Vulcan Response to United States Code Data for Interoperability (USCDI) V5

April 15, 2024

United States Core Data for Interoperability (USCDI) | Interoperability Standards Advisory (ISA) (healthit.gov)

Vulcan FHIR Community Comments on Draft USCDI Version 5

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.

The following comments have been submitted on behalf of the Vulcan HL7 FHIR Accelerator Program's Community Members. Vulcan is a member-driven 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

Adverse Events (AE) is 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

The table below provides consolidated feedback from the Vulcan members, part of the HL7 FHIR 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
1	Visit Schedule	Add	Visit schedules for patients and clinical trial subjects, including schedules consisting of multiple visits at predefined intervals over a period of time, such as for regimens, tests, related procedures included in clinical trial.
2	Clinician Schedule	Add	Appointment schedules and other availability information for clinicians, in order to match their availability to patient schedules
3	Appointment	Add	Information about individual appointments that are set up for patients and clinical trial subjects
4	Resource Allocation	Add	Information about the availability of resources necessary for specific patient visits
5	Patient-Reported Outcomes	Add	Questionnaires for patients to complete to report outcomes; and questionnaire responses containing information provided by patients regarding outcomes of treatments they have received
6	Environmental Factors	Add	Information about the environment of the patient or clinical research subject, which may have impacted their health and/or the outcomes of treatments they have received
7	Investigational Product	Add	In order to capture adverse event data related to a clinical trial, it is necessary to capture information about the product or treatment that is the focus of the study.
8	Clinical Trial Protocol	Add	In order to capture adverse event data related to a clinical trial, it is necessary to capture information about the study protocol.
9	Patient Consent	Add	Patient consent status for a clinical trial is important context for trial-related adverse events.
10	Adverse Event Severity	Add	Adverse event data related to a clinical trial includes standardized grading criteria for adverse event severity.

#	Reference (Data Class / Data Element)	Suggestion Type (Change, Add, Remove)	Comment
11	Medical History	Add	USCDI currently includes Health Concerns and Problems. Clinical trial protocols commonly require identifying a subject's medical history. Some EHRs (including Epic) support this today by including FHIR Condition data with a category of 'medical-history'.
12	Medication Administration	Add	While USCDI includes a Medication category, the current interpretation (as indicated by US Core) limits this to medication orders and dispenses, and does not include administrations that are part of an encounter. This data is necessary for clinical trials. [This was also included in last year's Vulcan feedback.]
13	Laboratory Organization	Add	The CLIA identifier and name of the laboratory that performs the laboratory test. This information is needed as part of many clinical trials.
14	Performance Status	Add	Performance status using either ECOG or Karnofsky scale is relevant to the vast majority of oncology trials. Structured data (using LOINC terms) would facilitate completion of case report forms. Assessment of the patient (how capable, mobility etc)
15	Pathology Reports	Add	Structured representation of pathology reports should include a standardized term for the procedure performed and explicit values for the finding, either quantitative or qualitative.
16	Radiology Reports	Add	Structured representation of radiology reports should include a standardized term for the imaging performed and explicit values for the finding, either quantitative or qualitative.
17	Patient Encounter	Add	Flag to indicate encounter is part of research study. Also includes Study ID and visit ID by default.