A Programming Methodology for Creating CDISC Domain Data Sets

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Abstract

The process of creating CDISC domain data sets requires more than SAS® programming skills. And, certainly, a cursory knowledge of CDISC standards is hardly adequate. Even with a specifications document that explains the transformations of collected clinical data to respective CDISC domain variables, the domain data sets often fall short of the CDISC standard. In fact, the challenge of the data conversion project is often underestimated, despite the employ of proficient SAS programmers who have the advantage of a specifications document, but perhaps having only limited knowledge of CDISC and clinical data. Moreover, the creation of CDISC domain data sets often requires complicated Data step programming in order to create the target domain data set. And, when one considers the minutia involving CDISC standards, such as the order of the variables, their respective labels, and case-sensitivity issues, the programming task becomes even more daunting. This paper highlights a programming methodology for creating CDISC domain data sets.

Keywords

CDISC, SDTM, Conversion, Programming, Methodology.

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