3 April 2015

Karen DeSalvo, MD, MPH, MSc

National Coordinator

Office of the National Coordinator for Health IT

Department of Health and Human Services

200 Independence Ave, SW

Washington, DC 20201

Dear Dr. DeSalvo,

On behalf of the Clinical Data Interchange Standards Consortium (CDISC), we are pleased to provide written comments to ONC in response to the Interoperability Roadmap document, Connecting Health and Care for the Nation A Shared Nationwide Interoperability Roadmap DRAFT Version 1.0. CDISC appreciates the opportunity to leverage our members’ expertise in commenting on the Roadmap. We look forward to continuing our work with ONC as a host for the Learning Health Community and a contributor to the HIT Standards Committee.

CDISC is a global standards development organization (SDO). In the U.S. CDISC is registered as a 501(c)(3) non-profit charitable organization. CDISC Europe Foundation (CEF) and its Asian affiliate (CEF Hong Kong Branch) qualifies within the EU as a Research Organization or a small-medium enterprise (SME). CDISC is pleased to have over 350 member organizations across the global research/healthcare arena. CDISC is committed to maximizing the value of medical and research information to streamline the research process and to accelerate the translation of research findings into clinical decisions that benefit patients around the globe. CDISC has been made possible by the efforts and support of thousands of dedicated volunteers, collaborating to realize the CDISC vision and mission. CDISC global consensus-based standards for medical research and its link with healthcare are vendor-neutral, platform-independent and freely available via the CDISC website.

*The CDISC Vision is to inform patient care and safety through higher quality medical research*. The Interoperability Roadmap lays out a plan that builds on one of CDISC’s Core Principles: *Catalyze global collaboration to maximize sharing of information, minimize duplication of effort and foster the evolution of a global learning healthcare system.* CDISC is committed to engaging, supporting and educating key stakeholders in the public and private sectors to ensure standards-based interoperability between EHR’s and Clinical Research Systems and streamlining workflows to accelerate learning health cycles.

Please find our comments in the attached pages. Thank you for the opportunity to comment.

Sincerely,



Rebecca D. Kush, PhD

President and CEO, CDISC

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*Specifically, the Roadmap focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. Although this near-term target focuses on individuals and care providers, interoperability of this core set of electronic health information will also be useful to community-based services, social services, public health and the research community. This includes standardized data elements, such as demographics, that will enable better matching and linking of electronic health information across all systems and platforms.*

*These standardized data elements support better stratification of electronic health information when aggregated to identify and address important issues such as health disparities and also support research and evidence-based personalized medicine. The intersection of clinical and administrative electronic health information is a critical consideration, but is out of scope for the Roadmap at this particular time. Use cases, standards, technologies and tools that leverage both administrative and clinical electronic health information will be an important topic to address in future iterations. There are also many aspects of health IT beyond interoperability that are important and will be critical to a learning health system, including technology adoption, data quality, usability and workflow. However, these topics are out of scope for this Roadmap at this particular time and deserve separate, dedicated attention.*

|  |  |
| --- | --- |
| Interoperability Roadmap Recommended Common Clinical Data Set | Patient Data Gaps |
| * Patient name
* Sex
* Date of birth
* Race
* Ethnicity
* Preferred language
* Smoking status
* Problems
* Medications
* Medication allergies
 | * Laboratory test(s)
* Laboratory value(s)/result(s)
* Vital signs
* Care plan field(s), including goals and instructions
* Procedures
* Care team members
* Immunizations
* Unique device identifier(s) for a patient’s implantable device(s)
* Notes/narrative
 | * Goals for Care
* Direction
	+ Advance directives
	+ Value-based direction
* Caregiver/support team
 |

**CDISC Comments**:

In an effort to ensure that data most important to the patient and to a learning health system is collected in a standard way, we agree that a common clinical data set based on a common taxonomy must be developed and utilized in order to optimize interoperability. CDISC recommends that ONC enable the development of a common clinical data set by sponsoring an industry collaborative among relevant SDOs to establish a consensus-based core dataset that is common to research and healthcare. The following core dataset was established using a global, consensus-based process to support global clinical research; it is called CDISC CDASH and has been a standard since 2008. This dataset represents data that are required for all clinical research studies and paves the way for the clinical research standards that are soon to be required to support an application to FDA for approval of new therapies. Such a dataset that is common to research and healthcare could provide a glide path to a learning health system and interoperability. CDASH can be generated (using existing IHE profiles) from the CCD. The IHE profile RFD is a workflow profile that has been shown to significantly decrease the time to pull structured data in a standard format from EHRs. The synergistic use of HL7 CCD, IHE RFD and CDISC CDASH can currently pave the way to a learning health system. These standards and processes are available now and have been demonstrated.

Clinical Data Acquisition Standards Harmonization (CDASH)

18 Domains

|  |  |
| --- | --- |
| Common Identification Variables | Exposure (EX) |
| Common Timing Variables | Inclusion and Exclusion Criteria (IE) |
| Adverse Events (AE) | Laboratory Test Results (LB) |
| Comments (CO) | Medical History (MH) |
| Prior & Concomitant Medications (CM) | Physical Examination (PE) |
| Demographics (DM) | Protocol Deviations (DV) |
| Disposition (DS) | Subject Characteristics (SC) |
| Drug Accountability (DA) | Substance Use (SU) |
| ECG Test Results (EG) | Vital Signs (VS) |

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*“Will improve the health of individuals and populations. This learning health system will accomplish this by generating information and knowledge from data captured and updated over time – as an ongoing and natural by-product of contributions by individuals, care delivery systems, public health programs and* ***clinical research*** *– and sharing and disseminating what is learned in timely and actionable forms that directly enable individuals, clinicians and public health entities to separately and collaboratively make informed health decisions…The proximal goal of a learning health system is to efficiently and equitably serve the learning needs of all participants, as well as the overall public good.*

*Taken from the Learning Health Community’s Preamble”*

**CDISC Comment:** We comment ONC for including the Learning Health Community’s core values in this document and completely support them. CDISC hosts the Learning Health Community and leads the Essential Standards to Enable Learning (ESTEL) initiative. We encourage ONC to include the standards and products that CDISC has developed over the past 17 years, linking them with healthcare standards to facilitate a learning health system. This could accelerate the process, which we feel is ready to be supported now and should not be delayed or deferred.

On Pg. 24:

**LHS Requirements**

**Building Block**

**Core Technical Standards and Functions:**

*J. Consistent Data Formats and semantics: Common formats (as few as necessary to meet the needs of learning health system participants) are the bedrock of successful interoperability. Systems that send and receive electronic health information generate these common formats themselves or with the assistance of interface engines or intermediaries (e.g., HIOs, clearinghouses, third-party services.) The meaning of electronic health information must be maintained and consistently understood as it travels from participant to participant. Systems that send and receive information may or may not store standard values natively and therefore may rely on translation services provided at various points along the way.*

*M. Accurate identity matching: Whether aggregated in a repository or linked "just in time," electronic health information from disparate sources must be accurately matched to prevent information fragmentation and erroneous consolidation. As a learning health system evolves, more than individual/patient-specific information from health records will be matched and linked, including provider identities, system identities, device identities and others to support public health and* ***clinical research****.*

**CDISC Comments**: CDISC agrees with the above section of the Roadmap and encourages ONC to look at the Shared Health and Research Electronic Library (SHARE) as a repository that could support EHR-enabled clinical research. Such activities have been demonstrated in Europe and could readily be brought to the U.S.

On Page 54:

 *Table 4: Critical Actions for Care Providers Partner with Individuals to Deliver High Value Care*

*D6. Innovation and Generation of New Knowledge and Evidence.*

*2015-2017*

1. *Call to action: Providers currently engaged in* ***clinical research*** *and quality improvement should work together with research institutions and other public and private stakeholders to establish a strategic plan for research and the generation of new knowledge.*

*2018-2020*

1. *Call to action: Providers should further engage with research community and should routinely offer patients and families participation in research and quality improvement programs.*

*2021-2024*

*5. Call to action: Technology developers should enable patient-centered and future clinical research methods for accelerated deployment of research findings into clinical care.*

**CDISC Comment:**

Since 2000, CDISC has been collaborating with key clinical research stakeholders around the world, building consensus on Global Clinical Research Standards that are currently being required by Health Regulators including Japan PMDA and US FDA. CDISC is in full support of this Call to Action. We believe clinical research is an important component of a learning health system where healthcare can inform clinical research as well as clinical research informing healthcare.

**CDISC would prioritize the following Use Cases:**

**#56**

**#16**

**#20**

**CDISC agrees with HIMSS in support of the following recommendations.**

***Building Block #1: Rules of Engagement and Governance***

* **HIMSS supports a public-private interoperability governance process that provides a market mechanism to ensure better coordination of industry interoperability and standards development efforts**

The new governance process needs to be an action-oriented group, focused on getting the desired health system outcome of widespread interoperability and not simply talking about how to get there. Rather than having one organization as a convener of this joint public-private sector stakeholder effort, there should be a governing council or federation created that allows each sector or stakeholder group to have a voice in guiding these plans and processes forward in the advancement of interoperability.

There are several considerations that need to be included in the development of an interoperability governance process. These include:

* Clarity and consistency throughout the process with stated goals and objectives.
* A unified direction and defined priorities.
* The ability to balance existing health information exchange efforts and innovative emerging capabilities.
* The harmonization of like work, that allow for minimum duplication.
* Inter-network interoperability.
* A clear, objective, and fair process that balances stakeholder representation.
* Offering incentives for adoption.

The interoperability initiative domains that need to be represented in developing such a coordinated governance framework should include:

* Networks (such as DirectTrust, Commonwell, eHealth Exchange, State/Regional HIOs, Surescripts)
* Testing Bodies/Certifiers/Accreditors
* Standards Development and Profiling Organizations
* Consortia/Trade Groups
* Public-Private Collaboratives
* Professional Societies (e.g. AMA, ANA, AAFP, ACP)

***Building Block #2: Supportive Business, Clinical, Cultural, and Regulatory Environments***

HIMSS supports ONC’s approach in the Interoperability Roadmap of looking at public and private policy levers beyond Meaningful Use to foster interoperability and health information exchange.

In order to support and recognize the achievements of projects, healthcare delivery organizations, and individuals that enhance health IT, HIMSS recommends that notable advancements are rewarded to ensure that ONC can capitalize on both public and private sector policy levers.

In relation to clinical research FDA is requiring CDISC standards for electronic regulatory submission of human clinical trial information as well as encouraging use of standards based interoperability approaches.

* **Health IT needs to be carefully and precisely woven into user workflow with a focus on shared decision-making in order to move towards a more interoperable system**

HIMSS recognizes the importance of a successful workflow, specifically when providers are heavily engaged in their clinical environments. In regards to evaluating workflow, the levels of interoperability, as defined in the [HIMSS Health IT Interoperability Definition](http://www.himss.org/files/FileDownloads/HIMSS%20Interoperability%20Definition%20FINAL.pdf), could be used to define levels of health IT achievement in specific workflows. For any vendor or healthcare delivery organization, the applicable workflows would be evaluated based on the ability to execute data flow and end-to-end exchange. A true qualification level will be based on the weakest link. Level 0 is the default until an organization or product can prove its ability to act in accordance with “foundational” standards for the parts of the workflow it executes.

***Building Block #4: Certification and Testing to Support Adoption and Optimization of Health IT Products and Services***

HIMSS agrees with ONC’s approach that certification should be used to test that health IT systems and devices conform to standards, and also to certify that the technology has the ability to interoperate with other data sources so that users can exchange and use information from other systems. Our vision of an interoperable health IT ecosystem makes the right data available to the right people at the right time across products and organizations in a way that can be relied upon and meaningfully used by recipients.

Figuring out how to consistently represent data has been a complex undertaking that requires various information systems and technologies produced independently by a multitude of manufacturers to employ standards and specifications by which they document healthcare details and uniformly exchange them. Ensuring that those standards are adequately incorporated into health IT products to accomplish their objectives is the make-or-break step in the quest for interoperability.

For Building Block #4, we emphasize the following points:

* **HIMSS supports the idea of a well-coordinated, diverse, and complementary set of certification and testing programs that are administered by a variety of different entities, both inside and outside of government**

Since 1998, IHE has achieved consensus on a common framework for going about the business of applying health IT standards to the real world. Its principal contribution to interoperability has been to narrow down (constrain) how pivotal information of a health IT system is conceived and packaged when processing that information and using it for clinical care. IHE calls the solutions to a particular use case an “Integration Profile” and the specifications are described in a “[Technical Framework](http://www.ihe.net/Technical_Frameworks/).”

This process—developing Integration Profiles for clinical and IT functions, providing the specifications to implement them, and operating from clinical scenarios to ground them in the way health professionals conduct their business— has gotten the health sector closer to pragmatic interoperability.

To date, CDISC has developed with IHE 10 integration profiles.

* **HIMSS is pleased that the Interoperability Roadmap calls for establishing innovative certification and testing programs for new technologies as well as new settings of care**

HIMSS supports the need for certification and testing programs for provider and non-provider systems such as network technologies and resources, payer systems, population health resources and systems employed for patient engagement as all of these different technologies become part of a Learning Health System. Certification in support of a Learning Health System must be specific and focused on the areas that have the greatest impact on interoperability.

Overall, to achieve the greatest success, broad alignment and consolidation of current industry efforts will more rapidly ensure consistent adoption of standards and policies for health IT applications used across settings of care. Moreover, ONC should continue to work with established standards bodies (including IHE, CDISC, HL7, DICOM and others) to develop, harmonize and disseminate comprehensive standards that provide the foundation for interoperability certification criteria.

***Building Block #5: Core Technical Standards and Functions***

HIMSS supports the ideas advanced in the Interoperability Roadmap about how foundational the consistent implementation, use of standards, and broad access to technology services are to a Learning Health System.

The national interoperability governance process has a prominent place in developing core technical standards and functions. HIMSS supports an interoperability governance that is a coordinated effort between the federal agencies and the private sector, where ONC helps to set national priorities and focus, and then empowers private sector stakeholder groups to come together (with ONC and other federal agencies) to implement and enable interoperability efforts.

In this model, detailed standards development and generation of other deliverables is left to organizations, vendors, and others outside the federal governance process. HIMSS and our healthcare community colleagues can offer important expertise and resources to ensure all stakeholders’ perspectives are included as Interoperability Roadmap milestones are developed.

For core technical standards, HIMSS encourages ONC to focus on being the convener and a facilitator that drives:

* + *Consensus* with key stakeholder groups representing the breadth of the health IT ecosystem on core standards and technology, as well as expected timeframes.
		- *Harmonization* of redundant and duplicative standards, and other guidance to healthcare delivery organizations, vendors, and developers to decrease confusion.
		- *Delivery* of proven detailed and domain specific (local) standards, best practices, and implementation guides by teams led by stakeholder consortia including SDOs, professional organizations, technology consortia, and advocacy organizations as appropriate, comprehensively covering the domains making up the full health IT ecosystem, using core standards and technology building blocks where possible.
		- *Inclusion* with roles for all stakeholders.

“Through coordinated governance,” is an often-used phrase in this section of the Interoperability Roadmap. Given the frequency of its use, HIMSS encourages ONC to utilize that process to answer many of the specifics surrounding technical standards and functions. Since the governance process should include all the relevant interoperability stakeholder organizations, using that process to finalize many of these questions is the best way to proceed.

For Building Block #5, HIMSS emphasizes the following points:

* **HIMSS supports the development of the Interoperability Standards Advisory and the process outlined in the Interoperability Roadmap for publishing an annual update of the best available standards and implementation guides**

The Standards Advisory is a sound model to use for enabling priority functions in a Learning Health System. The most appealing part of the model is its flexibility in providing a list of the best available standards—there are no mandates for technology developers to use particular standards, only publication of the best available standards and facilitation of competition between standards for selection. Technology vendors, certification programs, and governing bodies can choose to use or not to use the standards on the list. HIMSS is diligently working to prepare its public comments on the Advisory document, and will have substantive comments to deliver in early May 2015.

Although the Interoperability Standards Advisory is a good model, HIMSS would like to note that there are several private sector processes already underway to publicize and highlight best available standards. ONC should strive to ensure that those processes that are working are not interrupted, but should be capitalized upon in the development of the Interoperability Standards Advisory.

As noted in the Interoperability Roadmap, standards development organizations (SDOs) such as IHE and HL7 and CDISC are collaborating on several projects, but generally where applicable standards are not widely implemented, and may require additional curation, refinement, or harmonization.

Since the governance process for the Interoperability Roadmap emphasizes and empowers private sector stakeholder groups to come together (with ONC and other federal agencies) to implement and enable interoperability efforts, ONC should try to find a way to capture what is already working in standards development and fill the gaps with this new effort.

* **HIMSS encourages ONC to use the new interoperability governance process to finalize the Priority Interoperability Use Cases**

The list of proposed use cases presented in the Interoperability Roadmap is a good start for this effort. HIMSS presents several ideas below about how to look at and evaluate the use cases in the draft document. However, we suggest that ONC use the coordinated governance process to refine and prioritize the list and then arrange it for development of technical standards, policies and implementation specifications.

HIMSS notes several principles for ONC and the governance activity to consider as this process moves forward:

* Ensure that use cases are included that focus on standards related to quality measurement and quality improvement.
* Move beyond the flow of data for care and health processes in the use cases to include the flow of data for public health, quality, billing, and other components. These other domains need to be considered when discussing use cases to ensure that the data is interoperable.
* Add a person-centric theme to the use cases so that they are not solely focused on health system or population health-related improvements.
* Ensure that the use cases demonstrate the flow of patient data, as this should allow for more rapid patient-centered improvements to be implemented.
* Design the use cases to advance a more collaborative care framework between providers and patients and not be focused on use cases for transactional purposes as a way to measure interoperability.