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| Project Scope Statement for:  Record Entry Lifecycle Event Metadata using FHIR |
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| HL7 Electronic Health Record Work Group |
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| The objective of this document is to communicate the type of activities a group is undertaking to achieve specific objectives or to produce specific work products. It’s intended for projects to produce standards or Implementation Guides as well as infrastructure projects. |

**Template Usage Information:**

* Replace **Highlighted Courier New** text with appropriate content.
* To use Track Changes, turn off “protection” by clicking on Tools > Unprotect Document
* For assistance in completing each section, refer to [Appendix A](#Appendix_A).
* Information on the Project Approval Process is documented in [Appendix B](#Appendix_B).
* For FAQs (Frequently Asked Questions), refer to [Appendix C](#_Appendix_C_–)
* Submit template change requests to PMO@HL7.org

1. Project Name and ID

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| [*Click here*](#Project_Name_help) *to go to Appendix A for more information regarding this section.* | *An ID will be assigned by Project Insight* |
| **Definition of Record-Entry Lifecycle-Event Metadata (using FHIR)** | Project ID: |
| |  |  | | --- | --- | |  | TSC Notification Informative/DSTU to Normative Date : | | |
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1. Sponsoring Group(s) / Project Team

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

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| Primary Sponsor/Work Group (**1 Mandatory**) | **Electronic Health Record WG** |
| Co-sponsor Work Group(s) | FHIR |
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| **Project Team:** |  |
| Project facilitator (**1** **Mandatory**) | **Gary Dickinson** |
| Other interested parties and their roles | **Josh Mandel, FHIR Liaison to EHR WG; Diana Warner, Reed Gelzer, RM-ES Co-Facilitators;**  **John Ritter, EHR WG Co-Chair, PHR WG Co-Facilitator; Kathleen Connor; Steve Hufnagel, Tony Weida, Diana Proud-Madruga, Lloyd McKenzie, Helen Stevens, Thomas Lukasik, Serafina Versaggi, Pat Van Dyke** |
| Multi-disciplinary project team (recommended) |  |
| Modeling facilitator | **Steve Hufnagel** |
| Publishing facilitator | N/A |
| Vocabulary facilitator | **Pat Van Dyke** |
| Domain expert rep | **Diana Warner, Reed Gelzer, MD** |
| Business requirement analyst |  |
| Conformance facilitator (for IG projects) |  |
| Other facilitators (SOA, SAIF) | **Josh Mandel** |
|  |  |
| Implementers **(2** **Mandatory** for DSTU projects): | |
| 1) | |
| 2) | |

**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. Project Definition
   1. Project Scope

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

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| **This is the initial step of a multi-phase project to identify and define the set of “key” FHIR resources related to the domain of EHR and PHR System Functional Models and Records Management Evidentiary Support Functional Profile. As further phases are identified, additional Project Scope Statements will be submitted.**  **These resources 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 project will identify FHIR Resource coverage of EHRS FM requirements and potential FHIR gaps.**  **Expected FHIR resources to be produced include:**  **• Metadata related to EHR System Record Entry Lifecycle and Lifespan (including Provenance-related metadata)**  **• Other resources to support trusted EHR/PHR Record Management, including Record Lifecycle and Lifespan**  **In addition, as the committee deems appropriate and time availability permits, it will define a small number of FHIR extensions relevant to domain content and expected to be necessary to support consistent early implementations.** |

* 1. Project Need

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| **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 the set of essential resource definitions related to the domain of EHR and EHR systems, PHR and PHR systems, including Records Management and Evidentiary Support (RM-ES). The first step constrains this to Record Entry Lifecycle and Lifespan metadata.** |

* 1. Success Criteria

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| **This project will be deemed to be successful if:**   1. **The essential domain resources (as confirmed by the FHIR governance body) have been defined and successfully passed DSTU ballot.** 2. **A small set of FHIR extensions have been vetted and registered in HL7 FHIR extension repository.** |

* 1. Project Objectives / Deliverables / Target Dates

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| *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_Deliv_TgtDate_help) *for further information and an* *[EXAMPLE](#Project_Obj_Deliv_TgtDate_Example_help)* | **Target Date** *(in WGM or ballot cycle format, e.g.*  *‘2010 Sept WGM’ or*  *‘2010 Jan Ballot’)* |
| **Resource proposals have been submitted and endorsed for development by FHIR governance body** | **September 21, 2014** |
| **Resource content ready for inclusion in the second FHIR DSTU ballot** | **Per the second FHIR DSTU ballot schedule** |
| **Resources pass DSTU ballot** | **Per the second FHIR DSTU ballot schedule** |
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* 1. Project Requirements

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| **Requirements are specified in Record and Trust Infrastructure Sections of ISO/HL7 10781 EHR System Functional Model Release 2 and in the Information Infrastructure Section of ISO/HL7 16527 PHR System Functional Model Release 1. Also: ISO 21089 Trusted End-to-End Information Flows. Additional requirements and sources may be considered.** |

* 1. Project Risks

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| --- | --- | --- | --- |
| Risk Description | **Availability of time and resources, ability to deliver against immediate deadlines** | | |
| Impact Description | **Delayed approval, testing and adoption** | | |
| Probability: | |  |  |  | | --- | --- | --- | | High | Medium | Low | | Severity: | |  |  |  | | --- | --- | --- | | High | Medium | Low | |
| Mitigation Plan | **To be specified.** | | |

* 1. Project Dependencies

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| **The artifacts produced by this project will be balloted as part of the FHIR DSTU project (Project Insight ID TBD).** |

* 1. Project Document Repository Location

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| **http://wiki.hl7.org/index.php?title=EHR\_Interoperability\_WG** |

* 1. Backwards Compatibility

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| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Are the items being produced by this project backward compatible? | Yes | No | Don’t Know | N/A | |

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| **Mappings between existing static models and created resources may eventually be defined, but this work is out of scope for this project.** |

1. Products

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

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| --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | |  | Non Product Project- (Educ. Marketing, Elec. Services, etc.) | | |  |  | | --- | --- | |  | V3 Documents - Knowledge | |
| |  |  | | --- | --- | |  | Arden Syntax | | |  |  | | --- | --- | |  | V3 Foundation – RIM | |
| |  |  | | --- | --- | |  | Clinical Context Object Workgroup (CCOW) | | |  |  | | --- | --- | |  | V3 Foundation – Vocab Domains & Value Sets | |
| |  |  | | --- | --- | |  | Domain Analysis Model (DAM) | | |  |  | | --- | --- | |  | V3 Messages - Administrative | |
| |  |  | | --- | --- | |  | Electronic Health Record (EHR) | | |  |  | | --- | --- | |  | V3 Messages - Clinical | |
| |  |  | | --- | --- | |  | Functional Profile | | |  |  | | --- | --- | |  | V3 Messages - Departmental | |
| |  |  | | --- | --- | |  | V2 Messages – Administrative | | |  |  | | --- | --- | |  | V3 Messages - Infrastructure | |
| |  |  | | --- | --- | |  | V2 Messages - Clinical | | |  |  | | --- | --- | |  | V3 Rules - GELLO | |
| |  |  | | --- | --- | |  | V2 Messages - Departmental | | |  |  | | --- | --- | |  | V3 Services – Java Services (ITS Work Group) | |
| |  |  | | --- | --- | |  | V2 Messages – Infrastructure | | |  |  | | --- | --- | |  | V3 Services – Web Services | |
| |  |  | | --- | --- | |  | V3 Documents – Administrative (e.g. SPL) | | |  |  | | --- | --- | |  | - New Product Definition - | |
| |  |  | | --- | --- | |  | V3 Documents – Clinical (e.g. CDA) | | |  |  | | --- | --- | |  | - New/Modified HL7 Policy/Procedure/Process - | |
| |  |  | | --- | --- | |  | FHIR Resources | | |  |  | | --- | --- | |  | FHIR Extensions | |

1. Project Intent (check all that apply)

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

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| |  |  | | --- | --- | |  | Create new standard | |  | Revise current standard (see text box below) | |  | Reaffirmation of a standard | |  | New/Modified HL7 Policy/Procedure/Process | |  | 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 Adopted | |  | Externally developed IG is to be Endorsed | |

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| **Resources are targeted for publication as part of the second FHIR DSTU ballot.** |

* 1. Ballot Type (check all that apply)

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| |  |  | | --- | --- | |  | 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) | | |

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| **This project will not ballot directly. Instead, content will be combined with resources from other committees and jointly balloted as part of the 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.*

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| |  |  | | --- | --- | |  | Joint Copyrighted Material will be produced | |

1. Project Approval Dates

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

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| Sponsoring Group Approval Date | **2014/06/24** |
| Steering Division Approval Date | **SD Approval Date CCYY-MM-DD** |

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| |  |  |  | | --- | --- | --- | | [PBS Metrics and Work Group Health Reviewed](http://gforge.hl7.org/gf/download/docmanfileversion/7241/10172/PBSMetricGuidanceforSDCoChairs2013Final.doc)? (required for SD Approval) | Yes | No | |

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| FHIR Governance Committee Approval Date | **FG Approval Date CCYY-MM-DD** |
| Technical Steering Committee Approval Date | **TSC Approval Date CCYY-MM-DD** |
| |  |  |  | | --- | --- | --- | | Joint Copyright Letter of Agreement received? (req'd for Joint Copyrighted material) | Yes | No | | |

1. External Project Collaboration

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

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| **In producing resources, the committee will consult specifications from a wide variety of external organizations, including OpenEHR, IHE, various affiliates, government organizations and other SDOs. However, this consultation will not require direct interaction with these other organizations. (Though some may be involved in the ballot review process.)**  **ISO TC215 WG1/WG2, AHIMA.** |

* 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*

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| **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

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

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| 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) |

1. Realm

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

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

1. Strategic Initiative Reference – For PMO/TSC Use Only

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

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| This section used only for Strategic Initiative Projects.   |  |  | | --- | --- | |  | 1. HL7 Recognition | |  | 1. HL7 Internal Processes | |  | 1. HL7 Implementation | |

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