

Date Conversions in SDTM and ADaM Datasets

Huei-Ling Chen, Merck & Co., Inc., Rahway, NJ

Lily Zhang, Merck & Co., Inc., Rahway, NJ

Lili Chen, Merck & Co., Inc., Rahway, NJ

ABSTRACT

CDISC (Clinical Data Interchange Standards Consortium) has recommended using the SDTM (Study Data Tabulation Model) data structure to store source data, and the ADaM (Analysis Data Model) data structure to store data for statistical analysis and reporting. The SDTM IG (Implementation Guide) requires using the international standard ISO8601 format to store dates and times. The ISO8601 standard represents dates and times as text. However, dates and times in ADaM datasets are numeric. The purpose of this paper will be to answer how to convert a text date or time from source data into the ADaM date/time format and how to convert a numeric date or time to ISO8601 standard format. This paper provides simple and straightforward syntax and examples to illustrate the conversion methods. In addition, methods to impute the partial date or time are also discussed in this paper.

KEYWORDS

SDTM, ADaM, ISO8601 Format, PUT, INPUT, INTNX

INTRODUCTION

EXAMPLES OF SDTM DTC VARIABLE

A SDTM dataset is source data that will be converted to an analysis dataset (ADaM) to produce the final report and listing. The collected date and time in the SDTM dataset is represented as a character variable. As an example, the date/time variables AESTDTC (Start Date/Time of Adverse Event) and AEENDTC (End Date/Time of Adverse Event) collected in the SDTM dataset AE (Adverse Experiences) are defined as characters in the following:

SUBJID	DOMAIN	AESTDTC	AEENDTC
11111	AE	2007-06-03T15:22:39	2009-03-15T10:52:07
22222	AE	2007-06-03T15:22	2009-03-15T10:52
33333	AE	2007-06-03T15	2009-03-15T10
44444	AE	2007-06-03	2009-03-15
55555	AE	2007-03	2009-03
66666	AE	2007-06	2009-06
77777	AE	2007-02	2009-02
88888	AE	2006-02	2008-02
99999	AE	2007	2009

Attributes:

Variable	Type	Len	Format	Label
AESTDTC	Char	19	\$19.	Start Date/Time of Adverse Event
AEENDTC	Char	19	\$19.	End Date/Time of Adverse Event

Here ISO8601 format [YYYY-MM-DDThh:mm:ss] is used for SDTM DTC variables. "T" is used as a separator to divide the date and time portions.

EXAMPLES OF ADaM DATE / TIME VARIABLE

The following example shows the date/time variable CFDTC from the CF domain and the ADaM variables ADTM, ADT, and ATM derived from CFDTC. The ADaM Date/Time variables are numeric variables, formatted so as to be more easily readable.

SUBJID	DOMAIN	CFDTC	ADTM	ADT	ATM
11111	CF	2009-05-15T21:27:00	2009-05-15T21:27:00	2009-05-15	21:27:00
22222	CF	2009-06-12T09:31:00	2009-06-12T09:31:00	2009-06-12	09:31:00
33333	CF	2010-07-13T20:05:00	2010-07-13T20:05:00	2009-07-13	20:05:00

Attributes:

Variable	Type	Label
ADTM	Num	Analysis Datetime
ADT	Num	Analysis Date
ATM	Num	Analysis Time

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