2019-02-20 Characteristics of Realm Transferable Standards Specifications

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

Enter the name of the project here: Characteristics of Realm Transferable Standards Specifications	
⚠ **PSS-1329 - Jira project doesn't exist or you don't have permission to view it.**	

Project ID:	1524	

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.

	TSC Notification: Informative/STU to Normative	Date: Submission date
X	- or - Direct to Normative (no STU) (includes reaffirmations)	

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		No
Select the unit of measure used in the standard; if no measurements are in the standard, select N/A		N/A	U.S.	Metric	Both
	Investigative Project (aka PSS-Lite)	Date :			

Check this box when the project is investigative or exploratory in nature, which allows limited project scope definition. 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 for Investigative Project. 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

Primary Sponsor/Work Group **(1 (And Only 1) Allowed)**	Architecture Review Board

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

Co-sponsor Work Group(s): (Enter co-sponsor approval dates in Section 6.d Project Approval Dates)	International Council
Indicate the level of involvement that the co-sponsor will have for this project:	
Y Request formal content review prior to ballot	
Y Request periodic project updates. Specify period	WGM
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.

Project facilitator (**1Mandatory**)	@Anthony Julian
Other interested parties and their roles	Standards Governance Board (SGB), HL7 Terminology Authority (HTA)
Multi-disciplinary project team (recommended)	
Modeling facilitator	**Ron G. Parker**
Publishing facilitator	**Lorraine Constable**
Vocabulary facilitator	**TBD**
Domain expert rep	**TBD**
Business requirement analyst	
Conformance facilitator (for IG projects)	
Other facilitators (SOA, etc)	
Implementers **(2Mandatory** 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

> **Describe the project; include what is expected to be accomplished/delivered along with specified features and functions. Include whether the deliverable(s) are universal, realm specific or applicable to various realms. Be sure to spell out all acronyms as these are carried forward to the NIB (Notice of Intent to Ballot) for ballot announcements..**

The purpose of the proposed project is to provide guidance to HL7 International on what the distinguishing characteristics are for a standards specification to be transferable, and readily implementable, across countries.

The scope of the project is the production of a guidance document for all current and future international standards work done in HL7. The intent is not to create a difficult process or barriers to standards development, but rather to make it easier for the work being done to be more internationally transferable where appropriate. The scope may also include potential criteria for assessing conformity of candidate international specifications to that guidance. It is proposed that the proposed owner / accountability for application of the document be the Standards Governance Board.

3.b. Project Need

> **This information is required by ANSI for all ballots. Briefly explain the reason behind the need for this project. This may be related to legislative requirements, industry need, or similar justifications.**
> **.**

HL7, as an SDO established in the USA under ANSI rules, has encouraged international participation in order to:

-     enrich the standards it produces;

-     make them applicable and useful globally.

In the last two HL7 WGM's it has become increasingly clear to that there is a lack of clarity or consistent understanding on what it means to be developing standards intended for international adoption. Given that HL7 is positioned as an International SDO, many of us can be forgiven for presuming that all work done within the SDO should be developed in a way that allows the specifications to be transferable to, and usable by, other countries. However, practically speaking, it is also clear that the nature of the work being done is driven by the compelling need of participant communities to achieve strategic objectives in terms of their operational context. Given the preponderance of member representation from the United States, combined with the incentives, directives and accompanying (welcome) funding arising from ONC, and proposed rule making by HHS, this often means the business problems to be solved have a distinctly US national, rather than international, perspective to them.

While International Affiliate members play very key and supportive roles in the work being done, and while International Affiliates are able to vote on resulting work, these alone are not enough to ensure that specifications are readily "transferable" to other national realms. There seems to be a lack of organizational guidance and "mindfulness", in some cases, about what the characteristics of a truly international standards specification should be (including both what is and is not desirable).

Another side effect of this is that, while many international participants successfully and productively inform the work, other international countries still see the work as purely realm centric, and not applicable or transferable. This has a particular impact on the international adoption of FHIR.

A contributing factor may be that, while external countries are distinctly and formally recognized, the USA as a "realm" is not clearly distinguished as a distinct international member body (the US Realm Steering Committee notwithstanding).

While implementation guides are used to contextualize the implementation of specifications, these guides are also often realm-specific. While International Affiliates are responsible for implementation guides for their own realms, there are IG's that are being balloted at the international level that are not actually meant to be adopted universally. However, the International Patient Summary joint project between HL7 and CEN 251 presents one example of an HL7 project that successfully involved a broader international perspective. There are also opportunities to work with other international organizations such as IHE.

As seen in recent FHIR ballots, many IG's relevant to the United States are balloted on the normative track without considering international requirements. Building IGs from a more international perspective may reduce the number of identical implementation guides.

The goal of this project is to address the need for HL7 to:

- be aware of the structural, terminological, and implementation aspects of standards specifications that are intended as candidate international standards
- to recognize when a specification may indeed be realm, rather than internationally applicable
- to provide a path forward where the international community sees HL7 International work products as more readily implementable and relevant globally
- to encourage that, where specifications have broad clinical applicability, the work is done in a way that is transferable between realms

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.		Yes
	x	No
		Unknown

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

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).	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
First draft of guidance document	September 2019

Informative ballot	2020 January Ballot
Publication	May 2020
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.	May 2020

3.f.   Common Names / Keywords / Aliases

What common name does your group use to refer to the product(s) produced? What alternative names, aliases and keywords does your group use to refer to the product(s) that will be produced? Some examples: C-CDA, LRI, eDOS.
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3.g. Lineage

If your project creates a Post-Release 1 version; indicate the name of the prior product and if it is supplanting, replacing or coexisting with a previous release:

3.h. Project Dependencies

Enter any dependencies or the name & Project Insight ID of project(s) that this project is dependent upon to achieve its objectives:

Projects and their Project Insight IDs can be found via http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?ref=common

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).

A template to create a Project Page on the HL7 Wiki is available at: http://wiki.hl7.org/index.php?title=Template:Project_Page.

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

RTSS Documents

3.j.   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?		Yes		No		Unknown	X	N/A
(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?		Yes		No		Unknown	X	N/A
If Yes, please enter the vocabularies:								

4. Products (check all that apply)

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

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?

5. Project Intent (check all that apply)

X	Create new standard			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;	
				Externally developed IG is to be (select one):	
	White Paper (select one):			Adopted - OR -		Endorsed
X	Balloted Informative OR		Non-balloted WG White Paper		N/A (Project not directly related to an HL7 Standard)	

If revising a current standard, indicate the following:

- **Name of the standard being revised:**	
- **Date it was published (or request for publication, or ANSI designation date)**	
- **Rationale for revision**	
- **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.)**	

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

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

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?			
Was the content externally developed ? :	*Y/N*		
Is this a hosted (externally funded) project? (not asking for amount just if funded)		Yes	No

6.b. 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.**		

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		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
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		
	Other: Indicate other stakeholders, vendors or providers not listed above.				

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

Sponsoring Work Group Approval Date:	**WG Approval Date**	**2019-03-12**
Administrative review – in parallel with Work Group Approval		
Co-Sponsor Group Approval Date	**International Council**	**2019-05-05**
Family Management Group Approval Date(s)		
CIMI Projects: CIMI Management Group	**CIMI MG Approval Date**	**N/A**
CDA Projects: CDA Management Group	**CDA MG Approval Date**	**N/A**
FHIR Projects: FHIR Management Group	**FMG Approval Date**	**N/A**
V2/Publishing Projects: V2 Management Group	**V2 MG Approval Date**	**N/A**
US Realm Projects: US Realm Steering Committee Approval (Email WG approved PSS to: tscpm@HL7.org)	**USRSC Approval Date**	**N/A**
Affiliate Specific Projects: Affiliate Approval Date	**Affiliate Approval Date**	**N/A**
Submit PSS to Steering Division after all of the above approvals are received		
Steering Division (of Primary Sponsor WG) Approval Date:	**SD Approval Date CCYY-MM-DD**	**N/A**

Last PBS Metrics Score:		Green		Yellow		Red
PBS Metrics Reviewed? (required for SD Approval if not green)		Yes		No		

ARB and Steering Division approval may be in parallel		
Architectural Review Board Approval Date: (required for externally developed content)	**ARB Approval Date**	**N/A**
TSC Approval		

If applicable, TSC has received a Joint Copyright/Distribution Agreement (containing the verbiage outlined within the SOU), signed by both parties.		Yes	No	N/A	

| Technical Steering Committee Approval Date:
(Email SD WG approved PSS to: tscpm@HL7.org) | **TSC Approval Date** | **2019-05-20** |