

PSS for Clinical Data Exchange (CDex) Update 1



Warning:

Do not launch ANY of the links while your are in create or edit mode. There is a good chance all of your work will be gone.

Template Usage Information:

- Submit template change requests to PMO@HL7.org
- For Reaffirmations, please refer to the FAQ in [HI7 Project Scope Statement Instructions](#) for a list of which sections and fields should be completed

1. Project Name and ID

Enter the name of the project here: Clinical Data Exchange (CDex)						
Project ID:	1495					
Complete this section for all "Direct to Normative" ballot projects and when a project proceeds from "Informative to Normative" or "STU to Normative".						
Forward PSS to the TSC (via tscpm@HL7.org); this triggers American National Standards Institute (ANSI) Project Initiation Notification (PINS) submission.						
X	TSC Notification: Informative/STU to Normative				Date	20 Dec 2018
	- or - Direct to Normative (no STU) (includes reaffirmations)					
Identify ISO, IEC or ISO/IEC standard to be adopted in text box below						
Enter info here if an ISO, IEC, or ISO/IEC Standard is to be adopted as an American National Standard; Enter the designation of the standard(s) to be adopted:						
Includes text from ISO, IEC or ISO/IEC standard: Check here if this standard includes excerpted text from one or more ISO, IEC or ISO/IEC standards, but is not an identical or modified adoption.					Yes	No
Select the unit of measure used in the standard; if no measurements are in the standard, select N/A					N/A	U.S. Metric Both
	Investigative Project (aka PSS-Lite)				Date :	
Check this box when the project is investigative or exploratory in nature, which allows limited project scope definition. Sections 1-Project Name, 2-Sponsoring Group(s)/Project Team, 3a-Project Scope, 3b-Project Need, 3e-Project Objectives/Deliverables/Target Dates, 3i-Project Document Repository, 6b-[Realm, if known], and 6d-[applicable Approval Dates] are required for Investigative Project. 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.						

2. Sponsoring Group(s) / Project Team

2.a. Primary Sponsor/Work Group

Primary Sponsor/Work Group (1 (And Only 1) Allowed)	Patient Care
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2.b. Co-sponsor Work Group(s)

Co-sponsor Work Group(s): (Enter co-sponsor approval dates in Section 6.d Project Approval Dates)		Attachments Structured Documents
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	WGMs
	Other Involvement. Specify details here:	

2.c. Project Team

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

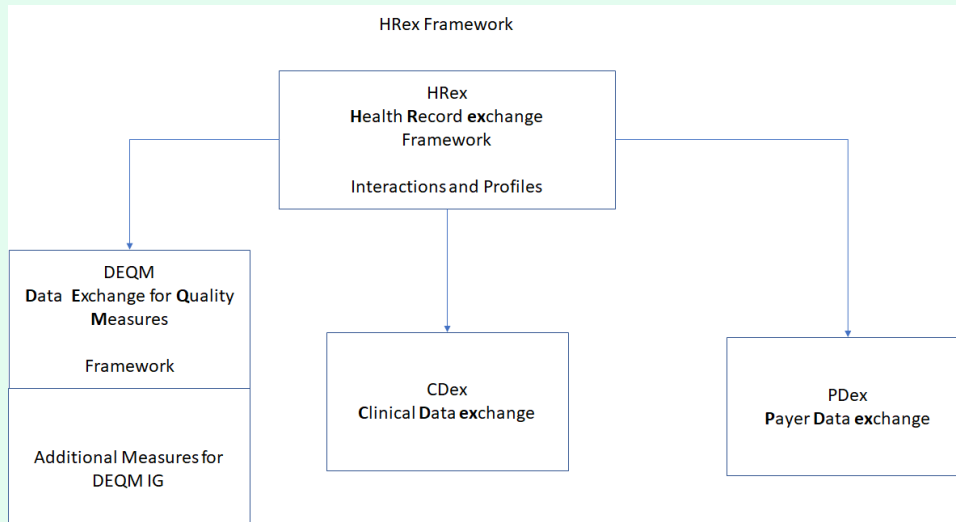
Project facilitator (1Mandatory)	Lisa Nelson, Rick Geimer
Other interested parties and their roles	Viet Nguyen (technical FHIR support)
Multi-disciplinary project team (recommended)	

Modeling facilitator	Rick Geimer
Publishing facilitator	
Vocabulary facilitator	Viet Nguyen
Domain expert rep	Lisa Nelson, Rick Geimer, Gay Dolin
Business requirement analyst	Robert Dieterle, Linda Michaelsen
Conformance facilitator (for IG projects)	Rick Geimer
Other facilitators (SOA, etc)	
Implementers (2Mandatory for STU projects)	
<i>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.</i>	
1) United Health	
2) Humana	

3. Project Definition

3.a. Project Scope

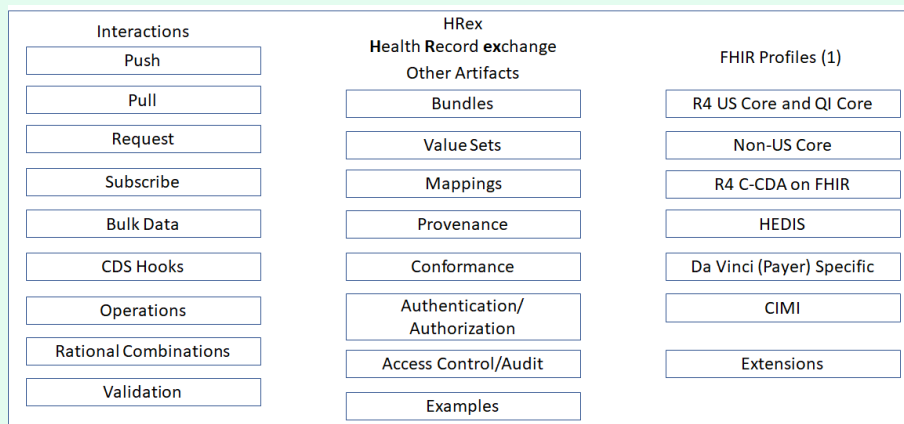
The Clinical Data exchange (CDex) is part of the larger Da Vinci use case for Health Record exchange (HRex).



After careful evaluation, the eHRx project was decomposed into four independent efforts (and tied to 4 separate PSSs). The exchange of Quality Measures was included in the existing work on the Data Exchange for Quality Measures (DEQM) that is sponsored by the CQI workgroup. The exchange of Payer Data (PDex) is sponsored by Financial Management. The overall HRex Framework is planned to be sponsored by the Clinical Interoperability Council (CIC) and we looking to a combination of Structured Documents, Patient Care and Attachments to sponsor the work on e Clinical Data exchange (CDex).

The scope of the CDex project is to defined combinations of exchange methods (push, pull, subscribe, ...), specific payloads (Documents, Bundles, and Individual Resources), search criteria, conformance, provenance, and other relevant requirements to support specific exchanges of clinical information between provider and other providers and/or payers. The goal is to identify, document and constrain very specific patterns of exchange so that providers and payers can reliably exchange information for patient care (including coordination of care), risk adjustment, quality reporting, identifying that requested services are necessary and appropriate (e.g. should be covered by the payer) and other uses that may be documented as part of this effort. Clinical data payloads will include C-CDA, C-CDA on FHIR, compositions, bundles, specific resources, and bulk data exchange. This list is intended to be illustrative and not prescriptive. The project will address patient consent where appropriate.

This project will reference, where possible the "standards" defined by the Health Record exchange (HRex) Framework Implementation Guide which in turn will utilize prior work from Argonaut, US Core and QI Core effort for FHIR R4. The following diagram depicts the anticipated scope of the HRex Framework IG.



Notes:
1) Existing work is adopted by reference

The ultimate goal is to support the exchange of provider data on specific patients/members for better patient care with other providers and payers using technology that support FHIR R4 release of the FHIR standard.

The project team plans to work with existing FHIR artifacts where possible. If changes are necessary, the project team will work with the responsible Work Group to review and implement (via tracker items or new PSS) any necessary enhancements to base FHIR resources, extensions, and/or profiles.

Updated to R4 only

3.b. Project Need

Providers and Payers need access to provider information regarding current and prior healthcare services planned for or received by the patient/member to more effectively manage the patients care. Currently, no FHIR implementation guides exist to standardize the method of exchange (push, pull, triggers, subscription, etc.) and the formal representation (e.g. Documents, Bundles, Profiles and Vocabulary) for the range of exchanges between providers and providers or providers and payers of current and emerging interest to the involved parties. This implementation guide will provide a standard for adoption by both payers and providers for the exchange of provider originated information.

3.c. 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 for additional guidance, including sample spreadsheets that may be used to conduct the security risk assessment.

	Yes
X	No
	Unknown

3.d. External Drivers

None

3.e. 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).

Target Date (in WGM or ballot cycle format, e.g.

'2017 Sept WGM' or '2017 Jan Ballot')

Ballot for Comment (First Ballot Cycle)	2019 May Ballot
Submit for STU Ballot (Second Ballot Cycle)	2019 Sep Ballot
Complete STU Reconciliation	2020 Jan WGM
Request STU Publication	2020 Jan WGM
Submit for STU 2 Ballot (Third Ballot Cycle)	2020 Sep Ballot
Complete STU 2 Reconciliation	2021 Jan WGM
Request STU 2 Publication	2021 Jan WGM
STU Period	2021 Jan -2022 Jan
Submit for Normative Ballot	2022 May Ballot
Complete Normative Reconciliation	2022 Sep WGM
Submit Publication Request	2022 Oct

Project End Date (all objectives have been met)	2022 Dec
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3.f. Common Names / Keywords / Aliases

Clinical Data exchange, CDex, Da Vinci

3.g. Lineage

n/a

3.h. Project Dependencies

HealthRecord Exchange Framework

3.i. HL7-Managed Project Document Repository Location

Projects must adhere to the [TSC's guidelines](#) (which were approved on 2016-04-04 and summarized in [Appendix A](#)).

A template to create a Project Page on the HL7 Wiki is available at: http://wiki.hl7.org/index.php?title=Template:Project_Page.

Enter the SPECIFIC URL of the HL7-MANAGED SITE where supporting project documents, deliverables, ballot reconciliation work and other project information will be kept.

HTTP: <http://confluence.hl7.org/pages/viewpage.action?pageId=> or above this link.

3.j. Backwards Compatibility

Are the items being produced by this project backward compatible?	<input checked="" type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Unknown	<input checked="" type="checkbox"/>	X	<input type="checkbox"/>	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?	<input checked="" type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Unknown	<input checked="" type="checkbox"/>	X	<input type="checkbox"/>	N/A
(Refer to TSC position statement on new projects using R2B for more information on the current V3 data types)										
If you check no, please explain the reason:										
If desired, enter additional information regarding Backwards Compatibility.										

3.k. External Vocabularies

Will this project include/reference external vocabularies?	<input checked="" type="checkbox"/>	X	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Unknown	<input type="checkbox"/>	N/A
If Yes, please enter the vocabularies: HCPCS, SNOMED, CPT, ICD, RxNorm, LOINC										

4. Products (check all that apply)

	Arden Syntax	V2 Messages – Administrative
	Clinical Information Modeling Initiative (CIMI)	V2 Messages - Clinical
	Clinical Context Object Workgroup (CCOW)	V2 Messages - Departmental
	Domain Analysis Model (DAM)	V2 Messages – Infrastructure
	Electronic Health Record (EHR) Functional Profile	V3 Domain Information Model (DIM / DMIM)
X	FHIR Extensions	V3 Documents – Administrative (e.g. SPL)
X	FHIR Implementation Guide (enter FHIR product version below)	V3 Documents – Clinical (e.g. CDA)
X	FHIR Profiles (enter FHIR product version below)	V3 Documents - Knowledge
?	FHIR Resources	V3 Foundation – RIM
	Guidance (e.g. Companion Guide, Cookbook, etc)	V3 Foundation – Vocab Domains & Value Sets
	Logical Model	V3 Messages - Administrative
	New/Modified/HL7 Policy/Procedure/Process	V3 Messages - Clinical
	New Product Definition (please define below)	V3 Messages - Departmental
	New Product Family (please define below)	V3 Messages - Infrastructure
	Non Product Project - (Educ. Marketing, Elec. Services, etc.)	V3 Rules - GELLO
	White Paper	V3 Services – Java Services (ITS Work Group)
	Creating/Using a tool <u>not</u> listed in the HL7 Tool Inventory	V3 Services – Web Services (SOA)

If you checked New Product Definition or New Product Family, please define below:

For FHIR IGs and FHIR Profiles, what product version(s) will the profiles apply to?

R4

5. Project Intent (check all that apply)

	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;
			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)

If revising a current standard, indicate the following:

- **Name of the standard being revised:**

- **Date it was published (or request for publication, or ANSI designation date)**

- **Rationale for revision**

- **The relationship between the new standard and the current standard (is it designed to replace the current standard, a supplement to the current standard, etc.)**

5.a. Ballot Type (check all that apply)

<input checked="" type="checkbox"/>	Comment (aka Comment-Only)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Joint Ballot (with other SDOs)
<input type="checkbox"/>	Informative	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A (project won't go through ballot)
<input checked="" type="checkbox"/>	STU to Normative - OR -	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Normative (no STU)
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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

5.b. 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?	<input type="checkbox"/>	<input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No
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6. Project Logistics

6.a. External Project Collaboration

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?	10%		
Was the content externally developed ? :	Y	Da Vinci	
Is this a hosted (externally funded) project? (not asking for amount just if funded)	X	Yes	No

6.b. Realm

<input type="checkbox"/>	Universal	- OR -	<input checked="" type="checkbox"/>	Realm Specific
<input type="checkbox"/>		<input type="checkbox"/>		Check here if this standard balloted or was previously approved as realm specific standard
U.S.	Includes IG references, vocabulary and profiles that are specific to the US healthcare system Support US Healthcare workflows			

6.c. 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
<input checked="" type="checkbox"/>	Clinical and Public Health Laboratories	<input checked="" type="checkbox"/>	Pharmaceutical	<input type="checkbox"/>	Clinical and Public Health Laboratories
<input checked="" type="checkbox"/>	Immunization Registries	<input checked="" type="checkbox"/>	EHR, PHR	<input checked="" type="checkbox"/>	Emergency Services
<input checked="" type="checkbox"/>	Quality Reporting Agencies	<input checked="" type="checkbox"/>	Equipment	<input type="checkbox"/>	Local and State Departments of Health

X	Regulatory Agency	X	Health Care IT	X	Medical Imaging Service
	Standards Development Organizations (SDOs)	X	Clinical Decision Support Systems	X	Healthcare Institutions (hospitals, long term care, home care, mental health)
X	Payors	X	Lab		Other (specify in text box below)
X	Other (specify in text box below)		HIS		N/A
	N/A		Other (specify below)		
			N/A		
Other: Federal Healthcare Agencies (e.g. CMS), Providers (e.g. Physicians)					

6.d. Project Approval Dates

Click here to go to [HL7 Project Scope Statement Instructions#Appendix A](#) for more information regarding this section.
Approvals are by simple majority vote of the approving body

Sponsoring Work Group Approval Date:	WG Approval Date	1/17/2019														
Administrative review – in parallel with Work Group Approval																
Co-Sponsor Group Approval Date	Attachments (need to verify date)	1/17/2019														
	Structured Documents	1/17/2019														
Family Management Group Approval Date(s)																
CIMI Projects: CIMI Management Group	CIMI MG Approval Date	N/A														
CDA Projects: CDA Management Group	CDA MG Approval Date	N/A														
FHIR Projects: FHIR Management Group	FMG Approval Date	2/27/2019														
V2/Publishing Projects: V2 Management Group	V2 MG Approval Date	N/A														
US Realm Projects: US Realm Steering Committee Approval (Email WG approved PSS to: tscpm@HL7.org)	USRSC Approval Date	2/26/2019														
Affiliate Specific Projects: Affiliate Approval Date	Affiliate Approval Date	N/A														
Submit PSS to Steering Division after all of the above approvals are received																
Steering Division (of Primary Sponsor WG) Approval Date:	SD Approval Date	2019-03-22														
<table border="1"> <tr> <td>Last PBS Metrics Score:</td> <td>X</td> <td>Green</td> <td></td> <td>Yellow</td> <td></td> <td>Red</td> </tr> <tr> <td>PBS Metrics Reviewed? (required for SD Approval if not green)</td> <td></td> <td>Yes</td> <td></td> <td>No</td> <td></td> <td></td> </tr> </table>			Last PBS Metrics Score:	X	Green		Yellow		Red	PBS Metrics Reviewed? (required for SD Approval if not green)		Yes		No		
Last PBS Metrics Score:	X	Green		Yellow		Red										
PBS Metrics Reviewed? (required for SD Approval if not green)		Yes		No												
ARB and Steering Division approval may be in parallel																
Architectural Review Board Approval Date: (required for externally developed content)	ARB Approval Date	N/A														
TSC Approval																
If applicable, TSC has received a Joint Copyright/Distribution Agreement (containing the verbiage outlined within the SOU), signed by both parties.	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>N/A</td> </tr> </table>		Yes	No	N/A											
Yes	No	N/A														
Technical Steering Committee Approval Date: (Email SD WG approved PSS to: tscpm@HL7.org)	TSC Approval Date															