Package 'safetyData'

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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.

 ${\tt adam_adlbc}$

 $adam_adlbc$

Description

ADaM adlbc data frame

Usage

adam_adlbc

adam_adlbh 3

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

adam_adlbh

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

adam_adlbhy

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.

4 adam_adqsnpix

adam_adqsadas

adam_adqsadas

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

adam_adqscibc

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

adam_adqsnpix

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 5

adam_adsl

adam_adsl

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

adam_adtte

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_advs

adam_advs

Description

ADaM advs data frame

Usage

adam_advs

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.

6 sdtm_ae

sdtm_ae

sdtm_ae

Description

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

Usage

sdtm_ae

Format

a data frame with 1191 rows and 35 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

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

AEHLGTCD 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

sdtm_cm 7

```
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
```

sdtm_cm

sdtm cm

Description

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

Usage

sdtm_cm

Format

a data frame with 7510 rows and 21 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

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

8 sdtm_dm

```
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

sdtm_dm

sdtm_dm

Description

Demographics data frame - One record per subject

Usage

sdtm_dm

Format

a data frame with 306 rows and 25 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

SUBJID text - Subject Identifier for the Study

RESTDTC date - Subject Reference Start Date/Time

RESTDTC date - Subject Reference End Date/Time

REXSTDTC datetime - Date/Time of First Study Treatment

REXENDTC datetime - Date/Time of Last Study Treatment

RESTEDTC datetime - Date/Time of Informed Consent

REPENDTC 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
```

sdtm_ds 9

```
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
```

 $sdtm_ds$

sdtm_ds

Description

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

Usage

sdtm_ds

Format

a data frame with 596 rows and 13 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

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

10 sdtm_ex

sdtm_ex sdtm_ex

Description

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

Usage

sdtm_ex

Format

a data frame with 591 rows and 17 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 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

sdtm_lb

sdtm_lb sdtm_lb

Description

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

Usage

sdtm_lb

Format

a data frame with 59580 rows and 23 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

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

LBORNRLO 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

12 sdtm_mh

sdtm_mh sdtm_mh

Description

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

Usage

sdtm mh

Format

a data frame with 1818 rows and 19 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

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

sdtm_qs

sdtm_qs sdtm_qs

Description

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

Usage

sdtm_qs

Format

a data frame with 121749 rows and 20 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

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

sdtm_sc

sdtm_relrec

 $sdtm_relrec$

Description

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

Usage

sdtm_relrec

Format

a data frame with 234 rows and 7 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

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

 $sdtm_sc$

 $sdtm_sc$

Description

Subject Characteristics data frame - One record per characteristic per subject

Usage

sdtm_sc

Format

a data frame with 254 rows and 14 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

SCSEQ integer - Sequence Number

sdtm_se

```
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
```

sdtm_se sdtm_se

Description

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

Usage

sdtm_se

Format

a data frame with 752 rows and 9 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

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

sdtm_suppdm

sdtm_suppae

sdtm_suppae

Description

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

Usage

sdtm_suppae

Format

a data frame with 1191 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
```

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

sdtm_suppdm

sdtm_suppdm

Description

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

Usage

sdtm_suppdm

sdtm_suppds 17

Format

a data frame with 1197 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

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
```

sdtm_suppds

sdtm_suppds

Description

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

Usage

sdtm_suppds

Format

a data frame with 3 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

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

18 sdtm_sv

sdtm_supplb

sdtm_supplb

Description

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

Usage

sdtm_supplb

Format

a data frame with 64403 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
```

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

sdtm_sv

sdtm_sv

Description

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

Usage

sdtm_sv

sdtm_ta 19

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

20 sdtm_ti

sdtm_te

sdtm_te

Description

Trial Elements data frame - One record per planned Element

Usage

sdtm_te

Format

a data frame with 7 rows and 7 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

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

sdtm_ti

sdtm ti

Description

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

Usage

 $sdtm_ti$

Format

a data frame with 31 rows and 6 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

IETESTCD text - Incl/Excl Criterion Short Name

IETEST text - Inclusion/Exclusion Criterion

IECAT text - Inclusion/Exclusion Category

TIRL text - Inclusion/Exclusion Criterion Rule

sdtm_ts 21

sdtm_ts

sdtm_ts

Description

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

Usage

sdtm_ts

Format

a data frame with 33 rows and 6 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

TSSEQ integer - Sequence Number

TSPARMCD text - Trial Summary Parameter Short Name

TSPARM text - Trial Summary Parameter

TSVAL text - Parameter Value
```

 $sdtm_tv$

sdtm_tv

Description

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

Usage

sdtm_tv

Format

a data frame with 21 rows and 9 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

VISITNUM float - Visit Number

VISIT text - Visit Name

VISITDY integer - Planned Study Day of Visit
```

22 sdtm_vs

```
ARMCD text - Planned Arm Code

ARM text - Description of Planned Arm

TVSTRL text - Visit Start Rule

TVENRL text - Visit End Rule
```

sdtm_vs

sdtm_vs

Description

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

Usage

sdtm_vs

Format

a data frame with 29643 rows and 24 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

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

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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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