**NOTE**: To use Track Changes, turn off “protection” by clicking on (pre-MS Word 2007) Tools > Unprotect Document or (MS Word 2007 and higher) Review > Protect Document.

**PSS-Lite/Investigative Projects: Sections surrounded by a BOLD OUTLINE must be completed for approval of "Investigative Projects" (a.k.a PSS-Lite).**

1. Project Name and ID

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | |  |
| **MedicationKnowledge and Medication Pattern - FHIR** | | | | Project ID: TBD |
|  |  | 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 | Date : | |
| **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 and Scope, 2-Sponsoring Group(s)/Project Team, 3a-Project Scope, 3b-Project Need, 3g-Project Objective, 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
   1. Primary Sponsor/Work Group

|  |  |
| --- | --- |
| Primary Sponsor/Work Group  **(1 (And Only 1) Allowed)** | **Pharmacy Work Group** |

* 1. Co-sponsor Work Group(s)

|  |  |
| --- | --- |
| Co-sponsor Work Group(s)  (Enter co-sponsor approval dates in Section 6.d Project Approval Dates) | Biomedical Research and Regulation |
| 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: | Monthly, at WGMs, etc. | | |  | Other Involvement. Specify details here: | Enter other involvement here | | | |

|  |  |
| --- | --- |
| Co-sponsor Work Group(s)  (Enter co-sponsor approval dates in Section 6.d Project Approval Dates) | Orders and Observations |
| 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: | Monthly, at WGMs, etc. | | |  | Other Involvement. Specify details here: | Enter other involvement here | | | |

* 1. Project Team

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

|  |  |
| --- | --- |
| Project facilitator (**1** **Mandatory**) | **Melva Peters** |
| Other interested parties and their roles | Patient Care, O&O, BR&R, CDS |
| Multi-disciplinary project team (recommended) |  |
| Modeling facilitator | **Jean Duteau** |
| Publishing facilitator | **N/A** |
| Vocabulary facilitator | **Julie James** |
| Domain expert rep | Melva Peters, John Hatem |
| Business requirement analyst |  |
| 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

|  |
| --- |
| This project will define a medication pattern or logical model that will be re-used across FHIR for all medication related resources as well as defining a new FHIR resource to support medication knowledge information.  The medication pattern will be used as the basis for the new resource. All existing medication resources and medication related resources under development by other Work Groups such as the IDMP resources in development by BR&R will be harmonized to align with the new pattern.  The proposed new resource will support the creation and querying for medication information e.g. drug classifications, images of medications, drug costs.  Medication information may be returned when reviewing more detailed information for a selected medication on a medication list or as part of a drug formulary or catalogue. |

* 1. Project Need

|  |
| --- |
| **Pharmacy Work Group has an existing Medication resource. This scope of this resource is to support prescribing, dispensing, and administering of medications as well as to record medication statements or history taking.**  **The Medication pattern is necessary to ensure that all resources intended to convey information about a medication are consistent.**  **This new resource is necessary to support use cases for querying for drug information including attributes such as drug classifications, images of medications, drug costs and/or coverages, etc. This resource could be used to return drug information as part of formulary or a catalogue.** |

* 1. 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](http://wiki.hl7.org/index.php?title=Cookbook_for_Security_Considerations) for additional guidance, including sample spreadsheets that may be used to conduct the security risk assessment. |  |  | **Yes** |
|  | x | **No** |
|  |  | **Unknown** |
|  |

* 1. External Drivers

|  |
| --- |
| **Describe any external schedules or calendars which may not be known outside of the project team that are driving target dates for this project.** |

* 1. Project Objectives / Deliverables / Target Dates

|  |  |
| --- | --- |
|  | **Target Date** |
| **Draft PSS** | **February 28, 2018** |
| **Close existing investigative project** | **April 15, 2018** |
| **Draft New Resource proposal** | **February 28, 2018** |
| **Approval of PSS and resource proposal by WG** | **February 28, 2018** |
| **Submit PSS to PMO** | **March 1, 2018** |
| **Approval of resource proposal by FMG** | **March 30, 2018** |
| **Approval of PSS by FMG** | **March 30, 2018** |
| **Approval of PSS by TSC** | **April 15, 2018** |
| **Develop draft resource for review** | **April 30, 2018** |
| **Review and update based on WG and implementer feedback** | **June 30, 2018** |
| **Draft Medication Pattern for review** | **August 30, 2018** |
| **September 2018 ballot – MedicationKnowledge Resource** | **August 30, 2018** |
| **Ballot reconciliation** | **November 30, 2018** |
| **Update Content based on ballot comments** | **December 30, 2018** |
| **Harmonize all medication resources with Medication pattern** | **December 30, 2018** |
| **January 2018 ballot** | **December 30, 2018** |
| **Ballot reconciliation** | **February 28, 2019** |
| **Publish** | **December 31, 2019** |
|  |  |
|  |  |
|  |  |
| **Project End Date** | **January 30, 2020** |

* 1. Common Names / Keywords / Aliases

|  |
| --- |
| **Pharmacy, Medication, Medication Knowledge Base, Drug Information, Medication Pattern** |

* 1. Lineage

|  |
| --- |
| **This work will be incorporated in to HL7 FHIR Releases.** |

* 1. Project Dependencies

|  |
| --- |
| **This project is dependent on the BR&R IDMP resources project** |

* 1. Project Document Repository Location

|  |
| --- |
| **HL7’s SVN repository.**  [**https://gforge.hl7.org/gf/project/fhir/scmsvn/?action=browse&path=%2Ftrunk%2Fbuild%2F&sortby=date&sortdir=down**](https://gforge.hl7.org/gf/project/fhir/scmsvn/?action=browse&path=%2Ftrunk%2Fbuild%2F&sortby=date&sortdir=down) |

* 1. Backwards Compatibility

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Are the items being produced by this project backward compatible? |  |  | Yes |  |  | No |  |  | Unknown |  | x | N/A |
|  |  |  |  |  |  |  |  |
| 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?  (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: | | | | | | | | | | | | |
| **If desired, enter additional information regarding Backwards Compatibility.** | | | | | | | | | | | | |

* 1. External Vocabularies

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Will this project include/reference external vocabularies? |  | x | Yes |  |  | No |  |  | Unknown |  |  | N/A |
|  |  |  |  |  |  |  |  |  |  |  |  |
| If yes, please list the vocabularies: SNOMED CT | | | | | | | | | | | | |

1. Products (check all that apply)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | 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) |
|  | 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)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Create new standard | | | |  |  | Supplement to a current standard | | |
| x | 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) | | |

|  |
| --- |
| **This work will be part of the FHIR standard** |

* 1. Ballot Type (check all that apply)

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

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

* 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 will be produced? |  |  | Yes |  | x | No |  |  |

1. Project Logistics
   1. 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? | **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 |  |  | No |

* 1. Realm

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

*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 | **x** | EHR, PHR |  | Emergency Services |
|  | | Quality Reporting Agencies |  | Equipment |  | Local and State Departments of Health |
| **x** | | Regulatory Agency |  | Health Care IT |  | Medical Imaging Service |
|  | | Standards Development Organizations (SDOs) | **x** | Clinical Decision Support Systems | **x** | Healthcare Institutions (hospitals, long term care, home care, mental health) |
| **x** | | Payors |  | Lab |  | Other (specify in text box below) |
|  | | Other (specify in text box below) | **x** | HIS |  | N/A |
|  | | N/A |  | Other (specify below) |  |  |
|  | |  |  | N/A |  |  |
| |  | | --- | | **Pharmacy Practice Management System vendors, Electronic Medical Record vendors, Drug Knowledge Base vendors** | | | | | | |

* 1. Project Approval Dates

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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: | **Pharmacy WG Approval Date CCYY-MM-DD** | | | | | | | | |
| Co-Sponsor Group Approval Date  (Copy this entire row for each co-sponsor; indicate the specific cosponsor that issued approval) | **BR&R Co-Sponsor Approval Date CCYY-MM-DD**  **O&O Co-Sponsor Approval Date CCYY-MM-DD**  **Patient Care Co-Sponsor Approval Date CCYY-MM-DD** | | | | | | | | |
| FHIR Project: [FHIR Management Group](http://www.hl7.org/Special/committees/fhirmg/leadership.cfm) Approval Date: | **FMG Approval Date CCYY-MM-DD** | | | | | | | | |
| 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): | x | 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 | |