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

Contextualized potential drug-drug interaction clinical decision support		Project ID:
	TSC Notification Informative/STU to Normative	Date :
	Investigative Project	Date :

2. Sponsoring Group(s) / Project Team

2.a. Primary Sponsor/Work Group

Primary Sponsor/Work Group **(1 (And Only 1) Allowed)**	**Clinical Decision Support WG**

2.b. Co-sponsor Work Group(s)

Co-sponsor Work Group(s) (Enter co-sponsor approval dates in Section 6.d Project Approval Dates)	**Pharmacy WG**	
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:	At 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 (**1 Mandatory**)	**Bryn Rhodes, Howard Strasberg, Guilherme Del Fiol, Richard Boyce**
Other interested parties and their roles	**Clinical Quality Information WG - Requests periodic project updates at WGMs**
Multi-disciplinary project team (recommended)	
Modeling facilitator	**Bryn Rhodes**
Publishing facilitator	**Bryn Rhodes**
Vocabulary facilitator	**Rob McClure**
Domain expert rep	**Richard Boyce, Melva Peters, Tom de Jong**
Business requirement analyst	
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) University of Pittsburgh Medical Center (interest)	
2) Wolters Kluwer Health (interest)	

3. Project Definition

3.a. Project Scope

Describe the project; include what is expected to be accomplished/delivered along with specified features and functions. Include whether the deliverables are universal, realm specific or applicable to various realms. Be sure to spell out all acronyms as these are carried forward to the NIB (Notice of Intent to Ballot) for ballot announcements.

This project seeks to develop an *implementation guide* for potential drug-drug interaction (PDDI) clinical decision support (CDS). The implementation guide will specify both a knowledge representation format for PDDI logic and CDS services for PDDI with electronic health record (EHR) systems. Specifically, the implementation guide will include specifications for:

1) How to represent PDDI logic in CQL and evidence in computational format using the FHIR Clinical Reasoning module.
2) How to use CDS Hooks as a mechanism for EHRs to request PDDI CDS from CDS services.

The project may raise the need to create new FHIR resource(s) (e.g., a resource to represent drug interactions) and/or FHIR profile(s) (e,g, for PDDI context representation). The current scope is the universal realm. We will consider potential realm-specific work in the future.

3.b. Project Need

This information is required by ANSI for all ballots. Briefly explain the reason behind the need for this project. This may be related to legislative requirements, industry need, or similar justifications.

New information regarding potential drug-drug interactions (PDDIs) is published every day in primary sources such as drug product labeling and the scientific literature. A PubMed search for publications indexed with the Medical Subject Headings keyword “Drug interactions” shows an average of 3,970 publications per year from 2000 through 2016. This suggests that the body of evidence about PDDIs is overwhelming and dynamic. Food and drug regulatory agencies in the United States, European Union, and Japan have issued guidance to industry recommending the use of drug product labeling to communicate potential involvements in drug interactions (Rekić et al. 2017). As it is impossible for clinicians to keep up with the PDDI evidence base, drug experts generate summaries of PDDI evidence from primary sources. These summaries bring PDDI knowledge to clinicians in the form of published drug information compendia, clinical decision support rules, and interaction checking applications. **However, there are currently no broadly accepted standards to guide these experts in the knowledge representation and services implementation of PDDI information that would be most effective for clinical decision support.** Without international coordination for the extensions and profiles used to express PDDI CDS, needless variation is certain to occur in implementations. This project will provide the opportunity for the international community to collaborate and come to consensus on patterns used in implementations.

This need for a standard representation of PDDI information was one of the topics addressed at two multi-stakeholder conference meetings/series (Hines et al. 2011; Scheife et al. 2015; Payne et al. 2015; Tilson et al. 2016). Attendees at both conferences included international stakeholders from drug information content providers, regulatory agencies, and academic organizations. Among the key recommendations was the following suggested set of core information that should be included for every PDDI mentioned in a clinically-oriented drug information resource (Payne et al. 2015):

- *Drugs involved*
- *Clinical consequences*

- *Frequency of exposure to the interacting drug pair*
- *Frequency of harm for persons who have been exposed to the interacting drug pair*
- *Contextual information/modifying factors*
- *Evidence*
- *Mechanism of the interaction*
- *Recommended actions*
- *Seriousness rating*

These core information elements are consistent with the results of a separate international Delphi study on how to improve the delivery of medication alerts within computerized physician order entry systems (Riedmann et al. 2011). This suggested list of core information elements includes some that are present in one or more of the 15 PDDI conceptual models analyzed in a recent comprehensive review by Herrero-Zazo, Segura-Bedmar, and Martínez (Herrero-Zazo et al. 2016). However, there is little commonality across the conceptual models on those elements that are included and no single conceptual model covers all 9 of the information elements. Moreover, the creation and maintenance of PDDI decision support generally requires considerable time and energy from highly trained domain experts. An additional need is to standardize the EHR context that is sent to CDS services. This includes context parameters that are currently not available but that, if present, would be useful for increasing the specificity of the CDS alerts. This is important to ensure that PDDI decision support can be implemented across a variety of systems.

Rekić D, Reynolds KS, Zhao P, Zhang L, Yoshida K, Sachar M, Piquette Miller M, Huang SM, Zineh I. Clinical Drug-Drug Interaction Evaluations to Inform Drug Use and Enable Drug Access. J Pharm Sci. 2017 Apr 21. pii: S0022-3549(17)30249-6. doi: 10.1016/j.xphs.2017.04.016. [Epub ahead of print] PubMed PMID: 28435142.

Hines LE, Murphy JE, Grizzle AJ, Malone DC. Critical issues associated with drug-drug interactions: highlights of a multistakeholder conference. Am J Health Syst Pharm. 2011 May 15;68(10):941-6. doi: 10.2146/ajhp100440. PubMed PMID:21546646.

Scheife RT, Hines LE, Boyce RD, Chung SP, Momper JD, Sommer CD, Abernethy DR, Horn JR, Sklar SJ, Wong SK, Jones G, Brown ML, Grizzle AJ, Comes S, Wilkins TL, Borst C, Wittie MA, Malone DC. Consensus Recommendations for Systematic Evaluation of Drug-Drug Interaction Evidence for Clinical Decision Support. Drug Saf. 2015 Feb. 38(2):197-206 http://link.springer.com/article/10.1007%2Fs40264-014-0262-8. PubMed PMID: 25556085. PMCID: PMC4624322

Payne, Thomas H., et al. "Recommendations to improve the usability of drug-drug interaction clinical decision support alerts." Journal of the American Medical Informatics Association (2015): ocv011.

Tilson H, Hines LE, McEvoy G, Weinstein DM, Hansten PD, Matuszewski K, le Comte M, Higby-Baker S, Hanlon JT, Pezzullo L, Vieson K, Helwig AL, Huang SM, Perre A, Bates DW, Poikonen J, Wittie MA, Grizzle AJ, Brown M, Malone DC. Recommendations for selecting drug-drug interactions for clinical decision support. Am J Health Syst Pharm. 2016 Apr 15;73(8):576-85. doi: 10.2146/ajhp150565. PubMed PMID: 27045070; PubMed Central PMCID: PMC50649

Riedmann D, Jung M, Hackl WO, Ammenwerth E. How to improve the delivery of medication alerts within computerized physician order entry systems: an international Delphi study. J Am Med Inform Assoc. 2011 Nov-Dec;18(6):760-6. Doi: 10.1136/amiajnl-2010-000006. Epub 2011 Jun 22. PubMed PMID: 21697293; PubMed Central PMCID: PMC3197982.

Herrero-Zazo, María, Segura-Bedmar, Isabel, and Martínez, Paloma. "Conceptual models of drug-drug

interactions: A summary of recent efforts." Knowledge-Based Systems 114 (2016): 99-107.

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

Describe any external schedules or calendars which may not be known outside of the project team that are driving target dates for this project.

N/A

3.e. Project Objectives / Deliverables / Target Dates

	Target Date
Submit for Ballot for Comments	2018 Sep Ballot
Complete Ballot for Comments Reconciliation	2018 Sep WGM
Submit for 1st STU Ballot	2019 May Ballot
Complete 1st STU Ballot Reconciliation	2019 May WG
Submit for 2nd STU Ballot	2019 Sep Ballot
Request STU Publication	2019 Oct
STU Period – 24 months	2019 Oct - 2021 Sep
Submit for Normative Ballot	2021 Sep Ballot
Complete Normative Reconciliation	2021 Sep WGM
Submit Publication Request	2021 Oct
Receive ANSI Approval	2021 Nov
Project End Date (all objectives have been met)	2022 Jan

3.f. Common Names / Keywords / Aliases

Drug-drug interaction, PDDI CDS

3.g. Lineage

N/A

3.h. Project Dependencies

HL7 FHIR Implementation Guide: CDS Hooks, Release 1 – 1234
Clinical Quality Expression Language – 1108
FHIR
Medication knowledge (investigative project from Pharmacy) - 1365

Enter any dependencies or the name & Project Insight ID of project(s) that this project is dependent upon to achieve its objectives. Projects and their Project Insight IDs can be found via http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?ref=common

3.i. Project Document Repository Location

Project page: http://wiki.hl7.org/index.php?title=PDDI_CDS

Document repository: https://github.com/HL7/PDDI-CDS

3.j. 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 for more information on the current V3 data types)			Yes			No			Unknown		X	N/A
If you check 'No' please explain the reason:												

3.k. External Vocabularies

Will this project include/reference external vocabularies?		X	Yes			No			Unknown			N/A
If yes, please list the vocabularies: ATC/**RxNorm, ICD10, SNOMED-CT, LOINC – all exemplar**												

4. Products (check all that apply)

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

5. Project Intent (check all that apply)

X	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;
	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)

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

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

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?			Yes		X	No		

6. Project Logistics

6.a. External Project Collaboration

W3C Healthcare and Lifesciences Working Group. A volunteer-based task force (https://www.w3.org/wiki/HCLSIG/DDI) was formed in January 2016 within the Health Care and Life Sciences Interest Group that operates publicly through the World Wide Web Consortium (W3C). The goal of the task force was to develop a minimal information model for drug interaction evidence and knowledge as part of an HIT standard like HL7. **The workgroup's results will serve as requirements and business knowledge for the current project.** The task force is in the process of finalizing a draft Interest Group Note that provides use cases, user stories, definitions, and exemplar potential drug-drug interaction descriptions for a minimal information model for drug interaction evidence and knowledge. These items are available for public use with no restrictions, including for the current project. Documents, meeting information, and announcements for this task force are managed at this Google Site page: https://sites.google.com/site/ddikrandir/home/ddi_info_model_taskforce. All persons who participated in the task force will be invited to both participate in the working group calls that discuss the current project and participate in the ballot process. The task force's work represents no more than 20% of the work to be completed for the current project.

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?	**20%**
Was the content externally developed (Y/N)?	Y **W3C Healthcare and Lifesciences Working Group**
Is this a hosted (externally funded) project? (not asking for amount just if funded)	Yes: ; No: X

6.b. Realm

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

Enter "U.S." or name of HL7 affiliate(s) here. Provide explanation/justification of realm selection. For projects producing deliverables applicable to multiple realms, document those details here.

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	
	Clinical and Public Health Laboratories	X	Pharmaceutical		Clinical and Public Health Laboratories
	Immunization Registries	X	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)	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
	N/A		Other (specify below)		
			N/A		

Other: Indicate other stakeholders, vendors or providers not listed above.
Commercial vendors of drug information compendia

6.d. Project Approval Dates

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:	**CDS WG Approval Date** 2018-02-07

Co-Sponsor Group Approval Date (Copy this entire row for each co-sponsor; indicate the specific cosponsor that issued approval)	**Pharmacy Co-Sponsor Approval Date 2018-02-12**
FHIR Project: FHIR Management Group Approval Date:	**FMG Approval Date CCYY-MM-DD or "N/A"**
Architectural Review Board Approval Date: (required for externally developed content)	**ARB Approval Date CCYY-MM-DD or "N/A"**
Steering Division (of Primary Sponsor WG) Approval Date:	**SD Approval Date CCYY-MM-DD**
Last PBS Metrics Score: ☐ Green ☐ Yellow ☐ Red PBS Metrics Reviewed? (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