

# Package ‘pharmaversesdtm’

June 6, 2024

**Type** Package

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

**Version** 1.0.0

**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: CDISC Submission Data Standards Team (2021) <[https://www.cdisc.org/system/files/members/standard/foundational/SDTMIG%20v3.4-FINAL\\_2022-07-21.pdf](https://www.cdisc.org/system/files/members/standard/foundational/SDTMIG%20v3.4-FINAL_2022-07-21.pdf)>.

**Language** en-US

**License** Apache License (>= 2.0)

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

**Depends** R (>= 3.5.0)

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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**

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>

---

ae_ophtha	<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 36 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 21 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_vaccine	<i>Demographics for Vaccine</i>
------------	---------------------------------

---

**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	<i>Disposition</i>
----	--------------------

---

**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 26669 rows and 24 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

*Exposures for Vaccine*

---

**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

*Findings About Clinical Events for Vaccine*

---

**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**

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**

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 *Medical History*

---

**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

*Ophthalmic Examinations for Ophthalmology*

---

**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	<i>Disease Response for Oncology</i>
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---

**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	<i>SDG</i>
--------	------------

---

**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	<i>Standardized MedDRA Queries</i>
--------	------------------------------------

---

**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

*Supplemental Qualifiers for Clinical Events for Vaccine*

---

**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	<i>Supplemental Tumor Results for Oncology</i>
-------------	--

---

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

---

**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`*Tumor Identification for Oncology*

---

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

---

**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_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

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