1. Project Name and ID

Public Health Case Report Update	Project ID:
☐ TSC Notification Informative/DSTU to Normative	Date :
☐ Investigative Project	Date :

2. Sponsoring Group(s) / Project Team

Primary Sponsor/Work Group (**1 Mandatory**)	Public Health and Emergency Response (PHER)
Co-sponsor Work Group(s)	Structured Documents (SDWG)
Co-Sponsor Group Approval Date	Co-Sponsor Approval Date CCYY-MM-DD
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: ☒ Other Involvement. Specify details here:	Project updates at WGMs The project will use the CDA Implementation Guide Quality Criteria and SDWG will review the work product using this Criteria.

Project Team:	
Project facilitator (**1 Mandatory**)	Maribeth Gagnon (CDC)
Other interested parties and their roles	John Roberts (PHER co-chair, Tennessee Department of Health) John Loonsk (Executive Sponsor, CGI Federal)
Multi-disciplinary project team (recommended)	
Modeling facilitator	Eric Haas (Contractor to APHL)
Publishing facilitator	Jean Duteau
Vocabulary facilitator	Riki Merrick (Contractor to APHL)
Domain expert rep	Erin Holt Coyne (Tennessee Department of Health)
Business requirement analyst	TBD
Conformance facilitator (for IG projects)	TBD
Other facilitators (SOA, SAIF)	

Implementers **(2 Mandatory** for DSTU 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) One or more vendors – providers of software to senders. OZ Systems (participation confirmed 3/19/2015)
2) One or more Public Health Authorities (State Departments of Health) – receivers. None identified at this time. TN is a probable participant if a sender can be located in Tennessee. Other states who were participants in the PHDSC pilot project are possible participants.
3) Hospitals and/or large provider organizations – senders of data to their respective public health authorities. None identified at this time.
4) Possible support for pilots is under consideration at the Association of State and Territorial Health Officers (ASTHO) as a part of their Public Health Community Platform activities.

3. Project Definition

3.a. Project Scope

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 core, initial message will be built from previous HL7 public health case reporting and C-CDA work as well as work done in the ONC S & I Framework PHRI project. It will produce a C-CDA DSTU and will lead to a follow-on project to develop a FHIR standard as well.

The initial, core public health case report will be limited to data that are established to exist in EHRs and closely parallel existing C-CDA 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.

So as to be able to de-duplicate case reports arriving via different work flows, a unique report identifier created by the responsible clinical care site is needed. Consideration will be given as to whether the C-CDA report identifier will fulfill all of these needs or whether an additional identifier is necessary.

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. The document will be based on Clinical Document Architecture (CDA) R2 using the common templates of Consolidated CDA (C-CDA) R2. It must adopt the C-CDA R2 US Realm Header; may further constrain.

(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

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. The publication of the common templates of Consolidated CDA (C-CDA) has won great acceptance and the PHCR standard must be revised to include this important standard.

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. Success Criteria

Publication of a DSTU Implementation Guide that is adopted by at least 2 senders and 2 receivers in its review period; significant participation in the project from many of the healthcare communities involved.

3.d. Project Risks

Risk Description: (1)	**Significant players in the domain may choose to use their own specifications and not support an interoperability standard (not of their own authorship).**
Impact:	☐ Critical ☒ Serious ☐ Significant ☐ Low
Likelihood:	☐ High ☒ Med ☐ Low
Risk Type:	☐ Requirements ☐ Resources ☒ Social-Political ☐ Technology
Risk To HL7:	☐ Internal to HL7 ☒ External to HL7
Mitigation Plan:	**By involving the major players (CDC, CSTE, IHE, others) in the update to the PHCR and basing the use case(s) on the realities and range of solutions acceptable to public health authorities who will actually be affected, any "non-players" will be marginalized and**

	encouraged by peer pressure to adopt the common standard.
Risk Description: (2)	**The specification will not meet the needs of one or more important groups in the domain. Most probable is the lack of support by state and local public health authorities, under-represented in most interoperability standards efforts and inaccurately "represented" by one or more of a number of national organizations who, with the best of intentions, attempt to provide the input not provided by actual public health authorities.**
Impact:	☐ Critical ☐ Serious ☒ Significant ☐ Low
Likelihood:	☐ High ☒ Med ☐ Low
Risk Type:	☐ Requirements ☐ Resources ☒ Social-Political ☐ Technology
Risk To HL7:	☐ Internal to HL7 ☒ External to HL7
Mitigation Plan:	**Attempts have been made (and will continue) to involve representatives of all significant domains, specifically including as many of the unique public health authority models as possible. For the evaluation of the core initial case data, a proactive strategy to reach out to existing public health practitioner working groups and individuals to garner input will be instituted.**
Risk Description: (3)	**It is unclear as to whether or not there are sufficient resources available to support the project over the length of time required to initially ballot as DSTU and eventually go on to ballot as normative. Will we have the level of commitment to get this all the way to Normative, or should we pursue Informative?**
Impact:	☐ Critical ☒ Serious ☐ Significant ☐ Low
Likelihood:	☐ High ☒ Med ☐ Low
Risk Type:	☐ Requirements ☒ Resources ☐ Social-Political ☐ Technology
Risk To HL7:	☐ Internal to HL7 ☒ External to HL7
Mitigation Plan:	**The initial ballot type, Informative or as DSTU, will be chosen with care, considering resources available and possible, Pros and Cons of each approach and any other factors applicable. In either case a Normative Standard is the eventual goal.**

3.e. Security Risks

Will this project produce executable(s), for example, schemas, transforms, stylesheets, executable program, etc. If so the project must review and document security risks.	☐ Yes	☒ No	☐ Unknown

3.f. External Drivers

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.g. Project Objectives / Deliverables / Target Dates

	Target Date
Sequence (1):	
Update the existing Implementation Guide, an Informative document, primarily to use C-CDA R2 Templates and ballot it as a DSTU.	2016 Jan Ballot
Reconcile ballot comments and revise the Implementation Guide, and request publication as a DSTU.	2016 Jan

DSTU Period – 12 months (but considering 24 months)	2016 Jan – 2017 Jan
Sequence (2): (while the IG is in its DSTU comment period)	
Prepare a "DAM-lite" analysis document to document use case(s) and actors for supplemental data use in conjunction with a core initial case report standard; submit as an Informative ballot.	2016 May Ballot
Reconcile ballot comments, revise the ballot document, and ballot as an second Informative ballot.	2016 May
Sequence 3: (bringing the two threads together)	
Use the DSTU comments and the published Informative Document to inform the changes to the DSTU Implementation Guide, or other documents, as appropriate. Revise the Implementation Guide and/or revise the Informative document for use as a basis for a major update to the Implementation Guide.	2016 Sep – 2017 May
Submit the Informative document for a third ballot and the Implementation Guide for first Normative Ballot	2017 May Ballot
Complete Normative Ballot Reconciliation	2017 Sep WGM
Submit Publication Request	2018 Oct
Receive ANSI Approval	2018 Nov
Project End Date (all objectives have been met)	2018 Dec

3.h. Common Names / Keywords / Aliases

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

3.i. Lineage

C-CDA - coexisting
2009 PHCR guide - replacing

3.j. Project Requirements

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

3.k. Project Dependencies

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

3.l. Project Document Repository Location

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

3.m. Backwards Compatibility

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

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

For V3, are you using the current data types? ☐ Yes ☒ No	
If you check 'No' please explain the reason: **We are using CDA Release 2, which is based on data types Release 1. This will be reviewed as a part of the project.**	

3.n. External Vocabularies

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

Will this project include/reference external vocabularies?	☒ Yes	☐ No	☐ Unknown	☐ N/A

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

☐ 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 Resources	☐ V3 Rules - GELLO
☐ FHIR Profiles	☐ V3 Services – Java Services (ITS Work Group)
☐ New/Modified/HL7 Policy/Procedure/Process	☐ V3 Services – Web Services (SOA)
☐ New Product Definition	
☐ New Product Family	

5. Project Intent (check all that apply)

☐ Create new standard ☒ Revise current standard (**see text box below**) ☐ Reaffirmation of a standard ☐ New/Modified HL7 Policy/Procedure/Process ☐ Withdraw an Informative Document ☐ N/A (Project not directly related to an HL7 Standard)	☐ Supplement to a current standard ☒ Implementation Guide (IG) will be created/modified Project is adopting/endorsing an externally developed IG: Specify external organization in Sec. 6 below; Externally developed IG is to be (select one): ☐ Adopted - OR - ☐ Endorsed

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)

☐ Comment Only ☐ Informative ☒ DSTU to Normative	☐ Normative (no DSTU) ☐ Joint Ballot (with other SDOs or HL7 Work Groups) ☐ N/A (project won't go through ballot)

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

6. Project Logistics

6.a. External Project Collaboration

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?	**approx. 50%**
Was the content externally developed (Y/N)? Yes, by ONC/S&IF	**Yes, see above**

Date of external content review by the ARB? TBD	**Approval date CCYY-MM-DD**	
Is this a hosted (externally funded) project?	☐ Yes	☒ No

6.b. Realm

☐ Universal	☒ Realm Specific
	☐ Check here if this standard balloted or was previously approved as realm specific standard
	U.S.

6.c. Project Approval Dates

Affiliate/US Realm Task Force Approval Date (for US Realm Specific Projects)	**USRTF Approval Date 2015-09-08**
Sponsoring Work Group Approval Date	**WG Approval Date 2015-06-25**
FHIR Project: FHIR Management Group Approval Date	**FMG Approval Date CCYY-MM-DD**
Steering Division Approval Date	**SD Approval Date CCYY-MM-DD**
PBS Metrics and Work Group Health Reviewed? (required for SD Approval)	☐ Yes ☐ No
Technical Steering Committee Approval Date	**TSC Approval Date CCYY-MM-DD**

TSC has received a Copyright/Distribution Agreement (which contains the verbiage outlined within the SOU), signed by both parties. ☐ Yes ☐ No

6.d. 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
☒ 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	

Public Health Agencies

6.e. Synchronization With Other SDOs / Profilers

Check all SDO / Profilers which your project deliverable(s) are associated with.		
☐ ASC X12	☐ CHA	☐ LOINC
☐ AHIP	☐ DICOM	☐ NCPDP
☐ ASTM	☐ GS1	☐ NAACCR
☐ BioPharma Association (SAFE)	☐ IEEE	☐ Object Management Group (OMG)
☐ CEN/TC 251	☒ IHE	☐ The Health Story Project
☐ CHCF	☐ IHTSDO	☐ WEDI
☐ CLSI	☐ ISO	☐ Other (specify below)

The IHE organization has and most likely will continue to develop profiles in the same space as this interoperability standadard but no conflict is anticipated because the IHE profiles will focus on specifications on which this standard is silent, e.g transport, and on integration with other standards and/or specifications, e.g. Structure Data Capture (SDC), not addressed in this standard.