Project Scope Statement
2016 Version
Release 1.1

HL7 Project Management Office
Project Services Work Group

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http://www.hl7.org/Special/committees/projectServices/leadership.cfm

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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

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.
- Information on the Project Approval Process is documented in Appendix B.
- For FAQs (Frequently Asked Questions), refer to Appendix C
- Submit template change requests to 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 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 Version of Electronic Initial Case Report (eICR)	Project ID:

		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, 2, 3a, 3b, 3g [limited, 6b [if known], and 6c [applicable] are required).
Investigative Project specific instructions are yellow highlighted.
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

Click here to go to Appendix A for more information regarding this section.

2.a. Primary Sponsor/Work Group

Primary Sponsor/Work Group **(1 (And Only 1) Allowed)**	**Public Emergency and Response Working Group.**

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

Co-sponsor Work Group(s) (Enter co-sponsor approval dates in Section 6.c Project Approval Dates)	Copy this entire table as needed for each co-sponsor

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:	Weekly
	Other Involvement. Specify details here:	Enter other involvement here

2.c. Project Team

Project facilitator (**1 Mandatory**)	**John Loonsk**
Other interested parties and their roles	Laura Conn
Multi-disciplinary project team (recommended)	
Modeling facilitator	**Enter a name here (or ask MnM for a name).**
Publishing facilitator	**With the exception of FHIR projects, mandatory if balloting in the same cycle as project submission**

Vocabulary facilitator	**Enter a name here (or ask Vocab for a name)**
Domain expert rep	
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)	

3. Project Definition

3.a. Project Scope

Click here to go to Appendix A for more information regarding this section and FHIR project instructions.

This project will determine and document a core, initial public health case report standard for use in reporting from Electronic Health Records to health departments as defined by public health authorities.

The initial, core public health case report will be limited to data that are established to exist in EHRs and closely parallel existing standards so as to constitute data that can be readily produced and delivered by EHRs. The work will also lay out next steps for additional data that could eventually be added to the core, initial case report and data that should be considered for secondary manual or electronic supplemental data reporting for specific conditions.

State and local Public Health Authorities are authorized by law to receive identified case report data. There have been some suggestions that there may be times where a state or local jurisdiction might choose to not initially receive patient name and identifying information until a case report is confirmed to meet all jurisdictional reporting requirements. While it is not anticipated that this will be the general case, future work will consider whether a pseudonymization option needs to be considered if it can be implemented in conjunction with expectations for the USA Realm header.

In addition to the needs for an initial core case report to flow from an EHR to a Public Health Authority (PHA), there are also considerations, in some circumstances, for information to flow back to the EHR from the PHA. Future work will include consideration of the circumstances where the initial, core case report and/or the following additional information will need to be supported in the context of this information flowing to responsible parties in clinical care: 1) A notice of reportability with reporting requirements, possibly from a public health decision support system, 2) a link to information about the condition in that geographical area, and 3) a link to a more information and/or procedural information about methods, forms, or formats, to submit supplemental data, when available, to provide more information to a case investigation, i.e. completion of the case report.

This project will accomplish several goals in a specific order. First, parallel efforts to:

(1) update the existing Implementation Guide (HL7 Implementation Guide for CDA Release 2:Public Health Case Reporting, Release 1) and get it into a Draft Standard for Trial Use evaluation period.

(2) document the use cases for how supplemental data can combine with a new core initial case report for Public Health Case Report interoperability standard(s) and evaluate the options for developing appropriate standard(s). This document will be published as an Informative document and will contain some but not all of the content of a Domain Analysis Model (DAM). This workflow study should consider the EHR perspective, representing the sender, as well as the public health perspective, representing the receiver.

(3+) The subsequent steps would be the development and publication of a document or documents that support the use cases identified by the Informative document from step 2. Other technologies will be incorporated as necessary to support the use case(s).

Future work will look at FHIR implementation, additional data to be considered for a core, initial report when they are readily available in EHRs, and supplemental data requirements identified during analysis. This initial scope includes development of an IG for only the core initial case report standard for PHCR, but it may be determined to include other products in subsequent phases.

The strategy for development undertaken by this project includes the use of a Draft Standard for Trial Use (DSTU) for actual development and

deployment feedback. Following the DSTU period, for a period of two years or less, a Normative standard will be balloted.

3.b. Project Need

Click here to go to Appendix A for more information regarding this section and FHIR project instructions.

In October, 2009 SDWG published an Informative Document, "HL7 Implementation Guide for CDA Release 2: Public Health Case Reporting, Release 1 (US Realm)." This document has not enjoyed wide adoption but it is widely believed to be a possible starting point for an implementation guide that would enjoy wide adoption.

Case reporting is part of the CMS and ONC NPRMs for Meaningful Use Stage III. Electronic case reporting is considered to be a critical public health need and a core initial case report is a needed component of a viable nationwide approach. The failure to have a workable case reporting standard will impede outbreak management and negatively impact the monitoring of disease trends.

3.c. Security Risks

Click here 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.			**Yes**
		X	**No**
			Unknown

3.d. External Drivers

Click here to go to Appendix A for more information regarding this section.

A core, initial case report standard is needed for Stage III of Meaningful Use. Whether used stand-alone or in conjunction with the other specifications, e.g. the IHE Structured Data Capture (SDC) standard mentioned in the NPRM for Stage III, a DSTU is needed for regulatory guidance and certification.

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). *Click here for further information, FHIR project instructions, and an EXAMPLE*	**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	December 2016
Example: Submit for STU Ballot(First Ballot Cycle)	2017 Jan Ballot

Example: Complete STU Reconciliation	2017 May WGM
Example: Submit for 2nd STU Ballot	2017 May Ballot
Example: Request STU Publication	2017 Sep WGM
Example: STU Period – 12 months	2018 Jan - 2015 Jan
Example: Submit for Normative Ballot	2018 May Ballot
Example: Complete Normative Reconciliation	2018 Sep WGM
Example: Submit Publication Request	2018 Oct
Example: Receive ANSI Approval	2019 Nov
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.**	**Enter Project End Date**

3.f. Common Names / Keywords / Aliases

Click here to go to Appendix A for more information regarding this section.

Public Health reporting, Public Health Case reporting, Reportable conditions, Notice of Reportability

3.g. Lineage

Click here to go to Appendix A for more information regarding this section.

C-CDA - coexisting
2009 PHCR guide - replacing

3.h. Project Dependencies

Click here to go to Appendix A for more information regarding this section.

http://www.hl7.org/Special/committees/pher/docs.cfm

3.i. Project Document Repository Location

Click here to go to Appendix A for more information regarding this section.

http://wiki.hl7.org/index.php?title=PHER_Public_Health_Case_Report_R2

3.j. Backwards Compatibility

Are the items being produced by this project backward compatible?			Yes			No			Unknown			N/A
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			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?			Yes			No			Unknown			N/A
			X									
If yes, please list the vocabularies: **At least LOINC, SNOMED CT, and RxNorm. Other standard vocabularies may be identified in the course of the project. The use of vocabulary content from the CDC's Vocabulary Access and Distribution Service (PHINVADS) will be**												

considered. Specifically, the use of code system / value set CDCPHINQUESTION will be considered.

4. Products (check all that apply)

Click here to go to Appendix A for more information regarding this section

	Non Product Project - (Educ. Marketing, Elec. Services, etc.)			V3 Domain Information Model (DIM / DMIM)
	Arden Syntax			V3 Documents – Administrative (e.g. SPL)
	Clinical Context Object Workgroup (CCOW)			V3 Documents – Clinical (e.g. CDA)
	Domain Analysis Model (DAM)			V3 Documents - Knowledge
	Electronic Health Record (EHR) Functional Profile			V3 Foundation – RIM
	Logical Model			V3 Foundation – Vocab Domains & Value Sets
	V2 Messages – Administrative			V3 Messages - Administrative
	V2 Messages - Clinical			V3 Messages - Clinical
	V2 Messages - Departmental			V3 Messages - Departmental
	V2 Messages – Infrastructure			V3 Messages - Infrastructure
	FHIR Implementation Guide			V3 Rules - GELLO
	FHIR Profiles			V3 Services – Java Services (ITS Work Group)
	FHIR Resources			V3 Services – Web Services (SOA)
	New/Modified/HL7 Policy/Procedure/Process			White Paper
	New Product Definition			
	New Product Family			

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

5. Project Intent (check all that apply)

Click here to go to Appendix A for more information regarding this section and FHIR project instructions.

	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;

	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)			

Because the Public Health Case Report R1 will appear to be the ancestor version of the document produced by this project. However R1 was published as an Informative document and therefore "Revise Current Standard" is not exactly correct. However " Implementation Guide (IG) will be created/modified" is certainly true.

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

Click here 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					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

Click here 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		

6. Project Logistics

6.a. External Project Collaboration

Click here to go to Appendix A for more information regarding this section and FHIR project instructions.

Several U.S. Government agencies and several NGOs have created some materials that will be used as reference material in this project. The organizations include the Office of the National Coordinator, Standards and Interoperability Framework (S&IF), the Association of State and Territorial Health Officers (ASTHO), the Council of State and Territorial Epidemiologists (CSTE), and others.

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	

6.b. Realm

Click here to go to Appendix A for guidelines regarding choosing Universal or Realm Specific.

	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. 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. Project Approval Dates

Click here to go to Appendix A for more information regarding this section.

Affiliate Approval Date (for Affiliate Specific Projects):	**Affiliate Approval Date CCYY-MM-DD or indicate "N/A"**
US Realm Steering Committee Approval Date (for US Realm Specific Projects):	**USRSC Approval Date CCYY-MM-DD or indicate "N/A"**
Sponsoring Work Group Approval Date:	**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)	**Co-Sponsor Approval Date CCYY-MM-DD**

FHIR Project: FHIR Management Group Approval Date:	**FMG Approval Date CCYY-MM-DD or "N/A"**
Architectural Review Board Approval Date:	**ARB Approval Date CCYY-MM-DD or "N/A"**
Steering Division Approval Date :	**SD Approval Date CCYY-MM-DD**

Last Work Group Health:		Green		Yellow		Red
PBS Metrics and Work Group Health Reviewed? (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		