**NOTE**: To use Track Changes, turn off “protection” by clicking on (pre-MS Word 2007) Tools > Unprotect Document or (MS Word 2007 and higher) Review > Protect Document.

**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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | |  |
| **International Chemotherapy Implementation Guide** | | | | 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-Project Name and Scope, 2-Sponsoring Group(s)/Project Team, 3a-Project Scope, 3b-Project Need, 3g-Project Objective, 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 Decision Support** |

* 1. Co-sponsor Work Group(s)

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

* 1. Project Team

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

|  |  |
| --- | --- |
| Project facilitator (**1** **Mandatory**) | **Mary Visceglia** |
| Other interested parties and their roles |  |
| Multi-disciplinary project team (recommended) |  |
| Modeling facilitator |  |
| Publishing facilitator | **Marten Smits, Bryn Rhodes** |
| 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) IBM | |
| 2) McKesson Digital Health | |

1. Project Definition
   1. Project Scope

|  |
| --- |
| **The Chemotherapy Implementation Guide will provide a container for common extensions, profiles, and guidance used in the expression of chemotherapy regimens in FHIR resources. The Guide will not contain any specific regimen content; rather, it is a repository for patterns and practices to provide a consistent basis for distribution of content based on the guide.** |

* 1. Project Need

|  |
| --- |
| **Chemotherapy is a universal-realm need driven by evidence-based care rather than regulation and/or policy. Without international coordination for the extensions and profiles used to express chemotherapy regimens, needless variation is certain to occur in implementations. This project will provide the opportunity for the international community to collaborate and come to consensus on patterns used in FHIR resources and implementations.** |

* 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. |  |  | **Yes** |
|  | X | **No** |
|  |  | **Unknown** |
|  |

* 1. External Drivers

|  |
| --- |
|  |

* 1. Project Objectives / Deliverables / Target Dates

|  |  |
| --- | --- |
|  | **Target Date** |
| **Submit for STU Ballot(First Ballot Cycle)** | **2017 Sep Ballot** |
| **Complete STU Reconciliation** | **2017 Oct WGM** |
| **Submit for 2nd STU Ballot** | **2018 Jan Ballot** |
| **Request STU Publication** | **2018 Feb** |
| **STU Period – 12 months** | **2018 Feb - 2019 Jan** |
| **Submit for Normative Ballot** | **2019 Jan Ballot** |
| **Complete Normative Reconciliation** | **2019 Jan WGM** |
| **Submit Publication Request** | **2019 Feb** |
| **Project End Date (all objectives have been met)** | **2019 Mar** |

* 1. Common Names / Keywords / Aliases

|  |
| --- |
| **Chemotherapy Templates, Protocols, Regimens, etc.** |

* 1. Lineage

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

* 1. Project Dependencies

|  |
| --- |
| **Dependent on FHIR STU3 (Requires resources of Clinical Reasoning Module, as well as CarePlan, CareTeam, MedicationRequest, etc.)**  [**http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?ref=common**](http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?ref=common) |

* 1. Project Document Repository Location

|  |
| --- |
| [**http://wiki.hl7.org/index.php?title=FHIR\_Chemotherapy\_IG**](http://wiki.hl7.org/index.php?title=FHIR_Chemotherapy_IG) |

* 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: | | | | | | | | | | | | |
|  | | | | | | | | | | | | |

* 1. External Vocabularies

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

1. Products (check all that apply)

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

|  |
| --- |
|  |

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; | | |
|  | 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) | | |

|  |
| --- |
|  |

* 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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | |
| For projects that have some of their content already developed: | | | | | | | |
| How much content for this project is already developed? |  | | | | | | |
| Was the content externally developed (Y/N)? |  | | | | | | |
| Is this a hosted (externally funded) project?  (not asking for amount just if funded) |  |  |  |  |  |  | |
|  |  | Yes |  | X | No |

* 1. Realm

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| X | Universal - OR - |  |  | Realm Specific |
|  | |  |  | Check here if this standard balloted or was previously approved as 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** |
| 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 |  |
| |  | | --- | |  | | | |

* 1. Project Approval Dates

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Affiliate Approval Date (for Affiliate Specific Projects): | **N/A** | | | | | | | | |
| US Realm Steering Committee Approval Date  (for US Realm Specific Projects): | **N/A** | | | | | | | | |
| Sponsoring Work Group Approval Date: | **CDS WG 2017-01-19** | | | | | | | | |
| Co-Sponsor Group Approval Date  (Copy this entire row for each co-sponsor; indicate the specific cosponsor that issued approval) | **Pharmacy CCYY-MM-DD**  **Patient Care CCYY-MM-DD** | | | | | | | | |
| FHIR Project: [FHIR Management Group](http://www.hl7.org/Special/committees/fhirmg/leadership.cfm) Approval Date: | **FMG Approval Date CCYY-MM-DD or “N/A”** | | | | | | | | |
| Architectural Review Board Approval Date:  (required for externally developed content) | **ARB Approval Date CCYY-MM-DD or “N/A”** | | | | | | | | |
| 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 | | | | | | | | | | |
| 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 | |