Package 'sdtmval'

October 23, 2023

Title Validate SDTM Domains

Version 0.4.1

Description Provides a set of tools to assist statistical programmers in validating Study Data Tabulation Model (SDTM) domain data sets. Statistical programmers are required to validate that a SDTM data set domain has been programmed correctly, per the SDTM Implementation Guide (SDTMIG) by 'CDISC' (https://www.cdisc.org/standards/foundational/sdtmig), study specification, and study protocol using a process called double programming. Double programming involves two different programmers independently converting the raw electronic data cut (EDC) data into a SDTM domain data table and comparing their results to ensure accurate standardization of the data. One of these attempts is termed 'production' and the other 'validation'. Generally, production runs are the official programs for submittals and these are written in 'SAS'. Validation runs can be programmed in another language, in this case 'R'.

```
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Encoding UTF-8

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    https://skgithub14.github.io/sdtmval/

BugReports https://github.com/skgithub14/sdtmval/issues

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Description

Trims the length of each text and date variable to the length specified in the spec and then assigns the attributes "label" and "width" to each column.

assign_meta_data 3

Usage

```
assign_meta_data(
  tbl,
  spec,
  datatype_col = "Data Type",
  var_col = "Variable",
  length_col = "Length",
  label_col = "Label"
)
```

Arguments tbl

spec a data frame with the columns "Variable" which has a value for each column in tbl, "Data Type" which specifies data types by column, "Length" which specifies the character limit for each column, and "Label" which specifies the

label for each column

datatype_col a string, the column in spec that contains the data types (which should include

the values "text" and "date"); default is "Data Type"

var_col a string, the column in spec that contains the domain variable names

a data frame containing a SDTM table

length_col a string, the column in spec that contains the character count limits for each

variable

label_col a string, the column in spec that contains the labels for each variable

Value

a modified copy of tbl with the meta data per specification

See Also

```
get_data_spec(), get_key_vars(), get_codelist()
```

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)

assign_SEQ

Assign SEQ numbers for a SDTM data set

Description

Assigns the "[DOMAIN]SEQ" number by sorting the data set by the specified variables and then grouping by "USUBJID".

Usage

```
assign_SEQ(tbl, key_vars, seq_prefix, USUBJID = "USUBJID")
```

Arguments

tbl a data frame, the SDTM table

key_vars a character vector of the key variables to sort by

seq_prefix a string, the prefix for SEQ as per the spec (usually the two letter domain abbre-

viation)

USUBJID a string, the column for the subject ID, USUBJID, default is "USUBJID"

Value

a sorted copy of the tbl data frame with the new SEQ column

```
df <- data.frame(
   USUBJID = paste("Subject", c(rep(1, 3), rep(2, 3))),
   XXTESTCD = paste("T", rep(c(2, 3, 1), 2))
)
assign_SEQ(df, key_vars = c("USUBJID", "XXTESTCD"), seq_prefix = "XX")</pre>
```

calc_DY 5

_	
C 2 1 /	c DY
card	- 10 1

Calculate a DY variable (day of study)

Description

Utilizes the DY method from the SDTM spec: --DTC-RFSTDTC+1 if --DTC is on or after RFSTDTC. --DTC-RFSTDTC if --DTC precedes RFSTDTC. This function can also be used for the ENDY method from the spec which has the same logic.

Usage

```
calc_DY(tbl, DY_col, DTC_col, RFSTDTC = "RFSTDTC")
```

Arguments

tbl	a data frame with the date column RFSTDTC and the column specified by the $\ensuremath{DTC_col}$ argument
DY_col	string, the name of the new DY column to create
DTC_col	string, the column in tbl which has the dates for which to calculated the DY value; should either already have a date class or be a character vector in the format YYYY-MM-DD
RFSTDTC	a string, the column to use for RFSTDTC, default is "RFSTDTC"; should either already have a date class or be a character vector in the format YYYY-MM-DD

Value

a modified copy of tbl with the new DY column

See Also

```
create_BLFL(), create_EPOCH()
```

```
df <- data.frame(
   DTC = c("2023-08-01", "2023-08-02", "2023-08-03", "2023-08-04"),
   RFSTDTC = rep("2023-08-02", 4)
)
calc_DY(df, DY_col = "XXDY", DTC_col = "DTC")</pre>
```

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convert_to_script

Convert SDTM QC code from a .Rmd file to .R script

Description

Wraps knitr::purl() to create an .R script from a .Rmd file. It can also auto-archive the .Rmd file to a [dir]/archive sub-directory. This is useful for turning first-attempt exploratory data analysis into production scripts once the validation code is complete.

Usage

```
convert_to_script(filename, dir = NULL, archive = FALSE)
```

Arguments

filename string, the file name of both the .Rmd file that will be read and the file name of the .R file to be written (do not include .Rmd or .R extension)

dir string, the directory where the .Rmd file is and the .R file will be written, default is NULL which means the current working directory will be used archive logical, whether to auto-archive the .Rmd file; default is FALSE

Details

- The resulting script will take the same name as the .Rmd file but with a different extension (.R)
- If [dir]/archive does not already exist, it will be created

Value

nothing

See Also

```
write_sessionInfo()
```

create_BLFL 7

create_BLFL	Create a BLFL column	
-------------	----------------------	--

Description

Utilizes the BLFL method from the SDTM spec to create a baseline flag: Equal to "Y" for last record with non-missing –ORRES on or before first dose date (RFSTDTC); NA otherwise.

Usage

```
create_BLFL(
   tbl,
   sort_date,
   domain,
   grouping_vars = "USUBJID",
   RFSTDTC = "RFSTDTC",
   compare_date_method = "on or before"
)
```

Arguments

tbl a data frame with the variables USUBJID, [domain]ORRES, RFSTDTC, and to col-

umn specified in the sort_date argument

sort_date a string, the column name by which to sort records within each USUBJID en-

try before assigning the BLFL value. This is also the date compared against RFSTDTC to determine the BLFL value. This column should either already have

a date class or be a character vector in the format YYYY-MM-DD

domain a string, the SDTM domain abbreviation

grouping_vars a character vector of columns to group by when assigning the BLFL, default is

"USUBJID". The order of this vector matters.

RESTDTC a string, the column to use for RESTDTC, default is "RESTDTC"; this columns

should either have a date class or a characer class in the YYYY-MM-DD format

 ${\tt compare_date_method}$

a string, one of c("on or before", "before") indicating where the baseline measurement should be evaluated on or before the study start date or just before;

default is "on or before"

Value

a modified copy of tbl with the new column [domain]BLFL

See Also

```
create_EPOCH(), calc_DY()
```

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Examples

```
df <- dplyr::tibble(</pre>
  USUBJID = c(
    rep(1, 3),
    rep(2, 3)
  ),
  XXORRES = c(
    1, 2, 2,
    1, 2, NA
  ),
  XXDTC = as.Date(c(
    "2017-02-05", "2017-02-06", "2017-02-07", "2017-02-05", "2017-02-06", "2017-02-07"
  )),
  RFSTDTC = as.Date(c(
    rep("2017-02-05", 3),
    rep("2017-02-07", 3)
  ))
)
create_BLFL(df, sort_date = "XXDTC", domain = "XX")
```

create_EPOCH

Create the EPOCH variable

Description

Utilizes the EPOCH method from the SDTM spec: Missing when --DTC is blank; equal to 'SCREENING' if --DTC if before RFXSTDTC; equal to 'TREATMENT' if --DTC is on or after RFXSTDTC and on or before RFXENDTC; equal to 'FOLLOW-UP' if --DTC is after RFXENDTC.

Usage

```
create_EPOCH(tbl, date_col, RFXSTDTC = "RFXSTDTC", RFXENDTC")
```

Arguments

tbl	a data frame with date class columns RFXSTDTC and RFXENDTC and the column given in the date_col argument
date_col	a string, the column name of the event date used to determine the EPOCH; this column can either have a date class or a character class in the YYYY-MM-DD format
RFXSTDTC	a string, the date column to use for RFXSTDTC, default is "RFXSTDTC"; this column can either have a date class or a character class in the YYYY-MM-DD format
RFXENDTC	a string, the date column to use for RFXENDTC, default is "RFXENDTC"; this column can either have a date class or a character class in the YYYY-MM-DD format

create_STAT 9

Value

a modified copy of tbl with the EPOCH column

See Also

```
create_BLFL(), calc_DY()
```

Examples

```
df <- data.frame(
   DTC = c("2023-08-01", "2023-08-02", "2023-08-03", "2023-08-04"),
   RFXSTDTC = rep("2023-08-02", 4),
   RFXENDTC = rep("2023-08-03", 4)
)
create_EPOCH(df, date_col = "DTC")</pre>
```

create_STAT

Assign STAT 'NOT DONE' status

Description

Creates a –STAT variable and, if all measurements for a visit were not done, also changes all – TESTCD values as "–ALL"

Usage

```
create_STAT(
   df,
   domain,
   nd_ind,
   nd_ind_cd = "Yes",
   USUBJID = "USUBJID",
   VISIT = "VISIT"
)
```

Arguments

df	a data frame to modify
domain	a string, the domain abbreviation in all caps
nd_ind	a string, the variable name in df that indicates if a test was not performed, usually a "Yes"/"No" or "Y"/"N" column
nd_ind_cd	a string, the code from the nd_ind column that signifies a test was not done, default is "Yes" $$
USUBJID	a string, the variable name in df that contains the subject identifier, default is "USUBJID" $$
VISIT	a string, the variable name in df that indicates a VISIT field, default is "VISIT"

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Value

```
a modified copy of df
```

Examples

```
df <- dplyr::tibble(
   USUBJID = paste("Subject", c(rep("A", 2), rep("B", 4), rep("C", 2))),
   VISIT = paste("Visit", c(1 , 2 , 1 , 1 , 2 , 2 , 2 , 2)),
   XXTESTCD = paste("Test", c(1 , 2 , 1 , 2 , 1 , 2 , 1 , 2)),
   ND = c("N", "N", "Y", "Y", "N", "N", "Y", "Y")
)
create_STAT(df = df, domain = "XX", nd_ind = "ND", nd_ind_cd = "Y")</pre>
```

dm

Example SDTM Domain 'DM'

Description

This is an example data set to simulate a SDTM production domain 'DM' which contains study start and end date information by subject. This can be used to test create_BLFL(), create_EPOCH(), and calc_DY().

Usage

dm

Format

'dm':

A data frame with 2 rows and 4 columns:

USUBJID Subject identifier **RFSTDTC** Study start date

RFXSTDTC First exposure date **RFXENDTC** Last exposure date

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edc_xx

Example EDC data for form/table 'XX'

Description

This is an example data set to simulate raw EDC data from the fake form/table 'XX'.

Usage

edc_xx

Format

'edc_xx':

A data frame with 8 rows and 6 columns:

STUDYID Study identifier

USUBJID Subject identifier

VISIT Visit name

XXTESTCD Test name, coded

XXORRES Test result

format_chars_and_dates

Format date and character columns for SDTM tables

Description

Converts all date columns to character class and replaces all NA values in character/date columns with "".

Usage

```
format_chars_and_dates(tbl)
```

Arguments

tbl

a data frame, the SDTM table

Details

This function should be applied as one of the last steps in the data process but before assign_meta_data().

Value

a modified copy of the tbl data frame

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See Also

```
trim_and_make_blanks_NA()
```

Examples

```
df <- data.frame(
  dates = as.Date(c("2017-02-05", NA)),
  strings = c(NA_character_, "this"),
  nums = c(1, NA)
)
format_chars_and_dates(df)</pre>
```

 $get_codelist$

Read in the code list from the specification for a specific domain

Description

Reads-in the "Codelists" sheet from the study's specification MS Excel file and then filters that code list by the variables in the domain

Usage

```
get_codelist(
  domain,
  dir,
  filename,
  var_col = "Variable",
  codelist_sheet = "Codelists",
  varid_col = "ID"
)
```

Arguments

domain string, SDTM domain or supplemental domain code

dir string, specification directory

filename string, file name of the specification

var_col a string, the column name in the domain spec sheet that contains the variables

for that domain, default is "Variable"

codelist_sheet a string, the sheet name of the spec's code list from the spec's .xlsx file, default

is "Codelists"

varid_col a string, the column name in the codelist_sheet table from the spec's .xlsx

file that contains the variable names, default is "ID"

Value

a data frame with the code list

get_data_spec 13

See Also

```
get_data_spec(), get_key_vars(), assign_meta_data()
```

Examples

get_data_spec

Read in the variable specification sheet for a SDTM data set

Description

Reads the specified domain variable specification sheet from an MS Excel file.

Usage

```
get_data_spec(domain, dir, filename, arrange_by = "Order")
```

Arguments

domain string, SDTM domain or supplemental domain code

dir string, specification directory

filename string, file name of the specification

arrange_by character vector, the column(s) by which to sort the domain sheet, default is

"Order"

Details

The readxl::read_excel() function will causes an access denied warning when reading in a read-only specification file. This does not affect the data import. Variables will be arranged in descending order per the "Order" column in the specification.

Value

a data frame of the variable specification for domain

See Also

```
get_key_vars(), get_codelist(), assign_meta_data()
```

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Examples

get_key_vars

Read in the key variables for a SDTM domain

Description

Reads the "Key Variables" column from the SDTM specification MS Excel file's "Datasets" sheet for the specified domain.

Usage

```
get_key_vars(
  domain,
  dir,
  filename,
  datasets_sheet = "Datasets",
  dataset_col = "Dataset",
  keyvar_col = "Key Variables"
)
```

Arguments

domain string, SDTM domain or supplemental domain code

dir string, specification directory

filename string, file name of the specification

datasets_sheet a string, the sheet name in the specification Excel file that has the key variables,

default is "Datasets"

dataset_col a string, the column name of the domains in the table in datasets_sheet, de-

fault is "Dataset"

keyvar_col a string, the column name of the key variables in the table in datasets_sheet,

default is "Key Variables"

Details

The readxl::read_excel() function will causes an access denied warning when reading in a read-only specification file. This does not affect the data import.

Value

a character vector of key variables for the specified domain

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See Also

```
get_data_spec(), get_codelist(), assign_meta_data()
```

Examples

impute_pdates

Impute start or end dates

Description

Imputes missing date elements for start or end dates. Partial dates should be in the format "UNKN-UN" or some combination of those characters and numbers (ie "2017-UN-UN"). Dates with no information or dates with a missing year will be converted to NA. For start dates, missing days are assumed to be the first of the month while missing months are assumed to be January. For end dates, missing days are assumed to be the last day of the month and missing months are assumed to be December.

Usage

```
impute_pdates(dates, ptype, input_sep = "-")
```

Arguments

dates a character vector of partial dates (which could also contain full dates) in the

format YYYY-MM-DD

ptype a string of either "start" or "end" indicating whether start or end dates should

be imputed, respectively

input_sep the character that separates date components in dates, default is "-"

Value

a date vector of imputed dates in the format YYYY-MM-DD

See Also

```
reshape_adates(), reshape_pdates(), trim_dates(), vignette("Dates")
```

read_edc_tbls

Examples

```
dates <- c(
   "UNKN-UN-UN",
   "2017-UN-UN",
   "2017-02-UN",
   "2017-UN-05",
   "2017-09-03",
   "UNKN-07-14",
   NA
)
impute_pdates(dates, ptype = "start")
impute_pdates(dates, ptype = "end")</pre>
```

read_edc_tbls

Import EDC data tables

Description

Reads-in EDC data table .csv files and puts them in a list.

Usage

```
read_edc_tbls(edc_tbls, dir)
```

Arguments

```
edc_tbls character vector of EDC table file names (without extension)
dir string, EDC data directory
```

Details

The file encoding will be UTF-8.

Value

a named list of data frames where the names are taken from edc_tbls and the data frames are the EDC data tables

See Also

```
read_sdtm_tbls()
```

```
edc_tbls <- c("xx", "vd")
edc_dir <- system.file("extdata", package = "sdtmval")
edc_dat <- read_edc_tbls(edc_tbls, dir = edc_dir)</pre>
```

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read_sdtm_tbls

Import SDTM data tables

Description

Reads-in SDTM data tables store as .sas7bdat files and puts them in a list.

Usage

```
read_sdtm_tbls(sdtm_tbls, dir)
```

Arguments

sdtm_tbls character vector of SDTM table file names (without extension)
dir string, the directory containing the production SDTM tables

Details

The file encoding will be UTF-8.

Value

a named list of data frames where the names are taken from sdtm_tbls and the data frames are the SDTM data

See Also

```
read_edc_tbls()
```

Examples

```
sdtm_tbls <- "dm"
sdtm_dir <- system.file("extdata", package = "sdtmval")
sdtm_dat <- read_sdtm_tbls(sdtm_tbls, dir = sdtm_dir)</pre>
```

reshape_adates

Reshape format of all dates (full and partial)

Description

Re-arranges full and partial dates in the general form of "MM/DD/YYYY" to the ISO 8601 format ("YYYY-MM-DD"). This function is appropriate for vectors with mixed full and partial dates because it will not convert the partial dates to NA which would occur if you used as .Date("02/UN/2017", format = "m/d/y").

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Usage

```
reshape_adates(dates)
```

Arguments

dates

a character vector of full and/or partial dates

Details

The date component separator in the input vector dates can be any character.

Value

a character vector of full and/or partial dates in the format "YYYY-MM-DD"

See Also

```
reshape_pdates(), impute_pdates(), trim_dates(), vignette("Dates")
```

Examples

```
dates <- c("02/05/2017", "UN/UN/2017", "02-05-2017", NA) reshape_adates(dates)
```

reshape_pdates

Reshape format of partial dates

Description

Re-arranges partial dates from a format of "UN-UNK-UNKN" ("DD-MMM-YYYY") to "UN/UN/UNKN" ("MM/DD/YYYY").

Usage

```
reshape_pdates(dates, output_sep = "/")
```

Arguments

dates a character vector of partial dates

output_sep the date component separator for the output, default is "/"

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Details

• The separator character between dates components for the input vector dates can be any commonly used date separator ("/", "-", ".", "").

- In the starting format, the month ("UNK") is a three letter abbreviation but, in the output format, the month is converted to a number
- The output format is a character vector, not a Date vector, to make some common SDTM date workflow operations easier
- The case of the input month abbreviation does not matter; "Feb", "feb", and "FEB" will yield the same results

Value

a character vector of partial dates in the format "UN/UN/UNKN" ("MM/DD/YYYY")

See Also

```
reshape_adates(), impute_pdates(), trim_dates(), vignette("Dates")
```

Examples

```
dates <- c(
   "UN-UNK-UNKN",
   "UN/UNK/UNKN",
   "UN-UNK-2017",
   "05-Feb-2017",
   "05-Feb-UNKN",
   NA
)
reshape_pdates(dates)</pre>
```

spec_codelists

Example 'Codelists' tab from a SDTM specification .xlsx file

Description

This table simulates an excerpt from a SDTM specification .xlsx file for the 'Codelists' tab which provides coded and decoded values from XXTESTCD and XXTEST variables, respectively. This data set can be used to test the get_codelist() function.

Usage

```
spec_codelists
```

spec_XX

Format

'spec_codelists':

A data frame with 3 rows and 3 columns:

ID The variable identifier/name

Term The coded term

Decoded Value The corresponding decoded value for the coded term

spec_datasets

Example 'Datasets' tab from a SDTM specification .xlsx file

Description

This table simulates an excerpt from a SDTM specification .xlsx file for the 'Datasets' tab which provides the key variables for the fake domain XX. This data set can be used to test the get_key_vars() function.

Usage

spec_datasets

Format

'spec_datasets':

A data frame with 1 row and 4 columns:

Dataset The domain

Description The domain description

Structure Defines what qualifies as a unique record

Key Variables The domain's key variables

spec_XX

Example domain specific tab from a SDTM specification .xlsx file

Description

This table simulates an excerpt from a SDTM specification .xlsx file for the fake domain tab XX which provides the labels, data types, and lengths by variable. This data set can be used to test the get_data_spec() and assign_meta_data() functions.

Usage

spec_XX

Format

'spec XX':

A data frame with 12 rows and 5 columns:

Order The order of the varibles in the data set

Dataset The domain abbreviation **Varible** The domain's variables

Label Variable labels

Data Type Variable data types

Length The maximum allowed length of an entry

```
trim_and_make_blanks_NA
```

Trim white space and make blanks NA

Description

Trims the white space on both sides of strings in a character vector and replaces blank values ("" and "") with NA for all columns in a data frame that have a character class.

Usage

```
trim_and_make_blanks_NA(tbl)
```

Arguments

tbl

a data frame, the SDTM table

Details

This function should be applied as one of the first steps in the data process to ensure consistent handling of all strings.

Value

a modified copy of the tbl data frame

See Also

```
format_chars_and_dates()
```

```
df <- data.frame(one = c(" a", "", " "))
trim_and_make_blanks_NA(df)</pre>
```

trim_dates

trim_dates

Trim unknown elements in partial dates

Description

Removes unknown elements from a partial date. For example, "2017–UN" is trimmed to "2017" and "2017–05-UN" is trimmed to "2017–05". Values of "UNKN-UN-UN" are converted to NA. Values where only the year and day are known are converted to just the year, ie "2017–UN-01" converts to "2017". Full dates are not modified.

Usage

```
trim_dates(dates, input_sep = "-")
```

Arguments

dates a character vector of partial dates in the format "UNKN-UN" ("YYYY-MM-DD");

full dates can also be included

input_sep the character that separates date components in the input vector dates, default

is "-"

Value

a character vector of trimmed partial dates and full dates

See Also

```
reshape_adates(), reshape_pdates(), impute_pdates(), vignette("Dates")
```

```
dates <- c(
"UNKN-UN-UN",
"2017-UN-UN",
"2017-02-UN",
"2017-UN-05",
"2017-09-03",
"UNKN-07-14",
NA
)
trim_dates(dates)
```

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νd

Example EDC data for form/table 'VD'

Description

This is an example data set to simulate raw EDC data from the 'VD' form/table which contains visit date information by subject.

Usage

vd

Format

'vd'

A data frame with 6 rows and 3 columns:

USUBJID Subject identifier

VISIT Visit name
VISITDTC Visit date

write_sessionInfo

Write R session information for a script to a .txt file

Description

Writes a .txt file of the output from utils::sessionInfo() with the file name [filename]_sessionInfo.txt. By creating a log of the R session conditions a script was run with, results from the script can be reproduced in the future.

Usage

```
write_sessionInfo(filename, dir = NULL)
```

Arguments

filename a string, the script file name (with or without .R extension)

dir a string, the directory to write to, default is NULL which means the current work-

ing directory will be used

Value

nothing

See Also

```
convert_to_script()
```

24 write_tbl_to_xpt

Examples

```
path <- tempdir()
write_sessionInfo(filename = "test.R", dir = path)</pre>
```

write_tbl_to_xpt

Write a SAS transport file (.xpt)

Description

Writes a data frame to a SAS transport file (.xpt) named like "[domain].xpt"

Usage

```
write_tbl_to_xpt(tbl, filename, dir = NULL, label = NULL)
```

Arguments

tbl a data frame to write

filename a string, the SDTM domain or supplemental domain name which will become

the file name and the name attribute of the transport file, the .xpt file extension

is optional

dir a string, the directory to write to, default is NULL

label a string, the data set name/label for the haven::write_xpt() name argument.

The default is NULL in which case the filename will be used. label must be $8\,$

characters or less.

Details

Files will be written using version 5 .xpt files

Value

nothing

```
tbl <- dplyr::tibble(one = as.numeric(1:3), two = letters[1:3])
path <- tempdir()
write_tbl_to_xpt(tbl, filename = "test.xpt", dir = path)</pre>
```

xx_no_meta_data 25

 $xx_no_meta_data$

Example SDTM domain table XX without meta data

Description

This data set is used to test the assign_meta_data() function and contains a fake SDTM domain XX but without label or lengths assigned to the column attributes.

Usage

xx_no_meta_data

Format

'xx_no_meta_data':

A data frame with 10 rows and 11 columns:

STUDYID Study identifier

USUBJID Subject identifier

XXSEQ Sequence number

XXTESTCD Coded test name

XXTEST Test name

XXORRES Measurement in original units

XXBLFL Baseline flag

VISIT Visit name

EPOCH EPOCH

XXDTC Measurement date

XXDY Measurement day of study

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