dictionary-coded text is derived into --DECOD. Because the PEORRES variable is modified instead of the topic variable for PE, the dictionary-derived text would be placed in PESTRESC. The variables used in each of the defined domains are:

Domain	Original Verbatim	Modified Verbatim	Standardized Value
AE	AETERM	AEMODIFY	AEDECOD
DS	DSTERM		DSDECOD
CM	CMTRT	CMMODIFY	CMDECOD
MH	MHTERM	MHMODIFY	MHDECOD
PE	PEORRES	PEMODIFY	PESTRESC

4.3.7 Use of "Yes" and "No" Values

Variables where the response is "Yes" or "No" ("Y" or "N") should normally be populated for both "Y" and "N" responses. This eliminates confusion regarding whether a blank response indicates "N" or is a missing value. However, some variables are collected or derived in a manner that allows only 1 response, such as when a single checkbox indicates "Yes". In situations such as these, where it is unambiguous to populate only the response of interest, it is permissible to populate only 1 value ("Y" or "N") and leave the alternate value blank. An example of when it would be acceptable to use only a value of "Y" would be for Last Observation Before Exposure Flag (-- LOBXFL) variables, where "N" is not necessary to indicate that a value is not the last observation before exposure.

> **Note:** Permissible values for variables with controlled terms of "Y" or "N" may be extended to include "U" or "NA" if it is the sponsor's practice to explicitly collect or derive values indicating "Unknown" or "Not Applicable" for that variable.

4.4 Actual and Relative Time Assumptions

Timing variables (SDTM Section 3.1.5, Timing Variables for All Classes) are an essential component of all SDTM subject-level domain datasets. In general, all domains based on the 3 general observation classes should have at least 1 timing variable. In the Events or Interventions general observation class, this could be the start date of the event or intervention. In the Findings observation class, where data are usually collected at multiple visits, at least 1 timing variable must be used.

The SDTMIG requires dates and times of day to be stored according to the international standard ISO 8601 (http://www.iso.org). ISO 8601 provides a text-based representation of dates and/or times, intervals of time, and durations of time.

4.4.1 Formats for Date/Time Variables

An SDTM DTC variable may include data that is represented in ISO 8601 format as a complete date/time, a partial date/time, or an incomplete date/time.

The SDTMIG template uses ISO 8601 for calendar dates and times of day, which are expressed as follows:

- YYYY-MM-DDThh:mm:ss(.n+)?(((+|-)hh:mm)|Z)?

where:

- [YYYY] = four-digit year
- [MM] = two-digit representation of the month (01-12, 01=January, etc.)
- [DD] = two-digit day of the month (01 through 31)
- [T] = (time designator) indicates time information follows
- [hh] = two digits of hour (00 through 23) (am/pm is NOT allowed)
- [mm] = two digits of minute (00 through 59)
- [ss] = two digits of second (00 through 59)
  The last two components, indicated in the format pattern with a question mark, are optional:

- [(.n+)?] = optional fractions of seconds
- [(((+|-)hh:mm)|Z)?] = optional time zone

Other characters defined for use within the ISO 8601 standard are:

- [-] (hyphen): to separate the time elements "year" from "month" and "month" from "day" and to represent missing date components.
- [:] (colon): to separate the time elements "hour" from "minute" and "minute" from "second"
- [/] (solidus): to separate components in the representation of date/time intervals
- [P] (duration designator): precedes the components that represent the duration

Spaces are not allowed in any ISO 8601 representations.

Key aspects of the ISO 8601 standard are as follows:

- ISO 8601 represents dates as a text string using the notation YYYY-MM-DD.
- ISO 8601 represents times as a text string using the notation hh:mm:ss(.n+)?(((+|-)hh:mm)|Z)?.
- The SDTM and the SDTMIG require use of the ISO 8601 extended format, which requires hyphen delimiters for date components and colon delimiters for time components. The ISO 8601 basic format, which does not require delimiters, should not be used in SDTM datasets.
- When a date is stored with a time in the same variable (as a date/time), the date is written in front of the time and the time is preceded with "T" using the notation YYYY-MM-DDThh:mm:ss (e.g. 2001-12-26T00:00:01).

Implementation of the ISO 8601 standard means that date/time variables are character/text data types. The SDTM fragment employed for date/time character variables is DTC.

4.4.2 Date/Time Precision

The concept of representing date/time precision is handled through use of the ISO 8601 standard. According to ISO 8601, precision (also referred to by ISO 8601 as "completeness" or "representations with reduced accuracy") can be inferred from the presence or absence of components in the date and/or time values. Missing components are represented by right truncation or a hyphen (for intermediate components that are missing). If the date and time values are completely missing, the SDTM date field should be null. Every component except year is represented as 2 digits. Years are represented as 4 digits; for all other components, 1-digit numbers are always padded with a leading zero.

The following table provides examples of ISO 8601 representations of complete and truncated date/time values using ISO 8601 "appropriate right truncations" of incomplete date/time representations. Note that if no time component is represented, the [T] time designator (in addition to the missing time) must be omitted in ISO 8601 representation.

	Date and Time as Originally Recorded	Precision	ISO 8601 Date/Time
1	December 15, 2003 13:14:17.123	Date/time, including fractional seconds	2003-12-15T13:14:17.123
2	December 15, 2003 13:14:17	Date/time to the nearest second	2003-12-15T13:14:17
3	December 15, 2003 13:14	Unknown seconds	2003-12-15T13:14
4	December 15, 2003 13	Unknown minutes and seconds	2003-12-15T13
5	December 15, 2003	Unknown time	2003-12-15
6	December, 2003	Unknown day and time	2003-12
7	2003	Unknown month, day, and time	2003

This date and date/time model also provides for imprecise or estimated dates, such as those commonly seen in Medical History. To represent these intervals while applying the ISO 8601 standard, it is recommended that the sponsor concatenate the date/time values (using the most complete representation of the date/time known) that describe the beginning and the end of the interval of uncertainty and separate them with a solidus, as shown in the following table.

	Interval of Uncertainty	ISO 8601 Date/Time
1	Between 10:00 and 10:30 on the morning of December 15, 2003	2003-12-15T10:00/2003-12-15T10:30
2	Between the first of this year (2003) until "now" (February 15, 2003)	2003-01-01/2003-02-15
3	Between the first and the tenth of December, 2003	2003-12-01/2003-12-10
4	Sometime in the first half of 2003	2003-01-01/2003-06-30

Other uncertainty intervals may be represented by the omission of components of the date when these components are unknown or missing. As previously mentioned, ISO 8601 represents missing intermediate components through the use of a hyphen where the missing component would normally be represented. This may be used in addition to "appropriate right truncations" for incomplete date/time representations. When components are omitted, the expected delimiters must still be kept in place and only a single hyphen is to be used to indicate an omitted component. Examples of this method of omitted component representation are shown in the following table.

	Date and Time as Originally Recorded	Level of Uncertainty	ISO 8601 Date/Time
1	December 15, 2003 13:15:17	Date/time to the nearest second	2003-12-15T13:15:17
2	December 15, 2003 ??:15	Unknown hour with known minutes	2003-12-15T-:15
3	December 15, 2003 13:??:17	Unknown minutes with known date, hours, and seconds	2003-12-15T13:-:17
4	The 15th of some month in 2003, time not collected	Unknown month and time with known year and day	2003---15
5	December 15, but can't remember the year, time not collected	Unknown year with known month and day	--12-15
6	7:15 of some unknown date	Unknown date with known hour and minute	-----T07:15

Note that row 6, where a time is reported with no date information, represents a very unusual situation. Because most data are collected as part of a visit, when only a time appears on a CRF, it is expected that the date of the visit would usually be used as the date of collection.

Using a character-based data type to implement the ISO 8601 date/time standard will ensure that the date/time information will be machine- and human-readable without the need for further manipulation, and will be platform- and software-independent.

4.4.3 Intervals of Time and Use of Duration for --DUR Variables

4.4.3.1 Intervals of Time and Use of Duration

As defined by ISO 8601, an *interval of time* is the part of a time axis, limited by 2 time "instants" such as the times represented in SDTM by the variables --STDTC and --ENDTC. These variables represent the 2 instants that bound an interval of time; the *duration* is the quantity of time that is equal to the difference between these time points.

ISO 8601 allows an interval to be represented in multiple ways. One representation, shown below, uses 2 dates in the format:

YYYY-MM-DDThh:mm:ss/YYYY-MM-DDThh:mm:ss

Although this example represents the interval (by providing the start date/time and end date/time to bound the interval of time), it does not provide the value of the duration (the quantity of time).

Duration is frequently used during a review; however, the duration timing variable (--DUR) should generally be used in a domain if it was collected in lieu of a start date/time (--STDTC) and end date/time (--ENDTC). If both --STDTC and --ENDTC are collected, durations can be calculated by the difference in these 2 values, and need not be in the submission dataset.

Both duration and duration units can be provided in the single --DUR variable, in accordance with the ISO 8601 standard. The values provided in --DUR should follow 1 of the following ISO 8601 duration formats:

PnYnMnDTnHnMnS
- or -
PnW

where the letter designation is defined as:

- [P] (duration designator): precedes the alphanumeric text string that represents the duration. Note that the use of the character "P" is based on the historical use of the term "period" for duration.

- [n] represents a positive number or zero.
- [W] is used as week designator, preceding a data element that represents the number of calendar weeks within the calendar year (e.g., P6W represents 6 weeks of calendar time).

The letter "P" must precede other values in the ISO 8601 representation of duration. The "n" preceding each letter represents the number of years, months, days, hours, minutes, seconds, or the number of weeks. As with the date/time format, "T" is used to separate the date components from time components.

Note that weeks cannot be mixed with any other date/time components such as days or months in duration expressions.

As is the case with the date/time representation in --DTC, --STDTC, or --ENDTC, only the components of duration that are known or collected need to be represented. As is the case with the date/time representation, if no time component is represented, the [T] time designator (in addition to the missing time) must be omitted in ISO 8601 representation.

ISO 8601 also allows that the "lowest-order components" of duration being represented may be represented in decimal format. This may be useful if data are collected in formats such as "one and one-half years", "two and a half weeks", "half a week" or "quarter of an hour" and the sponsor wishes to represent this "precision" (or lack of precision) in ISO 8601 representation. This is ONLY allowed in the lowest-order (right-most) component in any duration representation.

The following table provides some examples of ISO 8601-compliant representations of durations.

Duration as originally recorded	ISO 8601 Duration
2 years	P2Y
10 weeks	P10W
3 months 14 days	P3M14D
3 days	P3D
6 months 17 days 3 hours	P6M17DT3H
14 days 7 hours 57 minutes	P14DT7H57M
42 minutes 18 seconds	PT42M18S
One-half hour	PT0.5H
5 days 12¼ hours	P5DT12.25H
4 ½ weeks	P4.5W

Note that a leading zero is required with decimal values less than 1.

4.4.3.2 Interval with Uncertainty

When an interval of time is an amount of time (duration) following an event whose start date/time is recorded (with some level of precision, e.g., when one knows the start date/time and the duration following the start date/time), the correct ISO 8601 usage to represent this interval is:

YYYY-MM-DDThh:mm:ss/PnYnMnDTnHnMnS

where the start date/time is represented before the solidus or foreword slash [/], the "Pn…" following the solidus represents a "duration," and the entire representation is known as an "interval." Note that this is the recommended representation of elapsed time, given a start date/time and the duration elapsed.
When an interval of time is an amount of time (duration) measured prior to an event whose start date/time is recorded (with some level of precision, e.g., where one knows the end date/time and the duration preceding that end date/time), the syntax is:

PnYnMnDTnHnMnS/YYYY-MM-DDThh:mm:ss

where the duration, "Pn…", is represented before the solidus [/], the end date/time is represented following the solidus, and the entire representation is known as an "interval."

4.4.4 Use of the Study Day Variables

The permissible study day variables (i.e., --DY, --STDY, --ENDY) describe the relative day of the observation starting with the reference date as day 1. They are determined by comparing the date portion of the respective date/time variables (--DTC, --STDTC, and --ENDTC) to the date portion of the subject reference start date (RFSTDTC from the Demographics domain).