
Template Usage Information:

- Submit template change requests to PMO@HL7.org
- For Reaffirmations, please refer to the FAQ in HL7 Project Scope Statement Instructions for a list of which sections and fields should be completed

1. Project Name and ID

<table>
<thead>
<tr>
<th>ISO 13606-3/FHIR Implementation Guide</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enter the name of the project here:</strong></td>
</tr>
<tr>
<td><strong>Project ID:</strong></td>
</tr>
</tbody>
</table>

Complete this section for all “Direct to Normative” ballot projects and when a project proceeds from “Informative to Normative” or “STU to Normative”.

Forward PSS to the TSC (via tscpm@HL7.org); this triggers American National Standards Institute (ANSI) Project Initiation Notification (PINS) submission.

<table>
<thead>
<tr>
<th>TSC Notification:</th>
<th>Informative/STU to Normative</th>
<th>Date:</th>
<th>1/21/2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>- or -</td>
<td>Direct to Normative (no STU) (includes reaffirmations)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Identify ISO, IEC or ISO/IEC standard to be adopted in text box below

Enter info here if an ISO, IEC, or ISO/IEC Standard is to be adopted as an American National Standard; Enter the designation of the standard(s) to be adopted:

Includes text from ISO, IEC or ISO/IEC standard: Check here if this standard includes excerpted text from one or more ISO, IEC or ISO/IEC standards, but is not an identical or modified adoption.

Yes

Select the unit of measure used in the standard; if no measurements are in the standard, select N/A

<table>
<thead>
<tr>
<th>x</th>
<th>N/A</th>
<th>U.S.</th>
<th>Metric</th>
<th>Both</th>
</tr>
</thead>
</table>

Investigative Project (aka PSS-Lite)

Investigative Project specific instructions are highlighted in yellow. An investigative project must advance in two WGM cycles, requiring a full scope statement. Otherwise the project will be closed.

2. Sponsoring Group(s) / Project Team

2.a. Primary Sponsor/Work Group

<table>
<thead>
<tr>
<th>Primary Sponsor/Work Group</th>
<th>Electronic Health Record Work Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1 And Only 1 Allowed)</td>
<td></td>
</tr>
</tbody>
</table>

2.b. Co-sponsor Work Group(s)

<table>
<thead>
<tr>
<th>Co-sponsor Work Group(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Enter co-sponsor approval dates in Section 6.d Project Approval Dates)</td>
</tr>
</tbody>
</table>

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
- Other Involvement. Specify details here:

2.c. Project Team

All names should have confirmed their role in the project prior to submission to the TSC.

<table>
<thead>
<tr>
<th>Project facilitator (1Mandatory)</th>
<th>Gary Dickinson FHL7</th>
</tr>
</thead>
</table>

Warning:
Do not launch ANY of the links while your are in create or edit mode. There is a good chance all of your work will be gone.
Other interested parties and their roles

ISO TC215 WG1 (ISO 13940 and ISO 13606)
Dipak Kalra MD, ISO 13606 Lead
Björn-Erik Erlandsson, ISO WG1 Convenor

Multi-disciplinary project team (recommended)

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modeling facilitator</td>
<td>Steve Hufnagel PhD</td>
</tr>
<tr>
<td>Publishing facilitator</td>
<td></td>
</tr>
<tr>
<td>Vocabulary facilitator</td>
<td></td>
</tr>
<tr>
<td>Domain expert rep</td>
<td></td>
</tr>
<tr>
<td>Business requirement analyst</td>
<td>Helen Broberg (HL7 Sweden)</td>
</tr>
<tr>
<td>Conformance facilitator (for IG projects)</td>
<td></td>
</tr>
<tr>
<td>Other facilitators (SOA, etc)</td>
<td></td>
</tr>
</tbody>
</table>

Implementers *(Mandatory for STU projects)*

**FHIR Project Note:** The implementer requirement will be handled by the “balloting” project. Therefore work groups do not fill out the above section. However, feel free to list implementers specific to your work group’s resources if you know of any.

1)  
2)  

3. Project Definition

3.a. Project Scope
Preamble

In order to bring consistency and to maximise the smooth use of ICT by healthcare actors in the creation, representation, analysis and interoperable communication of health information, it is important that the various standards used to represent health information are as best aligned as possible.

EN ISO 13940:2015 (Contsys) defines a comprehensive concept model that applies to all aspects of clinical and patient workflows, and should therefore be the overarching domain model for the development of clinical information models.

EN ISO 13606 (EHRcom) defines a high-level interoperability framework, including an information model, for the communication of electronic health record information. It includes the archetype concept, which is a dominant formalism for representing clinical information models. Part 3 of this latter standard includes an intersection of the two standards, by defining a set of clinical reference models as “reference archetypes” derived from EN ISO 13940, which are the clinical information models corresponding to the most frequently used clinical concept models, that might be represented within persisted clinical information.

HL7 FHIR is rapidly becoming the most supported interoperability interface specification for the communication of health information, including clinical information. It also has a specialisation mechanism, through FHIR Resources, that would allow for the equivalent representation to clinical information models, as interface specifications.

These three standards environments are therefore probably the most important to align in order to allow accelerated development and adoption of sophisticated clinical information systems and of better interoperability between them.

1) What we intend to do:

The primary aim is to give the HL7 FHIR resources a conceptual, clinical context and clinical process foundation based on ISO 13940:2015 Health informatics -- System of concepts to support continuity of care (Contsys). A secondary aim is to harmonize the HL7 FHIR resources with reference information structures (CRIS) and reference archetypes in EN/ISO 13606-3:2019 Health informatics -- Electronic health record communication -- Part 3: Reference archetypes and term lists (13606-3).

The work will be done in three steps.

1. For each FHIR resource identify which concept or concepts as defined in Contsys that the resource is specifying information about. Suggest a text to add to the description of the resource about the related concept/concepts. Also relate the interpretation of the concept behind the FHIR resource in Contsys diagrams.

2. For each FHIR resource, based on the identified concept make a gap analysis and identify discrepancies between the attributes in the FHIR resource and the attributes in the related CRIS. Suggest if the identified gaps should be resolved by e.g. adding/changing an attribute to the resource or by creating an extension to the resource.

3. Based on analyses the marked concepts in the Contsys models identify need for and suggest new or needed changes/extensions of existing FHIR resources. The analysis should include if there is any clinically important concepts or characteristics in Contsys that has no corresponding FHIR resource for information. The analysis should also identify if there is more than one FHIR resource needed to apply for information concerning one concept. If found needed and relevant also suggest a solution for harmonization between concepts for clinical content and clinical context expressed in Contsys and capacity for information specifications applying FHIR resources.

2) Assistance we need from HL7 FHIR experts:

The project team should be built up by experts from the three standards (Contsys, 13606-3 and HL7 FHIR). Clinical competences should be included in all phases. The experts should have experience from development of the standard to be able to participate in the work and do the analysis, interpretations, comparisons and to suggest appropriate solutions where the standards is in disharmony. For HL7 FHIR is needed knowledge/experience for the development and need analyses behind the resources and extensions. For 13606-3 is corresponding requirements concerning the Clinical Reference Information Structures and the reference archetype needed. For Contsys is knowledge concerning the reasoning behind the selection and definition of the concepts and how these relate to each other needed.

3) What we intend to develop/ballot/publish (as HL7 and ISO TC215 products)?

- Project report including mapping tables in both directions between HL7 FHIR resources and Contsys concepts and 13606-3 (HL7 and ISO TC215 product)
- Description for each FHIR resource where the related Contsys concept or concepts is described (proposed to be published on the respective HL7 FHIR resource content page.) (HL7)
- Based on the results of the analysis
  - ISO 13606-3/FHIR Implementation Guide, including FHIR profiles and extensions (HL7 and ISO TC 215 product)
  - Suggestions for change of existing FHIR resources (HL7)
  - Suggestions for new FHIR resources (HL7)
  - Suggestions for change in upcoming periodic reviews in Contsys and 13606-3 (ISO TC 215 products)

3.b. Project Need

This project is intended to fill a gap between ISO 13606, ISO 13940 and HL7 FHIR Standards. The need is to establish formalisms for health information exchange and demonstrate harmonization between these key international Standards.

3.c. Security Risks

Will this project produce executable(s), for example, schemas, transforms, style sheets, executable program, etc. If so the project must review and document security risks. Refer to the Cookbook for Security Considerations for additional guidance, including sample spreadsheets that may be used to conduct the security risk assessment.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.d. External Drivers

No formal schedules or drivers other than a prevailing interest to pursue and complete the work as soon as feasible.

3.e. Project Objectives / Deliverables / Target Dates

Within each row, enter the explicit work product(s) / objective(s). Indicate their target date at the right in WGM/Ballot Cycle format. Include the project end date as the last objective (for standards projects, the end date will be the projected ANSI approval date).

<table>
<thead>
<tr>
<th>Work Product / Objective</th>
<th>Target Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete analysis and plan of action</td>
<td>By May 2019</td>
</tr>
<tr>
<td>Finalize suggestions for new FHIR resources or updates to existing FHIR resources</td>
<td>By Sep 2019</td>
</tr>
<tr>
<td>Complete ISO 13606-3/FHIR Implementation Guide with profiles and extensions</td>
<td>By Nov 2019</td>
</tr>
<tr>
<td>Ballot ISO 13606-3/FHIR Implementation Guide - first round ballot</td>
<td>Jan 2020 ballot</td>
</tr>
<tr>
<td>Submit Publication Request</td>
<td>Jul 2020</td>
</tr>
<tr>
<td>Project End Date</td>
<td>Sep 2020</td>
</tr>
</tbody>
</table>

3.f. Common Names / Keywords / Aliases

ISO 13606 Implementation Guide, 13606 IG

3.g. Lineage

N/A

3.h. Project Dependencies

N/A

3.i. HL7-Managed Project Document Repository Location
Projects must adhere to the TSC’s guidelines (which were approved on 2016-04-04 and summarized in Appendix A).


Enter the SPECIFIC URL of the HL7-MANAGED SITE where supporting project documents, deliverables, ballot reconciliation work and other project information will be kept.

TBD

3.j. Backwards Compatibility

Are the items being produced by this project backward compatible?  

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
<th>X</th>
<th>N/A</th>
</tr>
</thead>
</table>

If you check 'Yes' please indicate the earliest prior release and/or version to which the compatibility applies:

For V3, are you using the current data types?  

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
<th>X</th>
<th>N/A</th>
</tr>
</thead>
</table>

(Refer to TSC position statement on new projects using R2B for more information on the current V3 data types)

If you check no, please explain the reason:

If desired, enter additional information regarding Backwards Compatibility.

3.k. External Vocabularies

Will this project include/reference external vocabularies?  

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
<th>N/A</th>
</tr>
</thead>
</table>

If Yes, please enter the vocabularies: ISO, SKMT

4. Products (check all that apply)

<table>
<thead>
<tr>
<th>Product</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arden Syntax</td>
<td>V2 Messages – Administrative</td>
</tr>
<tr>
<td>Clinical Information Modeling Initiative (CIMI)</td>
<td>V2 Messages - Clinical</td>
</tr>
<tr>
<td>Clinical Context Object Workgroup (CCOW)</td>
<td>V2 Messages - Departmental</td>
</tr>
<tr>
<td>Domain Analysis Model (DAM)</td>
<td>V2 Messages – Infrastructure</td>
</tr>
<tr>
<td>Electronic Health Record (EHR) Functional Models</td>
<td>V3 Domain Information Model (DIM / DMIM)</td>
</tr>
<tr>
<td>X</td>
<td>FHIR Extensions</td>
</tr>
<tr>
<td>X</td>
<td>FHIR Implementation Guide (enter FHIR product version below)</td>
</tr>
<tr>
<td>X</td>
<td>FHIR Profiles (enter FHIR product version below)</td>
</tr>
<tr>
<td>X</td>
<td>FHIR Resources</td>
</tr>
<tr>
<td>X</td>
<td>Guidance (e.g. Companion Guide, Cookbook, etc)</td>
</tr>
<tr>
<td>Logical Model</td>
<td>V3 Messages - Administrative</td>
</tr>
<tr>
<td>New/Modified/HL7 Policy/Procedure/Process</td>
<td>V3 Messages - Clinical</td>
</tr>
<tr>
<td>New Product Definition (please define below)</td>
<td>V3 Messages - Departmental</td>
</tr>
<tr>
<td>New Product Family (please define below)</td>
<td>V3 Messages - Infrastructure</td>
</tr>
<tr>
<td>Non Product Project - (Educ. Marketing, Elec. Services, etc.)</td>
<td>V3 Rules - GELLO</td>
</tr>
<tr>
<td>White Paper</td>
<td>V3 Services – Java Services (ITS Work Group)</td>
</tr>
<tr>
<td>Creating/Using a tool not listed in the HL7 Tool Inventory</td>
<td>V3 Services – Web Services (SOA)</td>
</tr>
</tbody>
</table>

If you checked New Product Definition or New Product Family, please define below:
For FHIR IGs and FHIR Profiles, what product version(s) will the profiles apply to?

FHIR R4

5. Project Intent (check all that apply)

<table>
<thead>
<tr>
<th>Create new standard</th>
<th>Supplement to a current standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revise current standard (see text box below)</td>
<td>X Implementation Guide (IG) will be created/modified</td>
</tr>
<tr>
<td>Reaffirmation of a standard</td>
<td>Project is adopting/endorsing an externally developed IG:</td>
</tr>
<tr>
<td>New/Modified HL7 Policy/Procedure/Process</td>
<td>Specify external organization in Sec. 6 below;</td>
</tr>
<tr>
<td>White Paper (select one):</td>
<td>Externally developed IG is to be (select one):</td>
</tr>
<tr>
<td>Balloted Informativ OR</td>
<td>Adopted - OR -</td>
</tr>
<tr>
<td>Non-balloted WG White Paper</td>
<td>? Endorsed</td>
</tr>
</tbody>
</table>

If revising a current standard, indicate the following:

- Name of the standard being revised: N/A
- Date it was published (or request for publication, or ANSI designation date): N/A
- Rationale for revision: N/A
- The relationship between the new standard and the current standard (is it designed to replace the current standard, a supplement to the current standard, etc.) N/A

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

<table>
<thead>
<tr>
<th>Comment (aka Comment-Only)</th>
<th>Joint Ballot (with other SDOs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>X Informativ</td>
<td>N/A (project won't go through ballot)</td>
</tr>
<tr>
<td>STU to Normative - OR -</td>
<td>Normative (no STU)</td>
</tr>
</tbody>
</table>

If necessary, add any additional ballot information here. If artifacts will be jointly balloted with other SDOs, list the other groups.

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? Yes X No

6. Project Logistics

6.a. External Project Collaboration

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? 25%
6.b. Realm

<table>
<thead>
<tr>
<th>X</th>
<th>Universal</th>
<th>- OR -</th>
<th>Realm Specific</th>
</tr>
</thead>
</table>

Check here if this standard balloted or was previously approved as realm specific standard

Enter “U.S.” or name of HL7 affiliate(s) here. Provide explanation/justification of realm selection. For projects producing deliverables applicable to multiple realms, document those details here.

For Investigative projects, indicate if the project is planned to be Realm Specific or Universal, if known. Work Groups are encouraged designating project a Universal project initially, and discover which Realms can contribute to the work effort during the discovery phase of the project. Note: This status is subject to change during the investigative process.

6.c. 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

<table>
<thead>
<tr>
<th>Stakeholders</th>
<th>Vendors</th>
<th>Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunization Registries</td>
<td>EHR, PHR</td>
<td>Emergency Services</td>
</tr>
<tr>
<td>Quality Reporting Agencies</td>
<td>Equipment</td>
<td>Local and State Departments of Health</td>
</tr>
<tr>
<td>Regulatory Agency</td>
<td>X Health Care IT</td>
<td>Medical Imaging Service</td>
</tr>
</tbody>
</table>

X Standards Development Organizations (SDOs) | Clinical Decision Support Systems | X Healthcare Institutions (hospitals, long term care, home care, mental health) |

Payors | Lab | X Other (specify in text box below) |

X Other (specify in text box below) | HIS | N/A |

N/A | X Other (specify below) |

N/A

Other: Indicate other stakeholders, vendors or providers not listed above.
ISO 13606-3 Implementers, National/Regional EHR Programs

6.d. Project Approval Dates

Click here to go to HL7 Project Scope Statement Instructions#Appendix A for more information regarding this section. Approvals are by simple majority vote of the approving body

<table>
<thead>
<tr>
<th>Sponsoring Work Group Approval Date</th>
<th>WG Approval Date</th>
<th>2019-01-29</th>
</tr>
</thead>
</table>

Administrative review – in parallel with Work Group Approval

<table>
<thead>
<tr>
<th>Co-Sponsor Group Approval Date</th>
<th>List each Co-Sponsor and their Approval Date</th>
<th>N/A</th>
</tr>
</thead>
</table>

Family Management Group Approval Date(s)

CIMI Projects: CIMI Management Group | CIMI MG Approval Date | N/A |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CDA Projects: CDA Management Group</td>
<td>CDA MG Approval Date</td>
<td>N/A</td>
</tr>
<tr>
<td>FHIR Projects: FHIR Management Group</td>
<td>FMG Approval Date</td>
<td>N/A</td>
</tr>
<tr>
<td>V2/Publishing Projects: V2 Management Group</td>
<td>V2 MG Approval Date</td>
<td>N/A</td>
</tr>
<tr>
<td>US Realm Projects: US Realm Steering Committee Approval (Email WG approved PSS to: <a href="mailto:tscpm@HL7.org">tscpm@HL7.org</a>)</td>
<td>USRSC Approval Date</td>
<td></td>
</tr>
</tbody>
</table>

Affiliate Specific Projects: Affiliate Approval Date | Affiliate Approval Date | |

Submit PSS to Steering Division after all of the above approvals are received
<table>
<thead>
<tr>
<th>Steering Division (of Primary Sponsor WG) Approval Date:</th>
<th>SD Approval Date CCYY-MM-DD</th>
<th>2019-02-22</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last PBS Metrics Score:</td>
<td>X</td>
<td>Green</td>
</tr>
<tr>
<td>PBS Metrics Reviewed? (required for SD Approval if not green)</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**ARB and Steering Division approval may be in parallel**

<table>
<thead>
<tr>
<th>Architectural Review Board Approval Date:</th>
<th>ARB Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>(required for externally developed content)</td>
<td></td>
</tr>
</tbody>
</table>

**TSC Approval**

If applicable, TSC has received a Joint Copyright/Distribution Agreement (containing the verbiage outlined within the SOU), signed by both parties.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Technical Steering Committee Approval Date:</th>
<th>TSC Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Email SD WG approved PSS to: <a href="mailto:tscpm@HL7.org">tscpm@HL7.org</a>)</td>
<td></td>
</tr>
</tbody>
</table>