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| --- |
|  |
| Project Scope Statement  2017 Version  Release 1.1 |
| Original Approval Date: 2007  Last Reviewed Date: Q4, 2016  Review Cycle: Annual |
| HL7 Project Management Office  Project Services Work Group |
|  |
| **Point of Contact Name and Email:**  **David Hamill (**[**pmo@hl7.org**](mailto:pmo@hl7.org)**)**  **Co-Chairs of Project Services Work Group:** [**http://www.hl7.org/Special/committees/projectServices/leadership.cfm**](http://www.hl7.org/Special/committees/projectServices/leadership.cfm) |
| **Publication Date: January, 2017**  **Updated: February, 2017** |
|  |
| URL to download document:  <http://www.hl7.org/permalink/?ProjectScopeStatement> |
|  |
| For prior versions of this document refer to:  <http://www.hl7.org/Special/committees/projectServices/docs.cfm> |

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| The objective of this document is to communicate the type of activities a group is undertaking to achieve specific objectives or to produce specific work products. It’s intended for projects to produce standards or Implementation Guides as well as infrastructure projects. |

**Template Usage Information:**

* Replace **Highlighted Courier New** text with appropriate content.
* To use Track Changes, turn off “protection” by clicking on Tools > Unprotect Document; in Word 2010, select Review>Track Changes
* For assistance in completing each section, refer to [Appendix A](#Appendix_A).
* Information on the Project Approval Process is documented in [Appendix B](#Appendix_B).
* For FAQs (Frequently Asked Questions), refer to [Appendix C](#_Appendix_C_–)
* Submit template change requests to [PMO@HL7.org](mailto:PMO@HL7.org)
* PSS-Lite/Investigative Projects: Sections surrounded by a **BOLD OUTLINE** must be completed for approval of "Investigative Projects"

1. Project Name and ID

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [*Click here*](#Project_Name_help) *to go to Appendix A for more info regarding this section including guidance on naming conventions.* | | | | *An ID will be assigned by Project Insight* |
| **FHIR resources to support IDMP 11615 Product Standard** | | | | Project ID: xxxx |
|  |  | TSC Notification Informative/STU to Normative | Date : | |
| **Check this box when the project proceeds from Informative to Normative or STU to Normative status. Forward to the TSC for notification, as this triggers American National Standards Institute (ANSI) Project Initiation Notification (PINS) submission.** | | | |
|  |  | Investigative Project (aka PSS-Lite) | Date : 2017-09-14 | |
| **Check this box when the project is investigative or exploratory in nature, which allows limited project scope definition. Sections in bold outline are mandatory for project approval of an investigative project; all other sections are optional. Sections 1-Project Name, 2-Sponsoring Group(s)/Project Team, 3a-Project Scope, 3b-Project Need, 3e-Project Objectives/Deliverables/Target Dates, 3i-Project Document Repository, 6b-[Realm, if known], and 6d-[applicable Approval Dates] are required.**  **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.** | | | | |

1. Sponsoring Group(s) / Project Team

[*Click here*](#Sponsoring_Group_help) *to go to Appendix A for more information regarding this section.*

* 1. Primary Sponsor/Work Group

|  |  |
| --- | --- |
| Primary Sponsor/Work Group  **(1 (And Only 1) Allowed)** | **HL7 BR&R (Biomedical Research & Regulation)** |

* 1. Co-sponsor Work Group(s)

|  |  |
| --- | --- |
| Co-sponsor Work Group(s)  (Enter co-sponsor approval dates in Section 6.d Project Approval Dates) | **HL7 Pharmacy, HL7 O&O** |
| Indicate the level of involvement that the co-sponsor will have for this project:   |  |  |  | | --- | --- | --- | | X | Request formal content review prior to ballot | | |  | Request periodic project updates. Specify period: |  | | |  | Other Involvement. Specify details here: |  | | | |
|  |  |
|  | |

* 1. Project Team

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

|  |  |
| --- | --- |
| Project facilitator (**1** **Mandatory**) | **Panagiotis Telonis (EMA), Boris Brodsky (FDA)** |
| Other interested parties and their roles |  |
| Multi-disciplinary project team (recommended) |  |
| Modeling facilitator | **Rik Smithies** |
| Publishing facilitator |  |
| Vocabulary facilitator | **Julie James** |
| Domain expert rep | **Panagiotis Telonis (EMA), Mary-Ann Slack (FDA)** |
| Business requirement analyst | **Panagiotis Telonis (EMA), Mary-Ann Slack (FDA)** |
| Conformance facilitator (for IG projects) |  |
| Other facilitators (SOA, etc) |  |
|  |  |
| Implementers **(2** **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) | |

1. Project Definition
   1. Project Scope

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

|  |
| --- |
| **This project will commence the development of FHIR work and probably logical models and resources or possibly profiles, to support the content of the ISO 11615 IDMP Product standard, and other domain areas with similar requirements.** |

* 1. Project Need

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

|  |
| --- |
| **Drug industry regulators (EMA, FDA), and industry partners are engaged in exchanging product authorisation information, for the purpose of regulating and approving medicinal products. Proprietary messages and older HL7 standards are being used, and there is an appetite to do this work in the FHIR arena.** |

* 1. Security Risks

[*Click here*](#Security_Risks_help) *to go to Appendix A for more information regarding this section.*

|  |  |  |  |
| --- | --- | --- | --- |
| 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 Appendix A for additional instructions. |  |  | **Yes** |
|  | X | **No** |
|  |  | **Unknown** |

* 1. External Drivers

[*Click here*](#External_Drivers_help) *to go to Appendix A for more information regarding this section.*

|  |
| --- |
| **Stakeholders wish to use the industry standard methods to exchange ISO 11615 data, including use of JSON formats, and see FHIR as a good way to achieve their goals.** |

* 1. 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).*  [*Click here*](#Project_Obj_Del_TgtDates_help) *for further information, FHIR project instructions, and an* [*EXAMPLE*](#Project_Obj_Del_TgtDates_Example_help) | **Target Date** *(in WGM or ballot cycle format, e.g.*  *‘2017 Sept WGM’ or*  *‘2017 Jan Ballot’)* |
| **Enter objective/deliverable here.**  **All planned ballots and their target dates should be included**  **The example below is a "STU to Normative" path** | **Enter Target Date** |
| **Submit HL7 PSS** | **2017 September** |
| **Development of draft FHIR models for Products** | **2017 Q4 to 2018 Q1** |
| **Presentation of initial work** | **2018 Jan WGM** |
| **Incorporation of feedback and re-draft** | **Q1-Q2 2018** |
| **Present updated models** | **2018 May WGM** |
|  |  |
|  |  |
| **Project End Date (all objectives have been met)**  **Note: For PSS-Lite/Investigative Project, End date must be no more than two WGM cycles, e.g. project initiated at January WGM must complete investigation by September WGM.** | **2019 Jan WGM** |

* 1. Common Names / Keywords / Aliases

[*Click here*](#Common_Names_Keys_Aliasis_help) *to go to Appendix A for more information regarding this section.*

|  |
| --- |
| **ISO IDMP 11615. “MedicinalProduct” resource, possible name.** |

* 1. Lineage

[*Click here*](#Lineage_help) *to go to Appendix A for more information regarding this section.*

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* 1. Project Dependencies

[*Click here*](#Project_Dependencies_help) *to go to Appendix A for more information regarding this section.*

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* 1. Project Document Repository Location

[*Click here*](#Project_Doc_Repository_Location_help) *to go to Appendix A for more information regarding this section.*

|  |
| --- |
| **Resource content will be maintained in** [**http://gforge.hl7.org/svn/fhir/trunk/source**](http://gforge.hl7.org/svn/fhir/trunk/source)**. Additional project tracking and supporting project documents will be kept/referenced from here (correct URL even though group is now called BR&R):**  [**http://www.hl7.org/Special/committees/rcrim/index.cfm**](http://www.hl7.org/Special/committees/rcrim/index.cfm) |

* 1. Backwards Compatibility

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Are the items being produced by this project backward compatible? |  |  | Yes |  |  | No |  |  | Unknown |  | X | N/A |
|  |  |  |  |  |  |  |  |
|  | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| For V3, are you using the current data types?  (Refer to [TSC position statement on new projects using R2B](#TSC_position_statement_on_R2B) for more information on the current V3 data types) |  |  | Yes |  |  | No |  |  | Unknown |  | X | N/A |
|  | | |  | | |  |  |  |  |  |  |
| If you check 'No' please explain the reason: | | | | | | | | | | | | |
|  | | | | | | | | | | | | |

* 1. External Vocabularies

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Will this project include/reference external vocabularies? |  |  | Yes |  |  | No |  |  | Unknown |  | X | N/A |
|  |  |  |  |  |  |  |  |  |  |  |  |
| It is unlikely that specific external vocabularies will be included in the generic resources, except perhaps as example bindings. This is a similar approach to 11615 itself. Profiles and implementation guides would use region specific choices for vocabularies. | | | | | | | | | | | | |

1. Products (check all that apply)

[*Click here*](#Products_help) *to go to Appendix A for more information regarding this section*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Arden Syntax |  |  | V2 Messages – Administrative |
|  | Clinical Context Object Workgroup (CCOW) |  |  | V2 Messages – Clinical |
|  | Domain Analysis Model (DAM) |  |  | V2 Messages – Departmental |
|  | Electronic Health Record (EHR) Functional Profile |  |  | V2 Messages – Infrastructure |
|  | FHIR Extensions |  |  | V3 Domain Information Model (DIM / DMIM) |
|  | FHIR Implementation Guide |  |  | V3 Documents – Administrative (e.g. SPL) |
| X | FHIR Profiles |  |  | V3 Documents – Clinical (e.g. CDA) |
| X | FHIR Resources |  |  | V3 Documents – Knowledge |
|  | Guidance (e.g. Companion Guide, Cookbook, etc) |  |  | V3 Foundation – RIM |
| X | Logical Model |  |  | V3 Foundation – Vocab Domains & Value Sets |
|  | New/Modified/HL7 Policy/Procedure/Process |  |  | V3 Messages – Administrative |
|  | New Product Definition (please define below) |  |  | V3 Messages – Clinical |
|  | New Product Family (please define below) |  |  | V3 Messages – Departmental |
|  | Non Product Project - (Educ. Marketing, Elec. Services, etc.) |  |  | V3 Messages – Infrastructure |
|  | White Paper |  |  | V3 Rules – GELLO |
|  |  |  |  | V3 Services – Java Services (ITS Work Group) |
|  | Creating/Using a tool not listed in the [HL7 Tool Inventory](http://hl7-tools.herokuapp.com/) |  |  | V3 Services – Web Services (SOA) |

|  |
| --- |
| **If you checked New Product Definition or New Product Family, please define below:** |

1. Project Intent (check all that apply)

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

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

|  |
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|  |

* 1. Ballot Type (check all that apply)

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Comment (aka Comment-Only) | | |  |  | Joint Ballot (with other SDOs) |
|  | Informative | | |  | X | N/A (project won’t go through ballot) |
|  | STU to Normative - OR - |  | Normative (no STU) |  |  |  |

|  |
| --- |
| FHIR Project: This project will not ballot directly. Instead, content will be combined with resources from other committees and jointly balloted as part of the FHIR STU ballot (managed as a distinct TSC project). |

* 1. Joint Copyright

[*Click here*](#Joint_Copyright_help) *to go to Appendix A for more information regarding this section*

*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 |  |  |

1. Project Logistics
   1. External Project Collaboration

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SDOs: ISO/TC 215 WG6 and GS1 (SDO Joint Agreement)**  **Regulators: FDA and EMA (through bi-lateral agreement)** | | | | | | | |
| For projects that have some of their content already developed: | | | | | | | |
| How much content for this project is already developed? | **Indicate % here** | | | | | | |
| Was the content externally developed (Y/N)? | **If Yes, list developers** | | | | | | |
| Is this a hosted (externally funded) project?  (not asking for amount just if funded) |  |  |  |  |  |  | |
|  |  | Yes |  | x | No |

* 1. Realm

[*Click here*](#Realm_help) *to go to Appendix A for guidelines regarding choosing Universal or Realm Specific.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| X | Universal - OR - |  |  | Realm Specific |
|  | |  |  | 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.** | | |

* 1. Stakeholders / Vendors / Providers

[*Click here*](#Stakeholders_Customers_Providers_help) *to go to Appendix A for more information regarding this section*

*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 | **X** | Pharmaceutical |  | Clinical and Public Health Laboratories |
|  | | Immunization Registries |  | EHR, PHR |  | Emergency Services |
|  | | Quality Reporting Agencies |  | Equipment |  | Local and State Departments of Health |
| **X** | | Regulatory Agency | **X** | Health Care IT |  | Medical Imaging Service |
| **X** | | 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) |  |  |
|  | |  |  | N/A |  |  |
| |  | | --- | | **n/a for Investigational project** | | | | | | |

* 1. Project Approval Dates

[*Click here*](#Project_Approval_Dates_help) *to go to Appendix A for more information regarding this section.*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Affiliate Approval Date (for Affiliate Specific Projects): | **“N/A”** | | | | | | | | |
| US Realm Steering Committee Approval Date  (for US Realm Specific Projects): | **“N/A”** | | | | | | | | |
| Sponsoring Work Group Approval Date: | **WG Approval Date 2017-09-13** | | | | | | | | |
| Co-Sponsor Group Approval Date  (Copy this entire row for each co-sponsor; indicate the specific cosponsor that issued approval) | **TBC** | | | | | | | | |
| FHIR Project: [FHIR Management Group](http://www.hl7.org/Special/committees/fhirmg/leadership.cfm) Approval Date: | **“N/A”** | | | | | | | | |
| Architectural Review Board Approval Date:  (required for externally developed content) | **“N/A”** | | | | | | | | |
| Steering Division (of Primary Sponsor WG) Approval Date: | **SD Approval Date CCYY-MM-DD** | | | | | | | | |
| |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Last [PBS Metrics Score](http://gforge.hl7.org/gf/project/tsc/frs/?action=FrsReleaseBrowse&frs_package_id=169): |  | Green |  | Yellow |  | Red | | [PBS Metrics Reviewed](http://gforge.hl7.org/gf/download/docmanfileversion/9076/13967/PBS%20Metric%20Guidance%20for%20SD%20CoChairs%202016%20Final.doc)? (required for SD Approval if not green) | | |  | Yes |  | No | | | | | | | | | | |
| Technical Steering Committee Approval Date: | **TSC Approval Date CCYY-MM-DD** | | | | | | | | |
| TSC has received a Copyright/Distribution Agreement (containing the verbiage outlined within the SOU), signed by both parties. |  | | |  |  |  |  | |  |
|  |  | Yes |  | No | |  | N/A | |