***NOTE****: Please spell out all acronyms the first time the acronym occurs.*

*For Reaffirmations, please refer to the FAQ within Appendix C of the PSS\_with\_instructions template for a list of which sections and fields should be completed.*

**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

|  |  |
| --- | --- |
|  |  |
| **HL7 CDA R2 Implementation Guide: Gaps in Care Reporting** | Project ID:  |
| 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:  |
|  |  | - 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 in bold outline are mandatory for project approval of an investigative project; all other sections are optional. 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.****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.**  |

1. Sponsoring Group(s) / Project Team
	1. Primary Sponsor/Work Group

|  |  |
| --- | --- |
| Primary Sponsor/Work Group **(1 (And Only 1) Allowed)**  | **Clinical Quality Information WG** |

* 1. Co-sponsor Work Group(s)

|  |  |
| --- | --- |
| Co-sponsor Work Group(s)(Enter co-sponsor approval dates in Section 6.d Project Approval Dates) |  |
| 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:  | Monthly, at WGMs, etc. |
|  |  Other Involvement. Specify details here:  | Enter other involvement here |

 |

* 1. Project Team

*All names should have confirmed their role in the project prior to submission to the TSC.*

|  |  |
| --- | --- |
| Project facilitator (**1** **Mandatory**) | **Bo Borgnakke**  |
| Other interested parties and their roles | **John D’Amore** |
| Multi-disciplinary project team (recommended) |  |
|  Modeling facilitator | **Kanwarpreet Sethi** |
|  Publishing facilitator | **Eric Parapini**  |
|  Vocabulary facilitator |  |
|  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) MiHIN - Michigan Health Information Network Shared Services |
| 2) Diameter Health |

1. Project Definition
	1. Project Scope

|  |
| --- |
| **The scope of this project is to define a common set of data elements and a canonical representation for a ‘gap in care’ report. A gap in care report is a patient or listlevel report containing data identifying individual patient(s), the quality measure(s) being evaluated, the current compliance status of the patient with regards to that measure. In the case of non-compliance, representation for how specific measure criteria was not met will also be provided.****After a set of common data elements are defined, a canonical representation will be defined as a standard built on top of the existing CDA-based standards, like QRDA and C-CDA. This project will also provide exploratory mappings towards the FHIR Measure Report Resource.** |

* 1. Project Need

|  |
| --- |
| When clinical and claims data is evaluated against quality measure logic, there are patients that do not meet the measure’s logic for compliance. These patients do not meet the care standard being evaluated by the measure’s logic and represent what is known as ‘gaps in care.’ These gaps in care are often transmitted from payor to provider, quality registry to provider, and by provider to other providers through health information exchange. Receivers can be made aware of these ‘gaps’ and evaluate further steps to ‘close the gap’ by understanding the reasons why patients did not meet the care standard. This is done by sending a patient-identified report. Currently, there are no existing standards to represent a patient-level gap in care summary report. Payors and providers are currently using numerous proprietary, one-off formats to represent this data, resulting in inefficient and ineffective utilization. Having a common, structured, standardized representation provides the ability for payers and providers to use automated tools to generate, aggregate, and consume the gaps in care reports. Ideally, these standardized reports will be integrated into clinical decision support and provider workflow processes.The Michigan Health Information Network (MiHIN) hosts a collaborative group of the largest Michigan payors and provider groups that has defined a set of common data elements necessary to make these reports effective. This collaborative group is currently piloting a gaps in care distribution service using a Comma-Separated Values file format temporarily in lieu of a formal national standard to send and receive gaps in care data on an all-payer / all-patient basis. This model is currently in use across the state of Michigan and will be consulted for input during development of artifacts for this project.Diameter Health works with multiple Qualified Clinical Data Registries (QCDRs), which act to calculate and share quality measure performance among providers, provider groups, health systems and payors. Its technology has been certified by the National Committee for Quality Assurance for quality measurement. Diameter Health currently uses existing standards, such as C-CDA and QRDA to transmit such information. Having a uniform standard to identify ‘gaps in care’ is an interest to our QCDR clients who will be consulted for input during development of artifacts for this project. Standardizing the way gaps in care are represented will allow for a robust, interoperable method of communicating this critical information, leading to increased quality measure compliance rates and ultimately patient health outcomes.  |

* 1. 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](http://wiki.hl7.org/index.php?title=Cookbook_for_Security_Considerations) for additional guidance, including sample spreadsheets that may be used to conduct the security risk assessment. |  | X | **Yes** |
|  |  | **No** |
|  |  | **Unknown** |
|  |

* 1. External Drivers

|  |
| --- |
|  |

* 1. Project Objectives / Deliverables / Target Dates

|  |  |
| --- | --- |
|  | **Target Date** |
| **Submit for Ballot for first STU ballot cycle** | **2018 Sep WGM** |
| **Complete STU Reconciliation** | **2019 Jan WGM** |
| **Submit for 2nd STU Ballot** | **2019 May WGM** |
| **Request STU Publication** | **2019 May Ballot** |
| **STU Period – 12 months** | **2018 Sep WGM** |
| **Submit for Normative Ballot** | **2019 Jan - 2015 Jan** |
| **Complete Normative Reconciliation** | **2019 May Ballot** |
| **Submit Publication Request** | **2019 Sep WGM** |
| **Receive ANSI Approval** | **2019 Oct** |
| **Request STU Publication** | **2020 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** |

* 1. Common Names / Keywords / Aliases

|  |
| --- |
| **HEDIS Gaps in Care, Gaps in Care Reporting** |

* 1. 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.****N/A** |

* 1. Project Dependencies

|  |
| --- |
| **Projects and their Project Insight IDs can be found via** [**http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?ref=common**](http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?ref=common) |

* 1. HL7-Managed Project Document Repository Location

|  |
| --- |
| **Projects must adhere to the** [**TSC's guidelines**](#Project_Doc_Repository_Location_help) **(which were approved on** [**2016-04-04**](http://hl7tsc.org/wiki/index.php?title=2016-04-04_TSC_Call_Agenda) **and summarized in** [**Appendix A**](#Project_Doc_Repository_Location_help)**).** **http://wiki.hl7.org/index.php?title=Gaps\_In\_Care\_Project** |

* 1. Backwards Compatibility

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Are the items being produced by this project backward compatible? |  | X | Yes |  |  | No |  |  | Unknown |  |  | N/A |
|  |  |  |  |  |  |  |  |
| If you check 'Yes' please indicate the earliest prior release and/or version to which the compatibility applies: HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) STU Release 5 - US RealmHL7 CDA® R2 Implementation Guide: Consolidated CDA – STU 2.1 – US Realm |
|  |
| For V3, are you using the current data types? (Refer to [TSC position statement on new projects using R2B](#TSC_position_statement_on_R2B) for more information on the current V3 data types) |  |  | Yes |  | X | No |  |  | Unknown |  |  | N/A |
|  |  |  |  |  |  |  |  |
| If you check 'No' please explain the reason:  |
| This project will use be based on CDA standards, which use older datatypes.  |

* 1. External Vocabularies

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Will this project include/reference external vocabularies? |  |  | Yes |  |  | No |  | X | Unknown |  |  | N/A |
|  |  |  |  |  |  |  |  |  |  |  |  |
| If yes, please list the vocabularies: |

1. 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) |  | X | V3 Documents – Clinical (e.g. CDA) |
|  | FHIR Profiles (enter FHIR product version below) |  |  | V3 Documents - Knowledge |
| X | 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 |
|  | White Paper  |  |  | V3 Services – Java Services (ITS Work Group) |
|  | Creating/Using a tool not listed in the [HL7 Tool Inventory](http://hl7-tools.herokuapp.com/) |  |  | V3 Services – Web Services (SOA) |

|  |
| --- |
| **If you checked New Product Definition or New Product Family, please define below:****N/A** |
| **FHIR will be based on the FHIR R4 pre-publication set.** |

1. Project Intent (check all that apply)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| X | Create new standard |  | X | 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 |
|  |  | 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.)**
 |

* 1. 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.** |

* 1. 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? |  | X | Yes |  |  | No |  |  |

1. Project Logistics
	1. 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? | **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) |  |  |  |  |  |  |
|  | X | Yes |  |  | No |

* 1. Realm

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Universal - OR - |  | **X** | Realm Specific |
|  |  |  | Check here if this standard balloted or was previously approved as realm specific standard |
|  | **U.S. Realm**  |

* 1. 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 | **X** | EHR, PHR |  | Emergency Services |
| **X** | Quality Reporting Agencies |  | Equipment  |  | Local and State Departments of Health |
|  | Regulatory Agency | **X** | Health Care IT |  | Medical Imaging Service |
| **X** | Standards Development Organizations (SDOs)  |  | Clinical Decision Support Systems | **X** | Healthcare Institutions (hospitals, long term care, home care, mental health) |
| **X** | Payors  |  | Lab |  | Other (specify in text box below) |
|  | Other (specify in text box below) | **X** | HIS |  | N/A |
|  | N/A |  | Other (specify below) |  |  |
|  |  |  | N/A |  |  |
|

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

 |

* 1. Project Approval Dates

*Approvals are by simple majority vote of the approving body*

|  |  |
| --- | --- |
| Sponsoring Work Group Approval Date: | **CQI 2018-05-25** |
| **Administrative review – in parallel with Work Group Approval** |
| Co-Sponsor Group Approval Date | **Structured Documents 2018-05-24** |
| Family Management Group Approval Date(s) |
| CIMI Projects: [CIMI Management Group](http://www.hl7.org/special/committees/cicmg/leadership.cfm) | **N/A** |
| CDA Projects: [CDA Management Group](http://www.hl7.org/special/committees/cdamg/leadership.cfm) | **CDA MG Approval Date CCYY-MM-DD**  |
| FHIR Projects: [FHIR Management Group](http://www.hl7.org/Special/committees/fhirmg/leadership.cfm) | **N/A** |
| V2/Publishing Projects: [V2 Management Group](http://www.hl7.org/Special/committees/publishing/leadership.cfm) | **N/A** |
| US Realm Projects: US Realm Steering Committee Approval(Email WG approved PSS to: tscpm@HL7.org) | **USRSC Approval Date CCYY-MM-DD or indicate “N/A”** |
| Affiliate Specific Projects: 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** |
|

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Last [PBS Metrics Score](http://gforge.hl7.org/gf/project/tsc/frs/?action=FrsReleaseBrowse&frs_package_id=169): |  |  Green |  |  Yellow |  |  Red |
| [PBS Metrics Reviewed](http://gforge.hl7.org/gf/download/docmanfileversion/9076/13967/PBS%20Metric%20Guidance%20for%20SD%20CoChairs%202016%20Final.doc)? (required for SD Approval if not green)  |  |  Yes |  |  No |

 |
| **ARB and SGB approval may be in parallel** |
| [Architectural Review Board](http://www.hl7.org/special/Committees/arb/leadership.cfm) Approval Date:(required for externally developed content) | **ARB Approval Date CCYY-MM-DD**  |
| 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 CCYY-MM-DD** |