



July 31, 2017

Donald Rucker, MD  
National Coordinator for Health Information Technology  
US Department of Health and Human Services  
330 C Street, SW  
Washington, DC 20201

Dear Dr. Rucker:

We are pleased to provide written comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to the [2017 ONC Proposed Interoperability Standards Measurement Framework](#) on behalf of the Clinical Data Interchange Standards Consortium ([CDISC](#)). We look forward to continuing to participate in this and other ONC opportunities, such as the Interoperability Standards Advisory (ISA), to define, assess and support semantic and syntactic interoperability between and among clinical research and health systems. Though biomedical research is generally a small portion of the total operational considerations for our national health system, it is nonetheless a critical component for continued creation, assessment and delivery of new diagnostics, treatments and devices to care settings. Taken together, these efforts are important for helping to establish a learning health system through which data from electronic health records are utilized to inform both regulated and non-regulated clinical research to drive discoveries that will improve human health in a clinical setting.

Since its inception nearly 20 years ago, CDISC has been a world leader for biomedical research standards including research that utilizes data sourced from diverse electronic health systems. CDISC is a 501(c)3 global, non-profit charitable organization that develops data standards to streamline clinical research and enable connections to healthcare, empowering the valuable information offered by patients participating in research studies around the world. With support from CDISC member organizations and thousands of volunteer subject matter experts, CDISC has developed a set of comprehensive standards for clinical and translational research. These standards improve research data quality, foster efficiencies and reduce research costs in clinical trials, streamline processes, facilitate data sharing, and offer complete traceability from instantiation beginning at the electronic health record to submission to FDA (where applicable). In addition to a set of foundational research standards for the collection, aggregation, analysis, reporting, archiving and sharing of biomedical research data, CDISC and its collaborative partners have developed or is creating Therapeutic Area User Guides that define how to apply these standards to over 30 key disease areas ranging from Alzheimer's disease to prostate cancer and vaccines research.

CDISC has >430 members from diverse sectors such as academic health centers, biopharmaceutical, biotechnology, clinical research organizations (CROs), government, hospital systems and clinics, information technology, and other research or research-support organizations. On behalf of these members, CDISC has played an active role for years in efforts to electronically source (eSource) data from electronic health systems for clinical and translational protocols. These activities have included participation as a research representative on ISA task forces, creation of eSource standards with other standards development organizations (SDOs)

such as Health Information and Management Systems Society (HIMSS) as part of Integrating the Healthcare Enterprise (IHE), and participation and leadership in diverse projects that link healthcare delivery and clinical research by mobile devices, wearables, and other real-time sources as part of our Healthcare Link initiative. Together with our foundational and therapeutic area standards, CDISC has enabled its members and the global regulated and non-regulated research community to adopt and implement standards-based research processes, electronic systems for data capture and exchange, and submission and sharing of data.

CDISC agrees with the value that this proposed framework could provide in advancing the implementation and use of interoperability standards in the health IT community, where established data-driven measures can provide information to assess adoption, conformance, compliance, etc. Here, we provide feedback on the following questions posed within the request for information:

***1) Is a voluntary, industry-based measure reporting system the best means to implement this framework? What barriers might exist to a voluntary, industry-based measure reporting system, and what mechanisms or approaches could be considered to maximize this system's value to stakeholders?***

CDISC agrees that this approach is likely to have the best outcomes for implementing the framework, at least initially. The learning health and biomedical research communities, especially where they are part of academic and health system centers, are interested in improving interoperability of electronic health systems for use in research to feedback to a care setting. All members of the community, in particular non-profit organizations, have myriad “unfunded government mandates” placed upon them. These are generally recognized to be for public good, but a phase approach in which initial measures are voluntary would help reduce burden and provide time to adapt to any new mandates developed as a part or consequence of the framework.

CDISC recognizes that any reporting system will likely need robust and clear guidance with regard to federal expectations for compliance. Further, in order to maximize appropriate and compliant adoption of measures that have been found to be most effective or useful, a set of incentives must be considered. CDISC and its large membership community appreciate the opportunity to participate in dialogue about these barriers and mechanisms that may be taken to break them down or reduce them.

***2) What other alternative mechanisms to reporting on the measurement framework should be considered (for example, ONC partnering with industry on an annual survey)?***

CDISC supports the reuse of existing reporting systems to the fullest possible extent to manage burden on health and research stakeholders while leveraging the utilization of these data and systems. CDISC also suggests the exploration of the value of measurements not only of implementation within healthcare and related organizations, but also engaging with biomedical research organizations where appropriate. The flow of standardized data among interoperable health systems is tantamount. An important secondary use case around the flow of data from electronic health systems, reporting databases and other sources of so-called real world evidence to biomedical research systems would herald a true success of any national interoperability framework. As such engagement of CDISC and other key members of the research domain on how various potential reporting options may affect the nexus of healthcare and research could be

beneficial to public health.

**3) Does the proposed measurement framework include the correct set of objectives, goals, and measurement areas to inform progress on whether the technical requirements are in place to support interoperability?**

The proposed measurement framework includes objectives, goals and measurement areas that are generally consistent with supporting interoperability on a national scale. Because each of these areas such as architecture and data access are very high level, it will be critical to engage with a broad community of stakeholders to ensure that appropriate granularity is developed under these areas.

Given CDISC's long history of developing and maintaining standards that have recently become required for electronic submissions of trials to the FDA and Japan's Pharmaceuticals and Medical Devices Agency (PMDA), we understand that the creation of any standard or set of standards, alone, is not sufficient to ensure interoperability. Validation, conformance and compliance measures and monitoring are required to ensure consistent implementation of each standard across a variety of organizations and electronic systems. Specificity and clear guidance will be required for all measurement areas including both the definition of the area itself and the exact metrics and reporting requirements. Without such clarity, the value of the proposed measurement framework will be diminished. Use cases that define areas of need such as those from ISA and the Data Access Framework (DAF) can be leveraged and utilized for this purpose.

In addition to clear guidance, one measure that is missing currently is the assessment of the quality and consistency of accessible data. These measures will be critical to ensure that not only can health data be exchanged, but that they can be exchanged *meaningfully*. Rules must be established and implemented in validation tools and services to ensure such meaningful data exchange. Other secondary measures such as costs for implementation and maintenance can also be meaningful for long-term assessments, decision-making and considerations of future revised or new frameworks.

**4) What, if any gaps, exist in the proposed measurement framework?**

Please see CDISC's response to question 3 above.

**5) Are the appropriate stakeholders identified who can support collection of needed data? If not, who should be added?**

In addition to the stakeholders identified within the request for information, CDISC recommends engagement with additional federal agencies such as the FDA, Centers for Disease Control (CDC), National Institutes of Health (NIH) and patient advocacy groups who have a focus on utilizing data from healthcare systems. These groups are collecting data that serve both primary (delivery of healthcare) and secondary (biomedical research using eSourced data) use cases.

**6) Would health IT developers, exchange networks, or other organizations who are data holders be able to monitor the implementation and use of measures outlined in the report? If not, what challenges might they face in developing and reporting on these measures?**

Yes, they are likely to be able to monitor the implementation of standards and measures outlined in the report. Key for the success of this initiative will be the universally consistent application of measures across different sectors engaged in the delivery of care and research. A common approach to this challenge is to identify a small set of measures and, where possible, validation/conformance rules to ensure consistency.

**7) Ideally, the implementation and use of interoperability standards could be reported on an annual basis in order to inform the Interoperability Standards Advisory (ISA), which publishes a reference edition annually. Is reporting on the implementation and/or use of interoperability standards on an annual basis feasible? If not, what potential challenges exist to reporting annually? What would be a more viable frequency of measurement given these considerations?**

Reporting on the implementation and use of interoperability standards annually is feasible and should help guard against major gaps in reporting data. To reduce reporting burden on participating organizations, CDISC recommends that ONC create a draft reporting survey instrument and provide engaged stakeholders with the opportunity to comment on the balance of comprehensiveness in a set of core areas against simplicity and ease of completion to help ensure that the data received are of the highest utility.

**8) Given that it will likely not be possible to apply the measurement framework to all available standards, what processes should be put in place to determine the standards that should be monitored?**

As described above, CDISC recommends that existing use cases (e.g., from ISA or DAF) be utilized to determine which standards should be monitored. CDISC recommends that stratification be considered, such that the primary healthcare driver for these measurements can be considered as well as secondary use for biomedical research, patient advocacy groups (e.g., rare disease registries) though with reduced emphasis as compared to primary use cases. Though these are secondary to care, if they are not carefully considered alongside primary drivers, a disconnect may occur between these two strata that could result in a missed opportunity for improving public health as part of a learning health system

**9) How should ONC work with data holders to collaborate on the measures and address such questions as: How will standards be selected for measurement? How will measures be specified so that there is a common definition used by all data holders for consistent reporting?**

CDISC suggests that ONC work with *both* data holders and secondary users to solicit measures, definitions and rules for reporting. By utilizing existing primary and secondary use cases, ONC and stakeholders identified in the report and in CDISC's response to question 5 can work together to address how standards will be selected for measurement and how measures will be specified.

**10) What measures should be used to track the level of “conformance” with or customization of standards after implementation in the field?**

For clarity of guidance, CDISC recommends that conformance and validation measures be created for each area with indication as to whether they are required or recommended. RFC 2119 is a commonly adopted mechanism for such definition. These measures can be helpful in the development and maintenance of validation systems, though ongoing assessments through surveys and other measures will be needed to truly assess conformance, particularly where standards have been customized.

CDISC thanks the ONC for the opportunity to submit comments on the proposed 2017 framework to represent the importance of both primary and secondary needs for standards-based health data and systems interoperability. We look forward to continuing to participate in this important dialogue, thank you for your consideration of this input, and welcome any questions that you have on these comments.

Best regards,



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