Package 'pharmaverseraw'

May 23, 2025

Type Package

Title Raw Data for 'pharmaversesdtm' Package
Version 0.1.0
Description A set of raw datasets used to create SDTM domains in 'pharmaversesdtm' package.
License Apache License (>= 2.0)
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Author Rammprasad Ganapathy [aut, cre], Shiyu Chen [aut]
Maintainer Rammprasad Ganapathy <pre></pre>
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ae_raw

Adverse Events Raw Dataset

Description

A raw dataset used to create pharmaversesdtm::ae

Usage

ae_raw

Format

A data frame with 32 columns:

STUDY Study Identifier

PATNUM Patient Number

FOLDER Folder

FOLDERL Folder Label

IT.AETERM Reported Term for the Adverse Event

AEOUTCOME Outcome of 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

IT.AESEV Severity/Intensity

IT.AESER Serious Event

IT.AEREL Causality

IT.AEACN Action Taken with Study Treatment

AESCAN Involves Cancer

AESCNO Congenital Anomaly or Birth Defect

AEDIS Persist or Signif Disability/Incapacity

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IT.AESDTH Results in Death

IT.AESHOSP Requires or Prolongs Hospitalization

IT.AESLIFE Is Life Threatening

AESOD Occurred with Overdose

AEDTCOL Date/Time of Collection

IT.AESTDAT Start Date/Time of Adverse Event

IT.AEENDAT End Date/Time of Adverse Event

Details

Adverse Events

A raw dataset used to create pharmaversesdtm::ae

Author(s)

Shiyu Chen

Source

Access the source of the adverse events dataset.

dm_raw

Demographics Raw Dataset

Description

A raw dataset used to create pharmaversesdtm::dm

Usage

dm_raw

Format

A data frame with 13 columns:

STUDY Study Identifier

PATNUM Patient Number

IT.AGE Age

IT.SEX Sex

IT.ETHNIC Ethnicity

IT.RACE Race

COUNTRY Country

PLANNED_ARM Planned Arm

ds_raw

PLANNED_ARMCD Planned Arm Code
ACTUAL_ARM Actual Arm
ACTUAL_ARMCD Actual Arm Code
COL_DT Date of Collection
IC_DT Date of Informed Consent

Details

Demographics

A raw dataset used to create pharmaversesdtm::dm

Author(s)

Shiyu Chen

Source

Access the source of the demographics dataset.

ds_raw

Subject Disposition Raw Dataset

Description

A raw dataset used to create pharmaversesdtm::ds

Usage

ds_raw

Format

A data frame with 13 columns:

STUDY Study Identifier

PATNUM Patient Number

SITENM Site Name

INSTANCE Instance

FORM Form

FORML Form Label

IT.DSTERM Reason for Discontinuation

IT.DSDECOD Discontinuation Code

OTHERSP Other Reason for Discontinuation

DSDTCOL Date of Collection

DSTMCOL Time of Collection

IT.DSSTDAT Start Date of Subject Disposition

DEATHDT Death Date of Subject

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Details

Subject Disposition

A raw dataset used to create pharmaversesdtm::ds

Author(s)

Shiyu Chen

Source

Access the source of the subject disposition dataset.

ec_raw

Exposure as Collected Raw Dataset

Description

A raw dataset used to create pharmaversesdtm::ex

Usage

ec_raw

Format

A data frame with 14 columns:

STUDY Study Identifier

PATNUM Patient Number

VISITNAME Visit Name

FOLDER Folder

FOLDERL Folder Label

IT.ECREFID Study Treatment Label Identifier

DRUGAD Drug Administered

IT.ECSTDAT Study Treatment Start Date

IT.ECENDAT Study Treatment End Date

IT.ECDSTXT Dose of Study Treatment

IT.ECDOSU Dose Unit of Study Treatment

DOSFM Dose Form of Study Treatment

DOSFRQ Dose Frequency of Study Treatment

IT.ECROUTE Route of Administration

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Details

Exposure as Collected

A raw dataset used to create pharmaversesdtm::ex

Author(s)

Shiyu Chen

Source

Access the source of the exposure as collected dataset.

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