Health Level Seven International

HL7 was founded over three decades ago as a not-for-profit standards development organization and provides solutions for the healthcare industry’s information exchange challenges. These solutions help advance interoperability and enable the right people to access the right information when and where it’s needed.

- Founded in 1987
- ANSI-accredited standards developing organization (SDO)
- Committed to empowering health data interoperability
- Focused on developing standards and enabling their adoption and implementation

Supported by our members, HL7 is shaping the future of healthcare through making our standards and implementation guides freely available under licensing terms. By making our framework easier to adopt, implement and use, HL7 ultimately aims to increase health and wellness by improving healthcare delivery on a global scale.

• Each steering division elects two representatives to serve on the Technical Steering Committee (TSC) which votes on technical issues related to standards
• The TSC is also comprised of two representatives from HL7 affiliates and an Architectural Review Board representative

Education and Events
HL7 convenes three working group meetings per year which facilitate standards development and include tutorials and HL7 Fast Healthcare Interoperability Resources (FHIR®) Connectathons. In addition, HL7 and Firely also produce HL7 FHIR DevDays, the largest FHIR-only event in North America. HL7 also offers live and on-demand webinars, online courses and customized corporate training in onsite and virtual formats.

Collaboration
Recognizing that effective standards development requires collaboration with other SDOs and stakeholders, HL7 has established agreements with nearly 30 organizations. The agreements facilitate open communication throughout the industry and are published on HL7.org/about/agreements.cfm. HL7 is also a founding member of the SDO Charter Organization (SCO), a formal collaboration among SDOs which aims to facilitate the creation of industry-wide, interoperable standards that support meaningful improvements in healthcare outcomes.
HL7 Standards
HL7 standards are developed through the commitment and hard work of thousands of volunteers around the world. More than just a set of standards for data messaging, HL7's interoperability solutions include a family of technologies that provides a universal common framework for interoperability of healthcare data. By helping make healthcare IT systems interoperable, HL7 makes providers and organizations across the healthcare continuum more successful at achieving their goals.

Consolidated CDA
The Consolidated CDA (C-CDA) is an implementation guide that contains a library of CDA templates and is a result of joint efforts of HL7, Integrating the Healthcare Enterprise (IHE), Health Story Project and the Office of the National Coordinator (ONC) for Health IT.

EHR/PHR System Functional Models
The EHR System Functional Model (EHR-S FM) helps lay the groundwork for nationwide interoperability by providing common language parameters that can be used in developing systems that support electronic records.

The HL7 Personal Health Record System Functional Model (PHR-S FM) identifies the functions that should be included in a PHR and includes guidelines for data exchange between PHRs and EHRs.

RIM
The Reference Information Model (RIM) is the cornerstone of the HL7 Version 3 (V3) development process. An object model created as part of the V3 methodology, the RIM represents clinical data and identifies a life cycle of events.

Additional HL7 Standards
- Arden Syntax
- Claims Attachments
- Clinical Context Management (CCOW)
- Clinical Genomics: Genetic Variation Model
- Clinical Genomics: Pedigree Model
- HL7 Domain Analysis Model: Clinical Genomics Release 1
- HL7 Domain Analysis Model: Clinical Sequencing, Release 1
- Common Terminology Services (CTS)
- Decision Support Service Functional Model (SOA standard)
- GELLO
- Infobutton - Context Aware Retrieval
- Retrieve, Located, Update Service Functional Model (SOA standard)
- Structured Product Labeling (SPL)
The Arden Syntax for Medical Logic Modules (MLMs) is an ANSI-approved American National standard language for encoding medical knowledge and representing and sharing that knowledge among personnel, information systems and institutions. It is designed for organizations that require or develop systems that automatically assist physicians in decisions and alerts. It is a formalism for clinical knowledge representation that can be used by clinicians, knowledge engineers, administrators and others to implement clinical decision support (CDS) solutions to help improve the quality and safety of care.

The logic for making these decisions or issuing these alerts is encoded into health knowledge bases called MLMs, each of which contains sufficient knowledge to make a single decision. Contradiction alerts, management suggestions, data interpretations, treatment protocols, and diagnosis scores are examples of the health knowledge bases that can be represented using the Arden Syntax.

With an appropriate computer program (known as an event monitor), MLMs run automatically, generating advice where and when it is needed. For example, one MLM warns physicians when a patient develops new or worsening kidney failure.


Beginning in the summer of 1998, sponsorship of this standard was moved to HL7. The Clinical Decision Support and Arden Syntax Work Groups of HL7 oversee maintenance of the standard. Arden Syntax Version 2.0 was formally adopted by HL7 and approved by ANSI in August 1999.

In order to make the overall work group less technology-specific, the Arden Syntax was spun off into its own work group in January 2001, under the sponsorship of the Clinical Decision Support Work Group.

Version 2.1 of the standard was formally endorsed by HL7 and ANSI during 2002. Version 2.1 introduces a structured message as an optional part of the WRITE statement. Using this structure, which is encoded using an XML DTD, authors can specify many different parameters of an output message of a decision support system in a standard fashion. These include time outs and escalation information for alerts; embedded orders; subject; and recommendation.

The Arden Syntax standard is now at Version 2.10 and was approved by ANSI in November 2014. The key change in Version 2.10 over Version 2.9 is inclusion of a normative XML representation for Arden Syntax. This was done because the use of XML facilitates the development of tools such as syntax checkers and editors that can help increase the correctness of executable knowledge modules, and this in turn will foster the augmentation of the development and production environments for Arden, thereby increasing its utility.

Arden Syntax Version 2.10 is available for download from the HL7.org website.
Aimed at facilitating the integration of applications at the point of use, the Clinical Context Management Specification (CCOW) is an end-user-focused standard that complements HL7’s traditional emphasis on data interchange and enterprise workflow.

Using a technique known as context management, the clinical user’s experience is one of interacting with a single system, when in fact he or she may be using multiple, independent applications from many different systems, each via its native user interface.

By synchronizing and coordinating applications so that they automatically follow the user’s context, the CCOW standard serves as the basis for ensuring secure and consistent access to patient information from heterogeneous sources. The benefits include applications that are easier to use, increased utilization of electronically available information, and an increase in patient safety. Further, CCOW support for secure context management provides a healthcare standards basis for addressing HIPAA requirements. For example, CCOW enables the deployment of highly secure single sign-on solutions.

**IMPACT**

CCOW’s impact on the healthcare industry is apparent. All of the major HIS vendors ship both Windows and web-based CCOW-compliant applications, while vendors in virtually every segment of the clinical healthcare market have adopted the standard as well. VHA Inc.–a nationwide network of 1,900 leading community-owned healthcare organizations and their affiliated institutions require all of its new business partners to be CCOW-compliant. A growing number of healthcare organizations are also implementing context management solutions to link together diverse multi-vendor, multi-technology IT systems on an enterprise-wide basis.

**HOW IT WORKS**

The CCOW Work Group became a part of HL7 after starting out as an independent healthcare industry consortium. In a short time, the work group developed and ratified six versions of the CCOW standard. This unprecedented pace was, in part, due to the modular component-based nature of the architecture upon which the standard is based, enabling new specifications to be developed in a complementary and add-on manner.

CCOW’s Context Management Architecture (CMA) was founded on the principle that common context can be established across applications by identifying things, such as a patient concepts, or clinical encounters in a manner that different applications can nevertheless recognize. The core architecture is comprised of three main types of components: applications; a context manager that coordinates and synchronizes applications; and mapping agents that can represent the various synonymous real-world identifiers used to identify clinical patients, users, etc. The architecture defines the roles and responsibilities for each of these components and precisely prescribes the interfaces that enable them to communicate. The architecture does not define or dictate the implementation of any of the components.

The user sets the context using any CCOW-compliant application, such as to select a patient of interest. The application then tells the context manager that it wants to set the patient context and provides the context manager with an identifier that indicates the context subject, which, in this case, might be the medical record number for the patient of interest.

The context manager then tells the other applications that the context has been changed, and each application obtains the patient’s identifier from the context manager. Each application then adjusts its internal state and data display accordingly. This all happens in real-time.

Context links may be common or secure. Any application may set or get the context data for a common link. In contrast, only site-designated applications may set and/or get the context data for a secure link. Applications, the context manager and mapping agents use digital signatures to authenticate the messages they send and receive and to ensure the integrity of the data within these messages.

The basic idea is to provide a means for the various CCOW components to trust each other, for example, to enable applications to know that they are communicating with the real context manager (as opposed to a rogue application that is pretending to be a context manager).
One of the more elegant capabilities provided by the architecture is that the use of different context subject identifiers is hidden from applications. An application only needs to know its own identifiers. A mapping agent works in conjunction with the context manager to map the identifiers used by the application that sets the context to identifiers that may be understood by other context-sharing applications. For example, one application may use a hospital-assigned medical record number to identify patients, while another application in the same institution uses clinic-assigned medical record numbers to identify the same patients.

The CCOW architecture was designed to be easily implemented within all types of healthcare applications and using a variety of technologies. Particular emphasis was given to ensuring that CCOW compliance could be easily retrofitted into existing applications. It is not necessary for an application developer to implement a context manager or mapping agents, as these components are external to the application and can be obtained from other sources.

CCOW V1.0
Approved by ANSI in July 1999, CCOW V1.0 defined: The overall technology-neutral context management architecture (CMA), a core set of data definitions, rules for application user interfaces, and the translation of the CMA to Microsoft’s COM/ActiveX technology. The features of 1.0 include:

• General architecture for “linking” applications: Compliant applications “tune” to the same “context subject”— such as a user, patient or encounter.
• Key context management components: The context manager coordinates applications and mapping agents, which map between the various identifiers.
• End-to-end security: Context-based security enforces subject-level access privileges such that only site-designated applications may access the values for a particular subject.
• Patient Link: This is a common subject that enables applications to tune to the same patient.
• User Link: This is a secure subject that enables applications to securely tune to the same user.
• COM Technology Specification: This is a specification of all of the details needed to implement COM-based applications and mapping agents that plug-and-play with a context manager, including all of the necessary COM interfaces.

CCOW V1.1
Approved by ANSI in March 2000, CCOW V1.1 added support for:

• Dependent context subjects: A dependent subject may only be set when one or more other subjects that it depends upon are also set. This ensures that the complete context, which may be comprised of multiple subjects, is always self-consistent.
• Encounter subject: This subject enables applications to tune to the same clinical encounter for a particular patient. The encounter subject is dependent upon the patient subject, so it is not possible for an application to set the encounter subject without also setting the patient subject.

• Custom subjects: A custom subject is one whose data definition has not been published as part of a ratified CCOW specification. The CCOW specification for custom subjects provides a structured way for defining the necessary data definitions and ensures that the data definition for a custom subject will not collide with those defined by other organizations or by CCOW.

• Formal conformance statements: These statements define what an application, context manager, or other type of CCOW-defined component must be capable of doing in order to claim conformance. CCOW does not address the process of validating conformance, but these conformance statements clearly establish what it means to be compliant.

CCOW V1.2
ANSI approved in September 2000, CCOW V1.2 added:

• Web Technologies Specification: web technologies are quite different from the COM/ActiveX technologies defined for 1.0, but the technology mapping defined in 1.2 nevertheless enables interoperability between applications and mapping agents that employ either technology, as mediated by a context manager. Web-based applications and mapping agents send and receive URL-encoded HTTP messages to the context manager. These messages are analogous to the messages COM-based applications, mapping agents, and context managers send and receive, thereby providing the basis for interoperability between technologies.

• Capability to deploy over private and public networks. The security protocols and policies defined in the CMA are used in both scenarios, but web-based CCOW over public networks adds the use of Secure Socket Layer (SSL) as the communication substrate for all CCOW-based communication.

CCOW V1.3
CCOW V1.3 was approved by ANSI in June 2001. It added the concept of annotations:

Annotation subjects: Annotation subjects are comprised of data elements that describe something, as opposed to identify something. An annotation subject is always dependent upon an identity subject. For example, the patient subject is used for identifying the patient.

A hypothetical demographics annotation subject would contain the patient’s telephone number, address, and so on. The data for an annotation subject may only be set by annotation agent. There is an annotation agent for each annotation subject. After the context is set by an application, each available annotation agent is instructed by the context manager to add the appropriate annotation data to the context. Each site defines the data sources for its annotation agents. This ensures that applications will always see annotation data that comes from the source that is the authentic source for the data.

Two new context subjects were defined as well:

• Observation request subject: This subject enables applications to tune to the same clinical observation request, so that, for example, different applications can display the results of a particular lab test order.

• Certificate subject: This subject, which is an annotation subject (see below), enables applications to tune to the same X.509 compatible digital certificate, enabling different applications to nevertheless use the same user security credentials when digitally signing and/or encrypting data on behalf of the user.

CCOW V1.4
CCOW 1.4 was released as an ANSI-approved standard in August 2002. One of the key features is support for multiple context sessions on the same point-of-use device. Each session may be securely “owned” by a different user, although only one context session will be active at a time. Multiple context sessions enable the CCOW standard to be even more flexible when used by caregivers who need to share devices in a kiosk-like manner. Users can quickly and easily access their own sessions, and may “lock” their sessions when not in use and then return to their sessions at a later time.
Another key feature of CCOW V1.4 is support for action subjects. An action subject enables an application to request, via the context manager, that another application perform a task on behalf of the requesting application. The request is generally issued in response to a user input or gesture. For example, certain clinical applications require that the user be authenticated in order to enter data, even though the user is already signed-on. With an authentication action, a clinical application can request that the authentication application authenticate the user.

Because this communication is context-based, the two applications do not need to know about each other and yet can nevertheless service the same user. Other CCOW V1.4 features include: a new context manager interface, ContextFilter, that enables an application to indicate the specific context subjects about which it wants to be notified whenever the context for the subject is set; and a set of data definitions for linking applications based upon DICOM image studies.

CCOW 1.5
CCOW V1.5 was approved as an ANSI standard in August 2004 and reaffirmed in 2009. This version included the following:

- Added support for PKI-based secure binding.
- Revised conventions for naming keys containers.
- Added exception codes in table 5 for exceptions ImproperSignature Format and ContextNotActive. These exceptions had been mistakenly omitted.
- Added comment concerning use of FACILITY_NULL to define HRRSULTS.
- Removed the interface specification for IMappingAgent, as this interface had previously been deprecated.

CCOW 1.6
CCOW V1.6 was approved as an ANSI standard in February 2011. It updated CCOW to describe the use of Security Assertion Markup Language (SAML) within the CCOW architecture.

CCOW 1.6 is available on the www.HL7.org website.

CONCLUSION
The CCOW standard has evolved to address an increasing set of context management capabilities. Leveraging the architectural foundation established at the onset, the standard now embraces multiple technologies, a variety of context subjects, and an increasing array of context management mechanisms. This ongoing evolution has positioned CCOW as a pivotal resource in the years to come for provider organizations who need an effective way to extend the utility of yesterday’s legacy healthcare applications while introducing the breakthrough technologies of tomorrow.
What Are Clinical Documents?
Clinical documents are the core of a patient’s lifetime record. A “History & Physical,” “Discharge Summary” or an “X-ray Report” are all examples of clinical documents. Typically, they contain narrative as well as discrete data. While certain structures may apply across document types, like the common SOAP note structure, individual document types vary widely in content.

The HL7 CDA® defines clinical documents as having these characteristics:
• Persistence
• Stewardship
• Authentication
• Context
• Wholeness
• Human readability

Why should clinical documents be standardized?
A consistent approach to electronic clinical documents means that the critical information contained in the documents can be used independently of the applications on which they were produced. For example, a discharge summary created by an electronic health record can be rendered on standard browsers and a repository of transcription documents can be indexed with the same metadata as the output of an EHR. Information created today can be migrated to future systems with little or no data conversion. Findings encoded in clinical documents can be used for third-party decision support and mined at a later date for new applications.

What is CDA?
First published in 2000, the HL7 Clinical Document Architecture (CDA) is a leading standard for the exchange of healthcare information and has become a pillar of interoperability for clinical care and public health. CDA Release 2 utilizes a common syntax for all clinical documents. It preserves the integrity and structure of clinical documents. It conveys authenticated content with fidelity and supports discrete data representation that is both extractable and computable.

CDA Release 2 provides an exchange model for clinical documents — and brings the healthcare industry closer to the realization of an electronic medical record. By leveraging the use of XML, the HL7 Reference Information Model (RIM) and coded vocabularies, the CDA makes documents both machine-readable (so they are easily parsed and processed electronically) and human-readable (so they can be easily retrieved and used by the people who need them). CDA documents can be displayed using XML-aware web browsers or wireless applications such as cell phones.

CDA R2.1 was published in December 2019.

Who is using CDA?
There are large scale CDA implementations in North and South America, Europe and Asia Pacific. In the US, CDA is being implemented by groups such as NewYork Presbyterian, the US Military Health System, The Centers for Disease Control and Prevention, the University of Pittsburgh Medical Center, Queen Elizabeth II Hospital/Dalhousie University, Duke Clinical Research Institute, and many others. The Mayo Clinic is the largest single producer of CDA documents, producing thousands of CDAs every week with the anticipation of reaching 50,000 notes per week. Groups such as Integrating the Healthcare Enterprise (IHE) have also utilized CDA in their work. CDA is firmly in the plans for many of the nascent US HIEs and the US Military Health System. The CDA implementation guide, the Continuity of Care Document (CCD®) as well as the Consolidated CDA (C-CDA) were selected by the US Office of the National Coordinator for Health Information Technology as requirements for Meaningful Use in its set of standards, implementation specifications and certification criteria for EHR technology.
CDA Implementation Guides
Several implementation guides based on CDA have been published or are available as standards for trial use. They are as follows:

**CDA IG for Quality Reporting Document Architecture (QRDA)** - This implementation guide was supported by the Child Health Corporation of America (CHCA) with participation from the American College of Physicians, American Health Information Management Association (AHIMA), Alliance for Pediatric Quality, Iowa Foundation for Medical Care, The Collaboration of Performance Measure Integration with EHR Systems (“The Collaborative”), HITSP, Integrating the Healthcare Enterprise (IHE) and others. The guide covers patient-centric quality data reporting and lays out a framework for aggregate, population-based quality reports.

**CDA IG Clinical Oncology Treatment Plan and Summary** - This project developed a high-priority set of clinical oncology templates for CDA. This guide describes constraints on the CDA R2 header and body elements for the Clinical Oncology Treatment Plan and Summary document in the US Realm. It serves as a form of ongoing communication to augment the coordination of care between healthcare providers while a patient is receiving care. Providers involved in the care of the patient may include the patient’s primary care provider, medical oncologist, surgical oncologist, and radiation oncologist.

**CDA IG Patient Generated Document Header Template** - The integration of patient generated health data (PGHD) into HIT is an important change to the HIT ecosystem. Although patients have long been the source of information recorded in the EHR, this information has been gathered orally or in paper forms, and transcribed by the provider in a way that is assessed, interpreted and summarized. The original patient information may not be retained. Digital integration of PGHD provides the opportunity for patients to author data in a way that is consumable within the EHR. The purpose of this implementation guide is to develop a standard way within the current framework of structured documents in the evolving health information ecosystem to capture, record and make interoperable, patient generated information. The goal is to enable patients to participate and collaborate electronically with care team members.

**CDA IG for Healthcare Associated Infection (HAI) Reports** - This implementation guide was developed in conjunction with the Structured Documents Work Group and the Division of Healthcare Quality Promotion, National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC). The purpose of this implementation guide is to specify a standard for electronic submission of Healthcare Associated Infection (HAI) reports to the National Healthcare Safety Network (NHSN) of the CDC. It defines the overall approach and method of electronic submission and develops a set of appendices defining specific HAI report types. As reports are modified and new report types are defined, additional appendices will be developed and published by CDC and HL7.

**CDA IG – Exchange of C-CDA Based Documents; Periodontal Attachment - US Realm** - The Periodontal attachment is used to convey information about periodontal related services. This includes the business use of claims attachments, prior authorization and pre-determinations. It may also be used for other clinical data exchange functions as needed. The items defined for electronic supporting documentation were developed by the Standards Committee on Dental Informatics of the American Dental Association (ADA). Many of the items described in the attachments are based on an analysis of paper forms that have been used by dentists and payers in the past. Each possible attachment item, however, has been reviewed for appropriateness in an electronic format. This standard does not include diagnostic quality scanned images, or digital images in DICOM or other image file types to represent radiographs or pictures of patient conditions. These are included in a separate attachment if needed.
CDA IG Imaging Integration; Basic Imaging Reports in CDA and DICOM – The implementation guide for this informative document was developed by DICOM, with support from the HL7 Imaging Integration Work Group and the Health Story Project. It describes constraints on the CDA header and body elements for Diagnostic Imaging Reports, which contain a consulting specialist’s interpretation of image data. The guide is intended to convey the interpretation to the referring (ordering) physician and become part of the patient’s medical record.

CDA IG Care Record Summary – The purpose of this document is to describe constraints on the CDA Header and Body elements for Care Record Summary documents. A Care Record Summary document contains patient’s relevant health history for some time period. It is intended for communication between healthcare providers.

CDA IG CDA Framework for Questionnaire Assessments – The purpose of this IG is to specify a standard for electronic submission for CDA Questionnaire Assessments that will allow healthcare facilities to communicate reports in an interoperable, industry-standard format.

CDA IG Birth and Fetal Death Reporting – This implementation guide provides guidance and document infrastructure for transmitting medical/health information on live births and fetal deaths from a birthing facility setting to a jurisdictional vital records electronic registration system. It creates a standard format for transmitting vital records birth and fetal death information that serves as the basis for national and state information relevant for promoting public health and for aiding decision makers in setting policies, directing resources, managing problems, and identifying emerging health trends. The guide supports laying the foundation for standardized transmission of certain vital records information in a way that may improve the quality and timeliness of vital records birth and fetal death data collection and reporting. Additionally, it also supports data interoperability and data exchange between clinical systems and vital records electronic birth registration systems.

CDA IG for Consent Directives – This implementation guide was developed through the efforts of the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Veterans Affairs (VA), and the Social Security Administration (SSA). This document describes constraints on the CDA Header and Body elements used to express Privacy Consent Directive documents. It provides support for the exchange of privacy policies that can be enforced by consuming systems (e.g., scanned documents, computable structured entries).

CDA IG for Procedure Notes – This implementation guide was developed in conjunction with the Health Story Project. This document describes the constraints on the CDA Header and Body elements for Procedure Note documents. Procedures Notes are differentiated from Operative Notes in that the procedures documented do not involve incision or excision as the primary act. The Procedure Note or Report is created immediately following a non-operative procedure and records the indications for the procedure and, when applicable, post-procedure diagnosis, pertinent events of the procedure, and the patient’s tolerance of the procedure. The report should be sufficiently detailed to justify the procedure, document the course of the procedure, and provide continuity of care.

CDA IG – Personal Healthcare Monitoring Report – This implementation guide carries personal healthcare monitoring information, or patient measurement data taken by consumer medical devices. The primary use case around which the PHMR is designed is for the automated reporting of measurements taken by Personal Connected Healthcare Alliance (PCHA; formally Continua) compliant Personal Healthcare Monitoring (PHM) consumer devices outside of the health care provider facilities.
CDA IG – Level 3: Neonatal Care Report – This implementation guide was developed through the efforts of the Neonatal Care Report (NCR) Project supported by the Children’s Hospitals Neonatal Consortium (CHNC), a group of over 25 children’s hospital Neonatal Intensive Care Units (NICUs). This group developed a core data set of common data elements important to children’s hospital NICUs. This IG is intended to facilitate electronic extraction of a subset of the CHNC data set using a standard reporting specification in the form of a NCR to support performance and research.

CDA IG: Plan-to-Plan Personal Health Record (PHR) Data Transfer – CDA IG for Consult Directives – The implementation guide was created for the US payer stakeholder community and is intended to be used with the Accredited Standards Committee (ASC) X12 Patient Information (275) Implementation Guide, to ensure consistency in the implementation of US realm PHR data transfer functions between health plans. The guide provides health plans, with member consent, the ability to move the member’s payer-linked PHR information from the previous plan to the new plan when their health coverage changes. These exchanged documents will be known as “Plan to Plan Personal Health Record” or P2PPHR documents. The exchange of a P2PPHR could be initiated by a single member of an insurance plan or via a batch of records, if an insurance plan sponsor (i.e. employer) chose to change plans. This implementation guide also provides a potential framework for greater standards-based interoperability of PHRs between the consumer and the provider.

CDA IG Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers - US Realms - Population-based cancer surveillance is critical in North America for cancer control activities aimed at reducing the morbidity and mortality of cancer, the second leading cause of death in the US and the leading cause of death in Canada. Population-based public health central cancer registries across the US and most of Canada are mandated to collect complete and timely cancer diagnostic, treatment, and outcome data from hospitals, physician offices, treatment centers, clinics, laboratories, and other sources. Recent shifts in cancer treatment away from hospital settings and towards ambulatory healthcare settings are increasing the importance of ambulatory (non-hospital) healthcare providers’ data for cancer surveillance. As ambulatory healthcare providers adopt modern electronic health record (EHR) systems, the opportunity to automate cancer registry reporting from ambulatory healthcare provider settings is also increasing and becoming more feasible. This implementation guide provides clear and concise specifications for electronic reporting from ambulatory healthcare provider EHR systems to public health central cancer registries using CDA- based standards. This document is designed to guide EHR vendors and public health central cancer registries in the implementation of standardized electronic reporting. It includes both business rules and standardized specifications.

CDA IG Trauma Registry Data Submission - This implementation guide supports the submission of trauma registry data from provider institutions to registry data collectors using the CDA standard. The clinical specifications were developed by the American College of Surgeons’ Committee on Trauma with support from eighteen other professional societies.

CDA IG – Vital Records Death Reporting, US Realm - This implementation guide provides guidance and document infrastructure for transmitting death related information from a clinical setting to a vital records electronic death registration system (EDRS). This specification covers the transmission of death reporting data to the applicable jurisdictional vital records reporting agency.
CDA IG greenCDA® - The Clinical Document Architecture Release 2.0 (CDA R2) addresses universal requirements for exchange and management of structured clinical documents. The approach described in this document, greenCDA, maintains the full utility of the CDA R2 while defining a method of working with an implementation-specific XML (Extensible Markup Language) that is easier to implement.

The approach simplifies instance creation while it asserts as a primary principle that any simplification must also define a method to deliver valid, normative CDA.

We call this approach “greenCDA” because it is good for the environment.

CDA IG – Emergency Medical Services, Patient Care Report – The Emergency Medical Services (EMS) Patient Care Report (PCR) provides information about an EMS patient encounter and transport to a receiving institution—typically a hospital emergency department (ED). The information is predominantly clinical, but it also includes specific information concerning the incident, scene and resources utilized by EMS.

This implementation guide provides the out-of-hospital patient care report in a standard format and allows emergency department clinicians and other public health/healthcare providers familiarity with the layout of the report to read quickly and accurately.

The EMS PCR consolidates key information from the NEMSIS specification: implementers who provide NEMSIS data sets should be able to map their current reports into the PCR.

CDA IG for Exchange of Clinical Trial Subject Data; Patient Narratives – The scope of this CDA implementation guide is limited to the exchange of patient narratives, which are created as summary documents during the conduct of a clinical trial.

This guide focuses on a constrained data-set that supports the exchange of both human and machine readable content.

CDA IG – Genetic Test Reports – The purpose of this implementation guide is to specify a standard for genetic testing reports, targeted at both human readability and machine processability. Genetic tests have recently become an important tool in clinical care that further personalizes the care processes based on the patient's individual genetic makeup. Genetic testing methods are diverse and span from testing for known germline mutations in the context of single-gene disorders, to full sequencing of genes in tumor tissues looking for somatic variations in cancer cells. It is a universal specification and covers a variety of use cases.

The guide creates a common foundation of communication between various stakeholders of patient-specific genetic data, first and foremost, genetic testing laboratories and healthcare information systems. It also enables both human readability of genetic tests reports and processability by clinical decision support applications.

CDA IG: Clinical Summary Relevant and Pertinent Data – This guide is primarily focused on improving the relevance and pertinence of Consolidated CDA (C-CDA) documents as experienced by the clinician, which means as displayed or “rendered.” Other guides, including the C-CDA Companion Guide, focus mainly on the structured content. This is an informative document providing principles for development, and guidance on what information should and should not be present and appropriate in both coded clinical statements (entries) and narrative content in an automatically generated clinical summary (e.g., CCD, Discharge Summary, Referral Note, Consultation Note, etc.). It does not create new templates or models, but simply explains how to use existing C-CDA templates.
CDA IG – Long-Term Post-Acute Care Summary
- This guide describes the requirements to create a Long-Term Post-Acute Care (LT PAC) Summary Clinical Document Architecture (CDA) document. It leverages the CDA templates in the Consolidated CDA and introduces new templates when existing templates did not exist for new requirements.

A LTPAC Summary is a subset of elements from an existing questionnaire assessment instrument that are expressed using a “model of meaning” representation aligned with other CDA patterns published under Meaningful Use. The elements included in this guide were selected by members of the ONC’s Standards and Interoperability (S&I) Framework, under the Patient Assessment Summary Sub-Workgroup (PAS SWG). The members of the PAS SWG selected clinically relevant elements from the Minimum Data Set (MDS) and the Outcome and Assessment Information Set (OASIS).

This implementation guide creates a medical summary document to enable and support the transition of LT PAC patients across providers, and settings.

CDA IG – HIV/AIDS Services Report – This guide describes constraints on the Clinical Document Architecture Release 2 (CDA R2) header and body for an HIV/AIDS services report. The primary use case for this guide is the Ryan White HIV/AIDS Program Services Report (RSR) document. A RSR is an annual report to the Health Resources and Services Administration (HRSA), an agency of the US Department of Health and Human Services, by healthcare providers who receive funding for the Ryan White HIV/AIDS Program. The aim of the report is to provide HRSA with a confidential patient-level report of the services rendered to individuals seen by the healthcare providers under the Ryan White HIV/AIDS Program.

CDA IG – Patient Assessments – This implementation guide facilitates a standard electronic communication for electronic submission to CDA of their Questionnaire Assessments. These allow healthcare facilities and providers a standard way to communicate reports in an industry standard format. Questionnaire Assessments contain multiple questions with specific answers. These questions typically assess a variety of clinical domains (including the patient’s functional and disability status) and may include assessment scales to quantify the assessment. Questionnaire Assessments are instruments that have psychometric properties that contribute to the statistical adequacy of an instrument in terms of reliability, validity, and internal consistency.
CDA IG – Data Provenance – This guide was developed as a collaborative effort between HL7 and the US Health and Human Services Office of National Coordinators Standards and Interoperability Framework Data Provenance Initiative (DPROV). The IG is the result of a focused effort to identify existing opportunities within CDA R2 where basic provenance information about clinical and other care related information, who created it, when it was created, where it was created, how it was created, and why it was created, can be conveyed in a consistent and interoperable manner. Also conveyed is what action was taken – resulting in (documented by) the information captured. In particular, this IG builds upon the provenance preserving constraints in the Consolidated CDA and Data Segmentation for Privacy IGs, as well as reusing the CDA Consent Directive IG.

This IG provides guidance to any CDA R2 implementer on the use of CDA templates to represent data provenance. These templates may also be used as building blocks for conveying provenance using other information exchange standards.

CDA IG – Medication Therapy Management (MTM) Templates – This two-volume guide supports the documentation and communication needs of the expanding Medication Therapy Management (MTM) services arena and the CMS Medicare Part D reporting and patient information requirements for MTM. It is to be used for the exchange of medication related information including assessment results, recommendations for modifications to medication regimens, recommendations for other services (e.g., dietary or laboratory) and the results of interventions between/among providers, payers, pharmacy benefit managers (PBMs) and patients.

This guide defines templates within this library that are used for the documentation of MTM services, specifically:
• Medication Action Plan, Medication List
• Comprehensive Medication Review (CMR)
• Targeted Medication Review (TMR)
• Medication Therapy Outcomes

CDA IG – Patient-Friendly Language for Consumer User Interfaces – This IG is sponsored by the Department of Veterans Affairs (VA) and is a result of a focused effort to provide a plain language healthcare vocabulary for patient comprehension. This vocabulary is targeted specifically toward healthcare consumer user interfaces which create outputs for consumer consumption such as consent directives, reports of disclosures, and notices of privacy practices.

Patients are often uncomfortable with the provided technical/legal security and privacy jargon used in healthcare consumer user interface outputs for consumer consumption. This technical/legal jargon makes it difficult for patients to fully participate in decisions regarding their healthcare. By using plain language vocabulary mapped to technical/legal jargon, we increase the likelihood that patients understand the choices they make while ensuring that their choices are correctly translated across the system.

CDA IG – Additional CDA R2 Templates – Clinical Documents for Payers Set 1 – The purpose of this IG is to provide guidance on a standardized, implementable, interoperable electronic solution to reduce the time and expense related to the exchange of clinical and administrative information between and among providers and payers. This guide describes structured documentation templates that meet requirements for documentation of medical necessity and appropriateness of services to be delivered or that have been delivered in the course of patient care.

These document templates are designed for use when the provider needs to exchange more clinical information than is required by the C-CDA R2 document-level templates and/or must indicate why information for specific section-level or entry-level templates is not included. For example, payer policy may allow providers to submit any information they feel substantiates that a service is medically necessary and appropriate under the applicable coverage determination rules.
The ability to submit any supporting documentation is a provider’s right under these rules as is the ability to declare that specific information is not available or not applicable.

CDA IG – Ambulatory Healthcare Provider Reporting to Birth Defect Registries, US Realm
- This implementation guide was designed to guide EHR vendors and public health central birth defect registries in the implementation of standardized electronic reporting. It includes both business rules and standardized specifications. It was produced and developed through a collaborative effort of the Centers for Disease Control and Prevention (CDC), National Birth Defects Prevention Network (NBDPN), Michigan Department of Health and Human Services, representatives from several state public health central birth defect registries, and Altarum Institute.

CDA IG – Personal Advance Care Plan Document – US Realm
- This implementation guide was designed to share information created by an individual to express his or her care and medical treatment goals, preferences, and priorities for some future point in time, under certain circumstances when the individual cannot make medical treatment decisions or communicate his or her goals, preferences, and priorities with the care team. The purpose of the PACP document is to ensure that the information created by the individual is available and considered in clinical care planning, and the focus of the standard is sharing patient generated information. The standard provides a means to share this information in a standard way with a system that maintains a clinical record for the person.

CDA IG – Digital Signatures and Delegation of Rights
- This implementation guide provides a standardized method of applying digital signatures to CDA documents. The standard provides for multiple signers, signer’s declaration of their role, declaration of purpose of the signature, long-term validation of the digital signatures and data validation of the signed content.

This IG is a collaboration between HL7, the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator (ONC) Standards and Interoperability (S&I) Framework Electronic Submission of Medical Documentation (esMD) Initiative. It defines a method to imbed digital signatures in a CDA document and provides an optional method of specifying delegation of right assertions that may be included with the digital signatures. This guide will allow health plans, payers, and providers to accurately authenticate the authorized signer(s) of a CDA document and trust the validity and authenticity of signed medical documentation.

CDA IG – Public Health Case Report - US Realm - the Electronic Initial Case Report (eICR)
- The purpose of this implementation guide is to specify a standard for electronic submission of electronic initial public health case reports using the CDA. This implementation guide will allow healthcare providers to electronically communicate the specific data needed in initial public health case reports (required by state laws/regulations) to jurisdictional public health agencies in CDA format—an interoperable, industry-standard format.

CDA Attachment IG – Exchange of C-CDA Based Documents
- This implementation guide defines the requirements for sending and receiving standards-based electronic attachments. It does so by applying additional constraints onto standards in common use for clinical documentation and by defining requirements for sending and receiving systems for attachment request and response messages. It defines the set of attachment documents as those that contain the minimum standard metadata to support basic document management functions including identification of patients and providers, the type of document.
CDA Attachment IG – Exchange of C-CDA Based Documents - Continued – date of creation, encounter information, and a globally unique document identifier.

CDA IG – International Patient Summary – An International Patient Summary (IPS) document is an electronic health record extract containing essential healthcare information intended for use in the unscheduled, cross-border care scenario, comprising at least the required elements of the IPS data set. The IPS data set is a minimal and non-exhaustive patient summary data set, specialty agnostic, condition-independent, but readily usable by clinicians for the cross-border unscheduled care of a patient.

HL7 CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), R1 STU Release 2 - US Realm - CDC/NCHS currently employs two surveys to gather information regarding the utilization of health care services in the United States. The NAMCS focuses on ambulatory care and is based on a sample of visits to non-federally employed office-based physicians primarily engaged in direct patient care. The National Hospital Care Survey (NHCS) is based on a sample of visits to hospital inpatient, emergency, and outpatient departments. The surveys currently require manual data extraction. Field representatives visit physician practice locations for NAMCS, and hospitals for NHCS, to abstract survey data elements. Data captured include information on patient demographics, vital signs, medical history, reasons for visit, diagnoses, procedures and medications. Data is entered into a computer-based tool that sends data back to NCHS. This process is labor and resource intensive, costly, and does not take advantage of emerging health information technology. NCHS would like to automate this process and collect more data without needing to send field representatives to physician offices/hospitals and allow all selected physicians/hospitals to participate in the surveys by providing electronic files from their EHR to do so. The surveys contain patient encounter and facility components; this project will focus on the patient encounter components. Data from these surveys are widely used by health policy makers, health service researchers, epidemiologists and healthcare industry and other interested parties.

HL7 CDA® R2 Implementation Guide: Pharmacy Templates, Release 1 - This Implementation Guide provides CDA R2 templates for Medication Order and Medication Statement, Medication Dispense and Medication Administration that can be used by HL7 standards developers and external projects to develop models for pharmacy related content. The implementation guide is intended to provide consistency of pharmacy related models across all uses regardless of the method of transport by creating a library of Universal (UV) Pharmacy Templates that can be used by other Work Groups to derive constrained versions.

HL7 CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.0 - US Realm - The purpose of this implementation guide (IG) is to specify a standard for a response document for a public health electronic Initial Case Report (HL7 eICR v1.1) using HL7 Version 3 Clinical Document Architecture (CDA), Release 2 format. Through the Reportability Response, public health seeks to support bidirectional communication with clinical care for reportable conditions in CDA format—an interoperable, industry-standard format.
Clinicians who report to quality programs have expressed a need to more successfully exchange (both send and receive) data for quality. This both allows providers to ensure that patient care is adhering to quality standards without repeating care activities inappropriately and to benefit from accurate assessment of the care they provide. CMS, the largest implementer of quality measurement programs, generally allows clinical activity from any provider to certify the appropriate application of the evidence-based criteria described in the measures as long as any provider has taken the appropriate action. Therefore, the more sharing of quality information there is, the more clinicians benefit with improved performance scores, the fewer unnecessary activities are repeated, and less clinically indicated activities should be missed. Thus, the quality use case can advance interoperability in this way.

For more information on CDA R2 and accompanying implementation guides, please visit the HL7.org website.
The Consolidated CDA (C-CDA)

What is the Consolidated CDA?
The HL7 CDA® Release 2 Implementation Guide: Consolidated CDA Templates for Clinical Notes - US Realm) The Consolidated CDA implementation guide (commonly known as the C-CDA) contains a library of CDA templates, incorporating and harmonizing previous efforts from HL7, Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP).

The C-CDA represents harmonization of the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination (IHE PCC), and Continuity of Care (CCD®).

Why C-CDA?
1. The C-CDA provides a single source for implementers to find CDA templates for twelve different document types

2. Additionally, it enables business analysts and policy managers to gain a basic understanding of the use of CDA templates across multiple implementation use cases

3. Finally, it provides guidance for transfer of care in the CCD

What’s in the C-CDA?

The most recent version, C-CDA R2.1, was developed and produced by the HL7 Structured Documents Work Group. It updates the C-CDA R2 (2014) guide to support “on-the-wire” compatibility with R1.1 systems C-CDA Release 2.1 implementation guide, in conjunction with the CDA R2 standard, is to be used for implementing the following CDA documents and header constraints for clinical notes:

- Care Plan including Home Health Plan of Care (HHPoC)
- Consultation Note
- Continuity of Care Document (CCD)
- Diagnostic Imaging Reports (DIR)
- Discharge Summary
- History and Physical (H&P)
- Operative Note, Procedure Note
- Progress Note
- Referral Note
- Transfer Summary
- Unstructured Document
- Patient Generated Document (US Realm Header)

Companion and Supplemental Implementation Guides

C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 - The companion guide was developed by MaxMD under the management of HL7 as part of a grant awarded to HL7 by the Office of the National Coordinator for Health Information Technology (ONC). It provides essential implementer guidance to continuously expand interoperability for clinical information shared via structured clinical notes. The guidance supplements specifications established in then HL7 CDA® R2.1 IG: C-CDA Templates for Clinical Notes. This additional guidance is intended to make implementers aware of emerging expectations and best practices for C-CDA document exchange. The objective is to increase consistency and expand interoperability across the community of data sharing partners who utilize C-CDA for information exchange.

www.HL7.org
The Consolidated CDA (C-CDA)

Companion and Supplemental Implementation Guides Continued


This guide provides additional technical clarification and practical guidance to assist implementers to support best practice implementations of the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification. The guide is intended to:

• Explain basic CDA concepts that are important to understand, prior to implementing the 2015 Edition Health IT Certification Criteria
• Provide guidance on the 2015 Edition Health IT Certification Criteria and data representation in the C-CDA format, including the mapping of CCDS data definitions (170.102) and the “additional data” defined in 170.315(g)(6) C-CDA creation performance to the CDA templates included in the C-CDA Implementation Guide
• Highlight that guidance where it is optional in context of the certification program
• Highlight additional guidance and resources relevant to the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification


The summary types identified for Meaningful Use Stage 2 do not equate to a specific CDA document or purpose, but represent a collection of data requirements to be included for various MU2 objectives. The purpose of the guide is to supplement the Consolidated CDA Implementation Guide by providing additional clinical and functional context to assist implementers and offers practical guidance that is outside the scope of HL7 balloted standards.

HL7 CDA® R2 Implementation Guide: C-CDA R2.1; Advance Directives Templates, Release 1 - US Realm – This implementation guide addresses issues identified with the Advance Directives Templates defined in C-CDA R2.1. It does the following:

• Defines new versions for the existing Advance Directive templates to address these problems and to expand the guidance available within the templates to address implementers’ questions
• Clarifies different categories of advance directive documents including, advance care plans, living wills, and durable healthcare power of attorney documents
• Clarifies the difference between advance directives and portable medical orders
• Identifies the types of content that may be included in advance directives
• Defines three new Advance Directives templates

The Advance Care Planning Intervention template is used to exchange information about planned or performed activities associated with discussing advance care plans and educating people about advance directives. It includes guidance on how to populate service event information in the header when advance care planning review or educational
Companion and Supplemental Implementation Guides Continued

HL7 CDA® R2 Implementation Guide: C-CDA R2.1; Advance Directives Templates, Release 1 - US Realm Continued - services are provided. The Obligation Instruction template is used to record when the patient or the patient’s healthcare agent has instructed care providers to perform certain activities. The Prohibition Instruction template is used when patient or the patient’s healthcare agent has instructed care providers not to perform certain activities.

The implementation guide also provides updated value sets needed to support the structured data content specified for the new and revised templates.

HL7 CDA® R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Nutrition, Release 1 - US Realm - This implementation guide describes constraints on the Clinical Document Architecture Release 2 (CDA R2) header and body elements that are derived from requirements set forth by the Academy of Nutrition and Dietetics Nutrition Care Process and HL7 stakeholder work groups. The NCP is used by Registered Dietitians Nutritionists (RDN) and other nutrition and dietetics professionals as a systematic approach to providing high quality nutrition care.

Templates in this guide are specific to the four steps of the Nutrition Care Process: Nutrition Assessment and Reassessment, Nutrition Diagnosis, Nutrition Intervention, and Nutrition Monitoring and Evaluation. These templates are intended to promote nutrition interoperability across care settings and will create information suitable for reuse in transitions of care, quality measurement, public health reporting, research, and reimbursement.

C-CDA Supplemental Templates for Unique Device Identifier (UDI) for Implantable Medical Devices, Release 1 - US Realm - This guide focuses on the UDI requirements and any changes needed in C-CDA to exchange the individual UDI components in the healthcare system when devices are implanted in a patient. The UDI components include the Device Identifier (DI) and the following individual production identifiers:

- Lot or batch number
- Serial number
- Manufacturing date
- Expiration date
- Distinct identification code

Another known missing information requirement is tracking the implant status through various events - i.e., in addition to implanting a medical device, the device may be removed, made inactive (not removed from the body), replaced and/or entered into the record in error. Therefore, the status of the device is important to capture in the patient’s device record. (Refer to PHMR document for guidance).

In addition, there may be other associated clinically relevant information that will need to be documented along with the UDI - e.g., MRI Safety Information (e.g., safety status - MR Safe, MR Unsafe, MR Conditional or not included on label), or whether or not the Device is labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).

HL7 CDA® R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Pregnancy Status, Release 1 - US Realm - This implementation guide (IG) provides consistent guidance for capturing key pregnancy status information in healthcare information technology (HIT) products and contains optional supplemental pregnancy status templates for current C-CDA document types.
Companion and Supplemental Implementation Guides Continued

HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes, Occupational Data for Health Release 1 - US Realm - Continued

This guide was produced and developed through the efforts of a project supported by the Centers for Disease Control and Prevention, the Association of Public Health Laboratories, CGI Federal, Lantana Consulting Group, and HL7 Structured Documents Work Group, Orders and Observation Work Group, and Public Health Work Group, which provided expert advice and input to the representation of pregnancy status information.

The ability of public health agencies and clinical organizations to receive pregnancy status data, especially during an outbreak such as Zika virus, is vital to ensuring appropriate testing and follow-up care for patients, particularly exposed pregnant women and their infants. The need also applies for other reportable conditions where pregnancy status is relevant (e.g., Hepatitis, Syphilis, and HIV) and for other clinical and population health activities and for use in Public Health Organizations, the Title X Family Planning Program, and the Womens, Infants, and Children (WIC) Nutrition programs are users of pregnancy observation data. For example, pregnancy and postpartum status is relevant for selected conditions reported to public health agencies using electronic case reports.

No consensus existed on the minimum data elements for pregnancy status prior to the work of the ONC HIT Federal Advisory Committees, Public Health Task Force. There is no widely used existing standard that captures pregnancy status and associated data in an EHR and most systems have limited data to support the necessary information for pregnancy status. Pregnancy status documentation and data are captured inconsistently across healthcare organizations.

HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes; Occupational Data for Health Release 1 - US Realm - This implementation guide contains guidance, supporting material and new templates to implement support for Occupational Data for Health (ODH). ODH is primarily designed to facilitate clinical care, including population health; ODH also can be used to support public health reporting, population health, and similar value-based care. ODH is not designed to support billing activities. The scope of the work information includes:

- Employment status
- Retirement date
- Combat zone period
- Past or present job for the patient or a household member
- Usual work of the patient or a household member

The purpose of ODH is to facilitate the use of work information collected in health information systems, such as electronic health record systems. Currently, work information collected to facilitate patient care is typically recorded in free text notes and is not described in the same way across records. Therefore it is not easily referenced by care providers over time or when a patient is seen by multiple care providers. In addition, structuring work information as ODH would facilitate care by providing a means to review population health based on key factors. When organized as structured and defined data elements in ODH, work information could be utilized by the system to assist the provider with recognition and treatment of conditions related to or exacerbated by work, assist with return-to-work for patients with acute or chronic conditions, and support treatment decisions for conditions that are not related to work but can be affected by work, such as diabetes management. For the patient, this would be a similar experience to providing information in online job applications.
Companion and Supplemental Implementation Guides Continued

HL7 CDA® R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Infectious Disease, Release 1, STU 1 - US Realm – This guide defines optional additions to the C-CDA R2.1 Continuity of Care Document (CCD), Transfer Summary, and Discharge Summary standards. These additional templates are available for use in any other CDA document-type where needed. They specify infectious disease data that should be included in the above-mentioned documents or any other relevant CDA document-type when patients are transferred between healthcare facilities, discharged home, or discharged to locations other than home (e.g. law enforcement).

The goal of this guide is to improve standards-based exchanges of infectious disease data to improve health care and public health. The intent of this guide is to provide solutions that can be generalized and are not specific to healthcare-associated infection (HAI) reporting.

The laboratory templates found in this guide are designed to convey portions of a laboratory result that are deemed relevant to infectious disease diagnoses. The templates are not intended to represent an entire laboratory report.

Examples of Healthcare Administrative Activities requiring this supporting information include, but are not limited to, additional information:

- In support of a healthcare claim or encounter
- In support of healthcare services review (e.g., prior authorizations/precertifications, referrals)
- In support of post adjudicated claim audits

HL7 Implementation Guide for CDA® R2 - Supplement to Consolidated CDA for Attachments, Release 1 - This informative standard is intended to provide guidance in implementing the C-CDA for attachment purposes, including but not limited to claims/encounters, referrals, prior-authorizations, post-adjudicated claims audits, etc. It provides guidance to implementers as they exchange additional supporting information needed amongst payers/UMO’s (Utilization Management Organization) and providers.
What is the Continuity of Care Document?
The CCD® is a joint effort of HL7 and ASTM to foster interoperability of clinical data to allow physicians to send electronic medical information to other providers without loss of meaning, which will ultimately improve patient care. It passed balloting in February 2007 and was endorsed by the Healthcare Information Technology Standards Panel (HITSP) as the harmonized format for the exchange of clinical information, including patient demographics, medications and allergies. It was recognized by the US Department of Health and Human Services as part of HITSP’s first set of interoperability standards in January 2008. In 2010, the CCD was selected by the US Office of the National Coordinator for Health Information Technology as part of its initial set of standards, implementation specifications and certification criteria for EHR technology.

The CCD represents a complete implementation of ASTM’s Continuity of Care Record (CCR). It is intended as an alternate implementation to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture.

The CCD represents a complete implementation of CCR, combining HL7 technologies with the richness of CCR’s clinical data representation, and does not disrupt the existing data flows in payer, provider, or pharmacy organizations.

The CCD is an XML-based standard that specifies the structure and encoding of a patient summary clinical document. It provides a “snapshot in time,” constraining a summary of the pertinent clinical, demographic, and administrative data for a specific patient.

From its inception, CDA has supported the ability to represent professional society recommendations, national clinical practice guidelines, standardized data sets, etc.

The HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component (CS32) describes the document content summarizing a consumer’s medical status for the purpose of information exchange. The content may include administrative (e.g., registration, demographics, insurance, etc.) and clinical (problem list, medication list, allergies, test results, etc.) information. This component defines content in order to promote interoperability between participating systems such as Personal Health Record Systems (PHRs), Electronic Health Record Systems (EHRs), Practice Management Applications and others.

Integrating the Healthcare Enterprise has the CCD for Patient Care Coordination in several of its profiles.

HL7 CCD to ASCII Blue Button Transform Tool
The HL7 CCD to BlueButton Transformation Tool is a set of xslt transforms that enable the transformation of CCD, and Consolidated CDA CCD (DSTU release 1.0) files into a Blue Button text file that closely resembles the VA’s own Blue Button text file extracts. This set of transformation files, when applied to one of the aforementioned CCD versions, will create a Blue Button text file that a patient can use to view their own clinical data as well as pass it on to a care giver or provider.
The HL7 Clinical Genomics Work Group (CGWG) has developed several healthcare standards and products, particularly in the area of family health history and genetic test result reporting. It is currently working to expand both of these data models to include more data types, transmission methods, and use cases – supporting research, translational, clinical, and personalized medicine.

**Implementation Guides**
The HL7 CGWG has developed implementation guides for Family Health History (Version 3), for both Genetic Variation and Cytogenetics (extended Laboratory Reporting Version 2.5.1), and CDA Genetic Test Report, to enable the exchange of interrelated clinical and personalized genomic data between interested parties. In many cases, the exchange of family history and genomic data occurs between disparate organizations (healthcare providers, genetic labs, research facilities, etc.). Widely used standards are crucial for the usefulness of this data in healthcare practice and research.

**Family Health History (Pedigree) Model**
The CGWG has developed a family history model, which supports the transmission of a full patient pedigree, with disease, age of onset, and cause of death information for each relative. This data model was approved by the American National Standards Institute in 2007. The CGWG, working with governmental and private sector groups, was successful in getting family health history to be part of the final rule for Meaningful Use Stage 2. The model is designed to help improve healthcare quality by increasing the clinical value of collecting and using family health history for disease risk assessment, differential diagnosis, and to guide preventive screening interventions, and inform the clinically appropriate use of genetic testing. Risk analysis and genetic test result data are included in the model as an option. The model will improve clinical systems with new tools that not only move from paper to computer, but also move from text to coded data. An HL7-compliant family health history application will promote the sharing of data between healthcare providers, patients, and extended family members.

**Family History Model - Current Implementations**
Family health history is a convergence point of the electronic health record (EHR), a personal health record (PHR), genetics, and familial disease risk assessment in a way that enables clinical decision support applications to run effectively, in particular when it comes to prevention and early detection of hereditary disease. The U.S. Surgeon General’s online tool for family history, called My Family Health Portrait, has adopted the HL7 Version 3 Pedigree specifications. It can communicate with professional tools compliant with the HL7 Pedigree, such as the breast cancer risk program called Hughes RiskApps, developed at Massachusetts General Hospital.

An HL7 standard and Meaningful Use Stage
2 requirement called the Continuity of Care Document (CCD®) contains a patient health summary. Along with a list of past diagnoses, medications, lab results, etc., it can also include family health history information. HL7 CDA® documents (Clinical Document Architecture) are being developed that include disease-specific family histories, with pointers to a complete pedigree and history, as in a CDA for cancer reporting. Family history is also included as a resource in the HL7 Fast Healthcare Interoperability Resources (HL7 FHIR®).

**Genetic Test Result Reporting into the EHR (or the Genetic Variation Model)**

The use of genomic data in healthcare practice is rapidly becoming the new standard of care. The use in clinical trials research has also seen a wider adoption, especially in the areas of increased understanding of molecular pathways, cohort identification, bio-marker discovery, drug efficacy, drug toxicity, drug metabolism and companion diagnostics.

The rise in genetically-guided medicine will require that information available from molecular diagnostic tests be readily available to the clinician. In order to take full advantage of this data, it must be captured in a structured, interoperable format.

The Genetic Variation Model specifies the structure and semantics for the transmission of genetic findings from single or multiple gene testing using laboratory methods (such as SNP probes, genotyping, microarray, and sequencing) that focus on genetic changes, usually in the coding region(s) of one or a small number of genes. Coded annotations provide interpretive context to these findings for the coded communication of clinical implications in regards to a specific disease or medication.

Because the field of clinical genomics is advancing rapidly, it is common that new scientific information becomes relevant to a test that has already been performed. When test results are available in structured formats, variants that were previously reported as being of unknown significance can be reinterpreted with the benefit of new knowledge, or new algorithms. With the HL7 data messaging models, these new test interpretations can be automatically updated through a HL7-compliant interface. Finally, structured findings are also available for incorporation into large clinical data warehouses for management of patient populations with similar conditions, and when appropriate these data are also valuable for discovery research.

**Genetic Variation and HL7 Version 2 Messaging**

Because US laboratories use HL7 Version 2 to transmit clinical test results, this resulted in the creation of a Version 2 Genetic Variation implementation guide for the clinical environment. With the implementation of this data messaging model, genetic test results flow from the genetic testing laboratory into the EHR.
as structured data. From the EHR, these results can flow into another EHR or a PHR. The first transmission of this data (from the lab into the EHR) was performed using the HL7 Laboratory 2.5.1 message standard. Within this message the genetic data is highly structured and codified, which optimizes the data so that it can be readily transmitted between EHRs.

The implementation guide describes how to construct a data message for genetic test reporting to the EHR (HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Genetic Variation Model, Release 2 (US Realm)). Example messages in the guide include genetic disease analysis, pharmacogenomic based drug metabolism, and drug efficacy. The Release 2 update to the guide includes the ability to transmit large data sets for tumor profiling and sequencing. It also works for the large gene panels that many labs are offering today.

A message consistent with this model has been piloted transmitting genetic test results between the Laboratory for Molecular Medicine, Partners HealthCare Center for Personalized Genetic Medicine and the EHR for Partners Healthcare. The full HL7 Version 2 message, detailed in the implementation guide was piloted between a genetics laboratory at the Partners Center for Personalized Genomic Medicine and the EHR at Intermountain Healthcare. The pilot is currently being expanded to include ARUP, a large reference laboratory reporting into the Intermountain Healthcare’s EHR, and includes a software platform developed by Partners Healthcare Center for Personalized Genetic Medicine called GeneInsight.

**Version 2 and Cytogenetics**

A Version 2 Cytogenetic implementation guide is available. The ‘Genetic Variation’ implementation guide covers genetic mutations located within a gene, but doesn’t support the transmission of results for larger genetic changes found in cytogenetic testing. Currently, cytogenetic data is reported in text-based narrative form and requires development of a structured data model in order to make it available for clinical decision support, outcomes analysis, and other secondary usage, as well as support linkage to knowledge bases enabling clinical interpretations to remain up-to-date.

**Genetic Test Report for Clinical Document Architecture (CDA)**

The CGWG has developed a CDA-based Genetic Test Report (GTR) document specification. Genetic testing methods are diverse and span from testing for known germline mutations in the context of single-gene disorders, to full sequencing of genes in tumor tissues looking for somatic variations in cancer cells. There is also the emerging use of gene expression testing in clinical care. It is expected to see a growing use of research techniques adjusted for healthcare. As a consequence of that diversity, and the constantly growing number of laboratory techniques producing proprietary data sets, the CDA GTR offers report formats having emphasis on detailed...
but easy-to-understand interpretations of the test results, along with clinical recommendations. The report contains background information on the tests performed including references to the appropriate scientific studies. The GTR is a universal CDA implementation guide that can accommodate the aforementioned needs, and can be further refined to specific genetic testing reports, either realm specific or method-specific, or any other set of restrictions. In addition, this implementation guide will strive to serve both the research and clinical environment. The audience for the guide includes those seeking a report format with standard text narrative along with machine-processable data, compliant with the HL7 CDA base standard.

**HL7 Domain Analysis Model: Clinical Sequencing**

This domain analysis model (DAM) captures precision medicine's use cases to facilitate interoperability of genetic and genomic data. It was the basis for the design of FHIR Genomics, the genomics components designed under purview of the HL7 Clinical Genomics Work Group within FHIR Release 3. The DAM has also served as the foundation for underlying use cases selected for the Sync for Genes (www.sync4genes.org) program.

This DAM is applicable to various use cases in clinical genomics with an emphasis on clinical sequencing. The model describes and outlines a multitude of use cases and scenarios in which clinical sequencing testing is currently recommended (i.e. somatic testing) or in which patient genomics can be pertinent for clinical or commercial decision making (i.e. trial feasibility). Relevant stakeholders, standards, and workflow diagrams help to practically illustrate the testing and decision making process and the manner in which orders and information is exchanged between patients, clinicians, laboratory technicians, geneticists, EHR, government agencies, etc. The document further discusses the current and future challenges associated with the implementation and utilization of clinical genomics, and the intent of the document is to inform standards developers for the design of interoperable solutions to these challenges and use cases.

**HL7 Domain Analysis Model: Specimen**

This specification is the first release of a Domain Analysis Model for Specimen, documenting the conceptual information requirements for use cases provided by Clinical Genomics, Anatomic Pathology and Public Health Laboratories, as well as the business needs of the current Version 2 and Version 3 specimen models. It is intended to present the business requirements for data elements related to specimen for electronic data record systems (Electronic Health Record System, Personal Health Record System or Laboratory Information System).
HL7 Domain Analysis Model: Clinical Genomics

The document is part of an ongoing effort by the HL7 Clinical Genomics Work Group to identify common workflows and use cases to facilitate scalable and interoperable data standards for the breadth of clinical genomics scenarios. The Domain Analysis Model (DAM) is becoming a widely used reference for clinical genomics, covering a myriad of use cases, including emerging ones such as preimplantation genetic diagnosis, whole exome sequencing, RNA-sequencing and proteomics. The focus is on use cases that can be found in practice at some locations clinically today. In addition, each use case may include several alternative scenarios and workflows that are shown for comparison. The document presents narrative context and workflow diagrams to guide readers through the stages of each use case and details steps involving the various stakeholders such as patients, healthcare providers, laboratories and geneticists. This contextual knowledge aids in the development and implementation of software designed to interpret and communicate the relevant results in a clinical computer system, especially a patient’s electronic health record (EHR).

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The HL7 Common Terminology Services (HL7 CTS) standard defines an Application Programming Interface (API) that can be used by HL7 Version 3 software when accessing terminological content. Before proceeding, we need to first state some things that the CTS specification is not designed to do.

• The current version of CTS is not intended to be a complete terminology service. The scope of CTS is restricted to the functionality needed to design, implement and deploy an HL7 Version 3 compliant software package. In much the same spirit as the XML/SGML relationship, the HL7 CTS is meant to represent a proper subset of functionality that may be provided by more sophisticated APIs such as that represented by the OMG TQS specification.

• CTS is not intended to be a general purpose query language. It is intended to specify only the specific services needed in the HL7 implementation.

• CTS does not specify how the service is to be implemented. It is intentionally silent when it comes to service advertising and discovery, establishing and maintaining connections, and the delivery and routing of messages. It is presumed that a CTS implementation will use the underlying architecture that is most appropriate for the given implementation circumstances.

The HL7 Version 3 standards are based on a Reference Information Model (RIM), which is flexible and general in structure. Representation of information within this model is dependent on the availability of terminological resources which can be used to populate the properties of the model with appropriate semantic content. Whenever possible, the HL7 Version 3 standard references existing terminological resources instead of attempting to create a new resource within the standard itself.

These external terminological resources can vary considerably in both content and structure. The HL7 standard needs to be able to identify a minimum set of characteristics that any terminological resource must possess if it is to be used in an HL7 messaging environment. One approach to this task would be to specify a common data structure which all terminological resources would have to fit. This approach, however, is not without drawbacks. First, a common data structure would have to represent a ‘least common denominator’, which could mask more advanced content and functional characteristics that might be particular to a specific terminology. Another drawback is that this approach puts much of the responsibility for maintaining and updating the content on the HL7 standards body rather than the individual terminology developers.

The Common Terminology Services (CTS) specification was developed as an alternative to a common data structure. Instead of specifying what an external terminology must look like, HL7 has chosen to identify the common functional characteristics that an external terminology must be able to provide. As an example, an HL7 compliant terminology service will need to be able to determine whether a given concept code is valid within the particular resource. Instead of describing a table keyed by the resource identifier and concept code, the CTS specification describes an Application Programming Interface (API) call that takes a resource identifier and concept code as input and returns a true/false value. Each terminology developer is free to implement this API call in whatever way is most appropriate for them.

This document describes a set of API calls that represent the core functionality that will be needed by basic HL7 Version 3 applications.
CTS Release 2 (CTS R2) became a normative standard in February 2015. This document is the Service Functional Model for the Common Terminology Services 2 specification, which is specified under the Service Development Framework process under the auspices of the Healthcare Services Specification Project (HSSP). Further context is given in the overview section below, but one key point to note is that the Service Functional Model (SFM) provides a Service Interface specification, NOT the specification of a Service implementation. This is a critical distinction in terms of Service Oriented Architecture. There could be many different ways of implementing all or part of the functionality to support the behavior described in this specification.

The purpose of an HL7 SFM is to identify and document the functional requirements of services deemed important to healthcare. Accordingly, the CTS R2 service provides a critical component within the larger context of service specifications in that it defines both the expected behaviors of a terminology service and a standardized method of accessing terminology content. This consistent approach to terminology interaction will benefit other business context services by providing a level of terminology interoperability that currently only exists in a limited form.

The goal of the CTS R2 specification stack is to provide a standardized interface for the usage and management of terminologies. Terminologies provide the atomic building blocks of shared semantics. In a shared semantics environment, CTS R2 provides a modular, common and universally deployable set of behaviors which can be used to deal with a set of terminologies chosen by the users of the service in their deployment environment. The service will contribute to interoperability by supporting an easy access to the foundational elements of shared semantics. It will also foster the authoring of high-quality terminologies via its authoring profile. This goal is realized via the expansion of the original functionality outlined in HL7’s CTS Specification. CTS R2 defines the functional requirements of a set of service interfaces to allow the representation, access, and maintenance of terminology content either locally, or across a federation of terminology service nodes. The CTS R2 specification strives to expand on the original functionality outlined in HL7’s Common Terminology Service specification, specifically looking to:

- Establish the minimal common structural model for terminology behavior independent from any specific terminology implementation or interchange model, and how it is related to meta-data (information about data) and data (the information itself)
- Integrate into CTS R2 the functional coverage outlined in the existing CTS specification
- Specify both an information and functional model that addresses the relationships and use of terminology, e.g., how value sets are built and queried, and how terminological information is validated
- Specify the interactions between terminology providers and consumers – how terminology users can submit unambiguous requests for corrections and extensions and how revisions to content are identified, distributed and integrated into running systems
- Specify how mapping between compatible terminologies and data models is defined, exchanged and revised
- Specify how logic-based terminologies can be queried about subsumption and inferred relationships
- Engage broad community participation to describe the dimensions of use and purpose for vocabularies and value sets. This aim will attempt to harmonize these efforts

This version of the document includes several changes:

- Updated conceptual model of terminology
- More generic Detailed Functional Models
- Parameters for the Detailed Functional Model have been made consistent
The EHR-S FM standard will facilitate key advances in electronic health record systems across the continuum of care to enhance quality, safety and efficiency of patient care.

In February 2007, the HL7 Electronic Record Health System Functional Model (EHR-S FM) became the healthcare industry’s first American National Standards Institute (ANSI)-approved standard that specifies the functional requirements for an electronic health record system (EHR-S). In November 2009, the standard was published by the International Organization for Standardization (ISO), and became the first international standard to specify functional requirements for an EHR system. This version of the standard is referenced by HL7 as EHR-S FM Release 1.1 and by ISO as ISO 10781. It was also approved by ANSI in July 2012. The EHR-S FM Release 2 was published and approved by ANSI in 2014. Release 2 offers a more comprehensive set of functions and criteria. The work is informed by industry advances/directions, regulatory changes, learning from work from functional profiles, and participation by the international community. Other inclusions were made as a result of the multiple EHR system functional profiles that have been written on Functional Model Releases 1 and 1.1.

The standard has received broad industry input from more than a thousand clinicians, as well as from EHR vendors, payers, researchers, and others across the industry. The EHR-S FM outlines important features and functions that should be contained in an EHR system. The standard’s functional model contains approximately 1,000 conformance criteria across 160 functions, including medication history, problem lists, orders, clinical decision support, and those supporting privacy and security. The functions are described from a user perspective and enable consistent expression of EHR system functionality, while the conformance criteria serves as a reference for purchasers of EHR systems and vendors developing EHR software.

The EHR-S Functional Model is versatile, adaptable, and applicable across the continuum of care, supporting key advances in EHR systems. HL7 encourages healthcare stakeholders to participate in the development of profiles to support specific uses across the continuum of care. To date, a number of profiles have been developed.

FUNCTIONAL PROFILES

The Child Health Functional Profile, which provides critical electronic health record system functions to care for children in the United States, was developed in August 2007, and became an ANSI-approved standard in December 2008.

The Behavioral Health Functional Profile can be used by treatment provider organizations to select or build their own EHR systems; EHR software developers to guide their future product development efforts; certification organizations to certify EHR software; and healthcare payers as part of their criteria for pay-for-performance and other incentives. It also became an ANSI-approved standard in December 2008.
The Long-Term Care Functional Profile reflects the unique mandates and practices of the long-term care setting. This end product is an invaluable tool as LTC providers and IT vendors work to advance technology that enhances: patient safety, quality of care, efficiency, and continuity of care. This profile was approved by ANSI in September 2010.

The Electronic Health Record (EHR)/Clinical Research (CR) Profiles provides high-level functional requirements necessary for using EHR data for regulated clinical research. It also provides a roadmap towards an evolutionary process of integrating the environment that provides both patient care and data for clinical research. This functional profile encourages EHR vendors to incorporate functions into their products that are necessary to utilize the EHRs as a direct data source for clinical studies. It is intended to provide one overall view of the regulatory needs of clinical research with respect to electronic patient records.

The Records Management and Evidentiary Support Functional Profile provides functions in an EHR system that can help an organization maintain a legal record for business and disclosure purposes, help reduce a provider's administrative burden, and reduce costs and inefficiencies caused by redundant paper and electronic record keeping. This profile was approved by ANSI in August 2010.

The EHR Pharmacist/Pharmacy Functional Profile facilitates EHR systems capture of medication and clinical related data at the point of contact or point of care by specifying the functional requirements needed to support messaging among prescribers, pharmacist and pharmacy providers and other healthcare entities needing medication-related information. It was approved by ANSI in March 2012.

The EHR-S Vital Records Functional Profile - US Realm was published as an informative document in April 2012. It identifies Electronic Health Record system functions that support the capture of vital records (Birth, Fetal Death and Death-related) information at the point of contact or point of care. This profile articulates the functional requirements needed to support messaging among providers, states, local registrars, and federal agencies.

The EHR System Electronic Nutrition Care Process Record System (ENCPRS) Functional Profile is currently a standard for trial use. Developed with the American Dietetic Association’s Nutrition Care Process-Standardized Language committee, it is intended to provide high-level requirements necessary for using electronic health record data for Dietetics and Nutrition Practice using the Nutrition Care Process, and to further provide a roadmap toward a process of integrating the environment that provides data collection for both patient care in dietetics and nutrition care and for the purpose of dietetics and nutrition practice-based research. This functional profile is aimed at encouraging EHR vendors to incorporate functions into their products that are necessary to utilize the EHRs as a direct data source for patient care using the Nutrition Care Process and is intended to provide one overall view of the needs of dietetics and nutrition practice with respect to electronic patient records.

The project is aimed at developing a functional profile that identifies critical capabilities for the performance of nutrition services utilizing EHR
The EHR System Electronic Nutrition Care Process Record System (ENCPRS) Functional Profile - Continued - systems. This work will establish conformance to the HL7 International EHR-S Functional Model Release 1, under the advice and direction of the HL7 International EHR Work Group. A set of requirements is developed for using EHR systems in the documentation of the Nutrition Care Process. These requirements have been mapped into this functional profile and identify those portions of the HL7 EHR-S Functional Model that apply to patient care in the Nutrition Care Process. It further identifies additional functionality toward facilitating ease of use for those involved in patient care in the Nutrition Care Process, thus providing EHR vendors with conformance criteria that are specific to regulated tasks within the Nutrition Care Process in the HL7 International formats.

The EHR System ePrescribing Functional Profile was published in September 2014 as an informative document. Prescribers and pharmacies (pharmacists) have been communicating electronic prescription information using the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for several years. In July of 2004, sixteen participants from HL7 and NCPDP launched the NCPDP-HL7 Electronic Prescribing (eRx) Mapping Project. The goal of the project was to demonstrate the transmission of an electronic prescription from inpatient to outpatient setting and to develop a Mapping Guidance Document. The aspects of the mapping project are available from NCPDP and HL7 and may be used by the industry for mapping the electronic exchange of prescription information.

The EHR System Public Health Functional Profile (PHFP) was published in March 2015. It identifies functional requirements and conformance criteria for public health clinical information collection, management and exchanges that include specific public health programs (domains), namely: vital records; early hearing detection and intervention; chronic diseases (cancer surveillance); public health laboratory interactions (orders and results); occupational disease, injury, and fatality; health statistics; deep vein thrombosis and pulmonary embolism; birth defects; and adverse events. It articulates the functional requirements needed to support data exchange among providers and public health stakeholders including, but not limited to, states, local agencies, and federal agencies. This project is supported by the Centers for Disease Control and Prevention/National Center for Health Statistics. Expert input was sought from local, state and federal public health agencies, healthcare organizations, public health professional associations, schools of public health, health information technology vendor organizations, the private sector, and individuals interested in supporting development of the PHFP.

The Meaningful Use - US Realm Functional Profile was published as an informative document in August 2015. It identifies functional requirements and conformance criteria corresponding to US Meaningful Use Stage 1 and 2 certification criteria. The intent of the MU FP is to build the EHR-S FM to a common end point with US Meaningful Use EHR System Functional Requirements (as specified by US regulations, ONC Meaningful Use Certification Criteria and NIST Test Procedures).
HL7 EHR-S Functional Requirements: S&I Framework Laboratory Results Messages - US Realm was developed through the HHS/ONC Standards and Interoperability (S&I) Framework EHR-S Functional Requirements IG-Labs Work Group. This work is part of a larger effort, the goal of which is to create a suite of requirements documents for Electronic Health Record System (EHR-S) technology for laboratory orders and results harmonized for the US Realm.

The focus is to create an EHR-S Functional Requirements Implementation Guide for laboratory results reporting, which is compatible with the S&I Laboratory Results Interface (LRI) Implementation Guide. Additional US regulatory requirements, e.g., Clinical Laboratory Improvement Amendments (CLIA), and clinical best practices beyond the LRI IG have been considered in the development of this guide.

The Child Health Functional Profile Release 1; Developmental Screening and Reporting Services Derived Profile - US Realm - identifies the critical EHR capabilities for pediatric Developmental Screening and Reporting services. This standard reference content and functions from the existing HL7 EHR-S Functional Model, Release 2 and complements the HL7 Child Health Functional Profile. A set of functions and criteria are developed for vital functions relevant to the Developmental Screening and follow-up process as recommended by entities such as CMS, AAP and Bright Future’s schedule, thus providing EHR vendors with conformance standards that are specific and essential to pediatric Developmental Screening process in the US realm. The framework is designed to have further applications with other developmental or mental health screenings as well.

HL7 EHRS-FM Release 2: Immunization Functional Profile, Release 1
The HL7 Immunization Functional Profile describes functional characteristics and conformance criteria supporting immunization management and administration in clinical practice. This includes functions for interaction with immunization registries, for immunization history and forecast, for reconciliation of immunization administration over time, for immunization (vaccine) inventory management, supplements for patient educational material, adverse event recording and reporting and more.

CONCLUSION
A number of countries use HL7’s EHR-S Functional Model, including The Netherlands, Ireland, Japan, Korea, Spain and Thailand. For example, in Korea, the Center for Interoperable EHR developed a national EHR functionality standard to be implemented in public hospitals based on the EHR-S FM. In addition, the prototype EHR-S developed in 2009 for national university hospitals incorporated the EHR-S FM. Japan also expects that the EHR-S FM can be leveraged as a framework for EHR systems in the country. The General Practice Information Technology (GPIT) Group in Ireland has used the EHR-S FM to certify family practice software.

To see the EHR-S FM profiles, please visit: http://www.HL7.org/implement/standards/product_section.cfm?section=4&ref=nav.
In an industry overflowing with acronyms like V2, V3, CDA® and RIM, the main obstacle to healthcare interoperability is hardly a lack of standards—it’s finding a way to make those standards easier to understand, apply, manage, and implement.

That’s the philosophy behind the HL7 Fast Health Interoperability Standard (FHIR®), an exciting addition to the HL7 family of standards. Designed with a focus on simplicity, HL7 FHIR combines the best features of existing HL7 standards with the latest web technologies to make interoperable healthcare applications dramatically simpler, easier, and faster to develop.

HL7 FHIR (HL7.org/fhir) – Based on the most current web technologies, HL7 FHIR can be implemented in mobile health environments, social applications, and cloud communications, as well as in traditional server-based computing. One significant advantage of HL7 FHIR is its capacity to seamlessly enable data queries.

HL7 FHIR defines a set of “resources” to represent health and healthcare administration-related information. These resources express granular clinical and administrative concepts that can be electronically exchanged in order to quickly and effectively solve system interoperability problems in healthcare and related processes. The resources cover the basic elements of healthcare – patients, admissions, diagnostic reports, medications and problem lists – with their typical data elements and also support a range of richer and more complex clinical models. The simple direct definitions of the resources are based on thorough requirements gathering, formal analysis and extensive cross-mapping to other relevant standards.

These resources can easily be assembled into working systems that solve real world clinical and administrative problems at a fraction of the price of existing alternatives.

Why HL7 FHIR is Better
HL7 FHIR offers many improvements over existing standards:

- Fast and easy to implement (multiple developers have had simple interfaces working in a single day)
- Multiple implementation libraries, many examples available to kick-start development
- Interoperability out-of-the-box – base resources can be used as is, but can also be adapted for local requirements
- Evolutionary development from HL7 V2 and CDA – standards co-exist and leverage each other
- Strong foundation in web standards – XML, JSON, HTTP, Atom, OAuth, etc.
- Supports RESTful architectures and also exchanges information using messages or documents seamlessly
Flexibility
A central challenge for healthcare standards is how to handle variability caused by diverse healthcare processes. Over time, more fields and optionality are added to the specification, gradually adding cost and complexity to the resulting implementations. The alternative is relying on custom extensions, but these create many implementation problems.

HL7 FHIR solves this challenge by defining a simple framework for extending and adapting the existing resources. All systems, no matter how they are developed, can easily read these extensions and extension definitions can be retrieved using the same framework as retrieving other resources.

In addition, each resource carries a human readable text representation using HTML as a fall back display option for clinical safety. This is particularly important for complex clinical information where many systems take a simple textual/document based approach.

Adoption
HL7 FHIR is maturing as a standard, but there are significant implementations being developed around the world and throughout the domain of healthcare, covering national and regional clinical repositories, EHR extensibility projects, coordinated care, and basic healthcare infrastructure. Key development partners in the USA include the Apple, Argonaut Project, CARIN Alliance, CodeX, Da Vinci Project, Gravity Project Google, Logica Health (formerly HSPC), ONC/CMS, and many providers and vendors.

Status
HL7 FHIR Release 4 (R4) was published in December 2018. The most significant change in HL7 FHIR R4 is that the base platform of the standard passed a normative ballot and several potions of it were approved by the American National Standards Institute (ANSI) in 2019 (Infrastructure, Patient, Observation, and Terminology and Conformance). This means that future changes should be backward compatible so applications that implement the normative sections of R4 no longer risk being nonconformant to the standard. The following portions of the standard are now normative:

- The RESTful API, the XML and JSON formats, and the basic data types
- The Terminology Layer (CodeSystem and ValueSet)
- The Conformance Framework (StructureDefinition and CapabilityStatement)
- The key resources Patient and Observation
Future
The FHIR specification is expected to continue to evolve in the future as it responds to the interoperability needs of the robust FHIR implementation community. HL7’s priority for the next release is to bring more sections of the standard to normative status and continue to respond to the needs of the community that is building solutions. The FHIR Maturity Model (http://HL7.org/fhir/versions.html#maturity) helps implementers understand how the various parts of the standard are advancing through the standards development life-cycle.

HL7 FHIR Implementation Guides and Profiles
A number of FHIR implementation guides have been or are being developed, including Structured Data Capture, Data Access Framework and Quality.

HL7 FHIR Implementation Guide: Structured Data Capture (SDC)
This implementation guide is intended to support clinical systems in the creation and population of forms with patient-specific data. It defines a mechanism for linking questions in forms to pre-defined data elements to enable systems to automatically populate portions of the form based on existing data, either locally or by invoking an operation on a third-party system. Specifically, this implementation guide explains how the four resources (using defined profiles) – DataElement, Questionnaire, QuestionnaireAnswers, and ValueSet – can be used to support auto-population of forms and data extraction. It also describes secure interaction specifications using Representational State Transfers (REST) services to allow access, display, population, and saving of resources.

HL7 FHIR Profile: Data Access Framework (DAF)
The DAF identifies and recommends standards for the interoperable representation and transmission of data using the notion of a Query Stack which modularizes the various layers of the Data Access Framework.

The DAF FHIR Implementation Guide provides requirements and implementation guidance for the various layers of the DAF Query Stack which includes:

- Queries including structure, vocabularies and value sets
- Query results including structure, vocabularies and value sets
- Transport requirements
- Security and privacy controls required for data access

HL7 FHIR Profile: Quality
QICore FHIR profiles define the Quality Information and Clinical Knowledge (QUICK) logical model. The QUICK model, derived from QICore, provides a uniform way for clinical decision support and quality measures to refer to clinical data. Simultaneously, the QICore profiles provide a physical implementation of QUICK, making data for quality improvement applications accessible via the FHIR interface.
HL7 FHIR Profile: Pharmacy; Medication
This implementation guide is based upon the HL7 FHIR STU3 specification. It promotes the consistent use of pharmacy FHIR resources in US Realm Electronic Health Record Systems (EHRs) to provide consumer and provider access to patient medications. This implementation guide provides specific guidance on how to access a patients’ active and historical medications, including prescriptions, dispenses, administrations and statements. It also proposes a specific approach to creating new outpatient prescriptions and to record a dispensed medication.

HL7 FHIR Profile: US-Core
The US Core Implementation Guide defines the minimum conformance requirements for accessing patient data as defined by the Argonaut pilot implementations and the ONC 2015 Edition Common Clinical Data Set (CCDS). These requirements were originally developed, balloted, and published in HL7 FHIR DSTU2 as part of the ONC sponsored Data Access Framework (DAF) project. In addition to Argonaut, these profiles are used by DAF-Research, QI-Core, and CIMI, and are intended to be the foundation for future US Realm guides.

The US Core Implementation Guide provides requirements and implementation guidance which includes:
- Queries including structure, vocabularies and value sets
- Query/Results including structure, vocabularies and value sets
- Transport Requirements
- Security and Privacy controls required for data access

HL7 FHIR® Implementation Guide: Bulk Data, Release 1
This implementation guide defines secure FHIR export Operations that use this capability to provide an authenticated and authorized client with the ability to register as a backend service and retrieve all data in a FHIR server, data on all patients in a server, or data on a group of patients while optionally specifying data since a certain date. Applications can use the bulk data export functionality to facilitate data transfer among back-end systems, various organizations, and for reporting or public health use cases.

HL7 FHIR® Implementation Guide: Clinical Genomics, Release 1
Genomics is a rapidly evolving area of healthcare that involves complex data structures. There is significant value in sharing this information in a way that is consistent, computable and that can accommodate ongoing evolution of medical science and practice. The value comes from the ability to easily sort, filter and perform decision support on such information and the resulting improvements in care and reduction in costs such as the elimination of redundant testing. The implementation guide is also transmission protocol-independent - the data structures presented here could be used in RESTful, messaging, document or other paradigms.
HL7 FHIR® Implementation Guide: Clinical Genomics, Release 1, Continued
This guide covers all aspects of human genomic genomics-reporting, including:

- Representation of simple discrete variants, structural variants including copy number variants, complex variants as well as gross variations such as extra or missing chromosomes
- Representation of both known variants as well as fully describing de novo variations
- Germline and somatic variations
- Relevance of identified variations from the perspective of disease pathology, pharmacogenomics, transplant suitability (e.g. HLA typing), etc.
- Full and partial DNA sequencing, including whole genome and exome studies
- Mosaicism (differing genomic characteristics for different specimens from the same subject)
- Mitochondrial DNA variations

for this FHIR interface enable consumers/members/patients to understand the costs and alternatives for drugs that have been prescribed, and to compare their drug costs across different insurance plans.

This project defines a FHIR interface to a health insurer's drug formulary information for patients/consumers. A drug formulary is a list of brand-name and generic prescription drugs a health insurer agrees to pay for, at least partially, as part of health insurance coverage. Drug formularies are developed based on the efficacy, safety and cost of drugs. The primary use cases

HL7 FHIR® Implementation Guide: Electronic Case Reporting (eCR) - US Realm, Release 1
With the advent of FHIR standards, there is a need for FHIR implementation guidance to specify appropriate resources and transactions needed for the eCR process. FHIR offers opportunities to further enable automated triggering and reporting of cases from EHRs, to ease implementation and integration, to support the acquisition of investigation supplemental data, and to connect public health information (e.g., guidelines) and clinical workflow. Over time, FHIR may also support the distribution of reporting rules to clinical care to better align data authorities and make broader clinical data available to public health decision support services inside the clinical care environment.

HL7 FHIR® Implementation Guide: Electronic Long-Term Services and Supports (eLTSS) Implementation Guide (IG) is based on FHIR R4. It was developed to support exchange of data generated during the planning and provision of long-term services and supports and is currently scoped to data commonly found on long-term services and supports (LTSS) service plans.
HL7 FHIR® Implementation Guide: FHIRcast, Release 1
The FHIRcast specification describes the APIs used to synchronize disparate healthcare applications’ user interfaces in real time, allowing them to show the same clinical content to a user (or group of users).

Once the subscribing app knows about the session, the app may subscribe to specific workflow-related events for the given session. The subscription is verified and the app is notified when those workflow-related events occur; for example, by the clinician opening a patient’s chart. The subscribing app may initiate context changes by accessing APIs exposed by the Hub; for example, closing the patient’s chart. The app deletes its subscription to no longer receive notifications. The notification message describing the workflow event is a simple json wrapper around one or more FHIR resources.

FHIRcast is modeled on the webhook design pattern and specifically the W3C WebSub RFC, such as its use of GET vs POST interactions and a Hub for managing subscriptions. FHIRcast recommends the HL7 SMART on FHIR launch protocol for both session discovery and API authentication.

HL7 FHIR® Profile: Occupational Data for Health (ODH), Release 1
This implementation guide contains profiles to implement support for Occupational Data for Health (ODH). ODH is primarily designed to facilitate clinical care, including population health; ODH also can be used to support public health reporting, population health, and similar value-based care. ODH is not designed to support billing activities. This STU Ballot for the Occupational Data for Health (ODH) Implementation Guide (IG) is sponsored by the National Institute of Occupational Safety and Health (NIOSH), a federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. NIOSH is a part of the Centers for Disease and Prevention (CDC). The project to define ODH was done with a group representing a variety of stakeholders including NIOSH subject matter experts, epidemiologists, occupational health providers, and vendors.
The FHIR Community & FHIR Accelerators
Due to the many advantages HL7 FHIR offers, it is already implemented across the healthcare IT industry. HL7 FHIR Release 4 was published in December 2018. There are hundreds of implementations across 30 countries, including national and regional health records and information services.

Two key US-based communities have been leading stakeholder engagement as the standard continues to evolve:

**HL7® FHIR® Accelerator Program**
The HL7 FHIR Accelerator Program is designed to assist communities and collaborative groups across the global health care spectrum in the creation and adoption of high quality FHIR implementation guides or other standard artifacts to move toward the realization of global health data interoperability.

Current FHIR Accelerators include:
- **Argonaut Project**
  [http://www.argonautproject.org](http://www.argonautproject.org)
- **The CARIN Alliance**
  [https://www.hl7.org/carin/](https://www.hl7.org/carin/)
- **CodeX**
  [https://www.hl7.org/codex/](https://www.hl7.org/codex/)
- **Da Vinci Project**
  [https://www.hl7.org/about/davinci/](https://www.hl7.org/about/davinci/)
- **Gravity Project**
  [https://www.hl7.org/gravity/](https://www.hl7.org/gravity/)

**Other FHIR Communities**
- **Logica Health**
  [https://www.logicahealth.org/](https://www.logicahealth.org/)

Join the HL7 FHIR community now and have your say by joining chat.fhir.org, coming to a connectathon or following #FHIR on Twitter.

For more information, go to: [http://www.HL7.org/fhir/](http://www.HL7.org/fhir/).
The Personal Health Record System Functional Model (PHR-S FM) is the industry’s first technical standard to specify functionality for PHR systems. It became an ANSI-approved standard in May 2014. The PHR-S FM specifies features and functions necessary to create and effectively manage PHRs and that help an individual maintain a longitudinal view of his or her health history. Personal Health Record information is expected to be sent, received, or exchanged from multiple systems, including: electronic health record systems, insurer systems, payer systems, health information exchanges, public health systems, internet-based health education sites, clinical trials systems, and/or collaborative care systems.

The PHR-S FM provides guidelines that facilitate health information among different PHR systems and between PHR and EHR systems. The PHR-S FM serves as a general model that can be customized to the specific PHR models already in existence, such as stand-alone, web-based, provider-based, payer-based and employer-based systems. While the PHR-S FM is general in scope and was developed with an eye toward what is achievable today, it contains the flexibility necessary for product innovation and sets a vision for future PHR systems.

The HL7 EHR Work Group formed a PHR Work Group in 2005 in response to the growing awareness that personal health records are a valuable tool consumers can use to help them make informed healthcare decisions. While an abundance of PHR systems exist in today’s market, the industry lacked a functional standard to which these systems could conform. The creation of a PHR standard was essential because it outlines guidelines for systems to follow, facilitating the exchange of health information among different PHR systems as well as between PHR and EHR systems.

HL7’s PHR-S FM has benefited from the input of a broad range of stakeholders. The model was developed by a work group consisting of consumers, providers, health plans, vendors and health information management and information technology professionals. It is critical that a PHR system standard include criteria that are universal across a variety of PHR system models, yet at the same time, be easily adaptable to encourage product innovation.

The PHR-S FM can be applied to specific PHR models (stand-alone, web-based, provider-based, payer-based, or employer-based models). At the same time, the functional model is flexible enough to encourage product innovation. Due to broad stakeholder input, The PHR-S FM is a well-balanced and versatile functional model that can be applied across the continuum of care.

www.HL7.org
The Reference Information Model (RIM) is the cornerstone of the HL7 Version 3 development process. It is the combined consensus view of information from the perspective of the HL7 working group and the global HL7 affiliates. The RIM is the ultimate source from which all HL7 Version 3 protocol specification standards draw their information-related content.

The RIM is a static model of health and healthcare information as viewed within the scope of HL7 standards development activities. It is an object model and graphically represents the clinical data (domains) and identifies the life cycle of events that a message or groups of related messages will carry. As a shared model between all the domains and the model from which all domains create their messages, the RIM is essential to HL7’s ongoing mission of increasing precision of data. The RIM became an ANSI-approved standard in late 2003 and was published as an International Organization for Standardization (ISO) standard in September 2006.

The RIM provides a static view of the information needs of HL7 Version 3 standards. It includes class and state-machine diagrams and is accompanied by use case models, interaction models, data type models, terminology models, and other types of models to provide a complete view of the requirements and design of HL7 standards. The classes, attributes, state-machines, and relationships in the RIM are used to derive domain-specific information models that are then transformed through a series of constraining refinement processes to eventually yield a static model of the information content of an HL7 standard.

The HL7 Version 3 standard development process defines the rules governing the derivation of domain information models from the RIM and the refinement of those models into HL7 standard specifications. The rules require that all information structures in derived models be traceable back to the RIM and that their semantic and related business rules not conflict with those specified in the RIM. Therefore, the RIM is the ultimate source for all information content in HL7 Version 3 standards.

The RIM is used by HL7 affiliates to extend HL7 Version 3 standards to meet local needs. Through a process known as localization, Version 3 standard specifications are extended using the RIM as the source for new information content. This new information is derived from the RIM and refined in the same manner used to create the original specification.

Explicitly representing the connections that exist between the information carried in the fields of HL7 messages, the RIM is essential to HL7’s ongoing mission of increasing precision and reducing implementation costs.

The HL7 RIM, Release 7 was approved by ANSI in July 2016. It is available on the HL7 website at www.HL7.org.
The Decision Support Service was approved by ANSI in August 2011. The standard defines the functions, responsibilities, inputs, outputs, and expected behavior of a system component for evaluating patient data to reach patient-specific conclusions. A DSS, for example, can evaluate a patient’s health summary as encoded in a Continuity of Care Document (CCD®) and provide structured recommendations regarding the patient’s health maintenance and chronic disease management needs.

**Why produce an industry standard Decision Support Service?**

Quite simply, the Decision Support Service defines the collective set of behaviors that one would expect a clinical decision support engine to perform. This functionality is required by “Meaningful Use” regulations, and allows for the data collected in electronic health records and other clinical information systems to provide enhanced value for patients, clinicians, healthcare providers, and payers.

The challenge is that the lack of a standard makes the use of decision support services more costly and difficult. Without clearly defined expectations of how Decision Support Services should interface with health information systems, variants abound and interoperability suffers. Moreover, today it is very common that decision-support logic is embedded within applications. This approach is difficult to maintain and even harder to leverage across implementations.

**Don’t industry standard services (such as the Decision Support Service) limit vendor competition?**

Not necessarily. While industry standards specify how a consumer interacts with the service, these specifications have expressly left how these functions are supported out-of-scope. In other words, there is no predetermined knowledge modeling formalism, system design platform, or approach that is advocated in the standard. Vendors are able to compete based upon quality-of-service and the benefits of their specific implementation. Further, the specification includes mandatory and supplemental requirements (“nice-to-haves”), which can further stratify marketplace offerings.

**How does this relate to the OMG Technical Specification and to the Healthcare Services Specification Project (HSSP)?**

For DSS, HL7 has partnered with the OMG to produce technical specifications supporting Service Functional Models within OMG’s technology adoption process. To the healthcare industry, this provides value via OMG’s rigorous architectural approach, review process, and distributed systems expertise. For OMG, this relationship brings deep healthcare experience via HL7’s extensive international participation and vertical industry expertise. The [Clinical] Decision Support Service technical specification is freely available from http://www.omg.org/spec/CDSS. HSSP is a moniker for the collaboration activity between the groups.

DSS R2 was approved by in September 2018.
HL7 Version 3 Standard: Identification Service (IS), Release 1 — The Identification Service (IS) also known as the Identification and Cross-Reference Service (IXS) Service Functional Model define the functional requirements which provides a set of capabilities to manage and retrieve identifying information for various kinds of entities (people, organizations, devices etc.). It was approved by ANSI in 2014 and is available for download on the HL7.org website.

Formerly known as the Entity Identification Service (EIS) — was adopted as a normative HL7 specification in late 2009. It defines the functions, responsibilities, inputs, outputs, and expected behavior of a system component for managing identities, such as would be used in a Master Patient Index (MPI). Not limited to use for patients, the EIS SFM can be equally applied to manage identities for staff, providers, facilities, or any other “entities” needing identity management.

Why produce an industry standard Identification Service?

Quite simply, the Identity Cross-Reference Service defines the collective set of behaviors that one would expect system components such as an MPI to perform. This functionality is required of most healthcare organizations and supported by many vendors and products. The challenge is that each one does things a bit differently, thus, making them work together becomes exponentially complex. Without clearly defined expectations of what falls within the responsibility of the Identification Service, variants abound and interoperability suffers.

Don’t industry standard services (such as the Entity Identification Service) limit vendor competition?

Not necessarily. While industry standards specify how a consumer interacts with the service, these specifications have expressly left how these functions are supported out-of-scope. In other words, there is no predetermined matching algorithm, system design platform, or approach that is advocated in the standard. Vendors are able to compete based upon quality-of-service and the benefits of their specific implementation. Further, the specification includes mandatory and supplemental requirements (“nice-to-haves”), which can further stratify marketplace offerings.

How does this relate to the OMG Technical Specification and to the Healthcare Services Specification Project?

For IS, HL7 has partnered with OMG to produce technical specifications supporting Service Functional Models within OMG’s technology adoption process. To the healthcare industry, this provides value via OMG’s rigorous architectural approach, review process, and distributed systems expertise. For OMG, this relationship brings deep healthcare experience via HL7’s extensive international participation and vertical industry expertise.

Interested parties can download the standard from the HL7 website at: https://www.hl7.org/implement/standards/product_brief.cfm?product_id=87.
The Retrieve, Locate, Update Service Functional Model (RLUS SFM) Standard for Trial Use is a functional standard defining the capabilities, responsibilities, inputs, outputs, and expected behavior of a system component capable of querying information and returning data and metadata between systems. Although fairly abstract in nature, RLUS provides a generic query and retrieval mechanism that can be used for managing a multitude of information content via a standard access mechanism, promoting consistency within a heterogeneous environment.

For example, an organization may have a benefits/enrollment system, an electronic health record system, and a personal health record, and integrating information from among these systems can be complex. RLUS could be used to further this integration by building an RLUS-compatible interface into each of the above systems, and making a distributed RLUS call to retrieve pertinent information for a specific patient. The RLUS specification standardizes how disparate information types are managed and aggregated into a single result.

Further, since RLUS provides a mechanism for new, richly structured information content to be supported, integration based upon RLUS allows for new systems to come online and integrate into the organization’s infrastructure. RLUS specifies a collection of behaviors needed to manage inquiry, query, and retrieval of content. The “location” function allows for the return of candidate information, indicating the availability of matching records without actually returning their instances (for example, does the system have any positive zzzz lab results for patient X). Other interface behaviors specify how the targeted information can be retrieved or updated. Alternatively, RLUS provides a mechanism for a combined query and retrieval behavior. This is convenient when the user selection of candidate resources is not practical or reasonable.

What is the benefit to using RLUS?

Integration of new software packages in a heterogeneous environment creates an exponential integration problem. Each new system-to-system interface creates tremendous integration burden in terms of creating messages, mapping data fields, and potentially transforming data for use. Interface engines have a role to play here, but do not directly support complex queries among participating systems. RLUS allows for these complexities to reside within the systems that hold the data, shielding requestors from unnecessary detail. RLUS simplifies the ask-answer pattern, providing both rigor and clarity while supporting rigorous but flexible information contents. RLUS can also be used as a powerful tool to assist in categorizing and integrating information within an Enterprise. As RLUS provides a consistent set of functions and the ability to support a shared information model, it allows information to be queried in a consistent way even if information is represented in numerous ways. In this fashion, RLUS provides a powerful standardization mechanism that can support governance.
and authority boundaries within or outside of organizations.

Another architectural benefit RLUS provides is an ability to standardize interfaces in a single organization or as a cross-organizational interface. Used this way, RLUS allows organizations with internal legacy interfaces to communicate in a simple and standardized way, providing a common, consistent means of interacting among systems with minimal or no transformation burden.

How does this relate to the OMG Technical Specification and to the Healthcare Services Specification Project?

HL7 has partnered with OMG to produce detailed technical specifications that implement RLUS Service Functional Model within OMG's technology adoption process. To the healthcare industry, this provides value via OMG's rigorous architectural approach, review process, and distributed systems expertise. For OMG, this relationship brings deep healthcare experience via HL7's extensive international participation and vertical industry expertise. The Healthcare Services Specification Project (HSSP) (http://www.healthinterop.org) is a moniker for the collaboration between standards bodies creating these services standards, of which HL7 and OMG are participants. The RLUS technical specification is freely available on the HL7 website at: www.hl7.org/implement/standards/product_brief.cfm?product_id=89.
The Structured Product Labeling (SPL) specification is a document markup standard that specifies the structure and semantics of the content of authorized published information that accompanies any medicine licensed by a medicines licensing authority. These documents are known as “product label,” “package insert,” “prescribing information,” “product information,” “medicines information,” and under many other names. The precise definition and content of product labeling usually varies depending on the country. For example, in the United States, all written, printed, or graphic matter accompanying a medicinal product is called “labeling.” For human prescription drugs, the “content of labeling” includes all text tables and figures in the labeling described in 21CFR 201.57. Implementers of this standard should refer to regulations, definitions and guidances applicable for the realm in which the standard will be used.

An SPL document is created by an organization that is required by law to submit product information documentation because it is responsible for the creation or marketing of a product, or any other person or organization compelled by other motives to submit information about products, whether originally created or not. This includes original manufacturers, repackagers, relabelers, and public agencies or private information publishers that submit product information documents. Recipients of product label documents are any person or organization, including the public at large, or an agent of the public (such as a regulatory authority). The need to create SPL documents is typically governed by legal statutes which set points such as the completion of a new drug application (NDA), the change of product information or annual reports as requiring submission of an SPL document. This specification includes a detailed description of an information model for structured product labeling documents as well as the XML representation of that model. The information model is based on the HL7 Reference Information Model (RIM) and uses the HL7 Version 3 data types.

SPL is based on the HL7 Clinical Document Architecture (CDA), which specifies the structure and semantics of “clinical documents” for the purpose of exchange (see 3.1.1 Relationship of the SPL Specification to CDA®). The SPL Schema is defined as an XML entity. An SPL document references the SPL Schema.

This specification includes a detailed description of an information model for structured product labeling documents as well as the XML representation of that model.

THE PURPOSE OF THE SPL

The major purpose of the SPL specification is to facilitate the review, editing, storage, dissemination of, and access to, product labeling document content. It is intended to:

- Facilitate provision of the content of product labeling both electronically and in a human readable format. SPL documents can be exchanged across systems without the need for additional transformation steps.
- Improve dissemination of product labeling (both new product labeling and product labeling updates) to users of product labeling. The ability to provide the most up-to-date product labeling in a timely manner is considered to be critical to improving risk management of regulated products.
Facilitate more efficient evaluation of labeling changes by allowing more effective use of computer technology to compare different versions of labeling on a section by section basis.

Promote more coordinated data collection throughout the regulatory agency and improve processing, storage and archiving capabilities. Reduce or eliminate redundancies in data collection.

Improve access to information and enhance the ability to query and report on the content of labeling, allowing better support for specific analyses such as sub-population assessments of differences in products based on gender, race, age, and geographic location.

Improve interoperability of the regulatory agency’s systems with other clinical information systems.

Use standards to improve integration of clinical data.

Enhance patient safety by helping to provide prescribers and consumers with improved access to information needed to make better risk management decisions in a format that will enhance integration with other technical and clinical applications.

Support retention of legacy product labeling in databases.

Even though the SPL specification was designed analogous to the HL7 Clinical Document Architecture (CDA®), there are fundamental differences between the two specifications, for example:

- CDA documents involve a Patient — SPL documents do not.
- The potential for authentication is subtly different for product labeling documents than for CDA documents. While a product labeling document may be authenticated, and may even have a requirement for legal authentication in some realms, this authentication occurs on the officially approved version of the document rather than on each minor revision of the document in the process of finalizing it.

Although SPL does not give priority to delivery of patient care in the same way as CDA documents, which are directly associated with patient encounters, the goal of providing timely information about medical products ultimately serves patient care. The most recent version, Release 8, received ANSI approval in February 2018 and is available for download on the HL7 website at www.HL7.org.

The major purpose of the SPL specification is to facilitate the review, editing, storage, dissemination of, and access to product labeling document content.
HL7’s Version 2.x messaging standard is the workhorse of electronic data exchange in the clinical domain and arguably the most widely implemented standard for healthcare in the world. In 2010, HL7 Version 2 was selected by the US Office of the National Coordinator for Health Information Technology as part of its initial set of standards, implementation specifications and certification criteria for EHR technology.

The HL7 Version 2.x standard covers messages that exchange information in the general areas of:

- Patient Demographics
- Patient Charges and Accounting
- Patient Insurance and Guarantor
- Clinical Observations
- Encounters including Registration, Admission, Discharge and Transfer
- Orders for Clinical Service (Tests, Procedures, Pharmacy, Dietary and Supplies)
- Observation Reporting including Test Results
- The synchronization of Master Files between systems
- Medical Records Document Management
- Scheduling of Patient Appointments and Resources
- Patient Referrals—Specifically messages for primary care referral
- Patient Care and problem-oriented records.

Version 2.6 represents a major revision to Versions 2.5 and 2.5.1, refining and updating existing messages and adding new messages and domains all based upon proposals submitted and accepted by the HL7 membership. Modifications from Version 2.5.1 include:

- The addition of a new segment, UAC – User Authentication Credential, to ALL messages
- The replacement of the TS – Timestamp data type with the DTM – Date/Time data type
- The replacement of the CE – Coded Element data type with either the CNE – Coded with No Exceptions data type or the CWE – Coded with Exceptions data type
- The deprecation of the CNN, NDL, LA1 and LA2 data types
- The inclusion of “external” tables referencing a set of coded values defined and published by another standards organization assigned an HL7 number but without designation as an HL7 table (as was previously the practice)
- The revision of examples in all chapters to support HIPAA compliance
- The inclusion of a new chapter supporting electronic messaging transactions of claims and reimbursement data (which is produced for implementations of HL7 outside of the United States; in the United States, HIPAA law mandates an already in-use set of implementation guides of X12 messages for these purposes)
- The inclusion of a new chapter supporting electronic messaging transactions of supply chain management data within healthcare facilities
Version 2.7 was approved by ANSI in January 2011. Modifications from Version 2.6 include:

- The addition of a Conformance Length definition Chapter 2
- Numerous tables were moved to new chapter, Chapter 2C
- The deprecation of the IS data type in favor of CWE data type
- Introduction of new IAR (Allergy Reaction) message in Chapter 3, Patient Administration
- Introduction of new OML (Specimen shipment centric laboratory order) message in Chapter 4, Orders
- Introduction of new SHP (Specimen Shipment Manifest) in Chapter 7, Observations
- Introduction of new PRT (Participant Information Segment) in Chapter 7, Observations
- Introduction of Collaborative Care messages to Chapter 11, Patient Referral

Version 2.7.1 was released in 2012 as an addendum to Version 2.7. It provides select updates to chapters 2B, 2C, 4, and 7 to support the Laboratory Results and Orders Interface implementation guides for Meaningful Use Stage 2 in the USA. ANSI approved Version 2.7.1 in July 2012.

Version 2.8 was approved by ANSI in February 2014. There were numerous updates to Version 2.7.1 Some of the modifications from Version 2.7 include:

- All HL7, user-defined and externally-defined tables moved to chapter 2C
- All chapters updated to include the acknowledgement choreography in their trigger event definitions
- The addition of an introduction of requirements

Version 2.8.1 was approved by ANSI in August 2014. It contains a number of updates to support the Version 2 laboratory implementation guides that are intended to be referenced by ONC’s certification program editions.

Version 2.8.2 was approved by ANSI in September 2015. It is deemed necessary to support:

- The US Federal Government’s Health and Human Services (HHS) proposed Laboratory Implementation Guides supporting functionality for communicating an orderable lab test compendium, ordering laboratory tests, and reporting the lab results;
- The Australian national health IT initiative requiring vocabulary updates;
- The HHS initiative introducing universal device identifiers (UDI), The HHS initiative introducing universal device identifiers (UDI).

Version 2.9 was approved by ANSI in December 2019.

The Version 2.x standard can be downloaded from the HL7 website at www.HL7.org.
The Health Level Seven Version 3 (V3) Normative Edition — a suite of specifications based on HL7’s Reference Information Model (RIM) — provides a single source that allows implementers of V3 specifications to work with the full set of messages, data types, and terminologies needed to build a complete implementation.

The 2016 edition represents a complete suite of Version 3 specifications, each of which has received formal approval as either a normative standard or a draft standard for trial use. It includes standards for communications to document and manage the care and treatment of patients in a wide variety of healthcare settings. As such, it is a foundational part of the technologies needed to meet the global challenge of integrating healthcare information, in areas such as patient care and public health.

Throughout the course of Version 3 development, HL7 has focused on a few salient features that are its hallmarks. Benefits of Version 3 are:

- Focuses on semantic interoperability by specifying that information be presented in a complete clinical context that assures that the sending and receiving systems share the meaning (semantics) of the information being exchanged.
- Designed for universal application so that the standards can have the broadest possible global impact and yet be adapted to meet local and regional requirements.
- Provides consistent representation of data laterally across the various HL7 domains of interest and longitudinally over time as new requirements arise and new fields of clinical endeavor are addressed.
- Allows implementers to take advantage, at any point in time, of the latest and most effective implementation technologies available.
- Assures consistent development and the ability to store and manipulate the specifications in robust data repositories rather than as word-processing documents.

The Version 3 Normative Edition represents an approach to clinical information exchange based on a model driven methodology that produces messages and electronic documents expressed in XML syntax. The V3 specification is built around subject domains that provide storyboard descriptions, trigger events, interaction designs, domain object models derived from the RIM, hierarchical message descriptors (HMDs) and a prose description of each element. Implementation of these domains further depends upon a non-normative V3 Guide and normative specifications for: data types; the XML technical specifications (ITS) or message wire format; message and control “wrappers;” and transport protocols.

Version 3 has been implemented in Canada, the Netherlands, Mexico, Germany and Croatia. The United Kingdom National Health Service (NHS) uses specifications based on the HL7 Version 3 Reference Information Model, data types and methodology in nearly 2 million transactions per day. More details about the Version 3 product suite can be found on the HL7 website at http://www.hl7.org/implement/standards/product_brief.cfm?product_id=186.