Package 'pharmaversesdtm'

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Type Package

Title SDTM Test Data for the 'Pharmaverse' Family of Packages

Version 1.2.0

Description A set of Study Data Tabulation Model (SDTM) datasets from the Clinical Data Interchange Standards Consortium (CDISC) pilot project used for testing and developing Analysis Data Model (ADaM) datasets inside the pharmaverse family of packages. SDTM dataset specifications are described in the CDISC SDTM implementation guide, accessible by creating a free account on <https://www.cdisc.org/>.

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---

ae *Adverse Events*

Description

An updated SDTM AE dataset that uses the CDISC pilot project

Usage

```
ae
```

Format

A data frame with 35 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

AESEQ Sequence Number

AESPID Sponsor-Defined Identifier

AETERM Reported Term for the Adverse Event

AELLT Lowest Level Term

AELLTCD Lowest Level Term Code

AEDECOD Dictionary-Derived Term

AEPTCD Preferred Term Code

AEHLT High Level Term

AEHLTCD High Level Term Code

AEHLGT High Level Group Term

AEHLGTCD High Level Group Term Code

AEBODSYS Body System or Organ Class

AEBDSYCD Body System or Organ Class Code

AESOC Primary System Organ Class

AESOCCD Primary System Organ Class Code

AESEV Severity/Intensity

AESER Serious Event

AEACN Action Taken with Study Treatment

AEREL Causality

AEOUT Outcome of Adverse Event

AESCAN Involves Cancer

AESCONG Congenital Anomaly or Birth Defect

AESDISAB Persist or Signif Disability/Incapacity

AESDTH Results in Death

AESHOSP Requires or Prolongs Hospitalization

AESLIFE Is Life Threatening

AESOD Occurred with Overdose

AEDTC Date/Time of Collection

AESTDTC Start Date/Time of Adverse Event

AEENDTC End Date/Time of Adverse Event

AESTDY Study Day of Start of Adverse Event

AEENDY Study Day of End of Adverse Event

Details

Adverse Events

An updated SDTM AE dataset that uses the CDISC pilot project

Author(s)

Gopi Vegesna

Source

Access the source of the Adverse Events dataset.

---

ae_ophtha *Adverse Events for Ophthalmology*

Description

An example Adverse Events SDTM dataset with ophthalmology-specific variable `AELAT`

Usage

```
ae_ophtha
```

Format

A data frame with 37 columns:

STUDYID Study Identifier
DOMAIN Domain Abbreviation
USUBJID Unique Subject Identifier
AESEQ Sequence Number
AESPID Sponsor-Defined Identifier
AETERM Reported Term for the Adverse Event
AELLT Lowest Level Term
AELLTCD Lowest Level Term Code
AEDECOD Dictionary-Derived Term
AEPTCD Preferred Term Code
AEHLT High Level Term
AEHLTCD High Level Term Code
AEHLGT High Level Group Term
AEHLGTCD High Level Group Term Code
AEBODSYS Body System or Organ Class
AEBDSYCD Body System or Organ Class Code
AESOC Primary System Organ Class
AESOCCD Primary System Organ Class Code
AESEV Severity/Intensity
AESER Serious Event
AEACN Action Taken with Study Treatment
AEREL Causality
AEOUT Outcome of Adverse Event
AESCAN Involves Cancer
AESCONG Congenital Anomaly or Birth Defect
AESDISAB Persist or Signif Disability/Incapacity
AESDTH Results in Death
AESHOSP Requires or Prolongs Hospitalization
AESLIFE Is Life Threatening
AESOD Occurred with Overdose
AEDTC Date/Time of Collection
AESTDTC Start Date/Time of Adverse Event
AEENDTC End Date/Time of Adverse Event
AESTDY Study Day of Start of Adverse Event
AEENDY Study Day of End of Adverse Event
AELAT Laterality
AELOC Location

Details

Adverse Events for Ophthalmology

An example Adverse Events SDTM dataset with ophthalmology-specific variable `AELAT`

Source

Constructed using ae from the pharmaversesdtm package

`ce_vaccine` *Clinical Events for Vaccine*

Description

An example SDTM CE dataset for vaccine studies

Usage

```
ce_vaccine
```

Format

A data frame with 29 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

CESEQ Sequence Number

CELNKID Link ID

CELNKGRP Link Group ID

CETERM Reported Term for the Clinical Event

CEDECOD Dictionary-Derived Term

CELAT Laterality of Location of Clinical Event

CELOC Location of Clinical Event

CECAT Category for Clinical Event

CESCAT Subcategory for Clinical Event

CEPRESP Clinical Event Pre-Specified

CEOCCUR Clinical Event Occurrence

CESEV Severity/Intensity

CEREL Causality

CEOUT Outcome of Clinical Event

EPOCH Epoch

CEDTC Date/Time of Event Collection

CESTDTC Start Date/Time of Clinical Event

CEENDTC End Date/Time of Clinical Event

CEDUR Duration of Clinical Event

CETPT Planned Time Point Name

CETPTNUM Planned Time Point Number

CETPTREF Time Point Reference

CERFTDTC Date/Time of Reference Time Point

CEEVINTX Evaluation Interval Text

CESTAT Completion Status

CEREASND Reason Clinical Event Not Collected

Details

Clinical Events for Vaccine

An example SDTM CE dataset for vaccine studies

Source

Constructed by admiralvaccine developers

---

cm *Concomitant Medication*

Description

A SDTM CM dataset from the CDISC pilot project

Usage

```
cm
```

Format

A data frame with 22 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

CMSEQ Sequence Number

CMSPID Sponsor-Defined Identifier

CMTRT Reported Name of Drug, Med, or Therapy

CMDECOD Standardized Medication Name

CMINDC Indication

CMCLAS Medication Class

CMDOSE Dose per Administration

CMDOSU Dose Units

CMDOSFRQ Dosing Frequency per Interval

CMROUTE Route of Administration

VISITNUM Visit Number

VISIT Visit Name

VISITDY Planned Study Day of Visit

CMDTC Date/Time of Collection

CMSTDTC Start Date/Time of Medication

CMENDTC End Date/Time of Medication

CMSTDY Study Day of Start of Medication

CMENDY Study Day of End of Medication

CMENRTPT undocumented field

Details

Concomitant Medication

A SDTM CM dataset from the CDISC pilot project

Source

Access the source of the Concomitant Medication dataset.

`dm` *Demography*

Description

A SDTM DM dataset from the CDISC pilot project

Usage

```
dm
```

Format

A data frame with 25 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

SUBJID Subject Identifier for the Study

RFSTDTC Subject Reference Start Date/Time

RFENDTC Subject Reference End Date/Time

RFXSTDTC Date/Time of First Study Treatment

RFXENDTC Date/Time of Last Study Treatment

RFICDTC Date/Time of Informed Consent

RFPENDTC Date/Time of End of Participation

DTHDTC Date/Time of Death

DTHFL Subject Death Flag

SITEID Study Site Identifier

AGE Age

AGEU Age Units

SEX Sex

RACE Race

ETHNIC Ethnicity

ARMCD Planned Arm Code

ARM Description of Planned Arm

ACTARMCD Actual Arm Code

ACTARM Description of Actual Arm

COUNTRY Country

DMDTC Date/Time of Collection

DMDY Study Day of Collection

Details

Demography

A SDTM DM dataset from the CDISC pilot project

Source

Access the source of the Demography dataset.

dm_peds *Demographic Dataset-pediatrics*

Description

An updated SDTM DM dataset with pediatric patients

Usage

```
dm_peds
```

Format

A data frame with 26 columns:

STUDYID Study Identifier
DOMAIN Domain Abbreviation
USUBJID Unique Subject Identifier
SUBJID Subject Identifier for the Study
RFSTDTC Subject Reference Start Date/Time
RFENDTC Subject Reference End Date/Time
RFXSTDTC Date/Time of First Study Treatment
RFXENDTC Date/Time of Last Study Treatment
RFICDTC Date/Time of Informed Consent
RFPENDTC Date/Time of End of Participation
DTHDTC Date/Time of Death
DTHFL Subject Death Flag
SITEID Study Site Identifier
AGE Age
AGEU Age Units
SEX Sex
RACE Race
ETHNIC Ethnicity
ARMCD Planned Arm Code
ARM Description of Planned Arm
ACTARMCD Actual Arm Code
ACTARM Description of Actual Arm
COUNTRY Country
DMDTC Date/Time of Collection
DMDY Study Day of Collection
BRTHDTC Date/Time of Birth

Details

Demographic Dataset-pediatrics

An updated SDTM DM dataset with pediatric patients

Source

Constructed by admiralpeds developers

`dm_vaccine` *Demographics for Vaccine*

Description

An example SDTM DM dataset for vaccine studies

Usage

```
dm_vaccine
```

Format

A data frame with 28 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

SUBJID Subject Identifier for the Study

RFSTDTC Subject Reference Start Date/Time

RFENDTC Subject Reference End Date/Time

RFXSTDTC Date/Time of First Study Treatment

RFXENDTC Date/Time of Last Study Treatment

RFICDTC Date/Time of Informed Consent

RFPENDTC Date/Time of End of Participation

DTHDTC Date/Time of Death

DTHFL Subject Death Flag

SITEID Study Site Identifier

INVID Investigator Identifier

INVNAM Investigator Name

BRTHDTC Date/Time of Birth

AGE Age

AGEU Age Units

SEX Sex

RACE Race

ETHNIC Ethnicity

ARMCD Planned Arm Code

ARM Description of Planned Arm

ACTARMCD Actual Arm Code

ACTARM Description of Actual Arm

COUNTRY Country

DMDTC Date/Time of Collection

DMDY Study Day of Collection

Details

Demographics for Vaccine

An example SDTM DM dataset for vaccine studies

Source

Constructed by admiralvaccine developers

`ds` *Disposition*

Description

An updated SDTM DS dataset that uses the CDISC pilot project

Usage

```
ds
```

Format

A data frame with 13 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

DSSEQ Sequence Number

DSSPID Sponsor-Defined Identifier

DSTERM Reported Term for the Disposition Event

DSDECOD Standardized Disposition Term

DSCAT Category for Disposition Event

VISITNUM Visit Number

VISIT Visit Name

DSDTC Date/Time of Collection

DSSTDTC Start Date/Time of Disposition Event

DSSTDY Study Day of Start of Disposition Event

Details

Disposition

An updated SDTM DS dataset that uses the CDISC pilot project

Author(s)

Gopi Vegesna

Source

Access the source of the Disposition dataset.

`eg` *Electrocardiogram*

Description

An example of standard SDTM EG dataset to be used in deriving ADEG dataset

Usage

```
eg
```

Format

A data frame with 23 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

EGSEQ Sequence Number

EGTESTCD Test Code

EGTEST Test Name

EGORRES Original Result

EGORRESU Original Units

EGSTRESC Standard Character Result

EGSTRESN Standard Numeric Result

EGSTRESU Standard Units

EGSTAT Completion Status

EGLOC Location of Vital Signs Measurement

EGBLFL Baseline Flag

VISITNUM Visit Number

VISIT Visit Name

VISITDY Planned Study Day of Visit

EGDTC Date/Time of Measurements

EGDY Study Day of Vital Signs

EGTPT Planned Time Point Number

EGTPTNUM Time Point Number

EGELTM Planned Elapsed Time from Time Point Ref

EGTPTREF Time Point Reference

Details

Electrocardiogram

An example of standard SDTM EG dataset to be used in deriving ADEG dataset

Source

Generated dataset.

`ex` *Exposure*

Description

A SDTM EX dataset from the CDISC pilot project

Usage

```
ex
```

Format

A data frame with 17 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

EXSEQ Sequence Number

EXTRT Name of Actual Treatment

EXDOSE Dose per Administration

EXDOSU Dose Units

EXDOSFRM Dose Form

EXDOSFRQ Dosing Frequency per Interval

EXROUTE Route of Administration

VISITNUM Visit Number

VISIT Visit Name

VISITDY Planned Study Day of Visit

EXSTDTC Start Date/Time of Treatment

EXENDTC End Date/Time of Treatment

EXSTDY Study Day of Start of Treatment

EXENDY Study Day of End of Treatment

Details

Exposure

A SDTM EX dataset from the CDISC pilot project

Source

Access the source of the Exposure dataset.

`ex_ophtha` *Exposure for Ophthalmology*

Description

An example Exposure SDTM dataset with ophthalmology-specific variables such as `EXLOC` and `EXLAT`

Usage

```
ex_ophtha
```

Format

A data frame with 19 columns:

USUBJID Unique Subject Identifier

STUDYID Study Identifier

DOMAIN Domain Abbreviation

EXSEQ Sequence Number

EXTRT Name of Actual Treatment

EXDOSE Dose per Administration

EXDOSU Dose Units

EXDOSFRM Dose Form

EXDOSFRQ Dose Frequency per Interval

EXROUTE Route of Administration

EXLOC Location of Dose Administration

EXLAT Laterality

VISITNUM Visit Number

VISIT Visit Name

VISITDY Planned Study Day of Visit

EXSTDTC Start Date/Time of Treatment

EXENDTC End Date/Time of Treatment

EXSTDY Study Day of Start of Treatment

EXENDY Study Day of End of Treatment

Details

Exposure for Ophthalmology

An example Exposure SDTM dataset with ophthalmology-specific variables such as `EXLOC` and `EXLAT`

Source

Constructed using ex from the pharmaversesdtm package

`ex_vaccine` *Exposures for Vaccine*

Description

An example SDTM EX dataset for vaccine studies

Usage

```
ex_vaccine
```

Format

A data frame with 21 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

EXSEQ Sequence Number

EXLNKGRP Link Group ID

EXLNKID Link ID

EXTRT Name of Actual Treatment

EXCAT Category of Treatment

EXDOSE Dose per Administration

EXDOSU Dose Units

EXDOSFRM Dose Form

EXROUTE Route of Administration

EXLOC Location of Dose Administration

EXLAT Laterality

VISITNUM Visit Number

VISIT Visit Name

EPOCH Epoch

EXDTC undocumented field

EXSTDTC Start Date/Time of Treatment

EXENDTC End Date/Time of Treatment

EXDY undocumented field

Details

Exposures for Vaccine

An example SDTM EX dataset for vaccine studies

Source

Constructed by admiralvaccine developers

face_vaccine *Findings About Clinical Events for Vaccine*

Description

An example SDTM FACE for vaccine studies

Usage

```
face_vaccine
```

Format

A data frame with 30 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

FASEQ Sequence Number

FALNKGRP Link Group ID

FALAT Laterality

FALNKID Link ID

FALOC Location of the Finding About

FATESTCD Findings About Test Short Name

FATEST Findings About Test Name

FAOBJ Object of the Observation

FACAT Category for Findings About

FASCAT Subcategory for Findings About

FAEVAL Evaluator

FAORRES Result or Finding in Original Units

FAORRESU Original Units

EPOCH Epoch

FADTC Date/Time of Collection

FADY Study Day of Collection

FATPT Planned Time Point Name

FATPTNUM Planned Time Point Number

FATPTREF Time Point Reference

FARFTDTC Date/Time of Reference Time Point

FAEVLINT Evaluation Interval

FAEVINTX Evaluation Interval Text

FASTAT Completion Status

FAREASND Reason Not Performed

FASTRESC Character Result/Finding in Std Format

FASTRESN Numeric Result/Finding in Standard Units

FASTRESU Standard Units

Details

Findings About Clinical Events for Vaccine

An example SDTM FACE for vaccine studies

Source

Constructed by admiralvaccine developers

`get_terms` *An example function as expected by the* `get_terms_fun` *parameter of* `admiral::create_query_data()`

Description

An example function as expected by the `get_terms_fun` parameter of `admiral::create_query_data()`

Usage

```
get_terms(basket_select, version, keep_id, temp_env)
```

Arguments

`basket_select`	A basket_select object defining the terms
`version`	MedDRA version
`keep_id`	Should `GRPID` be included in the output?
`temp_env`	Temporary environment

`is_vaccine` *Immunogenicity Specimen Assessments for Vaccine*

Description

An example SDTM IS for vaccine studies

Usage

```
is_vaccine
```

Format

A data frame with 24 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

ISSEQ Sequence Number

ISTESTCD Immunogenicity Test/Exam Short Name

ISTEST Immunogenicity Test or Exam Name

ISCAT Category for Immunogenicity Test

ISORRES Result or Finding in Original Units

ISORRESU Original Units

ISSTRESC Character Result/Finding in Std Format

ISSTRESN Numeric Result/Finding in Standard Units

ISSTRESU Standard Units

ISSTAT Completion Status

ISREASND Reason Not Done

ISNAM Vendor Name

ISSPEC Specimen Type

ISMETHOD Method of Test or Examination

ISBLFL Baseline Flag

ISLLOQ Lower Limit of Quantitation

VISITNUM Visit Number

EPOCH Epoch

ISDTC Date/Time of Collection

ISDY Study Day of Collection

ISULOQ Upper Limit of Quantitation

Details

Immunogenicity Specimen Assessments for Vaccine

An example SDTM IS for vaccine studies

Source

Constructed by admiralvaccine developers

`lb` *Laboratory Measurements*

Description

An updated SDTM LB dataset that uses data from the CDISC pilot project

Usage

```
lb
```

Format

A data frame with 23 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

LBSEQ Sequence Number

LBTESTCD Lab Test or Examination Short Name

LBTEST Lab Test or Examination Name

LBCAT Category for Lab Test

LBORRES Result or Finding in Original Units

LBORRESU Original Units

LBORNRLO Reference Range Lower Limit in Orig Unit

LBORNRHI Reference Range Upper Limit in Orig Unit

LBSTRESC Character Result/Finding in Std Format

LBSTRESN Numeric Result/Finding in Standard Units

LBSTRESU Standard Units

LBSTNRLO Reference Range Lower Limit-Std Units

LBSTNRHI Reference Range Upper Limit-Std Units

LBNRIND Reference Range Indicator

LBBLFL Baseline Flag

VISITNUM Visit Number

VISIT Visit Name

VISITDY Planned Study Day of Visit

LBDTC Date/Time of Specimen Collection

LBDY Study Day of Specimen Collection

Details

Laboratory Measurements

An updated SDTM LB dataset that uses data from the CDISC pilot project

Author(s)

Annie Yang

Source

Access the source of the Laboratory Measurements dataset.

---

mh *Medical History*

Description

An updated SDTM MH dataset that uses data from the CDISC pilot project

Usage

```
mh
```

Format

A data frame with 28 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

MHSEQ Sequence Number

MHSPID Sponsor-Defined Identifier

MHTERM Reported Term for the Medical History

MHLLT Lowest Level Term

MHDECOD Dictionary-Derived Term

MHHLT High Level Term

MHHLGT High Level Group Term

MHCAT Category for Medical History

MHBODSYS Body System or Organ Class

MHSEV Severity/Intensity

VISITNUM Visit Number

VISIT Visit Name

VISITDY Planned Study Day of Visit

MHDTC Date/Time of History Collection

MHSTDTC Start Date/Time of Medical History Event

MHDY Study Day of History Collection

MHENDTC End Date/Time of Medical History Event

MHPRESP Medical History Event Pre-Specified

MHOCCUR Medical History Occurrence

MHSTRTPT Start Relative to Reference Time Point

MHENRTPT End Relative to Reference Time Point

MHSTTPT Start Reference Time Point

MHENTPT End Reference Time Point

MHENRF End Relative to Reference Period

MHSTAT Completion Status

Details

Medical History

An updated SDTM MH dataset that uses data from the CDISC pilot project

Author(s)

Annie Yang

Source

Access the source of the Medical History dataset.

`oe_ophtha` *Ophthalmic Examinations for Ophthalmology*

Description

A SDTM OE dataset simulated by Ophthalmology team

Usage

```
oe_ophtha
```

Format

A data frame with 25 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

OESEQ Sequence Number

OECAT Category for Ophthalmic Test or Exam

OESCAT Subcategory for Ophthalmic Test or Exam

OEDTC Date/Time of Collection

VISIT Visit Name

VISITNUM Visit Number

VISITDY Planned Study Day of Visit

OESTRESN Numeric Result/Finding in Standard Units

OESTRESC Character Result/Finding in Std Format

OEORRES Result or Finding in Original Units

OETEST Name of Ophthalmic Test or Examination

OETESTCD Short Name of Ophthalmic Test or Exam

OETSTDTL Ophthalmic Test or Exam Detail

OELAT Laterality

OELOC Location Used for the Measurement

OEDY Study Day of Visit/Collection/Exam

OEMETHOD Method of Test or Examination

OEORRESU Original Units

OESTRESU Standard Units

OESTAT Completion Status

OETPT Planned Time Point Name

OETPTNUM Planned Time Point Number

Details

Ophthalmic Examinations for Ophthalmology

A SDTM OE dataset simulated by Ophthalmology team

Author(s)

Gordon Miller

Source

Generated dataset.

---

pc *Pharmacokinetic Concentrations*

Description

A SDTM PC dataset simulated by Antonio Rodriguez Contesti

Usage

```
pc
```

Format

A data frame with 20 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

PCSEQ Sequence Number

PCTESTCD Pharmacokinetic Test Short Name

PCTEST Pharmacokinetic Test Name

PCORRES Result or Finding in Original Units

PCORRESU Original Units

PCSTRESC Character Result/Finding in Std Format

PCSTRESN Numeric Result/Finding in Standard Units

PCSTRESU Standard Units

PCNAM Vendor Name

PCSPEC Specimen Material Type

PCLLOQ Lower Limit of Quantitation

VISIT Visit Name

VISITNUM Visit Number

PCDTC Date/Time of Specimen Collection

PCDY Actual Study Day of Specimen Collection

PCTPT Planned Time Point Name

PCTPTNUM Planned Time Point Number

Details

Pharmacokinetic Concentrations

A SDTM PC dataset simulated by Antonio Rodriguez Contesti

Author(s)

Antonio Rodriguez Contesti

Source

Access the source of the Pharmacokinetic Concentrations dataset.

---

pp *Pharmacokinetic Parameters*

Description

A SDTM PP dataset simulated by Antonio Rodriguez Contesti

Usage

```
pp
```

Format

A data frame with 14 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

PPSEQ Sequence Number

PPTESTCD Parameter Short Name

PPTEST Parameter Name

PPCAT Parameter Category

PPORRES Result or Finding in Original Units

PPORRESU Original Units

PPSTRESC Character Result/Finding in Std Format

PPSTRESN Numeric Result/Finding in Standard Units

PPSTRESU Standard Units

PPSPEC Specimen Material Type

PPRFDTC Date/Time of Reference Point

Details

Pharmacokinetic Parameters

A SDTM PP dataset simulated by Antonio Rodriguez Contesti

Author(s)

Antonio Rodriguez Contesti

Source

Access the source of the Pharmacokinetic Parameters dataset.

---

qs_ophtha *Questionnaire for Ophthalmology*

Description

An example Questionnaires SDTM dataset with ophthalmology-specific questionnaire of NEI VFQ-25

Usage

```
qs_ophtha
```

Format

A data frame with 20 columns:

STUDYID undocumented field

DOMAIN undocumented field

USUBJID undocumented field

QSSEQ undocumented field

QSTESTCD undocumented field

QSTEST undocumented field

QSCAT undocumented field

QSSCAT undocumented field

QSORRES undocumented field

QSORRESU undocumented field

QSSTRESC undocumented field

QSSTRESN undocumented field

QSSTRESU undocumented field

QSBLFL undocumented field

QSDRVFL undocumented field

VISITNUM undocumented field

VISIT undocumented field

VISITDY undocumented field

QSDTC undocumented field

QSDY undocumented field

Details

Questionnaire for Ophthalmology

An example Questionnaires SDTM dataset with ophthalmology-specific questionnaire of NEI VFQ-25

Source

Constructed using qs from the pharmaversesdtm package

`rs_onco` *Disease Response for Oncology*

Description

A SDTM RS dataset simulated by Gopi Vegesna

Usage

```
rs_onco
```

Format

A data frame with 19 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

RSSEQ Sequence Number

RSLNKGRP Link Group

RSTESTCD Response Assessment Short Name

RSTEST Response Assessment Name

RSCAT Category for Response Assessment

RSORRES Response Assessment Original Result

RSSTRESC Response Assessment Result in Std Format

RSSTAT Completion Status

RSREASND Reason Response Assessment Not Performed

RSEVAL Evaluator

RSEVALID Evaluator Identifier

RSACPTFL Accepted Record Flag

VISITNUM Visit Number

VISIT Visit Name

RSDTC Date/Time of Response Assessment

RSDY Study Day of Response Assessment

Details

Disease Response for Oncology

A SDTM RS dataset simulated by Gopi Vegesna

Author(s)

Gopi Vegesna

Source

Access the source of the Disease Response for Oncology dataset.

`rs_onco_ca125` *Disease Response (GCIG)*

Description

A SDTM RS dataset using GCIG criteria. The dataset contains just a few patients. It is intended for vignettes and examples of ADaM dataset creation.

Usage

```
rs_onco_ca125
```

Format

A data frame with 13 columns:

STUDYID undocumented field

DOMAIN undocumented field

USUBJID undocumented field

RSSEQ undocumented field

RSTESTCD undocumented field

RSTEST undocumented field

RSCAT undocumented field

RSORRES undocumented field

RSSTRESC undocumented field

RSEVAL undocumented field

VISITNUM undocumented field

VISIT undocumented field

RSDTC undocumented field

Details

Disease Response (GCIG)

A SDTM RS dataset using GCIG criteria. The dataset contains just a few patients. It is intended for vignettes and examples of ADaM dataset creation.

Author(s)

Vinh Nguyen

Source

Generated dataset (rs_supprs_onco_ca125.R)

---

rs_onco_imwg *Disease Response (IMWG)*

Description

A SDTM RS dataset using IMWG criteria intended for examples of ADaM dataset creation

Usage

```
rs_onco_imwg
```

Format

A data frame with 17 columns:

STUDYID undocumented field

DOMAIN undocumented field

USUBJID undocumented field

RSSEQ undocumented field

RSLNKGRP undocumented field

RSTESTCD undocumented field

RSTEST undocumented field

RSCAT undocumented field

RSORRES undocumented field

RSSTRESC undocumented field

RSSTAT undocumented field

RSREASND undocumented field

RSEVAL undocumented field

VISITNUM undocumented field

VISIT undocumented field

RSDTC undocumented field

RSDY undocumented field

Details

Disease Response (IMWG)

A SDTM RS dataset using IMWG criteria intended for examples of ADaM dataset creation

Author(s)

Vinh Nguyen

Source

Derived from tr_onco_recist

`rs_onco_irecist` *Disease Response (iRECIST) for Oncology*

Description

A SDTM RS dataset using iRECIST intended for examples of ADaM dataset creation

Usage

```
rs_onco_irecist
```

Format

A data frame with 19 columns:

STUDYID undocumented field
DOMAIN undocumented field
USUBJID undocumented field
RSSEQ undocumented field
RSLNKGRP undocumented field
RSTESTCD undocumented field
RSTEST undocumented field
RSCAT undocumented field
RSORRES undocumented field
RSSTRESC undocumented field
RSSTAT undocumented field
RSREASND undocumented field
RSEVAL undocumented field
RSEVALID undocumented field
RSACPTFL undocumented field
VISITNUM undocumented field
VISIT undocumented field
RSDTC undocumented field
RSDY undocumented field

Details

Disease Response (iRECIST) for Oncology
A SDTM RS dataset using iRECIST intended for examples of ADaM dataset creation

Author(s)

Rohan Thampi

Source

Generated dataset.

`rs_onco_recist` *Disease Response (RECIST 1.1) for Oncology*

Description

A SDTM RS dataset using RECIST 1.1 intended for examples of ADaM dataset creation

Usage

```
rs_onco_recist
```

Format

A data frame with 14 columns:

DOMAIN undocumented field
STUDYID undocumented field
USUBJID undocumented field
VISITNUM undocumented field
VISIT undocumented field
RSTESTCD undocumented field
RSTEST undocumented field
RSORRES undocumented field
RSSTRESC undocumented field
RSEVAL undocumented field
RSEVALID undocumented field
RSACPTFL undocumented field
RSDTC undocumented field
RSSEQ undocumented field

Details

Disease Response (RECIST 1.1) for Oncology

A SDTM RS dataset using RECIST 1.1 intended for examples of ADaM dataset creation

Author(s)

Stefan Bundfuss

Source

Generated dataset.

sc_ophtha *Subject Characteristic for Ophthalmology*

Description

A SDTM SC dataset simulated by Ophthalmology team

Usage

```
sc_ophtha
```

Format

A data frame with 12 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

SCSEQ Sequence Number

SCTESTCD Subject Characteristic Short Name

SCTEST Subject Characteristic

SCCAT Category for Subject Characteristic

SCORRES Result or Finding in Original Units

SCSTRESC Character Result/Finding in Std Format

EPOCH Epoch

SCDTC Date/Time of Collection

SCDY Study Day of Examination

Details

Subject Characteristic for Ophthalmology

A SDTM SC dataset simulated by Ophthalmology team

Author(s)

Gordon Miller

Source

Generated dataset.

sdg_db *SDG*

Description

An example SDG dataset

Usage

```
sdg_db
```

Format

A data frame with 5 columns:

termchar undocumented field

sdg_name undocumented field

sdg_id undocumented field

termvar undocumented field

version undocumented field

Details

SDG

An example SDG dataset

Source

Access the source of the SDG dataset.

smq_db *Standardized MedDRA Queries*

Description

An example SMQ dataset

Usage

```
smq_db
```

Format

A data frame with 6 columns:

termchar undocumented field

scope undocumented field

smq_name undocumented field

smq_id undocumented field

version undocumented field

termvar undocumented field

Details

Standardized MedDRA Queries

An example SMQ dataset

Source

Generated dataset.

---

suppae *Supplemental Adverse Events*

Description

A SDTM SUPPAE dataset from the CDISC pilot project

Usage

```
suppae
```

Format

A data frame with 10 columns:

STUDYID Study Identifier

RDOMAIN Related Domain Abbreviation

USUBJID Unique Subject Identifier

IDVAR Identifying Variable

IDVARVAL Identifying Variable Value

QNAM Qualifier Variable Name

QLABEL Qualifier Variable Label

QVAL Data Value

QORIG Origin

QEVAL Evaluator

Details

Supplemental Adverse Events

A SDTM SUPPAE dataset from the CDISC pilot project

Source

Access the source of the Supplemental Adverse Events dataset.

`suppce_vaccine` *Supplemental Qualifiers for Clinical Events for Vaccine*

Description

An example SDTM SUPPCE for vaccine studies

Usage

```
suppce_vaccine
```

Format

A data frame with 9 columns:

STUDYID Study Identifier

USUBJID Unique Subject Identifier

RDOMAIN Related Domain Abbreviation

IDVAR Identifying Variable

IDVARVAL Identifying Variable Value

QNAM Qualifier Variable Name

QVAL Data Value

QLABEL Qualifier Variable Label

QORIG Origin

Details

Supplemental Qualifiers for Clinical Events for Vaccine

An example SDTM SUPPCE for vaccine studies

Source

Constructed by admiralvaccine developers

suppdm *Supplemental Demography*

Description

A SDTM SUPPDM dataset from the CDISC pilot project

Usage

```
suppdm
```

Format

A data frame with 10 columns:

STUDYID Study Identifier

RDOMAIN Related Domain Abbreviation

USUBJID Unique Subject Identifier

IDVAR Identifying Variable

IDVARVAL Identifying Variable Value

QNAM Qualifier Variable Name

QLABEL Qualifier Variable Label

QVAL Data Value

QORIG Origin

QEVAL Evaluator

Details

Supplemental Demography

A SDTM SUPPDM dataset from the CDISC pilot project

Source

Generated dataset.

suppdm_vaccine *Supplemental Qualifiers for Demographics for Vaccine*

Description

An example SDTM SUPPDM dataset for vaccine studies

Usage

```
suppdm_vaccine
```

Format

A data frame with 9 columns:

STUDYID Study Identifier

USUBJID Unique Subject Identifier

RDOMAIN Related Domain Abbreviation

IDVAR Identifying Variable

IDVARVAL Identifying Variable Value

QNAM Qualifier Variable Name

QVAL Data Value

QLABEL Qualifier Variable Label

QORIG Origin

Details

Supplemental Qualifiers for Demographics for Vaccine

An example SDTM SUPPDM dataset for vaccine studies

Source

Constructed by admiralvaccine developers

suppds *Supplemental Disposition*

Description

A SDTM SUPPDS dataset from the CDISC pilot project

Usage

```
suppds
```

Format

A data frame with 9 columns:

STUDYID Study Identifier

RDOMAIN Related Domain Abbreviation

USUBJID Unique Subject Identifier

IDVAR Identifying Variable

IDVARVAL Identifying Variable Value

QNAM Qualifier Variable Name

QLABEL Qualifier Variable Label

QVAL Data Value

QORIG Origin

Details

Supplemental Disposition

A SDTM SUPPDS dataset from the CDISC pilot project

Source

Access the source of the Supplemental Disposition dataset.

suppex_vaccine *Supplemental Qualifiers for Exposures for Vaccine*

Description

An example SDTM SUPPEX dataset for vaccine studies

Usage

```
suppex_vaccine
```

Format

A data frame with 9 columns:

STUDYID Study Identifier

USUBJID Unique Subject Identifier

RDOMAIN Related Domain Abbreviation

IDVAR Identifying Variable

IDVARVAL Identifying Variable Value

QNAM Qualifier Variable Name

QVAL Data Value

QLABEL Qualifier Variable Label

QORIG Origin

Details

Supplemental Qualifiers for Exposures for Vaccine

An example SDTM SUPPEX dataset for vaccine studies

Source

Constructed by admiralvaccine developers

suppface_vaccine *Supplemental Qualifiers for Findings About for Clinical Events for Vaccine*

Description

An example SDTM SUPPFACE dataset for vaccine studies

Usage

```
suppface_vaccine
```

Format

A data frame with 9 columns:

STUDYID Study Identifier

USUBJID Unique Subject Identifier

RDOMAIN Related Domain Abbreviation

IDVAR Identifying Variable

IDVARVAL Identifying Variable Value

QNAM Qualifier Variable Name

QVAL Data Value

QLABEL Qualifier Variable Label

QORIG Origin

Details

Supplemental Qualifiers for Findings About for Clinical Events for Vaccine

An example SDTM SUPPFACE dataset for vaccine studies

Source

Constructed by admiralvaccine developers

suppis_vaccine *Supplemental Qualifiers for Immunogenicity Specimen Assessments for Vaccine*

Description

An example SDTM SUPPIS dataset for vaccine studies

Usage

```
suppis_vaccine
```

Format

A data frame with 10 columns:

STUDYID Study Identifier

RDOMAIN Related Domain Abbreviation

USUBJID Unique Subject Identifier

IDVAR Identifying Variable

IDVARVAL Identifying Variable Value

QNAM Qualifier Variable Name

QLABEL Qualifier Variable Label

QVAL Data Value

QORIG Origin

QEVAL Evaluator

Details

Supplemental Qualifiers for Immunogenicity Specimen Assessments for Vaccine

An example SDTM SUPPIS dataset for vaccine studies

Source

Constructed by admiralpeds developers

`supprs_onco_ca125` *Supplemental Qualifiers for RS_ONCO_CA125*

Description

A SDTM supplemental RS dataset using GCIG criteria. It is intended to be used together with `rs_onco_ca125`.

Usage

```
supprs_onco_ca125
```

Format

A data frame with 9 columns:

STUDYID undocumented field

RDOMAIN undocumented field

USUBJID undocumented field

IDVAR undocumented field

IDVARVAL undocumented field

QNAM undocumented field

QLABEL undocumented field

QVAL undocumented field

QORIG undocumented field

Details

Supplemental Qualifiers for RS_ONCO_CA125

A SDTM supplemental RS dataset using GCIG criteria. It is intended to be used together with `rs_onco_ca125`.

Author(s)

Vinh Nguyen

Source

Generated dataset (rs_supprs_onco_ca125.R)

`supprs_onco_imwg` *Supplemental Qualifiers for RS_ONCO_IMWG*

Description

A SDTM supplemental RS dataset using IMWG criteria intended to be used with `rs_onco_imwg`

Usage

```
supprs_onco_imwg
```

Format

A data frame with 9 columns:

STUDYID undocumented field

RDOMAIN undocumented field

USUBJID undocumented field

IDVAR undocumented field

IDVARVAL undocumented field

QNAM undocumented field

QLABEL undocumented field

QVAL undocumented field

QORIG undocumented field

Details

Supplemental Qualifiers for RS_ONCO_IMWG

A SDTM supplemental RS dataset using IMWG criteria intended to be used with `rs_onco_imwg`

Author(s)

Vinh Nguyen

Source

Access the source of the Supplemental Qualifiers for RS_ONCO_IMWG dataset.

supptr_onco *Supplemental Tumor Results for Oncology*

Description

A SDTM SUPPTR dataset simulated by Gopi Vegesna

Usage

```
supptr_onco
```

Format

A data frame with 9 columns:

STUDYID Study Identifier

RDOMAIN Related Domain Abbreviation

USUBJID Unique Subject Identifier

IDVAR Identifying Variable

IDVARVAL Identifying Variable Value

QNAM Qualifier Variable Name

QLABEL Qualifier Variable Label

QVAL Data Value

QORIG Origin

Details

Supplemental Tumor Results for Oncology

A SDTM SUPPTR dataset simulated by Gopi Vegesna

Author(s)

Gopi Vegesna

Source

Access the source of the Supplemental Tumor Results for Oncology dataset.

sv *Subject Visits*

Description

A SDTM SV dataset from the CDISC pilot project with corrected duplicate observation

Usage

```
sv
```

Format

A data frame with 8 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

VISITNUM Visit Number

VISIT Visit Name

VISITDY Planned Study Day of Visit

SVSTDTC Start Date/Time of Visit

SVENDTC End Date/Time of Visit

Details

Subject Visits

A SDTM SV dataset from the CDISC pilot project with corrected duplicate observation

Source

Constructed by admiralvaccine developers

`tr_onco` *Tumor Results for Oncology*

Description

A SDTM TR dataset simulated by Gopi Vegesna

Usage

```
tr_onco
```

Format

A data frame with 24 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

TRSEQ Sequence Number

TRGRPID Group ID

TRLNKGRP Link Group

TRLNKID Link ID

TRTESTCD Tumor Assessment Short Name

TRTEST Tumor Assessment Test Name

TRORRES Result or Finding in Original Units

TRORRESU Original Units

TRSTRESC Character Result/Finding in Std Format

TRSTRESN Numeric Result/Finding in Standard Units

TRSTRESU Standard Units

TRSTAT Completion Status

TRREASND Reason Tumor Measurement Not Performed

TRMETHOD Method used to Identify the Tumor

TREVAL Evaluator

TREVALID Evaluator Identifier

TRACPTFL Accepted Record Flag

VISITNUM Visit Number

VISIT Visit Name

TRDTC Date/Time of Tumor Measurement

TRDY Study Day of Tumor Measurement

Details

Tumor Results for Oncology

A SDTM TR dataset simulated by Gopi Vegesna

Author(s)

Gopi Vegesna

Source

Generated dataset.

`tr_onco_recist` *Tumor Results (RECIST 1.1) for Oncology*

Description

A SDTM TR dataset using RECIST 1.1 intended for examples of ADaM dataset creation

Usage

```
tr_onco_recist
```

Format

A data frame with 19 columns:

DOMAIN undocumented field
STUDYID undocumented field
USUBJID undocumented field
TRGRPID undocumented field
TRLNKID undocumented field
TRTESTCD undocumented field
TRTEST undocumented field
TRORRES undocumented field
TRORRESU undocumented field
TRSTRESC undocumented field
TRSTRESN undocumented field
TRSTRESU undocumented field
VISITNUM undocumented field
VISIT undocumented field
TREVAL undocumented field
TREVALID undocumented field
TRACPTFL undocumented field
TRDTC undocumented field
TRSEQ undocumented field

Details

Tumor Results (RECIST 1.1) for Oncology

A SDTM TR dataset using RECIST 1.1 intended for examples of ADaM dataset creation

Author(s)

Stefan Bundfuss

Source

Generated dataset.

`ts` *Trial Design*

Description

A SDTM TS dataset from the CDISC pilot project

Usage

```
ts
```

Format

A data frame with 6 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

TSSEQ Sequence Number

TSPARMCD Trial Summary Parameter Short Name

TSPARM Trial Summary Parameter

TSVAL Parameter Value

Details

Trial Design

A SDTM TS dataset from the CDISC pilot project

Source

Access the source of the Trial Design dataset.

tu_onco *Tumor Identification for Oncology*

Description

A SDTM TU dataset simulated by Gopi Vegesna

Usage

```
tu_onco
```

Format

A data frame with 18 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

TUSEQ Sequence Number

TULNKID Link ID

TUTESTCD Tumor Identification Short Name

TUTEST Tumor Identification Test Name

TUORRES Tumor Identification Result

TUSTRESC Tumor Identification Result Std. Format

TULOC Location of the Tumor

TUMETHOD Method of Identification

TUEVAL Evaluator

TUEVALID Evaluator Identifier

TUACPTFL Accepted Record Flag

VISITNUM Visit Number

VISIT Visit Name

TUDTC Date/Time of Tumor Identification

TUDY Study Day of Tumor Identification

Details

Tumor Identification for Oncology

A SDTM TU dataset simulated by Gopi Vegesna

Author(s)

Gopi Vegesna

Source

Generated dataset.

`tu_onco_recist` *Tumor Identification (RECIST 1.1) for Oncology*

Description

A SDTM TU dataset using RECIST 1.1 intended for examples of ADaM dataset creation

Usage

```
tu_onco_recist
```

Format

A data frame with 16 columns:

DOMAIN undocumented field
STUDYID undocumented field
USUBJID undocumented field
VISIT undocumented field
VISITNUM undocumented field
TULOC undocumented field
TUTESTCD undocumented field
TUTEST undocumented field
TUORRES undocumented field
TUSTRESC undocumented field
TUMETHOD undocumented field
TULNKID undocumented field
TUEVAL undocumented field
TUEVALID undocumented field
TUACPTFL undocumented field
TUSEQ undocumented field

Details

Tumor Identification (RECIST 1.1) for Oncology

A SDTM TU dataset using RECIST 1.1 intended for examples of ADaM dataset creation

Author(s)

Stefan Bundfuss

Source

Generated dataset.

`vs` *Vital Signs*

Description

A SDTM VS dataset from the CDISC pilot project

Usage

```
vs
```

Format

A data frame with 24 columns:

STUDYID Study Identifier
DOMAIN Domain Abbreviation
USUBJID Unique Subject Identifier
VSSEQ Sequence Number
VSTESTCD Vital Signs Test Short Name
VSTEST Vital Signs Test Name
VSPOS Vital Signs Position of Subject
VSORRES Result or Finding in Original Units
VSORRESU Original Units
VSSTRESC Character Result/Finding in Std Format
VSSTRESN Numeric Result/Finding in Standard Units
VSSTRESU Standard Units
VSSTAT Completion Status
VSLOC Location of Vital Signs Measurement
VSBLFL Baseline Flag
VISITNUM Visit Number
VISIT Visit Name
VISITDY Planned Study Day of Visit
VSDTC Date/Time of Measurements
VSDY Study Day of Vital Signs
VSTPT Planned Time Point Name
VSTPTNUM Planned Time Point Number
VSELTM Planned Elapsed Time from Time Point Ref
VSTPTREF Time Point Reference

Details

Vital Signs

A SDTM VS dataset from the CDISC pilot project

Source

Generated dataset.

`vs_peds` *Vital signs Dataset-pediatrics*

Description

An updated SDTM VS dataset with anthropometric measurements for pediatric patients

Usage

```
vs_peds
```

Format

A data frame with 26 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

VSSEQ Sequence Number

VSTESTCD Vital Signs Test Short Name

VSTEST Vital Signs Test Name

VSPOS Vital Signs Position of Subject

VSORRES Result or Finding in Original Units

VSORRESU Original Units

VSSTRESC Character Result/Finding in Std Format

VSSTRESN Numeric Result/Finding in Standard Units

VSSTRESU Standard Units

VSSTAT Completion Status

VSLOC Location of Vital Signs Measurement

VSBLFL Baseline Flag

VISITNUM Visit Number

VISIT Visit Name

VISITDY Planned Study Day of Visit

VSDTC Date/Time of Measurements

VSDY Study Day of Vital Signs

VSTPT Planned Time Point Name

VSTPTNUM Planned Time Point Number

VSELTM Planned Elapsed Time from Time Point Ref

VSTPTREF Time Point Reference

VSEVAL Evaluator

EPOCH Epoch

Details

Vital signs Dataset-pediatrics

An updated SDTM VS dataset with anthropometric measurements for pediatric patients

Source

Constructed by admiralpeds developers

`vs_vaccine` *Vital Signs for Vaccine*

Description

An example SDTM VS dataset for vaccine studies

Usage

```
vs_vaccine
```

Format

A data frame with 23 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

VSSEQ Sequence Number

VSLNKID Link ID

VSLNKGRP Link Group ID

VSTESTCD Vital Signs Test Short Name

VSTEST Vital Signs Test Name

VSCAT Category for Vital Signs

VSSCAT Subcategory for Vital Signs

VSORRES Result or Finding in Original Units

VSORRESU Original Units

VSSTRESC Character Result/Finding in Std Format

VSSTRESN Numeric Result/Finding in Standard Units

VSSTRESU Standard Units

VSEVAL Evaluator

VSLOC Location of Vital Signs Measurement

EPOCH Epoch

VSDTC Date/Time of Measurements

VSDY Study Day of Vital Signs

VSTPT Planned Time Point Name

VSTPTNUM Planned Time Point Number

VSTPTREF Time Point Reference

Details

Vital Signs for Vaccine

An example SDTM VS dataset for vaccine studies

Source

Constructed by admiralvaccine developers

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