

Paper 353-2007

SAS Response: Concepts and Thoughts for a CDISC /FDA Pilot and Interfacing with HL7 RCRIM Projects

Edward Helton, SAS Institute Inc.

ABSTRACT

Enhancing institutional memory in the industry is a needed event. Standard data, data collection and data transmission is core to institutional memory for the biomedical research process. The first iteration of CDISC/FDA Pilot performed in 2006 was a strategic event for CDISC in demonstrating the semantic interoperability of the CDISC models when applied to an eCTD /E3 submission. Refinements through re-submission of the first iteration are underway regarding Define.XML, the working relationship between SDTM derived and ADaM analysis data set, ODM metadata extensions, etc. The second iteration of the pilot is gearing up and it has a focus on safety. We focus on the use of submitted sponsor trial data to FDA for the treatment of pediatric hypertension to address cross study, cross pharmacological class and cross therapeutic area product safety.

In parallel, CDISC has initiated the CDASH Project(a FDA Critical Path Project) to facilitate standards for data collection. Similarly HL7 RCRIM is initiating the CDISC Message project to explore and evaluate the movement of data for the FDA in ODM XML or as a HL7 V3 XML message. SAS has been very supportive of these pilots and projects. This presentation offers an update of their progress and the use of SAS.

No paper was submitted for publication.

CONTACT INFORMATION

Edward Helton
SAS Institute Inc.
ed.helton@sas.com

SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc. in the USA and other countries. ® indicates USA registration.

Other brand and product names are trademarks of their respective companies.