

Package ‘pharmaversesdtm’

October 25, 2024

Type Package

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

Version 1.1.0

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/>.

Language en-US

License Apache License (>= 2.0)

URL <https://pharmaverse.github.io/pharmaversesdtm/>,
<https://github.com/pharmaverse/pharmaversesdtm/>

Depends R (>= 3.5.0)

Encoding UTF-8

LazyData true

RoxygenNote 7.3.2

Suggests devtools, lintr, pkgdown, testthat, knitr, rmarkdown,
roxygen2, spelling, usethis, covr

NeedsCompilation no

Author Edoardo Mancini [aut, cre] (<https://orcid.org/0009-0006-4899-8641>),
Gayatri G [aut],
Kangjie Zhang [aut],
Pooja Kumari [aut],
Stefan Bundfuss [aut] (<https://orcid.org/0009-0005-0027-1198>),
Zelos Zhu [aut],
Sadchla Mascary [aut],
Vladyslav Shuliar [aut] (<https://orcid.org/0009-0008-2354-8999>)

Maintainer Edoardo Mancini <edoardo.mancini@roche.com>

Repository CRAN

Date/Publication 2024-10-25 07:30:02 UTC

Contents

| | |
|------------------|----|
| ae | 3 |
| ae_ophtha | 3 |
| ce_vaccine | 4 |
| cm | 4 |
| dm | 5 |
| dm_peds | 5 |
| dm_vaccine | 6 |
| ds | 6 |
| eg | 7 |
| ex | 7 |
| ex_ophtha | 8 |
| ex_vaccine | 8 |
| face_vaccine | 9 |
| get_terms | 9 |
| is_vaccine | 10 |
| lb | 10 |
| mh | 11 |
| oe_ophtha | 11 |
| pc | 12 |
| pp | 12 |
| qs_ophtha | 13 |
| rs_onco | 13 |
| rs_onco_imwg | 14 |
| rs_onco_irecist | 14 |
| rs_onco_recist | 15 |
| sc_ophtha | 15 |
| sdg_db | 16 |
| smq_db | 16 |
| suppae | 16 |
| suppce_vaccine | 17 |
| suppdm | 17 |
| suppdm_vaccine | 18 |
| suppds | 18 |
| suppex_vaccine | 19 |
| suppface_vaccine | 19 |
| suppis_vaccine | 20 |
| supprs_onco_imwg | 20 |
| supptr_onco | 21 |
| sv | 21 |
| tr_onco | 22 |
| tr_onco_recist | 22 |
| ts | 23 |
| tu_onco | 23 |
| tu_onco_recist | 24 |
| vs | 24 |
| vs_peds | 25 |

| | |
|-----------------------------------|-----------|
| <code>ae</code> | 3 |
| <code>vs_vaccine</code> | 25 |
| Index | 26 |

| | |
|-----------------|-----------------------|
| <code>ae</code> | <i>Adverse Events</i> |
|-----------------|-----------------------|

Description

An updated SDTM AE dataset that uses the CDISC pilot project

Usage

`ae`

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 1191 rows and 35 columns.

Source

<https://github.com/pharmaverse/pharmaversesdtm/blob/main/data/ae.rda>

| | |
|------------------------|---|
| <code>ae_ophtha</code> | <i>Adverse Events for Ophthalmology</i> |
|------------------------|---|

Description

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

Usage

`ae_ophtha`

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 1191 rows and 37 columns.

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

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 44 rows and 29 columns.

Source

Constructed by {admiralvaccine} developers

cm

Concomitant Medication

Description

A SDTM CM dataset from the CDISC pilot project

Usage

cm

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 7510 rows and 22 columns.

Source

<https://github.com/cdisc-org/sdtm-adam-pilot-project/blob/master/updated-pilot-submission-package/900172/m5/datasets/cdiscpilot01/tabulations/sdtm/cm.xpt?raw=true> # nolint

| | |
|----|-------------------|
| dm | <i>Demography</i> |
|----|-------------------|

Description

A SDTM DM dataset from the CDISC pilot project

Usage

dm

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 306 rows and 25 columns.

Source

<https://github.com/cdisc-org/sdtm-adam-pilot-project/blob/master/updated-pilot-submission-package/900172/m5/datasets/cdiscpilot01/tabulations/sdtm/dm.xpt?raw=true> # nolint

| | |
|---------|---------------------------------------|
| dm_peds | <i>Demographic Dataset-pediatrics</i> |
|---------|---------------------------------------|

Description

An updated SDTM DM dataset with pediatric patients

Usage

dm_peds

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 5 rows and 26 columns.

Source

Constructed by {admiralped} developers

`dm_vaccine`*Demographics for Vaccine*

Description

An example SDTM DM dataset for vaccine studies

Usage

```
dm_vaccine
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 2 rows and 28 columns.

Source

Constructed by {`admiralvaccine`} developers

`ds`*Disposition*

Description

An updated SDTM DS dataset that uses the CDISC pilot project

Usage

```
ds
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 850 rows and 13 columns.

Author(s)

Gopi Vegesna

Source

<https://github.com/pharmaverse/pharmaversesdtm/blob/main/data/ds.rda>

| | |
|----|--------------------------|
| eg | <i>Electrocardiogram</i> |
|----|--------------------------|

Description

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

Usage

eg

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 26717 rows and 23 columns.

| | |
|----|-----------------|
| ex | <i>Exposure</i> |
|----|-----------------|

Description

A SDTM EX dataset from the CDISC pilot project

Usage

ex

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 591 rows and 17 columns.

Source

<https://github.com/cdisc-org/sdtm-adam-pilot-project/blob/master/updated-pilot-submission-package/900172/m5/datasets/cdiscpilot01/tabulations/sdtm/ex.xpt?raw=true> # nolint

| | |
|-----------|-----------------------------------|
| ex_ophtha | <i>Exposure for Ophthalmology</i> |
|-----------|-----------------------------------|

Description

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

Usage

ex_ophtha

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 591 rows and 19 columns.

Source

Constructed using `ex` from the `{pharmaversesdtm}` package

| | |
|------------|------------------------------|
| ex_vaccine | <i>Exposures for Vaccine</i> |
|------------|------------------------------|

Description

An example SDTM EX dataset for vaccine studies

Usage

ex_vaccine

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 4 rows and 21 columns.

Source

Constructed by `{admiralvaccine}` developers

| | |
|--------------|---|
| face_vaccine | <i>Findings About Clinical Events for Vaccine</i> |
|--------------|---|

Description

An example SDTM FACE for vaccine studies

Usage

```
face_vaccine
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 307 rows and 30 columns.

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

| | |
|----------------------------|--|
| <code>basket_select</code> | A <code>basket_select</code> object defining the terms |
| <code>version</code> | MedDRA version |
| <code>keep_id</code> | Should GRPID be included in the output? |
| <code>temp_env</code> | Temporary environment |

is_vaccine

Immunogenicity Specimen Assessments for Vaccine

Description

An example SDTM IS for vaccine studies

Usage

is_vaccine

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 16 rows and 24 columns.

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

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 59580 rows and 23 columns.

Author(s)

Annie Yang

Source

<https://github.com/pharmaverse/pharmaversesdtm/blob/main/data/lb.rda>

| | |
|----|------------------------|
| mh | <i>Medical History</i> |
|----|------------------------|

Description

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

Usage

mh

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 1818 rows and 28 columns.

Author(s)

Annie Yang

Source

<https://github.com/cdisc-org/sdtm-adam-pilot-project/blob/master/updated-pilot-submission-package/900172/m5/datasets/cdiscpilot01/tabulations/sdtm/mh.xpt?raw=true> # nolint

| | |
|-----------|--|
| oe_ophtha | <i>Ophthalmic Examinations for Ophthalmology</i> |
|-----------|--|

Description

A SDTM OE dataset simulated by Ophthalmology team

Usage

oe_ophtha

Format

An object of class `grouped_df` (inherits from `tbl_df`, `tbl`, `data.frame`) with 15344 rows and 25 columns.

Author(s)

Gordon Miller

pc *Pharmacokinetic Concentrations*

Description

A SDTM PC dataset simulated by Antonio Rodriguez Contesti

Usage

pc

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 4572 rows and 20 columns.

Author(s)

Antonio Rodriguez Contesti

Source

<https://github.com/pharmaverse/pharmaversesdtm/blob/main/data/pc.rda>

pp *Pharmacokinetic Parameters*

Description

A SDTM PP dataset simulated by Antonio Rodriguez Contesti

Usage

pp

Format

An object of class `data.frame` with 2688 rows and 14 columns.

Author(s)

Antonio Rodriguez Contesti

Source

<https://github.com/pharmaverse/pharmaversesdtm/blob/main/data/pp.rda>

qs_ophtha

Questionnaire for Ophthalmology

Description

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

Usage

qs_ophtha

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 75922 rows and 20 columns.

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

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 5808 rows and 19 columns.

Author(s)

Gopi Vegesna

| | |
|--------------|--------------------------------|
| rs_onco_imwg | <i>Disease Response (IMWG)</i> |
|--------------|--------------------------------|

Description

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

Usage

rs_onco_imwg

Format

An object of class tbl_df (inherits from tbl, data.frame) with 65 rows and 17 columns.

Author(s)

Vinh Nguyen

| | |
|-----------------|--|
| rs_onco_irecist | <i>Disease Response (iRECIST) for Oncology</i> |
|-----------------|--|

Description

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

Usage

rs_onco_irecist

Format

An object of class tbl_df (inherits from tbl, data.frame) with 376 rows and 19 columns.

Author(s)

Rohan Thampi

| | |
|----------------|---|
| rs_onco_recist | <i>Disease Response (RECIST 1.1) for Oncology</i> |
|----------------|---|

Description

A SDTM RS dataset using RECIST 1.1. The dataset contains just a few patients. It is intended for vignettes and examples of ADaM dataset creation.

Usage

rs_onco_recist

Format

An object of class tbl_df (inherits from tbl, data.frame) with 66 rows and 14 columns.

Author(s)

Stefan Bundfuss

Source

The dataset is derived from tr_onco_recist.

| | |
|-----------|---|
| sc_ophtha | <i>Subject Characteristic for Ophthalmology</i> |
|-----------|---|

Description

A SDTM SC dataset simulated by Ophthalmology team

Usage

sc_ophtha

Format

An object of class tbl_df (inherits from tbl, data.frame) with 254 rows and 12 columns.

Author(s)

Gordon Miller

sdg_db

SDG

Description

An example SDG dataset

Usage

sdg_db

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 16 rows and 5 columns.

smq_db

Standardized MedDRA Queries

Description

An example SMQ dataset

Usage

smq_db

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 44 rows and 6 columns.

suppae

Supplemental Adverse Events

Description

A SDTM SUPPAE dataset from the CDISC pilot project

Usage

suppae

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 1191 rows and 10 columns.

Source

<https://github.com/cdisc-org/sdtm-adam-pilot-project/blob/master/updated-pilot-submission-package/900172/m5/datasets/cdiscpilot01/tabulations/sdtm/suppae.xpt?raw=true> # nolint

| | |
|----------------|--|
| suppce_vaccine | <i>Supplemental Qualifiers for Clinical Events for Vaccine</i> |
|----------------|--|

Description

An example SDTM SUPPCE for vaccine studies

Usage

suppce_vaccine

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 4 rows and 9 columns.

Source

Constructed by {admiralvaccine} developers

| | |
|--------|--------------------------------|
| suppdm | <i>Supplemental Demography</i> |
|--------|--------------------------------|

Description

A SDTM SUPPDM dataset from the CDISC pilot project

Usage

suppdm

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 1197 rows and 10 columns.

Source

<https://github.com/cdisc-org/sdtm-adam-pilot-project/blob/master/updated-pilot-submission-package/900172/m5/datasets/cdiscpilot01/tabulations/sdtm/suppdm.xpt?raw=true> # nolint

| | |
|----------------|---|
| suppdm_vaccine | <i>Supplemental Qualifiers for Demographics for Vaccine</i> |
|----------------|---|

Description

An example SDTM SUPPDM dataset for vaccine studies

Usage

```
suppdm_vaccine
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 2 rows and 9 columns.

Source

Constructed by {admiralvaccine} developers

| | |
|--------|---------------------------------|
| suppds | <i>Supplemental Disposition</i> |
|--------|---------------------------------|

Description

A SDTM SUPPDS dataset from the CDISC pilot project

Usage

```
suppds
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 3 rows and 9 columns.

Source

<https://github.com/cdisc-org/sdtm-adam-pilot-project/blob/master/updated-pilot-submission-package/900172/m5/datasets/cdiscpilot01/tabulations/sdtm/suppds.xpt?raw=true> # nolint

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

Description

An example SDTM SUPPEX dataset for vaccine studies

Usage

suppex_vaccine

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 4 rows and 9 columns.

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

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 4 rows and 9 columns.

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

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 16 rows and 10 columns.

Source

Constructed by {admiralvaccine} developers

| | |
|------------------|---|
| supprs_onco_imwg | <i>Supplemental Qualifiers for RS_ONCO_IMWG</i> |
|------------------|---|

Description

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

Usage

supprs_onco_imwg

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 19 rows and 9 columns.

Author(s)

Vinh Nguyen

supptr_onco

Supplemental Tumor Results for Oncology

Description

A SDTM SUPPTR dataset simulated by Gopi Vegesna

Usage

supptr_onco

Format

An object of class tbl_df (inherits from tbl, data.frame) with 55995 rows and 9 columns.

Author(s)

Gopi Vegesna

sv

Subject Visits

Description

A SDTM SV dataset from the CDISC pilot project. Duplicate observation for group variable USUBJID and VISIT is corrected.

Usage

sv

Format

An object of class tbl_df (inherits from tbl, data.frame) with 3559 rows and 8 columns.

Source

<https://github.com/cdisc-org/sdtm-adam-pilot-project/blob/master/updated-pilot-submission-package/900172/m5/datasets/cdiscpilot01/tabulations/sdtm/sv.xpt?raw=true> # nolint

tr_onco

Tumor Results for Oncology

Description

A SDTM TR dataset simulated by Gopi Vegesna

Usage

tr_onco

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 55995 rows and 24 columns.

Author(s)

Gopi Vegesna

tr_onco_recist

Tumor Results (RECIST 1.1) for Oncology

Description

A SDTM TR dataset using RECIST 1.1. The dataset contains just a few patients. It is intended for vignettes and examples of ADaM dataset creation.

Usage

tr_onco_recist

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 546 rows and 19 columns.

Author(s)

Stefan Bundfuss

| | |
|----|---------------------|
| ts | <i>Trial Design</i> |
|----|---------------------|

Description

A SDTM TS dataset from the CDISC pilot project

Usage

ts

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 33 rows and 6 columns.

Source

<https://github.com/cdisc-org/sdtm-adam-pilot-project/blob/master/updated-pilot-submission-package/900172/m5/datasets/cdiscpilot01/tabulations/sdtm/ts.xpt?raw=true> # nolint

| | |
|---------|--|
| tu_onco | <i>Tumor Identification for Oncology</i> |
|---------|--|

Description

A SDTM TU dataset simulated by Gopi Vegesna

Usage

tu_onco

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 7734 rows and 18 columns.

Author(s)

Gopi Vegesna

| | |
|----------------|---|
| tu_onco_recist | <i>Tumor Identification (RECIST 1.1) for Oncology</i> |
|----------------|---|

Description

A SDTM TU dataset using RECIST 1.1. The dataset contains just a few patients. It is intended for vignettes and examples of ADaM dataset creation.

Usage

tu_onco_recist

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 75 rows and 16 columns.

Author(s)

Stefan Bundfuss

| | |
|----|--------------------|
| vs | <i>Vital Signs</i> |
|----|--------------------|

Description

A SDTM VS dataset from the CDISC pilot project

Usage

vs

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 29643 rows and 24 columns.

Source

<https://github.com/cdisc-org/sdtm-adam-pilot-project/blob/master/updated-pilot-submission-package/900172/m5/datasets/cdiscpilot01/tabulations/sdtm/vs.xpt?raw=true> # nolint

| | |
|---------|---------------------------------------|
| vs_peds | <i>Vital signs Dataset-pediatrics</i> |
|---------|---------------------------------------|

Description

An updated SDTM VS dataset with anthropometric measurements for pediatric patients

Usage

vs_peds

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 164 rows and 26 columns.

Source

Constructed by {admiralped} developers

| | |
|------------|--------------------------------|
| vs_vaccine | <i>Vital Signs for Vaccine</i> |
|------------|--------------------------------|

Description

An example SDTM VS dataset for vaccine studies

Usage

vs_vaccine

Format

An object of class `grouped_df` (inherits from `tbl_df`, `tbl`, `data.frame`) with 28 rows and 23 columns.

Source

Constructed by {admiralvaccine} developers

Index

* datasets

ae, 3
ae_ophtha, 3
ce_vaccine, 4
cm, 4
dm, 5
dm_peds, 5
dm_vaccine, 6
ds, 6
eg, 7
ex, 7
ex_ophtha, 8
ex_vaccine, 8
face_vaccine, 9
is_vaccine, 10
lb, 10
mh, 11
oe_ophtha, 11
pc, 12
pp, 12
qs_ophtha, 13
rs_onco, 13
rs_onco_imwg, 14
rs_onco_irecist, 14
rs_onco_recist, 15
sc_ophtha, 15
sdg_db, 16
smq_db, 16
suppae, 16
suppce_vaccine, 17
suppdm, 17
suppdm_vaccine, 18
suppds, 18
suppex_vaccine, 19
suppface_vaccine, 19
suppis_vaccine, 20
supprs_onco_imwg, 20
supptr_onco, 21
sv, 21

tr_onco, 22
tr_onco_recist, 22
ts, 23
tu_onco, 23
tu_onco_recist, 24
vs, 24
vs_peds, 25
vs_vaccine, 25

ae, 3
ae_ophtha, 3

ce_vaccine, 4
cm, 4

dm, 5
dm_peds, 5
dm_vaccine, 6
ds, 6

eg, 7
ex, 7
ex_ophtha, 8
ex_vaccine, 8

face_vaccine, 9

get_terms, 9

is_vaccine, 10

lb, 10

mh, 11

oe_ophtha, 11

pc, 12
pp, 12

qs_ophtha, 13

rs_onco, 13
rs_onco_imwg, 14
rs_onco_irecist, 14
rs_onco_recist, 15

sc_ophtha, 15
sdg_db, 16
smq_db, 16
suppae, 16
suppce_vaccine, 17
suppdm, 17
suppdm_vaccine, 18
suppds, 18
suppex_vaccine, 19
suppface_vaccine, 19
suppis_vaccine, 20
supprs_onco_imwg, 20
supptr_onco, 21
sv, 21

tr_onco, 22
tr_onco_recist, 22
ts, 23
tu_onco, 23
tu_onco_recist, 24

vs, 24
vs_peds, 25
vs_vaccine, 25