Package 'admiralophtha'

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Type Package

Title ADaM in R Asset Library - Ophthalmology

Version 1.3.0

Description Aids the programming of Clinical Data Standards Interchange Consortium (CDISC) compliant Ophthalmology Analysis Data Model (ADaM) datasets in R. ADaM datasets are a mandatory part of any New Drug or Biologics License Application submitted to the United States Food and Drug Administration (FDA). Analysis derivations are implemented in accordance with the ``Analysis Data Model Implementation Guide" (CDISC Analysis Data Model Team, 2021, <https://www.cdisc.org/standards/foundational/adam/adamig-v1-3-release-package>).

License Apache License (>= 2)

URL https://pharmaverse.github.io/admiralophtha/, https://github.com/pharmaverse/admiralophtha/

BugReports https://github.com/pharmaverse/admiralophtha/issues/

Depends R (>= 4.1)

Imports admiral (>= 1.1.1), admiraldev (>= 1.1.0), dplyr (>= 1.0.5), hms (>= 0.5.3), lifecycle (>= 0.1.0), lubridate (>= 1.7.4), magrittr (>= 1.5), purrr (>= 0.3.3), rlang (>= 0.4.4), stringr (>= 1.4.0), tidyr (>= 1.0.2), tidyselect (>= 1.1.0)

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Contents

`admiralophtha_adbcva` *Best Corrected Visual Acuity Analysis Dataset*

Description

An example Best Corrected Visual Acuity (BCVA) analysis dataset

Usage

```
admiralophtha_adbcva
```

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 7672 rows and 116 columns.

Source

Derived from the OE and ADSL datasets using {admiral}, {admiralophtha} and the ADBCVA template.

See Also

Other datasets: admiralophtha_adoe, admiralophtha_advfq

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admiralophtha_adoe *Ophthalmology Exam Analysis Dataset*

Description

An example Ophthalmology Exam Analysis dataset

Usage

```
admiralophtha_adoe
```

Format

An object of class tbl_df (inherits from tbl, data.frame) with 19136 rows and 103 columns.

Source

Derived from the OE and ADSL datasets using {admiral}, {admiralophtha} and the ADOE template.

See Also

Other datasets: admiralophtha_adbcva, admiralophtha_advfq

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admiralophtha_advfq *Visual Function Questionnaire Analysis Dataset*

Description

An example Visual Function Questionnaire (VFQ) analysis dataset

Usage

```
admiralophtha_advfq
```

Format

An object of class tbl_df (inherits from tbl, data.frame) with 28798 rows and 41 columns.

Source

Derived from the ADSL and QS datasets using `{admiral}`, `{admiralophtha}` and the ADVFQ template. The full, open-source VFQ questionnaire can be accessed here.

See Also

Other datasets: `admiralophtha_adbcva`, `admiralophtha_adoe`

`convert_etdrs_to_logmar` *ETDRS –> LogMAR conversion*

Description

Convert ETDRS score to LogMAR units

Usage

```
convert_etdrs_to_logmar(value)
```

Arguments

`value`	object containing ETDRS score to convert to logMAR

Details

ETDRS value converted to logMAR as logMAR = -0.02 * ETDRS + 1.7

Source for conversion formula: Beck, R.W., et al. A computerized method of visual acuity testing. American Journal of Ophthalmology, 135(2), pp.194-205. doi:https://doi.org/10.1016/s0002-9394(02)01825-1.

Value

The input value converted converted to logMAR units

Author(s)

Rachel Linacre

Examples

```
library(tibble)
library(dplyr)
library(admiral)
library(admiraldev)

adbcva <- tribble(
  ~STUDYID, ~USUBJID, ~AVAL,
```

```
  "XXX001", "P01", 5,
  "XXX001", "P02", 10,
  "XXX001", "P03", 15,
  "XXX001", "P04", 20,
  "XXX001", "P05", 25
)

adbcva <- adbcva %>% mutate(AVAL = convert_etdrs_to_logmar(AVAL))
```

`convert_logmar_to_etdrs` *LogMAR –> ETDRS conversion*

Description

Convert LogMAR score to ETDRS units

Usage

```
convert_logmar_to_etdrs(value)
```

Arguments

`value`	object containing logMAR score to convert to ETDRS

Details

logMAR value converted to ETDRS as ETDRS = -(logMAR - 1.7) / 0.02

Source for conversion formula: Beck, R.W., et al. A computerized method of visual acuity testing. American Journal of Ophthalmology, 135(2), pp.194-205. doi:https://doi.org/10.1016/s0002-9394(02)01825-1.

Value

The input value converted to ETDRS units

Author(s)

Nandini R Thampi

Examples

```
library(tibble)
library(dplyr)
library(admiral)

oe <- tribble(
  ~STUDYID, ~USUBJID, ~OETESTCD, ~OEMETHOD, ~OESTRESN,
  "XXX001", "P01", "VACSCORE", "logMAR EYE CHART", 1.08,
```

```
  "XXX001", "P02", "VACSCORE", "logMAR EYE CHART", 1.66,
  "XXX001", "P03", "VACSCORE", "logMAR EYE CHART", 1.60,
  "XXX001", "P04", "VACSCORE", "ETDRS EYE CHART", 57,
  "XXX001", "P05", "VACSCORE", "ETDRS EYE CHART", 1
)

adbcva <- oe %>%
  filter(OETESTCD == "VACSCORE" & toupper(OEMETHOD) == "LOGMAR EYE CHART") %>%
  mutate(OESTRESN = convert_logmar_to_etdrs(OESTRESN))
```

`derive_var_afeye` *Derive Affected Eye*

Description

Derive Affected Eye (`AFEYE`) in occurrence datasets

Usage

```
derive_var_afeye(dataset, loc_var, lat_var, loc_vals = "EYE")
```

Arguments

`dataset`	Input dataset **[Deprecated]** Please use `dataset` instead.
`loc_var`	Location variable
`lat_var`	Laterality variable
`loc_vals`	`xxLOC` values for which `AFEYE` is derived **[Deprecated]** Please simply ensure `xxLAT` values are contained in `c("LEFT", "RIGHT", "BILATERAL")`.

Details

Affected Eye is derived in the occurrence dataset using laterality and Study Eye. This assumes Study Eye has already been added from ADSL.

Value

The input occurrence dataset with Affected Eye (`AFEYE`) added.

Author(s)

Lucy Palmen

Examples

```
library(tibble)
library(admiral)

adae1 <- tribble(
  ~STUDYID, ~USUBJID, ~STUDYEYE, ~AELOC, ~AELAT,
  "XXX001", "P01", "RIGHT", "EYE", "RIGHT",
  "XXX001", "P01", "RIGHT", "EYE", "LEFT",
  "XXX001", "P01", "RIGHT", "EYE", "",
  "XXX001", "P01", "RIGHT", "", "RIGHT",
  "XXX001", "P02", "LEFT", "", "",
  "XXX001", "P02", "LEFT", "EYE", "LEFT",
  "XXX001", "P04", "BILATERAL", "EYE", "RIGHT",
  "XXX001", "P05", "RIGHT", "EYE", "RIGHT",
  "XXX001", "P05", "RIGHT", "EYE", "BILATERAL",
  "XXX001", "P06", "BILATERAL", "", "",
  "XXX001", "P06", "BILATERAL", "", "RIGHT",
  "XXX001", "P07", "BILATERAL", "EYE", "BILATERAL",
  "XXX001", "P08", "", "EYE", "BILATERAL",
  "XXX001", "P09", "NONSENSE", "EYE", "BILATERAL",
  "XXX001", "P09", "BILATERAL", "EYE", "NONSENSE",
  "XXX001", "P09", "BILATERAL", "NONSENSE", "BILATERAL",
  "XXX001", "P10", "RIGHT", "EYE", "BOTH"
)

derive_var_afeye(adae1, loc_var = AELOC, lat_var = AELAT)

adae2 <- tribble(
  ~STUDYID, ~USUBJID, ~STUDYEYE, ~AELOC, ~AELAT,
  "XXX001", "P01", "RIGHT", "EYES", "RIGHT",
  "XXX001", "P02", "RIGHT", "RETINA", "LEFT",
  "XXX001", "P03", "LEFT", "", ""
)

derive_var_afeye(adae2, loc_var = AELOC, lat_var = AELAT, loc_vals = c("EYES", "RETINA"))
```

---

derive_var_bcvacritxfl

Adds CRITx/CRITxFL *pairs to BCVA dataset*

Description

[Superseded] The derive_var_bcvacritxfl() function has been superseded in favor of admiral::derive_vars_crit_fl

Adds a criterion variables CRITx and their corresponding flags CRITxFL to a dataset containing BCVA records

Usage

```
derive_var_bcvacritxfl(
  dataset,
  crit_var,
  bcva_ranges = NULL,
  bcva_uplims = NULL,
  bcva_lowlims = NULL,
  additional_text = "",
  critxfl_index = NULL
)
```

Arguments

dataset	Input dataset containing BCVA data (usually ADBCVA).
crit_var	Variable with respect to which CRITx/CRITxFL are derived (usually CHG or AVAL).
bcva_ranges	List containing one or more numeric vectors of length 2. For each vector c(a,b) in bcva_ranges, a pair of variables CRITx, CRITxFL is created with the condition: a <= crit_var <= b. If criterion flags of that type are not required, then leave as NULL.
bcva_uplims	List containing one or more numeric elements. For each element a in bcva_uplims, a pair of variables CRITx, CRITxFL is created with the condition: crit_var <= a. If criterion flags of that type are not required, then leave as NULL.
bcva_lowlims	List containing one or more numeric elements. For each element b in bcva_lowlims, a pair of variables CRITx, CRITxFL is created with the condition: crit_var >= b. If criterion flags of that type are not required, then leave as NULL.
additional_text	string containing additional text to append to CRITx
critxfl_index	positive integer detailing the first value of x to use in CRITxFL. If not supplied, the function takes the first available value of x, counting up from x = 1.

Details

This function works by calling derive_var_bcvacritxfl() once for each of the elements in bcva_ranges, bcva_uplims and bcva_lowlims. NOTE: if crit_var is equal to NA, then the resulting criterion flag is also marked as NA.

Value

The input BCVA dataset with additional column pairsCRITx, CRITxFL.

Author(s)

Edoardo Mancini

Examples

```
library(tibble)
library(admiral)
library(admiraldev)

adbcva1 <- tribble(
  ~STUDYID, ~USUBJID, ~AVISIT, ~BASETYPE, ~PARAMCD, ~CHG,
  "XXX001", "P01", "BASELINE", "LAST", "SBCVA", 0,
  "XXX001", "P01", "WEEK 2", "LAST", "FBCVA", 2,
  "XXX001", "P02", "BASELINE", "LAST", "SBCVA", -13,
  "XXX001", "P02", "WEEK 2", "LAST", "FBCVA", 5,
  "XXX001", "P03", "BASELINE", "LAST", "SBCVA", NA,
  "XXX001", "P03", "WEEK 2", "LAST", "FBCVA", 17
)

derive_var_bcvacritxfl(
  dataset = adbcva1,
  crit_var = exprs(CHG),
  bcva_ranges = list(c(0, 5), c(-5, -1), c(10, 15)),
  bcva_uplims = list(5, 10),
  bcva_lowlims = list(8),
  additional_text = ""
)

adbcva2 <- tribble(
  ~STUDYID, ~USUBJID, ~AVISIT, ~BASETYPE, ~PARAMCD, ~AVAL, ~CHG,
  "XXX001", "P01", "BASELINE", "LAST", "SBCVA", 4, NA,
  "XXX001", "P01", "BASELINE", "LAST", "SBCVA", 6, NA,
  "XXX001", "P01", "AVERAGE BASELINE", "AVERAGE", "SBCVA", 5, NA,
  "XXX001", "P01", "WEEK 2", "LAST", "SBCVA", -3, NA,
  "XXX001", "P01", "WEEK 4", "LAST", "SBCVA", -10, NA,
  "XXX001", "P01", "WEEK 6", "LAST", "SBCVA", 12, NA,
  "XXX001", "P01", "WEEK 2", "AVERAGE", "SBCVA", -2, -7,
  "XXX001", "P01", "WEEK 4", "AVERAGE", "SBCVA", 6, 1,
  "XXX001", "P01", "WEEK 6", "AVERAGE", "SBCVA", 3, -2
)

restrict_derivation(
  adbcva2,
  derivation = derive_var_bcvacritxfl,
  args = params(
    crit_var = exprs(CHG),
    bcva_ranges = list(c(0, 5), c(-10, 0)),
    bcva_lowlims = list(5),
    additional_text = " (AVERAGE)"
  ),
  filter = PARAMCD %in% c("SBCVA", "FBCVA") & BASETYPE == "AVERAGE"
)
```

`derive_var_studyeye` *Derive Study Eye*

Description

Derive Study Eye (`STUDYEYE`) in the ADSL dataset

Usage

```
derive_var_studyeye(dataset_adsl, dataset_sc, sctestcd_value = "FOCID")
```

Arguments

`dataset_adsl`	ADSL input dataset
`dataset_sc`	SC input dataset
`sctestcd_value`	`SCTESTCD` value flagging Study Eye selection records. Default: "FOCID".

Details

Study Eye is derived in ADSL using the "Study Eye selection" records in the SC SDTM dataset.

Value

The input ADSL dataset with an additional column named `STUDYEYE`

Author(s)

Edoardo Mancini

Examples

```
library(tibble)
library(admiral)

adsl <- tribble(
  ~STUDYID, ~USUBJID,
  "XXX001", "P01",
  "XXX001", "P02",
  "XXX001", "P03",
  "XXX001", "P04",
  "XXX001", "P05"
)

sc <- tribble(
  ~STUDYID, ~USUBJID, ~SCTESTCD, ~SCSTRESC,
  "XXX001", "P01", "FOCID", "OS",
  "XXX001", "P01", "ACOHORT", "COHORT1",
  "XXX001", "P02", "FOCID", "OD",
  "XXX001", "P02", "ACOHORT", "COHORT3",
```

```
  "XXX001", "P04", "FOCID", "OU",
  "XXX001", "P05", "FOCID", "OD",
  "XXX001", "P06", "FOCID", "OS"
)

derive_var_studyeye(adsl, sc)
```

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