***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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | |  |
| **C-CDA on FHIR Mappings and Profile Updates** | | | | Project ID: |
|  |  | TSC Notification: Informative/STU to Normative | Date: | |
|  |  | - or - Direct to Normative (no STU) |  | |
|  |  | Investigative Project | Date : | |
|  | | | | |

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

|  |  |
| --- | --- |
| Primary Sponsor/Work Group  **(1 (And Only 1) Allowed)** | **SDWG** |

* 1. Co-sponsor Work Group(s)

|  |  |
| --- | --- |
| Co-sponsor Work Group(s)  (Enter co-sponsor approval dates in Section 6.d Project Approval Dates) | FHIR-I |
| Indicate the level of involvement that the co-sponsor will have for this project:   |  |  |  | | --- | --- | --- | |  | Request formal content review prior to ballot | | | X | Request periodic project updates. Specify period: | At WGMs or as needed. | | |  | 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**) | **Lisa Nelson** |
| Other interested parties and their roles |  |
| Multi-disciplinary project team (recommended) |  |
| Modeling facilitator | **Rick Geimer, Grahame Grieve, Brett Marquard** |
| Publishing facilitator | **Lisa Nelson, Grahame Grieve** |
| Vocabulary facilitator | TBD |
| Domain expert rep | TBD |
| Business requirement analyst | TBD |
| Conformance facilitator (for IG projects) | TBD |
| 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) Lantana Consulting Group | |
| 2) Health Intersections (implement FHIR mappings in server) | |
| 3) | |

1. Project Definition
   1. Project Scope

|  |
| --- |
| **The January 2017 ballot of C-CDA on FHIR produced an initial implementation guide (IG) that aimed to address the C-CDA use case using Composition resource profiles that referenced US Core profiles. That work is complete and awaiting final publication. However, the project did not create definitive mappings between C-CDA and FHIR, nor did it address C-CDA templates that were not covered by US Core (other than suggesting which unprofiled FHIR resources could be used). Also, the C-CDA on FHIR profiles will need to be updated for FHIR R4.**  **This follow-on project will address the limitations above:**   1. **It will produce C-CDA to FHIR mappings (for bidirectional conversions) using the FHIR Mapping Language. The mappings will be done for FHIR R4.** 2. **It will prioritize C-CDA entry templates that already have corresponding FHIR profiles existing in the US Core Implementation Guide. Prioritization will be based on entry templates that are most commonly encountered in C-CDA documents and have been implemented by vendors in C-CDA. To support development of C-CDA to FHIR mappings, new FHIR profiles will be developed for the high priority C-CDA entry templates and published in a new C-CDA on FHIR Implementation Guide.** 3. **It also will add mappings for C-CDA entry templates considered high-priority, but not covered already by US Core profiles. (Note: It is not in the scope of this project to create new profiles within the US Core Implementation Guide.) Mappings will be for both the FHIR Profiles in US Core and the new FHIR Profiles developed in #2 above.** 4. **It also will address C-CDA profile updates to FHIR R4 documented in the C-CDA on FHIR Implementation Guide. (Note: It is assumed US Core will also update their profiles to FHIR R4 in parallel.)** 5. **Will produce CDA logical model in collaboration with FHIR-I**   **This work will be accomplished in stages. The extent to which progress will be made within the scope will be tailored to fit the funding and timing for each stage of development.**  **It is expected that HL7 (with ONC funding) will release an RFP to support some of this work.** |

* 1. Project Need

|  |
| --- |
| **As implementers begin to share C-CDA documents via FHIR APIs, inconsistency in the transformation between the representation of data from the C-CDA document in FHIR resources has been observed. As the use of FHIR APIs grows, the degree of inconsistency may increase if transformation mapping specifications are not developed. The transformation mappings are also required to support information exchange through FHIR APIs that results in creation of a C-CDA document.** |

* 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

|  |
| --- |
| **N/A** |

* 1. Project Objectives / Deliverables / Target Dates

|  |  |
| --- | --- |
|  | **Target Date** |
| **Estimate LOE resources/skills needed to complete the project, etc.** | **2018 April** |
| **HL7 develops and awards RFP** | **2018 April-May** |
| **FHIR-I updates CDA logical model** | **2018 April-May** |
| **Assemble test cases and testing infrastructure** | **2018 April-May** |
| **Prioritized document types and profiles mapped (i.e. CCD with Problems, Allergies, and Meds)** | **2018 August** |
| **Initial mappings tested and refined at FHIR Connectathon** | **2018 September** |
| **Additional profiles and mappings to complete CCD document type. Also update other document types that reuse those profiles and mappings. Incorporate updated US Core profiles.** | **2018 November** |
| **Submit for STU ballot** | **2019 January** |
| **Complete Reconciliation** | **2019 May** |
| **Apply changes from ballot** | **2019 July** |
| **Submit publication request** | **2019 September** |
| **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.** | **2019 September** |

* 1. Common Names / Keywords / Aliases

|  |
| --- |
| **C-CDA on FHIR Mappings and Profile Updates; CCDA on FHIR Mappings** |

* 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.** |

* 1. Project Dependencies

|  |
| --- |
| **C-CDA on FHIR Project Insight 1122. Dependent also on the US Core Profiles.** |

* 1. HL7-Managed Project Document Repository Location

|  |
| --- |
| [**http://wiki.hl7.org/index.php?title=C-CDA\_on\_FHIR\_Mappings\_and\_Profile\_Updates**](http://wiki.hl7.org/index.php?title=C-CDA_on_FHIR_Mappings_and_Profile_Updates)  **Project may be moved to confluence but a pointer to the confluence site would be placed in the wiki site as a forward reference to the new location.** |

* 1. Backwards Compatibility

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Are the items being produced by this project backward compatible? |  |  | Yes |  |  | No |  | X | Unknown |  |  | N/A |
|  |  |  |  |  |  |  |  |
| If you check 'Yes' please indicate the earliest prior release and/or version to which the compatibility applies:  The transform guidance that results from this project may inform implementers about issues that are not compatible/backward compatible when transforming back and forth between CCDA and CCDA on FHIR. | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| 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: | | | | | | | | | | | | |
| **If desired, enter additional information regarding Backwards Compatibility.** | | | | | | | | | | | | |

* 1. External Vocabularies

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Will this project include/reference external vocabularies? |  | X | Yes |  |  | No |  |  | Unknown |  |  | N/A |
|  |  |  |  |  |  |  |  |  |  |  |  |
| If yes, please list the vocabularies:  Project will reference value sets used in C-CDA and FHIR, which include SNOMED, LOINC, ICD-10, etc. | | | | | | | | | | | | |

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 |
| X | Guidance (e.g. Companion Guide, Cookbook, etc) |  |  | V3 Foundation – Vocab Domains & Value Sets |
| X | 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:**  **US-Core IG is USA STU Publication v3.0 Draft CI v3.0** |

1. Project Intent (check all that apply)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Create new standard | | | |  | X | Supplement to a current standard | | |
| X | 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) | | |

|  |
| --- |
| **This project will revise the previously balloted C-CDA on FHIR IG, adding C-CDA to FHIR mappings, refining existing profiles, and potentially creating new profiles.** |

* 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) |  |  |  |

|  |
| --- |
|  |

* 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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **ONC Funding will support some work associated with this project.** | | | | | | | |
| For projects that have some of their content already developed: | | | | | | | |
| How much content for this project is already developed? | **Some mappings to US Core Profiles has been developed, but explicit FHIR Mapping Language has not been used.** | | | | | | |
| Was the content externally developed (Y/N)? | **No** | | | | | | |
| Is this a hosted (externally funded) project?  (not asking for amount just if funded) |  |  |  |  |  |  | |
|  |  | Yes |  | X | 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 (C-CDA is a US Realm-specific standard | | |

* 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** |
| **X** | | Clinical and Public Health Laboratories | **X** | Pharmaceutical | **X** | Clinical and Public Health Laboratories |
| **X** | | Immunization Registries | **X** | EHR, PHR | **X** | Emergency Services |
| **X** | | Quality Reporting Agencies | **X** | Equipment | **X** | Local and State Departments of Health |
| **X** | | Regulatory Agency | **X** | Health Care IT | **X** | Medical Imaging Service |
| **X** | | Standards Development Organizations (SDOs) | **X** | Clinical Decision Support Systems | **X** | Healthcare Institutions (hospitals, long term care, home care, mental health) |
| **X** | | Payors | **X** | 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: | **SDWG Approval Date 2018-03-22** |
| **Administrative review – in parallel with Work Group Approval** | |
| Co-Sponsor Group Approval Date | **FHIR-I Approval Date 2018-03-19** |
| 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) | **2018-03-23** |
| FHIR Projects: [FHIR Management Group](http://www.hl7.org/Special/committees/fhirmg/leadership.cfm) | **2018-04-04** |
| 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 | X | 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** |