Structured Data Capture Initiative: Adverse Event Reporting

On 23 January, the U.S. Health and Human Services Office of the National Coordinator held the Standards and Interoperability Framework’s kickoff webinar for their new Structured Data Capture Initiative. This initiative seeks to define “necessary requirements that will enable clinical data captured in an electronic health record during episodes of care to be combined with additional data to supplement other purposes.” One of these purposes is to ensure the reporting of serious adverse events, with the aim of developing an Incident Report for the reporting of such instances.

While the HHS ONC has mentioned that it does not want to reinvent the wheel and that the SDC Initiative will collaborate with the international standards development community, of which CDISC is a part, it is important to note the work that CDISC and others have already done in the area of adverse event reporting, and ask the necessary question: is this yet another example of redundancy?

In 2008, a pilot project was launched between CDISC, CRIX, Pfizer, Brigham and Women’s Hospital, Partners Healthcare and Harvard Medical School, entitled ASTER, or “ADE (adverse drug events) Spontaneous Triggered Event Reporting.” This project sought to enable automated ADE collection through the EHR using CDISC and IHE’s Retrieve Form for Data Capture. The application that was developed was a novel concept – it directly downloaded data held in the EHR and allowed direct submission to the FDA, all in the correct format for the electronic reporting of individual case safety reports.1

The results were impressive. In the three-month timeframe that the pilot project was in progress, through the efforts of 30 ambulatory care physicians, over 200 reports were sent to the FDA, and it was found that the time to fill out a report was reduced from 34 minutes average to less an 1 minute per patient. 91% of those physicians had not even submitted ADE reports the prior year, and of those 200 reports that were filed, it was found that 20% of these ADEs were deemed serious.

The physicians involved in this study were impressed with the application and results, and 87% thought that ASTER would improve their ability to accurately report ADEs. A majority of these physicians even wanted to receive reports back from the FDA regarding actions taken based upon their sent reports and have the ability to view national data on similar reports. The ASTER project was found to solve problems for ADE reporters, patients and regulators. So what happened?

The project did not result in wide-scale implementation due to the necessity of the FDA to have a repository for ADE data retrieved through the ASTER process, as well as other reasons that seem to inhibit the adoption of new methods and technologies (including EHRs) in the clinical research world. This brought the project to a standstill.

In addition to the ASTER project, CDISC was instrumental in a project to include and harmonize Adverse Event semantics within the Biomedical Research Information Domain Group (BRIDG) Model, a model that harmonizes all of the CDISC standards and bridges healthcare and research. Starting in 2006, CDISC facilitated a group of Adverse Event experts from CDISC, the National Cancer Institute, Federal Adverse Event Task Force, and the Food and Drug Administration (FDA) to build an information model which included the Adverse Event concepts, their meanings and relationships. This information was then included in the BRIDG model. Since then, the FDA has added semantics to BRIDG based on the updated ICSR. Other projects have also added and continued to update information to the Adverse Event part of the BRIDG model. In software and standards development, using an information model such as BRIDG is a crucial part of the data requirements gathering step and should be used in the beginning of a project working with Adverse Event data. So now back to 2013...

It was impressive that throughout the SDC Initiative webinar, CDISC was mentioned as an integral component of this initiative, both through the use of already established CDISC standards and the necessity of our expertise in the area of research (although during the Patient-Safety Event Reporting segment of the webinar, it was said that the common data elements for reporting these instances was developed by AHRQ, both the common language and definitions as well as the rules for data collection, all developed from entities from within HHS, without collaboration with CDISC, which is rather disconcerting to those of us who do research as a livelihood). No mention was made of the ASTER project. When discussing the process workflow of getting patient safety information from the EHR to the HHS ONC’s “Incident Reporting System,” supposedly important elements from the EHR will be extracted using a “Structured Data Capture” tool. This sounds familiar (if you are confused, this would be RFD, which was developed by CDISC).

The thing that has changed, and the reason why this new initiative is not redundant of efforts past, is not because there has been a recent development by CDISC or from any other standards development organization regarding how to record adverse events, but is directly due to the fact that this initiative has not only the full cooperation of the government, but is an initiative that is actually being spearheaded by the government, requiring them to make certain changes. One of the points of the Patient Safety and Quality Improvement Act of 2005, which was detailed as part on this new initiative, was the “establishment of a network of patient safety databases.” While they didn’t go into the specifics of how this would work, if done correctly, this could solve the largest problem that the ASTER project faced – submission of ADE data.

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2 For more information about BRIDG, please see [www.bridgmodel.org](http://www.bridgmodel.org).
My hope is that they will use the work that has been done by organizations like CDISC in this area to ensure that adverse drug event information is efficiently and effectively collected, aggregated and shared with not only physicians so that they can make better choices in treatments, but with the general public, so that patients can take more of an active role in their own medical care. This effort has the opportunity to be incredibly successful, so long as the many entities and organizations involved in efforts to retrieve data from EHRs for further purposes are brought to the table and prior work is leveraged.

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