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Submitted electronically to:
https://www.healthit.gov/isa/ONDEC

RE: ONC's Draft United States Core Data for Interoperability (USCDI) Version 4.0

Thank you for the opportunity to review and provide comments on the draft USCDI V4.0, the standardized set of health data classes and constituent data elements for nationwide, interoperable health data exchange. As USCDI data elements increase in granularity and precision, greater opportunities arise to support the use of real-world data (RWD) for clinical research.

CDISC recommends the following data classes and data elements be added to USCDI v4.0:

- Research
  - Study Name
  - Status
- Outcomes
  - Serious Adverse Event

We suggest, in addition to the various terminologies present within the USCDI data elements, that the NIH NCI Enterprise Vocabulary System (EVS) C-Codes be added where appropriate. The NCI Metathesaurus (NCIm) is a wide-ranging terminology database that covers most terminologies used by NCI for clinical care, translational and basic research. Its core reference terminology and biomedical ontology maps 7.5 million terms from more than 100 sources into 3.2 million concepts. Adding NCI C-Codes will facilitate clinical research from the point of care and beyond. The EVS C-Codes are required for regulatory submissions to FDA and Japan's PMDA and are currently used by researchers around the world.

RWD plays an increasingly important role in clinical research and health care decision making. CDISC supports the development of ONCs USCDI Common Data Elements, which facilitate the use of rich electronic health data from sources outside the regulatory submission use case while ensuring consistency and reliability of the data.

It is well-known that, because RWD is not collected with research as its primary purpose, there are significant challenges in using and representing these data for research purposes. These challenges include bias, data variability and heterogeneity, which can make analysis of RWD difficult and resource consuming. There are numerous benefits of connecting RWD to CDISC

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Standards: structuring the data in a format compatible with FDA review tools, fostering data sharing, facilitating cross-study and metadata analysis.

CDISC began as a volunteer grass roots initiative in 1997 in response to the need to better structure and improve the quality and consistency of data in clinical research. Today, CDISC is a global non-profit standards development organization (SDO) with 40 employees and 85 contractors. Over 1100 volunteers across the research spectrum contribute their time and expertise to developing CDISC standards.

Required by the FDA and Japan's Pharmaceuticals and Medical Devices Agency (PMDA), recommended by the China National Medical Products Administration (NMPA) and adopted by the world's leading research organizations, CDISC Standards enable the accessibility, interoperability, and reusability of data. With the help of CDISC standards, the entire research community can maximize the value of data for more efficient and meaningful research that has invaluable impact on global health. Additionally, CDISC collaborates with fellow SDOs to develop standards that are synergistic to support a learning health system based upon high-quality research.

CDISC has been involved in several successful initiatives that have leveraged RWD in clinical research:

- The PHUSE Research on FHIR collaboration included participants from CDISC, FDA, and industry to produce several pilots and associated papers demonstrating the use of FHIR to provide RWD to populate CDISC datasets and CRFs. The papers produced as part of this program are listed on the CDISC website.
- CDISC completed the FDA BAA (HHSF223201510105C), which demonstrated eSource using HL7 FHIR resources and the CDISC ODM Data Exchange standard. This research used FHIR to retrieve EHR data to pre-populate ODM-based case report forms for a multi-center study with sites from different health systems. Novel middleware software was developed to arbitrate the exchange.
- CDISC worked with the HL7's Biomedical Regulation & Research (BR&R) Work Group to develop a FHIR to CDISC Laboratory Data Mapping Overview with the goal of facilitating the flow of data into submission data sets. CDISC and PHUSE are working with the BR&R group to develop the CDISC ODM to FHIR Mapping to map the entirety of ODM and its extensions (SDM-XML, Define-XML, CTR-XML) to FHIR resources.
- CDISC participated in the OHDSI Clinical Trials Working Group to publish the "Clinical trial conventions for the OMOP Data Model," which mapped data formatted in CDISC's Study Data Tabulation (SDTM) to OMOP. A summary of this work can be found on the OHDSI web site.
- CDISC published the FHIR to CDISC Joint Mapping Implementation Guide v1.0, which provides a mapping to extract EHR data into the SDTM. The Implementation Guide is also posted to the HL7 website and provides the same content in a format similar to other FHIR implementation guides.

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Thank you for your consideration of our comments. We welcome the opportunity to engage in further discussion on this important topic.

Sincerely,

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Sam Hume, DSc, VP, Data Science
Rhonda Facile, MS, VP, Partnerships and Business Development
Bess LeRoy, MPH, Head, Standards Innovation
Amy Palmer, MPH, Head, Standards Development
Rebecca Baker, MS, MHA, BSN, RN, Standards Development

References:

- https://evs.nci.nih.gov/
- https://www.nlm.nih.gov/research/umls/index.html
- https://ncim.nci.nih.gov/ncimbrowser/