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Replace **Highlighted Courier New** text with appropriate content.

To use Track Changes, turn off “protection” by clicking on Tools > Unprotect Document; in Word 2010, select Review>Track Changes

1. Project Name and ID

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| --- | --- |
| [*Click here*](#Project_Name_help) *to go to Appendix A for more info regarding this section including guidance on naming conventions.* | *An ID will be assigned by Project Insight* |
| **Common Clinical Registry Framework: Core Data Elements for Registry Interoperability** | Project ID: |

1. Sponsoring Group(s) / Project Team

[*Click here*](#Sponsoring_Group_help) *to go to Appendix A for more information regarding this section.*

* 1. Primary Sponsor/Work Group

|  |  |
| --- | --- |
| Primary Sponsor/Work Group  **(1 (And Only 1) Allowed)** | **Clinical Interoperability Council** |

* 1. Co-sponsor Work Group(s)

|  |  |  |
| --- | --- | --- |
| Co-sponsor Work Group(s)  (Enter co-sponsor approval dates in Section 6.d Project Approval Dates) | **Clinical Information Modeling Initiative (CIMI): Susan Matney**  **Public Health: Laura Rappleye**  **Patient Care: Laura Heermann Langford**  **EHR: Michael Brody, Gary Dickenson**  **Clinical Quality Information (CQI):  Walter Suarez** | **Formal review**  **Periodic updates**  **Periodic updates**  **Periodic updates**  **Review & updates** |
| Indicate the level of involvement that the co-sponsor will have for this project:  (as above)   |  |  |  | | --- | --- | --- | | x | Request formal content review prior to ballot | | | x | Request periodic project updates. Specify period: | **Periodic updates at the WGM** | | |  | 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**) | **Seth Blumenthal** |
| Other interested parties and their roles |  |
| Multi-disciplinary project team (recommended) |  |
| Modeling facilitator | **AbdulMalik Shakir** |
| Publishing facilitator | **Amy Nordo** |
| Vocabulary facilitator | **Rob Hausam, Susan Matney, Sarah Ryan** |
| Domain expert rep | **James Tcheng** |
| Business requirement analyst | **Laura Heermann Langford, Julia Skapik, Anita Walden** |
| 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) | |
| 2) | |

1. Project Definition
   1. Project Scope

[*Click here*](#Project_Scope_help) *to go to Appendix A for more information regarding this section and FHIR project instructions.*

|  |
| --- |
| **This project will identify and define, where not already defined, and harmonize a set of common clinical data elements (CDEs) that are generalizable across most clinical registries. For the purposes of this project, by CDEs we mean clinical data elements that are expected to be used in most registries. Data that are generally collected regardless of the type of patient or clinical care provided e.g., demographics, history, immunizations, vital signs, smoking status. This set of CDEs will not contain data that are mostly specific to medical specialties e.g., cardiology data.**  **The development of the CDEs will be informed as much as practical by existing standards and recommendations, including but not limited to ONC, the Medical Device Epidemiology Network, an FDA public-private partnership (MDEpiNet), US Core and FHIR, similar work from the ONC Health IT Standards Committee, and similar international efforts. The data element set we develop will be applicable to registries within the US and globally.** |

* 1. Project Need

[*Click here*](#Project_Need_help) *to go to Appendix A for more information regarding this section and FHIR project instructions.*

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| **The number of registries has grown considerably in recent years, and the volume and variety of data flowing in and out of registries is increasing. Organizations participating in registries are challenged with the work of capturing and submitting data to multiple registries, each in many cases with their own data submission requirements. Some medical specialty and healthcare professional societies and associations operate multiple registries and want to be able to more easily generate reports covering multiple registries. These registry programs containing multiple individual registries have encountered barriers due to variation in data formats and data models. These programs would also like to be able to obtain data directly from EHRs and other clinical information systems, but the inconsistency in data element names and formats makes this type of interoperability challenging. Defining a core set of CDEs with consistent naming conventions and definitions along with terminology bindings will facilitate interoperability between registries and their source data systems, as well as with other registries.**  **This project aims to identify and define a minimum set of CDEs that can be utilized in registries, EHRs and other clinical information systems. The CDEs will be compiled from existing sources as appropriate, to create a set useful for registries, and any new CDEs needed will be modeled. The project will work to harmonize the data elements across HL7 where they may be domain specific.**  **The HL7 Domain Analysis Model “Domain Analysis Model: Common Clinical Registry Framework, Release 1” (CCRF DAM) will be updated to contain the CDEs, setting the stage for the development in a future project of a FHIR IG containing the CDEs.**  **Link to published DAM:**  **http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=467** |

* 1. Security Risks

[*Click here*](#Security_Risks_help) *to go to Appendix A for more information regarding this section.*

|  |  |  |  |
| --- | --- | --- | --- |
| 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 Appendix A for additional instructions. |  |  | **Yes** |
|  | x | **No** |
|  |  | **Unknown** |

* 1. External Drivers

[*Click here*](#External_Drivers_help) *to go to Appendix A for more information regarding this section.*

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* 1. Project Objectives / Deliverables / Target Dates

|  |  |
| --- | --- |
| *Within each row, enter the explicit work product(s) / objective(s). Indicate their target date at the right in WGM/Ballot Cycle format. Include the project end date as the last objective (for standards projects, the end date will be the projected ANSI approval date).*  [*Click here*](#Project_Obj_Del_TgtDates_help) *for further information, FHIR project instructions, and an* [*EXAMPLE*](#Project_Obj_Del_TgtDates_Example_help) | **Target Date** *(in WGM or ballot cycle format, e.g.*  *‘2017 Sept WGM’ or*  *‘2017 Jan Ballot’)* |
| 1. **Inventory registry common data element information needs and existing CDE sets from sources including but not limited to ONC, the Medical Device Epidemiology Network, an FDA public-private partnership (MDEpiNet) and FHIR** | **2018 Jan** |
| 1. **Develop a proposed CDE set and gain multistakeholder input to refine and prioritize the set. Use venues such as PCPI, a nonprofit organization focused on delivery system performance improvement, and Clinical Information Interoperability Initiative (CIIC) conferences and meetings for this, in particular the 2018 PCPI Spring Conference, to be held March 19-21 at the Ritz-Carlton, Pentagon City, Arlington, VA.** | **2018 March** |
| 1. **Continuing clinical review of prioritized CDEs list through other avenues such as the CIIC Spring Meeting, webinars, etc.** | **2018 March-May** |
| 1. **Synthesize the CDEs set from the various sources and input from the above vetting activities** | **2018 May** |
| 1. **Harmonize the CDEs set as needed from existing profiles i.e., FHIR US Core and the QI Core implementation guides** |  |
| 1. **Select or develop a model and incorporate it as a class model within the CCRF DAM. Draft CDEs with definitions (model) in a format that can be reviewed by domain experts. Update the current DAM to include a diagram that reflects the CDEs.** | **2018 August** |
| 1. **Involve CIMI, MDEpiNet, PCPI and others for feedback on draft CDEs** | **2018 September** |
| 1. **Engage CIMI WG to convert CDEs into CIMI Models** | **2019 January** |
| 1. **Ballot Informative CDEs through a revised CCRF DAM** | **2019 May** |
| 1. **Project End Date (all objectives have been met)** | **2019 September** |

* 1. Common Names / Keywords / Aliases

[*Click here*](#Common_Names_Keys_Aliasis_help) *to go to Appendix A for more information regarding this section.*

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| **Registry Common Data Elements (CDEs)** |

* 1. Lineage

[*Click here*](#Lineage_help) *to go to Appendix A for more information regarding this section.*

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* 1. Project Dependencies

[*Click here*](#Project_Dependencies_help) *to go to Appendix A for more information regarding this section.*

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* 1. Project Document Repository Location

[*Click here*](#Project_Doc_Repository_Location_help) *to go to Appendix A for more information regarding this section.*

|  |
| --- |
| **http://wiki.hl7.org/index.php?title=Registry\_CDEs** |

* 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 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| SNOMED CT, LOINC, RXNorm | | | | | | | | | | | | |

1. Products (check all that apply)

[*Click here*](#Products_help) *to go to Appendix A for more information regarding this section*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Arden Syntax |  |  | V2 Messages – Administrative |
|  | Clinical Context Object Workgroup (CCOW) |  |  | V2 Messages - Clinical |
| x | Domain Analysis Model (DAM) |  |  | V2 Messages - Departmental |
|  | Electronic Health Record (EHR) Functional Profile |  |  | V2 Messages – Infrastructure |
|  | FHIR Extensions |  |  | V3 Domain Information Model (DIM / DMIM) |
|  | FHIR Implementation Guide |  |  | V3 Documents – Administrative (e.g. SPL) |
|  | FHIR Profiles |  |  | V3 Documents – Clinical (e.g. CDA) |
|  | FHIR Resources |  |  | V3 Documents - Knowledge |
|  | Guidance (e.g. Companion Guide, Cookbook, etc) |  |  | V3 Foundation – RIM |
| x | 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) |

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1. Project Intent (check all that apply)

[*Click here*](#Project_Intent_help) *to go to Appendix A for more information regarding this section and FHIR project instructions.*

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Create new standard | | | |  |  | 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; | | |
|  | 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) | | |

|  |
| --- |
| Revise CCRF DAM |

* 1. Ballot Type (check all that apply)

[*Click here*](#Ballot_Type_help) *to go to Appendix A for more information regarding this section and FHIR project instructions.*

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| --- | --- | --- | --- | --- | --- | --- |
|  | Comment (aka Comment-Only) | | |  |  | Joint Ballot (with other SDOs) |
| x | Informative | | |  |  | N/A (project won’t go through ballot) |
|  | STU to Normative - OR - |  | Normative (no STU) |  |  |  |

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* 1. Joint Copyright

[*Click here*](#Joint_Copyright_help) *to go to Appendix A for more information regarding this section*

*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

[*Click here*](#External_Project_Collaboration_help) *to go to Appendix A for more information regarding this section and FHIR project instructions.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **We expect active collaboration with:**   * **MDEpiNet, specifically its Project RAPID Informatics and GUDID WG** * **PCPI through its NQRN program, a network of registry stewards and others interested in registries, NQRN’s Interoperability WG and its Registries on FHIR project**   **CIIC**  **CDC**  **CMS (desired)**  **ONC (anticipate interest from them on our CDEs, and we plan to provide feedback to them on their published CCDS)**  **ISO**  **It is anticipated that a new project will be started after this project, to develop a FHIR implementation guide that contains these CDEs and references the updated CCRF DAM.** | | | | | | | |
| 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 |  |  | No |

* 1. Realm

[*Click here*](#Realm_help) *to go to Appendix A for guidelines regarding choosing Universal or Realm Specific.*

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

* 1. Stakeholders / Vendors / Providers

[*Click here*](#Stakeholders_Customers_Providers_help) *to go to Appendix A for more information regarding this section*

*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 |
| **x** | 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 |
| **x** | Standards Development Organizations (SDOs) | **x** | 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 |
| **x** | Patient Registries |  | Other (specify below) | **x** | Ambulatory Practices |
|  |  |  | N/A | **x** | IDNs |

* 1. Project Approval Dates

[*Click here*](#Project_Approval_Dates_help) *to go to Appendix A for more information regarding this section.*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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: | **2018-01-24** | | | | | | | | |
| Co-Sponsor Group Approval Date  (Copy this entire row for each co-sponsor; indicate the specific cosponsor that issued approval) | **EHR: 2017-11-21** | | | | | | | | |
| Co-Sponsor Group Approval Date | **Public Health: 2017-11-09** | | | | | | | | |
| Co-Sponsor Group Approval Date | **Patient Care: 2017-11-17** | | | | | | | | |
| Co-Sponsor Group Approval Date | **CIMI: 2017-12-14** | | | | | | | | |
| Co-Sponsor Group Approval Date | **CQI: 2018-02-04** | | | | | | | | |
| FHIR Project: [FHIR Management Group](http://www.hl7.org/Special/committees/fhirmg/leadership.cfm) Approval Date: | **N/A** | | | | | | | | |
| Architectural Review Board Approval Date:  (required for externally developed content) | **N/A** | | | | | | | | |
| Steering Division (of Primary Sponsor WG) Approval Date: | **SD Approval Date 2018-05-07** | | | | | | | | |
| |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | 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 2018-05-07** | | | | | | | | |
| TSC has received a Copyright/Distribution Agreement (containing the verbiage outlined within the SOU), signed by both parties. |  | | |  |  |  |  | |  |
|  |  | Yes |  | No | |  | N/A | |