A d-Wise Case Study: Validating Clinical Trial Data using the d-Wise Reveal Platform and OpenCDISC Validator for CDISC Compliance

Introduction

In June of 2013, d-Wise Technologies, Inc. (d-Wise), a solutions provider that offers product and consulting solutions for clinical trial optimization, metadata management and clinical data standards implementation, released the latest version of their web-based search platform, *Reveal 2.0*.[1] d-Wise has found that Reveal, when combined with OpenCDISC Validator, a free utility for ensuring clinical data compliance with CDISC standards, can expedite the validation of clinical data in a compliant way.

When paired with OpenCDISC Validator, Reveal can facilitate validation for CDISC SDTM, ADaM and Define.xml clinical data standards compliance. As organizations get closer to submitting new drug applications and amendments for eventual marketing approval from regulatory authorities, the ability to find and aggregate data and validate data to CDISC standards becomes increasingly important. With Reveal, organizations can accelerate their review and perform ad-hoc validation of their clinical trial data.

The d-Wise Reveal Platform

Reveal is unique because in addition to searching unstructured data like documents, it searches the contents of clinical datasets and other common data structures. Reveal also performs these searches across an unlimited number of studies (even if they reside in different repositories), multiple data stores, and easily integrates with 3rd party analytics tools and other utilities. During a webinar demonstration, Reveal was shown to return data within seconds from spreadsheets, PDF, XML, SAS and Word documents, and these files could be opened and reviewed directly within the Reveal platform. When conducting a search for keywords like "CDISC," "SDTM" or "headache" for instance, it is possible to retrieve and isolate terms contained *inside* datasets and documents, even multiple tabbed Excel spreadsheets, a common tool for capturing CDISC standards.[2]

The Reveal platform demonstrated the retrieval of various file types, the ability to open those files, and then examine and verify compliance to CDISC through the OpenCDISC Validator tool. After a short validation process, it is also possible to get an error report containing warnings and notices about the data, with indication as to the severity of each error. Searches and validation for CDISC ADaM and Define.xml were also demonstrated.

Results

Using the Reveal tool has been proven to speed up the time it takes to search for specific terminology, target data or specific clinical data standards-based data contained within datasets or documents. Utilization of this tool has been found to cut down searches that otherwise would have taken days or even weeks to mere seconds. Implementation and use of CDISC standards, from the start, as well as

[1] For more information about Reveal, visit: http://www.youtube.com/watch?v=OAY0t4UJWUU&feature=youtu.be.
[2] To see use cases on the Reveal Platform, visit: http://www.d-wise.com/use-cases-data-warehouse-search-/.

employment of a tool like Reveal for validation purposes, can enhance efficiency and productivity, improving processes.