HL7 Project Scope Statement (PSS)

Based on Jan-Sep 2016 CIMI-Sponsored HL7 Investigative-Study
"*Information Model Integration*" Report, dated September 25, 2016
Available at: https://1drv.ms/w/s!AlkpZJej6nh_k9dlCRdJv51X0tFp9A

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Oct 29, 2016

1. Project Name and ID

Project_Name_help

Integration of Information Models and Tools	Project ID:
☐ TSC Notification Informative/DSTU to Normative	Date:
☐ Investigative Study	Date:

2. Sponsoring Group(s) / Project Team

Sponsoring_Group_help

Primary Sponsor/Work Group (**1 Mandatory**)	• CIMI workgroup approved PSS on 10/6/2016
Co-sponsor Work Group(s)	
Co-Sponsor Group Approval Date	• EHR Workgroup approved the PSS on 10/4/2016 • HSI Workgroup approved the PSS on 10/21/2016 • CDS Workgroup approved the PSS on 10/5/2016 • CQI Workgroup approved the PSS on 10/7/2016 • SOA Workgroup approved the PSS on 10/24/2016 • CIC Workgroup approved the PSS on TBD • PC Workgroup approved the PSS on TBD • CBCC Workgroup approved the PSS on 10/24/2016 • FHA MB FHA Managing Board 11/2/2016 pending

Indicate the level of involvement that the co-sponsor will have for this project:
☐ Request formal content review prior to ballot
☒ Request periodic project updates. Specify period: **HL7 WG meetings**
☐ Other Involvement. Specify details here:

Project Team:	
Project facilitator (**1 Mandatory**)	Steve Hufnagel — Project facilitator Nona Hall — DoD/VA IPO, FHA, ONC-OST facilitator
Other interested parties and their roles	Galen Mulrooney — CIMI Co-chair, FHIM lead modeller Steve Wagner — FHIM Program Manager Mark Janczewski — EHR Co-chair Susan Matney — PC Co-chair, Intermountain Health Jay Lyle — PC co-chair Ken Kawamoto — CDS co-chair Floyd Eisenberg — CQI co-chair Claude Nanjo — CQI & CQF facilitator Richard Esmond — CQI & CQF Industry Proponent (PenRad) Anita Walden — CIC co-chair Rob McClure — Vocab facilitator Mike Davis — Privacy & Security co-chair

	Gary Dickinson EHR S&I Simplification co-chair Nancy Orvis DoD Proponent* Bart Bartholomew DoD Proponent* Bob Bishop VA Proponent* Keith Campbell VA Proponent* Ken Rubin VA Proponent* Mike Davis VA Proponent* Nona Hall IPO Proponent* Gail Kalbfleisch FHIM & SIGG Sponsor, FHA-Director* Mitra Rocca FDA Proponent and HL7 CIC cochair* Nicolay Lipskiy CDC Proponent* Julia Skapik ONC/OST Proponent* Ken Salyards SAMHSA Jason Lee The Open Group Healthcare Forum * This project will not proceed without FHA Managing Board (IPO DoD & VA and ONC/OST) endorsement and sponsorship.
Multi-disciplinary project team (recommended)	YES
Modeling facilitator	Galen Mulrooney, Jay Lyle, Joey Coyle, Patrick Langford, Claude Nanjo
Publishing facilitator	**TBD**
Vocabulary facilitator	Rob McClure
Domain expert rep	**PC**: Jay Lyle, Susan Matney **CQI/CQF/CDS:** Claude Nanjo, Floyd Eisenberg, Ken Kawamoto Julia Skapik **SOLOR:** Keith Campbell **FHIM:** Galen Mulrooney **CIC:** Anita Walden and Mitra Rocca **CIMI:** Stan Huff **EHR:** Gary Dickinson, Mark Janczewski **SOA:** Ken Ruben **FHIR:** Grahame Grieve **HSI:** John Donnelly **CDA/C-CDA**: Gay Dolin
Business requirement analyst	Bob Bishop, Nancy Orvis and Nona Hall
Conformance facilitator (for IG projects)	Steve Hufnagel
Other facilitators (SOA, SAIF, Communications/Strategy/Governance)	**SOA:** Ken Ruben **SAIF:** Steve Hufnagel, **Communications/Strategy/Government:** Nona Hall BSN, John Scott MD

Implementers **(2 Mandatory** for DSTU projects)
DoD, VA, PenRad Inc., Intermountain Healthcare TBD: FDA & CDC

3. Project Definition

- **Alternative Solution Considered**
  - **No action**: to not act sustains the 'here-and-now, my-plate-is-full condition' as well as stove-piped, discordant efforts. This is unacceptable
  - **Stove-piped efforts** contribute to mapping chaos and models-models-everywhere conundrum constraining interoperability and shared meaning. No one asset can offer needed semantically interoperability solution: Integration (of models/tooling) a must!
  - **Terminology Mapping in isolation**. This is an incomplete solution.

- **Continued 'as is' use of FHIR** to accelerate implementation proliferates even more data inconsistencies and FHIR Profiles continue to satisfy only point-to-point interoperability (quick wins) vs desired enterprise-level semantic interoperability.

➢ **Disadvantages**

- Terminology Mapping while important, particularly if legacy data has not been mapped to the national standard, is an incomplete solution Terminology Mapping is insufficient because legacy-systems and locally-configured modern systems often do not maintain consistent data sets with consistent semantic and consistent provenance data to ensure patient safety and quality of care. Considering there are also far more complex use cases and in turn data structures that must be addressed in order to meet the demands of a Learning Health System extended actions are required.
- Modeling challenges if unaddressed also pose disadvantages. Using an analogy, SMEs regard the current state in that most of the efforts occur earnestly trying to build that ultimate skyscraper, however it occurs as if starting on the third floor – a solution without a foundation of informational and terminology models. That state is compounded by the number of projects that are initiated and/or vendors that hold their own proprietary models, which without a shared foundation of information models sustains no shared meaning and is not interoperable.
- Resources such as FHIR while appealing to an implementer have compromised data content / consistencies. For example:
  - Standards use different formats and rules for 'simple' things like name, address, dates or gender. Resulting in EHR-systems that after decades cannot uniformly exchange this 'simple' ubiquitous data; let alone 'complex' clinical health data.
  - HL7 EHR Interoperability workgroup, in its analysis of "Record Entry Lifecycle Event Metadata using FHIR," found substantial provenance (who, what, when, where and how) inconsistencies among FHIR resources.
  - The SOLOR and LEGO team found FHIR tries to define things such as attributes for anatomy, that are not based on a particular model of anatomy, and thus, semantic overlap occurs, with the burden of reconciliation, which may not even be possible, if left to the end user.

3.a. Project Scope Project_Scope_help

This project intends to demonstrate how computable interoperability can be achieved through the coordination of the CIMI Logical Model with physical message models such as FHIR.

❖ **This project will be delivered through pilots** by exercising agile iterations, tests, and integration cycles aimed at assessing the feasibility and implement-ability of such an approach and capturing / applying lessons learned after each pilot. Briefly, this project's technical objectives are to

- define the foundational architecture and expressivity for the CIMI logical model and ensure alignment with standard clinical terminology models,
- explore formal and computable processes for the transformation of logical models into various physical representations and vice-versa, and
- further develop and evolve tooling to assist in the authoring, visualization, implementation, maintenance, curation and deployment of these models, e.g., for use in clinical decision support.

❖ **A combination of efforts is required** to support legacy systems and enable modern system implementations by leveraging a Model Driven Architecture (MDA). First we will do a Tooling Analysis of Alternatives task to identify the requirements necessary to bring about the right selection of tooling to support this work. Further, the modeling and clinical community will build on the FHIR core and DAF work to address content by evolving a process engagement strategy with all applicable communities in order to be 'where the action is'.

❖ **Model-Driven Architecture midterm and long term solution:** We propose that we start with near term pilots to

validate and refine proposed approaches, address governance and communications strategies to demonstrate, share and gain lessons-learned in support of a seamless mid and long term MDA approach. This approach consists of:

- **Model Convergence** - Collectively the alignment of SOLOR, FHIM, CIMI, CQF and EHRS-FM will form a common Reference Model aka Common Logical Information Model (CLIM). In is important to note that through SOLOR we achieve normalized structure-and-form of clinical terminology, with a clear separation of semantics. This improves software reuse, shared tooling, reduced learning curve, shared post coordination models and simplified data analysis.
- **Model Integration** - Using MDA, the CLIM will be aligned with various implementation paradigms, such as FHIR and CDA. result offers integrated reference information models (initialing founded on FHIM-CIMI-CQF models) enabled via the SOLOR[1].
- **Model Use** – Using MDA, applications will leverage consistent FHIR or CDA profiles for domain specific implementations that are based on a common logical foundation (e.g., CLIM).

❖ **A CIMI - curated Common Logical Information Model (CLIM) will:**

- Establish a seamless FHIR model driven architectural approach and tools, resulting from CIMI Reference Model's patterns (AKA reference archetypes) and Semantic Anchors to converge on the FHIR core; tools can efficiently generate FHIR profiles and extensions from FHIM harmonized CIMI Detailed Clinical Models (DCMs), Clinical Quality Framework (CQF) Knowledge artifacts (KNARTs), electronic Clinical Quality Measures (eCQMs), etc;
- Develop SOLOR Semantic bindings for FHIR structural elements providing consistent concept definitions and a clean separation of model semantics; and
- Address overlap by identifying where various FHIR resources (e.g., Observation, DiagnosticReport) and related profiles actually refer to the same thing, such as a lab result vs a physical exam finding.

❖ **We will Identify the Projects with willing parties** that will implement the outputs including enhanced FHIR Profiles such as but not limited to

- HL7 PC WG Skin Assessment and HL7 EHR WG Immunization Projects *****
- Medication List, enhance FHIR Resource
- Document Types discordance between DoD and VA
- ACOG "Data Elements"
- CQF – FHIR – Argonaut opportunities
- IPO-sponsored FHIR JET assessing SIGG (Standards Implementation Guide Generator) *****
- DoD/VA Health Data Sharing Business Line Workgroups (Population Health)
- Plan of Care Order Transcription / Resulting challenges
- Explore use of FHIM to support EHR System Functional Model for immunization management. *****
- Connectathon outputs

***** Recommended/Underway

❖ **For each pilot** we will do the following steps:

1. Create domain analysis model (DAM)
2. Identify the data elements needed to support the project and / or the clinical content gaps in FHIR
3. Identify the FHIM classes and FHIR Profiles that support the data elements; address gaps, as needed
4. Make the detailed Clinical Information Model Initiative (CIMI) models utilizing SOLOR for the source of terminology / vocabulary
5. Place model in a registry that is publicly available
6. Approve the model
7. Construct application (s)
8. Test the FHIR Profile / application for compliance with the model and standards

[1] Systematized Nomenclature of Medicine (SNOMED) with extensions for Logical Observation Identifiers Names and Codes (LOINC) and RXNorm terminology

9. Put the applications in operational use & evaluate their value
10. **Parallel Activities**: We will analyze model and tooling requirements and review existing tools. We will then prioritize model and tooling development based on identified requirements to meet pilot and long-term objectives. Also we will establish a development and testing "sandbox" to support the pilots.
    - For the models, we will
        - Collect, manage, and prioritize requirements to guide the development of the integrated models to support better alignment of the CIMI Logical Models with their physical targets. We will consider a number of models such as:
            - Terminologies and terminology models including but not limited to SNOMED-CT, LOINC, and RxNorm
            - Existing work on the SNOMED extension for LOINC and RXNorm terminology framework developed by the VA
            - Current work on the Federal Health Information Model (FHIM)
            - The Clinical Information Model Initiative (CIMI)
            - ONC initiatives such as the Clinical Quality Framework (CQF and QI-Core), the Data Access Framework (DAF), the Standard Data Capture Initiative (SDC)
            - The Fast Health Interoperability Resources (FHIR) and (Consolidated) Clinical Document Architecture
            - The Quality Data Model, vMR, and QUICK
            - Align information models with the EHR System Functional Model to identify data context, lifecycle and conformance-test criteria, as appropriate.
    - For the tools, we will
        - Collect, manage, and prioritize requirements for tooling to support this effort. In particular, this effort shall focus on tooling for:
            - Authoring and visualizing the aligned models
            - Registries for the publication of detailed clinical models (DCMs)
            - Managing model artifacts (e.g., governance)
            - The generation of consistent FHIR logical and resource profiles and extensions
            - The generation of CDA/C-CDA, NIEM, JSON APIs etc.
            - For the Tooling Analysis of Alternatives task, review existing tools based on tooling requirements to identify suitability, gaps and enhancement potential. **Tool review** should include (but is not limited to) the following tools and libraries:
                - Open Health Tools (OHT)
                - OpenEHR tooling including ADL libraries and the ADL Workbench
                - FHIR Reference Implementation and HAPI FHIR
                - Federal Health Architecture (FHA) Semantic Interoperability Guide Generator (SIGG) including
                    - Message Driven Message Interoperability (MDMI)*,
                    - Model Driven Health Tools (MDHT)*

                    *Already part of existing contract enabling insights to be gained in longstanding tooling determinations
                - IHTSDO Workbench with ISAAC plugin
                - UML tools such as Sparx Enterprise Architect, NoMagic MagicDraw with AML profiles, etc.
                - Symedical and TermSpace terminology maintenance tools
    - For SIGG[2], we will.
        - Annotate FHIM Model (Once)
        - Annotate Target Model (FHIR, or other)
        - Use FHIM and Target
            - Generate Traceability and Gap Analysis
            - Generate Implementation (if applicable)

[2] Standards Implementation Guide Generator (SIGG = MDHT + MDMI) to generate implementation models, such as FHIR

- Use Target
  - Generate MDMI Map*
  - ** Repeat Steps 2 through 4 for other target models (C-CDA, VA, DOD, etc.)*
- Explore Terminology Management Software that is comprehensive and addresses multiple health care terminology management needs. Software able to provide flexible runtime services (APIs) and customizable platforms for the acquisition, maintenance, and distribution of the needed terminologies (standard, local, proprietary, or free-text) will be sought. Centralized control of terminology by supplying content, tools, and integration software in one enterprise solution.
- Automate searching, downloading, and updating content assets: Access to content assets including standard terminologies, HL7 value sets, reference maps, and more.
- Create New Content: Choose authoring, mapping, modeling, normalization, and other capabilities.
- Add on additional modules for distribution, remote access, and other advanced functionality.
- Easily integrate sophisticated term search, relationship navigation, and real-time interoperability with runtime web services (APIs).
- Inform/institute governance processes to support CM.

▪ Update tooling features to support interoperating among different tooling and to ensure it becomes fully supportive of SOLOR:
- Developers to work interoperability between COTS tools identified and the (VHA) ISAAC file formats
- A transition plan (away from any COTS tooling) that includes business requirements for what functionality must be present in the VA-development in progress to enable transition/full interoperability to the VA environment in the event a tool's migration is concluded to be warranted. The plan ensures no unanticipated vendor lock.
- A comprehensive license review to ensure no "vendor lock" related to IP restrictions
- A comprehensive review of version management and configuration management for selected COTS tooling with a gap analysis with respect to ISAAC version management and configuration management.
- A gap analysis with respect to support for OWL 2 EL profile + concrete domains (classification functions, editing functions, version management functions).
- A non-viral open license (Apache 2 preferred) to an API and comprehensive import/export formats for Symedical so that we can execute interoperability independent of the vendor
- STAMP-based version control and modular dependencies in a scalable and safe way proposed for the Informatics Architecture. Release management, continuous integration developing in Java and developing Maven plugins (for java) as necessary.
- Development of quality metrics with respect to terminology as Java plugins for Informatics Architecture.

▪ Finally, we will prioritize modeling and tooling development based on identified requirements to meet pilot and long-term objectives.

3.b. Project Need

Our clinical goal is "to help people live the healthiest lives possible" by enabling a Learning Health System supporting areas such as, but not limited to, Precision Medicine.

- **This requires** data that is computable, usable, extensible, and interpretable across disparate systems - a state that currently does not exist.
- **The solution** proposed capitalizes on the inroads made with the exchange of data, standards and standards adoption, but brings back a focus on the data in order to make additional and necessary advancements.

Our IT objective is to make the appropriate data available when it is needed, where it is needed and how it is needed. Specifically, we plan to integrate (or unify) existing models, with semantically-consistent computable-data, including provenance data (who, what, when, where, why, how) across different platforms, e.g., Population Health, Care Coordination, Clinical Decision Support, EHR patient documentation systems, etc. using tooling to generate various implementation styles,

including but not limited to HL7 Fast Healthcare Interoperable Resources (FHIR). Underlying to the integration of Information Models is the adoption of the principle advocating a clear separation of modeling semantics into a widely used HL7 / ISO standard.

To meet the demands, the following needs to be considered:

1. To help address FHIR inconsistencies by promoting a solution not only supportive of the implementation community but the clinical (content) community as well. FHIR has been adept at addressing the implementation (agile) needs, but even the best of implementation accelerators, like FHIR with its extensions and profiles, allows for far too much variation between implementation projects. The proliferation of FHIR Profiles deters from the desired semantic interoperability state.
2. To strengthen existing terminology and information modeling assets through integration efforts that will target semantic structural and terminology modeling overlap applying sound principles predicated on the separation of the semantic models.
3. To replace the tendency where projects create yet another unique information model (e.g., through a mapping exercise) as opposed to leveraging existing modeling assets.
4. To help extend fidelity of the data supporting profiles of the Argonaut Project (for example); FHIM/CIMI adds detailed content for plug-n-play interoperability currently not addressed
    a. Lab measurements
    b. Patient measurements
    c. Physical exam
    d. Intake and Output
    e. Assessment instruments: Apgars, Braden, Pain Scales, etc.

The ROI/benefit is efficiency and effectiveness, from the standards'-based reuse of knowledge artifacts thereby maintaining consistent data meaning, reducing the need for mapping of data, and improved patient-safety and quality-of-care by building on lessons learned and not repeating past mistakes.

The benefit of a standardized reusable modeling-foundation ("stack") is computable-interoperability aka interpretability across time, locations, systems and care contexts, assuming the re-usable "stack" is standardized and has widespread implementation. This information-model "stack" foundation is mission-essential for

- collection, communication, aggregation and interpretation of patient data to accelerate secondary uses in public health, disease surveillance, post-approval monitoring, and patient-centered outcomes research.
- health-related services including telecare, clinical decision support, research, and quality measurement, improving healthcare access, quality, and uniformity.
- patients, clinicians, and the public to realize major benefits from improved care coordination, reduction of medical errors, and decreased costs resulting in healthier lives.

This PSS's goal is to address the pervasive data inconsistencies deterring interoperability, reusability and shared meaning through Integration of Information Modeling assets enabled by tooling to enhance implementation accelerators such as FHIR.

As offered via Open Health Group's August 2016 primer: "*Advancing Healthcare Interoperability"*

Increasingly, the "models, models everywhere" challenge is considered a fundamental barrier to advancing full and ubiquitous healthcare interoperability (in the public and private sectors, in the US, and globally). The phrase is a play on Samuel Taylor Coleridge's famous quote: "water, water everywhere, but not a drop to drink". "Models, models everywhere" expresses the frustration that comes from developing multiple elaborate and important models that nevertheless fail to interoperate. The frustration with the inability of models to work together is understandable. Unless any two models are entirely independent of each other (unlikely), any two working together would produce more value than the sum of each working alone, siloed. As it

impacts healthcare delivery, device and drug innovation, administrative and business efficiency, safety, data security, integration of electronic health records, and analyzing big data, the "models, models everywhere challenge" is very real. It is very expensive. We can do better by coordinating information models – a significant challenge in itself.

The essential point we make is that "yes", the healthcare interoperability problem is a complex one, as several decades of work and many models attest to. We argue that agreement across models – i.e., the CIMI and FHIM – on a foundation of shared and useful meanings is essential to interoperation and to reaping the higher-level contributions built into the multiplicity of individual models.

This PSS's objective is to ultimately produce via iterative pilots SOLOR/FHIM/CIMI/CQF/ DAF-based FHIR Profiles which will not only address the needs of the Implementation Community but also the needs of the Clinical (content) Community. The following steps serve to reach this objective:

1. Promote use of free & open models; foundational to interoperability
2. Maintain a clean separation of clinical model semantics using SNOMED, LOINC and RxNorm
3. Build upon and improve existing work; in particular DAF and FHIR core
4. Begin with the Integration of SOLOR+FHIM+CIMI+CQF+DAF=CLIM set of harmonized models, as the Enabling Foundation
5. Integrate tooling to support models to extend the utility of these asset
6. Use models and tools to generate standards and implementation artifacts
7. Advance in constructive steps through pilots and agile developments
8. Support with corresponding Communication, Interoperability & Governance strategies

This PSS is based on the

Achieving Computable Interoperability with a HL7/ISO "Common Logical Information Model (CLIM)"

CIMI Sponsored HL7 Investigative-Study and Task Force

Supporting documents are viewable and downloadable at

HL7 Project Scope Stmt.	https://1drv.ms/w/s!AlkpZJej6nh_k9dYlvNWaZ3DLPKSYg
Briefing Slides	https://1drv.ms/p/s!AlkpZJej6nh_k9dE-b_DAO8HSNNT6Q
Slides-Notes Pages PDF	https://1drv.ms/b/s!AlkpZJej6nh_k9daUH18BNQFOwtNrg
Final Report	https://1drv.ms/w/s!AlkpZJej6nh_k9dQ2qQnRuQM8gbu8A
Technical Forum Summary	https://1drv.ms/w/s!AlkpZJej6nh_k9gyRVADgOvM5SlJkQ
Preliminary Report	https://1drv.ms/w/s!AlkpZJej6nh_k9YPmsR8Hl6zTlQ0NQ
Work Breakdown MPP	https://1drv.ms/u/s!AlkpZJej6nh_k9dK5WOB8zkkUuaKgA
Work Breakdown PDF	https://1drv.ms/b/s!AlkpZJej6nh_k9dfYSeXPGjTRJ2cAg
Work Breakdown XLSD	https://1drv.ms/x/s!AlkpZJej6nh_k9dgBSgLrTfaKYcG2A
CIMI Practitioners' Guide	https://1drv.ms/w/s!AlkpZJej6nh_k6ZUeG7W6TaWcbTZ4Q

Some of these documents will be updated throughout 2016

Note that many networks and systems block the use of clickable links; where, You must copy the link into a browser to access the content.

3.c. Success Criteria

1. Established governance and Communications in year 1
2. Successful pilot studies in year 1 and year 2.
3. ONC and Federal Partner Projects use our models and tools for developments
4. Model integration in year 1.
5. Tool integration in year 2.
6. Models and tools can create consistent FHIR profiles and extensions by end of year 2
7. Enhanced FHIR Profiles
8. Progress toward HL7 standardization on an annual basis.

3.d. Project Risks

Risk Description:	
Impact:	☒ Critical ☐ Serious ☐ Significant ☐ Low
Likelihood:	☐ High ☒ Med ☐ Low
Risk Type:	☐ Requirements ☐ Resources ☒ Social-Political ☐ Technology
Risk To HL7:	☒ Internal to HL7 ☒ External to HL7
Mitigation Plan:	Communications, Strategic Interoperability, Governance, Engagement Plans and The Open Group collaboration

3.e. Security Risks

Will this project produce executable(s), for example, schemas, transforms, stylesheets, executable program, etc. If so the project must review and document security risks.	☐ Yes	☒ No	☐ Unknown

3.f. External Drivers

DoD and VA EHR modernization and interoperability, CDC Public Health initiatives, FDA, CMS and FDA initiatives.

3.g. Project Objectives / Deliverables / Target Dates

Project_Obj_Deliv_TgtDate_help	Target Date
Pilot Study Implementation Guides and Lessons Learned Comments Only Ballot	Ad-hoc
HL7 Informative Ballot*	2017Q4
HL7 Draft Standard for Trial Use (DSTU) 1*	2018Q4
HL7 Draft Standard for Trial Use (DSTU) 2*	2019Q4
HL7 Normative Standard*	2020Q4
ISO Normative Standard*	2021Q4

Note *

US Realm CLIM contains

- Versioned SOLOR, FHIM, QICore, DCMS, KNARTS, DAF
- FHIR Profiles, Extensions and Implementation Guides

ISO (International Realm) CLIM contents TBD

- ISSUE (to be resolved): RxNorm, QICore & DAF are not international

Project Plan

We plan to do up to 2-4 TBD pilots/yr., which will each be about 4-6 months. There is some overlay of the projects, and model and tools harmonization and integration and communication outreach and collaboration with stakeholders will run in parallel with the pilots. Of great advantage is the fact this is considered a well-known (national/international) complex problem. Several activities were in place to include an HL7 Investigative Study to leverage / accelerate producing efficiencies for our expanded

partner base. Funding is being proposed, we will in many cases leverage certain of the Project Plan steps/assets. The tasks listed below are the steps for any pilot or project and the metric is the completion of the step. An expanded plan via Microsoft Project is also evolving.

Task	**Projected Start Date** MM/DD/YY	**Projected Completion Date** MM/DD/YY
1.0 Governance	2/1/2017	12/30/2018
1.1 Identify, assess and execute funding options	2/1/2017	5/1/2017
1.2 Transition current governance	2/1/2017	5/1/2017
1.3 Assess and execute follow-on Governance Oversight	5/1/2017	8/1/2017
1.4 Assess and Execute Governance of Assets and Infrastructure	2/1/2017	12/30/2018
1.5 Reporting	3/30/2017	Quarterly / Ongoing
2.0 Pilot projects (2-4/year, 4-6 mo. cycle)	2/1/2017	12/31/18
2.1 Call for pilot participation	2/1/2017	Quarterly
2.2 Select Pilot Projects	3/1/2017	Quarterly
2.3 Execute pilot lifecycles (each pilot repeats these notional steps)	4/1/2017	Q 4-6 months
2.3.1 Create/leverage a domain analysis model (DAM)	4/1/2017	Start + 1-2 weeks
2.3.2 Identify the data elements needed to support the project	4/15/2017	Start + 2 weeks
2.3.3 Identify the FHIM classes and FHIR Profiles that support the data elements; address gaps	4/15/20175	Start + 2-4 weeks
2.3.4 Make the detailed CIMI models utilizing SOLOR for the source of terminology / vocabulary	4/15/2017	Start + 4 weeks
2.3.5 Approve the models and profiles	6/15/2017	6/30/2017
2.3.6 Place model / FHIR profiles in a registry that is publicly available	7/10/2017	7/10/2017
2.3.7 Construct application(s) using models and profiles	7/1/2017	8/30/2017
2.3.8 Test the FHIR Profile / application for compliance with the model and standards	9/1/2017	9/15/2017
2.3.9 Put the application in operational test use & evaluate its value	9/30/2017	12/30/2017 & Quarterly Rprt
2.3.10 Parallel Activities: (Tooling Analysis of Alternatives / Selection; MDA Models/tools, integration, maintenance, development and testing)	2/1/2017	12/31/18
3.0 **Communications and Outreach**	2/1/2017	Ongoing
3.1 Establish communications capabilities	2/1/2017	8/1/2017
3.2 Federal Partner Outreach	3/1/2017	Ongoing
3.3 Industry outreach	3/1/2017	Ongoing

3.h. Common Names / Keywords / Aliases

CLIM, SOLOR, FHIM, CIMI, DCM, CQF, KNART, eCQM, FHIR, NIEM, CDA, C-CDA, JSON, HL7, SIGG, MDHT, MDMI

3.i. Lineage

NA

3.j. Project Requirements

Objectives: The intent is to ultimately produce via iterative pilots SOLOR/FHIM/CIMI/CQF/ DAF-based FHIR Profiles which will not only address the needs of the Implementation Community but also the needs of the Clinical (content) Community. The following steps serve to reach this objective:

- Promote use of free & open models; foundational to interoperability
- Maintain a clean separation of clinical model semantics using SNOMED, LOINC and RxNorm
- Build upon and improve existing work; in particular DAF and FHIR core
- Begin with the Integration of SOLOR+FHIM+CIMI+CQF+DAF=CLIM set of harmonized models, as the Enabling Foundation
- Integrate tooling to support models to extend the utility of these asset
- Use models and tools to generate standards and implementation artifacts
- Advance in constructive steps through pilots and agile developments
- Support with corresponding Communication, Interoperability & Governance strategies

3.k. Project Dependencies

FHIM, CIMI, CQF, EHR-S FM, FHIR, SIGG (MDHT-MDMI)

3.l. Project Document Repository Location

HL7 CIMI wiki

3.m. Backwards Compatibility

Click here to go to Appendix A for more information regarding this section and FHIR project instructions.

Are the items being produced by this project backward compatible?	☐ Yes	☐ No	☒ Unknown	☐ N/A

For V3, are you using the current data types?	☒ Yes	☒ No see * below
If you check 'No' please explain the reason:		
* We are currently using the V3 data types; but, we are also investigating using the FHIR data types to better align the MDA approach with FHIR.		

3.n. External Vocabularies

Click here to go to Appendix A for more information regarding this section.

Will this project include/reference external vocabularies?	☒ Yes	☐ No	☐ Unknown	☐ N/A
If yes, please list the vocabularies: Vocabularies used are, but not limited to, SNOMED, LOINC, RxNorm				

4. Products

☐ Non Product Project-	☐ V3 Domain Information Model (DIM / DMIM)
☐ Arden Syntax	☐ V3 Documents – Administrative (e.g. SPL)
☐ Clinical Context Object Workgroup (CCOW)	☐ V3 Documents – Clinical (e.g. CDA)
☐ Domain Analysis Model (DAM)	☐ V3 Documents - Knowledge
☐ Electronic Health Record (EHR) Functional Profile	☐ V3 Foundation – RIM
☒ Logical Model	☐ V3 Foundation – Vocab Domains & Value Sets
☐ V2 Messages – Administrative	☐ V3 Messages - Administrative
☐ V2 Messages - Clinical	☐ V3 Messages - Clinical
☐ V2 Messages - Departmental	☐ V3 Messages - Departmental
☐ V2 Messages – Infrastructure	☐ V3 Messages - Infrastructure
☐ FHIR Resources	☐ V3 Rules – GELLO
☒ FHIR Profiles	☐ V3 Services – Java Services (ITS Work Group)
☐ New/Modified/HL7 Policy/Procedure/Process	☐ V3 Services – Web Services (SOA)
☐ New Product Definition	
☐ New Product Family	

5. Project Intent (check all that apply)

Project_Intent_help

☒ Create new standard ☐ Revise current standard (**see text box below**) ☐ Reaffirmation of a standard ☐ New/Modified HL7 Policy/Procedure/Process ☐ Withdraw an Informative Document ☐ N/A (Project not directly related to an HL7 Standard)	☐ Supplement to a current standard ☐ Implementation Guide (IG) will be created/modified Project is adopting/endorsing an externally developed IG: Specify external organization in Sec. 6 below; Externally developed IG is to be (select one): ☐ Adopted - OR - ☐ Endorsed

5.a. Ballot Type (check all that apply)

☐ Comment Only ☒ Informative ☒ DSTU to Normative	☐ Normative (no DSTU) ☒ Joint Ballot with ISO ☐ N/A (project won't go through ballot)

5.b. Joint Copyright

Check this box if you will be pursuing a joint copyright. Note that when this box is checked, a Joint Copyright Letter of Agreement must be submitted to the TSC in order for the PSS to receive TSC approval.

☒ Joint Copyrighted Material **will be produced with ISO in about year 4**

6. Project Logistics

6.a. External Project Collaboration

External_Project_Collaboration_help

Include SDOs or other external entities you are collaborating with, including government agencies as well as any industry outreach. Indicate the nature and status of the Memorandum of Understanding (MOU) if applicable.		
For projects that have some of their content already developed:		
How much content for this project is already developed?	75-90% (estimated)	
Was the content externally developed (Y/N)? YES	FHA FHIM, VA SOLOR, HL7 CQF, SMEs via CIMI, DoD, VA, IPO, ONC/OST, FHA and Intermountain Healthcare	
Date of external content review by the ARB?	**Approval date TBD**	
Is this a hosted (externally funded) project? (not asking for amount just if funded)	☒ Yes	☐ No

6.b. Realm

☒ Universal	☐ Realm Specific
	☐ Check here if this standard balloted or was previously approved as realm specific standard

6.c. Project Approval Dates

Project_Approval_Dates_help

Affiliate/US Realm Task Force Approval Date (for US Realm Specific Projects)	**USRTF Approval Date**	**TBD**
Sponsoring Work Group Approval Date	**WG Approval Date**	**TBD**
FHIR Project: FHIR Management Group Approval Date	**FMG Approval Date**	**TBD**
Steering Division Approval Date	**SD Approval Date**	**TBD**
PBS Metrics and Work Group Health Reviewed? (required for SD Approval)	☐ Yes ☐ No	
Technical Steering Committee Approval Date	**TSC Approval Date**	**TBD**

TSC has received a Copyright/Distribution Agreement (which contains the verbiage outlined within the SOU), signed by both parties. ☐ Yes ☐ No

6.d. Stakeholders / Vendors / Providers

This section must be completed for projects containing items expected to be ANSI approved, as it is an ANSI requirement for all ballots

Stakeholders	Vendors	Providers

☒ Clinical and Public Health Laboratories	☒ Pharmaceutical	☒ Clinical and Public Health Laboratories
☒ Immunization Registries	☒ EHR, PHR	☒ Emergency Services
☒ Quality Reporting Agencies	☒ Equipment	☒ Local and State Departments of Health
☒ Regulatory Agency	☒ Health Care IT	☒ Medical Imaging Service
☒ Standards Development Organizations (SDOs)	☒ Clinical Decision Support Systems	☒ Healthcare Institutions (hospitals, long term care, home care, mental health)
☒ Payors	☒ Lab	☐ Other (specify in text box below)
☒ Other (specify in text box below)	☒ HIS	☐ N/A
☐ N/A	☐ Other (specify below)	
Federal Health Architecture, Federal Agencies and their Commercial and academic Partners	☐ N/A	

6.e. Synchronization With Other SDOs / Profilers

Synchro_SDO_Profilers_help

Check all SDO / Profilers which your project deliverable(s) are associated with.		
☐ ASC X12	☐ CHA	☒ LOINC
☐ AHIP	☒ DICOM	☒ NCPDP
☐ ASTM	☐ GS1	☐ NAACCR
☐ BioPharma Association (SAFE)	☐ IEEE	☐ Object Management Group (OMG)
☒ CEN/TC 251	☒ IHE	☐ The Health Story Project
☐ CHCF	☒ IHTSDO	☐ WEDI
☐ CLSI	☒ ISO	☒ Other (specify below) The Open Group Healthcare Forum

CDC	US Center for Disease Control	ISAAC	VA tool for SOLOR
CDS	Clinical Decision Support	ISO	International Standards Organization
CIMI	Clinical Information Model Initiative	JIF	VA/DOD Joint Incentive Fund
CQI	Clinical Quality Information	KNART	Knowledge Artifact
CQF	Clinical Quality Framework	LOINC	Logical Observation Identifiers Names and Codes
CLIM	Common Logical Information Model	MDHT	Model Driven Health Tool
DAF	Data Access Framework	MDMI	Model Driven Message Interface
DCM	Detailed Clinical Model	ONC/OST	US Office of the Natl. Coordinator / Office of Science and Tech.
DOD	US Department of Defense	PMP	Program Management Plan
DSTU	Draft Standard for Trial Use	PSS	Project Scope Statement
EDW	Electronic Data Warehouse	RXNORM	US National Library of Medicine naming system for drugs
FDA	US Federal Drug Agency	SIGG	Standards Implementation Guide Generator
FHA	US Federal Health Architecture	SOLOR	SNOMED extension for LOINC & RXNorm
FHIM	US Federal Health Information Model	TLC	ONC/OST Technical Learning Center
FHIR	HL7 Fast Health Information Resource	VA	US Veterans Administration
HIEA	DoD VA IPO Health Interoperability Exchange Alliance	VCS	Version Control System for for collaboration
HL7	Health Level Seven	WBS	Work Breakdown Structure
IPO	US DoD and VA Interagency Program Office		

PENDING ACTION ITEMS

1. 2016-10-24 coordinate with HL7 US Realms Steering Committee
2. CIC and PC co-sponsor?
3. Get Project ID
4. FHA MOU
5. OpenGroup MOU
6. Staff through HL7 Steering Committee, ARB and TSC
7.