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Customer Case Study: The Use of Metadata in the CDISC SDTM/ADaM Pilot Project

Gregory Steffens, Eli Lilly and Co.

ABSTRACT

The CDISC SDTM/ADaM pilot project created a test submission to the FDA using CDISC data and metadata standards in order to test that these standards meet FDA requirements. In his presentation, Steffens discusses how metadata was used in this project to describe, build and validate the data, as well as automate the creation of the "define.xml" metadata file. Steffens designed this technology for use at Eli Lilly and implemented it in the CDISC pilot project.

It consists of standard metadata set structures and a set of validated SAS macros that use the information in this metadata to create a data specification, create 0-observation data sets that conform to the data specification, validate the data against the data specification, sort observations, reorder variables to match the order in the define file, create the "define.xml" file and create a user format catalog of code and decode values. The data specification is required in the FDA submission.

Creating the data specification prescriptively at the start of the project and putting this information into metadata so that it is available to SAS programs to support automation, gives a much greater payback for this effort, as compared to descriptive metadata created at the end of the project. Prescriptive metadata also improves the quality of the data specification since it is being used by staff creating the database. Ambiguous and incomplete specifications are identified and resolved as part of the data-creation process, resulting in a clear and complete data specification for the FDA.

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CONTACT INFORMATION

Gregory Steffens
Eli Lilly and Co.
steffensgc@lilly.com