

Paper 119-30

Investigational Data in XML according to the CDISC Operational Data Model

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ABSTRACT

The Study Data Tabulation Model was adopted by the FDA in July 2004, and the intention is to make the Analysis Data Model active very soon as well. As a result, SAS®, like other software vendors, is developing technology and solutions to meet the industry requirements for the use of these models. The use of the Operational Data Model for the structure of common data repositories is very important as well.

We first wish to discuss the Base SAS technology and tools that are used, and to report on investigational data in XML according to the CDISC Operational Data Model (ODM) v1.2 schema in Base SAS. The model represents study metadata, data, and administrative data associated with a clinical trial. The implications of data transmission using this standard will be discussed, including how to display data in ODM v1.2 format, how to validate imported and exported data, and how to otherwise assess conformance of the data with the model. Special attention will also be paid to the implementation of the Study Data Tabulation Model and the Analysis Data Model in regulatory submissions to carry out the process in Base SAS and to support CDISC standards in the most common analysis and reporting software in the industry.

Validation of these processes is critical to compliance. Our experiences with the pharmaceutical industry will be used as case studies to consider structure, content and format required of SAS software to make the application and utilization of CDISC standards perform in a compliant manner.

NOTE

No paper was made available for publication. Please contact the author directly.

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