Product Stability Data Pilot Project Completion Announcement

Summary: The Food and Drug Administration (FDA) announces the completion of a pilot that began in 2006 and was conducted to test the Health Level 7 (HL7) data interchange standard for the submission of product stability data to FDA. Participants in the pilot project drafted an Implementation Guide and an Input Tool Requirements Specification. Participants generated stability messages for several products through use of previously submitted stability data. Stability messages were then viewed in an analysis and data presentation tool developed for the FDA. Deficiencies in the message schema were identified and remedied in release 2 of the eStability message. Release 2 will be balloted as a Draft Standard for Trial Use (DSTU).

Product Stability Data Pilot Project

1. Background

HL7 is an international, open, American National Standards Institute (ANSI) accredited standards development organization that focuses on standards for the exchange of information related to health care. The Regulated Clinical Research Information Management (RCRIM) technical committee in HL7 has developed an XML standard for the exchange of product stability data based on the HL7 version 3 reference information model. The Stability Data Standard was adopted by HL7 by a vote of the full membership in May 2005 and was adopted as an ANSI standard in October 2005. FDA is currently considering the adoption of the standard.

2. Pilot Goals

The goal of the pilot was to evaluate product stability data submitted in electronic format as a method to consistently present data to the agency and promote a more efficient review.

3. Pilot Objectives

The objectives of the pilot project were to assist in the evaluation of the data interchange standard, provide data for testing the analytical tools designed to facilitate the review of product stability data, and obtain feedback from reviewers and pharmaceutical companies on the creation and use of standardized product stability data. To facilitate achieving the pilot goals, members addressed the following tasks:

a) Reviewed the Implementation Guide (IG) and made clarifications where necessary.

b) Developed nomenclatures for codes.

c) Specified input tool requirements to convert stability data to XML.

d) Tested open source XForm and Excel input tools that were developed for the pilot program.

e) Generated stability data in XML on data that were previously submitted. The XML files were then demonstrated to the FDA in the iStudyViewer Prototype from Up-To-Data.

f) Identified impediments in the stability message schema that were corrected in revised schema. The parts of the message that presented problems were:

   a. The use of PQ as the data type for testing results.

   b. The expiration Time value did not comply with ISO 8601 format for duration.

   c. It was possible to create messages that were syntactically correct, but failed semantically and could not be graphed in the viewer that prescribe to certain semantics. Optional nesting of storage conditions in the StudyOnBatch tag allowed for more than one storage condition to be present in a file.

   d. The component hierarchy in the specification section of the message must match the component hierarchy in testing section of the message.

   e. A method to link related stability messages is necessary.

4. Pilot Project Conclusions and Recommendations

The pilot project evaluated the Stability Data Standard, and generated XML messages from existing data for testing the viewer tools designed to facilitate the review of product stability data. An input tool specification was developed but none of the open source tools provided all of the desired functionality. It was determined that vendor involvement to develop easier ways to convert the data to XML is essential to the successful adoption of the Stability Data Standard. The deficiencies in the message were addressed in release 2. Release 2 allows messages to be associated and links the storage directly to the StudyOnBatch and other identifier changes. The members in the pilot recommend that release 2 be balloted and converted to a DSTU.

Follow Up Schedule

Activities	Target Date
Revise IG	3/17/08
Scope Statement	3/18/08
Revise Input Tool Requirement	3/31/08
Submit for Ballot (IG and release 2)	6/29/08
Vendor meeting	7/16/08
Ballot Vote (IG and release 2)	8/4/08 to 9/8/08
Ballot Reconciliation (IG and release 2)	9/14-19/08

For Further Information

Department of Health and Human Services, Food and Drug Administration [Docket No. 2006N–0181]

http://www.fda.gov/oc/datacouncil/stability.html

http://www.estability.org/

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