***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 Implementation Guide for CDA® Release 2: NHSN Healthcare Associated Infection (HAI) Reports for Long Term Care Facilities (LTCF-CDA)**  **and**  **HL7 Implementation Guide for FHIR® Release 4: NHSN Healthcare Associated Infection (HAI) Reports for Long Term Care Facilities (LTCF-FHIR)** | | | | | | | | | | | | | 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](mailto: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 | | | | | | | | | | | | | | | |
| NA | | | | | | | | | | | | | | | |
| 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 | |  | **X** | No |
|  | |  | |  |  |  |
| Select the unit of measure used in the standard; if no measurements are in the standard, select N/A | |  | **X** | 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)** | Structured Documents Work Group |

* 1. Co-sponsor Work Group(s)

|  |  |
| --- | --- |
| Co-sponsor Work Group(s)  (Enter co-sponsor approval dates in Section 6.d Project Approval Dates) | Public Health Work Group |
| 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**) | **Jeneita Bell** |
| Other interested parties and their roles | Public Health Work Group  Clinical Quality Implementation WG |
| Multi-disciplinary project team (recommended) |  |
| Modeling facilitator | Zabrina Gonzaga ([zabrina.gonzaga@lantanagroup.com](mailto:zabrina.gonzaga@lantanagroup.com))  Sarah Gaunt (sarah.gaunt@lantanagroup.com) |
| Publishing facilitator | Zabrina Gonzaga ([zabrina.gonzaga@lantanagroup.com](mailto:zabrina.gonzaga@lantanagroup.com))  Sarah Gaunt (sarah.gaunt@lantanagroup.com) |
| Vocabulary facilitator | Zabrina Gonzaga ([zabrina.gonzaga@lantanagroup.com](mailto:zabrina.gonzaga@lantanagroup.com))  Sarah Gaunt (sarah.gaunt@lantanagroup.com) |
| Domain expert rep | Jeneita Bell; Mindy Durrance (mdq1@cdc.gov ) |
| 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) MatrixCare | |
| 2) PointClickCare | |

1. Project Definition
   1. Project Scope

|  |
| --- |
| With feedback from LTCF Vendors and CDC, this project will develop, in parallel, two setting specific implementation guides (IG):   * *HL7 Implementation Guide for CDA® Release 2: NHSN Healthcare Associated Infection (HAI) Reports for Long Term Care Facilities (LTCF-CDA)* * *HL7 Implementation Guide for FHIR® Release 4: NHSN Healthcare Associated Infection (HAI) Reports for Long Term Care Facilities (LTCF-FHIR)*   These IGs will support electronic submission of HAI data to the National Healthcare Safety Network (NHSN). The intent of this project is to establish an electronic submission standard that is vendor-neutral that leverages LTCF existing workflows and eliminates duplicate documentation. This project will work with LTCF EHR vendors to identify data elements for use in the NHSN HAI surveillance definition. |

* 1. Project Need

|  |
| --- |
| The current status of healthcare information technology in LTCFs is both a challenge and an opportunity. While adoption of EHRs and other electronic systems lags behind the uptake in other settings, the possibilities for public health to partner with technology developers and implementers—and collaboratively influence the design and use of systems as they evolve in the LTCF arena—is in many ways greater than in the acute care sector. Further, because several leading technology vendors in the LTCF market seek to provide analytics services as well as technology systems, links between public health and vendors can be leveraged in ways that yield benefits for surveillance and prevention that are tightly coupled to business models and growth.  Capitalizing on the promise of a public-private sector partnership calls for strategic vision and plans that are actualized by achieving near-term successes with specific projects and deliverables. One promising initiative is joint development of plans and work products to enable LTCF EHRs to serve as source systems for reporting HAI data to NHSN via industry electronic messages. NHSN, working closely with the Health Level Seven (HL7) standards development organization and HL7 consultants, has developed and maintained electronic HAI reporting implementation guidance for EHRs and infection surveillance system vendors in the acute care arena. That experience, and the working relationships developed over a 10-year partnership, are an important foundation for a collaborative effort in which NHSN, HL7, HL7 consultants, and LTCFs EHRs vendors join forces to advance the field of electronic HAI reporting in the LTCF sector. |
|  |

* 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

|  |
| --- |
| **CDC/NHSN Application Release cycles** |

* 1. Project Objectives / Deliverables / Target Dates

|  |  |
| --- | --- |
|  | **Target Date** |
| Project Scope Statement (PSS) | 2018 Jan |
| Draft Template Content | 2019 February |
| Notice of Intent to Ballot (NIB) | 2019 February |
| Pre-ballot Review and approval | 2019 March |
| Final Ballot Content submitted for STU Ballot | 2019 March |
| Start STU Reconciliation | 2019 May WGM |
| Complete STU Reconciliation | 2019 July |
| Request STU Publication | 2019 August |
| Project End Date (all objectives have been met) | 2019 September |

* 1. Common Names / Keywords / Aliases

|  |
| --- |
| Healthcare Associated Infection (HAI) Report for Long Term Care Facilities (LTCF), LTCF HAI Report, NHSN, laboratory identifiend (LabID) Event, Clostridium difficile infections (CDI), Multidrug-Resistant Organism’ (MDRO) and Clostridiodes difficlie (C. diff) |

* 1. Lineage

|  |
| --- |
| NA |

* 1. Project Dependencies

|  |
| --- |
| None |

* 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)**).**  **Enter the SPECIFIC URL of the HL7-MANAGED SITE where supporting project documents, deliverables, ballot reconciliation work and other project information will be kept. A template to create a Project Page on the HL7 Wiki is available at: http://wiki.hl7.org/index.php?title=Template:Project\_Page.** |

* 1. 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](#TSC_position_statement_on_R2B) for more information on the current V3 data types) |  |  | Yes |  |  | No |  |  | Unknown |  | x | N/A |
|  | | |  | | |  |  |  |  |  |  |
| If you check 'No' please explain the reason: | | | | | | | | | | | | |
| **NA** | | | | | | | | | | | | |

* 1. External Vocabularies

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Will this project include/reference external vocabularies? |  | x | Yes |  |  | No |  |  | Unknown |  |  | N/A |
|  |  |  |  |  |  |  |  |  |  |  |  |
| If yes, please list the vocabularies:  SNOMED CD, LOINC, cdcNHSN, RxNorm, Standard Occupational Classification, NUCCProviderCodes | | | | | | | | | | | | |

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) |
| X | FHIR Extensions |  |  | V3 Documents – Administrative (e.g. SPL) |
| x | FHIR Implementation Guide (enter FHIR product version below) |  | x | 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](http://hl7-tools.herokuapp.com/) |  |  | 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 Release 4** |

1. Project Intent (check all that apply)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| x | 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) | | |

|  |
| --- |
| **NA** |

* 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? |  |  | Yes |  | x | 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) |  |  |  |  |  |  | |
|  |  | Yes |  |  | No |

* 1. Realm

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Universal - OR - |  | **x** | Realm Specific |
|  | |  |  | Check here if this standard balloted or was previously approved as realm specific standard |
|  | | **US** | | |

* 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 |
| **x** | | Regulatory Agency | **x** | 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.** | | | | | | |

* 1. Project Approval Dates

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

|  |  |
| --- | --- |
| Sponsoring Work Group Approval Date: | **WG Approval Date CCYY-MM-DD** |
| **Administrative review – in parallel with Work Group Approval** | |
| Co-Sponsor Group Approval Date | **List each Co-Sponsor and their Approval Date CCYY-MM-DD  or indicate “N/A”** |
| 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  or “N/A”** |
| FHIR Projects: [FHIR Management Group](http://www.hl7.org/Special/committees/fhirmg/leadership.cfm) | **FMG Approval Date CCYY-MM-DD  or “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](mailto: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) | **“N/A”** |
| 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](mailto:tscpm@HL7.org)) | **TSC Approval Date CCYY-MM-DD** |