**HL7 Project Scope Statement (PSS)**

Based on Jan-Sep 2016 CIMI-Sponsored HL7 Investigative-Study

“*Information Model Integration*” Report, dated September 25, 2016

Is available at: <https://1drv.ms/w/s!AlkpZJej6nh_k9dlCRdJv51X0tFp9A>

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**Last Updated Jun 6, 2017 TSC Approved**

1. Project Name and ID

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| [Project\_Name\_help](#Project_Name_help) | |  |
| **Integration of Information Models and Tools (IIM&T)** | | Project ID: **1316** |
| |  |  | | --- | --- | |  | TSC Notification Informative/DSTU to Normative Date: | |  | |
|  | | |
| |  |  | | --- | --- | |  | Investigative Study Date: **Jan 2016 to** Sep 2016 | | | |
| FinalReport is available at:<https://1drv.ms/w/s!AlkpZJej6nh_k9dlCRdJv51X0tFp9A> | | |

1. Sponsoring Group(s) / Project Team

[Sponsoring\_Group\_help](#Sponsoring_Group_help)

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| --- | --- |
| Primary Sponsor/Work Group (**1 Mandatory**) | CIMI workgroup approved PSS on 10/6/2016 |
| Co-sponsor Work Group(s) | CBCC, CIC, CDS, CQI, DEV, EHR, EST, FMG, HSI, Security, SOA |
| Co-Sponsor Group Approval Date | - DEV Workgroup approved the PSS on 11/4/2016  - 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  - CBCC Workgroup approved the PSS on 10/24/2016  - FHA Managing Board approved the PSS on 11/2/2016  FHIR Managing Board approved the PSS on 2017/02/01  - Security approved PSS on 2/28/2017 for security, privacy,  terminology and involvement in lifecycle and provenance concerns.  - CIC Workgroup approved the PSS on 01/18/2017  - EST Workgroup approved PSS on 05/11/2017 |
| 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: |  | | | |
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| **Project Team:** |  |
| Project facilitator (**1** **Mandatory**) | Steve Hufnagel FHIM-CIMI Project facilitator for FHA  Nona Hall DoD/VA IPO, DoD, VA, 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 VHA Security Architect  Gary Dickinson EHR S&I Simplification co-chair  Michael van der Zel EST liason  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 co-chair  Nicolay Lipskiy CDC Proponent  Julia Skapik ONC/OST Proponent  Ken Salyards SAMHSA  Jason Lee The Open Group Healthcare Forum  Mario Hyland, AEGIS Corp., Testing SME |
| Multi-disciplinary project team (recommended) | YES |
| Modeling facilitator | Galen Mulrooney, Claude Nanjo, Richard Esmond, Jay Lyle, Joey Coyle, Patrick Langford |
| Publishing facilitator | Claude Nanjo |
| 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, Susan Matney  **FHIM:** Galen Mulrooney, Jay Lyle, Rob McClure,  Sean Muir, Steve Hufnagel  **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, Mario G Hyland |
| 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, FDA & CDC (potential) | |

1. 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.
  1. Project Scope [Project\_Scope\_help](#Project_Scope_help)

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| 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 US CORE 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]](#footnote-2).   + **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, Diagnostic\_Report) and related profiles 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   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 (US CORE), 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]](#footnote-3), 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)       * 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. |

* 1. Project Need

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| * **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    1. Lab measurements    2. Patient measurements    3. Physical exam    4. Intake and Output    5. 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. |
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| **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/ US CORE-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 US CORE and FHIR core 4. Integration of SOLOR+FHIM+CIMI+CQF+US CORE=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 |

* 1. Success Criteria

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| 1. Established governance and Communications in year 1 2. Pilot-Projects lessons-learned feeding CIMI Principles and Reference Models 3. ONC, Federal Partner Projects, commercial venders use our models and tools for developments 4. Model integration or harmonization in year 1. 5. Tool integration or harmonization in year 2. 6. Models and tools can create consistent FHIR profiles and extensions by end of year 2 7. Consistent FHIR Profiles and Extensions 8. Progress toward HL7 and ISO standardization on an annual basis. |

* 1. Project Risks

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| Risk Description: | Uptake by developers, implementers, venders |
| 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 |
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* 1. Security Risks

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| 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 |

CIMI collaborates with other HL7 workgroups and organizations; where, they produce and possibly ballot implementation artifacts. This project’s scope is limited to the integration of Information Models and Tools, resulting in an HL7-balloted Clinical Common Logical Information Model (CLIM) and its architectural framework.

* 1. External Drivers

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

* 1. Project Objectives / Deliverables / Target Dates

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| [Project\_Obj\_Deliv\_TgtDate\_help](#Project_Obj_Deliv_TgtDate_help) | **Target Date** |
| CIMI Practitioners’ Guide | Maintained on CIMI Wiki |
| HL7 Comments Only Ballot | Jan 2017 |
| HL7 Informative Ballot\* | May 2017 |
| HL7 Draft Standard for Trial Use (DSTU) 1\* | Sep 2017 |
| HL7 Draft Standard for Trial Use (DSTU) 2\* | Sep 2018 |
| HL7 Normative Standard\* | Sep 2019 |
| ISO Normative Standard\* | Sep 2020 |

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## \* Project Plan

We plan to do up-to 6 pilots/yr., which will each be done in 4-6 month sprints. 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 notional steps for any pilot or project and the metric is the completion of the step.

|  |  |  |
| --- | --- | --- |
| 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 |
|  |  |  |

* 1. Common Names / Keywords / Aliases

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

* 1. Lineage

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| HL7 CIMI WIKI |

* 1. Project Requirements

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| **Objectives**: The intent is to ultimately produce via iterative pilots SOLOR/FHIM/CIMI/CQF/ US CORE-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 US Core, QI Core and FHIR core * Begin with the Integration of SOLOR+FHIM+CIMI+CQF+US CORE=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 |

* 1. Project Dependencies

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

* 1. Project Document Repository Location

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| HL7 CIMI Wiki; where, final artifact(s) will be published on an HL7 managed site. |

* 1. Backwards Compatibility

[*Click here*](#Backwards_Compatibility_help) *to go to Appendix A for more information regarding this section and FHIR project instructions.*

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| 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. | | | | |

* 1. External Vocabularies

[*Click here*](#External_Vocabularies_help) *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 | | | | |

1. 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 | |  |
|  | |

1. Project Intent (check all that apply)

[Project\_Intent\_help](#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 |  | Endorsed | |
|  | |

* 1. 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) | | |
|  | |
|  | |

* 1. 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 | |

The intention is to later publish with ISO in about year 4

1. Project Logistics
   1. External Project Collaboration

[External\_Project\_Collaboration\_help](#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? | 60% (estimated) | |
| Was the content externally developed (Y/N)? hybrid | 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? YES | **Approval date Nov 29, 2016** | |
| Is this a hosted (externally funded) project? (not asking for amount just if funded) | Yes | No |

6.a.Realm

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

* 1. Project Approval Dates

[Project\_Approval\_Dates\_help](#Project_Approval_Dates_help)

|  |  |
| --- | --- |
| Affiliate/US Realm Task Force Approval Date  (for US Realm Specific Projects) | **USRTF Approval Date** NA |
| Sponsoring Work Group Approval Date | **WG Approval Date** NA |
| FHIR Project: FHIR Management Group Approval Date | **FMG Approval Date** 2017-02-01 |
| Steering Division Approval Date | **SD Approval Date** 2017-03-07 |
| |  |  |  | | --- | --- | --- | | [PBS Metrics and Work Group Health Reviewed](http://gforge.hl7.org/gf/download/docmanfileversion/7241/10172/PBSMetricGuidanceforSDCoChairs2013Final.doc)? (required for SD Approval) | Yes | No | | |
| Technical Steering Committee Approval Date | **TSC Approval Date** 2017-06-09 |
| |  |  |  | | --- | --- | --- | | TSC has received a Copyright/Distribution Agreement (which contains the verbiage outlined within the SOU), signed by both parties. **NA** | Yes | No | | |

* 1. 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 |  |
| |  | | --- | |  | | | |

* 1. Synchronization With Other SDOs / Profilers

[Synchro\_SDO\_Profilers\_help](#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 |
|  | | |

**2017Q1 Summary and Status**

Figure 4 IIM&T Goal: Computable Semantic-Interoperability

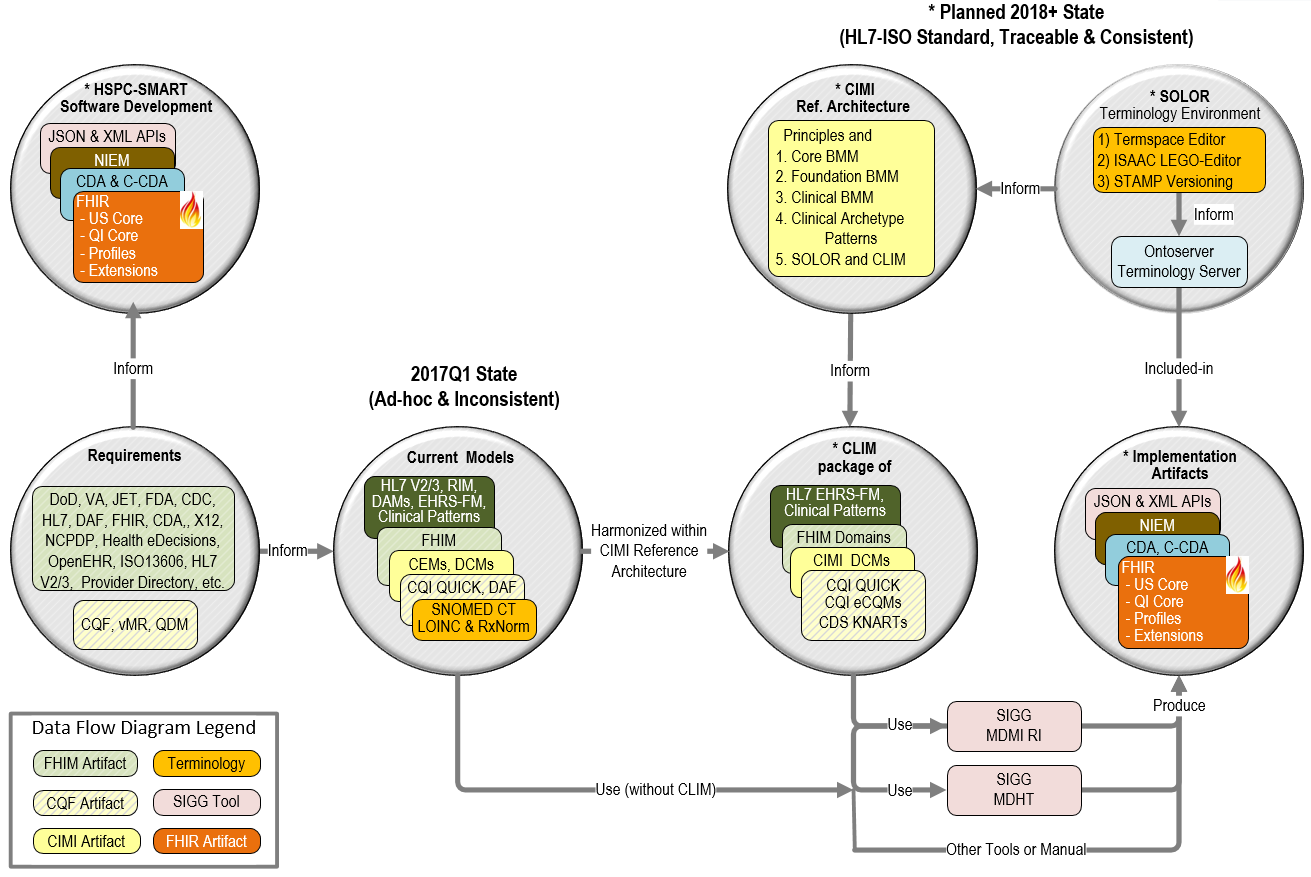


Figure 5 IIM&T Model Driven Development Strategy

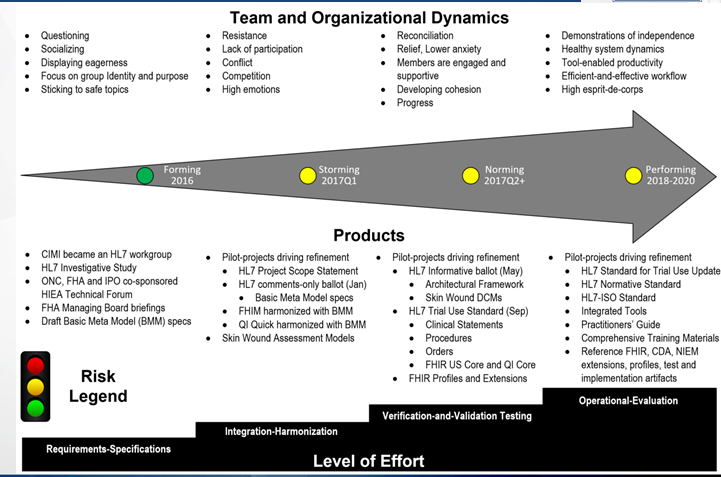


Figure 6: IIM&T Plan of Milestones and Actions (POA&M)

# Acronyms

*“When I use a word, it means just what I choose it to mean — neither more nor less.” [Alice in Wonderland, 1892, Lewis Carroll]*

|  |  |  |  |
| --- | --- | --- | --- |
| BMM | CIMI Basic Meta Model components | ISAAC | VA tool for SOLOR |
| CEM | Intermountain Clinical Element Models | ISO | International Standards Organization |
| CIMI | HL7 Clinical Information Model Initiative | JIF | VA/DOD Joint Incentive Fund |
| CLIM | HL7 Common (Clinical) Logical Information Model | KNART | CDS Knowledge Artifact |
| CQI | HL7 Clinical Quality Information | LOINC | Logical Observation Identifiers Names and Codes |
| CQF | HL7 Clinical Quality Framework | MDHT | Model Driven Health Tools |
| DAF | ONC Data Access Framework | MDMI | Model Driven Message Interoperability |
| DCM | Detailed Clinical Model | ONC/OST | US Office of the Natl. Coordinator / Office of Science and Tech. |
| eCQM | CQI Electronic Clinical Quality Measure | PMP | Program Management Plan |
| STU | HL7 Standard for Trial Use | PSS | Project Scope Statement |
| EDW | Electronic Data Warehouse | QUICK | CQI Quality Information and Clinical Knowledge logical model. |
| FDA | US Federal Drug Agency | RXNorm | US National Library of Medicine naming system for drugs |
| FHA | US Federal Health Architecture | SIGG | Standards Interoperability Guide Generator |
| FHIM | US Federal Health Information Model | SOLOR | SNOMED extension for LOINC & RXNorm |
| FHIR | HL7 Fast Health Information Resource | TLC | ONC/OST Technical Learning Center |
| HIEA | DoD VA IPO Health Interoperability Exchange Alliance | VA | US Veterans Administration |
| HcDir | ONC-FHA Provider Healthcare Directory. | VCS | Version Control System for collaboration |
| IPO | US DoD and VA Interagency Program Office | VSAC | NLM Value Set Authority |

# References

HL7 IIM&T Project Scope Statements <https://1drv.ms/f/s!AlkpZJej6nh_lIQOuPJcL2rf5BVoXQ>

IIM&T Technical Forum Summary <https://1drv.ms/w/s!AlkpZJej6nh_k9gyRVADgOvM5SlJkQ>

IIM&T Work Breakdown Structure <https://1drv.ms/f/s!AlkpZJej6nh_lKc00J3Kh2BTkopPnA>

IIM&T Briefing Slides <https://1drv.ms/p/s!AlkpZJej6nh_k9dE-b_DAO8HSNNT6Q>

IIM&T Newsletters <http://wiki.hl7.org/index.php?title=CIMI_Newsletters>

IIM&T Reports <https://1drv.ms/w/s!AlkpZJej6nh_k9dQ2qQnRuQM8gbu8A>

CIMI web-site <https://www.opencimi.org>

* CIMI BMM Browser <http://models.opencimi.org/cimi_doc/>
* CIMI Architype-Model Browser <https://www.opencimi.org/model-browser>

CIMI Wiki <http://wiki.hl7.org/index.php?title=Clinical_Information_Modeling_Initiative_Work_Group>

* CIMI Minutes <http://wiki.hl7.org/index.php?title=CIMI_Minutes>

US CORE Wiki <https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/DAF+Home>

Skin and Wound Assessment Pilot Wiki <http://wiki.hl7.org/index.php?title=PC_CIMI_Proof_of_Concept>

SNOMED CT: <http://ihtsdo.org/index.html>

Expression Constraint Guide <https://confluence.ihtsdotools.org/display/DOCECL/Expression+Constraint+Language+-+Specification+and+Guide>

**Questions?**

Contact Facilitators at:

[Nona.G.Hall.civ@mail.mil](mailto:Nona.G.Hall.civ@mail.mil)

[Stephen.Hufnagel@ApprioInc.com](mailto:Stephen.Hufnagel@ApprioInc.com)

1. Systematized Nomenclature of Medicine (SNOMED) with extensions for Logical Observation Identifiers Names and Codes (LOINC) and RXNorm terminology [↑](#footnote-ref-2)
2. Standards Implementation Guide Generator (SIGG = MDHT + MDMI) to generate implementation models, such as FHIR, CDA, NIEM, etc. [↑](#footnote-ref-3)