopedias. Where definitions of terms are taken from recognized sources, specific references are included.

8.4 The Action-Verb Structure (Normative)

The Action-Verbs to be used for writing conformance criteria in the EHR-S FM and the PHR-S FM are organized in two hierarchies, each with its own specific set of Action-Verbs to:

- Secure and operationalize systems;
- Manage data and the health record.

Each hierarchy consists of Action-Verbs that collectively represent a logical set of actions.

8.4.1 Secure (System) Hierarchy

The Secure System hierarchy, as show in Table 6, provides Action-Verbs for controlling access (authenticating and authorizing users), tracking activities (logging and auditing), and sustaining operations. This hierarchy has one parent, Secure (System), and three (3) intermediate children: Control Access, Track, and Sustain (Operations).

Secure (System)				
Control Access		Track		Sustain (Operations)
Authenticate	Authorize	Log	Audit	

Table 6: Action-Verbs supporting the Secure System Hierarchy

- Control Access: to limit the use of a system to only those who are permitted
- Track: to govern; control; administrate; oversee; inspect; examine; assess; observe; monitor; police; enforce; check
- Sustain (Operations): to keep the system running correctly (e.g., sustain operations; quality; integrity; throughput; mirror; reliability; failover; failsafe; versioned; virus-free; leak-free; up-to-date; safeguard)

8.4.2 Data Management Hierarchy

The Data Management hierarchy provides Action-Verbs for the complete range of data handling actions by a system. The hierarchy, as show in Table 7 has one parent, Manage (Data), and six (6) children with subsets: Capture, Maintain, Render, Exchange, Determine, and Manage-Data-Visibility.

Manage (Data)										
Capture	Maintain			Render			Exchange	Determine		Manage Data Visibility
Auto-populate Enter Import Receive	Store Archive Backup Decrypt Encrypt Recover Restore Save	Update Annotate Attest Edit Harmonize Integrate Link/Unlink Tag/Untag	Remove Delete Purge	Extract	Present	Transmit	Export Import Receive Transmit	Analyze	Decide	De-Identify/ Re-Identify Hide/ Unhide Mask/ Unmask

Table 7: Action Verbs supporting the Data Management Hierarchy

The first three subsets cover the capture, maintenance and rendering of data as follows:

- Capture:
  - Auto-populate fields of data based on partially filled information
  - Enter data manually
  - Import data from an external source (which may be a device)
  - Receive data from another system (which may be a device)
- Maintain:
  - Store:
    - Archive data to external media
    - Backup data on backup storage media
    - Encrypt data for security and privacy purposes
    - Decrypt data to reverse encryption
    - Recover/Restore data from backup
    - Save data on local media
  - Update:
    - Annotate data with notes
    - Attest data to verify and approve
    - Edit data by modifying it
    - Harmonize data across multiple sources
    - Integrate data together
    - Link data to other data
    - Unlink data to remove prior linkage(s)
    - Tag data with labels
    - Untag data to remove prior label(s)
  - Remove:
    - Delete/Purge to remove data from storage media or directory(ies)
- Render:
  - Extract data based on certain criteria
  - Present data on an attached device
  - Transmit data to external systems or devices

The next subset pertains to the Exchange of data from one part or system to another or others:

- Exchange:
  - Export (transfer) data in a format that can be used by other systems
  - Import data from an external source (which may be a device)
  - Receive data from another system (which may be a device)
  - Transmit data to another party/system

The next subset provides verbs for the determination of actions in processing data:

- Determine:
  - Analyze data using rules and analytical steps
  - Decide appropriate actions as a result of that analysis

The final subset allows the construct of statements restricting the visibility of data and reversing those actions:

- Manage-Data-Visibility:
  - De-Identify data as to prevent associating the data to a specific person
  - Re-Identify data to reverse a prior de-identification
  - Hide data so that only authorized users can see that the data exist
  - Unhide data to reverse a prior hide operation
  - Mask data so that users can see that the data exist but only authorized users can actually view the actual data
  - Unmask data to reverse a prior mask operation

8.4.3 How Action-Verbs are defined

Action-Verbs are defined in the following manner:

For an Action-Verb that has a parent, the Action-Verb's definition will start with the immediate parent verb and then a restatement of the meaning of the Action-Verb, followed by at least one (1) example labeled as such. Examples will use the Action-Verb being defined with explanatory descriptions where relevant. Such as:

- PRESENT (Action-Verb): To RENDER (the parent Action-Verb) data by delivering the data to local users in a meaningful and appropriate way. For example, the system may PRESENT an alert automatically when a newly-arriving laboratory value is received that is out of normal range.

For a top level Action-Verb, the definition will include the next immediate level of children, followed by at least one (1) example labeled as such. Examples will use the Action-Verb being defined with explanatory descriptions where relevant. An illustrative example follows:

- MANAGE (DATA) (Action-Verb): To handle data by capturing, maintaining, rendering and exchanging data, determining actions about data, and managing data visibility. For example, the system shall provide the ability for a user to MANAGE patient and family preferences as they pertain to current treatment plans.

Table 8 lists the full set of eligible Action-Verbs and their logical construction:

Action-Verb	Construction
Analyze	To DETERMINE actions in the flow of processing data by comparing, correlating, or weighting certain data and by applying clinical or business rules, hence leading to a decision (see DECIDE). For example, the system may ANALYZE patient information using a drug-interaction database and a set of clinical rules. Another example is that the system may ANALYZE various protocols relative to a patient's condition. Another example is that a person may ANALYZE a proposed update to a patient's home address and DECIDE to reject the proposed update.
Annotate	To UPDATE data by attaching comments or notes to the data without editing the data. For example, an Attending physician may ANNOTATE the information entered by the Resident physician before signing the report.
Archive	To STORE data by moving the data to long-term storage media and deleting or purging data on the original online storage, according to scope of practice, organizational policy, and/or jurisdictional law. For example, the system at the Oak Street Hospital automatically ARCHIVES patient-related data that is older than eight years by encrypting and compressing it, moving it to long-term storage, purging it, identifying the data by month and year, and creating a pointer to the archived data. Another example is that a system may automatically ARCHIVE outpatient clinic schedules that are being replaced.
Attest	To UPDATE information by ATTESTing that an EHR record (or part of an EHR record) is genuine.. For example, a resident physician may ATTEST that the information contained in an EHR record was created by her. Another example is that

Action-Verb	Construction
	an attending physician may annotate a resident's version of the record and then ATTEST to those changes. Note: Attestations may be applied, affixed or bound to an EHR record, for example, via a digital signature, certification, or other verifying mark.
Audit	To TRACK system-initiated or user-initiated activities by analyzing logs based on policies or rules. For example, the system may automatically AUDIT the daily log for multiple-failed-logon-attempts. Another example is that an administrator may AUDIT the excessive use of extraordinary (i.e., "break-the-glass") access to certain patient information in the Emergency Department.
Authenticate	To CONTROL ACCESS to a system by validating the identity of a user, another system or a device before authorizing access. For example, the system may AUTHENTICATE Dr. Jones by validating his identity using a UserID and a biometric device. Another example is that the system rejects Sara Smith's attempt to AUTHENTICATE to the system after three failed password entries.
Authorize	To CONTROL ACCESS to a system by applying permissions to use certain functionality or to view certain data. For example, the system may AUTHORIZE Dr. Jones, an Emergency Department physician, to view Emergency Department patient records (note: We assume that the administrator has entered a set of permissions for all Emergency Department physicians). Another example is that the system does not AUTHORIZE deletion by Sara Smith of a patient record that has already been signed.
Auto-populate	To CAPTURE data by inputting it automatically using previously-existing data, providing a default value, or deriving it from other data, or by following various data-entry business rules. For example, the system may AUTO-POPULATE the city, state/province, and country fields when a user enters a zip-code. Another example is that the system may AUTO-POPULATE a newborn's home address with the mother's home address.
Backup	To STORE data by placing a copy of the data onto an electronically-accessible device for preservation in case the original is lost, corrupted, or destroyed. For example, a system may BACK UP the incremental changes made to a patient's record by storing it locally on a daily basis. Another example is that an administrator may BACK UP a complete copy of certain data by storing it at an offsite facility.
Capture	To MANAGE data by auto-populating, entering, importing, or receiving the data, either through human intervention or automated means. For example, a system may CAPTURE patient's data entered by a physician through the keyboard or sent by the physician using a mobile device. Another example is that the system may CAPTURE laboratory results by automatically receiving laboratory data or by keyboard entry for locally performed tests.
Control Access	To AUTHENTICATE users and/or systems and AUTHORIZE access to functionality and/or data. For example, the system may CONTROL ACCESS to the patient's data by authenticating Dr. Jones' identity and authorizing him to update his patient's records. Another example is the system may CONTROL ACCESS to the system by refusing a hospital visitor the ability to authenticate to the system. NOTE: the set of CONTROL ACCESS Action-Verbs requires data specifying permissions. This permission data is managed via the MANAGE data Action-Verbs set.
Decide	To DETERMINE actions in the processing of data by choosing a certain alternative based on an analysis, and acting accordingly. For example, the system may DECIDE to render a notification to off-duty nurses to report for duty based on clinic rules and the receipt of a tornado alert. Another example is that the system may DECIDE to RENDER an alert to a clinician that a prescribed drug is contraindicated with the patient's listed allergies, based on the analysis conducted.
Decrypt	To STORE data by converting encrypted data back into its original form, so it can be understood. For example, the system may DECRYPT clinical data received from an authenticated external laboratory system.
De-identify	To MANAGE-DATA-VISIBILITY by removing identifiers from data in such a way that the risk of identifying an individual is very small under the circumstances, as specified by scope of practice, organizational policy, and/or jurisdictional law. For example, a system may DE-IDENTIFY data for a researcher who wants to perform an analysis of drug effectiveness on diabetic patients. Another example is where a hospital may DE-IDENTIFY data for a set of patients to transmit to a university professor looking for illustrative cases for educational work.

Action-Verb	Construction
Delete	To REMOVE data by making it inaccessible to the application. For example, a user may DELETE an existing patient-appointment at the request of the patient. Note: In the case where the data becomes invalid but needs to remain in the system, the word “TAG” is preferred over the word “DELETE” or the word “Nullify”. This type of action is considered a data “Tagging” process and not a data deletion process. For example, a health information management professional may desire to TAG a certain clinical term as obsolete, but the term needs to remain in the system for backward compatibility purposes.
Determine	To MANAGE data by analyzing it and making a decision based on the analysis. For example, the system may DETERMINE the possible severity of a patient’s allergic reaction to a proposed drug by analyzing the patient’s profile against a drug database and deciding whether the clinician should be presented with an alert or not. Another example is that a system may DETERMINE the next steps in a workflow based on an analysis of a patient’s laboratory results, the patient’s profile, and the clinical rules of the clinic, this analysis leading to a decision as to the appropriate next steps in the clinical process.
Edit	To UPDATE data by correcting, amending, appending, or augmenting the data. For example, the physician may EDIT the patient’s home address by correcting the civic number from 368 to 638 Oak Street. Another example is that a physician may EDIT existing notes about an injury by appending an x-ray picture of a broken bone.
Encrypt	To STORE data by transforming the data into a form that is difficult to understand by unauthorized people or systems. For example, the system may ENCRYPT sensitive information such as the patient’s financial information.
Enter	To CAPTURE data by inputting it manually (for example, via a keyboard) or through other input devices. For example, the user may manually ENTER the patient’s street address via the keyboard. Another example is that the user may ENTER the patient’s body weight via an electronic weight scale.
Exchange	To MANAGE data by importing, receiving, exporting, or transmitting the data between systems. For example, the PHR Account Holder may exchange family history information with the PHR systems of other family members.
Extract	To RENDER data by locating, retrieving and possibly assembling data based on certain criteria and for certain purposes. For example, a system may EXTRACT for a clinician all the x-ray reports regarding the patient’s chest. Another example is that the system may automatically EXTRACT allergy history when the physician enters a prescription. Another example is that a system may EXTRACT for a researcher the number of pneumonia-like cases treated at the Emergency Department within a specific time period. Another example is that a system may EXTRACT and aggregate information using a cohort of patients who have pneumococcal disease and categorize that cohort by specific age-ranges.
Harmonize	To UPDATE data by aligning and reconciling it with other information in the system, or with the data of another system (or systems). For example, the system may HARMONIZE a patient’s new home address with the data of systems of other members of the care-team.
Hide	To MANAGE-DATA-VISIBILITY by making specific information invisible so that the existence of the information is not expressed except to authorized users; viewers of the patient record receive no indication that the hidden information exists or does not exist. For example, the system may HIDE the existence of a patient’s psychiatric record from all viewers except for the patient’s psychiatrist. Note: the verb “unhide” is an acceptable verb to reverse the action of hiding.
Import	To CAPTURE data into a local system by proactively accessing data from an external source and then downloading and integrating the data into the local system. For example, the system may IMPORT the latest drug trial data every Friday evening. Another example is that the user may IMPORT various sets of best practices related to juvenile diabetes.
Inactivate	To maintain control of data by removing access to the data in such a way as the data is no longer active for a certain reason. For example, the PHR Account Holder may no longer employ a list of local oncologists, while the PHR Account Holder is stationed in another country for a while.
Integrate	To UPDATE data by merging other data with the existing data in a controlled manner. For example, a user may INTEGRATE summaries of health care services that were

Action-Verb	Construction
	provided in another jurisdiction into the patient's local record. Another example is that an EHR system may INTEGRATE a single-sign-on application with the EHR system's existing user-authentication services. Another example is that an EHR system may INTEGRATE multiple third-party modules to enhance its capabilities.
Link	To UPDATE data by associating one piece of data with another piece of data. For example, the system may LINK a patient's encounter note with the patient's laboratory results. Another example is that a system may LINK attestable changes to a patient's record to the author's identifying information.
Log	To TRACK system-initiated or user-initiated activities (including access to data and/or functionality, attempts to access data and/or functionality, actions performed on data and/or functionality, and changes to system characteristics or versions) by storing a chronological trace of these activities. For example, the system may LOG the fact that modifications were made to a patient's record by storing the date, time, and identity of the user who modified the record as well as what changes were made to that record. Another example is that the system may LOG the fact that updates were applied to a drug-interaction database table, by storing the date and time at which it was updated.
Maintain	To MANAGE data by storing, updating, and/or removing the data within a system. For example, a system may provide the ability for a clinician to MAINTAIN data by keeping or discarding it. Another example is that a system may provide the ability for a clinician to MAINTAIN data by correcting or annotating it.
Manage (Data)	To handle data by capturing, maintaining, and rendering data, determining actions about data, and managing data visibility. For example, the system may provide the ability for a user to MANAGE patient and family preferences as they pertain to current treatment plans. Another example is that a clinician's system may provide the ability for the clinician to MANAGE patient data by creating a patient's record, updating a clinical note, utilizing clinical decision support tools, and transmitting the patient's billing information.
Manage-Data-Visibility	To MANAGE data by de-identifying/re-identifying, masking/unmasking or hiding/unhiding that data. For example, the system may provide the ability for an administrator to MANAGE-DATA-VISIBILITY in terms of who is allowed to view what specific patient data.
Mask (verb)	To MANAGE-DATA-VISIBILITY by obscuring (masking) specific data elements in order that this information is not available except to authorized users; viewers of the patient record can see that the data exists but cannot see actual contents. For example, the administrator may MASK the pregnancy status of all patients who are below the age of eighteen except for the obstetric unit staff. Note: the verb "unmask" is an acceptable verb to reverse the action of masking.
Present	To RENDER data by delivering the data to local users in a meaningful and appropriate way. For example, the system may PRESENT to a physician (upon manual request) a list of patients who are scheduled for care today, ordered by time-of-day, with the patient's known diagnosis using the physician's preferred terminology and language of choice. Another example is that the system may PRESENT an alert automatically when a newly-arriving laboratory value is received that is out of normal range. Another example is that a system may PRESENT to a physician a patient's lung respiration sounds. Another example is that a system may PRESENT patient-instructions using an audio and video system. Note: It is reasonable to assume that any data that is presented ought to be formatted, filtered, translated, transformed, mapped, and/or normalized, etc., as appropriate.
Pseudonymize	To MAINTAIN data by creating a pseudonym for its subject. For example, the name "Robert Q. Jamison" may be replaced with a pseudonym such as "John Smith" in a health care document before sharing it with others.
Purge	To REMOVE data by making it unrecoverable at the storage and/or media-level. For example, the system may PURGE the patient record for John Smith according to a rule that targets all records that are older than seven years. (Note: Destroy and Purge are synonyms; PURGE is the preferred term.)
Receive	To CAPTURE data from an external source by taking in that data without manual / real-time user intervention. For example, the system may RECEIVE various emails for a clinician who will later review them. Another example is that the system may RECEIVE from authenticated and authorized external systems laboratory results for a given patient. Another example is that the system may RECEIVE a facsimile transmission from an external device.

Action-Verb	Construction
Recover	To STORE data by rebuilding original data using backups of data. For example, the system may RECOVER last week's data following a hard disk failure, using an offsite backup copy. (See BACKUP.)
Re-identify	To MANAGE-DATA-VISIBILITY by combining data in such a way that the patient's identity is re-established according to scope of practice, organizational policy, and/or jurisdictional law. For example, the system may RE-IDENTIFY de-identified data by providing a key that allows authorized users to re-establish the link between a given patient and that patient's de-identified data.
Remove	To MAINTAIN data by making the data inaccessible or unrecoverable according to scope of practice, organizational policy, and/or jurisdictional law. For example, a system may, at a physician's request, REMOVE by purging patient information that was received by mistake. Another example is that a system may, upon request by an administrator, REMOVE by deletion the schedule of outpatient clinic opening hours. NOTE 1: The data may be deleted either by removing the data's pointer from the directory or by overwriting the data in such a way that the original data is unrecoverable. NOTE 2: In the case where the data becomes invalid but needs to remain in the system, the word TAG is preferred over the word REMOVE or "Nullify". This type of action is considered a data "Tagging" process and not a data deletion process. For example, a health information management professional may desire to TAG a certain clinical term as obsolete, but the term needs to remain in the system for backward compatibility purposes.
Remove Access	To MAINTAIN data by disallowing access to the data in such a way as the data can no longer be retrieved.
Render	To MANAGE data by extracting, presenting and transmitting data to users or systems. For example, the system may RENDER a list of patients with a given disease that has been extracted from the clinic's active patient records. For example, the system may RENDER laboratory results by presenting them on a computer screen. Another example is that the system may RENDER data by transmitting a drug prescription to a pharmacy.
Restore	To STORE data to the production system by using previously archived data. For example, the system may RESTORE patient-encounter data for a returning patient whose data had been archived due to inactivity. Another example is that the system may RESTORE, for evidentiary support, patient data that had been archived after the patient expired. (See ARCHIVE.)
Save	To STORE data by placing it onto an electronically-accessible device for preservation. For example, a clinician may SAVE a given patient's demographic data or a newly-prescribed medication. Another example is that an administrator may SAVE an updated list of physicians that have practice privileges at the local hospital.
Secure (System)	To ensure system reliability and integrity by controlling access to system functionality and/or data, tracking activities, and sustaining system operations. For example, the system may provide the ability for an administrator to SECURE a system by setting configuration parameters for controlling access, tracking, and sustaining system operations. Another example is that the system may SECURE access to a patient's record by controlling access to its content, tracking users who have modified the patient's record, and sustaining the record's availability on a continual basis.
Send	To OUTPUT data from the PHR Account Holder's system by exporting it in such a way as to (passively, automatically) route it to another system. For example, a PHR Account Holder's system may (passively, automatically) send weekly reports to a diabetes specialist's system regarding the PHR Account Holder's current weight.
Store	To MAINTAIN data by backing up, decrypting, encrypting, restoring and saving that data onto electronically accessible devices. For example, a clinician may STORE a given patient's demographic data or a newly-prescribed medication. Another example is that an administrator may configure a system to STORE progressive copies of certain data on a regularly-scheduled basis for backup purposes. Note: data may be stored as plain text or in encrypted or compressed form.
Sustain (operations)	To SECURE a system by promoting actions that enable the system to perform predictably and as intended. For example, a system may SUSTAIN (OPERATIONS) by applying business rules that enforce role-based access to the authorization management portion of the system, thus protecting the PHR Account Holder's data according to pre-determined security and privacy rules.

Action-Verb	Construction
Synchronize	To OUTPUT data from the PHR Account Holder's system by exporting it in such a way as to coordinate certain data with another system (or systems). For example, the PHR Account Holder may coordinate the medications prescribed by two physicians with a list of home remedies so that each relevant, authorized stakeholder has a current list of the PHR Account Holder's medications/remedies.
Tag	To UPDATE data by marking it for special use. For example, a nurse may TAG the previous week's records for patients that presented with a severe cough and fever. Another example is that a general practitioner may TAG certain data for review by an oncologist. Another example is that an administrator may TAG an interchange standard version as being deprecated. Note: see "flag" if the meaning is to signal a situation. Note: the verb "untag" is an acceptable verb to reverse the action of tagging.
Track	To SECURE a system by logging and auditing system-initiated and/or user-initiated activities. For example, the system may TRACK the amount of time that the system was unavailable last month. Another example is that the system may provide the ability for an administrator to TRACK the number of active users of a newly-installed set of system functionality.
Transmit	To RENDER data by delivering the data to devices or other systems in a meaningful and appropriate way. For example, the system may (without human intervention) TRANSMIT an alert to a physician's beeper. Another example is that the system may (upon human intervention) TRANSMIT a given patient's encounter summary to an external facility. Another example is that the system may TRANSMIT data to another facility after mapping local codes to national codes. Note: It is reasonable to assume that any data that is transmitted ought to be formatted, filtered, translated, transformed, mapped, and/or normalized, etc., as appropriate.
Unhide	To MANAGE-DATA-VISIBILITY by making visible the existence of previously hidden information (see HIDE). For example, the system may provide the ability for a patient to UNHIDE his psychiatric record, and hence the existence of that part of his record becomes visible to all authorized clinicians.
Unmask	To MANAGE-DATA-VISIBILITY by making masked information visible. For example, the administrator my desire to UNMASK certain patient financial information for the admission Department. For example, a system may provide the ability for an emergency department physician to UNMASK a patient's pregnancy status that was presented by the system as "******", to reveal a status of "Pregnant".
Untag	To UPDATE data by removing marking for special use. For example, a nurse may UNTAG the previous week's records for patients that presented with a severe cough and fever that had been previously tagged. Another example is that a general practitioner may UNTAG certain data after completion of review another provider.
Update	To MAINTAIN data by annotating, editing, harmonizing, integrating, linking and tagging the data. For example, a clinician may UPDATE a patient's medication dosage. Another example is that the system may UPDATE a patient's record.

Table 8: Action Verbs and their Logical Construction

8.4.4 Deprecated Action-Verbs

The use of verbs that are specific in definition and use allows for greater understanding and consistency of conformance criteria throughout the model.

In this Glossary, the term "deprecated" is used to identify Action-Verbs that were used in conformance criteria (in previous FM Releases) but are not part of the updated hierarchy of Action-Verbs. It is recommended that deprecated Action-Verbs not be used in Conformance Criteria.

Table 9 lists a set of deprecated verbs and possible alternatives:

Deprecated Action-Verb	Possible Alternative(s)
Access	Instead, use CONTROL-ACCESS if the context is one of controlling access to the system.. Use RENDER or PRESENT or another relevant Action-Verb when the context is one of accessing data.

Deprecated Action-Verb	Possible Alternative(s)
Affirm	Instead, use TAG (with an appropriate qualifier). Affirm, Assert, Declare, Indicate, and State are synonyms.
Alert	Instead, use “RENDER or PRESENT or TRANSMIT an alert to a person or another system (including a device)”. An Alert typically occurs after analyzing some data and arriving at a decision that someone must be alerted. See DETERMINE for some examples.
Amend	Instead, use EDIT.
Append	Instead, use the term EDIT. This means editing data by adding new data to existing data.
Assert	Instead, use TAG (with an appropriate qualifier). Affirm, Assert, Declare, Indicate, and State are synonyms.
Augment	Instead, use EDIT, ANNOTATE, or LINK with the appropriate qualifiers. Augmentation is the addition of information to existing healthcare data.
Calculate	Instead, use “DETERMINE and STORE” or “DETERMINE and PRESENT”, as appropriate in the context.
Compute	Instead, use “DETERMINE and STORE” or “DETERMINE and PRESENT” as appropriate in the context.
Configure	Instead, use “MANAGE configuration parameters for…”. For example, the user may desire to STORE configuration parameters regarding the preferred type of human language. Another example is that an administrator may UPDATE configuration parameters that control external access to the system by restricting access during the weekends.
Conform	To comply... Note: The verb ‘Conform’ is used with a special meaning in the FM and is not part of the Action-Verb model. It is a special instruction for including the functional requirements of one function in another function. For example: “The system SHALL conform to function IN.1.1 (Entity Authentication)”.
Correct	Instead, use EDIT.
Create	Instead, use “DETERMINE and STORE” or “DETERMINE and RENDER” or “DETERMINE and PRESENT” as appropriate to the context.
Declare	Instead, use TAG (with an appropriate qualifier). Affirm, Assert, Declare, Indicate, and State are synonyms.
Deprecate	Instead, use TAG with an appropriate qualifier. Deprecation of certain information may be required when that data becomes invalid, but needs to remain in the system. For example, a health information management professional may desire to TAG a certain clinical term as deprecated, but the term is retained in the system for backward compatibility purposes.
Destroy	
Disable-Access	Instead, use “CONTROL ACCESS by removing permissions to use specific functionality and/or manage specific data”.
Disclose	Instead, use “RENDER and TAG” with a label that identifies the data’s purpose as “for disclosure use only”.
Display	Instead, use PRESENT.
Document	Instead, use ENTER, or “TAG with” appropriate references, or “LINK to” sources.
Eliminate	Instead, use DELETE or PURGE as applicable.
Export	Use RENDER instead.
Flag	Instead, use “RENDER an alert”, or “PRESENT an alert”, or “TRANSMIT a notice”, if the intent is to signal a situation (i.e. flag a situation).

Deprecated Action-Verb	Possible Alternative(s)
Generate	Instead, use “DETERMINE and STORE” or “DETERMINE and PRESENT” or “DETERMINE and RENDER“ as appropriate to the context.
Grant-Access	Instead, use CONTROL ACCESS.
Identify	Instead, use other Action-Verbs adapted to the context. . For example, instead of ‘…to uniquely identify a patient…’, one should say ‘…to MAINTAIN a unique identifier for a patient…’ Another example is: instead of ‘…to help identify the patient...’, use ‘…help DETERMINE the identity of the patient.’.
Input	Instead, use CAPTURE, ENTER, RECEIVE, IMPORT or AUTO-POPULATE, depending on the context and scope of actions described.
Label (verb)	Use “TAG with a label”.
Merge	Instead, use INTEGRATE.
Modify Access	Instead, use: “MANAGE data regarding permissions”
Notify	Instead, use “RENDER or PRESENT or TRANSMIT a notification to a person or another system (including a device)”.
Nullify	Instead, use “TAG as nullified”.
Obsolete	Instead, use “TAG as obsolete”.
Order	Instead, use “ENTER the parameters for an order”.
Permit Access	Instead, use “AUTHENTICATE a user and AUTHORIZE access based on permissions assigned to that user”.
Persist	Instead, use “STORE“.
Print	Instead, use RENDER, PRESENT, OR TRANSMIT, depending on the context.
Prioritize	Instead, use “TAG with a priority level”, or “DETERMINE priorities”.
Provide access to	Instead, use CONTROL ACCESS, or PRESENT, as appropriate to the specific context.
Query	Instead, use ANALYZE or RENDER (or its children Action-Verbs), because queries or searches are implied when rendering or analyzing data.
Reactivate	Instead, use TAG with an appropriate qualifier. Reactivation of certain information may be required when that data, previously deprecated or made inactive, becomes valid again. For example, a health information management professional may desire to TAG a certain clinical term as reactivated.
Reconcile	Instead, use ANALYZE and DECIDE, or DETERMINE, or HARMONIZE depending on the context and the meaning intended.
Record	Instead, use STORE (or its children Action-Verbs).
Reject	Instead, use ‘’PRESENT or RENDER a message of rejection” or “TAG as rejected”.
Replace	Instead, use EDIT, or “DELETE the old and SAVE the new”, or “TAG as obsolete and SAVE the new”, based on the context.
Report	Instead, use “RENDER a report”, or “PRESENT a report”.
Repudiate	Instead, use “TAG as repudiated or rejected”.
Retain	Instead, use STORE (with the possible addition of language that includes the notion that retention management may be needed to accommodate scope of practice, organizational policy, or jurisdictional law). For example, the system may provide the ability to STORE personal health information, and DELETE that data only as allowed by the organization’s data-retention policies.

Deprecated Action-Verb	Possible Alternative(s)
Revoke-Access	Instead, use “CONTROL ACCESS by eliminating permissions to use system functionality or to manage data”.
Search	Instead, use ANALYZE or RENDER (or its children action-verbs), because queries or searches are implied when rendering or analyzing data. For example, instead of saying “The system SHALL provide the ability to search patient records based on previous names”, one can say ‘‘The system SHALL provide the ability to PRESENT a list of records with possible patient name matches using previous patient names”.
Select	Instead, use “ENTER a selection”.
Sign	Instead, use “TAG-with-authenticated-signature”. For example, a system may TAG a patient note with an authenticated signature when the physician completes the patient’s note.
State	Instead, use TAG with an appropriate qualifier. Affirm, Assert, Declare, Indicate, and State are synonyms.
Support	Instead, use “PRESENT templates to do XYZ”, or DETERMINE, or other Action-Verbs depending on the context and functionality to specify.
Suspend-Access	Instead, use “CONTROL ACCESS by temporarily withholding permissions to use system functionality or to manage data”.
Synthesize	Instead, use “ANALYZE and STORE” or “ANALYZE and PRESENT”.
Trigger	Instead, depending on the context, use “DECIDE on a course of action based on an analysis of certain data and rules”, or “DECIDE and RENDER some information (for example, an alert or a notification) based on the analysis of certain data and rules”.
View	Instead, use PRESENT.
Term	Instead use...

Table 9: Deprecated Action-Verbs and Possible Alternative(s)

8.5 Guidelines for Use (Reference)

Contributors to the contents of the EHR-S and PHR-S FMs must be thoroughly familiar with this ‘Guidelines For Use’ Section. It is critical to the integrity of the FMs that key terms have a consistent meaning throughout each FM specification.

8.5.1 General Guidance

Throughout the EHR-S and PHR-S FMs, terms used for stating Conformance Criteria (CC) must respect meanings as conveyed in the definitions provided in this Glossary. Using the Action-Verbs rigorously will result in clearly written Conformance Criteria (CC) and help ensure consistent communication of functional requirements. Furthermore, combining various functional models and functional profiles is facilitated when a controlled set of terms is used consistently. Therefore, use of synonyms (as replacements) or local jargon should be avoided.

In the FMs, Statements and Descriptions should be written in ‘business-like language’ defining, in business and user terms, system capabilities that support user needs. CCs should be written from the system’s perspective, with rigor and consistency across functional areas, using Action-Verbs and the guidelines; CCs should not be duplicates of the Statements and Descriptions. However, scope-wise, both Statement/Description and corresponding CCs must address the same functionalities.

CCs represent a fundamental component of the FMs by defining its functionalities in precise terms. Significant efforts were invested in developing a set of Action-Verbs with precise definitions that must be used in the construction of CC. The next section provides specific guidance on how CC should be composed.

Since various realms may require the use of certain terms (for example, a term that is embedded in national law), this FM Glossary maintains a realm-independent perspective. The long-term intent is to construct CCs that are computable and easy to validate as to their grammar and contents when it is relevant (i.e., use list of approved Action-Verbs).

8.5.2 Constructing Rigorous Conformance Criteria

Rigor, clarity and consistency in crafting CCs are of paramount importance. The following rules are to be followed whenever possible:

- It is generally preferable to use separate CCs instead of trying to include multiple actions in a single criterion, unless such a combination provides for an economy of statements and is unambiguous.
- Where an action can be performed both automatically by the system and manually upon initiation by the user, CCs should be composed with the “provide the ability to” phrase incorporated.

Selected verbs in conformance criteria should be at the proper level of granularity. If a parent verb in a hierarchy is used, then it means that the actions of all the children verbs under it are pertinent and applicable:

- For example, instead of saying MAINTAIN clinical data which would imply storage, update and deletion of data, one would say STORE and UPDATE data if deletion of data was not allowed.
- For example, if a given CC expects EDIT and TAG to be reasonable application of the function, but that ANNOTATE, HARMONIZE, INTEGRATE, LINK are unreasonable, then the word MAINTAIN should be avoided in lieu of the more precise “EDIT and TAG”.
- An example of multiple Action-Verbs: “The system SHALL provide the ability to CAPTURE, STORE, EDIT, and TAG-as-deprecated entries in an xxx registry or directory to keep it current.”

The general grammar to use in developing rigorous CCs has the following structure:

- “The system [SHALL | SHOULD | MAY] [provide the ability to] [Action-Verb] [functionality object(s)] [participant(s)] [qualifier(s)] [‘according to user preference, scope of practice, organizational policy, and/or jurisdictional law’]”.
- The system is the subject of all the Conformance Criteria.
- [SHALL | SHOULD | MAY]. It is mandatory that one – and only one – of these three qualifier verbs be used. Meanings are defined in EHR-S FM Conformance Clause document and are repeated here for convenience:
  - SHALL – to indicate a mandatory functional requirement to be followed (implemented) in order to conform. Synonymous with ‘is required to’.
  - SHOULD – to indicate an optional yet recommended functional requirement, one that is particularly suitable, without mentioning or excluding others. Synonymous with ‘is permitted and recommended’.
  - MAY – to indicate an optional (permissible) functional requirement. Synonymous with ‘is permitted’.
- [provide the ability to]: optional phrase used to convey when the functional requirement may be either initiated by user action or automatically by system rules. System rules may be configurable.
- [Action-Verb]: mandatory. The Action-Verb must come from the standardized list enumerated in this Glossary and respect the definitions provided. When another verb would appear preferable, it is suggested to look for that verb in the Glossary definition section where it may be listed with suggestions for a replacement verb and composition. This guide provides numerous examples.
- [functionality object(s)]: mandatory. Identifies the object(s) of the functional requirement.
- [participant(s)]: optional. Covers users (or external systems) that participate or are affected by the specified function.
- [qualifier(s)]: optional. This may relate to time, interval, condition(s). Can include (for example): “automatically”, “manually”, “in real time”, “according to the business rules”
- [“according to user preference, scope of practice, organizational policy, and/or jurisdictional law”]: optional, when the action can be governed by relevant practices, policies and/or laws.

Note that “The system SHALL…” means that the system is required to perform the relevant function when all factors and specified conditions are met.

Some examples of rigorous CCs follow:

- The system SHALL provide the ability to PRESENT the list of scheduled patients according to selected criteria such as provider name, dates, time of day, nature of visit, etc. using language of choice.
- IF a provider attempts to prescribe a drug using the system, THEN the system SHALL DETERMINE whether interactions exist between the newly prescribed drugs and the medications on the patient’s current medication list, and RENDER an appropriate response to the provider, according to scope of practice, organizational policy, and/or jurisdictional law.

The verb ‘Conform’ is used with a special meaning in the FM and is not part of the Action-Verb model. It is a special instruction for including the functional requirements of one function in another function:

- For example: The system SHALL conform to function TI.1.1 (Entity Authentication).

9 Glossary Supplement: Record Lifecycle Events and Descriptions (Normative)

Developed (in part) by the HL7 EHR/Security WG Vocabulary Alignment Project

Incorporated in:

HL7 FHIR Core R4 and FHIR Record Lifecycle Event Implementation Guide (RLE IG)

ISO 21089:2018 Trusted End-to-End Information Flows

ISO/HL7 10781:2020 EHR System Functional Model Release 2.1

ISO/HL7 16527:2020 PHR System Functional Model Release 2

9.1 Record Lifecycle Events (See RI.1.1.1)

Access/View Record Lifecycle Event - occurs when an agent causes the system to obtain and open a record entry for inspection or review.

Add Legal Hold Record Lifecycle Event - occurs when an agent causes the system to tag or otherwise indicate special access management and suspension of record entry deletion/destruction, if deemed relevant to a lawsuit or which are reasonably anticipated to be relevant or to fulfill organizational policy under the legal doctrine of “duty to preserve”.

Amend (Update) Record Lifecycle Event - occurs when an agent makes any change to record entry content currently residing in storage considered permanent (persistent).

Archive Record Lifecycle Event - occurs when an agent causes the system to create and move archive artifacts containing record entry content, typically to long-term offline storage.

Attest Record Lifecycle Event - occurs when an agent causes the system to capture the agent’s digital signature (or equivalent indication) during formal validation of record entry content.

Decrypt Record Lifecycle Event - occurs when an agent causes the system to decode record entry content from a cipher.

De-Identify (Anononymize) Record Lifecycle Event - occurs when an agent causes the system to scrub record entry content to reduce the association between a set of identifying data and the data subject in a way that may or may not be reversible.

Deprecate Record Lifecycle Event - occurs when an agent causes the system to tag record entry(ies) as obsolete, erroneous or untrustworthy, to warn against its future use.

Destroy/Delete Record Lifecycle Event - occurs when an agent causes the system to permanently erase record entry content from the system.

Disclose Record Lifecycle Event - occurs when an agent causes the system to release, transfer, provision access to, or otherwise divulge record entry content.

Encrypt Record Lifecycle Event - occurs when an agent causes the system to encode record entry content in a cipher.

Extract Record Lifecycle Event - occurs when an agent causes the system to selectively pull out a subset of record entry content, based on explicit criteria.

Link Record Lifecycle Event - occurs when an agent causes the system to connect related record entries.

Merge Record Lifecycle Event - occurs when an agent causes the system to combine or join content from two or more record entries, resulting in a single logical record entry.

Originate/Retain Record Lifecycle Event - occurs when an agent causes the system to: a) initiate capture of potential record content, and b) incorporate that content into the storage considered a permanent part of the health record.

Pseudonymize Record Lifecycle Event - occurs when an agent causes the system to remove record entry content to reduce the association between a set of identifying data and the data subject in a way that may be reversible.

Re-activate Record Lifecycle Event - occurs when an agent causes the system to recreate or restore full status to record entries previously deleted or deprecated.

Receive/Retain Record Lifecycle Event - occurs when an agent causes the system to a) initiate capture of data content from elsewhere, and b) incorporate that content into the storage considered a permanent part of the health record.

Re-identify Record Lifecycle Event - occurs when an agent causes the system to restore information to data that allows identification of information source and/or information subject.

Remove Legal Hold Record Lifecycle Event - occurs when an agent causes the system to remove a tag or other cues for special access management had required to fulfill organizational policy under the legal doctrine of “duty to preserve”.

Report (Output) Record Lifecycle Event - occurs when an agent causes the system to produce and deliver record entry content in a particular form and manner.

Restore Record Lifecycle Event - occurs when an agent causes the system to recreate record entries and their content from a previous created archive artefact.

Transform/Translate Record Lifecycle Event - occurs when an agent causes the system to change the form, language or code system used to represent record entry content.

Transmit Record Lifecycle Event - occurs when an agent causes the system to send record entry content from one (EHR/PHR/other) system to another.

Unlink Record Lifecycle Event - occurs when an agent causes the system to disconnect two or more record entries previously connected, rendering them separate (disconnected) again.

Unmerge Record Lifecycle Event - occurs when an agent causes the system to reverse a previous record entry merge operation, rendering them separate again.

Verify Record Lifecycle Event - occurs when an agent causes the system to confirm compliance of data or data objects with regulations, requirements, specifications, or other imposed conditions based on organizational policy.

Annex A
(normative)

Function List

Three formats of the EHR-S FM function list are included for the reader's convenience at https://standards.iso.org/iso/10781/ed-1/en They are:

- EHRS_FM_R2_FunctionList.csv,
- EHRS_FM_R2_FunctionList.html, and
- EHRS_FM_R2_FunctionList.pdf.

NOTE Some systems will need a style sheet to render the .html version of the function list. It is also available at https://standards.iso.org/iso/10781/ed-1/en and listed as “fuctional-model.”

Annex B
(informative)
Glossary of Terms for the EHR-S FM

Term	Definition	Reference
Access	1) obtain, open, inspect, review and/or make use of health data or information 2) specific type of interaction between a subject and an object that results in the flow of information from one to the other	CPRI, modified ISO 21089:2018 GCST
Access control	1) means to ensure that access to assets is authorized and restricted based on business and security requirements 2) means to ensure that the resources of an electronic system can be accessed only by authorized entities in authorized ways 3) prevention of an unauthorized use of a resource, including the prevention of use of a resource in an unauthorized manner	ISO/IEC 27000:2009 ISO/IEC 2382-8:1998, modified ISO 21089:2018
Accountability	1) property that ensures that the actions of an entity may be traced uniquely to that entity 2) obligation of an individual or organization to account for its activities, for completion of a deliverable or task, accept responsibility for those activities, deliverables or tasks, and to disclose the results in a transparent manner	ISO/IEC 2382-8:1998 ISO 7498-2:1998, modified ISO 18308:2011 ISO 21089:2018
Accuracy	(data) extent that recorded data reflect the actual underlying information	ISO 21089:2018
Accurate	correct; conformity to truth or to a standard or model	Olsen, Jack E., Data Quality: The Accuracy Dimension, Morgan Kaufmann Publishers, San Francisco, CA, 2003 Merriam-Webster Dictionary
Active order	Active – In a state of action. Order – Request for a specific action.	America Heritage Dictionary, Second College Edition, 1991
Activity	See health care activity	
Actor (in the healthcare system)	1) human, organization, or a system entity that can participate in an action 2) with respect to an action, entity that participates in or observes that action	ISO/IEC 15414:2015, modified ISO 21089:2018
Advanced Directive	a legal document (such as a living will) signed by a competent person to provide guidance for medical and health-care decisions (such as the termination of life support or organ donation) in the event the person becomes incompetent to make such decisions	Merriam-Webster
Adverse reaction	a negative or unexpected reaction to a drug or medical procedure (a reaction can range from mild to life-threatening)	

Adverse sensitivity	a condition expected to result in undesirable physiologic reaction to an amount of a substance that would not produce a reaction in most individuals	
After Action	(review/report) a detailed critical summary or analysis of a past event (such as a clinical intervention) made for the purposes of re-assessing decisions and considering possible alternatives for future reference	
Agent	1) (conscious) entity that takes conscious actions, such as an individual, organization, business unit 2) (delegated) entity that has been delegated (e.g. authority, a function) by and acts for another (in exercising the authority, performing the function) 3) (healthcare) individual, organization, business unit, medical device (e.g. instrument, monitor) and software (e.g. application) which a) performs a role in the provision of healthcare services and/or b) is accountable for actions related to, and/or c) ascribed in, the health record 4) (programmed) entity that takes programmed actions, such as software or a device 5) (responsible) entity that bears some form of responsibility for an activity taking place, for the existence of an entity, or for another agent's activity	ISO 21089:2018 (1,2,4,5) CEN 12265:2014, modified (3)
Aggregate (Population Health context)	the consolidation of information from cohorts of individuals, families, or other groupings that is associated because of similar social, personal, health care, or other needs or interests. Note: aggregate-level data is sometimes de-identified in the Population Health context.	
Aggregate Data	data that has been collected from two or more sources and combined into a single dataset	
Aggregation	process to combine standardized data and information [SOURCE: JCAHO, modified]	ISO 21089:2018 JCAHO
Alert (used as noun)	an indication from a system or device that a condition exists requiring assessment and possible action.	
Allergy	an exaggerated immune response or reaction to a substance that is generally not harmful. The manifestation of an allergy includes a variety of physiologic responses (e.g. rash, itching, hypotension, anaphylaxis) and can be dependent on the route of exposure (inhalation, skin contact, ingestion).	MedLine Plus US National Institute of Health/National Library of Medicine
Anonymize	1) process that removes the association between the identifying data set and the data subject 2) remove personally identifying particulars or characteristics from record content so that the original source or data subject cannot be known	ISO 21089:2018 (2)
API	application program interface: set of routines, protocols, and tools for building software applications. An API specifies how software components should interact.	
Appropriate	suitable or proper in the circumstances	
Architecture	1) structure of components, their inter-relationships, and the principles and guidelines governing their design and evolution over time 2) set of principles on which the logical structure and interrelationships to an organization and business context are based. Note: Software architecture is the result of software design activity 3) set of design artefacts or descriptive representations that are relevant for describing an object such that it can be produced to requirements (quality) as well as maintained over the period of its useful life (change)	The Open Group Architectural Framework (TOGAF):2009 (1) ISO 21089:2018 (2) Zachman - Enterprise Architecture: 1996 (3)

Archive	1) process of moving one or more EHR extracts to off-line storage in a way that ensures the possibility of restoring them to on-line storage when needed without loss of meaning. Wherever possible, archived data should be technology-independent so that future users do not have dependencies on obsolete technology from the past 2) create, update or move an archive artifact with health record content for long-term, typically offline storage, external to the source system	ISO 18308:2011 (1) ISO 21089:2018 (2)
Assessment	1) (in medicine and nursing) an evaluation or appraisal of a condition 2) the process of making such an evaluation 3) (in a problem-oriented medical record) an examiner's evaluation of the disease or condition based on the patient's subjective report of the symptoms and course of the illness or condition and the examiner's objective findings, including data obtained through laboratory tests, physical examination, medical history, and information reported by family members and other health care team members.	Mosby's Medical Dictionary:2009
Associate	to maintain data by updating it in such a way as to draw connections between disparate data; to establish/maintain a relationship between two or more entities	
Assurance	1) (surety) grounds for surety, certainty or confidence about something 2) (security) grounds for confidence that an entity meets its claimed level of protection, including security objectives 3) (system services) development, documentation, testing, procedural and operational activities carried out to ensure a system's services do in fact provide the claimed level of function, performance and usability	ISO/IEC 15408-1:2009, modified (1) OMG, modified (2,3)
Atomic Data Elements	indivisible units of data	
Attest, Attestation	1) affirm, certify and/or authenticate a specific unit of information is true and genuine 2) (authenticity/accuracy) declare that record entry content exists, is authentic, accurate and true and therefore that it can be trusted 3) (completion) declare that record entry content exists and is complete for the purpose intended 4) (evidentiary) provide or serve as clear evidence of and thus certify and record applicable administrative (or “legal”) responsibility for a particular unit of information	ISO 21089:2018 (2,3,4)
Audit	1) mechanism employed to record and examine activities of an agent 2) systematic and independent examination of accesses, additions, or alterations to electronic health records to determine whether the activities were conducted, and the data were collected, used, retained or disclosed according to organizational standard operating procedures, policies, good clinical practice, and/or applicable regulatory requirement(s), and to recommend necessary changes in controls, policies or procedures	ISO 21089:2018 (1)

Audit Trail	1) (evidence of information operations) record that captures details such as additions, deletions, or alterations of information in an electronic record without obliterating the original record. An audit trail facilitates the reconstruction of the history of such actions relating to the electronic record. 2) (evidence of resource utilization) record of the resources which were accessed and/or used by whom 3) (evidence of system use/activities) chronological record of system activities that is sufficient to enable the reconstruction, reviewing and examination of the sequence of environments and activities surrounding or leading to an operation, a procedure, or an event in a transaction from its inception to final results	ISO 7498-2:1998 (2) GCST (3)
Authentic	1) (object, entity, record) is what it purports to be; genuine and of undisputed origin; bona fide; based on facts, accurate and reliable 2) genuine; true; having the character and authority of an original; duly vested with all necessary formalities and legally attested; competent, credible, and reliable as evidence 3) object state or status, deemed present (authentic) or non-present (not authentic), on the basis of a given data object's responses to conformance testing on three questions: a. what does the object provider purport the object to be? b. what is the specification for that object? c. what means are offered to verify that 1=2?	ISO 21089:2018 (1) Downing v. Brown, 3 Colo. 590 (2) thelawdictionary.org (2) Altiglieri, et al, in "Diagnosing and Treating Legal Ailments of the Electronic Health Record: Toward an Efficient and Trustworthy Process for Information Discovery and Release" in The Sedona Conference Journal, Summer 2017, p. 233 (3)
Authenticate, Authentication	1) process proving something is real, true, or genuine 2) (data) process of verification of the integrity of data that have been captured, stored or transmitted 3) (data source) process of corroboration that the source of data received is as claimed 4) (identity of entity) process to provide assurance regarding the claimed identity of an entity (e.g. subject, user, author) 5) (health record entries) process to verify that an entry exists, is complete, accurate and final 6) (object) process to assure the identity of an object 7) satisfaction of the requirement of authenticating or identifying an item of evidence, where the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is	ISO 21089:2018 (1,2,3) ISO/IEC 10181-2:1996, modified (4) JCAHO, modified (5) ASTM E1762: 2013, modified (6) US Federal Rules of Evidence (7)
Authority	body that has legal powers and rights	ISO/IEC 2382-8:1998
Authorize, Authorization	1) granting of rights, which includes granting of privileges to access data and functions 2) prescription that a particular behaviour must not be prevented	ISO 7498-2:1998, modified (1) ISO/IEC 15414:2015 (2)
Authorized User	user who may, in accordance with the Security Policy, perform an operation	ISO/IEC 15408:1999
Automatically	qualifier used to indicate that the action will be done by the system, independently of any user intervention	
Auto-Populate	system process that automatically fills in input fields with data that are already known/available within the systems database	

Availability	1) (accessibility/usability) property of being accessible and useable upon demand by an authorized entity 2) (non-concealment) prevention of the unauthorized withholding of information or resources	ISO 7498 2:1998 (1) ITSEC (2)
Background Process	system processes running behind the scene without human initiation, interaction or intervention. Sometimes employed to perform certain maintenance activities.	Oracle Database Administrator Guidance, modified
Backup	a copy of data for the specific intent of ensuring its preservation and possible restoration in case the original is lost, corrupted, or destroyed	
Behavioral Healthcare	range of services for individuals at risk of, or suffering from mental, addictive, or other behavioral health disorders	SAMHSA
Best practice	practices that incorporate the best objective information currently available regarding effectiveness and acceptability	SAMHSA
Bind, Binding	process of associating two related elements of information. Examples: a) one may bind an author's (digital) signature to the corresponding health record content created by that author; b) one may bind certain metadata to an electronic document; c) one may bind a certain laboratory results (report) to a corresponding laboratory order.	
Boundaries	border or limit	
Business Rule	statement that defines or constrains some aspect of the business, intended to assert business structure, or to control or influence the behavior of the business. Examples include (but are not limited to) coding, billing, claim filing and reimbursement, resource management (personnel, beds, supplies, equipment), workflow optimization, and clinical decision support.	The Business Rules Group:2013
Business Unit	discrete and accountable function or sub-function within an organization. Example: A business unit can include a department, service or specialty within a healthcare provider organization.	ISO 21089:2018
Care	provision of accommodations, comfort and treatment to an individual subject of care (patient); also implying responsibility for safety	JCAHO
Care Guidelines (synonymous with Health Care Guidelines)	1) recommendations offered by a care giver to a patient 2) recommendations recognized by care providers as being appropriate. In general, care guidelines are based on expert knowledge of assessing, treating and/or managing a particular medical condition.	US Agency for Health Research and Quality
Care Plan, Treatment Plan	tool used by clinicians to plan and coordinate care for an individual patient that aids in understanding and coordinating the actions that need to be performed for the subject of care (patient)	
Care Process	task or set of tasks that is/are clinically-oriented; typically comprised of care planning, care delivery, and follow up tasks	
Care Team	group of individuals who provide health care to an individual for a given health care episode, health care setting or with regard to a health condition	
Cascade	something arranged or occurring in a series or in a succession of stages typically such that each stage derives from or acts upon the product of the preceding	
Chain-of-Trust Agreement	statement of requirements that certain administrative procedures will be implemented to guard the integrity, confidentiality and availability of sensitive data, where the sender and receiver agree to protect the data electronically transmitted between them	

Change Log, Change Histry	record of revisions/updates that have occurred over time; a log that can serve as an audit record for activity in a file or record system	
Chronicity	attributes or dimensions that can be associated with a chronic condition, including: a) time period (e.g., childhood, pubescence, constant); b) duration of condition (e.g., brief, extended, sustained, habitual); c) duration of episode (e.g., sleeping hours, self-limiting, consistent); d) level (e.g., mild, moderate, or severe condition or pain); e) and/or periodicity or frequency (e.g., a seasonal allergy).	
Clinical Decision Support	1) use of data to discover, guide and/or justify the proper course of care (or interventions) to support health and health care activities 2) type of system or algorithm (logic) that assists health care providers in making clinical decisions	
Clinical Document, Clinical Documentation	1) documents (records) created in the course of supporting health and providing health care serices; may be used in support of clinical decisions 2) documentation of clinical observations and services, with the following characteristics: a) persistence (a clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements); b) stewardship (a clinical document is maintained by a person or organization entrusted with its care); c) potential for authentication (a clinical document is an assemblage of information that may be legally authenticated); d) wholeness – (authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document); e) human readability (a clinical document is human readable)	
Clinical image	non-textual, pictorial depiction of clinical information (e.g., a radiograph, picture, video, or waveform)	
Clinical information	data related to the health/health care of an individual collected from or about an individual receiving health care services. It may include a caregiver's objective measurement or subjective evaluation of a patient's physical or mental state of health; descriptions of an individual's health history and family health history; diagnostic studies; decision rationale; descriptions of procedures performed; findings; therapeutic interventions; medications prescribed; description of responses to treatment; prognostic statements; and descriptions of socio-economic and environmental factors related to the patient's health.	CPRI:1996 ASTM 1769:1997
Clinical Practice Guideline (CPG)	statement that includes recommendations intended to optimize patient care. It is informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.	Board on Health Care Services, US Institute of Medicine (IOM), National Academies of Science:2011
Clinical process	the set of interrelated or interacting health care activities performed by one or more health care professionals	ISO 18308:2011
Clinician	health professional who delivers health services directly to a patient/client	ISO 12773-1:2009
Clinical tasks	discrete health and health care actions whose results are recorded in clinical documents	
Code set(s)	group of keys or indices used for encoding data elements, such as tables of terms, medical concepts (e.g., medical diagnostic codes or medical procedure codes)	HIPAA:1996, modified ISO 21089:2018
Coding system	organized, managed collection of codes, each of which has associated designations, meanings and in some cases relationships, properties or rules	HL7 Vocabulary Work Group, modified

Coding Scheme	collection of rules that maps the elements of one set on to the elements of a second set. Note: The two sets considered here are: a) a set of 'code meanings' (or 'coded set'), and b) a set of 'code values' (or 'code set'). Those sets are not, per se, part of the coding scheme.	ISO 18308:2011 ISO/IEC 2382-4:1999
Coded	references a vocabulary, code set or value set (e.g., SNOMED, LOINC)	
Cohort	1) group of individuals who share a common exposure, experience or characteristic 2) study group of individuals, some of whom are exposed to a variable of interest, in which subjects are followed over time. Cohort studies can be prospective or retrospective.	American Medical Association
Compendium	(in the context of Pharmacy) collected body of information detailing the standards of strength, purity, and quality of drugs	
Complete Health Record	final, assembled and authenticated, health record for an individual. A health record is complete when a) its contents reflect the diagnosis, results of diagnostic tests, therapy rendered, condition and progress (of the subject of care), and condition (of the subject of care) at discharge, and b) its contents, including any required clinical résumé or final progress notes, are assembled and authenticated, and all final diagnoses and any complications are recorded without use of symbols or abbreviations.	JCAHO ISO 21089:2018
Completeness	(record) extent to which relevant records are present and the fields in each record are populated appropriately	ISO 21089:2018
Concept	unit of knowledge created by a unique combination of characteristics	ISO 18308:2011 ISO 1087-1:2000
Confidentiality	1) (not disclosed) property that information is not made available or disclosed to unauthorized individuals, entities or processes 2) (controlled release) condition in which information is shared or released in a controlled manner 3) (labeling) status accorded to data or information indicating that it is sensitive for some reason, and that therefore it needs to be protected against theft or improper use and must be disseminated only to individuals or organizations authorized to have it 4) (need to know) restriction of access to data and information to individuals who have a need, a reason and permission for access	ISO 13606-4:2019, modified (1) US National Research Council (2) US Office of Technology Assessment (3) JCAHO (4)
Conform	to comply. Note: The verb 'Conform' is used with a special meaning in the FM and is not part of the Verb Hierarchy. Instead it is a special instruction for including the functional requirements of one function in another function. For example: "The system SHALL conform to function TI.1.1 (Entity Authentication)...".	
Conformance	fulfillment of specified requirements by a product, process, or service.	HL7 EHR-S/PHR-S Functional Model Chapter 2: Conformance Clause
Conformance Criteria	statements of requirement indicating the behavior, action, capability that constitutes implementation of the function	HL7 EHR-S/PHR-S Functional Model Chapter 2: Conformance Clause
Conformance clause	section of a specification that defines the requirements, criteria, or conditions to be satisfied in order to claim conformance	HL7 EHR-S/PHR-S Functional Model Chapter 2: Conformance Clause

Conformance statement	statement associated with a specific implementation of a profile of the EHR-S or PHR-S Functional Model.	HL7 EHR-S/PHR-S Functional Model Chapter 2: Conformance Clause
Consent, Informed Consent	1) agreement, approval, or permission as to some act or purpose given voluntarily by a competent person 2) communication process between the caregiver and the (subject of care), and which may refer to consent for treatment, special procedures, release of information and advance directives [which give instructions regarding the (subject of care's) wishes in special medical situations] 3) voluntary agreement with what is being done or proposed (express or implied)	ISO 18308:2011 (1) CPRI (2) Canadian Institute for Health Information (CIHI) (3)
Consumer (in relation to healthcare services)	1) individual who may become a subject of care 2) person who is the receiver of health-related services and who is an actor in a health information system 3) person requiring, scheduled to receive, receiving or having received a healthcare service	ISO 12773-1:2009 (1)
Continuity of Care	component of patient care quality consisting of the degree to which the care needed by a patient is coordinated among practitioners and across organizations and time	ISO 21089:2018
Credentials	1) (identity) data that are transferred to establish the claimed identity of an entity 2) (healthcare practice) documented evidence of (a healthcare professional's) licensure, education, training, experience, or other qualifications	ISO/IEC 2382:2015 (1) JCAHO (2)
Criteria	expected level(s) of achievement, or specifications against which performance can be assessed	JCAHO
Critical Value, Panic Value	diagnostic result (e.g., from laboratory, radiology, pathology) on a patient that must be reported immediately to the care provider and which may require urgent therapeutic action or intervention	
Current medication	1) medication that a patient is actively using, either on a regular basis or on an ad hoc basis (e.g., “two pills as needed for pain”) 2) medication that has been dispensed to a patient and whose administration has not yet been completed according to the medication’s intended duration, dose, frequency, and quantity	
Dashboard	user interface based on predetermined reports, indicators and data fields, upon which the end user can apply filters and graphical display methods to answer pre-determined business questions, which is often intuitive and suited to regular use with minimal training	
Data	(healthcare) information elements which are input, stored, processed or output by the automated information system which support the clinical and business functions of a healthcare organization	
Data aggregation	process by which data is collected, manipulated and expressed in summary form to provide information. Data aggregation is primarily performed for reporting purposes, policy development, health service management, research, statistical analysis, and population health studies.	ISO TS 18308:2011
Data Attribute, Data Element, Data Item	single unit of data that in a certain context is considered indivisible	ISO 21089:2018
Data Consistency	for the uses intended, subject (data) elements that are clear and well defined enough to yield similar results in similar analyses	ISO 21089:2018

Data Enterer	A person who transfers content, written or dictated by someone else, into a clinical document. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own interpretation, and the Data Enterer adds that information to the electronic system. In other words, a Data Enterer transfers information from one source to another (e.g. transcription from paper form to electronic system).	
Data Integrity	1) (non-alteration) property that data has not been altered or destroyed in an unauthorized manner 2) (wholeness) accuracy, consistency and completeness of data/record content	ISO 7498-2:1998 (1) JCAHO, modified (2)
Data Quality	1) degree to which a given data set satisfies the requirements of its intended use 2) aggregate construct composed of conformance with end-use requirements including specifications for accurate, timely, relevant, complete, understood, and trusted 3) fitness for use for a particular task 4) conformance with a specification for a defined end-use	Olsen, Jack E., Data Quality: The Accuracy Dimension, Morgan Kaufmann Publishers, San Francisco, CA, 2003 (1,2) Kahn, MG, Raebel, MA, Glanz, JM, Riedlinger, K and Steiner, JF. A Pragmatic Framework for Single-site and Multisite Data Quality Assessment in Electronic Health Record-based Clinical Research. Med Care. 2012 (3)
Data Reliability	for the uses intended, subject (data) elements that demonstrate accuracy, completeness, integrity, stability, repeatability and precision	JCAHO, modified
Data Transmission	sending of data or information from one location to another location; exchange of data between person and program, or program and program, when the sender and receiver are remote from each other	CPRI JCAHO
Data Validity, Data Validation	1) process used to determine if data are accurate, complete, or meet specified criteria. Note: Data validation may include format checks, completeness checks, check key tests, reasonableness checks, and limit checks 2) verification of correctness (reflecting the true situation)	ISO/IEC 2382-8:1998 (1) JCAHO (2)
Decision support system	See "Clinical Decision Support"	
Decrypt, Decryption	1) process of making encrypted data reappear in its original unencrypted form; reversal of a corresponding reversible encipherment 2) decode or render information readable by algorithmically transforming ciphertext into plaintext	ISO 7498-2:1989 (1) HL7 v3 ObligationPolicy value set, modified (2)
De-identification	process of removing the association between a set of identifying data and the data subject	ISO 25237:2008
Delegate	give authority, function, or responsibility to another	ISO/IEC 15414:2015, modified
Demographic Data	data related to identifying an individual (such as name, date of birth, age, gender, etc.). May also include emergency and other types of contact information for the individual and administrative data (such as health insurance eligibility)	
Deprecate	(data/record content) designate data/record content as obsolete, erroneous or untrustworthy, as indication against its future use	ISO 21089:2018
Derived profile	profile created from an existing profile	HL7 EHR-S Functional Model Chapter 2: Conformance Clause

Destroy	(data/record content) purge or expunge data/record content stored in electronic or magnetic media, typically based on explicit criteria, so that it is completely unreadable and cannot be accessed or used	ISO 21089:2018
Digital Signature	1) electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified 2) data appended to, or a cryptographic transformation of a data unit that allows a recipient of the data unit to prove the source, signer and integrity of the data unit and protect against forgery; this term is usually reserved for digital values or checksums calculated using asymmetric techniques, where only the originator of the message can generate the digital signature but many people can verify it	HIPAA (1) ISO 7498-2:1998, modified (2)
Directive	instruction how to proceed or act	
Directory	index or catalog of entities (e.g., individuals or organizations)	
Disable-Access		
Disclose	release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information	HIPAA
Disclosure	(health information) release of information to third parties within or outside the healthcare provider organization from an individual's (health) record with or without the consent of the individual to whom the record pertains	CPRI
Disease management	system of coordinated healthcare interventions and communications for persons and populations with particular sickness, illness or ailment	
Discrete capture	(data) input of an individual item of data	
Discrete data	data that contains distinct or separate values	
Dispense (a medication)	[See "Fill (a prescription or a medication order)"]	
Document	See "Clinical Document"	
Documentation	process of recording information in the (health) record	JCAHO
Download	to copy or move programs or information into a computer's memory, especially from a large datastore or the internet	
Effectiveness	(of care) degree to which the care is provided in the correct manner, given the current state of knowledge, to achieve the desired or projected outcome for the subject of care (patient)	JCAHO
e.g.	for example ("exempli fratia" in Latin)	
EHR	electronic health record See "Electronic Health Record"	
EHR-S FM	HL7 Electronic Health Record System Functional Model	

Electronic Health Record	1) comprehensive, structured set of clinical, demographic, environmental, social, and financial data and information in electronic form, documenting the health care given to a single individual 2) Information relevant to the wellness, health and health care of an individual, in computer-processable form and represented according to a standardized information model 3) repository of (organized sets of) information regarding the health of a subject of care, in computer processable form 4) a virtual compilation of non-redundant health data about a person across a lifetime, including facts, observations, interpretations, plans, actions, and outcomes. Health data include information on allergies, history of illness and injury, functional status, diagnostic studies, assessments, orders, consultation reports, treatment records, etc. Health data also include wellness data such as immunization history, behavioural data, environmental information, demographics, health insurance, administrative data for care delivery processes, and legal data such as consents	ASTM E1769:1995 (1) ISO 18308:2011 (2) ISO 20514:2015, modified (3) CPRI:1995 (4)
Electronic Health Record Architecture	generic structural components from which all EHRs are built, defined in terms of an information model	ISO 18308:2011
Electronic Health Record System	system for recording, retrieving and handling information in electronic health records	ISO 18308:2011 ISO 13606-1:2019
Electronic Consult (e-Consult), Teleconsultation	healthcare consultation carried out remotely using audiovisual telecommunications between doctor and subject of care (patient)	
Electronic Referral (e-Referral), Tele-referral	an act of referring someone (typically to a specialist) for consultation, review, or further action via an electronic service	
Electronic Signature (e-Signature)	electronic sound, symbol, or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the contract or record	
Employer	in occupational health, the company, organization, or individual that provides compensation (either direct or indirect) for a job, as reported by the person.	HL7 Occupational Data for Health Project
Employment Status	in occupational health, a person's self-reported, coded economic relationship to work (e.g. having one or more jobs) for a specified time period. Generally, employment status refers to whether or not a person has at least one job (i.e., is working for compensation), unemployed (i.e., searching for work for compensation), or not in the labor force (e.g., disabled, chooses not to work, etc.).	HL7 Occupational Data for Health Project
Encounter	interaction between a subject of care (patient) and care provider(s) for the purpose of obtaining and/or providing healthcare-related service(s)	
Encrypt	encode or render information unreadable by algorithmically transforming plaintext into ciphertext where data are temporarily re-arranged into an unreadable or unintelligible form for confidentiality, transmission, or other security purposes	HL7 Version 3 Standard: Security and Privacy Ontology, Release 1, modified

Encryption	process of encoding a message so that its meaning is not obvious	US Office of Technology Assessment
Enterprise	commercial or industrial activity or organization or business that has specific social objectives that serve its primary purpose	
Entity	1) physical, digital, conceptual, or other kind of thing with some fixed aspects, such as a person, body, or object 2) something or someone that has a separate, distinct and identifiable existence; something or someone that has a unique identity (e.g., a person, an organization)	W3C, modified (1)
Entry	[See "Record Entry"]	
Event	1) noteworthy occurrence that has a location in time and space 2) (patient) anything that takes place or happens to the patient or is related to the patient, especially something important such as an incident (e.g. adverse event), procedure or diagnosis 3) (trigger) stimulus that causes a noteworthy change in the state of an object, or a signal that invokes the behaviour of an object	HL7 Reference Information Model (3)
Evidence	1) (demonstrate truth) everything that is used to determine or demonstrate the truth of an assertion 2) (fulfill burden of proof) currency by which one fulfills the burden of proof	ISO 21089:2018
Exchange	(information) act of people and organizations passing information from one to another, especially electronically	
Explicit Consent	permission that is freely and directly given, expressed either viva voice or in writing.	ISO 18308:2011
Externally-Sourced	(information) Refers to an information object captured from outside the immediate system (e.g., EHR system), e.g., faxes, referral authorizations, consultant reports, laboratory results, encounter notes from another healthcare organization	
Extract	1) select, copy out or cite a set of health data/record content, typically based on explicit criteria 2) remove for separate consideration or publication.	ISO 21089:2018
Family History	record of health information about a subject of care's (patient's) close relatives; including e.g., disorders, environment, lifestyle, age at and cause of death	
Fast Track	route, course, or method that provides for more rapid results than usual	
Fetal Death	Death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy and which is not an induced termination of pregnancy. The death is indicated by the fact that after such expulsion or extraction, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.	
Fill (a prescription or a medication order)	assign, count, label, and disburse/transport dose(s) of a medication in preparation for administration to a subject of care (patient). Note: In the FM the term "fill" represents the combined notions of medication filling and prescription.	
Filter	ability to programmatically separate and constrain data into specific value sets	
Flow Sheet	tabular summary of information that is arranged to display the values of variables as they change over time	CEN TC251

FM	functional model, (i.e., HL7 Electronic Health Record System Functional Model, HL7 Personal Health Record Functional Model)	
Formulary	preferred list of drug products that typically limits the number of medications available within a therapeutic class for purposes of purchasing, ordering, dispensing, administration and reimbursement. A government body, third-party insurer or health plan, or a provider organization may compile a formulary and its constraints may be mandatory.	
Function	1) computation which takes some arguments or inputs and yields an output; any particular input yields the same output every time. 2) subroutine (software process) which returns a value	
Generic Orders	general diagnostic or treatment orders	
Genotype	1) genetic makeup, as distinguished from the physical appearance, of an organism or a group of organisms 2) combination of alleles located on homologous chromosomes that determines a specific characteristic or trait	American Heritage Science Dictionary:2005
Genetic Disorder (also Genetic Illness, Inherited Disorder)	disease or condition caused by an absent or defective gene or by a chromosomal aberration (e.g., Down Syndrome)	American Heritage Science Dictionary:2005
Guidelines	1) indication or outline of recommendations (e.g., for use/guidance in clinical practice) 2) systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances	
Health Care, Healthcare	activities, services, or supplies related to the health of an individual, including: a) preventative, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, counselling, service, or procedure with respect to the physical or mental condition, or functional status, of a patient or affecting the structure or function of the body; b) sale or dispensing of a drug, device, equipment, or other item pursuant to a prescription; or c) procurement or banking of blood, sperm, organs, or any other tissue for administration to patients	HIPAA ISO 18308:2011 ISO 21089:2018
Health Care Activity, Healthcare Activity	undertakings (such as assessments, interventions) that comprise a healthcare service	ISO 12773-1:2009
Health Care Agent, Healthcare Agent	See "Agent"	
Health Care Informatics, Healthcare Informatics	scientific discipline that is concerned with the cognitive, information processing and communication tasks of healthcare practice, education and research, including the information science and technology to support these tasks	Directory of the European Standardization Requirements for Healthcare Informatics and Telematics v2.1

Health Care Organization, Healthcare Organization	See "Health Care Provider"	
Health Care Party, Healthcare Party	Individual or organization involved in the process of health care	ISO 18308:2011
Health Care Professional, Healthcare Professional	1) (care provision) individual who is entrusted with the direct or indirect provision of defined healthcare services to an individual subject of care or to populations 2) (qualification) person that is authorized by a nationally recognized body to be qualified to perform certain health services. Note: The types of registering or accrediting bodies differ in different countries and for different professions. Nationally recognized bodies include local or regional governmental agencies, independent professional associations and other formally and nationally recognized organizations. They may be exclusive or non-exclusive in their territory. Examples of health professionals are physicians, registered nurses and pharmacists.	ISO 21089:2018, modified (1,2) CEN 1613:1994, modified (1,2)
Health Care Provider, Healthcare Provider	1) individual or organization licensed, certified or otherwise authorized or permitted to, directly or indirectly, administer or provide health care services, to individuals (patients) or populations, in the ordinary course of business or practice of a profession, including a health care facility 2) generic term used to describe many types of organizations that provide healthcare services	ISO 13606-4:2019, modified (1) ISO 18307:2001, modified (2) JCAHO, modified (2)
Health Care Service, Healthcare Service	service provided (by a health care provider) with the intention of directly or indirectly improving the health of the person or populations to whom it is provided	ISO 12773-1:2009
Health Condition	aspect of a person or group's health that may require some form of intervention. Note: These interventions can be anticipatory or prospective, such as enhancing wellness, wellness promotion or illness prevention (e.g., immunization), also symptoms, health problems (not yet diagnosed), diagnoses (known or provisional), e.g., a) diabetes, or physiological changes that affect the body as a whole or one or more of its parts, b) benign positional vertigo, and/or affect the person's well-being, c) psychosis, and/or affect the person's usual physiological state, d) pregnancy, lactation.	ISO 12773-1:2009
Health Information	1) information about a person relevant to his or her health 2) any information, whether oral or recorded in any form or medium, that a) is created or received by a healthcare provider, health plan, public health authority, employer, life insurer, school or university, or healthcare clearing-house; and b) relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual	ISO 18308:2011 (1) HIPAA (2)
Health Insurance Carrier, Health Plan, Payer	individual or group plan that provides, or pays the cost of, medical care; may be public or private entity	HIPAA, modified
Health Issue	concern or situation related to the health of a subject of care, as identified or stated by a specific health care party	ISO 18308:2011, modified

Health Record	account compiled by healthcare providers of a variety of subject of care (patient) health information, such as assessment findings, treatment details and progress notes	JCAHO, modified
Health Record Entry	See "Record Entry"	
Health-related Factors, Social Determinants of Health	1) circumstances, influences, causes or issues that affect or describe a patient's ability to receive or respond to treatment, or maintain wellness (including physical, mental, social, spiritual, community, and/or economic dimensions). A patient's strengths (positive factors) or weaknesses (negative factors) may impact a patient's care or recovery and may be recorded as part of the EHR to support the development of care plans and treatment options (e.g. coverage by insurance (typically a positive factor) versus unemployment (typically a negative factor). Examples of factors include: family support, financial support, health insurance levels, good overall health, employment status/type, access to care, and education level. Heath-related factors may be included in a patient's problem list (e.g. ambulatory status, or addictions). 2) conditions in the places where people live, learn, work, and play affect a wide range of health risks and outcomes	CDC:2018 (2)
Identifier	1) (claimed) piece of information used to claim an identity, before a potential corroboration by a corresponding authenticator 2) (unique) identity information that unambiguously distinguishes one entity from another one in a given identity domain	ISO 13606-1:2019, modified (1) ISO 21089:2018
i.e.	that is to say or in other words ("id est" in Latin)	
Immunization History	history of immunization (vaccination) events for a subject of care (patient)	
Implied Consent	consent inferred from signs, actions, or facts, or by inaction or silence	ISO 18308:2011
Including	indicates a minimum set of values or options which must be instantiated	
Indelible	impossible to remove or erase	ISO 21089:2018
Individually Identifiable Health Information	information, including demographic information collected from an individual, that a) is created or received by a healthcare provider, health plan employer, or healthcare clearing-house; and b) relates to the past, present or future physical or mental health or condition of an individual, the provision of healthcare to an individual, or the past, present, or future payment for the provision of healthcare to an individual, and i) identifies the individual, or ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual	HIPAA
Industry	in occupational health, self-reported title (with associated code) that identifies the kind of business (i.e., primary business activity), conducted by a person's employer.	HL7 Occupational Data for Health Project
Information	interpreted set(s) of data that can assist in decision making; data to which meaning is assigned, according to context and assumed conventions	JCAHO, modified US National Security Council, modified
Integrity	(message) proof that message content has not altered, deliberately or accidentally in any way, during transmission See also "Data Integrity"	ISO/IEC 7498-2:1998

Interchange standards	standards specifying the form(s), method(s) and mechanisms by which information, typically electronic data, are exchanged	
Internet Engineering Task Force (IETF)	large open international community of network designers, operators, vendors, and researchers concerned with the evolution of the Internet architecture and the smooth operation of the Internet	
Interoperability	1) (semantic) ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged 2) (standards-based) ability for data to be shared across clinicians, laboratory, hospital, pharmacy and patient, facilitated by data exchange schema and standards, regardless of the application or application vendor; also, ability of health information systems to work together within and across organizational boundaries in order to advance the health status of, and the effective delivery of healthcare for, individuals and communities.	IEEE:1990, modified (1) ISO 21089:2018 (1,2)
Interoperate, Interoperation	coordinate information, services, and/or functionality among systems	
Interpretation	conclusion that a health care provider (or possibly machine - in the form of clinical decision support) comes to based upon knowledge and scrutiny/analysis of information available (e.g., in the course of diagnosis/treatment of a subject's (patient's) condition	
Intervention	1) action(s) whose purpose is to improve health or to alter the course of a disease 3) action(s) taken to maximize the prospects of achieving goals of care, including the removal of barriers to success	
Input mechanism	approach, typically utilizing a user interaction device, for data input, (e.g., keyboard and mouse)	
Intolerance	non-immunological adverse physiological sensitivity to a substance; may be manifest by an inability to endure, withstand, absorb, or metabolize a substance (e.g. lactose)	
Jurisdictional Law	statute and/or legal requirement of a domain or realm	
Legal Hold, Litigation Hold	operation that tags or otherwise cues special access management and destruction suspension for Record Entries deemed relevant, consistent with organization policy under the legal doctrine of “duty to preserve”, also notifying records owners and other designated parties of the special data controls on access, retention, and destruction processes	ISO 21089:2018
Legal Hold Release, Litigation Hold Release	operation that untags or otherwise removes cues for special access management and destruction suspension for record entries as organization policy had required under the legal doctrine of “duty to preserve”, also notifying records owners and other designated parties of the release of special data controls and that the organization will resume normal data retention and destruction processes; provide notification to the records owners of the release of data and that the organization will resume normal data retention and destruction processes	ISO 21089:2018
Lifecycle	(record entry) stages during the lifespan of a health record entry instance	ISO 21089:2018
Lifecycle Event	(record entry) operation occurring during the course of record entry instance lifespan such as: originate, retain, amend (update), attest, exchange (transmit, receipt), access/view	ISO 21089:2018
Lifespan	(record entry) period of time from the point of record entry instance origination to the point of record entry instance loss, destruction or deletion	ISO 21089:2018

Link	(record entries) perform an operation that connects (establish a relationship between) two or more separate but related health records so that access or use of one necessarily means equal access to ability to use of all the connected records	ISO 21089:2018
Logical Record	reference to a data record that is independent of its physical location; may be physically stored in two or more locations	
Longitudinal Personal Health Record, Lifetime Personal Health Record	permanent, coordinated record of significant information, in chronological sequence; may include all historical data collected or be retrieved as a user designated synopsis of significant demographic, genetic, clinical and environmental facts and events maintained within an automated system	ASTM E1384:2013
Maintain	keep, preserve and support	
Manage	take charge of; master	
Management	conducting, administering, supervising	
Mask. Masking	1) conceal from view, disguise or hide 2) process of obscuring (masking) specific data elements within data stores. It ensures that sensitive data is replaced with realistic but not real data. The goal is that sensitive customer information is not available outside of the authorized environment. Effective data masking requires data to be altered in a way that the actual values cannot be determined or reengineered, functional appearance is maintained, so effective testing is possible.	
Master File	dataset containing definitional entries in common across system, business units and, in some cases, organizational boundaries (e.g., master files may include data group and attribute definitions, security policy and domain definitions, security classification and clearance definitions, healthcare service definitions, care protocol definitions)	ISO 21089:2018
Master Patient Index	catalog within a given healthcare organization which serves as a directory to patients (subjects of care)	CPRI, modified
MAY	indicates an optional, permissible action	
Measure	collect quantifiable data about a function or process	JCAHO
Medical	relating to the study or practice of medicine	
Medication reconciliation	comprehensive evaluation of a patient's medication regimen any time there is a change in therapy in an effort to avoid medication errors (e.g., omissions, duplications, dosing errors, or drug interactions), and to observe the patient's medication compliance and adherence patterns. The medication reconciliation process should include a comparison of the existing and previous medication regimens and should occur at every transition of care in which new medications are ordered, existing orders are rewritten, existing orders are adjusted, or if the patient has added nonprescription medications to [his or her] self-care.	American Pharmacists Association
Merge	(record entries) perform an operation that combines or joins the content of two or more health records, resulting in a single logical record entry (e.g., includes health records found to be registered as separate patients but are really one)	ISO 21089:2018
Message	logically ordered dataset designed to communicate essential information between systems	ISO 21089:2018

Messaging Standard	in the context of Health IT, specifies the structure and format of electronic data exchange, enabling disparate healthcare applications to exchange key sets of clinical and administrative data	HL7
Metadata	data that define and describes other data	ISO/IEC 11179-3:2003 ISO 1087-1:2000
Need-to-Know	requirement for access to, knowledge, or possession of the classified information in order to perform tasks, functions or services	ISO/IEC 2382:2015, modified
Network	electronic data transmission facility which can comprise just a point-to-point wire link between two devices, or a complex arrangement of transmission lines	ISO 21089:2018
Non-repudiation	(of origination, of submission, of receipt) service that provides proof of the integrity and source of data (both in an unforgeable relationship) and that only the signer can have created the associated signature, which can be verified by any party	ASTM E1762:2013, modified
Notes	brief record of facts, topics, or thoughts, often captured as an aid to memory; clinical documents are forms of clinical notes	
Notice, Notification	information presented or transmitted to an interested party; may not require recipient's action or response	
Obfuscation	action of making something obscure, unclear, or unintelligible	
Occupation	in occupational health, self-reported title (with an associated code) that identifies a person's type of work, i.e., the set of activities or tasks that a person is paid to perform or, if unpaid, the person's contribution to a household/family business/community	HL7 Occupational Data for Health Project
On-Demand	as soon as or whenever required	
Order	prescription of a qualified health care professional regarding diagnostic testing and/or treatment of a subject of care (patient)	
Order sets	1) pre-defined template that provides support in making clinical decisions for a specific condition or medical procedure 2) a grouping of orders that standardizes and expedites the ordering process for a common clinical scenario	
Originate	(record entry) create or initiate an entry in a persistent datastore, such as an electronic or personal health record (EHR/PHR)	ISO 21089:2018
Organization	unique framework of authority within which a person or persons act, or are designated to act towards the same purpose	ISO 6523:1998
Organizational Policy	generally adopted by a governance body within an organization: 1) deliberate system of principles to guide decisions and achieve rational outcomes 2) statement of intent, typically implemented as a procedure or protocol	
Outcome	1) result of the performance (or non-performance) of a function or process(es) 2) condition or occurrence traceable to a cause	JCAHO, modified
Output	produce and deliver health record content in the form and manner expected by a viewer or recipient (e.g., printout, visual rendering, tagged or delimited data stream)	ISO 21089:2018
Party	natural person or any other entity considered to have the same rights, powers and duties of a natural person	ISO/IEC 15414:2015

Patient	1) subject of care 2) individual who is receiving or registered as eligible to receive healthcare services or having received healthcare services	ISO 21089:2018, modified (2)
Patient and Family Preferences	health care treatment choices influenced by but not limited to language, religious, or cultural preferences selected by the subject of care (patient) and his/her family	
Patient Identifier	set of data that is used for uniquely distinguishing one patient from another patient	
Patient Record	See "Health Record"	
Patient Representative	designated to bearing the character or power of the patient; acting for the patient's benefit, e.g. guardian, legal representative, surrogate, or advocate	UK CancerWeb
Patient Safety	See "Safety"	
Patient-Level Data	within the context of the Population Health arena, refers to data that is collected (and analyzed) regarding a single patient (e.g., "Person123 is left-handed"). Note: patient-level data may be de-identified.	
Patient-Originated Data	Data provided and/or entered by the subject of care (patient), e.g., an individual (or their representative) may provide or enter health information from personal memory and/or by using information that was recorded on a piece of paper	American Academy of Pediatrics:2011
Performance	way in which an individual, group or organization carries out, accomplishes and fulfils its important functions and processes, usually with regard to effectiveness	JCAHO, modified
Performance Indicator, Performance Measure	standard or criteria used to assess the capabilities of functions, processes and outcomes within an organization; quantification of processes and outcomes using one or more dimensions of performance, such as timeliness or availability.	JCAHO, modified
Permission (Parental)	affirmation or agreement, provided by the parent or guardian of a patient, to undertake a clinical action; in most cases, clinicians have an ethical (and legal) obligation to obtain parental permission to undertake recommended medical interventions See also "Consent, Informed Consent"	American Academy of Pediatrics:2011
Persistent	1) data in a final form intended as a permanent record, such that any subsequent modification is recorded together with the original data 2) existing or remaining in the same state for an indefinitely long time	ISO 21089:2018 (2)

Pesonal Health Information (PHI)	1) information about an identifiable person which relates to the physical or mental health of the individual, or to provision of health services to the individual, and which may include: a) information about the registration of the individual for the provision of health services; b) information about payments or eligibility for healthcare with respect to the individual; c) a number, symbol or particular assigned to an individual to uniquely identify the individual for health purposes; d) any information about the individual collected in the course of the provision of health services to the individual; e) information derived from the testing or examination of a body part or bodily substance; f) identification of a person (e.g. a health professional) as provider of healthcare to the individual 2) information that concerns a person's health, medical history, medical treatment or genetic characteristics in a form that enables the person to be identified	ISO 27799:2008 (1) MEDSEC (2)
Personal Health Record (PHR)	health record, or part of a health record, for which the subject of care or a legal representative of the subject of care is the data controller	ISO 18308:2011
Phenotype	physical appearance of an organism as distinguished from its genetic makeup; the phenotype of an organism depends on which genes are dominant and on the interaction between genes and environment	American Heritage Science Dictionary:2005
PHR	personal health record See "Personal Health Record"	
PHR-S FM	HL7 Personal Health Record System Functional Model	
PHR Account	1) provides the PHR Account Holder with: a) access to his or her personal health data and b) access to the functions of a PHR system 2) conceptually similar to a bank account (e.g., health record bank), which provides controlled access to data and to the functions of the system in which the data are stored; may be hosted on a stand-alone personal computer, within an EHR system (i.e., as a portal), a web-based system, or other portable electronic device	
PHR Account Holder	1) subject of the PHR Account, controls access to and permissions of the PHR Account, and controls the movement of data in and out of the PHR Account 2) synonymous with the terms “patient” or “consumer.” Note: In certain PHR Account matters related to decision making, the term PHR Account Holder is also meant to include the PHR Account Holder Proxy, as he or she may be the PHR Account Holder’s substitute decision maker.	
PHR Account Holder Proxy	person who is appropriately authorized to act on behalf of the PHR Account Holder within the PHR Account; can be a family member, friend or substitute decision maker	
PHR Application	set of software that offers PHR functionality and related services to PHR Account Holders through individual PHR Accounts	

PHR Authorization	permission granted by a PHR Account Holder to an Authorized PHR User to use function(s) of the PHR System for intended and permitted purposes. PHR Authorizations may be to specific individuals or to specific remote computer systems. PHR Authorizations also may be role-based, i.e., granted to a class of individuals or a class of remote computer systems. PHR Authorizations may include varying levels of access, e.g., “read-only,” “write-only,” “read/write,” etc. The exact permissions and levels of PHR Authorizations may vary based on different PHR Sponsors and PHR Service Providers.	
PHR Service Provider	organization that delivers PHR Application(s) to PHR Account Holders. A PHR Service Provider may offer PHR Applications directly to PHR Account Holders or indirectly via contracted PHR Sponsors. PHR Service Providers are often PHR system vendors, enabling the distinction between direct PHR Application providers and third-party sponsors (such as physician offices or hospitals). See "PHR Sponsor".	
PHR Sponsor	entity that provides PHR Account Holders access to a given PHR Application (e.g., a physician office, a health system, an employer, a pharmacy, a health plan). A PHR Sponsor may not necessarily be the same entity as the PHR Service Provider.	
Policy	1) set of rules related to a particular purpose. A rule can be expressed as an obligation, an authorization, a permission or a prohibition. 2) formal, approved description of how a governance, management of clinical care process is defined, organized and carried out	ISO/IEC 15414:2015 (1) JCAHO (2)
Population Health	1) art, process, science and a product of enhancing the health condition of a specific number of people within a given geographical area 2) health outcomes of a group of individuals, including the distribution of such outcomes within the group	
Practice Guideline	See "Guideline"	
Prevention	actions taken to: 1) reduce susceptibility or exposure to health problems (primary prevention) 2) detect and treat disease in early stages (secondary prevention) 3) alleviate the effects of disease and injury (tertiary prevention)	
Primary Record	records captured and maintained for the chief purpose of: a) supporting individual health and providing healthcare; b) clinical use including care, interventions and decision making	ISO 21089:2018
Principal	highest in rank, authority, character, importance, or degree; most considerable or important; chief; main (e.g., principal diagnosis)	
Principal provider	healthcare provider who is the most responsible and accountable for managing or coordinating the members of a care team(s) that deliver health care to an individual	
Principle	an accepted or professed rule of action or conduct, an adopted rule or method for application in action	

Privacy	1) quality or state of being hidden from, or undisturbed by, the observation or activities of other persons 2) 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 about that individual and the ability of an individual or group to seclude themselves, or information about themselves, and thereby express themselves selectively 3) right of individuals to keep information about themselves from being disclosed to anyone 4) (information practices) security principle that protects individuals from the collection, storage and dissemination of information about themselves and the possible compromises resulting from unauthorized release of that information	AHIMA, modified (1,2,3) ISO/IEC 2382-8:2015, modified (2,3) HL7 Security Work Group (4)
Problem	(clinicial) issue for which an assessment is made and a plan or intervention is initiated	ISO 12773-1:2009, modified
Problem List	1) list that includes the most important health problems facing a subject of care (patient) such as nontransitive illnesses or diseases and injuries suffered; may include signs and symptoms 2) list of a patient's problems that serves as an index to his or her record 3) list of current and active diagnoses as well as past diagnoses relevant to the current care of the patient	US Centers for Medicare and Medicaid Services (CMS) (3)
Process	sequence of goal-directed, interrelated series of actions, events, mechanisms, or steps taking place in a prescribed manner and leading to the accomplishment of some result	ISO/IEC 15414:2015, modified
Profile	(EHR or PHR System) Functional Model subset, in which functions have been designated for particular purposes, domains, services, specialties or care settings. A Functional Profile (FP) allows selection of functions and conformance criteria from the base FM, as well and revisions and extensions to those functions and criteria.	HL7 EHR/PHR System Functional Model Chapter 2: Conformance Clause
Protocol	1) (care) written plan specifying the procedures to be followed in giving a particular examination, conducting research, or providing care for a particular condition 2) set of instructions that describe the procedure to be followed when investigating a particular set of findings for a subject of care (patient), or the method to be followed in the management of a given disease	ISO 21089:2018 (1)
Provide the ability to ...	phrase that conveys the notion that the corresponding FM-specified system functionality will enable a user to perform a given task, rather than having the system perform the task itself (i.e., without user intervention)	
Provider	See "Health Care Provider"	
Pseudonymize, Pseudonymization	1) removal of individually identifiable data/record content by replacing with identity-bearing content for another entity 2) sub-class of de-identification which can be performed with or without the possibility of re-identifying the subject of the data/record content	ISO 25237:2017, modified ISO 21089:2018, modified
Public Health	1) area of health care that deals with the health of populations in geo-political areas, such as States and counties 2) field of medicine concerned with safeguarding and improving the health of the community as a whole	Dorland's Medical Dictionary
Purpose	1) (of use) context and conditions of data/record use at a specific point in time, and within a specific setting 2) (of a system) practical advantage or intended effect of the system	ASTM 1986:2013, modified (1) ISO/IEC 15414:2015 (2)

Quality	1) character, characteristic or property of anything that makes it good or bad, commendable or reprehensible, thus the degree of excellence that a thing possesses 2) totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs or fitness for use.	JCAHO, modified CEN TC251, modified
Quality Improvement	approach to the continuous study and improvement of the processes of providing healthcare services to meet the needs of patients and others	JCAHO
Reactivate	(record entry) recreate or restore full status to health records and their content from a previous state of deletion or deprecation	ISO 21089:2018
Real-time	actual time during which something takes place; the system may partly analyze the data in real time (as it comes in)	
Receive	capture an exchange artifact (e.g., message, document, API resource) from an external system or entity (e.g., acquire data objects that exist elsewhere for potential inclusion in an EHR or PHR record)	ISO 21089:2018
Recommendation	a suggestion or proposal as to the best course of action, especially one put forward by an authoritative body See "Guidance"	
Record	See "Health Record"	
Record Entry	1) (evidentiary) persistent documentation, recording or evidence of facts, context, findings and observations, with associated supporting system data or metadata, regarding an action taken to support individual health or provide healthcare 2) (indivisible notation) semantically indivisible clinical statement which may be structurally large or small, but which loses meaning if broken up 3) (instance) discrete notation, recording instance or dataset in (EHR/PHR/other) system datastore, suitably attributed, which forms part of, or a whole, contribution to a health(care) record at one place and time	ISO 21089:2018 (1,2) ISO 18308:2011, modified (3) ISO 13606-2:2019, modified (3)
Registry	1) directory-like system that focuses solely on managing data pertaining to one conceptual entity 2) server capable of holding data for the systematic and continuous follow up of information objects maintained in accordance with specific rules	Canada Health Infoway (1) ISO 21089:2018
Re-identify	restore information to data that would allow the identification of the source of the information or the information subject	HL7 Version 3 Standard: Security and Privacy Ontology, Release 1
Release of Information	disclosure of documents containing (subject of care-) identifiable information to a third party requestor	CPRI
Reminder	type of notification that is specifically to prompt the recipient with information they may have previously received (e.g. an appointment reminder); distinct from an alert, where immediate action is required	
Report	1) make or present an official or formal account or summary of 2) formal rendering (e.g., document) that gives information about a particular subject	ISO 21089:2018
Repudiate, Repudiation	denial by a user or a system that it was the source of certain information or the sender or receiver of a message or the agent of an action requested from the system	ASTM E1762:2013, modified
Resource	entity which is essential to some behaviour and which requires allocation or may become unavailable because it is in use or used up	ISO/IEC 15414:2015

Resource Utilization	1) process of making the best use of available resources in order to achieve a particular objective 2) total amount of resources consumed, compared against the amount of resources planned for a specific process	
Restore	1) (record entry) recreate record entries and their content from a previously created archive artifact 2) produce another object with the same content as one previously backed up (i.e., recreate a readily usable copy) or reinstate an information system back to an error-free and secure state from which normal operation can resume	ISO 21089:2018 HL7 Version 3 Standard: Security and Privacy Ontology, Release 1
Result	1) conclusion or end to which any course or condition of things leads, or which is obtained by any process or operation 2) set of information including all essential or useful data relevant to the outcome of an analytical investigation and corresponding procedure (e.g., diagnostic findings)	
Retain	(record entry) store and maintain (in a persistent datastore) health records after their point of origination, update, receipt, re-identification, restoration, decryption, etc.	ISO 21089:2018
Retention	maintenance and preservation of information in some form (e.g. paper, microfilm, or electronic storage) for a given period of time	CPRI
Role	function or responsibility assumed by a person in the context of a health care event	
Safety	1) (normative) quality of a product to meet applicable standards and practices for design, construction or manufacture 2) (patient) prevention of accidental or preventable injuries and mitigation of harm caused by errors of omission or commission that are associated with healthcare, and involving the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur 3) (perceived) users' level of comfort and perception of risk	ISO 21089:2018 (1,2,3) US National Quality Forum (2)
Save	keep (data) by moving a copy to a storage location	
Scope of Practice	services that a qualified health professional is deemed competent to perform, and permitted to undertake in keeping with the terms of their professional license	
Seamless	smooth and continuous, with no apparent gaps or spaces between one part and the next; perfectly cosistent and coherent	
Secondary Data	1) record that is derived from the primary record and contains selected data elements 2) record that is derived/extracted from the primary record for specific purposes of use	ASTM E1384:2013
Security	1) (data) combination of availability, confidentiality, integrity and accountability including protection of data from intentional, accidental or unintentional alteration or destruction, or copying or disclosure to unauthorized persons, whether in storage, processing, or transit 2) (system safeguards) result of effective protection measures including safeguards for protection of information systems against software deficiencies, operating mistakes, or sabotage, against the denial of service to authorized users or the provision of service to unauthorized users, including those measures necessary to detect, document and counter such threats	CEN 13608-1:2005 (1) JCAHO (1) MEDSEC, modified (1) US National Security Council (2) US Institute of Medicine (2)

Security Policy	1) (information) set of laws, rules, and practices that regulate how an organization manages, protects and distributes sensitive information 2) (system) plan or course of action adopted for providing computer security including a statement of information values, protection responsibilities and organization commitment for a system	US Department of Defense (1) ISO/IEC 2382:2015 (2) US Office of Technology Assessment (2)
Send	See "Transmit"	
Severity Level	signal of urgency or escalation; relative impact of a situation; may be used by people responding to an incident as a way to describe their current assessment of a situation to relay to others	
Semantic interoperability	See "Interoperability"	
SHALL	Indicates a mandatory requirement to be followed (implemented) in order to conform. Synonymous with “is required to”.	HL7 EHR-S Functional Model Chapter 2: Conformance Clause
SHOULD	Indicates an optional yet recommended action, one that is particularly suitable. Synonymous with “is permitted and recommended”.	HL7 EHR-S Functional Model Chapter 2: Conformance Clause
SIG	instructions that direct a patient regarding the recommended use of a medication (abbreviation for Signetur – “Let it be labeled” - in Latin)	
Single Logical Patient Record	See "Logical Record"	
Situational Criterion	criterion that is required if the circumstances given are applicable	HL7 EHR/PHR Syste Functional Model Chapter 2: Conformance Clause
Social Determinants of Health	See "Health-related Factors"	
Specialized Views	customized view which may be based on encounter specific values, clinical protocols and business rules	
Standard	1) document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. Note: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits. 2) technical specification which addresses a business requirement, has been implemented in viable commercial products, and, to the extent practical, complies with recognized standards organizations such as ISO	ISO/IEC Guide 2 (1)
Standards of Practice	specification (guiding principles) that describe responsibilities and define safe practice, including: professional standards, ethical guidelines, entry-level competencies, provincial/regional regulations, standards of care, and practice guidelines See "Guidelines" and "Safety"	
Store	See "Save"	
Structured Data	data that can be slotted into discrete fields and enumerated or codified	

Subject of Care	one or more individuals scheduled to receive or who are receiving or have received health care services. Note: The terms “patient” and “client” are synonymous with subject of care in a health record context and are commonly used instead of the more formal term “subject of care”.	ISO 12773-1:2009, modified ISO 13606-1:2018. modified
Suitable	possessing the qualities that are right, needed, or appropriate for the task or use	ISO 21089:2018
Summary	abbreviated version of something that has been said or written, containing only the main points	
Syntactic Interoperability	See "Interoperability"	
Systematic	pursuing defined objective(s) in a planned, step-by-step manner	JCAHO
Task	Unit of work. A task (in health care) may be a clinical task (i.e., a task that occurs as part of the process of providing care for a patient) or a non-clinical task (e.g., an administrative task such as updating the list of providers who have admitting privileges at the local hospital). A task may arise in an ad hoc fashion or may appear according to a schedule. A task may be placed on a list and assigned to a person, a group of people, or to an automated mechanism; a task may also be shared, reassigned, prioritized (or re-prioritized), routed, corrected, updated, cancelled, or suspended.	
Term	word or words corresponding to one or more concepts	
Terminological System	structured human and machine-readable representation of healthcare concepts and relationships	
Terminology Services	set of services that present and apply vocabularies, both controlled and uncontrolled, including their member terms, concepts and relationships. This is done for purposes of searching, browsing, discovery, translation, mapping, semantic reasoning, subject indexing and classification, harvesting, alerting, etc.	
Text	1) data in the form of words or alphabetic characters 2) human-readable sequence of characters	
Timestamp	digital record of the time of occurrence of a particular event	
Transact Data	act of processing a logical unit of information (e.g., data received from an external system may be committed (or “transacted”) to a local database	
Transform, Transformation	1) convert and/or encode source health record content into exchange artifacts such as HL7 v2/v3 messages, CDA/CCDA documents or FHIR resources 2) convert or change data/record content from one format to another, from one arrangement to another, from one structure to another	ISO 21089:2018, modified
Translate	(record entry) convert data content from one coding/classification system to another or from one human language to another or express the sense of (words or text) in another language (e.g. English translated to Spanish)	HL7 Version 3 Standard: Security and Privacy Ontology, Release 1
Transmit	(record entry) initiate communication of health record content from one system to another; send or convey from one person or place to another; send or forward, as to a recipient or destination	ISO 21089:2018
Treatment Option	consideration of one of several remedies with the object of effecting a resolution or cure	
Treatment Plan	See "Care Plan"	
Treatment Protocol	See "Protocol"	

Trigger	event that causes an action to be taken (e.g., message transmittal)	
Trust	1) (confidence) have reliance, faith, or hope 2) assured reliance on the character, strength, or truth of someone or something	ISO 21089:2018
Trusted Information Exchange Environment	environment which ensures integrity, confidentiality, and availability of data in the process of information exchange between participating parties; may be based on a "chain of trust" agreement	
Truth	1) quality or state of being true in accordance with the body of real things, events and facts 2) maintain fidelity to an original or to a standard, proposition or principle.	ISO 21089:2018
Unique Identifier	See "Identifier"	
Unlink	(record entries) undo an operation that previously connected two or more health records, rendering them separate again	ISO 21089:2018
Unmerge	(record entries) perform an operation that reverses a previously executed merge operation	ISO 21089:2018
Unstructured Data	data that is not slotted into discrete fields and enumerated or codified; opposite of structured data	
Unstructured Text	lacking a definite structure or organization; not formally organized or systematized	
Update	perform an operation that results only in the revision or alteration of an object	HL7 Vocabulary Alignment Project
Upload	transfer (data) from one computer to another, typically to one that is larger or remote from the user or is functioning as a server	
Use	(of health information) sharing, employment, application, utilization, examination, or analysis of such information	HIPAA
User	person or other entity authorized by a provider to use some or all of the services provided by the provider	COACH OMG
User Role	collection of defining attributes that characterize a population of users and their intended interactions with the system	
Validate	confirm that the contents of data objects meet the needs of identified stakeholders (e.g., healthcare providers, patients), often involving acceptance and suitability; verify correctness (to reflect the true situation)	Project Management Body of Knowledge, modified JCAHO, modified
Verify	confirm and notate that record/data content is true, accurate and/or justified based on reviewing, inspecting or testing or evaluate the compliance of data objects with specified requirements based on organizational policy	Project Management Body of Knowledge, modified
Versioning	management of multiple revisions of the same unit of information, or of a software application	
View	1) look at attentively or inspect 2) representation of an object or collection of objects for use by visual capture, rendered electronically or in print	ISO 21089:2018

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Annex C
(informative)

Background

C.1 What is HL7?

Established in 1987, Health Level Seven (HL7) is an American National Standards Institute (ANSI) accredited, not-for-profit standards-development organization, whose mission is to provide standards for the exchange, integration, sharing, and retrieval of electronic health information; support clinical practice; and support the management, delivery and evaluation of health services. ANSI accreditation, coupled with HL7's own procedures, dictates that any standard published by HL7 and submitted to ANSI for approval, be developed and ratified by a process that adheres to ANSI's procedures for open consensus and meets a balance of interest requirement by attaining near equal participation in the voting process by the various constituencies that are materially affected by the standard (e.g., vendors, providers, government agencies, consultants, non-profit organizations). This balance of interest goal ensures that a particular constituency is neither refused participation nor is it allowed to dominate the development and ratification of a proposed standard. More information and background on ANSI is available on their website at: http://www.ANSI.org

C.2 The HL7 Electronic Health Records Work Group

The HL7 Electronic Health Records Special Interest Group (EHR SIG) was established in the spring of 2002. In the spring of 2003 the HL7 group began efforts to develop a standardized functional specification for Electronic Health Records Systems (EHR-S). In May 2004 the SIG was promoted to a full HL7 Technical Committee, becoming the EHR TC. The EHR TC is intended primarily to serve as a body which promotes the uptake of Electronic Health Record (EHR) implementation by standardizing the functions that may be present, based on user selection, in an EHR-S.

The Department of Health and Human Services, the Veterans Health Administration, the Health Information Management Systems Society and the Robert Wood Johnson Foundation, in a public-private partnership, approached HL7 to accelerate their existing work to develop a consensus standard to define the functions of an EHR-S. HL7, through its EHR SIG, responded by developing an EHR-S Functional Model that passed ballot as a Draft Standard for Trial Use (DSTU) in April 2004. The Functional Model DSTU was published and formally registered with the American National Standards Institute (ANSI) in July 2004. The Functional Model was then balloted and passed as a normative standard as part of the January 2007 HL7 Work Group Meeting and is now registered as a normative standard with ANSI

Learning important lessons from the ballot process, a Functional Model with a clearer, more simplified list of functions, has been created. The HL7 EHR System Functional Model provides a reference list of functions that may be present in an Electronic Health Record System (EHR-S). The Function List is described from a user perspective with the intent to enable consistent expression of system functionality. This EHR-S Model, through the creation of Functional Profiles, 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 or primary care in another country).

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a) Dick, Richard S. et al. *The Computer-Based Patient Record: An Essential Technology*. National Academy Press, Washington, D.C., 1997. ISBN: 0-309-08684-1

b) Johns, Merida L., PhD, RHIA *Health Information Management Technology: An Applied Approach, 3rd Edition.* AHIMA, Chicago, IL, 2010. ISBN: 9781584262596

c) ISO 16527:2023, Health Informatics – HL7 personal health record system functional model, Release 2

(*Continued from second cover*)

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 13940 : 2015 Health Informatics —System of concepts to support continuity of care	IS/ISO 13940 : 2015 Health informatics — System of concepts to support continuity of care	Identical
ISO/TR 20514 : 2005 Health Informatics — Electronic health record — Definition, scope and context	IS/ISO/TR 20514 : 2005 Health informatics — Electronic health record — Definition, scope and context	Identical

The Committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decide that they are acceptable for use in conjunction with this standard:

International Standard/ Other Publication	*Title*
ASTM E1769 : 1995	Standard guide for properties of electronic health records and record systems
	HL7 fast health interoperable resources (FHIR), release 4, January 2019
	HL7 FHIR record lifecycle event implementation guide, part of FHIR core release 4, January 2019
ISO/TS 21089 : 2018	Health informatics — Trusted end-to-end information flows

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