March 7, 2024

Monica M. Bertagnolli, MD
Director
U.S. National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

Re: NIH Request for Information (RFI) on NIH Strategic Plan for Data Science (2023-2028)
Submitted electronically to: strategic-plan-rfi@od.nih.gov

Dear Director Bertagnolli:

The response of Health Level Seven (HL7) International regarding the RFI on NIH’s Strategic Plan for Data Science (2023-2028) is below. NIH highlights increased utilization of Health Level Seven International’s Fast Healthcare Interoperability Resources (HL7® FHIR®) throughout its plan and notes on page 9 that, “a key to success in data interoperability is the development and use of agreed upon standards.”

HL7 lends its cooperative hand at the highest levels to NIH in making these goals a reality. HL7, its Work Groups and FHIR Accelerators are addressing the RFI topics to: (1) increase data sharing, integrity and security; (2) modernize data infrastructure; (3) advance data science; (4) develop AI capacity; and (5) promote cross-disciplinary collaborations that accelerate scientific discovery. This includes public/private partnerships and alignment of activities across the Federal sector. This letter includes perspectives from our leadership, Policy Advisory Committee, Public Health Work Group and the Vulcan HL7 FHIR Accelerator, connecting clinical research and healthcare. We would welcome further dialogue with you about this topic that is critical to the future of our nation’s healthcare. Should you have any questions about the attached, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of HL7 International at cjaffe@HL7.org.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
HL7 International

Julia Skapik, MD, MPH
Board of Directors, Chair
HL7 International

1 National Institutes of Health (NIH), NIH Strategic Plan for Data Science (2023-2028);
HL7 Comments: Specific RFI Themes

HL7’s overarching NIH RFI comments and relevant resources and expertise our organization can offer NIH, are listed below. Additionally, specific comments are also offered below for the overarching goals of the NIH Strategic Plan for Data Science (2023-2028):

Goal 1: Improve Capabilities to Sustain the NIH Policy for Data Management and Sharing
Goal 2: Develop Programs to Enhance Human Derived Data for Research
Goal 3: Provide New Opportunities in Software, Computational Methods, and Artificial Intelligence
Goal 4: Support for a Federated Biomedical Research Data Infrastructure
Goal 5: Strengthen a Broad Community in Data Science

Section I: Overarching HL7 RFI Comments

HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena. As such, we stand ready to support NIH in better understanding the promises, complexities and challenges at the crossroads of standards, interoperability and data science and in effectively implementing the initiatives proposed in the NIH Strategic Plan for Data Science (2023-2028).

Particularly, HL7 notes and strongly supports the overarching goal listed on page 17 of the NIH’s Strategic Plan for Data Science (2023-2028) to, “further advance NIH’s goal to bridge the gap between healthcare settings and applied and clinical research, NIH will strengthen the use of ontologies with vocabularies and terminologies (e.g., SNOMED, LOINC) and exchange standards such as FHIR. NIH will partner with health data standards bodies and organizations and other federal agencies that work with health data standards.”

HL7 also supports implementing other overarching initiatives proposed in the NIH Strategic Plan for Data Science (2023-2028) such as:

- **Maximizing the Power of HL7 FHIR** - Promoting development, training, and adoption of FHIR to enable further tools for clinical research and for data exchange in research infrastructure, cohort discovery, and applied real world research. Leveraging and building on the HL7 FHIR standard to exchange and share not only EHR data, but also phenotypic data obtained from clinical and genomics studies, clinical records and related social determinants of health data, and eventually other data from medical devices and wearable sensors, provides promising new avenues for clinical research.

- **Interoperability** - Creating interoperable data storage and management systems, including in the cloud. Developing methods to promote computational interoperability across data repositories and knowledge bases.

- **Priority Disease Standards** - Developing new programs to support innovative approaches in data curation, harmonization, and validation and increasing support for communities to develop and implement new standards in priority disease areas.
Section II: HL7 Standards Divisions, Work Groups and Critical Resources

- **HL7 Standards Development and Implementation Divisions** – HL7 has well-established Standards Development and Standards Implementation Divisions that are key resources for NIH in executing a robust, informed NIH Strategic Plan for Data Science (2023-2028). The Divisions address industry needs and increase the impact of HL7 standards. The HL7 Standards Development Division focuses on the development and maintenance of HL7 specifications while the Standards Implementation Division concentrates on helping communities discover, access and understand the specifications as well as test their implementations. Please be in touch with the following HL7 executives to address specific standards issues:
  - Daniel Vreeman, DPT; HL7 Chief Standards Development Officer (Dan@hl7.org)
  - Diego Kaminker, HL7 Deputy Chief Standards Implementation Officer (Diego@hl7.org)

- **HL7 Work Groups, Accelerators and Other Efforts** - HL7 Work Groups, FHIR Accelerators and special initiatives are conducting cutting-edge healthcare, interoperability and standards work very relevant to the NIH’s Strategic Plan for Data Science (2023-2028). We urge NIH to seek out the practical and field-leading expertise of these HL7 groups. HL7 executive and policy leaders can facilitate structured, focused dialogue. A few examples of these HL7 groups are below. And, a full HL7 Work Group listing can be accessed at: [http://www.hl7.org/Specia/committees/index.cfm?ref=nav](http://www.hl7.org/Specia/committees/index.cfm?ref=nav).

  - **AI Initiative** – HL7 has an established AI Initiative and Taskforce, which can be of specific help to NIH and its efforts. HL7 is working on AI in collaboration with multiple partners -- in both the public and private sectors -- to develop standards, Implementation Guides (IGs) and related policies to ensure the reliability, safety and security of AI.

  - **Learning Health Systems Work Group** – HL7 has a specific Work Group focused on developing a Domain Analysis Model (DAM) for Learning Health Systems as related to the adaptive systems described in the Institute of Medicine (IOM) reports. This includes the development of abilities in such Learning Health Systems to make use of real time data and analytics and making such information available to everyone, including patients. Standards requirements analysis by the Learning Health Systems Work Group using this DAM will inform updates and development of HL7 standards to enable a learning health system. Information on the HL7 Learning Health Systems Work Group can be accessed at: [https://www.hl7.org/Special/committees/lhs/index.cfm](https://www.hl7.org/Special/committees/lhs/index.cfm)

  - **Public Health Work Group and Helios** – Issues of public health and research are central in the NIH’s Strategic Plan for Data Science (2023-2028). Links to the HL7 Public Health Work Group and HELIOS FHIR Public Health Accelerator (HELIOS) are at:
    - [http://www.hl7.org/Special/committees/pher/index.cfm](http://www.hl7.org/Special/committees/pher/index.cfm)
    - [https://confluence.hl7.org/display/PH](https://confluence.hl7.org/display/PH)
Security Work Group – Given the prominence of data management, sharing, harmonization and interoperability issues in the NIH’s Strategic Plan for Data Science (2023-2028), HL7 highlights the resource of its Security Work Group. Information on the HL7 Security Work Group can be accessed at: http://www.hl7.org/Special-committees/secure/index.cfm

CodeX Acclerator (Cancer Issues) – HL7 recommends NIH examine the FHIR-related activities in the Cancer domain – e.g., HL7 CodeX and related federal and private investments in Cancer Moonshot-related work. These investments from development through implementation plus ongoing maintenance support “rapid” growth of FHIR-based information exchange specifications in those domains. The maintenance over time is critical as FHIR, system implementations and public health or research work in and of itself evolves over time. More information on the CodeX Acclerator can be found at: https://confluence.hl7.org/display/COD.

Gravity Project Acclerator (SDOH Issues) – HL7 encourages NIH to explore HL7 efforts related to environmental determinants of health (EdoH) and social determinants of health (SDoH) efforts, like the Gravity Project. More information can be found at: https://thegravityproject.net/.

Vulcan Acclerator (Clinical Care and Research) – HL7’s Vulcan FHIR Accelerator and its diverse membership works to close the gap between clinical care and clinical research through: bridging existing gaps, strategically connecting industry collaborations, maximizing collective resources and delivering integrated tools and solutions. More information about HL7’s Vulcan FHIR Acclerator can be found at: https://hl7vulcan.org/

HL7 WGM Education and Training Opportunities - HL7 encourages NIH to explore opportunities for key interested parties to convene and work together in real-time. HL7 highlights that its Working Group Meetings (WGMs) are valuable networking and learning opportunities for our communities. HL7 also encourages NIH to explore opportunities to offer resources and experiential learning to the research community (and, concurrently, public health) where possible. The September 2024 WGM will have additional sessions and education for people with non-technical backgrounds and varying levels of experience and expertise in interoperability and standards.

Section III: Goal-Specific HL7 RFI Comments

Specific comments are offered below related to the overarching goals of the NIH Strategic Plan for Data Science (2023-2028).

Goal 1: Improve Capabilities to Sustain the NIH Policy for Data Management and Sharing
• **Policy Incentives and Levers** - HL7 recommends NIH consider incentives and/or policy levers for any revised or new data management and sharing policies executed under its Strategic Plan for Data Science (2023-2028).

• **Knowledge Management and Concordance (FHIR)** - HL7 recommends that NIH evaluate how HL7 FHIR data standards and relevant FHIR Implementation Guides (IG) could be used for knowledge management and concordance, as it relates to data management and sharing. HL7 stands ready to aid NIH in this task.

• **Data Steward Program Coordination** - HL7 encourages NIH to explore ways in which any newly established data steward program could be coordinated with other Network of the National Library of Medicine (NNLM) activities, such as vocabulary efforts (e.g., existing vocabulary work via the Value Set Authority Center (VSAC)).

• **Public Health Authorities, Bidirectional Data Exchange and HL7** - HL7 highlights the role of Public Health Authorities (PHAs) in providing important data for healthcare research efforts and encourages NIH to consider support for a bidirectional exchange of research findings, so that the supplying organizations (i.e., PHAs) benefit from the secondary use of public health data. Additionally in relation to PHAs, HL7 urges NIH to consider whether there are opportunities to use HL7 and its associated data models for sharing and integrating data sources.

• **Enhancing NIH and ONC Coordination (USCDI and USCDI+)** - HL7 notes that NIH and the U.S. Office of the National Coordinator for Health IT (ONC) are engaged in U.S. Core Data for Interoperability Plus (USCDI+) initiatives. HL7 recommends NIH and ONC consider efforts to further integrate and extend the core data that is included and iterated upon via the U.S. Core Data for Interoperability (USCDI) to USCDI+, and in doing so, meet the purposes of multiple agencies and key interested parties. HL7 recommends NIH seek out the expertise of the HL7’s US Realm Steering Committee and Vulcan FHIR Accelerator in efforts relevant to this goal. More information about the US Realm Steering Committee can be found on-line at: https://www.hl7.org/Special/Committees/usrealm/index.cfm

**Goal 2: Develop Programs to Enhance Human Derived Data for Research**

• **Data Validation and Quality** - Regarding programs to enhance human derived data for research, HL7 recommends a strategic emphasis on data validation, as well as data quality, to ensure that efforts are realized. Some examples from public health include:
  o The American Immunization Registry Association (AIRA) has focused on addressing quality in immunization information systems (IIS) and may have lessons learned to share. AIRA is also very much involved HL7 Work Groups and HL7 HELIOS FHIR Accelerator efforts.
  o The Association of Public Health Laboratories’ (APHL) efforts around the electronic case reporting (eCR) data quality initiative are noteworthy.
• **HL7 Expertise: Primary and Secondary Data Uses** - HL7 and its Public Health Work Group in particular, has valuable expertise regarding challenges with primary and secondary data uses. We encourage your consultation with our organization. HL7 stands ready to shed light on this important issue and share lessons learned. A relevant example is HL7’s creation of the Clinical Registry Extraction and Data Submission (CREDS) IG. Participants and authors navigated reliance on highly specialized/proprietary vocabularies (e.g., in the research community) alongside a desire to align with classifications/vocabularies for clinical use. The IG authors examined over 2,000 codes used in a single registry to identify opportunities for concordance or mapping. More information on the CREDS IG can be found at: [https://build.fhir.org/ig/HL7/fhir-registry-protocols-ig/index.html](https://build.fhir.org/ig/HL7/fhir-registry-protocols-ig/index.html).

• **Standards for Re-Use of Data at the Point-of-Care** - HL7 emphasizes the importance of encouraging the data science and research communities to implement and require the use of standards to reuse data captured at the point of care. If research efforts continue to create their own definitions and practices in isolation, this significantly hampers the ability to use real-world data and creates additional barriers for participation in those activities.

**Goal 3: Provide New Opportunities in Software, Computational Methods, and Artificial Intelligence**

• **HL7 and Artificial Intelligence (AI) Efforts** - HL7 is supportive of NIH plan-related activities to ensure artificial intelligence (AI) is developed equitably, inclusively and with minimal biases. We highlight our HL7 AI Initiative, which can be of specific help to NIH and its efforts. HL7 is working on AI in collaboration with multiple partners -- in both the public and private sectors -- to develop standards, Implementation Guides (IGs) and related policies to ensure the reliability, safety and security of AI. We are happy to link and connect NIH with the leadership of the HL7 AI Initiative.

• **Federal Data Initiative Alignment** - HL7 is supportive of NIH aligning with other data modernization efforts in the federal sphere and will collaborate in advancing this NIH Strategic Plan for Data Science goal.

**Goal 4: Support for a Federated Biomedical Research Data Infrastructure**

• **Lessons from Public Health** - HL7 is encouraged to see the objectives in Goal 4, and notes that public health’s data modernization efforts have been similarly focused. We encourage you to engage with the HL7 Public Health Working Group for on-going information sharing.

**Goal 5: Strengthen a Broad Community in Data Science**

• **HL7 WGMs and Building Community** - HL7 reiterates the value of the quarterly HL7 Working Group Meetings (WGMs) for shared learning and networking. More information on HL7 WGMs can be accessed at: [http://www.hl7.org/events/workgroupmeetings.cfm?ref=nav](http://www.hl7.org/events/workgroupmeetings.cfm?ref=nav)

• **Links Between Public Health Informatics and Research** - There are certain roles in public health that have fostered naturally strong informaticists (e.g., epidemiologists). HL7 encourages
NIH to explore whether there are similar roles in research, and what lessons can be learned from public health. For example:

- Today, in public health, much of the informatics communications and training is targeted to epidemiologists, but public health needs for that same training and awareness amongst others (e.g., Information technology professionals, legal counsels and privacy experts). Unfamiliarity with modern data solutions or exchanges can, at times, lead to delays in pilots or projects getting off the ground. HL7 encourages NIH to evaluate the necessary multidisciplinary training and related participation incentives that will support its goals,