

**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

<b>MedicationKnowledge and Medication Logical Model - FHIR</b>		Project ID: TBD
<input type="checkbox"/>	TSC Notification Informative/STU to Normative	Date :
<p><b>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.</b></p>		
<input type="checkbox"/>	Investigative Project	Date :
<p>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.</p>		

## 2. Sponsoring Group(s) / Project Team

### 2.a. Primary Sponsor/Work Group

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

### 2.b. 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
<p>Indicate the level of involvement that the co-sponsor will have for this project:</p> <p><input type="checkbox"/> Request formal content review prior to ballot</p> <p><input checked="" type="checkbox"/> Request periodic project updates. Specify period: <u>Joint meeting at WGM</u></p> <p><input checked="" type="checkbox"/> Other Involvement. Specify details here: <u>Review of logical model and harmonization requirements</u></p>	

Deleted: Monthly, at WGMs, etc.

Deleted: Enter other involvement here

Co-sponsor Work Group(s) (Enter co-sponsor approval dates in Section 6.d Project Approval Dates)	Orders and Observations
<p>Indicate the level of involvement that the co-sponsor will have for this project:</p> <p><input type="checkbox"/> Request formal content review prior to ballot</p> <p><input checked="" type="checkbox"/> Request periodic project updates. Specify period: <u>Before ballot material is being prepared</u></p> <p><input type="checkbox"/> Other Involvement. Specify details here: <u>Enter other involvement here</u></p>	

Deleted: Monthly, at WGMs, etc.

### 2.c. Project Team

<u>HL7 Pharmacy MedicationKnowledge and Medication Pattern PSS 20180414.docx</u>	2017 Release 1.1	Page 1 of 6
--	------------------	-------------

Deleted: HL7 Project Scope Statement v2017\_template\_only

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, 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)	

Deleted: O&O, BR&R,

Implementers (2 Mandatory for STU projects)
<i>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.</i>
1)
2)

### 3. Project Definition

#### 3.a. Project Scope

This project will define a medication knowledge resource to 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.

Taking the medication resource as well as the new medication knowledge resource and IDMP related resources under development in BR&R as the starting point, a FHIR logical model for medication will be developed. This logical model will be re-used across FHIR for all medication related resources.

All medication related resources (for example, those under development in Pharmacy and BR&R for IDMP) will be harmonized to align with the new logical model.

Deleted:

Deleted:

#### 3.b. 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 logical model 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.

#### 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.

<input type="checkbox"/>	Yes
<input checked="" type="checkbox"/>	No
<input type="checkbox"/>	Unknown

Deleted: HL7 Project Scope Statement v2017\_template\_only

### 3.d.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.

### 3.e.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 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 Logical Model for review	July 31, 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 Logical Model	December 30, 2018
January 2018 ballot	December 30, 2018
Approval of resource proposal by FMG	January 30, 2019
Ballot reconciliation	February 28, 2019
Publish	December 31, 2019
Project End Date	January 30, 2020

- Deleted: Approval of resource proposal by FMG
- Deleted: March 30, 2018
- Deleted: August 30, 2018
- Deleted: 8
- Deleted: January 2018 ballot ... [1]

### 3.f. Common Names / Keywords / Aliases

Pharmacy, Medication, Medication Knowledge Base, Drug Information, Medication Pattern, Medication Logical Model

### 3.g.Lineage

This work will be incorporated in to HL7 FHIR Releases.

### 3.h.Project Dependencies

This project is dependent on the BR&R IDMP resources project (Project 1367)

### 3.i. 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>

### 3.j. Backwards Compatibility

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

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

[HL7 Pharmacy MedicationKnowledge and Medication Pattern PSS 20180414.docx](#) 2017 Release 1.1 Page 3 of 6

Deleted: HL7 Project Scope Statement v2017\_template\_only

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?

Yes  No  Unknown  N/A

If yes, please list the vocabularies: SNOMED CT

### 4. Products (check all that apply)

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

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

### 5. Project Intent (check all that apply)

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

This work will be part of the FHIR standard

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

<input type="checkbox"/> Comment (aka Comment-Only)	<input type="checkbox"/> Joint Ballot (with other SDOs)
<input type="checkbox"/> Informative	<input type="checkbox"/> N/A (project won't go through ballot)
<input type="checkbox"/> STU to Normative - OR - <input type="checkbox"/> 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)

### 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  No

### 6. Project Logistics

#### 6.a. External Project Collaboration

[HL7 Pharmacy Medication Knowledge and Medication Pattern PSS 20180414.docx](#)

2017 Release 1.1

Page 4 of 6

Deleted: HL7 Project Scope Statement v2017\_template\_only

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)	<input type="checkbox"/> Yes <input type="checkbox"/> No

### 6.b. Realm

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.

### 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

Stakeholders	Vendors	Providers
Clinical and Public Health Laboratories	<input checked="" type="checkbox"/> Pharmaceutical	Clinical and Public Health Laboratories
Immunization Registries	<input checked="" type="checkbox"/> EHR, PHR	Emergency Services
Quality Reporting Agencies	Equipment	Local and State Departments of Health
<input checked="" type="checkbox"/> Regulatory Agency	Health Care IT	Medical Imaging Service
Standards Development Organizations (SDOs)	<input checked="" type="checkbox"/> Clinical Decision Support Systems	<input checked="" type="checkbox"/> Healthcare Institutions (hospitals, long term care, home care, mental health)
<input checked="" type="checkbox"/> Payers	Lab	Other (specify in text box below)
Other (specify in text box below)	<input checked="" type="checkbox"/> HIS	N/A
N/A	Other (specify below)	N/A
	N/A	

Pharmacy Practice Management System vendors, Electronic Medical Record vendors, Drug Knowledge Base vendors

### 6.d. 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 2018-03-05 BR&R Co-Sponsor Approval Date 2018-03-13
Co-Sponsor Group Approval Date (Copy this entire row for each co-sponsor; indicate the specific cosponsor that issued approval)	O&O Co-Sponsor Approval Date 2018-03-22
FHIR Project: FHIR Management Group Approval Date:	FMG Approval Date 2018-03-28
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: PBS Metrics Reviewed? (required for SD Approval if not green)	<input checked="" type="checkbox"/> Green <input type="checkbox"/> Yellow <input type="checkbox"/> Red <input type="checkbox"/> Yes <input type="checkbox"/> No

- Deleted: CCYY-MM-DD
- Deleted: CCYY-MM-DD
- Deleted: CCYY-MM-DD
- Deleted: 1 Patient Care Co-Sponsor Approval Date CCYY-MM-DD
- Deleted: CCYY-MM-DD
- Deleted: HL7 Project Scope Statement v2017\_template\_only

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

**Deleted:** HL7 Project Scope Statement v2017\_template\_only

January 2018 ballot

December 30, 2018