Package 'pharmaversesdtm'

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Version 1.4.1

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License Apache License (>= 2.0)

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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

`ag_neuro` *Procedure Agents Dataset-neuro*

Description

A SDTM AG dataset recording details of agents such as a PET tracer used in procedures

Usage

```
ag_neuro
```

Format

A data frame with 13 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

AGSEQ Sequence Number

AGTRT Reported Agent Name

AGCAT Category for Agent

AGDOSE Dose per Administration

AGDOSEU Dose Units

AGROUTE Route of Administration

AGLNKID Link ID

VISITNUM Visit Number

VISIT Visit Name

AGSTDTC Start Date/Time of Agent

Details

Procedure Agents Dataset-neuro

A SDTM AG dataset recording details of agents such as a PET tracer used in procedures

Source

Constructed by admiralneuro developers

---

be *Biospecimen Events*

Description

A synthetic SDTM BE domain representing specimen collection, aliquoting, and culturing events, with linkage to MB and MS domains

Usage

```
be
```

Format

A data frame with 13 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

BESEQ Sequence Number

BEREFID Reference ID

BELNKID Link Identifier

BETERM Reported Term for the Biospecimen Event

BECAT Category for Biospecimen Event

BELOC Anatomical Location of Event

VISITNUM Visit Number

BEDTC Date/Time of Specimen Collection

BESTDTC Start Date/Time of Biospecimen Event

BEENDTC End Date/Time of Biospecimen Event

Details

Biospecimen Events

A synthetic SDTM BE domain representing specimen collection, aliquoting, and culturing events, with linkage to MB and MS domains

Source

Access the source of the Biospecimen Events dataset.

`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 End Relative to Reference Time Point

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 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

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

ARMNRS Reason Arm and/or Actual Arm is Null

ACTARMUD Description of Unplanned Actual Arm

Details

Demography

A SDTM DM dataset from the CDISC pilot project

Source

Access the source of the Demography dataset.

`dm_metabolic` *Demographic Dataset-metabolic*

Description

A SDTM DM dataset for metabolic studies

Usage

```
dm_metabolic
```

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

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

ARMNRS Reason Arm and/or Actual Arm is Null

ACTARMUD Description of Unplanned Actual Arm

Details

Demographic Dataset-metabolic

A SDTM DM dataset for metabolic studies

Source

Constructed by admiralmetabolic developers

`dm_neuro` *Demographic Dataset-neuro*

Description

A SDTM DM dataset for Alzheimer's disease studies

Usage

```
dm_neuro
```

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
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
ARMNRS Reason Arm and/or Actual Arm is Null
ACTARMUD Description of Unplanned Actual Arm

Details

Demographic Dataset-neuro

A SDTM DM dataset for Alzheimer's disease studies

Source

Constructed by admiralneuro developers

dm_peds *Demographic Dataset-pediatrics*

Description

An updated SDTM DM dataset with pediatric patients

Usage

```
dm_peds
```

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
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
ARMNRS Reason Arm and/or Actual Arm is Null
ACTARMUD Description of Unplanned Actual Arm

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 30 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

ARMNRS Reason Arm and/or Actual Arm is Null

ACTARMUD Description of Unplanned Actual Arm

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 ECG Test Short Name

EGTEST ECG Test Name

EGORRES Result or Finding in Original Units

EGORRESU Original Units

EGSTRESC Character Result/Finding in Std Format

EGSTRESN Numeric Result/Finding in Standard Units

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

Contains a set of 4 unique Test Short Names and Test Names:

EGTESTCD	EGTEST
ECGINT	ECG Interpretation
HR	Heart Rate
QT	QT Duration
RR	RR Duration

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 19 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
EXSTDTC Start Date/Time of Treatment
EXENDTC End Date/Time of Treatment

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

Contains a set of 3 unique Test Short Names and Test Names:

FATESTCD	FATEST
DIAMETER	Diameter
OCCUR	Occurrence Indicator
SEV	Severity/Intensity

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_ada *Immunogenicity Specimen Assessments for ADA*

Description

A SDTM IS dataset containing relevant antidrug antibody assessment studies

Usage

```
is_ada
```

Format

A data frame with 27 columns:

STUDYID Study Identifier
DOMAIN Domain Abbreviation
USUBJID Unique Subject Identifier
ISSEQ Sequence Number
ISTESTCD Immunogenicity Test/Exam Short Name
ISTEST Immunogenicity Test or Examination Name
ISBDAGNT Binding Agent
ISCAT Category for Immunogenicity Test
ISORRES Results or Findings in Original Units
ISORRESU Original Units
ISSTRESC Character Result/Finding in Std Format
ISSTRESN Numeric Results/Findings in Std. Units
ISSTRESU Standard Units
ISSTAT Completion Status
ISREASND Reason Not Done
ISNAM Vendor Name
ISSPEC Specimen Type
ISBLFL Baseline Flag
ISLLOQ Lower Limit of Quantitation
VISITNUM Visit Number
VISIT Visit Name
VISITDY Planned Study Day of Visit
EPOCH Epoch
ISDTC Date/Time of Collection
ISDY Study Day of Visit/Collection/Exam
ISTPT Planned Time Point Name
ISTPTNUM Planned Time Point Number

Details

Immunogenicity Specimen Assessments for ADA

A SDTM IS dataset containing relevant antidrug antibody assessment studies

Contains a set of 2 unique Test Short Names and Test Names:

ISTESTCD	ISTEST
ADA_BAB	Binding Antidrug Antibody
ADA_NAB	Neutralizing Binding Antidrug Antibody

Author(s)

Kristin Dahnert

Source

Generated dataset

`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

Contains a set of 4 unique Test Short Names and Test Names:

ISTESTCD	ISTEST
I0019NT	I0019NT Antibody
J0033VN	J0033VN Antibody
M0019LN	M0019LN Antibody
R0003MA	R0003MA Antibody

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

Contains a set of 47 unique Test Short Names and Test Names:

LBTESTCD	LBTEST
ALB	Albumin
ALP	Alkaline Phosphatase
ALT	Alanine Aminotransferase
ANISO	Anisocytes
AST	Aspartate Aminotransferase
BASO	Basophils

BASOLE	Basophils/Leukocytes
BILI	Bilirubin
BUN	Blood Urea Nitrogen
CA	Calcium
CHOL	Cholesterol
CK	Creatine Kinase
CL	Chloride
COLOR	Color
CREAT	Creatinine
EOS	Eosinophils
EOSLE	Eosinophils/Leukocytes
GGT	Gamma Glutamyl Transferase
GLUC	Glucose
HBA1C	Hemoglobin A1C
HCT	Hematocrit
HGB	Hemoglobin
K	Potassium
KETONES	Ketones
LYM	Lymphocytes
LYMLE	Lymphocytes/Leukocytes
MACROCY	Macrocytes
MCH	Ery. Mean Corpuscular Hemoglobin
MCHC	Ery. Mean Corpuscular HGB Concentration
MCV	Ery. Mean Corpuscular Volume
MICROCY	Microcytes
MONO	Monocytes
MONOLE	Monocytes/Leukocytes
PH	pH
PHOS	Phosphate
PLAT	Platelet
POIKILO	Poikilocytes
POLYCHR	Polychromasia
PROT	Protein
RBC	Erythrocytes
SODIUM	Sodium
SPGRAV	Specific Gravity
TSH	Thyrotropin
URATE	Urate
UROBIL	Urobilinogen
VITB12	Vitamin B12
WBC	Leukocytes

Author(s)

Annie Yang

Source

Access the source of the Laboratory Measurements dataset.

`lb_metabolic` *Laboratory Measurements Dataset-metabolic*

Description

A SDTM LB dataset containing relevant laboratory measurements for metabolic studies

Usage

```
lb_metabolic
```

Format

A data frame with 24 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

LBFAST Fasting Status

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 Dataset-metabolic

A SDTM LB dataset containing relevant laboratory measurements for metabolic studies

Contains a set of 9 unique Test Short Names and Test Names:

LBTESTCD	LBTEST
ALB	Albumin
ALP	Alkaline Phosphatase
AST	Aspartate Aminotransferase
CHOL	Cholesterol
GGT	Gamma Glutamyl Transferase
GLUC	Glucose
HBA1CHGB	Hemoglobin A1C/Hemoglobin
INSULIN	Insulin
TRIG	Triglycerides

Source

Constructed by admiralmetabolic developers

---

lb_neuro *Laboratory Test Dataset-neuro*

Description

A SDTM LB domain dataset containing laboratory test results for Alzheimer's Disease studies

Usage

```
lb_neuro
```

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 Test Dataset-neuro

A SDTM LB domain dataset containing laboratory test results for Alzheimer's Disease studies

Contains a set of 4 unique Test Short Names and Test Names:

LBTESTCD	LBTEST
AMYLB42	Lumipulse G Beta-Amyloid 1-42-N Plasma
ASYNASAA	Alpha Synuclein Seed Amplification Assay (CSF)
PTAB42R	Lumipulse G pTau 217/Beta-Amyloid 1-42 Plasma Ratio
PTAU217	Lumipulse G pTau 217 Plasma

Source

Constructed by admiralneuro developers

`lb_onco_pcwg3` *Laboratory Measurements (PSA) for Oncology*

Description

A SDTM LB dataset for prostate cancer studies intended for examples of ADaM dataset creation

Usage

```
lb_onco_pcwg3
```

Format

A data frame with 18 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

LBSTRESC Character Result/Finding in Std Format

LBSTRESN Numeric Result/Finding in Standard Units

LBSTRESU Standard Units

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 (PSA) for Oncology

A SDTM LB dataset for prostate cancer studies intended for examples of ADaM dataset creation

Contains a set of 1 unique Test Short Name and Test Name:

LBTESTCD	LBTEST
PSA	Prostate Specific Antigen

Author(s)

Tomoyuki Namai

Source

Generated dataset

mb *Microbiology Specimen*

Description

A synthetic SDTM MB domain representing microbiology findings and linkage to MS domain (ms)

Usage

```
mb
```

Format

A data frame with 21 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

MBSEQ Sequence Number

MBGRPID Group ID

MBREFID Reference ID

MBLNKGRP Link Group ID

MBTESTCD Microbiology Test or Finding Short Name

MBTEST Microbiology Test or Finding Name

MBTSTDTL Measurement, Test or Examination Detail

MBORRES Result or Finding in Original Units

MBORRESU Original Units

MBRSLSCL Result Scale

MBSTRESC Result or Finding in Standard Format

MBSTRESN Numeric Result/Finding in Standard Units

MBSTRESU Standard Units

MBSPEC Specimen Material Type

MBLOC Specimen Collection Location

MBMETHOD Method of Test or Examination

VISITNUM Visit Number

MBDTC Date/Time of Collection

Details

Microbiology Specimen

A synthetic SDTM MB domain representing microbiology findings and linkage to MS domain (ms)

Contains a set of 6 unique Test Short Names and Test Names:

MBTESTCD	MBTEST
GMNCOC	Gram Negative Cocci
GNROD	Gram Negative Rods
GPRCOC	Gram Positive Cocci
MCCOLCNT	Colony Count
MCORGIDN	Microbial Organism Identification
MTBCMPLX	Mycobacterium tuberculosis complex

Source

Access the source of the Microbiology Specimen 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.

`ms` *Microbiology Susceptibility*

Description

A synthetic SDTM MS domain with susceptibility results and linkage to MB domain (mb)

Usage

```
ms
```

Format

A data frame with 23 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

MSSEQ Sequence Number

MSREFID Reference ID

NHOID Non-host Organism ID

MSGRPID Group ID

MSLNKID Link ID

MSTESTCD Short Name of Assessment

MSTEST Name of Assessment

MSAGENT Agent Name

MSCONC Agent Concentration

MSCONCU Agent Concentration Units

MSORRES Result or Finding in Original Units

MSORRESU Original Units

MSSTRESC Result or Finding in Standard Format

MSSTRESN Numeric Result/Finding in Standard Units

MSSTRESU Standard Units

MSSPEC Specimen Material Type

MSLOC Location Used for the Measurement

MSMETHOD Method of Test or Examination

VISITNUM Visit Number

MSDTC Date/Time of Collection

Details

Microbiology Susceptibility

A synthetic SDTM MS domain with susceptibility results and linkage to MB domain (mb)

Contains a set of 3 unique Test Short Names and Test Names:

MSTESTCD	MSTEST
DIAZOINH	Diameter of the Zone of Inhibition
MIC	Minimum Inhibitory Concentration
MICROSUS	Microbial Susceptibility

Source

Access the source of the Microbiology Susceptibility dataset.

nv_neuro *Neurological Assessment Dataset-neuro*

Description

A SDTM NV dataset containing neurological assessments or test results

Usage

```
nv_neuro
```

Format

A data frame with 21 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

NVSEQ Sequence Number

NVLNKID Link ID

NVTESTCD Short Name of Nervous System Test

NVTEST Name of Nervous System Test

NVCAT Category for Nervous System Test

NVLOC Location Used for the Measurement

NVMETHOD Method of Test or Examination

NVNAM Vendor Name

NVORRES Result or Finding in Original Units

NVORRESU Original Units

NVSTRESC Character Result/Finding in Std Format

NVSTRESN Numeric Result/Finding in Standard Units

NVSTRESU Standard Units

VISITNUM Visit Number

VISIT Visit Name

NVDTC Date/Time of Collection

NVDY Study Day of Collection

NVLOBXFL Last Observation Before Exposure Flag

Details

Neurological Assessment Dataset-neuro

A SDTM NV dataset containing neurological assessments or test results

Contains a set of 3 unique Test Short Names and Test Names:

NVTESTCD	NVTEST
SUVR	Standardized Uptake Value Ratio
UPSIT	University of Pennsylvania Smell Identification Test
VR	Qualitative Visual Classification

Source

Constructed by admiralneuro developers

`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

Contains a set of 4 unique Test Short Names and Test Names:

OETESTCD	OETEST
CSUBTH	Center Subfield Thickness
DRSSR	Diabetic Retinopathy Sev Recode Value
IOP	Intraocular Pressure
VACSCORE	Visual Acuity Score

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 21 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

VISITDY Planned Study Day of Visit

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

Contains a set of 1 unique Test Short Name and Test Name:

PCTESTCD	PCTEST
XAN	XANOMELINE

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

Contains a set of 10 unique Test Short Names and Test Names:

PPTESTCD	PPTEST
AUCALL	AUC All
AUCLST	AUC to Last Nonzero Conc
CLST	Last Nonzero Conc
CMAX	Max Conc
LAMZ	Lambda z

LAMZHL	Half-Life Lambda z
LAMZNPT	Number of Points for Lambda z
RCAMINT	Ae
RENALCL	CLR
TMAX	Time of CMAX

Author(s)

Antonio Rodriguez Contesti

Source

Access the source of the Pharmacokinetic Parameters dataset.

`qs_metabolic` *Questionnaire Dataset-metabolic*

Description

A SDTM QS dataset containing COEQ data (Control of Eating Questionnaire) for metabolic studies. Note that University of Leeds are the copyright holders of the Control of Eating Questionnaire (CoEQ) and the test data included within pharmaversesdtm as well as the ADCOEQ code are for not-for-profit use only within admiralmetabolic and pharmaverse-related examples/documentation. Any persons or companies wanting to use the CoEQ should request a license to do so from the following link.

Usage

```
qs_metabolic
```

Format

A data frame with 18 columns:

STUDYID Study Identifier

USUBJID Unique Subject Identifier

DOMAIN Domain Abbreviation

VISIT Visit Name

VISITNUM Visit Number

VISITDY Planned Study Day of Visit

QSBLFL Baseline Flag

QSDTC Date/Time of Finding

QSDY Study Day of Finding

QSCAT Category for Questionnaire

QSTEST Questionnaire Test Name

QSTESTCD Questionnaire Test Short Name

QSORRES Result or Finding in Original Units

QSORRESU Original Units

QSSTRESC Character Result/Finding in Std Format

QSSTRESN Numeric Result/Finding in Standard Units

QSSTRESU Standard Units

QSSEQ Sequence Number

Details

Questionnaire Dataset-metabolic

A SDTM QS dataset containing COEQ data (Control of Eating Questionnaire) for metabolic studies. Note that University of Leeds are the copyright holders of the Control of Eating Questionnaire (CoEQ) and the test data included within pharmaversesdtm as well as the ADCOEQ code are for not-for-profit use only within admiralmetabolic and pharmaverse-related examples/documentation. Any persons or companies wanting to use the CoEQ should request a license to do so from the following link.

Contains a set of 21 unique Test Short Names and Test Names:

QSTESTCD	QSTEST
COEQ01	How hungry have you felt?
COEQ02	How full have you felt?
COEQ03	How strong was your desire to eat sweet foods?
COEQ04	How strong was your desire to eat savoury foods?
COEQ05	How happy have you felt?
COEQ06	How anxious have you felt?
COEQ07	How alert have you felt?
COEQ08	How contented have you felt?
COEQ09	During the last 7 days how often have you had food cravings?
COEQ10	How strong have any food cravings been?
COEQ11	How difficult has it been to resist any food cravings?
COEQ12	How often have you eaten in response to food cravings?
COEQ13	Chocolate or chocolate flavoured foods
COEQ14	Other sweet foods (cakes, pastries, biscuits, etc)
COEQ15	Fruit or fruit juice
COEQ16	Dairy foods (cheese, yoghurts, milk, etc)
COEQ17	Starchy foods (bread, rice, pasta, etc)
COEQ18	Savoury foods (french fries, crisps, burgers, pizza, etc)
COEQ19	Generally, how difficult has it been to control your eating?
COEQ20	Which one food makes it most difficult for you to control eating?
COEQ21	How difficult has it been to resist eating this food during the last 7 days?

Source

Constructed by admiralmetabolic developers

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 Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

QSSEQ Sequence Number

QSTESTCD Question Short Name

QSTEST Question Name

QSCAT Category of Question

QSSCAT Subcategory for Question

QSORRES Finding in Original Units

QSORRESU Original Units

QSSTRESC Character Result/Finding in Std Format

QSSTRESN Numeric Finding in Standard Units

QSSTRESU Standard Units

QSBLFL Baseline Flag

QSDRVFL Derived Flag

VISITNUM Visit Number

VISIT Visit Name

VISITDY Planned Study Day of Visit

QSDTC Date/Time of Finding

QSDY Study Day of Finding

Details

Questionnaire for Ophthalmology

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

Contains a set of 29 unique Test Short Names and Test Names:

QSTESTCD	QSTEST
VFQ101	Your Overall Health Is
VFQ102	Eyesight Using Both Eyes Is
VFQ103	How Often You Worry About Eyesight
VFQ104	How Often Pain in and Around Eyes
VFQ105	Difficulty Reading Newspapers
VFQ106	Difficulty Doing Work/Hobbies
VFQ107	Difficulty Finding on Crowded Shelf
VFQ108	Difficulty Reading Street Signs
VFQ109	Difficulty Going Down Step at Night
VFQ110	Difficulty Noticing Objects to Side
VFQ111	Difficulty Seeing How People React
VFQ112	Difficulty Picking Out Own Clothes
VFQ113	Difficulty Visiting With People
VFQ114	Difficulty Going Out to See Movies
VFQ115	Are You Currently Driving
VFQ115C	Difficulty Driving During Daytime
VFQ116	Difficulty Driving at Night
VFQ116A	Driving in Difficult Conditions
VFQ119	Eye Pain Keep You From Doing What You Like
VFQ120	I Stay Home Most of the Time
VFQ121	I Feel Frustrated a Lot of the Time
VFQ124	I Need a Lot of Help From Others
VFQ125	Worry I'll Do Embarrassing Things
VFQ1A03	Difficulty Reading Small Print
VFQ1A04	Difficulty Figure Out Bill Accuracy
VFQ1A05	Difficulty Shaving or Styling Hair
VFQ1A06	Difficulty Recognizing People
VFQ1A07	Difficulty Taking Part in Sports
VFQ1A08	Difficulty Seeing Programs on TV

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

Contains a set of 4 unique Test Short Names and Test Names:

RSTESTCD	RSTEST
NEWLPROG	New Lesion Progression
NTRGRESP	Non-target Response
OVRLRESP	Overall Response
TRGRESP	Target Response

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 Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

RSSEQ Sequence Number

RSTESTCD Assessment Short Name

RSTEST Assessment Name

RSCAT Category for Assessment

RSORRES Result or Finding in Original Units

RSSTRESC Character Result/Finding in Std Format

RSEVAL Evaluator

VISITNUM Visit Number

VISIT Visit Name

RSDTC Date/Time of Assessment

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.

Contains a set of 1 unique Test Short Name and Test Name:

RSTESTCD	RSTEST
OVRLRESP	Overall Response

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 Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

RSSEQ Sequence Number

RSLNKGRP Link Group ID

RSTESTCD Assessment Short Name

RSTEST Assessment Name

RSCAT Category for Assessment

RSORRES Result or Finding in Original Units

RSSTRESC Character Result/Finding in Std Format

RSSTAT Completion Status

RSREASND Reason Not Done

RSEVAL Evaluator

VISITNUM Visit Number

VISIT Visit Name

RSDTC Date/Time of Assessment

RSDY Study Day of Assessment

Details

Disease Response (IMWG)

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

Contains a set of 1 unique Test Short Name and Test Name:

RSTESTCD	RSTEST
OVRLRESP	Overall Response

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 Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

RSSEQ Sequence Number

RSLNKGRP Link Group ID

RSTESTCD Assessment Short Name

RSTEST Assessment Name

RSCAT Category for Assessment

RSORRES Result or Finding in Original Units

RSSTRESC Character Result/Finding in Std Format

RSSTAT Completion Status

RSREASND Reason Not Done

RSEVAL Evaluator

RSEVALID Evaluator Identifier

RSACPTFL Accepted Record Flag

VISITNUM Visit Number

VISIT Visit Name

RSDTC Date/Time of Assessment

RSDY Study Day of Assessment

Details

Disease Response (iRECIST) for Oncology

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

Contains a set of 6 unique Test Short Names and Test Names:

RSTESTCD	RSTEST
IRECLIND	Last iRECIST Assessment Indicator
NEWLIND	New Lesion Indicator
NEWLPROG	New Lesion Progression
NTRGRESP	Non-target Response
OVRLRESP	Overall Response
TRGRESP	Target Response

Author(s)

Rohan Thampi

Source

Generated dataset.

`rs_onco_pcwg3` *Disease Response (PCWG3) for Oncology*

Description

A SDTM RS dataset for oncology studies using PCWG3 criteria intended for examples of ADaM dataset creation

Usage

```
rs_onco_pcwg3
```

Format

A data frame with 14 columns:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

RSSEQ Sequence Number

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

RSEVAL Evaluator

VISITNUM Visit Number

VISIT Visit Name

RSDTC Date/Time of Response Assessment

RSDY Study Day of Response Assessment

Details

Disease Response (PCWG3) for Oncology

A SDTM RS dataset for oncology studies using PCWG3 criteria intended for examples of ADaM dataset creation

Contains a set of 3 unique Test Short Names and Test Names:

RSTESTCD	RSTEST
BONERESP	Bone Response
OVRLRESP	Overall Response
SFTSRESP	Soft Tissue Response

Author(s)

Tomoyuki Namai

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 Domain Abbreviation
STUDYID Study Identifier
USUBJID Unique Subject Identifier
VISITNUM Visit Number
VISIT Visit Name
RSTESTCD Assessment Short Name
RSTEST Assessment Name
RSORRES Result or Finding in Original Units
RSSTRESC Character Result/Finding in Std Format
RSEVAL Evaluator
RSEVALID Evaluator Identifier
RSACPTFL Accepted Record Flag
RSDTC Date/Time of Assessment
RSSEQ Sequence Number

Details

Disease Response (RECIST 1.1) for Oncology

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

Contains a set of 1 unique Test Short Name and Test Name:

RSTESTCD	RSTEST
OVRLRESP	Overall Response

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

Contains a set of 1 unique Test Short Name and Test Name:

SCTESTCD	SCTEST
FOCID	Focus of Study-Specific Interest

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 Reported Term

sdg_name Name

sdg_id Name ID

termvar Variable

version Version

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 Reported Term

scope Scope

smq_name Name

smq_id Name ID

version Version

termvar Variable

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

suppnv_neuro *Supplemental for Neurological Assessment Dataset-neuro*

Description

A SDTM SUPPNV dataset containing additional information about neurological assessments or test results

Usage

```
suppnv_neuro
```

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 for Neurological Assessment Dataset-neuro

A SDTM SUPPNV dataset containing additional information about neurological assessments or test results

Source

Constructed by admiralneuro 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 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 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 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 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

Contains a set of 5 unique Test Short Names and Test Names:

TRTESTCD	TRTEST
DIAMETER	Diameter
LDIAM	Longest Diameter
LPERP	Longest Perpendicular
SUMDIAM	Sum of Diameter
TUMSTATE	Tumor State

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 Domain Abbreviation

STUDYID Study Identifier

USUBJID Unique Subject Identifier

TRGRPID Group ID

TRLNKID Link ID

TRTESTCD Tumor/Lesion Assessment Short Name

TRTEST Tumor/Lesion 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

VISITNUM Visit Number

VISIT Visit Name

TREVAL Evaluator

TREVALID Evaluator Identifier

TRACPTFL Accepted Record Flag

TRDTC Date/Time of Tumor/Lesion Measurement

TRSEQ Sequence Number

Details

Tumor Results (RECIST 1.1) for Oncology

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

Contains a set of 3 unique Test Short Names and Test Names:

TRTESTCD	TRTEST
LDIAM	Longest Diameter
LPERP	Longest Perpendicular
TUMSTATE	Tumor State

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

Contains a set of 1 unique Test Short Name and Test Name:

TUTESTCD	TUTEST
TUMIDENT	Tumor Identification

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 Domain Abbreviation

STUDYID Study Identifier

USUBJID Unique Subject Identifier

VISIT Visit Name

VISITNUM Visit Number

TULOC Location of the Tumor/Lesion

TUTESTCD Tumor/Lesion ID Short Name

TUTEST Tumor/Lesion ID Test Name

TUORRES Tumor/Lesion ID Result

TUSTRESC Tumor/Lesion ID Result Std. Format

TUMETHOD Method of Identification

TULNKID Link ID

TUEVAL Evaluator

TUEVALID Evaluator Identifier

TUACPTFL Accepted Record Flag

TUSEQ Sequence Number

Details

Tumor Identification (RECIST 1.1) for Oncology

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

Contains a set of 1 unique Test Short Name and Test Name:

TUTESTCD	TUTEST
TUMIDENT	Tumor Identification

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

Contains a set of 6 unique Test Short Names and Test Names:

VSTESTCD	VSTEST
DIABP	Diastolic Blood Pressure
HEIGHT	Height
PULSE	Pulse Rate
SYSBP	Systolic Blood Pressure
TEMP	Temperature
WEIGHT	Weight

Source

Generated dataset.

`vs_metabolic` *Vital signs Dataset-metabolic*

Description

A SDTM VS dataset for metabolic studies

Usage

```
vs_metabolic
```

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 Dataset-metabolic

A SDTM VS dataset for metabolic studies

Contains a set of 9 unique Test Short Names and Test Names:

VSTESTCD	VSTEST
BMI	Body Mass Index
DIABP	Diastolic Blood Pressure
HEIGHT	Height
HIPCIR	Hip Circumference
PULSE	Pulse Rate
SYSBP	Systolic Blood Pressure
TEMP	Temperature
WEIGHT	Weight
WSTCIR	Waist Circumference

Source

Constructed by admiralmetabolic developers

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

Contains a set of 4 unique Test Short Names and Test Names:

VSTESTCD	VSTEST
BMI	BMI
HDCIRC	Head Circumference
HEIGHT	Height
WEIGHT	Weight

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

Contains a set of 1 unique Test Short Name and Test Name:

VSTESTCD	VSTEST
TEMP	Temperature

Source

Constructed by admiralvaccine developers

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