Vulcan Response to United States Code Data for Interoperability (USCDI) V4

April 17, 2023

https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#draft-uscdi-v4

The following comments have been submitted on behalf of the *Vulcan HL7 FHIR Accelerator Program*. Questions and clarifications can be obtained through contact at vulcan@hl7.org.

Vulcan is part of the HL7 FHIR Accelerator Program, focusing on the development of interoperability standards for clinical and translational research. Vulcan brings over 40 organizations together to provide an open, transparent and non-biased community for standards development and implementation.

The current program includes the development of Implementation Guides / standards for:

- ***Real Word Data (RWD):*** Extract data from EHRs in a standardized format to support clinical research and especially submission to Regulators
- ***Schedule of Activities (SOA):*** Represent the schedule of activities in FHIR from a spreadsheet. Enable the consistent description, timing and identification of each activity in a study
- ***Phenotypic Data:*** To increase the availability of high-quality standardized phenotypic information for genomic research and genomic medicine
- ***Electronic Product Information (ePI)***: Define a common structure for product information (monographs) that supports cross-border exchange of data for patients
- ***Adverse Events (AE):*** Support standardizing the reporting and format of an adverse event. Improve the maturity of the relevant FHIR resources
- ***FHIR to OMOP:*** Support the development of FHIR to OMOP data transfer for better analysis of clinical data for research

RWD, ePI and SOA are currently being balloted by HL7 and we expect these to be declared as STU (Standard for Trial Use) in the coming months. Vulcan is also actively pursuing additional use cases / projects to support the research community in the coming months, as well as implementation of our STU standards through pilots, proof of concepts and real-world implementations. Vulcan leverages HL7 Connectathons to validate the standards developed by our members.

We are happy to provide comments through this comment process and welcome the opportunity to work with ONC on USCDI to enhance support for clinical and translational support in HL7 FHIR.

Vulcan Comments

Draft USCDI v4 includes USCDI v3, 20 new data elements, and one new data class. Please reference the **Draft USCDI v4 document** and the **ONC Standards Bulletin 23-1** for more information. ONC is accepting feedback through comments on this website through Monday, April 17, 2023 at 11:59 p.m. Eastern time.

The table below provides feedback from the Vulcan, part of the HL7 FHIR Vulcan Accelerator Program. Questions and clarifications can be obtained through contact at vulcan@hl7.org.

#	Reference (Data Class / Data Element)	Suggestion Type (Change, Add, Remove)	Comment	Existing Text	Proposed Text
1	Allergy & Intolerances - Substance (Non-Medication)	Add	Add UNII to applicable list of applicable code systems. UNII provides a more comprehensive set of Food and Environmental allergens. See: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3756252/		Add coding set
2	Facility Information	Add	Many facilities are part of a larger health system or IDN, and it would be helpful to understand this information.		Affiliated System - word or words to represent the parent organization, health system, or IDN that this facility is affiliated with, or operated within.
3	Facility Information	Add	Contact information, specifically address of facility should be included to help identify the geography of where the care was received, to help with downstream record location and retrieval		Address - Place where Facility is physically located
4	Medication	Add	Should the Indication be coded against the Condition CT? Eg SNOMED-CT/ICD-10		Add coding set
5	Average Blood Pressure	Change	Please clarify the "Average Blood Pressure" by stating this is the Arithmetic mean value for each systolic and diastolic blood pressures. Clarify that this is the is not the same as the "Mean Blood Pressure (MBP)" which = Diastolic Blood Pressure (DBP) = 1/3[Systolic Blood Pressure (SBP)-DBP].	Mean value of two or more blood pressure readings in a specified time period. Usage note: Must include both systolic and diastolic components of the mean and specify	Arithmetic mean value of two or more blood pressure readings in a specified time period. Usage note: Must include systolic arithmetic mean and diastolic arthrimetric

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				the relevant time period of measurements.	mean specifying the relevant time period of the measurements.
6	Demographics, Sex Sex For Clinical Use	Change	Recommend clarifying the term Sex since there are data elements for "Sexual Orientation" and "Gender Identity." There is an opportunity to define the term Sex as "Birth Sex". Most clinical trials in the past had two options (assumed as birth sex). One could say that historically, the male and female documentation in healthcare has predominantly been about birth sex. The medical history and medical record progress notes were where additional gender, sex orientation, etc. would be found. There have been many discussions in many settings regarding this challenging topic. The reason for the suggestion is to provide the ability to understand clinical research based on birth sex over time. There is varying physiology on each of these sex, sexual orientation, gender, etc. data points, but the lion's share of the historical clinical research and health data is based on birth sex. The NCI Thesaurus has the concept of "Sex at Birth" defined as "The physical sexual characteristics of the neonate at birth". Additionally, suggest the additional values recommended by commenters in the past regarding Sex for Clinical Use defined as "sex category aligned with the expected typical observations for male or female at the time of the encounter." LOINC Code 99501-9. Including these concepts under Demographics may cover many of the identified issues in the string of comments from stakeholders. Note there are multiple Data Elements suggested in the "Sex For Clinical Use" proposed Data Class. These are	1. Sex defined as: "Documentation of a specific instance of sex and/or gender information." 2. Promote Sex for Clinical Use. Currently not defined and includes numerous subsets according to use case.	1. Sex defined as "Documentation of the sex identified on the birth certificate at the time of birth." 2. Promote "Sex for Clinical Use" under Demographics Data Class. 3. Define "Sex for Clinical Use" as: "Sex category aligned with the expected typical observations for male or female at the time of the encounter."

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			context related and qualifiers of the "Sex For Clinical Use" data element.		
7	General comment	Change	Referencing multiple 'competing' terminologies/vocabularies for any given attribute in the USCDI threatens meaningful/semantic interoperability. In addition, some of the currently referenced terminologies/vocabularies have gaps that will preclude certain use cases. For example, for the regulated clinical research use case, the global standard terminology is the C-codes, which are maintained by NIH/NCI EVS and CDISC. Optimally, there should be one terminology (which may eventually be a complementary/harmonized set of terminologies) referenced for each attribute. This goal has been a challenge the past few decades, primarily due to political (not technical) challenges. ONC could serve a coordinating role in this regard that would benefit the health system all of us as patients.		
8	Medication Administration Date Medication Administered Medication Administered Code Medication Administration Dose Medication Administration Dose Units Medication Administered Reason Reference Medication Administered Performer	Change	The record of an actual administration of a medication to a patient is one of the most central healthcare use cases. Currently a suite of Medication administration-related concepts are in the Level 2 section of USCDI. All of these are central healthcare components so the longer the data for these concepts remain wildly unstandardized in US EHRs, the longer there will be no realistic expectation of interoperability. These are the center of patient-provider data exchange and the continued lack of standardized representation of these concepts should be the single driving reason for their inclusion in USCDI version 4. In addition, an example justification from a RWD Research perspective: Retrospective analyses of healthcare data are becoming a		

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	Medication Administration Status		more common tool in clinical research for safety or efficacy for new indications of existing medications. In such analyses there may be one or more "exposure" drugs (ie, the drug of interest) and one or many "concomitant" medications. Researchers and regulatory reviewers will need to know enough information of the status of a drug administration where applicable. This information will supply critical differential information with which a researcher or regulatory reviewer can assess the relative probability of the listed drug record actually resulting in consumption by the patient. They can then determine the utility of the information in the context of the specific research and evidence generation needs of any given clinical study.		
9	Procedures; Time of Procedure	Change	There is a request for comment regarding aligning the encounter with the date/time of the procedure. This will inhibit real world data used in clinical research as a persons labs may change if they become unstable. Many times, the procedure occurs as the date of the encounter because patients will be admitted for a particular procedure for that encounter. It is not generalizable and not a good practice to use the encounter date for the date/time of the procedure. For procedures such as surgery, the date as in month-day-year may be all that is needed. Link to term: https://www.healthit.gov/isa/taxonomy/term/1456/draft-uscdi-v4	There is text stating that ONC is considering using the date of admission as the date of the procedure.	Use the date of the procedure.
10	Health Status Assessment: Physical Activity, Physical Activity Vital Sign	Change	Example is not correct. "Physical Activity Vital Sign" is a "Vital Sign" taken during "Physical Activity". This would be similar to a "Vital Sign" taken during "Surgery" or a "Procedure". Consider adding examples of Strenuous Exercise, Moderate Exercise, Light Exercise. See list here:		Separate Vital Sign from Physical Activity. These are separate concepts.

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			Search term: "Exercise" https://ncit.nci.nih.gov/ncitbrowser/pages/home.jsf Link to page: https://www.healthit.gov/isa/taxonomy/term/7736/draft-uscdi-v4		
11	Health Status Assessment: Substance Use and Alcohol Use	Change	Consider adding text to state that "Substance Use" is other than "alcohol" and "tobacco". It may be good to have a larger category of "Substance Use" with subcategories of Alcohol, Tobacco, Other Substance Use. Link to page: https://www.healthit.gov/isa/uscdi-data-class/health-status-assessments#draft-uscdi-v4	Existing text has substance use as an additional category other than tobacco and alcohol.	Consider adding "Substance Use" as a larger category with "Alcohol", "Tobacco", etc. as subcategories.