# Project Name and ID

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| **Cross-Paradigm Implementation Guidance for Medical Device Data Sharing with Patient Care System** | | | | **Project ID: TBD** |
|  |  | 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, 2, 3a, 3b, 3g [limited, 6b [if known], and 6c [applicable] are required).**  **Investigative Project specific instructions are yellow highlighted.**  **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

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| Primary Sponsor/Work Group  **(1 (And Only 1) Allowed)** | **Patient Care Work Group**  -This project was discussed informally with the PC WG at the Hl7 WGM in Baltimore (Thursday Q4, 9/22/2016). The scope of this project is of interest but the bandwidth of the work group to ballot another project may be a problem. Before bringing it to the discussion with the PC WG members, the project facilitator (Ioana Singureanu) will join the PC WG co-chairs on October 10th, 2016. |

* 1. Co-sponsor Work Group(s)

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| Co-sponsor Work Group(s)  (Enter co-sponsor approval dates in Section 6.c Project Approval Dates) | **Clinical Decision Support (CDS) Work Group** |
| 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: HL7 WGM | WGM. | | | X |  | Other Involvement. Specify details here: **Medical device results can be  consumed by a variety of enterprise system after their initial use at the point of care. These results may be applied to support clinical decision  support. This was discussed with Patient Care WG at the September WGM. The  enjoyment with CDA will include use case analysis documented in the May 2017  Domain Analysis Model ballot.** |  | | | |

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| Co-sponsor Work Group(s)  (Enter co-sponsor approval dates in Section 6.c Project Approval Dates) | **Healthcare Devices (DEV) Work Group** |
| 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: HL7 WGM | WGM. | | | X |  | Other Involvement. Specify details here: **Share examples C-CDA templates**  **and implementation guidance specific to Medical Device Interoperability (e.g Vital Signs) and review the use cases added to the Detailed Clinical**  **Models for Medical Devices DAM.** |  | | | |

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| Co-sponsor Work Group(s)  (Enter co-sponsor approval dates in Section 6.c Project Approval Dates) | **Structured Documents (SD) WG** |
| 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: HL7 WGM | WGM. | | | X |  | Other Involvement. Specify details here: **Share examples C-CDA templates**  **and implementation guidance specific to Medical Device Interoperability (e.g Vital Signs) and consistent with the Detailed Clinical**  **Models for Medical Devices DAM** |  | | | |
| Co-sponsor Work Group(s)  (Enter co-sponsor approval dates in Section 6.c Project Approval Dates) | **FHIR Infrastructure WG** |
| 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: HL7 WGM | WGM. | | | X |  | Other Involvement. Specify details here: **Share examples resources based on  DAF and Vital Signs IG profiles that conform to the Detailed Clinical**  **Models for Medical Devices DAM, share HAPI FHIR sample code if applicable** |  | | | |

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| Co-sponsor Work Group(s)  (Enter co-sponsor approval dates in Section 6.c Project Approval Dates) | **Conformance WG** |
| 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: HL7 WGM | WGM. | | | X |  | Other Involvement. Specify details here: **Share examples and reuse**  **Conformance statements and cross-paradigm testing guidance based on the**  **Detailed Clinical Models for Medical Devices DAM** |  | | | |
| Co-sponsor Work Group(s)  (Enter co-sponsor approval dates in Section 6.c Project Approval Dates) | **Orders and Observation (O&O) WG** |
| 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: HL7 WGM | WGM. | | | X |  | Other Involvement. Specify details here: **Collaborate on requirements  harmonization and the on-going development of examples, and**  **implementation guidance specific to Medical Device  Interoperability (e.g. Vital Signs) consistent with the DAM.  Leverage UDI project findings and apply resulting guidance to  identify and reference medical devices sending measurements and parameters to information system and Meaningful Use certified EHR systems using a  UDI-enabled device identity.** |  | | | |

Clinical Quality

CDA

* 1. Project Team

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| Project facilitator (**1** **Mandatory**) | Ioana Singureanu (VA) – Conformance co-chair |
| Other interested parties and their roles | Greg Staudenmaier (VA), Nancy Orvis(DoD), Julia Skapik (ONC), Terrie Reed (FDA), Behnaz Minaei (FDA), John Garguilo (NIST), John Rhoads (Philips) |
| Multi-disciplinary project team (recommended) |  |
| Modeling facilitator | Ioana Singureanu (VA) |
| Publishing facilitator | Ioana Singureanu (VA) |
| Vocabulary facilitator | Serafina Versaggi (VA) |
| Domain expert rep | Catherine Hoang (VA) |
| Business requirement analyst | Holly Miller (VA) |
| Conformance facilitator (for IG projects) | Ioana Singureanu (VA) |
| Other facilitators (SOA, etc.) | Ken Rubin (VA) |
|  |  |
| 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) **Department of Veterans’ Affairs** | |
| 2) Department of Defense (TBD) | |

1. Project Definition
   1. Project Scope

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| **This cross-paradigm implementation guide is intended to support implementers and enable the exchange of medical device reported data with HER systems capable of exchange standard based messages, documents, and resources HL7 Meaningful Use IGs (e.g. CDA R2 C-CDA 2.1 IG, Hl7 Version 2 LRI) and emerging IGs (e.g. FHIR Data Access Framework – DAF). This project both reuses and expands the contents of the**  [HL7 Version 3 Domain Analysis Model (DAM): Detailed Clinical Models for Medical Devices (DCM4MD), Release 1](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=392)  **as the basis for requirements and additional constraints to CDA, HL7 Version, and FHIR Implementation guides applicable in the US to improve support medical device interoperability.**  This project builds upon the previous, [DCM4MD Release1, DAM](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=392), Domain Analysis Model (DAM) work to describe the information exchanged by medical devices with information systems using reusable Detailed Clinical Models (DCM. The DCMs are providing full semantics and structural description of measurements, settings, and other events reported by devices using standard clinical terminology. The analysis process associated with DAMs is used here to identify the context and content of DCMs as units of information intended to enable interoperability across devices and systems.  The DCMs and the associated DAM enable semantic interoperability for medical device measurements across devices and information system regardless of the information exchange standard used to move the information across (e.g. HL7 Version 2.x, HL7 CDA, etc.).  The revised DAM is intended to improve consensus building regarding interoperability requirements and workflow automation between the business stakeholders, clinicians, vendors, and integrators (both IT and clinical engineering) by involving the involving the clinicians in the definition of information relevant to interoperability with medical devices.  Based on the DAM, the project team will harmonize existing specifications including Vital Signs profile definition (<http://www.hl7.org/FHIR/2016Sep/observation-vitalsigns.html>) to develop consistent guidance to implementers using HL7 standards to convey medical device observation to information systems and EHR systems. |

* 1. Project Need

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| **In the US, medical devices are expected to exchange information with certified EHR systems using Meaningful Use standard and terminology. This includes not only documents conforming to Consolidated CDA V 2.1 but also HL7 Version 2 transactions and FHIR resources.**  **This project leverages past requirements analysis (DCM for Medical Devices DAM) and elaborates it to document additional requirement that help harmonize existing implementation guidance. The resulting guidance will be applied to conformance artifcats (IGs, profiles and templates) of HL7 Version 2.5.2 (and later), CDA R2, and, and FHIR.**  **The project addresses the need for consistent guidance based on consensus-based requirements.** |

* 1. Security Risks

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

* 1. External Drivers

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| **Meaningful Use standards adoptions and emerging FHIR IGs for US implementation** |

* 1. Project Objectives / Deliverables / Target Dates

|  |  |
| --- | --- |
|  | **Target Date** |
| **Informative 1: DCM for Medical Devices DAM Release 2** | **MAY 2017 Ballot** |
| **Informative publication** | **2017 June** |
| **Informative 2: Cross-paradigm guidance** | **SEPT 2017** |
| **Informative publication** | **2018 January** |

* 1. Common Names / Keywords / Aliases

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| --- |
| **Cross-Paradigm Medical Device Data Sharing with Information Systems Implementation Guidance using Detailed Clinical Models for Medical Devices** |

* 1. Lineage

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| --- |
| This is a new PSS for a cross-paradigm guidance document that updates and builds upon the **Detailed Clinical Models for Medical Devices (DCM4MD), Release 1 (Product Id:392).** |

* 1. Project Dependencies

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| **This guidance Based on Detailed Clinical Models for Medical Devices (DCM4MD), Release 2. This revision to the Detailed Clinical Models for Medical Devices (DCM4MD), Release 1 will be the first ballot under this PSS.** |

* 1. Project Document Repository Location

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| --- |
| * **HL7 GForge Page:**  DCM for Medical Devices  * **http://gforge.hl7.org/gf/project/dcmmd/** * **http://gforge.hl7.org/gf/project/dcmmd/frs/?action=FrsReleaseBrowse&frs\_package\_id=148** |

* 1. Backwards Compatibility

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Are the items being produced by this project backward compatible? |  | X | Yes |  |  | No |  |  | Unknown |  |  | N/A |
|  |  |  |  |  |  |  |  |
|  | | | | | | | | | | | | |
| 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) |  | X | Yes |  |  | No |  |  | Unknown |  |  | 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:  This IG reuses the value sets and coding systems specified in C-CDA 2.1, FHIR Data Access Framework and FHIR Vital Signs profile as much as possible. | | | | | | | | | | | | |

1. Products (check all that apply)

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|  | 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) |  | X | 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 |
| X | V2 Messages – Clinical (IG/profiles) |  |  | V3 Messages – Clinical |
|  | V2 Messages – Departmental |  |  | V3 Messages – Departmental |
|  | V2 Messages – Infrastructure |  |  | V3 Messages – Infrastructure |
|  | FHIR Implementation Guide |  |  | V3 Rules – GELLO |
| X | FHIR Profiles |  |  | V3 Services – Java Services (ITS Work Group) |
|  | FHIR Resources |  |  | V3 Services – Web Services (SOA) |
|  | New/Modified/HL7 Policy/Procedure/Process |  |  | White Paper |
|  | New Product Definition |  |  |  |
|  | New Product Family |  |  |  |

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| * Reuses [HL7 Version 3 Domain Analysis Model (DAM): Detailed Clinical Models for Medical Devices (DCM4MD), Release 1](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=392) * Enhances the DAM in Release 2:***HL7 Version 3 Domain Analysis Model (DAM): Detailed Clinical Models for Medical Devices (DCM4MD), Release 2*** * Provides implementation guidance for C-CDA implementers * Provides implementation guidance for HL7 Version 2 implementers * Provides implementation guidance and sample resource using FHIR profiles |

1. Project Intent (check all that apply)

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

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| [HL7 Version 3 Domain Analysis Model (DAM): Detailed Clinical Models for Medical Devices (DCM4MD), Release 1](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=392) (Product id: 392) |

* 1. Ballot Type (check all that apply)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | 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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| **If necessary, add any additional ballot information here. If artifacts will be jointly balloted with other SDOs, list the other groups.** |

* 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 |  |  | No |  |  |

1. Project Logistics
   1. External Project Collaboration

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Include SDOs or other external entities you are collaborating with, including government agencies as well as any industry outreach. Indicate the nature and status of the Memorandum of Understanding (MOU) if applicable.** | | | | | | | |
| For projects that have some of their content already developed: | | | | | | | |
| How much content for this project is already developed? | **Indicate % here** | | | | | | |
| Was the content externally developed (Y/N)? | **If Yes, list developers** | | | | | | |
| Is this a hosted (externally funded) project?  (not asking for amount just if funded) |  |  |  |  |  |  | |
|  |  | Yes |  |  | No |

* 1. Realm

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| --- | --- | --- | --- | --- |
|  | Universal - OR - |  | **X** | Realm Specific: United States |
|  | |  |  | Check here if this standard balloted or was previously approved as realm specific standard |
|  | | **Enter “U.S.” or name of HL7 affiliate(s) here. For projects producing deliverables applicable to multiple realms, document those details here.**  **For Investigative projects, indicate if the project is planned to be Realm Specific or Universal, if known. Work Groups are encouraged designating project a Universal project initially, and discover which Realms can contribute to the work effort during the discovery phase of the project. Note: This status is subject to change during the investigative process.** | | |

* 1. Project Approval Dates

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Affiliate Approval Date (for Affiliate Specific Projects): | **NA** | | | | | | | | |
| US Realm Steering Committee Approval Date  (for US Realm Specific Projects): | **USRSC Approval Date** | | | | | | | | |
| Sponsoring Work Group Approval Date: | **CBCC WG Approval Date** | | | | | | | | |
| Co-Sponsor Group Approval Date  (Copy this entire row for each co-sponsor; indicate the specific cosponsor that issued approval) | **Conformance Approval Date**  **SDWG Approval**  **O&O Approval**  **FHIR-I Approval** | | | | | | | | |
| FHIR Project: [FHIR Management Group](http://www.hl7.org/Special/committees/fhirmg/leadership.cfm) Approval Date: | **FMG Approval Date** | | | | | | | | |
| Architectural Review Board Approval Date: | **N/A** | | | | | | | | |
| Steering Division Approval Date : | **SD Approval Date CCYY-MM-DD** | | | | | | | | |
| |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Last Work Group Health: |  | Green |  | Yellow |  | Red | | [PBS Metrics and Work Group Health Reviewed](http://gforge.hl7.org/gf/download/docmanfileversion/7241/10172/PBSMetricGuidanceforSDCoChairs2013Final.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 | |