INTRODUCTION: The HL7 International EHRS-FM (EHR System Functional Model) outlines important features and functions that should be contained in an EHR system; where, through the creation of functional profiles, this model provides a standard description and common understanding of functions for healthcare settings, such as a US-Realm (country) Profile and Federal Agency Sub-Profiles; where, DoD-and-VA Sub-Profiles can include each agency’s mission needs, goals, objectives and specific test-criteria.

To date, HL7 has developed or is developing profiles for areas such as:
- emergency care,
- long term care,
- child health,
- behavioral health
- Record Management and Evidentiary Support (RMES)
- US Meaningful Use objectives and test criteria
- eight public health sub-profiles.

This presentation recommends the creation of a US Realm (country) Profile including:
- US legislative mandates, such as ARRA, HIPAA, CLIA and
- US Department of Health and Human Services regulations, such as
  - HL7 V2.51 messaging standards,
- CDA/CCDA documents
- CMS’s Meaningful Use
The goal of the Electronic Health Record (EHR) Work Group is to support the HL7 mission of developing standards for EHR data, information, functionality, and interoperability; where, that includes

- Functional-and-Information Requirements for Electronic Health Records (EHR) and systems (EHRS),
- Functional-and-Information Requirements for Personal Health Records (PHR) and systems (PHRS),

An objective of the EHR Interoperability WG team is to create a clear, complete, concise, correct and consistent ‘2017 EHR System Function and Information (EHRS-FIM) R3.0 in Sparx Systems Enterprise Architect tool; where, a DoD-VA EHRS-FM-FHIR-FHIM can address the structural-consistency issues identified by the VA negative ’2013 R2 ballot.

A second objective of the EHR Interoperability WG is to produce a Meaningful-Use profile for ‘2014 R2.0 & planned ‘2017 R3.0

The objective of the Resource Management Evidentiary Support (RM-ES) project team, within the EHR WG is to provide expertise on records management, compliance, and data/record integrity and related to governance to support the use of medical records for clinical care and decision-making, business, legal and disclosure purposes.

NOTE: EHRS-FM does NOT imply a specific architectures or workflows; but, profiles can be architecture & workflow specific.
MISSION: DoD-and-VA Data Sharing

HIT GOAL: Continuity-of-Care across the care-continuum, including Quality-of-Care, Patient-Safety, Care Efficacy-and-Efficiency

OBJECTIVES: Support patient-care and benefits-adjudication, by getting the right-Information to the right-person at the right-time.

1. Fit-for-Purpose Data, when-and-where it is needed by clinicians provided-by agile, aligned and interoperable systems.
3. Project Management Accountability and Audit Readiness using EHR System Functional Model (EHRS-FM) to baseline, roadmap, categorize and configuration manage DoD-VA Data-Sharing architecture.

Background:

- In 2009, The VLER (Virtual Lifetime Electronic Record) program was initiated by the President to enable the DoD and VA and their partners to proactively provide the full continuum of services and benefits to Servicemen and Veterans made possible by effective, efficient, and secure standards-based information sharing; where, the 2009 ARRA-HITECH (American Recovery and Reinvestment act included Health Information Technology for Economic and Clinical Health) legislation funded the IPO (Interagency Program Office), ONCHIT (Office of the National Coordinator for Health Information Technology) managed nwhin (Nation-Wide Health Information Network) gateway and DoD-VA integrated EHR System (iEHR) initiative. Goals were set for “the utilization of an EHR for each person in the United States by 2014 and the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information.”
- From 2009 through the end of 2012, the IPO, nwhin Connect and iEHR approaches were explored and lessons were learned; where, IPO focus evolved to monitoring and reporting to congress and the ONC evolved nwhin connect to eHealth Direct.
- In 2013, and the DoD and VA Secretaries changed the Healthcare IT mission from integrated to interoperable EHR systems; where, the Health IT Goal focuses on continuity-of-care across the care-continuum, including Quality-of-Care, Patient-Safety, Care Efficacy-and-Efficiency; and where, the 2014 National Defense Authorization Bill mandates the IPO and GAO to monitor and report on DoD and VA Data-Sharing interoperability to congress, as a prerequisite for DoD-and-VA receiving incremental funding.

Health IT Must Make Clinical Operations Effective and Efficient:

1. The Health IT objective is to Support patient-care and benefits-adjudication, by getting the right-Information to the right-person at the right-time; where this objective breaks down into:
2. Getting Fit-for-Purpose Data, when-and-where it is needed by clinicians provided-by agile, aligned and interoperable systems.

This brief recommends using EHR System Functional Model (EHRS-FM) as the baseline to

- Project Management Accountability and Audit Readiness; where, roadmap, categorize and configuration manage DoD-VA Data-Sharing exchange-architecture.
The DoD and VA have supported the development of the HL7 EHR System Functional Model (EHRS-FM) for over ten years; where, release-2 was published in March 2014.

- A US-Federal-Realm EHRS-FM-FHIR-FHIM profile, which includes DoD and VA Sub-Profiles can be developed to address Agency concerns-and-needs; where, the profiles can
- Provide Knowledge-Management Traceability and an Interoperability-Dashboard among Legislative, Business, Information, Behavior, System-Implementation Perspectives;
- Provide a high return-on-investment for Agency support to HL7; FHIM, HITSP, S&I Framework and Agency informatics-research; where, the profiles can be a
  - Standardized and peer-reviewed reference model for DoD, VA and partner interoperability;
  - Harmonization and Configuration-Management umbrella for FHIM, FHIR, S&I Framework;

**BENEFITS; where the EHRS-FM can**

1. Facilitate describing end-user values such as patient safety, quality outcomes and efficacy and efficiency in terms of standard EHR-S functions’ conformance criteria.
2. Promote a common understanding of EHR functions; where, developers, vendors, users and other interested parties can plan-and-evaluate EHRS requirements-specifications for acquisition, development, test and certification.
3. Provide the necessary framework to drive the requirements and applications of next level standards, such as EHR content, coding, information models, constructs and interoperability for information portability between sub-systems of and across EHR-Ss.
4. Establish a standards-based method by which each realm (country) can apply these EHR functions to care settings, uses and priorities
5. Inform those concerned with secondary use of EHR data and national infrastructure what functions can be expected in an EHR System

- **EHRS-FM-FHIR-FHIM** Profile can be a **Reference Function-and-Information Model** for IPO-and-GAO monitoring-and-Reporting and Agency Test-and-Certification
  - Including EHRS functions mapped-to DoD-VA Integrated Business Reference Model (iBRM) activities
  - Including EHRS functions mapped-to DoD-VA Agency Business Process Models
  - Including EHRS functions mapped-to DoD-VA Requirements, including Information Exchange (IE)
- **HITSP and S&I Framework** provide **Reference-Enterprise Use-Cases and ISs**
- **Meaningful Use Stage 2** provides **Reference-Enterprise Quality-Indicators**
- **FHIM** provides a **Reference-Enterprise Information-Architecture**
- **LEGOs** (Lightweight Expression of Granular Objects) facilitates clinical evidence-based medicine, population analytics and decision support
- **DoD-VA-HHS** Health Standards Profile (HSP) provides an **Enterprise Standards Architecture**
- **DoD-VA Information Exchanges** linked to HSP provides an **Enterprise Exchange-Architecture**
- **FHIM-LEGObased FHIR Profile** is an **Enterprise Interoperability Architecture** including
  - Data Management Services (DMS), CDA/CCDA documents and NIEM messages
- **ONC/FHA** can expand this strategy to harmonize with other applicable agencies
This slide shows the content of the Informatics Architecture and how it can be made traceable to the Business Architecture and Systems Exchange-Architecture, using the RHRS-FM.

**DATA-SHARING DRIVERS:** VLER, ARRA, NDAA, MU2, CLIA

**INFORMATICS GOAL**: Evidence-Based Medicine, Population-Health Analytics and Clinical Decision-Support

**INTEROPERABILITY OBJECTIVES**: Consistent Structure-Semantics-Security-Services-Transport Models

**APPROACH**: Common Information Interoperability Framework (CIIF) using Informatics Architecture Acceleration (ISAAC)

- **IE Content-and-Semantics** can come from Federal Health Information Model (FHM) elements bound to SNOMED, LOINC, RxNorm terminology within a structure, called LEGO (Lightweight Expression of Granular Objects) containing a SNOMED semantic assertion-and-classifier; where, LEGOs enable construction of meaningful information exchanges-of computable-medical-information in support of analytics, evidence-based-medicine and decision-support applications that can enhance the quality, safety and efficacy of patient-care.

- **IE Structure** can be specified by Model Driven Health Tool (MDHT) transformations of logical LEGOs into implementable HL7 Fast Healthcare Interoperability Resources (FHIR), CDA/CCDA document and National Information Exchange Model (NIEM) message schemas.

- **IE Security, Transport, Services, Workflow** are generally managed as a part of a system's infrastructure and service agreements.

- **Record Management and Evidentiary Support (RM-ES)** constraints can be in accordance with scope-of-practice, organizational-policy and US law.

**Lightweight Expression of Granular Objects (LEGOs)** are based on the Simple Information Model (SIM) Framework

- Organizes clinical information in a maximally reusable way
- Designed to resolve the long-standing tension between “terminology models” and “information models”
- The terminology plays the central role, and the information model is reduced to a bare minimum container.

Where, the SIM approach is

- Constructed around SNOMED CT taxonomy, with Extensions
- Deployed alongside a description logic classifier (e.g., EL++)
- Allows clinical statements of arbitrary complexity to be constructed as needed
- Preserves the ability to aggregate and analyze the clinical information later

**LEGO model instantiated as an XML Schema (polymorphic Object)**

**Key feature** is an assertion structure composed of:

- **Observable** element in the form of an assertion
- **SOLOR** (SNOMED, LOINC, RxNorm) pre-or-post coordinated expression
- Expression representing the subject of the assertion (i.e., the “question” or “what is being observed”)
- **Qualifier** element
- How the observable-assertion is acquired (e.g., by interview or physical exam or an HL7 “null flavor”)
- **Value** element (e.g., Boolean or numeric value)
- The value of the expression in the observable (i.e., the “answer” or observation result)
- **Timing** element (optional interval)
- Period of time during which the assertion was valid
This slide shows how Informatics tools and concepts can be integrated into a factory-like process to develop Interoperability Specifications and Implementation Guides to support a run-time environment.

**Informatics Architecture Acceleration (ISAAC) Lightweight Expression of Granular Objects (LEGOs) for Semantic Interoperability**

- EHRS-FM functions can organize Information Exchange Requirements (IERs)
- IHTSDO/ISAAC Open-Tooling Framework (OTF) eclipse-plugin for SNOMED CT, with extended EL++ classification can transform FHIM classes or Detailed Clinical Models (DCMs aka CIMI Archetypes), using highly-reusable SOLOR (SNOMED, LOINC, RXnorm) pre-or-post coordinated terminology value-sets into Lightweight Expression of Granular Objects (LEGOs), defining a bottom-up Informatics architecture for the construction of IER Interoperability Specifications.

- Based on the IHTSDO Observables Model, LEGO self-contained units of knowledge transform patient data into a normalized SCS; where, the SCSs are the foundation for the large-scale exchange of computable medical information in support of analytics and decision support applications that can enhance the quality, safety, efficacy of patient care.

- IHTSDO/ISAAC workbench can combine LEGO pieces into complex Structured Content Specifications (SCS); where,

- **MDHT** (Model Driven Health Tool) can transform these SCSs to FHIR profiles for DoD-VA Data Management Services (DMS), NIEM messages, CDA/CCDA documents.
This slide shows how a Master Knowledge Index (MKI) version of a Requirements Traceability Matrix (RTM) can provide traceability to a US-Realm EHRs-FM-FHIR-FHIM Profile with DoD-and-VA Sub-Profiles can include traceability; where, the MKI can be kept simple in Excel or extended to support architectural analysis using Protégé, using the standard W3C Resource Description Framework (RDF):

- HITSP/S&I Framework/Agency Use-Case (UCs), Interoperability Specifications (ISs), Agency integrated Business Reference Model (iBRM), Business Process Models (BPM), requirements and Health Standards Profile (HSP) are maintained; where, UCs describe and constrain business entities, processes, activities and Information Exchange (IE) and ISs define IE content structure-semantics-transport-security-services and (optional) workflow; and where,

- EHRs functions can be mapped to UC business processes-and-activities, clinical-guidelines/best-practices, Agency requirements and IEs, Meaningful-Use objectives-and-criteria, Quality Reporting Document Architecture (QRDA), legislative-mandates, and DoD-VA-HHS Healthcare Standards Profile (HSP).

Knowledge management can prevent staff and projects from constantly reinventing the wheel, can provide a baseline for progress measurement, can reduce the burden on expert availability and attrition, can enable visual thinking and make evidence-based analytics tangible, and can effectively manage large volumes of information to help stakeholders have better and faster outcomes. Knowledge management can help solve many common business problems and can increase effectiveness by improving:

1. **Business Decisions** by facilitating access to expertise and evidence-based analytics.
2. **Efficiency and Productivity** by having timely access to knowledge
3. **Innovation** through wider and borderless access to knowledge
4. **Access to Know-How** by capturing explicit and tacit knowledge
5. **Stakeholder Satisfaction** by focusing on mission-oriented outcomes.
6. **Quality** with cross-functional collaboration and knowledge-reuse
7. **Audit Readiness** by managing business capability lifecycle traceability
This slide shows how the HL7 Service Aware Interoperability Framework (SAIF) and its Enterprise Compliance and Conformance Framework (ECCF) can be used as an interoperability dashboard; where fit-for-purpose architectural views would be assessed and risk-managed.

The DoD, VA and IPO’s ECCF’s goal is to ensure Working Interoperability (WI) among stakeholders:

- Working Interoperability is an instance of two “trading partners” — human beings, organizations, or systems, successfully exchanging data or coordinating behavior to accomplish a defined task, such as population analytics, Evidence Based Medicine or Decision Support.
- The ECCF’s purpose is to manage the traceability among architectural artifacts and implementations of those requirements-specified.
- The objective of a fully qualified ECCF is to be a clear, complete, concise, correct, consistent and traceable interoperability specification, which is easy-to-use.
- An ECCF can be a Risk-Assessment Framework, which supports Configuration-Management Baselines throughout a business-capability lifecycle.
- An ECCF is used to specify information exchange interoperability and implementation Requirements-Specification conformance statements for documents, messages and services.
- An ECCF provides a template, called a Specification Stack (SS), for specify business objects, components, capabilities, applications and systems organized as a matrix of
  - Perspective columns (Enterprise, Information, Computational, Engineering and Technical) and
  - Abstraction rows (Conceptual, Logical and Implementable).

The HL7 SAIF ECCF shows a super set of common architectural-artsifacts. All the listed artifacts may NOT be required by the DoD-VA EHRS-FM profile; other artifacts may be included. Within each cell

1. You manage traceability within columns and consistency across layers.
2. ECCF asserts, as true or false, that a set of conformance assertions are met within an implementation of a Specification Stack (SS); where,
3. The ECCF identifies risks potential needing mitigation across the organization’s Business Capability Lifecycles.
DoDAF V2.0 focuses on architectural "data", rather than on developing individual "products". In general, data can be collected, organized, and stored by a wide range of architecture tools developed by commercial sources. It is anticipated that these tools will adopt the DoDAF Meta Model (DM2) Physical Exchange Specification (PES) for the exchange of architectural data. Conformance ensures that reuse of information, architecture artifacts, models, and viewpoints can be shared with common understanding.

DoDAF conformance is achieved when:
- The data in a described architecture is defined according to the DM2 concepts, associations, and attributes.
- The architectural data is capable of transfer in accordance with the PES.

**DODAF 2.0 Views**

<table>
<thead>
<tr>
<th>AV-1: Overview and Summary Information</th>
<th>AV-2: Integrated Dictionary</th>
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<table>
<thead>
<tr>
<th>DIV-1: Conceptual Data Model, DIV-2: Logical Data Model, DIV-3: Physical Data Model</th>
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<thead>
<tr>
<th>OV-6: Operational Rules Model, OV-6b: State Transition Description, OV-7: Event-Trace Description</th>
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<tbody>
<tr>
<td>OV-4: Organizational Relationships Chart</td>
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<tr>
<td>OV-5: Operational Activity Decomposition Tree, OV-5b: Operational Activity Model</td>
</tr>
<tr>
<td>OV-6a: Operational Rules Model, OV-6b: State Transition Description</td>
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<tr>
<th>PV-1: Project Portfolio Relationships, PV-2: Project Timelines, PV-3: Project to Capability Mapping</th>
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<tr>
<td>StdV-1: Standards Profile, StdV-2: Standards Forecast</td>
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<tr>
<td>StdV-3: Systems-Systems Matrix, StdV-4: Systems Functionality Description</td>
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<tr>
<td>StdV-5a: Operational Activity to Systems Function Traceability Matrix, StdV-5b: Operational Activity to Systems Task Matrix</td>
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<tr>
<td>StdV-6: Systems Resource Flow Matrix, StdV-7: Systems Measures Matrix</td>
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<tr>
<td>StdV-8: Systems Evolution Description, StdV-9: Systems Technology &amp; Skills Forecast</td>
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<tr>
<td>StdV-10a: Systems Rules Model, StdV-10b: Systems State Transition Description</td>
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</tbody>
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<tr>
<th>SvcV-1: Services Context Description, SvcV-2: Services Resource Flow Description</th>
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<td>SvcV-3a: Systems-Services Matrix, SvcV-3b: Services-Services Matrix</td>
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<tr>
<td>SvcV-3c: Systems Event-Trace Description, SvcV-4: Services Functionality Description, SvcV-5: Operational Activity to Services Traceability Matrix</td>
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BENEFITS of a US Realm (country) Profile and DoD and VA Sub-Profiles; where the profiles can
1. Facilitate describing end-user, US national, DoD and VA values such as patient safety, quality outcomes, efficacy and efficiency in terms of standard EHR-S functions’ conformance criteria.
2. Promote a common understanding of DoD-and-VA EHR clinical and administrative user’s specific needs; where, developers, vendors, IPO, GAO, Congress, the White House and other interested parties can plan-and-evaluate EHRS requirements-specifications for acquisition, development, test and certification.
3. Provide a common Informatics-Framework to manage consistent Interoperability-Specifications, Implementation-Guides and applications of next-level standards for EHR message, document and service content, coding, information models and terminology binding, reusable constructs-and-profiles, resulting in data-sharing interoperability across EHRSs and organizations.
4. Establish a standards-based method by which the EHR functions describe typical US, DoD and VA care settings, workflows and data
5. Inform those concerned with secondary use of US, DoD and VA HER-data and US National and/or Federal Agency infrastructure what functions can be expected in EHR-System and data-exchange-architectures; where, a US-Realm (country) profile can include the Federal Health Information Model (FHIM), HHS mandated standards, implementation guides, objectives and criteria.

Governance Concerns
1. ONC should sponsor, IPO should manage the overall effort and the ICIB should govern the effort.
2. Does ONC/DoDAVA/IPO/NIH or GAO resource the following?
   A. US-Realm EHRS-FM Profile
      1) Meaningful-Use criteria Inclusion-and-maintenance
      2) ARRA, NOAA, HIPAA, CLIA etc. conformance-traceability inclusion-and-maintenance
      3) HITSP & S&I Framework Use-Case Simplification inclusion-and-maintenance
      4) FHIM, EHR-FM and FHIR harmonization-and-maintenance
      5) LEGO harmonization-and-maintenance with FHIM
      6) FHIR Profile from FHIM and LEGOs creation-and-maintenance
   Use-and-maintenance of ISAAC-and-EDH Tooling
   B. DoD-and-VA Sub-Profiles
      1) iBRM and Use-Cases harmonization, maintenance-and-inclusion
      2) Data-Sharing IERs Interoperability-Specifications maintenance-and-traceability
      3) HARB Information Exchange Tool maintenance
      4) HARB Health Standards Profile (HSP) and IER-to-HSP mapping maintenance
      5) Investment Portfolio, systems’ architecture, test and certification traceability
   C. Other agencies (e.g., IHS, FDA, HHS, CDC, CMS, NCI) Sub-Profiles
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HL7 EHR WG Weekly Calls
(770) 657-9270 Code: 510269#

- Rec Mgmt/Evidentiary Support: Mon 12 Noon ET
- EHR Interop WG (Release 3): Tues 1PM ET
- EHR Interop WG (Meaningful Use): Tues 2PM ET
- EHR Work Group (Plenary): Tues 3PM ET ← status of all workgroups given here
- Personal Health Record WG: Wed 12 noon ET
- EHR Usability WG: Wed 3PM ET
Document Change History

1. Mar 12, 2014-A First Draft [Steve Hufnagel]
2. Mar 13, 2014-B Remove HDD [Mike Lincoln],
   • Added ISAAC/LEGO [Catherine Hoang]
   • Added Enterprise Information Architecture [Steve Hufnagel]
4. Mar 15, 2014-D Added Executive Summary Section [Steve Hufnagel]
5. Mar 17, 2014-E Added Knowledge Engineering (KE) [Steve Hufnagel]
   • Added Data Management Strategy (DMS) [Steve Hufnagel]
6. Mar 18, 2014-F Added ISAAC/LEGO details [Keith Campbell]
7. Mar 19, 2014-G Added Gartner CPR generation Levels, EBM (Nona Hall)
   • Added iBRM & iPRM [Jan Kamorowski], Added Executive Summary slide [Greg Staudenmaier],
     Added NIST Tooling Strategy [Gary Dickinson]
   • Modified tone to be objective [Catherine Hoang], Added S&I Framework and ECCF slides [Steve Hufnagel]
9. Mar 24, 2014-I Split Executive Summary into 3 slides [Steve Hufnagel]
10. Mar 25, 2014-J Moved SAIF ECCF to Executive Summary [Nona Hall]
    • Added DoDAF ECCF to backup [Nona Hall]
11. Mar 26, 2014-K Added Executive Summary Diagram [Steve Hufnagel]
13. April 15, 2014-M Broke brief into 3 parts (Executive Summary, EHRS-FM, Informatics)
    • Added DoD-VA Clinical Mission at front [Paul Tibbitts], Added Governance Issues at end in notes pages [Paul Tibbitts], Moved Talking Points Slides to Notes Pages [Nona Hall], Moved Lego description to Part 1 [Steve Hufnagel]
Acronyms

IBRM Integrated Business Reference Model
IE Information Exchange
IER Information Exchange Requirements
IHR Integrated Electronic Health Record
IG Implementation Guide
IHTSDO International Health Terminology Standards Development Organization
IS Interoperability Specification
IHS Indian Health Service
IHTSDO International Health Terminology Standards Development Organization
IN Information Infrastructure
IPO Interagency Program Office
ISAAC Informatics Architecture ACCELERATION
IT Information Technology
JSON Javascript Object Notation
LEGQ Lightweight Expression of Granular Objects
IPO DoD-VA Interagency Program Office
ISO International Standards Organization
IHTSDO International Health Terminology Standards Development Organization
JCAHO Joint Commission on Accreditation of Healthcare Organizations
KE Knowledge Engineering
LEGQ Lightweight Expression of Granular Objects
LOGIC Logical Observation Identifiers, Names and Codes
MDHT Model Driven Health Tool
MHS US Military Health System
MU2 Meaningful Use stage-2
NCI US National Cancer Institute
NQA National Committee for Quality Assurance
NDEM US National Information Exchange Model
NIST US National Institute of Standards and Testing
ONC Office of the National Coordinator
OTF Open Tooling Framework
PHR Personal Health Record
PHeS Personal Health Record System
PHS Population Health Support
PQYX JCAHO quality initiative to support hospitals and long-term care facilities
PDR Preliminary Design Review
QIO Quality Improvement Organization
QDA Quality Reporting Document Architecture
R1 R2 R3 Release-1 Release-2 and Release-3
RI Record Infrastructure
RLUS Retrieve, Locate, Update Service
SAI Standards and Interoperability
SAIF HL7 Service Aware Interoperability Framework
SCHIP Surgical Care Improvement Project
SCS Structure Content Specification
SDO Standards Development Organization
SIM Simple Information Model
SLA Service Level Agreement
SNOMED CT Systematized Nomenclature of Medicine-Clinical Terms
SOLOR SNOMED, LOINC, RDW
SRR System Requirements Review
SW Software
TC Technical Committee
TI Trust Infrastructure
UC Use Case
VA US Veterans Affairs Agency
VLER Virtual Lifelong Electronic Record
WG Work Group
XML Exchange Markup Language