

Package ‘safetyData’

January 19, 2021

Title Clinical Trial Data

Description Example clinical trial data sets formatted for easy use in R.

Version 1.0.0

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Encoding UTF-8

LazyData true

RoxygenNote 7.1.1

Depends R (>= 3.0)

NeedsCompilation no

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Repository CRAN

Date/Publication 2021-01-19 09:50:02 UTC

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adam_adae	<i>adam_adae</i>
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Description

ADaM adae data frame

Usage

adam_adae

Format

a data frame with 1191 rows and 55 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/adam/README.md> for more details and full data specification.

adam_adlbc	<i>adam_adlbc</i>
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Description

ADaM adlbc data frame

Usage

adam_adlbc

Format

a data frame with 74264 rows and 46 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/adam/README.md> for more details and full data specification.

adam_adlbh	<i>adam_adlbh</i>
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Description

ADaM adlbh data frame

Usage

adam_adlbh

Format

a data frame with 49932 rows and 46 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/adam/README.md> for more details and full data specification.

adam_adlbhy	<i>adam_adlbhy</i>
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Description

ADaM adlbhy data frame

Usage

adam_adlbhy

Format

a data frame with 9954 rows and 43 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/adam/README.md> for more details and full data specification.

adam_adqsadas	<i>adam_adqsadas</i>
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Description

ADaM adqsadas data frame

Usage

adam_adqsadas

Format

a data frame with 12463 rows and 40 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/adam/README.md> for more details and full data specification.

adam_adqscibc	<i>adam_adqscibc</i>
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Description

ADaM adqscibc data frame

Usage

adam_adqscibc

Format

a data frame with 730 rows and 36 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/adam/README.md> for more details and full data specification.

adam_adqsnpix	<i>adam_adqsnpix</i>
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Description

ADaM adqsnpix data frame

Usage

adam_adqsnpix

Format

a data frame with 31140 rows and 41 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/adam/README.md> for more details and full data specification.

adam_adsl	<i>adam_adsl</i>
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Description

ADaM adsl data frame

Usage

adam_adsl

Format

a data frame with 254 rows and 48 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/adam/README.md> for more details and full data specification.

adam_adtte	<i>adam_adtte</i>
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Description

ADaM adtte data frame

Usage

adam_adtte

Format

a data frame with 254 rows and 26 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/adam/README.md> for more details and full data specification.

adam_advsv	<i>adam_advsv</i>
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Description

ADaM advsv data frame

Usage

adam_advsv

Format

a data frame with 32139 rows and 34 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/adam/README.md> for more details and full data specification.

sdm_ae

*sdm_ae***Description**

Adverse Events data frame - One record per adverse event per subject

Usage

```
sdm_ae
```

Format

a data frame with 1191 rows and 35 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 AESEQ integer - Sequence Number
 AESPID text - Sponsor-Defined Identifier
 AETERM text - Reported Term for the Adverse Event
 AELLT text - Lowest Level Term
 AELLTCD integer - Lowest Level Term Code
 AEDECOD text - Dictionary-Derived Term
 AEPTCD integer - Preferred Term Code
 AEHLT text - High Level Term
 AEHLTCD integer - High Level Term Code
 AEHLGT text - High Level Group Term
 AEHLGTC integer - High Level Group Term Code
 AEBODSYS text - Body System or Organ Class
 AEBDSYCD integer - Body System or Organ Class Code
 AESOC text - Primary System Organ Class
 AESOCCD integer - Primary System Organ Class Code
 AESEV text - Severity/Intensity
 AESER text - Serious Event
 AEACN text - Action Taken with Study Treatment
 AEREL text - Causality
 AEOUT text - Outcome of Adverse Event
 AESCAN text - Involves Cancer

AESCONG text - Congenital Anomaly or Birth Defect
 AESDISAB text - Persist or Signif Disability/Incapacity
 AESDTH text - Results in Death
 AESHOSP text - Requires or Prolongs Hospitalization
 AESLIFE text - Is Life Threatening
 AESOD text - Occurred with Overdose
 AEDTC date - Date/Time of Collection
 AESTDTC date - Start Date/Time of Adverse Event
 AEENDTC date - End Date/Time of Adverse Event
 AESTDY integer - Study Day of Start of Adverse Event
 AEENDY integer - Study Day of End of Adverse Event

 sdm_cm

 sdm_cm

Description

Concomitant Medications data frame - One record per recorded medication occurrence or constant-dosing interval per subject

Usage

sdm_cm

Format

a data frame with 7510 rows and 21 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 CMSEQ integer - Sequence Number
 CMSPID text - Sponsor-Defined Identifier
 CMTRT text - Reported Name of Drug, Med, or Therapy
 CMDECOD text - Standardized Medication Name
 CMINDC text - Indication
 CMCLAS text - Medication Class
 CMDOSE integer - Dose per Administration
 CMDOSU text - Dose Units
 CMDOSFRQ text - Dosing Frequency per Interval

CMROUTE text - Route of Administration
 VISITNUM float - Visit Number
 VISIT text - Visit Name
 VISITDY integer - Planned Study Day of Visit
 CMDTC date - Date/Time of Collection
 CMSTDTC date - Start Date/Time of Medication
 CMENDTC date - End Date/Time of Medication
 CMSTDY integer - Study Day of Start of Medication
 CMENDY integer - Study Day of End of Medication

 sdm_dm

sdm_dm

Description

Demographics data frame - One record per subject

Usage

sdm_dm

Format

a data frame with 306 rows and 25 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 SUBJID text - Subject Identifier for the Study
 RFSTDTC date - Subject Reference Start Date/Time
 RFENDTC date - Subject Reference End Date/Time
 RFXSTDTC datetime - Date/Time of First Study Treatment
 RFXENDTC datetime - Date/Time of Last Study Treatment
 RFICDTC datetime - Date/Time of Informed Consent
 RFPENDTC datetime - Date/Time of End of Participation
 DTHDTC datetime - Date/Time of Death
 DTHFL text - Subject Death Flag
 SITEID text - Study Site Identifier
 AGE integer - Age
 AGEU text - Age Units

SEX text - Sex
 RACE text - Race
 ETHNIC text - Ethnicity
 ARMCD text - Planned Arm Code
 ARM text - Description of Planned Arm
 ACTARMCD text - Actual Arm Code
 ACTARM text - Description of Actual Arm
 COUNTRY text - Country
 DMDTC date - Date/Time of Collection
 DMDY integer - Study Day of Collection

 sdm_ds

 sdm_ds

Description

Disposition data frame - One record per disposition status or protocol milestone per subject

Usage

sdm_ds

Format

a data frame with 596 rows and 13 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 DSSEQ integer - Sequence Number
 DSSPID text - Sponsor-Defined Identifier
 DSTERM text - Reported Term for the Disposition Event
 DSDECOD text - Standardized Disposition Term
 DSCAT text - Category for Disposition Event
 VISITNUM float - Visit Number
 VISIT text - Visit Name
 DSDTC datetime - Date/Time of Collection
 DSSTDTC date - Start Date/Time of Disposition Event
 DSSTDY integer - Study Day of Start of Disposition Event

sdm_ex

*sdm_ex***Description**

Exposure data frame - One record per constant dosing interval per subject

Usage

sdm_ex

Format

a data frame with 591 rows and 17 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 EXSEQ integer - Sequence Number
 EXTRT text - Name of Actual Treatment
 EXDOSE integer - Dose per Administration
 EXDOSU text - Dose Units
 EXDOSFRM text - Dose Form
 EXDOSFRQ text - Dosing Frequency per Interval
 EXROUTE text - Route of Administration
 VISITNUM float - Visit Number
 VISIT text - Visit Name
 VISITDY integer - Planned Study Day of Visit
 EXSTDTC date - Start Date/Time of Treatment
 EXENDTC date - End Date/Time of Treatment
 EXSTDY integer - Study Day of Start of Treatment
 EXENDY integer - Study Day of End of Treatment

sdm_lb	<i>sdm_lb</i>
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Description

Laboratory Tests Results data frame - One record per analyte per planned time point number per time point reference per visit per subject

Usage

sdm_lb

Format

a data frame with 59580 rows and 23 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification.

Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 LBSEQ integer - Sequence Number
 LBTESTCD text - Lab Test or Examination Short Name
 LBTEST text - Lab Test or Examination Name
 LBCAT text - Category for Lab Test
 LBORRES text - Result or Finding in Original Units
 LBORRESU text - Original Units
 LBORNRL0 text - Reference Range Lower Limit in Orig Unit
 LBORNRHI text - Reference Range Upper Limit in Orig Unit
 LBSTRESC text - Character Result/Finding in Std Format
 LBSTRESN integer - Numeric Result/Finding in Standard Units
 LBSTRESU text - Standard Units
 LBSTNRLO integer - Reference Range Lower Limit-Std Units
 LBSTNRHI integer - Reference Range Upper Limit-Std Units
 LBNRIND text - Reference Range Indicator
 LBBLFL text - Baseline Flag
 VISITNUM float - Visit Number
 VISIT text - Visit Name
 VISITDY integer - Planned Study Day of Visit
 LBDTC datetime - Date/Time of Specimen Collection
 LBDY integer - Study Day of Specimen Collection

sdm_mh

*sdm_mh***Description**

Medical History data frame - One record per medical history event per subject

Usage

sdm_mh

Format

a data frame with 1818 rows and 19 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 MHSEQ integer - Sequence Number
 MHSPID text - Sponsor-Defined Identifier
 MHTERM text - Reported Term for the Medical History
 MHLLT text - Lowest Level Term
 MHDECOD text - Dictionary-Derived Term
 MHHLT text - High Level Term
 MHHLGT text - High Level Group Term
 MHCAT text - Category for Medical History
 MHBODSYS text - Body System or Organ Class
 MHSEV text - Severity/Intensity
 VISITNUM float - Visit Number
 VISIT text - Visit Name
 VISITDY integer - Planned Study Day of Visit
 MHDTC date - Date/Time of History Collection
 MHSTDTC date - Start Date/Time of Medical History Event
 MHDY integer - Study Day of History Collection

sdm_qs

sdm_qs

Description

Questionnaires data frame - One record per questionnaire per question per time point per visit per subject

Usage

```
sdm_qs
```

Format

a data frame with 121749 rows and 20 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 QSSEQ integer - Sequence Number
 QSTESTCD text - Question Short Name
 QSTEST text - Question Name
 QSCAT text - Category of Question
 QSSCAT text - Subcategory for Question
 QSORRES text - Finding in Original Units
 QSORRESU text - Original Units
 QSSTRESC text - Character Result/Finding in Std Format
 QSSTRESN integer - Numeric Finding in Standard Units
 QSSTRESU text - Standard Units
 QSBLFL text - Baseline Flag
 QSDRVFL text - Derived Flag
 VISITNUM float - Visit Number
 VISIT text - Visit Name
 VISITDY integer - Planned Study Day of Visit
 QSDTC date - Date/Time of Finding
 QSDY integer - Study Day of Finding

sdm_relrec	<i>sdm_relrec</i>
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Description

Related Records data frame - One record per related record, group of records or datasets

Usage

sdm_relrec

Format

a data frame with 234 rows and 7 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 RDOMAIN text - Related Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 IDVAR text - Identifying Variable
 IDVARVAL text - Identifying Variable Value
 RELTYPE text - Relationship Type
 RELID text - Relationship Identifier

sdm_sc	<i>sdm_sc</i>
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Description

Subject Characteristics data frame - One record per characteristic per subject

Usage

sdm_sc

Format

a data frame with 254 rows and 14 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 SCSEQ integer - Sequence Number

SCTESTCD text - Subject Characteristic Short Name
 SCTEST text - Subject Characteristic
 SCCAT text - Category for Subject Characteristic
 SCORRES text - Result or Finding in Original Units
 SCORRESU text - Original Units
 SCSTRESC text - Character Result/Finding in Std Format
 SCSTRESN integer - Numeric Result/Finding in Standard Units
 SCSTRESU text - Standard Units
 SCDTC date - Date/Time of Collection
 SCDY integer - Study Day of Examination

 sdm_se

sdm_se

Description

Subject Elements data frame - One record per actual Element per subject

Usage

sdm_se

Format

a data frame with 752 rows and 9 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 SESEQ integer - Sequence Number
 ETCD text - Element Code
 ELEMENT text - Description of Element
 SESTDTC date - Start Date/Time of Element
 SEENDTC date - End Date/Time of Element
 SEUPDES text - Description of Unplanned Element

 sdm_suppae

sdm_suppae

Description

Supplemental Qualifiers for AE data frame - One record per IDVAR, IDVARVAL, and QNAM value per subject

Usage

sdm_suppae

Format

a data frame with 1191 rows and 10 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 RDOMAIN text - Related Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 IDVAR text - Identifying Variable
 IDVARVAL text - Identifying Variable Value
 QNAM text - Qualifier Variable Name
 QLABEL text - Qualifier Variable Label
 QVAL text - Data Value
 QORIG text - Origin
 QEVAL text - Evaluator

 sdm_suppdm

sdm_suppdm

Description

Supplemental Qualifiers for DM data frame - One record per IDVAR, IDVARVAL, and QNAM value per subject

Usage

sdm_suppdm

Format

a data frame with 1197 rows and 10 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 RDOMAIN text - Related Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 IDVAR text - Identifying Variable
 IDVARVAL text - Identifying Variable Value
 QNAM text - Qualifier Variable Name
 QLABEL text - Qualifier Variable Label
 QVAL text - Data Value
 QORIG text - Origin
 QEVAL text - Evaluator

 sdm_supps

sdm_supps

Description

Supplemental Qualifiers for DS data frame - One record per IDVAR, IDVARVAL, and QNAM value per subject

Usage

sdm_supps

Format

a data frame with 3 rows and 10 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 RDOMAIN text - Related Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 IDVAR text - Identifying Variable
 IDVARVAL text - Identifying Variable Value
 QNAM text - Qualifier Variable Name
 QLABEL text - Qualifier Variable Label
 QVAL text - Data Value
 QORIG text - Origin
 QEVAL text - Evaluator

 sdm_supplb

sdm_supplb

Description

Supplemental Qualifiers for LB data frame - One record per IDVAR, IDVARVAL, and QNAM value per subject

Usage

sdm_supplb

Format

a data frame with 64403 rows and 10 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 RDOMAIN text - Related Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 IDVAR text - Identifying Variable
 IDVARVAL text - Identifying Variable Value
 QNAM text - Qualifier Variable Name
 QLABEL text - Qualifier Variable Label
 QVAL text - Data Value
 QORIG text - Origin
 QEVAL text - Evaluator

 sdm_sv

sdm_sv

Description

Subject Visits data frame - One record per actual visit per subject

Usage

sdm_sv

Format

a data frame with 3559 rows and 8 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdtm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 VISITNUM float - Visit Number
 VISIT text - Visit Name
 VISITDY integer - Planned Study Day of Visit
 SVSTDTC date - Start Date/Time of Visit
 SVENDTC date - End Date/Time of Visit

 sdtm_ta

sdtm_ta

Description

Trial Arms data frame - One record per planned Element per Arm

Usage

sdtm_ta

Format

a data frame with 8 rows and 10 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdtm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 ARMCD text - Planned Arm Code
 ARM text - Description of Planned Arm
 TAETORD integer - Order of Element within Arm
 ETCD text - Element Code
 ELEMENT text - Description of Element
 TABRANCH text - Branch
 TATRANS text - Transition Rule
 EPOCH text - Epoch

sdm_te	<i>sdm_te</i>
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Description

Trial Elements data frame - One record per planned Element

Usage

sdm_te

Format

a data frame with 7 rows and 7 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 ETCD text - Element Code
 ELEMENT text - Description of Element
 TESTRL text - Rule for Start of Element
 TEENRL text - Rule for End of Element
 TEDUR text - Planned Duration of Element

sdm_ti	<i>sdm_ti</i>
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Description

Trial Inclusion/ Exclusion Criteria data frame - One record per I/E criterion

Usage

sdm_ti

Format

a data frame with 31 rows and 6 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 IETESTCD text - Incl/Excl Criterion Short Name
 IETEST text - Inclusion/Exclusion Criterion
 IECAT text - Inclusion/Exclusion Category
 TIRL text - Inclusion/Exclusion Criterion Rule

sdm_ts	<i>sdm_ts</i>
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Description

Trial Summary data frame - One record per trial summary parameter value

Usage

sdm_ts

Format

a data frame with 33 rows and 6 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 TSSEQ integer - Sequence Number
 TSPARMCD text - Trial Summary Parameter Short Name
 TSPARM text - Trial Summary Parameter
 TSVAl text - Parameter Value

sdm_tv	<i>sdm_tv</i>
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Description

Trial Visits data frame - One record per planned Visit per Arm

Usage

sdm_tv

Format

a data frame with 21 rows and 9 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification. Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 VISITNUM float - Visit Number
 VISIT text - Visit Name
 VISITDY integer - Planned Study Day of Visit

ARMCD text - Planned Arm Code
 ARM text - Description of Planned Arm
 TVSTRL text - Visit Start Rule
 TVENRL text - Visit End Rule

sdm_vs

sdm_vs

Description

Vital Signs data frame - One record per vital sign measurement per time point per visit per subject

Usage

sdm_vs

Format

a data frame with 29643 rows and 24 columns. See <https://github.com/SafetyGraphics/safetyData/blob/main/data-raw/sdm/README.md> for more details and full data specification.
 Columns:

STUDYID text - Study Identifier
 DOMAIN text - Domain Abbreviation
 USUBJID text - Unique Subject Identifier
 VSSEQ integer - Sequence Number
 VSTESTCD text - Vital Signs Test Short Name
 VSTEST text - Vital Signs Test Name
 VSPOS text - Vital Signs Position of Subject
 VSORRES text - Result or Finding in Original Units
 VSORRESU text - Original Units
 VSSTRESC text - Character Result/Finding in Std Format
 VSSTRESN integer - Numeric Result/Finding in Standard Units
 VSSTRESU text - Standard Units
 VSSTAT text - Completion Status
 VSLOC text - Location of Vital Signs Measurement
 VSBLFL text - Baseline Flag
 VISITNUM float - Visit Number
 VISIT text - Visit Name
 VISITDY integer - Planned Study Day of Visit
 VSDTC date - Date/Time of Measurements

VSDY integer - Study Day of Vital Signs
VSTPT text - Planned Time Point Name
VSTPTNUM integer - Planned Time Point Number
VSELTM text - Planned Elapsed Time from Time Point Ref
VSTPTREF text - Time Point Reference

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