Package 'pharmaverseadamjnj'

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Title J&J Innovative Medicine ADaM Test Data
Version 0.0.1
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Description

adae modified from pharmaverseadam

Usage

adae

Format

A data frame with 1191 rows and 78 variables:

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

adae 3

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

ASTDTM Analysis Start Date/Time

ASTDTF Analysis Start Date Imputation Flag

ASTTMF Analysis Start Time Imputation Flag

AENDTM Analysis End Date/Time

AENDTF Analysis End Date Imputation Flag

AENTMF Analysis End Time Imputation Flag

ASTDT Analysis Start Date

AENDT Analysis End Date

ASTDY Analysis Start Relative Day

AENDY Analysis End Relative Day

ADURN Analysis Duration (N)

ADURU Analysis Duration Units

LDOSEDTM End Date/Time of Last Dose

ASEV Analysis Severity/Intensity

AREL Analysis Causality

TRTEMFL Treatment Emergent Analysis Flag

ASEVN Analysis Severity/Intensity (N)

AOCCIFL 1st Max Sev./Int. Occurrence Flag

AETOXGR Standard Toxicity Grade

AETOXGRN Standard Toxicity Grade (N)

AEACN_DECODE Action Taken with Study Treatment

DOSEDY Day of Study Drug

DOSEU Treatment Dose Units

DOSEON Treatment Dose at Record Start

4 adae

AECONTRT Concomitant or Additional Trtmnt Given

CQ01NAM Customized Query 01 Name

CQ02NAM Customized Query 02 Name

CQ03NAM Customized Query 03 Name

AESMIE Other Medically Important Serious Event

ACAT1 Analysis Category 1

AESER_DECODE Serious Event

AEREL_DECODE Causality

AEOUT_DECODE Outcome of Adverse Event

AOCCFL 1st Occurance within Subject Flag

AOCCPFL 1st Occurance within Preferred Term Flag

AOCCSFL 1st Occurrence of SOC Flag

TRT01A Actual Treatment for Period 01

SAFFL Safety Population Flag

AGE Age

SEX Sex

RACE Race

RACE_DECODE Race

STUDYID Study Identifier

AGEGR1 Pooled Age Group 1

Source

data from pharmaverseadam.

See Also

adae adaefmq adcm adeg adex adexsum adlb adsl adttesaf advs# nolint

Examples

head(data("adae"))

adaefmq 5

adaefmq adaefmq

Description

adae modified from pharmaverseadam to include FDA Medical Query information

Usage

adaefmq

Format

A data frame with 1979 rows and 81 variables:

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 AEDECOD

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

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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

ASTDTM Analysis Start Date/Time

ASTDTF Analysis Start Date Imputation Flag

ASTTMF Analysis Start Time Imputation Flag

AENDTM Analysis End Date/Time

AENDTF Analysis End Date Imputation Flag

AENTMF Analysis End Time Imputation Flag

ASTDT Analysis Start Date

AENDT Analysis End Date

ASTDY Analysis Start Relative Day

AENDY Analysis End Relative Day

ADURN Analysis Duration (N)

ADURU Analysis Duration Units

LDOSEDTM End Date/Time of Last Dose

ASEV Analysis Severity/Intensity

AREL Analysis Causality

TRTEMFL Treatment Emergent Analysis Flag

ASEVN Analysis Severity/Intensity (N)

AOCCIFL 1st Max Sev./Int. Occurrence Flag

AETOXGR Standard Toxicity Grade

AETOXGRN Standard Toxicity Grade (N)

AEACN_DECODE Action Taken with Study Treatment

DOSEDY Day of Study Drug

DOSEU Treatment Dose Units

DOSEON Treatment Dose at Record Start

AECONTRT Concomitant or Additional Trtmnt Given

CQ01NAM Customized Query 01 Name

CQ02NAM Customized Query 02 Name

CQ03NAM Customized Query 03 Name

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AESMIE Other Medically Important Serious Event

ACAT1 Analysis Category 1

AESER_DECODE Serious Event

AEREL_DECODE Causality

AEOUT_DECODE Outcome of Adverse Event

AOCCFL 1st Occurance within Subject Flag

AOCCPFL 1st Occurance within Preferred Term Flag

AOCCSFL 1st Occurrence of SOC Flag

TRT01A Actual Treatment for Period 01

SAFFL Safety Population Flag

AGE Age

SEX Sex

RACE Race

RACE_DECODE Race

STUDYID Study Identifier

AGEGR1 Pooled Age Group 1

FMQNAM FMQNAM

FMQSOC FMQSOC

FMQCLASS FMQCLASS

Source

data from adae from pharmaverseadam and, FDA_FMW_Consolidated_List.rds and FDA_FMQ_References.rds

See Also

adae adaefmq adcm adeg adex adexsum adlb adsl adttesaf advs# nolint

Examples

head(data("adaefmq"))

8 adcm

adcm adcm

Description

adcm modified from pharmaverseadam

Usage

adcm

Format

A data frame with 7276 rows and 62 variables:

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

ASTDTM Analysis Start Date/Time

ASTDTF Analysis Start Date Imputation Flag

ASTTMF Analysis Start Time Imputation Flag

AENDTM Analysis End Date/Time

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AENDTF Analysis End Date Imputation Flag

AENTMF Analysis End Time Imputation Flag

ASTDT Analysis Start Date

AENDT Analysis End Date

ASTDY Analysis Start Relative Day

AENDY Analysis End Relative Day

ADURN Analysis Duration (N)

ADURU Analysis Duration Units

ONTRTFL On Treatment Record Flag

PREFL Pre-treatment Flag

FUPFL Follow-up Flag

ANL01FL Analysis Flag 01

AOCCPFL 1st Occurrence of Preferred Term Flag

APHASE Phase

APHASEN Description of Phase N

TRTP Planned Treatment

TRTA Actual Treatment

CMLVL1 Preferred ATC Text for ATC Level 1

CMLVL2 Preferred ATC Text for ATC Level 2

CMLVL3 Preferred ATC Text for ATC Level 3

CMLVL4 Preferred ATC Text for ATC Level 4

CMBASPRF Base Preferred Term

CMPRESP CM Pre-specified

CMOCCUR CM Occurrence

CMINDCSP Indication Specification

CMDOSTXT Dose Description

CMENRF End Relative to Reference Period

CQ01NAM Customized Query 01 Name

CQ02NAM Customized Query 02 Name

CQ03NAM Customized Query 03 Name

CQ04NAM Customized Query 04 Name

CQ05NAM Customized Query 05 Name

CQ06NAM Customized Query 06 Name

CQ07NAM Customized Query 07 Name

TRT01A Actual Treatment for Period 01

SAFFL Safety Population Flag

TRTSDT Date of First Exposure to Treatment

10 adeg

Source

data from pharmaverseadam.

See Also

adae adaefmq adcm adeg adex adexsum adlb adsl adttesaf advs# nolint

Examples

```
head(data("adcm"))
```

adeg

adeg

Description

adeg modified from pharmaverseadam

Usage

adeg

Format

A data frame with 11844 rows and 70 variables:

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

EGSEQ Sequence Number

EGTESTCD ECG Test or Examination Short Name

EGTEST ECG Test or Examination 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 Lead Location Used for Measurement

EGBLFL Baseline Flag

VISITNUM Visit Number

VISIT Visit Name

VISITDY Planned Study Day of Visit

EGDTC Date/Time of ECG

adeg 11

EGDY Study Day of ECG

EGTPT Planned Time Point Name

EGTPTNUM Planned Time Point Number

EGELTM Planned Elapsed Time from Time Point Ref

EGTPTREF Time Point Reference

ADTM Analysis Datetime

ATMF Analysis Time Imputation Flag

ADY Analysis Relative Day

PARAMCD Parameter Code

AVAL Analysis Value

AVALC Analysis Value (C)

ADT Analysis Date

ATPTN Analysis Timepoint (N)

ATPT Analysis Timepoint

AVISIT Analysis Visit

AVISITN Analysis Visit (N)

DTYPE Derivation Type

ONTRTFL On Treatment Record Flag

ANRLO Analysis Normal Range Lower Limit

ANRHI Analysis Normal Range Upper Limit

ANRIND Analysis Reference Range Indicator

BASETYPE Baseline Type

ABLFL Baseline Record Flag

BASEC Baseline Value (C)

CHG Change from Baseline

PCHG Percent Change from Baseline

ANL01FL Analysis Flag 01-Analysis Value

TRTP Planned Treatment

TRTA Actual Treatment

ASEQ Analysis Sequence Number

AVALCAT1 Analysis Value Category 1

AVALCA1N Analysis Value Category 1 (N)

CHGCAT1 Change from Baseline Category 1

CHGCAT1N Change from Baseline Category 1 (N)

PARAM Parameter

PARAMN Parameter (N)

TRTEMFL Treatment Emergent Analysis Flag

ANL02FL Analysis Flag 02-By Visit Value

ANL03FL Analysis Flag 03-Maximum Value

APOBLFL Post-Baseline Record Flag

CRIT1 Analysis Criterion 1

CRIT1FL Criterion 1 Evaluation Result Flag

CRIT2 Analysis Criterion 2

CRIT2FL Criterion 2 Evaluation Result Flag

BASE Baseline Value

BNRIND Baseline Reference Range Indicator

BASECAT1 Baseline Category 1

TRT01A Actual Treatment for Period 01

SAFFL Safety Population Flag

STUDYID Study Identifier

AGE Age

SEX Sex

RACE_DECODE Race

Source

data from pharmaverseadam.

See Also

adae adaefmq adcm adeg adex adexsum adlb adsl adttesaf advs# nolint

Examples

head(data("adeg"))

adex

adex

Description

adex modified from pharmaverseadam

Usage

adex

Format

A data frame with 591 rows and 128 variables:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

EXSEQ Sequence Number

EXTRT Planned Treatment

EXDOSE Adjusted Dose

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

EXADJ Reason for Dose Adjustment

EXPLDOS Planned Dose

TRTSDT Date of First Exposure to Treatment

TRTSDTM Datetime of First Exposure to Treatment

TRTEDTM Datetime of Last Exposure to Treatment

ASTDTM Analysis Start Datetime

ASTDTF Analysis Start Date Imputation Flag

ASTTMF Analysis Start Time Imputation Flag

AENDTM Analysis End Datetime

AENDTF Analysis End Date Imputation Flag

AENTMF Analysis End Time Imputation Flag

ASTDY Analysis Start Relative Day

AENDY Analysis End Relative Day

EXDURD Duration of Treatment (Days)

ASTDT Analysis Start Date

AENDT Analysis End Date

DOSEO Dose O

PDOSEO PDose O

PARAMCD Parameter Code

AVAL Analysis Value

AVALC Analysis Value (C)

PARCAT1 Parameter Category 1

PARAM Parameter

PARAMN Parameter (N)

AVALCAT1 Analysis Value Category 1

ASEQ Analysis Sequence Number

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 Treatment Category Code

ARM Treatment Group

ACTARMCD Actual Arm Code

ACTARM Actual Treatment Group

COUNTRY Country

DMDTC Date/Time of Collection

DMDY Study Day of Collection

TRT01P Planned Treatment for Period 01

TRT01A Actual Treatment for Period 01

TRTSTMF Time of First Exposure Imput. Flag

TRTETMF Time of Last Exposure Imput. Flag

TRTEDT Date of Last Exposure to Treatment

TRTDURD Total Treatment Duration (Days)

SCRFDT Screen Failure Date

EOSDT End of Study Date

EOSSTT End of Study Status

FRVDT Final Retrievel Visit Date

RANDDT Date of Randomization

DTHDT Date of Death

DTHDTF DTHDTF

DTHADY Relative Day of Death

LDDTHELD Elapsed Days from Last Dose to Death

DTHCAUS DTHCAUS

DTHDOM DTHDOM

DTHCGR1 DTHCGR1

LSTALVDT Date Last Known Alive

SAFFL Safety Population Flag

RACEGR1 Pooled Race Group 1

AGEGR1 Age Group

REGION1 Geographic Region 1

LDDTHGR1 Last Dose to Death - Days Elapsed Grp 1

DTH30FL Death Within 30 Days of Last Trt Flag

DTHA30FL Death After 30 Days from Last Trt Flag

DTHB30FL Death Within 30 Days of First Trt Flag

ATRT Analysis name of Treatment

DAEXPDTC Date of Exposure

EXLOT Lot Number

ADOSE Analysis Dose

TRT01PN Planned Treatment for Period 01 (N)

AVISITN Visit Number

AVISIT Visit Label

TRT01AN Actual Treatment for Period 01 (N)

AOCCUR Analysis Occurrence

RACE_DECODE Race

ACAT1 Analysis Category 1

AREASOC Analysis Reason for Occur Value

AREASOO Other Analysis Reason for Occur Value

AADJ Analysis Reason for Dose Adjustment

AADJPOTH Other Anal Reason for Dose Adjust Prior

AADJP Analysis Reason for Dose Adjustment Prior

AACTDU Analysis Action Taken During Study Trt

AACTDU1 Act Takn Dur Infus-Full Dose Admined

AACTDU2 Act Takn Dur Infus-Infusion Aborted

AACTDU3 Act Takn Dur Infus-Infusion Interrupted

AACTDU4 Act Takn Dur Infus-Infusion Rate Decrsed

AACTDU5 Act Takn Dur Infus-Infusion Rate Incrsed

AADJOTH Other Anal Reason for Dose Adjustment

ACAT2 Analysis Category 2

AACTPR Action Taken Prior to Infudion Start

AACTPR_DECODE Action Taken Prior to Infusion Start

ASCHDOSE Analysis Scheduled Dose

ASCHDOSU Analysis Scheduled Dose Units

ADOSFRM Analysis Dose Form

ADOSU Analysis Dose Units

ADOSFRQ Analysis Dosing Frequency per Interval

AROUTE Analysis Route of Administration

ATVINF Analysis Total Volume Infused

ATVINFU Analysis Total Volume Infused Units

AINFRAT Analysis Infusion Rate

AINFRAU Analysis Infusion Rate Unit

Source

data from pharmaverseadam.

See Also

adae adaefmq adcm adeg adex adexsum adlb adsl adttesaf advs# nolint

Examples

```
head(data("adex"))
```

adexsum 17

adexsum

adexsum

Description

adex modified from pharmaverseadam

Usage

adexsum

Format

A data frame with 2794 rows and 25 variables:

USUBJID Unique Subject Identifier

PARAMCD Parameter Code

PARAM Parameter

AVAL Analysis Value

AVALCAT1 Analysis Value Category 1

AVALCA1N Analysis Value Category 1 (N)

CRIT1 Analysis Criterion 1

CRIT1FL Criterion 1 Evaluation Result Flag

CRIT2 Analysis Criterion 2

CRIT2FL Criterion 2 Evaluation Result Flag

CRIT3 Analysis Criterion 3

CRIT3FL Criterion 3 Evaluation Result Flag

CRIT4 Analysis Criterion 4

CRIT4FL Criterion 4 Evaluation Result Flag

CRIT5 Analysis Criterion 5

CRIT5FL Criterion 5 Evaluation Result Flag

CRIT6 Analysis Criterion 6

CRIT6FL Criterion 6 Evaluation Result Flag

CRIT7 Analysis Criterion 7

CRIT7FL Criterion 7 Evaluation Result Flag

AVISIT Analysis Visit

AVISITN Analysis Visit (N)

TRT01A Actual Treatment for Period 01

SAFFL Safety Population Flag

STUDYID Study Identifier

Source

data from adex from pharmaverseadam

See Also

adae adaefmq adcm adeg adex adexsum adlb adsl adttesaf advs# nolint

Examples

```
head(data("adexsum"))
```

adlb

adlb

Description

adlb modified from pharmaverseadam

Usage

adlb

Format

A data frame with 83640 rows and 152 variables:

STUDYID Study Identifier

DOMAIN Domain Abbreviation

USUBJID Unique Subject Identifier

LBSEQ Sequence Number

LBTESTCD Lab Test or Examination Short Name

LBTEST Lab Test or Examination Name

LBCAT Category for Lab Test

LBORRES Result or Finding in Original Units

LBORRESU Original Units

LBORNRLO Reference Range Lower Limit in Orig Unit

LBORNRHI Reference Range Upper Limit in Orig Unit

LBSTRESC Character Result/Finding in Std Format

LBSTRESN Numeric Result/Finding in Standard Units

LBSTRESU Standard Units

LBSTNRLO Reference Range Lower Limit-Std Units

LBSTNRHI Reference Range Upper Limit-Std Units

LBNRIND Reference Range Indicator

LBBLFL Baseline Flag

VISITNUM Visit Number

VISIT Visit Name

VISITDY Planned Study Day of Visit

LBDTC Date/Time of Specimen Collection

LBDY Study Day of Specimen Collection

TRTSDT Date of First Exposure to Treatment

TRTEDT Date of Last Exposure to Treatment

TRT01A Actual Treatment for Period 01

TRT01P Planned Treatment for Period 01

ADT Analysis Date

ADY Analysis Relative Day

PARAMCD Parameter Code

PARAM Parameter

PARAMN Parameter (N)

PARCAT1 Parameter Category 1

AVAL Analysis Value

AVALC Analysis Value (C)

ANRLO Analysis Normal Range Lower Limit

ANRHI Analysis Normal Range Upper Limit

DTYPE Derivation Type

AVISIT Analysis Visit

AVISITN Analysis Visit (N)

ONTRTFL On Treatment Record Flag

ANRIND Analysis Reference Range Indicator

BASETYPE Baseline Type

ABLFL Baseline Record Flag

BASE Baseline Value

BASEC Baseline Value (C)

BNRIND Baseline Reference Range Indicator

CHG Change from Baseline

PCHG Percent Change from Baseline

ATOXDSCL Analysis Toxicity Description Low

ATOXDSCH Analysis Toxicity Description High

ATOXGRL Analysis Toxicity Grade Low

ATOXGRH Analysis Toxicity Grade High

ATOXGR Analysis Toxicity Grade

BTOXGRL Baseline Toxicity Grade Low

BTOXGRH Baseline Toxicity Grade High

BTOXGR Baseline Toxicity Grade

R2BASE Ratio to Baseline

R2ANRLO Ratio of Analysis Val compared to ANRLO

R2ANRHI Ratio of Analysis Val compared to ANRHI

SHIFT1 Shift from Baseline to Analysis Value

SHIFT2 Shift from Baseline to Overall Grade

ANL01FL Analysis Flag 01

LVOTFL Last Value On Treatment Record Flag

TRTP Planned Treatment

TRTA Actual Treatment

ASEQ Analysis Sequence Number

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

TRTSDTM Datetime of First Exposure to Treatment

TRTSTMF Time of First Exposure Imput. Flag

TRTEDTM Datetime of Last Exposure to Treatment

TRTETMF Time of Last Exposure Imput. Flag

TRTDURD Total Treatment Duration (Days)

SCRFDT Screen Failure Date

EOSDT End of Study Date

EOSSTT End of Study Status

FRVDT Final Retrievel Visit Date

RANDDT Date of Randomization

DTHDT Date of Death

DTHDTF DTHDTF

DTHADY Relative Day of Death

LDDTHELD Elapsed Days from Last Dose to Death

DTHCAUS DTHCAUS

DTHDOM DTHDOM

DTHCGR1 DTHCGR1

LSTALVDT Date Last Known Alive

SAFFL Safety Population Flag

RACEGR1 Pooled Race Group 1

REGION1 Geographic Region 1

LDDTHGR1 Last Dose to Death - Days Elapsed Grp 1

DTH30FL Death Within 30 Days of Last Trt Flag

DTHA30FL Death After 30 Days from Last Trt Flag

DTHB30FL Death Within 30 Days of First Trt Flag

TRT01PN Planned Treatment for Period 01 (N)

TRT01AN Actual Treatment for Period 01 (N)

AVALU Analysis Value - Units

ANL02FL Analysis Record Flag 02-Analysis Value

TRTEMFL Treatment Emergent Analysis Flag

COUNTRY_DECODE Country

RACE_DECODE Race Description

ETHNIC_DECODE Ethnicity Description

PARCAT2 Parameter Category 2

PARCAT3 Parameter Category 3

PARCAT4 Parameter Category 4

PARCAT5 Parameter Category 5

PARCAT6 Parameter Category 6

MCRIT2ML Multi-Response Criterion 2 Evaluation

MCRIT1ML Multi-Response Criterion 1 Evaluation

MCRIT1MN Multi-Response Criterion 1 Eval (N)

MCRIT2MN Multi-Response Criterion 2 Eval (N)

MCRIT1 Analysis Multi-Response Criterion 1

MCRIT2 Analysis Multi-Response Criterion 2

APOBLFL Post-Baseline Record Flag

LBSTNRHQ Reference Limit Higher

LBSTNRLQ Reference Limit Lower

ATOXGRN Analysis Toxicity Grade (Numeric)

ADTM Analysis Date/Time

ATPT Analysis Timepoint

TR01SDT Start Date of Treatment for Period 01

TR01EDT End Date of Treatment for Period 01

ANL03FL Analysis Record Flag 03 - Protocol Visit

ANL04FL Analysis Flag 04

ANL05FL Analysis Flag 05

ANL06FL Analysis Flag 06

ANL07FL Analysis Flag 07

ANL08FL Analysis Flag 08

ANL09FL Analysis Flag 09

ANL10FL Analysis Flag 10

ANL14FL Analysis Flag 14

ANL15FL Analysis Flag 15

ANL16FL Analysis Flag 16

Source

data from pharmaverseadam.

See Also

adae adaefmq adcm adeg adex adexsum adlb adsl adttesaf advs# nolint

Examples

head(data("adlb"))

adsl 23

adsl adsl

Description

adsl modified from pharmaverseadam

Usage

adsl

Format

A data frame with 306 rows and 106 variables:

STUDYID Study Identifier

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

TRT01P Planned Treatment for Period 01

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TRT01A Actual Treatment for Period 01

TRTSDTM Datetime of First Exposure to Treatment

TRTSTMF Time of First Exposure Imput. Flag

TRTEDTM Datetime of Last Exposure to Treatment

TRTETMF Time of Last Exposure Imput. Flag

TRTSDT Date of First Exposure to Treatment

TRTEDT Date of Last Exposure to Treatment

TRTDURD Total Treatment Duration (Days)

SCRFDT Screen Failure Date

EOSDT End of Study Date

EOSSTT End of Study Status

FRVDT Final Retrievel Visit Date

RANDDT Date of Randomization

DTHDT Date of Death

DTHDTF Date of Death Imputation Flag

DTHADY Relative Day of Death

LDDTHELD Elapsed Days from Last Dose to Death

DTHCAUS DTHCAUS

DTHDOM DTHDOM

DTHCGR1 DTHCGR1

LSTALVDT Date Last Known Alive

SAFFL Safety Population Flag

RACEGR1 Pooled Race Group 1

AGEGR1 Pooled Age Group 1

REGION1 Geographic Region 1

LDDTHGR1 Last Dose to Death - Days Elapsed Grp 1

DTH30FL Death Within 30 Days of Last Trt Flag

DTHA30FL Death After 30 Days from Last Trt Flag

DTHB30FL Death Within 30 Days of First Trt Flag

TRT01PN Planned Treatment for Period 01 (N)

TRT01AN Actual Treatment for Period 01 (N)

AGEGR1N Pooled Age Group 1 (N)

SEX_DECODE Sex

WEIGHTBL Weight (kg)

WGTGR1N Weight Group 1 (N)

WGTGR1 Weight Group 1

HEIGHTBL Height (cm)

adsl 25

BSABL Body surface area (m2)

BMIBL Body mass index (kg/m2)

BMIBLG1N BMI at Baseline Group 1 (N)

BMIBLG1 BMI at Baseline Group 1

COUNTRY_DECODE Country

RACE DECODE Race

RFICDT Date of Informed Consent

ETHNIC_DECODE Ethnicity

STRAT1R Strat Factor 1 Value Used for Rand

STRAT2R Strat Factor 2 Value Used for Rand

RANUM Randomization Number

RANDDTM Datetime of Randomization

EOTSTT End of Treatment Status

DCTREAS Reason for Discontinuation of Treatment

LTVISIT Last Treatment Visit

DCTREASP Reason Specify for Discont of Treatment

DCTDT End of Study Date

DCSREAS Reason for Discontinuation from Study

DCSREASP Reason Spec for Discont from Study

LSVISIT Last Study Visit

TRTEDY Treatment Relative End Day

SCRNFL Screened Population Flag

SCRFFL Screen Failure Flag

DCSCREEN Reason for Discont During Screening

ENRLFL Enrolled Population Flag

RANDFL Randomized Flag

ITTFL Intent-To-Treat Population Flag

FASFL Full Analysis Set Population Flag

PPROTFL Per-Protocol Population Flag

LSTSVDT Last Subject Visit (SV) Date

EOSDY Study Day of Study Termination

UNBLNDFL Subject Blind Broken

RESCRNFL Re-screened Flag

DTHTRTFL Death on Treatment Flag

DTHCAUSP Cause Spec for Death

DTHAFTFL Death After 30 Days of Last Treatment

DTH60TFL Death Within 60 Days of First Treatment

26 adttesaf

UNBLNDDY Study Day of Unblinding

UNBREAS Reason For Unblinding

LDOSE Last Dose

LDOSU Last Dose Unit

DTHTERM Reported Cause of Death

LDSTODTH Days from Last Dose to Death

DTHDY Study Day of Death

Source

data from pharmaverseadam.

See Also

adae adaefmq adcm adeg adex adexsum adlb adsl adttesaf advs# nolint

Examples

```
head(data("adsl"))
```

adttesaf

adttesaf

Description

adtte_onc modified from pharmaverseadam

Usage

adttesaf

Format

A data frame with 2032 rows and 9 variables:

USUBJID Unique Subject Identifier

PARAMCD Parameter Code

PARAM Parameter

AVAL Analysis Value

CNSR Censor

STARTDT Start Date

ADT Analysis Date

TRT01A Actual Treatment for Period 01

SAFFL Safety Population Flag

advs 27

Source

data from adtte_onc from pharmaverseadam

See Also

adae adaefmq adcm adeg adex adexsum adlb adsl adttesaf advs# nolint

Examples

```
head(data("adttesaf"))
```

advs

advs

Description

advs modified from pharmaverseadam

Usage

advs

Format

A data frame with 40702 rows and 78 variables:

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

28 advs

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

ADT Analysis Date

ADY Analysis Relative Day

PARAMCD Parameter Code

AVAL Analysis Value

ATPTN Analysis Timepoint (N)

ATPT Analysis Time Point

AVISIT Analysis Visit

AVISITN Analysis Visit (N)

DTYPE Derivation Type

ONTRTFL On Treatment Record Flag

ANRLO Analysis Normal Range Lower Limit

ANRHI Analysis Normal Range Upper Limit

A1LO Analysis Range 1 Lower Limit

A1HI Analysis Range 1 Upper Limit

ANRIND Analysis Reference Range Indicator

BASETYPE Baseline Type

ABLFL Baseline Record Flag

CHG Change from Baseline

PCHG Percent Change from Baseline

ANL01FL Analysis Flag 01

TRTP Planned Treatment

TRTA Actual Treatment

ASEQ Analysis Sequence Number

AVALCAT1 Analysis Value Category 1

AVALCA1N Analysis Value Category 1 (N)

PARAM Parameter

PARAMN Parameter (N)

AVALC Analysis Value (C)

ANL02FL Analysis Flag 02-By Visit Value

APOBLFL Post-Baseline Record Flag

BASE Baseline Value

advs 29

BNRIND Baseline Reference Range Indicator

ADTM Analysis Date/Time

CRIT1 Analysis Criterion 1

CRIT1FL Criterion 1 Evaluation Result Flag

CRIT2 Analysis Criterion 2

CRIT2FL Criterion 2 Evaluation Result Flag

CRIT3 Analysis Criterion 3

CRIT3FL Criterion 3 Evaluation Result Flag

ATOXDSCL Analysis Toxicity Description Low

ATOXDSCH Analysis Toxicity Description High

ATOXGRL Analysis Toxicity Grade Low

ATOXGRH Analysis Toxicity Grade High

ATOXGR Analysis Toxicity Grade

ANL06FL Analysis Flag 06-Minimum Value

ANL05FL Analysis Flag 05-Worst Tox Grade High

ANL04FL Analysis Flag 04-Worst Value

ANL03FL Analysis Flag 03-Maximum Value

TRTEMFL Treatment Emergent Analysis Flag

TRT01A Actual Treatment for Period 01

SAFFL Safety Population Flag

STUDYID Study Identifier

AGE Age

SEX Sex

RACE_DECODE Race

Source

data from pharmaverseadam.

See Also

adae adaefmq adcm adeg adex adexsum adlb adsl adttesaf advs# nolint

Examples

head(data("advs"))

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