

Package ‘pharmaversesdtm’

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Type Package

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

Version 1.3.0

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/>>.

License Apache License (>= 2.0)

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ae	<i>Adverse Events</i>
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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
CEPRES 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	<i>Concomitant Medication</i>
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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	<i>Demography</i>
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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_metabolic

Demographic Dataset-metabolic

Description

A SDTM DM dataset for metabolic studies

Usage

dm_metabolic

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

Demographic Dataset-metabolic
 A SDTM DM dataset for metabolic studies

Source

Constructed by admiralmetabolic developers

dm_peds	<i>Demographic Dataset-pediatrics</i>
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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	<i>Demographics for Vaccine</i>
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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	<i>Disposition</i>
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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	<i>Exposure</i>
----	-----------------

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_optha	<i>Exposure for Ophthalmology</i>
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Description

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

Usage

ex_optha

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	<i>An example function as expected by the get_terms_fun parameter of admiral::create_query_data()</i>
-----------	---

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	<i>Immunogenicity Specimen Assessments for Vaccine</i>
------------	--

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

 1b

Laboratory Measurements

Description

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

Usage

1b

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
LBORNRL0 Reference Range Lower Limit in Orig Unit
LBORNRLHI 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
LBORNRLLO Reference Range Lower Limit in Orig Unit
LBORNRLHI 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

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
MHDTTC 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

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 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
 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 pharamversesdtm as well as the ADCOEQ code are for not-for-profit use only within admiralmetabolic and pharamverse-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

QSBFL 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 pharmanversesdtm as well as the ADCOEQ code are for not-for-profit use only within admiralmetabolic and pharmanverse-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
QSBFL 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
VFQ1	Your Overall Health Is
VFQ10	Difficulty Noticing Objects to Side
VFQ11	Difficulty Seeing How People React
VFQ12	Difficulty Picking Out Own Clothes
VFQ13	Difficulty Visiting With People
VFQ14	Difficulty Going Out to See Movies

VFQ15	Are You Currently Driving
VFQ16	Difficulty Driving During Daytime
VFQ17	Difficulty Driving at Night
VFQ18	Driving in Difficult Conditions
VFQ19	Eye Pain Keep You From Doing What You Like
VFQ2	Eyesight Using Both Eyes Is
VFQ20	I Stay Home Most of the Time
VFQ21	I Feel Frustrated a Lot of the Time
VFQ22	I Need a Lot of Help From Others
VFQ23	Worry I'll Do Embarrassing Things
VFQ24	Difficulty Reading Small Print
VFQ25	Difficulty Figure Out Bill Accuracy
VFQ26	Difficulty Shaving or Styling Hair
VFQ27	Difficulty Recognizing People
VFQ28	Difficulty Taking Part in Sports
VFQ29	Difficulty Seeing Programs on TV
VFQ3	How Often You Worry About Eyesight
VFQ4	How Often Pain in and Around Eyes
VFQ5	Difficulty Reading Newspapers
VFQ6	Difficulty Doing Work/Hobbies
VFQ7	Difficulty Finding on Crowded Shelf
VFQ8	Difficulty Reading Street Signs
VFQ9	Difficulty Going Down Step at Night

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
NTRGRES	Non-target Response
OVRLRESP	Overall Response
TRGRES	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	<i>Disease Response (iRECIST) for Oncology</i>
-----------------	--

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
OVLRESP	Overall Response
TRGRESP	Target Response

Author(s)

Rohan Thampi

Source

Generated dataset.

rs_onco_pcw3

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_pcw3

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

RS DY 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 4 unique Test Short Names and Test Names:

RSTESTCD	RSTEST
BONERESP	Bone Response
OVRLRESP	Overall Response
SFTSRESP	Soft Tissue Response
TMRESP	Tumor Marker 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	<i>Supplemental Qualifiers for Clinical Events for Vaccine</i>
----------------	--

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 admiralsvaccine 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	<i>Supplemental Qualifiers for Demographics for Vaccine</i>
----------------	---

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	<i>Supplemental Qualifiers for Exposures for Vaccine</i>
----------------	--

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	<i>Supplemental Qualifiers for Findings About for Clinical Events for Vaccine</i>
------------------	---

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	<i>Supplemental Qualifiers for Immunogenicity Specimen Assessments for Vaccine</i>
----------------	--

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 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	<i>Tumor Results (RECIST 1.1) for Oncology</i>
----------------	--

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

TORRES Result or Finding in Original Units

TORRESU 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	<i>Tumor Identification (RECIST 1.1) for Oncology</i>
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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	<i>Vital signs Dataset-metabolic</i>
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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	<i>Vital Signs for Vaccine</i>
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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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