



Health Level Seven[®] International
Unlocking the Power of Health Information

An ANSI accredited standards developer

October 5, 2012

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2012-N-0780

To whom it may concern:

As published in Docket No. FDA-2012-N-0780, The Food and Drug Administration (FDA) has announced a meeting entitled “Regulatory New Drug Review: Solutions for Study Data Exchange Standards,” the purpose of which is to solicit input from industry, technology vendors, and other members of the public regarding the advantages and disadvantages of current and emerging open, consensus-based standards for the exchange of regulated study data. FDA also seeks input from stakeholders and other members of the public.

In conjunction with key stakeholder communities, HL7 International has been actively developing standards to improve interoperability between clinical research and healthcare for over ten years. Early implementations used HL7 V2.5 for clinical trial transactions. More recently, HL7 V3-based messaging and document exchange has emerged as a best practice, endorsed by regulatory agencies, sites and sponsors alike, for representation of clinical trial transactions. This has been particularly driven by growing acceptance of the BRIDG model, produced by the Biomedical Research Integrated Domain Group within the Clinical Data Interchange Standards Consortium (CDISC), and maintained in close collaboration with the Regulated Clinical Research Information Management (RCRIM) Work Group within HL7 International.

This collaborative approach helps to ensure that the underlying HL7 standards and the BRIDG model continue to evolve to meet stakeholder needs and greater consistency in the use of terminology for communication in the regulated clinical space. This approach also has the benefit of being based on the HL7 V3 Reference Information Model (RIM), which harmonizes the communication of healthcare data. The RIM is shared across all clinical domains and, as such, provides a consistent basis from which messages and documents are created for different domains. The result is standards for communication of clinical and research data that have a high degree of consistency, re-use, and interoperability.

HL7 International provides a wide variety of RIM-derived standards to meet business process needs in the clinical research domain including V3 messages and structured documents based on HL7 Clinical Document Architecture (CDA). CDA is the fastest growing standard for clinical documents and is being widely implemented to meet Electronic Health Record and Meaningful Use requirements. HL7 offers a template repository to assist in the rapid development and re-use of CDA templates.

3300 Washtenaw Ave., Suite 227 • Ann Arbor, MI 48104-4261 • USA
Office: +1 (734) 677-7777 • Fax: +1 (734) 677-6622 • E-mail: hq@HL7.org • Website: www.HL7.org

Health Level Seven and HL7 are registered trademarks of Health Level Seven International. Registered in the U.S. Trademark Office.

By using combinations of these standards, the collection, sharing and communication of information for clinical research and healthcare can address a variety of needs. HL7 standards offer a variety of options to send structured data with or without human readable text in a messaging or document paradigm. These standards also offer the potential to streamline and automate the collection of clinical research information that is maintained in EHRs.

HL7 International is also excited about its promising future standard, Fast Healthcare Interoperability Resources (FHIR), which is inspired by the strengths of V2 and V3 and derived from the RIM. Utilizing a collection of predefined "resources", this developing standard and its associated methodology is targeted to provide standards, for both messages and documents, that are easier to implement with capability to address emerging technology such as mobile health.

HL7 International believes that FDA should consider the use of a variety of HL7 standards, both messaging and documents, as they are quite suitable for the FDA's needs. The use of a message or a document and the specifics of the standards should be based on the use case and form of data in the exchange. For use in the Clinical Research space, however, we believe this must be done in concert with CDISC and CDISC data structures. We believe that the best approach to standardization would be the result of consensus-based collaboration.

In terms of being open, the CDISC BRIDG model for clinical research has always been available without charge. All of HL7's standards and some other HL7 intellectual property is also in the process of being made available without charge. In terms of standards development, the clinical and clinical research communities are welcome to participate in the development of these standards at little or no cost.

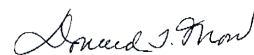
HL7 and CDISC standards also have the benefit of growing international acceptance and engagement.

Thank you for the opportunity to address the issues with respect to the future standards for the exchange of regulated study data.

Sincerely,



Charles Jaffe, MD, PhD, FACP, FACMI
Chief Executive officer



Donald T. Mon, PhD
Chairman of the Board