SETTING THE RECORD STRAIGHT

The Future of ODM, SDTM and CDISC

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When rumors increase, and when there is an abundance of noise and clamor, believe the second report. Alexan

In recent weeks, there have been a number of rumors about the Clinical Data Interchange Standards Consortium use by the Food and Drug Administration (FDA). These whispers suggest that the Study Data Tabulation Model (that the Operational Data Model (ODM) should no longer be used. The rumors have caused confusion at best and This is a second report—an attempt to clarify what's happened and how the industry should move forward.

CDISC, to state the obvious, is a *global* standards organization. While the FDA plays a vital role in the drug de other global stakeholders that use CDISC standards. CDISC's influence extends as far east as Japan, Australia and Europe.

An International Agenda

Just as biopharmaceutical communities are expanding globally, CDISC is being asked to meet with regulatory a representatives in Singapore, India and Brazil. CDISC has Liaison A status with the International Standards Organ works closely on global standards harmonization with CEN, ISO and HL7 as a member of the Joint Initiative Cou

The FDA, naturally, receives and processes vast amounts of information. This information is currently submitte files (XPT), HL7 V3 messages and Excel files. The FDA has stated that, going forward, HL7 V3 messages are the health care information. HL7 V3 messages are already in use to carry content to the Janus data warehouse, the stru integrated case safety report (ICSR) and regulated product submission (RPS) messages.

Currently, the FDA eCTD guidance specifies the use of SAS transport files for the transport of clinical observat major limitation. The flat file format of SAS transport files does not inherently capture relationships between stud

design. Adding these relationships post-facto is invariably incomplete, inefficient and inconsistently handled.

Long Live SDTM

As a result, as FDA has stated since 2004, it would like to move away from the SAS transport file format towar clinical observations that inherently relate the observations both with each other (such as the HL7 ICSR) and with collection. This will ensure such data can be reliably and consistently conveyed to FDA information systems now currently these important relationships are not often captured (or are captured inconsistently) at the point of data c systems (EHRs) come into more widespread use, the opportunity to capture such relationships automatically at the will increase.

So why the sudden flurry of concerns? Why the muddying of the waters?

The FDA has stated that SDTM will be used for the content for electronic submission of data tabulations. For th files will be the mechanism to transport the SDTM data to the agency. At that point, there will be a transition in th FDA from SAS transport to HL7 V3 messages. SDTM content will *not* disappear. It may well evolve during this t disappear.

By aligning the SDTM content with the HL7 transport technology and the HL7 Reference Information Model (the SDTM standard and provide industry and regulators with a more robust content standard.

Indeed, SDTM is so well received by FDA reviewers that they have become familiar with its structure and have internal training. CDISC will ensure FDA personnel have adequate training in the use of SDTM, ADaM and adva delivered using face-to-face as well as computer-based virtual learning methods. This contract is a testament to the

Future ODM Role

The work on developing the HL7 V3 messages to transport the SDTM has only just started, and there are many the process to ensure an optimal transition. The content of SDTM will evolve but will remain stable and consisten on what is important—the science.

It is true the FDA canceled an ODM pilot project investigating the use of ODM for the submission of eCRFs to Given the transition to HL7 V3 messages, this decision makes sense at FDA and as a global scientific policy.

But the CDISC ODM is not on the sidelines or, as rumored, “dead.” Far from it. FDA, for starters, is not oppose purposes. The CDISC ODM standard has many valuable uses at the front end of the medical research process. It is exchanging case report form (CRF) data and its associated metadata, in particular the recently published CDASH

Looking Ahead

Tools which employ ODM can be certified. To date, two of the largest vendors (Medidata and Phase Forward) h hoping to follow, as are a growing set of sponsors that are demanding such certification from their vendors. When exchanging data, archiving data, keeping an audit trail secure while ensuring compliance to the relevant regulation doing this. Period. ODM is based on robust XML technology and is a future-proof standard no matter what happe

The take-home message is fairly simple. CDISC wants to see the separation of **content** from **transport** of the d investment in data standards is protected. How to achieve this? By developing the Biomedical Research Integratec harmonize all of the existing standards, uniting them as one. BRIDG represents the clinical research domain in the Information Model (RIM); it was initiated at the recommendation of HL7 experts.

Moving Forward

CDISC had the foresight to form a collaborative relationship with HL7 in 2001. Since then, it has approached c a global process. For the CDISC global community, BRIDG is vital to ensure that any particular data point can flo research process and not just be submitted to a regulatory authority.

In the forthcoming months, an updated CDISC technical roadmap will be available with the aim to continue to s standards that will support clinical research and health care, as well as regulatory authorities worldwide. Maintain enable the CDISC technical strategy to ensure consistency across the CDISC standards, stability of the CDISC sta accommodate both industry and government.

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Comment 1

Thanks for clarifying the role and evolution of CDISC. To paraphrase Mark Twain, “Reports of my death have

I would like to clarify that SAS remains an strong supporter of CDISC, even as the SAS transport file delivery provides, and will continue to develop, technology specifically designed to enable CDISC adoption, including s models, and emerging delivery techniques.

Dave Handelsman, Business Solutions Manager, SAS

»» Posted by: **dhandelsman** at November 5, 2008 10:09 AM

Comment 2

Thanks to the CDISC people for clarifying this - there has been a lot of worries (even panic) in the industry.
A few remarks however: the number of certified ODM applications is 8, and not 2 as suggested.
Furthermore, it is my personal opinion that the FDA has made a huge mistake by choosing HL7-v3-XML mess the development of these messages is heavily disputed. One of the reasons is that these messages are essentially most XML experts consider these messages as an abuse of XML. Even Gartner has criticized this development. Early implementers have reported that it is ... extremely difficult to implement.
As an XML expert, I recently wrote an article “Ten good reasons why an HL7-XML message is not always the standard (and especially not for submission data)”, which can be found at: http://www.xml4pharma.com/HL7-X XML_for_CDISC_Standards.pdf.
It will soon be followed by an article “Ten things HL7 should do to make their HL7-v3-XML messages XML-c Everyone will agree that submission data are essentially clinical data. As the article states, there is already an ex clinical data: the CDISC ODM standard. From a technological point of view, it is far superior to HL7-v3-XML submission data too?
The FDA however decided to reinvent the wheel (though they do not have XML expertise themselves).
There is indeed a big need for replacing SAS transport (30 year old technology), but replacing it by HL7-v3-XM standards) is in my opinion not a big step forward.

»» Posted by: **Jozef Aerts** at November 5, 2008 10:19 AM