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analyze the Study Data Tabulation Model (SDTM) and the Analysis Data Model (ADaM) data and prepare clinical trial data for regulatory submission. Updated to reflect the 2017 FDA mandate for adherence to CDISC standards, this new edition covers creating and using metadata, developing conversion specifications, implementing and

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validating SDTM and
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Edition (CRF) designs,
variable names, and
data formats for the
different compounds
on which they worked.
When it came time to

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integrate the data for a regulatory submission, a substantial amount of time was spent deciding on the structure and variable names to be used for the integrated

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For decades researchers and programmers have used SAS to analyze, summarize, and report clinical trial data. Now Chris Holland and Jack Shostak have updated their popular *Implementing CDISC Using SAS*, the first comprehensive book on applying clinical research data and metadata to the Clinical Data Interchange Standards

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implementing CDISC
standards on clinical
trial data. The second
is to introduce readers
to tools based on SAS
that cannot only
facilitate the
implementation
process but also
facilitate the ultimate
goal of analyzing your

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data once it follows a CDISC standard. Some of these tools are actual SAS products. Some are SAS macros provided by the authors.

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2 Implementing CDISC Using SAS: An End-to-End Guide

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organizations undergoing mergers. During the late 1990s and early 2000s, many CROs consolidated as well. In addition to the numerous data standards they had to keep track of among their various clients, CRO SAS programmers also had to deal with

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balk at proposals to implement CDISC

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standards when they

see the up-front price

tag associated with it.

Some organizations got

burned by trying to

implement the Study

Data Tabulation Model
(SDTM) too

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Framework. ... The
metadata for a data set
contained within a
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document must be specified using the CDISC Define-XML standard. Each CDISC ...

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strategies. Intended for practitioners who want to move beyond the 'whys' of CDISC, this book does a marvelous job at helping bridge the gap between theory and practice.

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CDISC Chief Standards Officer, Peter Van Reusel, presented the ambitious new CDISC 360 project aimed at improving the use of the CDISC standards in the coming years. Stijn Rogiers (SAS) provided a good summary on

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the issues related to
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standards. This edition reflects the 2017 FDA mandate for adherence to CDISC standards.

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Jack Shostak manages a group of statistical programmers and is an Associate Director of Statistics at the Duke Clinical Research

Institute. He is the author of SAS

Programming in the Pharmaceutical

Industry and coauthor of Common Statistical Methods for Clinical Research with SAS

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