PSS for FHIR Implementation Guide for Transfusion and Vaccination Adverse Event Reporting

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.

Template Usage Information:

- Submit template change requests to PMO@HL7.org
- For Reaffirmations, please refer to the FAQ in HI7 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: FHIR Implementation Guide for Transfusion and Vaccination Adverse Event Reporting								
Project ID:	*1644*							
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		
	- 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	**X**	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)**	Biomedical Research and Regulation

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

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

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

	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**)	Jean Duteau
Other interested parties and their roles	Orders & Observations - update the WG on any work with BiologicallyDerivedProduct (extensions and/or updating requirements) Centers for Disease Control (specific contact to be named) - update with project work and include in project meetings
Multi-disciplinary project team (recommended)	
Modeling facilitator	**Jean Duteau**
Publishing facilitator	**Jean Duteau**
Vocabulary facilitator	**Jean Duteau**
Domain expert rep	**Jeff Beers (IBM), Shayan Hobbi (IBM)**
Business requirement analyst	N/A
Conformance facilitator (for IG projects)	N/A
Other facilitators (SOA, etc)	N/A
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) IBM BEST C2 Project	
2) MedStar	

3. Project Definition

3.a. Project Scope

The FHIR Implementation Guide provides a set of profiles for detection, validation, reporting, and ultimately recording/persisting Adverse Events associated with blood transfusions and vaccinations. There are two sets of profiles with the first set intended to enable the detection, validation, and recording of conditions and observations on a patient's record that would indicate the occurrence of an Adverse Event. The second set of profiles provides mappings to the ICH Individual Care Study Report (ICSR) specifications, specifically FDA's FAERS (FDA Adverse Event Reporting System) and VAERS (Vaccine Adverse Event Reporting System) implementations of those specifications, for the purposes of allowing the submission of Adverse Event Case Reports to FDA using the FHIR profiles after they have been transformed into the current XML specifications.
This FHIR implementation guide will use the US Core profiles. If this FHIR implementation guide is unable to use a US Core profile, we will request approval from the US Realm Steering Committee, and provide the US Realm Steering Committee an approved rationale for deviation in the implementation guide where applicable.

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..

3.b. Project Need

Vendor implementations of FHIR servers, along with the US Core Profiles, lack many of the granular data elements needed for detection and reporting of adverse events related to biologic products. Due to this limitation, provider networks often resort to manual creation of these reports and have not widely pursued electronic submission of adverse event reports to regulatory agencies like the FDA. To facilitate electronic reporting of adverse events, and interoperability of data for patients experiencing these events, this implementation guide gives guidance on the data elements needed for detection, validation, and reporting of biologics-related adverse events. This includes data elements needed to capture the granular details of exposure to the suspect drug/biologic, along with documenting the adverse event/outcome associated with the suspect drug/biologic.

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. **.**

3.c. Security Risks

We will be producing a standard FHIR Implementation Guide. These IGs have schemas, style sheets, and such, but it will be no different than other FHIR IGs.

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

None

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')*
Development of Implementation Guide ready for Connectathon	**2021 January**
Testing at HL7 FHIR Connectathon	**2021 January FHIR Connectathon**
Ready for First STU Ballot	**2021 May Ballot**
Complete STU Reconcilation	**2021 June**
STU Publication	**2021 July**
STU Period	**2021 July - 2022 July**
Normative Ballot	**2022 September Ballot**
Complete Normative Ballot Reconciliation	**2022 October**
Normative Publication	**2022 November**
Project End Date (all objectives have been met)	**2022 November 27**

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. **.**

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.
FHIR Implementation Guide for Transfusion and Vaccination Adverse Event Reporting

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? (Refer to TSC position statement on new projects using 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.									

3.k. External Vocabularies

Will this project include/reference external vocabularies?	X	Yes		No		Unknown		N/A
If Yes, please enter the vocabularies: SNOMED CT, MedDRA, LOINC, ICD-10, ICCBBA ISBT (blood product codes)								

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)
X	FHIR Extensions		V3 Documents – Administrative (e.g. SPL)
X	FHIR Implementation Guide (enter FHIR product version below)		V3 Documents – Clinical (e.g. CDA)
X	FHIR Profiles (enter FHIR product version below)		V3 Documents - Knowledge
	FHIR Resources		V3 Foundation – RIM
	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
	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? **FHIR R4**

5. Project Intent (check all that apply)

	Create new standard				Supplement to a current standard		
	Revise current standard (see text box below)			X	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
		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)

	Informative					N/A (project won't go through ballot)
X	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?	50%			
Was the content externally developed ? :	*Y*	IBM BEST C2 Project (Jean Duteau)		
Is this a hosted (externally funded) project? (not asking for amount just if funded)	X	Yes		No

6.b. Realm

	Universal	- OR -	**X**	Realm Specific
				Check here if this standard balloted or was previously approved as realm specific standard
U.S.	We are providing a guide for a specific implementation of the universal ICH ICSR standard - FDA's VAERS and FAERS specifications. **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	**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)		Clinical Decision Support Systems	X	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: BR&R	**WG Approval Date**	**2020-07-21**
Administrative review – in parallel with Work Group Approval		
Co-Sponsor Group Approval Date: Patient Care	**List each Co-Sponsor and their Approval Date**	**2020-07-23**
Co-Sponsor Group Approval Date: Public Health	**List each Co-Sponsor and their Approval Date**	**2020-07-27**
CDA Projects: CDA Management Group	**CDA MG Approval Date**	**N/A**
FHIR Projects: FHIR Management Group	**FMG Approval Date**	**2020-07-22**
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**	**2020-07-28**
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**	**2020-08-07**

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

ARB and Steering Division approval may be in parallel		
Architectural Review Board Approval Date: (required for externally developed content)	**ARB Approval Date**	**2020-08-20**
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 / X / N/A	
Technical Steering Committee Approval Date: (Email SD WG approved PSS to: tscpm@HL7.org)	**TSC Approval Date**	