Trip Report for
3-4 CIMI Meeting and
5-7 HL7 Workgroup Meeting, Atlanta GA
Stephen Hufnagel PhD, October 8, 2015

Since January 2011, the Clinical Information Modeling Initiative (**CIMI**)[1] has been an international collaboration dedicated to providing a single curated collection of detailed specifications for the representation of health information content. In this way semantically interoperable[2] information may be created and shared in health records, messages, and documents.

The CIMI Strategic Goal is to be able to share data, applications, reports, alerts, protocols, and decision support modules with anyone in the WORLD with "plug-n-play" interoperability. The CIMI objectives are to have
  1) Shared repository of detailed clinical information models
  2) One single formalism (now supports both ISO 13606 archetypes and OMG UML)
  3) A common set of base data types
  4) Formal bindings of the models to standard coded terminologies
  5) Open repository and models that are free for use at no cost
  6) Models that support multiple contexts
  7) Target domains
      a) EHR data storage
      b) Message and service payloads
      c) Decision logic (queries of EHR data)
      d) Clinical trials data (clinical research)
      e) Quality measures
      f) Normalization of data for secondary use
      g) Creation of structured data entry screens
      h) Capture of coding output from NLP

FHIM[3] and CIMI are analogous logical models; where,
  • CIMI preferred models are text archtypes; while, FHIM models are graphical UML
  • Ultimately, CIMI and FHIM have the potential to be iso-semantic models; where,
      o CIMI starts with atomic concepts and then constructs complex clinical concepts.
          ▪ CIMI focus is clinical models,
          ▪ Currently, CIMI is limited to laboratory models; but,
          ▪ Intermountain Health is prepared to donate a large number of models.
      o FHIM starts with high-level domains adding clinical concepts and fidelity (top-down)
          ▪ FHIM has completed approximately 17 of 32 health related domains
          ▪ FHIM has a broad health care focus, including
              • administration, finance,

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[1] See www.openCIMI.org

[2] In healthcare, interoperability is the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged [HIMSS]. S&I Framework defines semantic interoperability as having consistent Structure, Semantics, Security, Services and Transport (S4T).

[3] **FHIM** is Federal Health Information Model

- Behavioral and population health etc.

Gary Dickinson, EHR work-group co-chair and I discussed the proposed HL7 US Realm Health Care Architecture with HL7s' Stan Huff (board chairman), Chuck Jaffe (CEO) and John Quinn (CTO), who indicated that they support the proposal.
- such an architecture was recommended by the
  - 2014 JASON report[4]
  - 2014 HL7 Annual Report
- Stan supported CIMI and FHIM model assimilation; where,
  - there will be an iso-semantic relationship between models
  - There would be a common data dictionary of terms.
  - FHIM emphasizes holistic top down domain-by-domain coverage
  - CIMI emphasizes detailed clinical models produced by clinicians.
  - Tools manage the consistency of the models.
  - The HL7 CIMI workgroup and EHR workgroup would facilitate the development and balloting of the proposed HL7 US Realm Health Architecture, with other workgroups, such as PC, CIC, SOA, Vocab., O&O, etc. as co-sponsors.

The HL7 meeting was predominated by the relationship of FHIR to the multitude of HL7 workgroups. As predicted by the Gartner Hype-cycle for representing the maturity, adoption and social application of specific technologies.

- FHIR is at or is approaching Gartner's "Peak of Inflated Expectations"; where, FHIR's 2011 breakthrough kicked things off. Early proof-of-concept stories and interest triggered significant publicity and early adoption. Interoperability connect-a-thons have engaged early adopters who are producing FHIR extensions and profiles; but, ambiguous and inconsistent FHIR resource implementations are not always resulting in the desired ad-hoc universal plug-and-play interoperability.
- FHIR is approaching Gartner's "trough of disillusionment; where, the cause of disillusionment is the proliferation of ambiguous and inconsistent FHIR resource extensions and profiles, which degrade semantic interoperability.
- The proposed tool-based HL7 US Realm Health Architecture is proposed as the Gartner "Slope of Enlightenment" to serve as "*a coordinated architecture and a technology for advancing interoperability … to loosely-couple healthcare data sharing networks*" [2014 Jason Report] with a holistic, agile, aligned and interoperable organizing paradigm to ensure future interoperability; so that, FHIR can benefit the enterprise with consistent Structure, Semantics, Security, Services and Transport (S4T).
- As a result, the Gartner "Plateau of Productivity" for FHIR can facilitate mainstream adoption; because, the proposed HL7 US Realm Health Architecture adds the criteria for assessing provider viability are more clearly defined within the architecture. The technology's broad market applicability, relevance, and return on investment can clearly pay off with a clear, complete, concise, correct and consistent FHIR implementation paradigm curated via the HL7 US Realm Health Architecture, with complete tool maintained software development lifecycle traceability within the architecture and to legislation and jurisdictional policies and rules.

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[4] *A Robust Health Data Infrastructure* AHRQ Publication No. 14-0041-EF, April 2014.
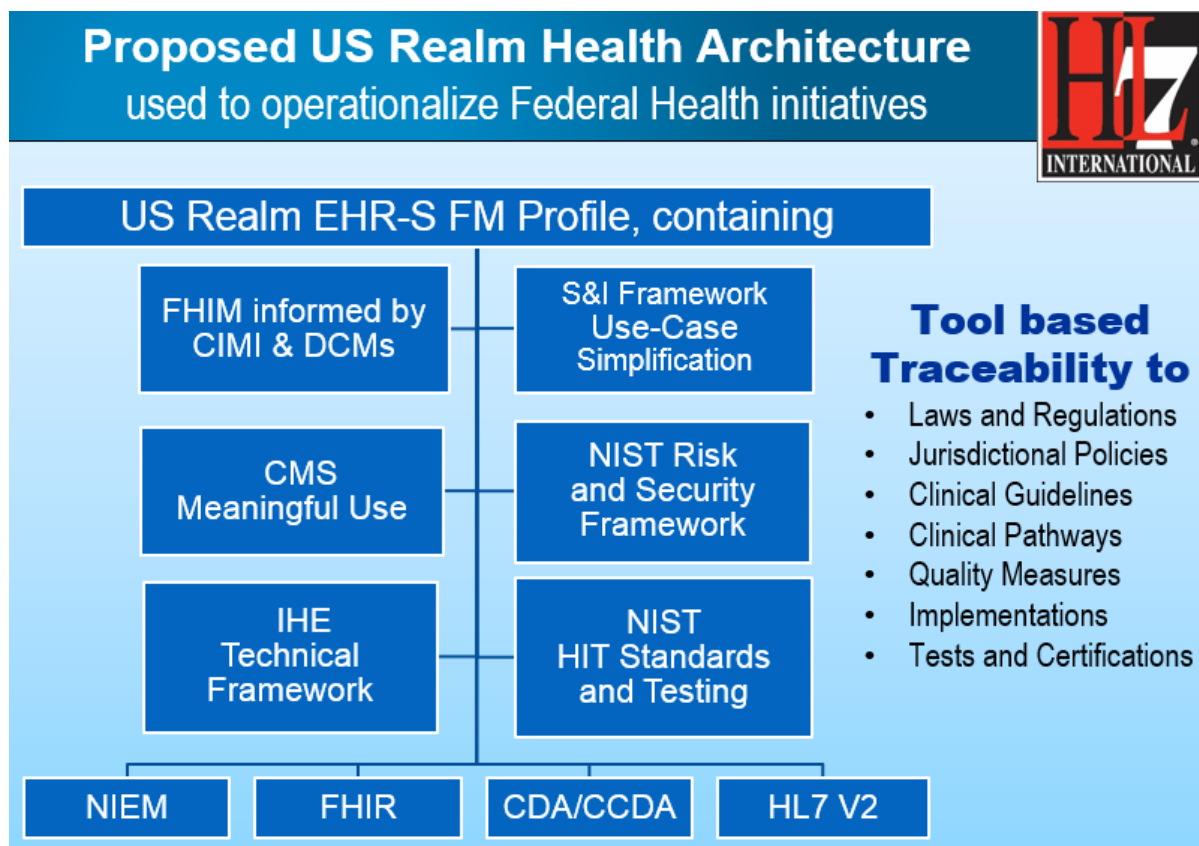
APPENDIX: Discussion

A notional user-story / use-case might be
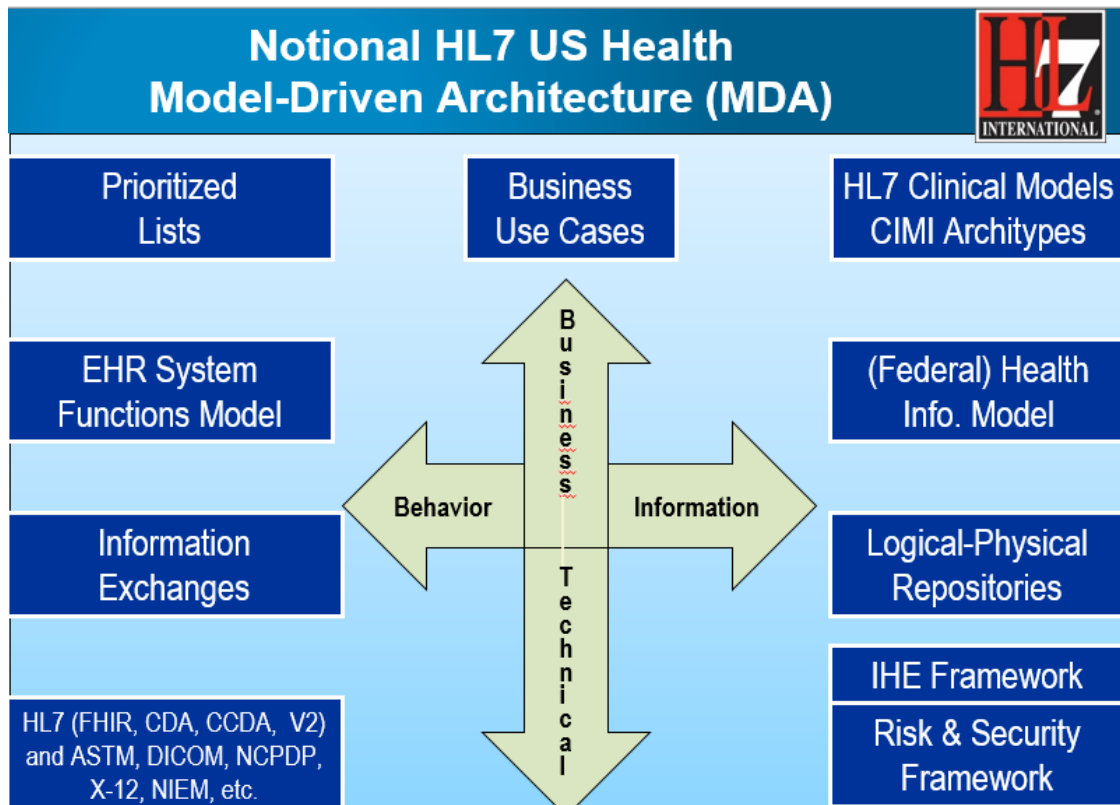
1. <u>Clinician Lists</u> prioritize Health Data Sharing (HDS) mission needs; where, the lists inform
2. <u>Business Use Cases</u> (UCs) developed by Analysts
    1. S&I Framework Use-Case Simplification initiative has developed use-case resources and tooling.
    2. Legacy use-Cases are decomposed into reusable events, actions, data & information exchanges.
3. <u>UCs constrain System Objects, Capabilities, Services, and Information Exchange Requirements (IERs)</u> described by Analysts and Architects, who are informed by
    1. EHR-S System Functional Model
    2. FHIM, constrained by HL7 Detailed Clinical Models (DCMs) and CIMI models
4. <u>System Logical-Physical Repositories</u> are specified by Architects and Designers, based on
    1. System Objects, Capabilities, and Services specified as FHIM subsets.
5. <u>System Information Exchanges</u> are specified by Architects & Designers, based on
    1. MDHT (FHIM) generated Implementation Guides (IGs) for NIEM, FHIR, CCDA or
    2. HL7 V2, NCPDM, X12, etc. Implementation Guides
    3. FHIM-based queries to obtain required data from Physical Repositories.
    4. NIST Security Framework and IHE Technical Framework to manage the exchanges.
    5. NIST SP-800 Risk Assessment/Management Framework to manage network risk.
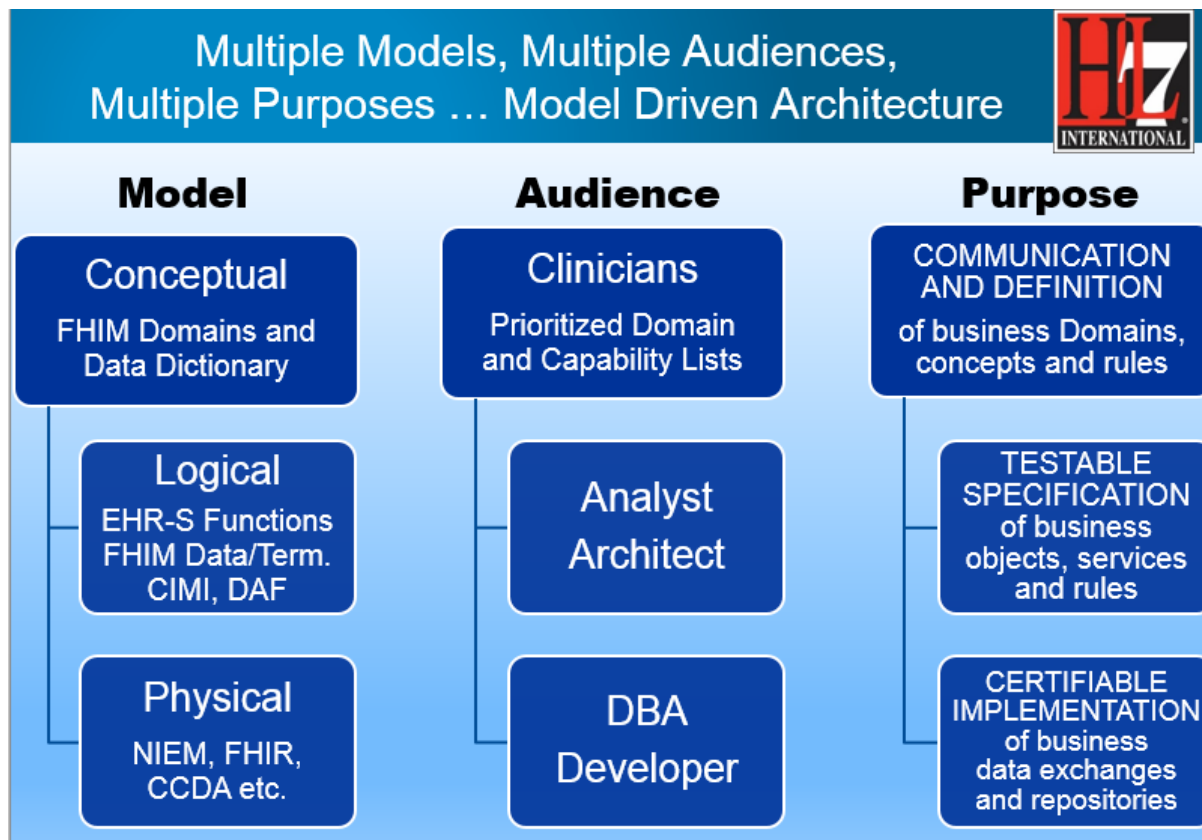
The proposed Approach to US Realm Health Architecture is a tool-based US Realm EHR-S FM Profile to Empower Developers with Model Driven Architecture (MDA)

a) EHR-S Functional Model as "umbrella"
   i) Traceability to jurisdictional laws, regulations and policies
   ii) CMS Meaningful Use objectives and criteria
   iii) Traceability to clinical guidelines, pathways and quality measures
b) S&I Framework Use-Cases Simplification Framework, including
   i) AHIC/HITSP use cases, NIST/CDC immunization use case,
   ii) Others as requested by Federal Agencies
c) Federal Health Information Model (FHIM), with bindings / mappings to
   i) NLM's US Extension to SNOMED CT, LOINC, RxNorm, NCPDP etc.
   ii) NIEM, FHIR, CDA, CCDA
   iii) HL7 & **CIMI** detailed clinical models and archetypes
d) Implementation guides and reference implementations considering
   i) Integrating the Healthcare Enterprise (IHE) Technical Framework
   ii) DOD-VA Data Access Framework and Model Driven Health Tool
   iii) Healthcare Services Platform Consortium **(HSPC)** software-module APIs
   iv) NIST Cybersecurity Framework, Standards and Testing

Proposed US Realm Health Architecture used to operationalize Federal Health initiatives

US Realm EHR-S FM Profile, containing

- FHIM informed by CIMI & DCMs
- S&I Framework Use-Case Simplification
- CMS Meaningful Use
- NIST Risk and Security Framework
- IHE Technical Framework
- NIST HIT Standards and Testing
- NIEM
- FHIR
- CDA/CCDA
- HL7 V2

Tool based Traceability to
- Laws and Regulations
- Jurisdictional Policies
- Clinical Guidelines
- Clinical Pathways
- Quality Measures
- Implementations
- Tests and Certifications

Notional HL7 US Health Model-Driven Architecture (MDA)

Above is the proposed architecture structure and below is its proposed users and uses.

Notional Software Development Lifecycle HL7 US Health MDA Users and Uses
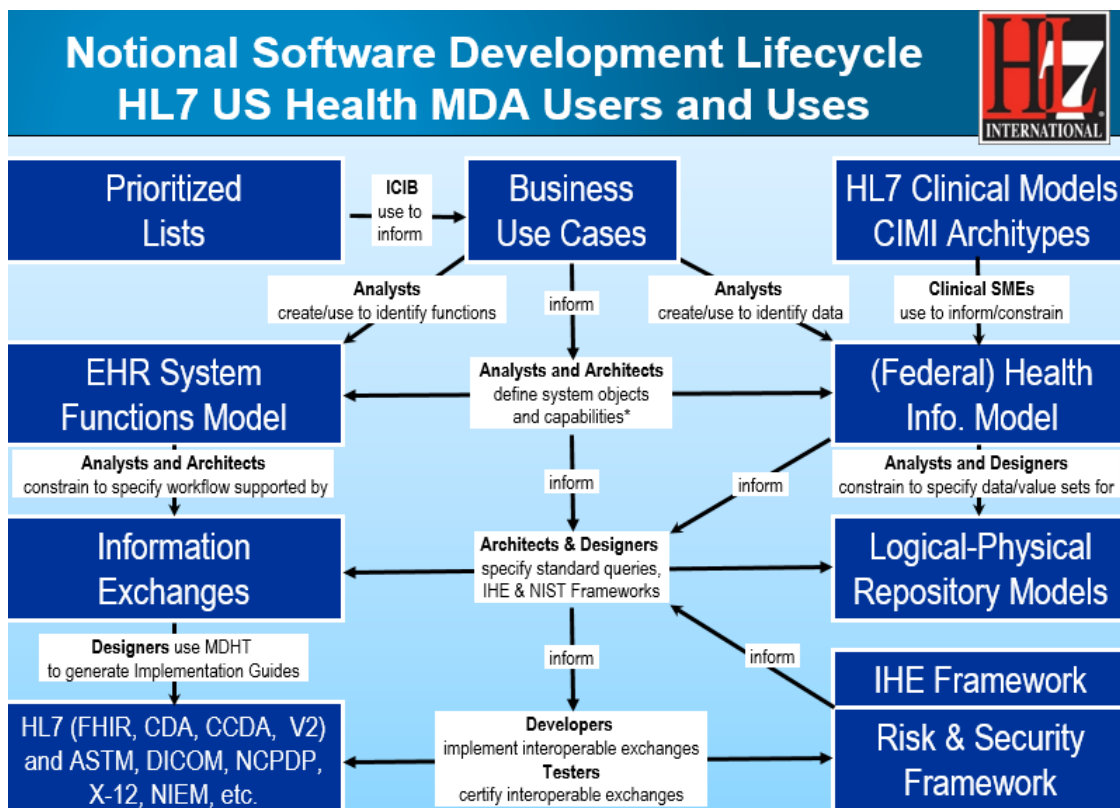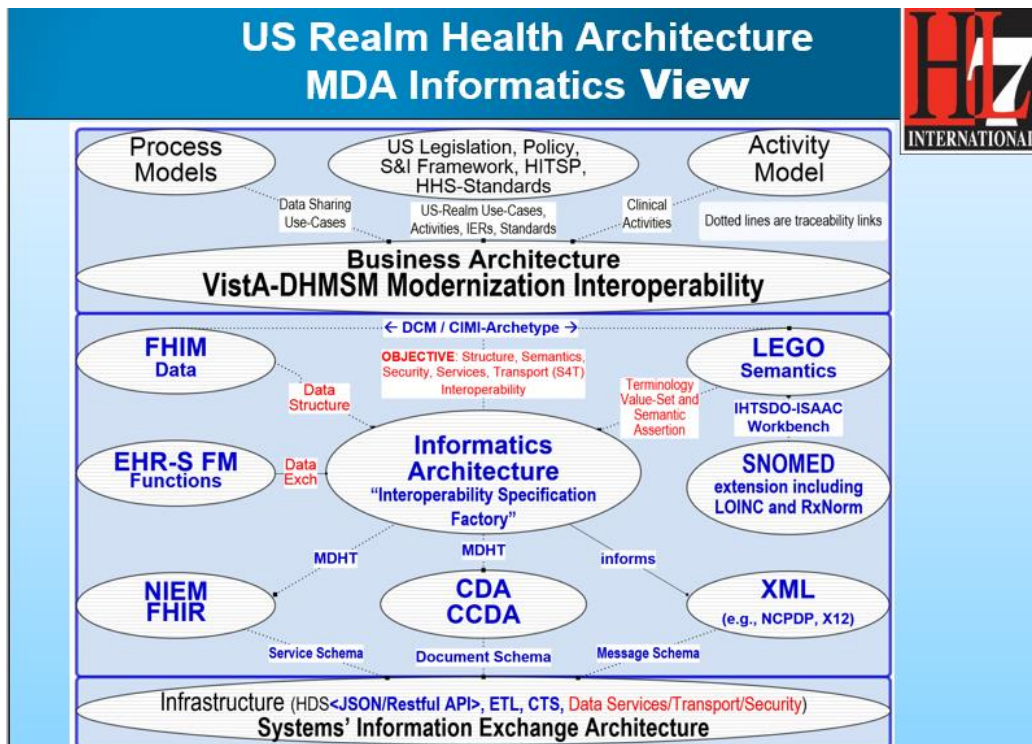
The Proposed HL7 Schedule for the US Realm EHR-S FM Profile is

- Sept/Dec 2015 – HL7 Project Scope Statement
- Sept/Oct 2016 – HL7 Immunization-Prototype Comments Only Ballot
- Sept/Oct 2017 – HL7 Draft Standard for Trial Use (DSTU) Ballot 1
- Sept/Oct 2018 – HL7 Draft Standard for Trial Use (DSTU) Ballot 2
- Sept/Oct 2019 – HL7 Normative Ballot
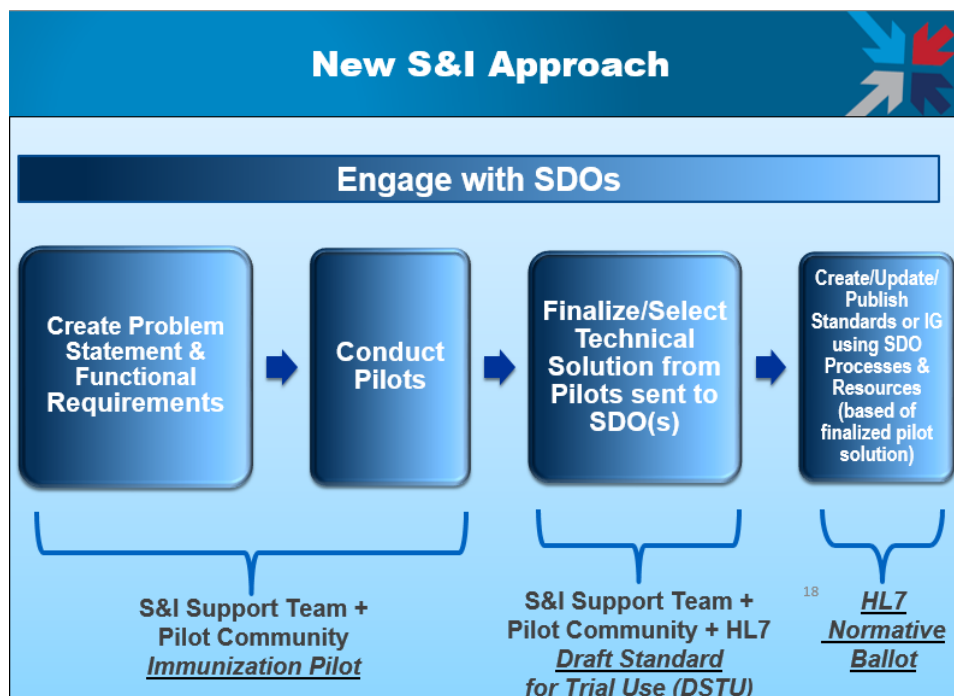
Tooling for US Realm Health Architecture

US Realm Health Architecture (aka EHR-S FM profile) in XML/XMI format supporting:
1) IBM Rational Software Architect, Troux Transformation Platform,
2) Sparx Enterprise Architect, Open Source Papyrus
3) Open Health Tools (OHT) Model Driven Health Tool (MDHT)
   a) CDA, CCDA, NIEM, FHIR, HL7 V2 Implementation Guides
4) NIST sponsored Prometheus Use Case Authoring Tool (UCAT)
5) Others as requested by Federal Agencies.

The expected benefit of the HL7 US Realm Health Architecture is to enhance the national health IT agenda:

1) Open and consistent national HIE interoperability via SDO participation
2) Empowering government agencies, industry, contractors and academia to efficiently and effectively implement nation-wide solutions for interoperable and secure health information exchange (HIE) that address federal agency business priorities while protecting citizen privacy.
3) Providing Full Lifecycle Traceability
4) Clear, complete, concise, correct, consistent model driven arch./design/test/cert.
5) Consolidated HHS:ONC endorsed HIT artifacts in a freely accessible tool form.
6) Supporting innovation with open-source development, education and training.

Acronyms

CDA	Clinical Document Architecture	IM	Information Management
CCDA	Consolidated CDA	IT	Information Technology
CMS	Centers for Medicare & Medicaid Services	JIP	DOD-VA Joint Interoperability Plan
DAF	Data Access Framework	MDHT	Model Driven Health Tool
DBA	Database Analyst	NIEM	National Information Exchange Model
EHR-S FM	EHR System Functional Model	NIST	National Institute of Standards and Technology
FHIM	Federal Health Information Model	NLM	National Library of Medicine
FHIR	Fast Healthcare Interoperability Resource		
GFI	Government Furnished Information	ONC	Office of the National Coordinator
HIT	Healthcare Information Technology	S&I	Standards and Interoperability
HHS	Health and Human Services Agency	SDO	Standards Development Organization
ICIB	Interagency Clinical Informatics Board	SME	Subject Matter Expert
IHE	Integrating the Healthcare Enterprise	V2	HL7 Version 2 Messaging

Glossary of Key Artifacts/Models Compared-and-Contrasted to FHIM

- **FHIM** refines the conceptual HL7 Reference Model into a logical Reference Information Model which focuses on clinically related domains and the superset of entities, associations and their attributes and value set, based on the Federal Use Cases and SME input. FHIM is intended to be constrained to particular applications (e.g., immunization management system/registry).

    HL7 (Detailed) Clinical Models and CIMI Architypes start with clinical concepts (e.g., temperature) and necessary / provenance meta-data needed to inform FHIM.

- **EHR-S FM** functions are associated with CIMI/FHIM Logical entities to define system objects, capabilities and Services.

- **ICIB Lists and associated Use Cases** provide a context for the use of the various models.

- **S&I initiatives** have been mapped to FHIM; where for example, an interoperable Data Access Framework (DAF) must be a FHIM subset.

- **NIEM, FHIR, CDA, CCDA, HL7 V2, NCPDP, HL7 v12** are implementation paradigms; where for interoperability, they must be consistent FHIM sub-sets.

    - **NIEM, FHIR, CDA, CCDA** implementation guides can be generated by **MDHT** using FHIM

    - **HL7 V2, NCPDP, X12** are XML messages, which already have implementation guides.

- **IHE Technical Framework** defines specific standards-based systems integration implementations to achieve effective sharing of medical information.

- **NIST Risk and Security Frameworks** establish cybersecurity risk assessments and a structure to create, guide, assess and improve comprehensive cybersecurity programs.