**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

|  |  |  |
| --- | --- | --- |
|  | |  |
| **Develop FHIR sequence resource for Clinical Genomics** | | Project ID: 1217 |
| |  |  | | --- | --- | |  | TSC Notification Informative/DSTU to Normative Date : | |  | |
|  | | |
| |  |  | | --- | --- | |  | Investigative Project Date : | | | |
|  | | |

1. Sponsoring Group(s) / Project Team

|  |  |
| --- | --- |
| Primary Sponsor/Work Group (**1 Mandatory**) | **Clinical Genomics** |
| Co-sponsor Work Group(s) | Orders and Observation |
| Co-Sponsor Group Approval Date | 2015-05-13 |
| 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 Team:** |  |
| Project facilitator (**1** **Mandatory**) | **Jonathan Holt, Mollie Ullman-Cullere, Jeremy Warner, Gil Alterovitz** |
| Other interested parties and their roles | Siew Lam - Reviewer |
| Multi-disciplinary project team (recommended) |  |
| Modeling facilitator | Lloyd McKenzie, Grahame Grieve, and Ewout Kramer |
| Publishing facilitator |  |
| Vocabulary facilitator | Mollie Ullman-Cullere for LOINC, |
| Domain expert rep | Mollie Ullman-Cullere, Jonathan Holt |
| Business requirement analyst |  |
| Conformance facilitator (for IG projects) |  |
| 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) National Marrow Donor Program | |
| 2) Vanderbilt | |
| 3) Harvard/Boston Children’s Hospital | |

1. Project Definition
   1. Project Scope

|  |
| --- |
| **This project will identify and define extensions, profiles, terminologies standards and resources necessary for the reporting of clinical genetic/genomic/biomolecular findings and interpretations related to the domain of clinical genetics/genomics sufficient for precision medicine. This includes items like extensions, profiles, domain specific examples, implementation guides, and a sequencing resource. This work will be defined using the available FHIR tooling and in accordance with documented quality guidelines and balloted as part of the initial FHIR specification. The GeneticsObservation profile will then be extended to allow for links to sequence.**  **In addition, as the committee deems appropriate and time availability permits, it will define a FHIR extensions relevant to domain content and expected to be necessary to support consistent early implementations including ability to link to external data, knowledge, and lab organizations.** |

* 1. Project Need

|  |
| --- |
| **FHIR is a major new initiative by HL7 intended to significantly speed and enhance interoperability between healthcare systems. The FHIR methodology is dependent on the existence of a number of discrete data structure definitions called “resources”. This project will create a sequence resource definition related to the domain of clinical genomics.** |

* 1. Success Criteria

|  |
| --- |
| **Essential domain resource (as confirmed by the FHIR governance body) will be defined and successfully passed DSTU ballot.**  **FHIR extensions have been vetted and registered in HL7 FHIR extension repository.** |

* 1. Project Risks

|  |  |
| --- | --- |
| Risk Description: | **None** |
| 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: | **Document the mitigation plan.** |
| **Copy this entire table as needed to define multiple project risks.** | |

* 1. 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 |

* 1. External Drivers

|  |
| --- |
| **FHIR ballot schedule** |

* 1. Project Objectives / Deliverables / Target Dates

|  |  |
| --- | --- |
|  | **Target Date** |
| **Resource proposals have been submitted and endorsed for development by FHIR governance body** | **Sept 1, 2015** |
| **Resource content ready for inclusion in next FHIR DSTU ballot** | **Nov. 1, 2015** |
|  |  |
| **Mark CG FHIR Profiles in FHIR core as deprecated** | **May 2018** |
| **STU Ballot of FHIR IG** | **May 2018** |
| **Pull CG IG profiles out of FHIR Core (per FMG guidance)** | **Sep 2018** |
| **STU Ballot of FHIR IG, based on reconcilliation of comments from May 2018 ballot** | **Sept 2018** |
| **Reconcile and publish FHIR IG STU** | **Dec 2018** |
|  |  |

* 1. Common Names / Keywords / Aliases

|  |
| --- |
| **CG FHIR project, SMART Genomics on FHIR (portions of this project bring this work officially into HL7 mainstream vs green field activity)** |

* 1. Lineage

|  |
| --- |
| **This work will be incorporated in to HL7 FHIR releases.** |

* 1. Project Requirements

|  |
| --- |
| **Project documents will be maintained on the main HL7 website under the Clinical Genomics working group document repository.** |

* 1. Project Dependencies

|  |
| --- |
| **Project id: 1123 Name: FHIR 2nd DSTU Ballot**  **Or appropriate follow-on ballot (e.g. FHIR 3rd DSTU)**  **The artifacts produced by this project will be balloted as part of the FHIR DSTU project.** |

* 1. Project Document Repository Location

|  |
| --- |
| **Main HL7 website Clinical Genomics document repository** |

* 1. Backwards Compatibility

[*Click here*](#Backwards_Compatibility_help) *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: | | | | |
| **Mappings between existing static models and created resources may eventually be defined, but this work is out of scope for this project.** | | | | |

* 1. External Vocabularies

[*Click here*](#External_Vocabularies_help) *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:  Clinical genomic specific vocabularies will be incorporated as needed to map to international standards in the field. This may include HGNC (human gene nomenclature committee) gene symbols, HGVS (human genetic variation society) nomenclature, which are already used in several published HL7 clinical genomic standards. | | | | |

1. 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 | |  |
|  | |

1. 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 |  | Endorsed | |
|  | |

* 1. 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) | | |
| **This work will be part of the FHIR ballot.**  **Implementation Guides will be balloted separately** | |
| **This project will not ballot directly. Instead, content will be combined with resources from other committees and jointly balloted as part of the next FHIR DSTU ballot (managed as a distinct TSC project).** | |

* 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 | |

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)? |  | |
| Date of external content review by the ARB? |  | |
| Is this a hosted (externally funded) project? (not asking for amount just if funded) | Yes | No |

* 1. Realm

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

* 1. Project Approval Dates

|  |  |
| --- | --- |
| Affiliate/US Realm Task Force Approval Date  (for US Realm Specific Projects) | **USRTF Approval Date CCYY-MM-DD** |
| Sponsoring Work Group Approval Date | **WG Approval Date 2015-04-13** |
| Steering Division Approval Date | **SD Approval Date CCYY-MM-DD** |
| |  |  |  | | --- | --- | --- | | [PBS Metrics and Work Group Health Reviewed](http://gforge.hl7.org/gf/download/docmanfileversion/7241/10172/PBSMetricGuidanceforSDCoChairs2013Final.doc)? (required for SD Approval) | Yes | No | | |
| FHIR Project: FHIR Management Group Approval Date | **FMG Approval Date 2018-02-14** |
|  | |
| 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 | | |

* 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. 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) |