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Submitted electronically: Health IT Feedback and Inquiry Portal (https://inquiry.healthit.gov/)
RE: 2024-2030 Federal Health IT Strategic Plan

Thank you for the opportunity to review and provide comments on the draft Federal Health IT Strategic Plan for 2024-2030. Overall, we commend ONC for a very clear and comprehensive plan. We are pleased to see that Accelerating Research and Innovation is one of the four goals.

Clinical Data Interchange Standards Consortium (CDISC) was founded as a volunteer group in 1997 and incorporated in 2000 as a standards development organization (SDO) to develop data standards for clinical research and its link with healthcare. Global data standards for research have now been developed to support the entire research process, from digital protocols and case report forms through data collection (by patient) to aggregation of data across all patients in a research study, creation of tables, statistical analyses and reporting. The CDISC formats for the Study Data Tabulation Model (SDTM) and analysis Datasets (ADaM) are now required by FDA and Japan's PMDA as data formats for submission of applications for all new drugs. CDISC standards are encouraged by other regulators around the globe. CDISC has over 500 member organizations and worldwide adoption of CDISC standards by a variety of organizations, including academics, biopharma, clinical research organizations and others. CDISC is recognized as a Liaison D organization by the International Standards Organization (ISO).

In addition to the foundational standards that address data that are common across all studies (e.g. demographics, medical history, medications), CDISC led the Coalition For Accelerating Standards and Therapies (CFAST) partnership (FDA, NIH, CDISC, TransCelerate and patient advocacy groups) to develop data standards for over 50 therapeutic areas that touch billions of lives. Notably, the CDISC standards are harmonized among one another and implementation guides for these standards are not conflicting (i.e. one IG will not 'break' another).

CDISC is a member of the Vulcan and CodeX HL7 FHIR accelerators and initiated the workgroup within HL7 that is now known as BR&R. CDISC has also developed interoperability specifications and profiles through IHE to demonstrate how HL7 and CDISC standards are complementary (not competing). CDISC is now working with FDA, NIH/NCI and NCATS and ONC on the Common Data Model Harmonization (CDMH) Phase 3 Code Mapping Services and on an EU project called xSHARE to develop standards to ensure the European EHR exchange Format (EEHRxF) will support research and public health, leveraging the International Patient Summary (IPS).

CDISC will be pleased to do what we can to support the ONC Strategic Goal to Accelerate Research and Innovation. Specifically, we have already been working through the CDMH P3 project to map USCDI/US Core FHIR Elements to CDISC SDTM and to register these mappings as data element concepts (ISO 11179) with NCI in the caDSR. The HL7 FHIR to CDISC SDTM mapping implementation guide will be updated with these recent domains. CDISC terminology has been curated and maintained by NCI Enterprise Vocabulary Services since 2008 and it open and freely available (as are the CDISC standards).

It is extremely important to have well-defined, curated and maintained terminology to support semantic interoperability from beginning to end for research. The CDISC content/terminology standards are available for protocol development and data collection such that one can initiate a research study 70-90% faster by using CDISC standards from the beginning. Significant time is also saved during the data tabulation and analysis stages of the research study if data are collected in a standard format at the start.

One of the barriers to accelerating research and the use of real world data (RWD) to augment clinical research data has been that EHRs have historically used their own proprietary and./or disparate data standards, thus necessitating mapping and/or re-entry of data for clinical research (i.e. swivel chair technology). Having a standard set of healthcare data for initiating clinical research (e.g. USCDI+ and IPS in Europe) could mean that significant time and resources could be saved (and quality improved) by not having to re-map or re-enter data for every research study. Patient having access to their own health data could also mean they could 'opt in' to be screened for a research study, thus saving time related to informed consent and gaining access to baseline/summary healthcare data.

CDISC was built on a motto of 'strength through collaboration' and would be pleased to leverage existing work towards the success of ONC in achieving this research goal (as well as goals to ensure patients have access to their own health data). CDISC believes that ONC can be the bridge for the standards ecosystem to make the world healthier (both structurally with the data models and semantically with the terminology, using NCIt as the core).

Specific recommendations are as follows:

- A mimimal set of core common data elements (CDEs) and data element concepts (DECs), which include the valuset or codelist, should be required across HHS, especially NIH and FDA for baseline healthcare data. The DECs are important to ensure semantic interoperability, and it is also critical that there be a core standard set such that researchers are not faced with a choice of dozens of CDEs for the same data field; not all CDEs are robust or 'equal in value' nor will the use of disparate CDEs for the same data field enable interoperability. CDISC standards have one set of controlled terminology, not multiple choices for a given data field. This is how the CDISC standards are harmonized from beginning to end. We recommend leveraging this NCIt terminology as much as possible; NCI EVS has spent years curating and maintaining it, and it is quite a mature set, including definitions and codes, downloadable in 6 formats

- We recommend that USCDI+, mCODE and the CDISC oncology therapeutic area user guides be harmonized. This will augment the foundational core data elements with important elements for **cancer** research and care and accelerate research and innovation.

- CDISC content (metadata and terminology) can be transported using FHIR. This is how the standards are complementary and SDOs can work together. Such 'standards in synchronous use' is demonstrated with the Vulcan AE implementation guide and is being developed for the ICH global research protocol template (a collaboration among ICH, CDISC and Vulcan).

- It would be helpful if the USCDI and the IPS could be harmonized. Currently, there are ISO, HL7 and IHE IPS documents and they do not completely reflect USCDI. The CDMH P3 and EU xSHARE projects, which are leveraging USCDI/US Core FHIR IG and IPS/IPS FHIR IG, respectively) are complementary and could be extremely beneficial to support healthcare globally, including research and public health.

- The Regulation on a European Health Data Space (EHDS) recently approved new rules to protect the health of citizens and improve the resilience of health systems. Notably they set out to establish a strong legal framework for the re-use of health data for research, innovation and public health purposes. The aim is to develop life-saving treatments and personalized medicine and improve European crisis preparedness. The two main aims: place the citizen at the center of their healthcare and allow the use of health data for research and public health under strict conditions.

Again, CDISC finds the ONC Strategic Plan to be an excellent document expressing a bold and commendable vision. CDISC will be pleased to do what we can to support the ONC Strategic Goal to Accelerate Research and Innovation and the entire plan in general. Please do not hesitate to call on us to collaborate on these future efforts.

Kind regards,

Rhonda Facile

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CDISC