

Package ‘cdashQC’

January 4, 2017

Title Quality control for TFLs

Version 0.1.3

Depends R(>= 3.1.1)

Imports lubridate(>= 1.6.0),
reshape2(>= 1.4.1),
dplyr(>= 0.5.0),
haven(>= 0.2.1),
knitr(>= 1.14)

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Description This package creates table and listings for QC of cdash format data.

License What license is it under?

LazyData TRUE

RoxygenNote 5.0.1

NeedsCompilation no

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clean_lab	<i>Clean the lab test data set.</i>
-----------	-------------------------------------

Description

clean the lab data, handling rechecks/unscheduled included.

Usage

```
clean_lab(lab, ex, included)
```

Arguments

lab	the dataset returned by create_lab
ex	the ex data set.
included	the included data set.

Value

lab data with necessary variables kept for further summarization.

See Also

[create_lab](#) and [create_included](#)

codes	<i>the data set codes.</i>
-------	----------------------------

Description

A dataset containing the lab test code and its corresponding full name

Usage

```
codes
```

Format

a data frame containing all possible LB_TESTC and the corresponding full names.

TESTNUM Maybe the number code?

LB_TESTC the code for laboratory test

TTL the full name

COLWIDE The column width? ...

Source

<https://github.com/statswork/cdashQC/tree/master/data-raw/>

count_percent	<i>add percentage to a frequency table</i>
---------------	--

Description

count to percent

Usage

```
count_percent(data, var1, var2, digit_keep = 3)
```

Arguments

data	the data should contain at least 2 columns
var1	which column should be the group
var2	which columns are used to calculate percentage (could be a vector)
digit_keep	how many digits should be kept.

Value

a data frame

Examples

```

trait = rep(c("A", "B", "C"), 3); subtype = paste(trait, rep(1:3, each=3), sep = "")
data <- data.frame(trait, subtype, count1 = rpois(9, 5), count2 = rpois(9, 10))
count_percent(data, var1= 1, var2 = 3:4)

r1 <- get_summary_stats(eg, group = "PERIOD", var = "EG_TEST")
count_percent(r1, var1 = 1, var2 = 3:5)

```

create_aet	<i>do what createaet does.</i>
------------	--------------------------------

Description

createaet.

Usage

```
create_aet(ae, ex, included, improv = 99)
```

Arguments

ae	the dataset ae read from sas
ex	the dataset ex read from sas
included	the dataset included from sas, can be created using create_included()
improv	the same argument as the sas macro createaet

Value

aet the data

create_baseline	<i>create baseline indicator.</i>
-----------------	-----------------------------------

Description

create an extra column indicating whether the current row should be considered as baseline.

Usage

```
create_baseline(data, var_identifier = "_TEST")
```

Arguments

data	currently support vs, eg and lb_cq.
var_identifier	a string that can be used to identify the variable name e.g.(VS_TEST, EG_TEST, LB_TEST)

Value

a data frame with an extra column status whose value could be one of BASELINE, POSTDOSE and PREDOSE (NOT BASELINE)

See Also[guess_base_phour](#)

create_dem	<i>create the demographics data.</i>
------------	--------------------------------------

Usage

```
create_dem(dm, ex, vs, included)
```

Arguments

dm	the dm data set
ex	the ex data set
vs	the vs data set
included	the included data set created by create_included

Value

a data frame

See Also[create_included](#)

create_eg	<i>create variable columns for the ECGs parameters.</i>
-----------	---

Description

dcast the ecg variables

Usage

```
create_eg(eg)
```

Arguments

eg	the dataset eg read from sas
----	------------------------------

Value

eg1 data with necessary variables kept for further summarization.

create_included	<i>do what new_create_included does.</i>
-----------------	--

Description

create_included.

Usage

```
create_included(ex, dm, cr, ds)
```

Arguments

ex	the dataset ex read from sas
dm	the dataset dm read from sas
cr	the dataset cr read from sas
ds	the dataset ds read from sas

Value

the included data set

create_lab	<i>create the lab test data set.</i>
------------	--------------------------------------

Description

create the lab data

Usage

```
create_lab(lb_cq)
```

Arguments

lb_cq	the dataset lb_cq read from sas
-------	---------------------------------

Value

lab data with necessary variables kept for further summarization.

create_phour	<i>Create protocol hour</i>
--------------	-----------------------------

Description

Create protocol hour variable if it's not already in the data set.

Usage

```
create_phour(data)
```

Arguments

data either eg, vs or lb_cq

Value

the same data set with one more column if Phour is created, otherwise returns the input data.

create_vs	<i>create the vital sign data set.</i>
-----------	--

Description

create the vs data

Usage

```
create_vs(vs)
```

Arguments

vs the dataset dm read from sas

Value

vs data with necessary variables kept for further summarization.

format_time	<i>Format the time variable in a data set</i>
-------------	---

Description

Format the time variable in a data set

Usage

```
format_time(data, date = "AE_STD_T", time = "AE_STT_M")
```

Arguments

data	the data which contains the time variables
date	the date variable
time	the time (in seconds)

Value

the same data set but time has been changed to "hh:mm:ss" format.

get_summary_stats	<i>get summary statistics</i>
-------------------	-------------------------------

Usage

```
get_summary_stats(data, group = "EX_TRT_C", var = "race", na.rm = TRUE)
```

Arguments

data	the data
group	which column should be the group
var	which columns are used to summarize
na.rm	should missing value be removed? TRUE by default.

Value

a data frame

Examples

```
SEQ = rep(c("A", "B", "C"), 3); subtype = sample(c("ONE", "TWO", "THREE"), 9, replace = TRUE)
data <- data.frame(SEQ, subtype, BMI = rnorm(9, 25, 4), HEIGHT = rnorm(9, 175, 3))
get_summary_stats(data, group = "SEQ", var = "subtype")
get_summary_stats(data, group = "SEQ", var = "BMI")
```

guess_base_phour	<i>find the baseline hour for each test</i>
------------------	---

Description

find the baseline hour for each test category

Usage

```
guess_base_phour(data, var_identifier = "_TEST")
```

Arguments

`data` currently support vs, eg and lb_cq.

`var_identifier` a string that can be used to identify the variable name e.g.(VS_TEST, EG_TEST, LB_TEST)

Value

a data frame where by-subject baseline hour is determined.

Examples

```
# the following two will give you exactly the same result
r1 <- guess_base_phour(vs)
r2 <- guess_base_phour(vs, var_identifier = "VS_TEST")

# If you want to find baseline hours for eg, the following two methods are equivalent
r3 <- guess_base_phour(eg)
r4 <- guess_base_phour(eg, var_identifier = "EG_TEST")
```

guess_race_age	<i>race and ethnicity indicator, age.</i>
----------------	---

Description

create necessary variable for the demographic summary tables and listing.

Usage

```
guess_race_age(dm, ex)
```

Arguments

`dm` the dataset dm read from sas

`ex` the dataset ex read from sas

Value

a data frame with additional columns listed as follows

race	the race of the subject
ethnic	has two levels, "NOT HISPANIC OR LATINO" and "HISPANIC OR LATINO".
EX_TRT_C	the treatment groups
ptno	convert CLIENTID to numerical values of subject number
age	Age calculated from start date of treatment

guess_reps	<i>guess the number of replicates</i>
------------	---------------------------------------

Description

guess the number of replicates for each PERIOD/PHOUR/TESTCODE

Usage

```
guess_reps(data, var_identifier = "_TEST")
```

Arguments

data currently support eg and vs
var_identifier,
 which columns is the variable for test code names.

Value

a data frame containing number of reps per PERIOD/PHOUR/TESTCODE

Examples

```
d1 <- guess_reps(eg)
```

guess_test	<i>guess the name of the test</i>
------------	-----------------------------------

Description

guess the name of the test code: it should end with var_identifier.

Usage

```
guess_test(data, var_identifier = "_TEST")
```

Arguments

data currently support eg and vs
var_identifier,
 which columns is the variable for test code names.

Value

the test code

Examples

guess_test(eg)

lab_oor	<i>Find OOR</i>
---------	-----------------

Description

Find the out-of-range values

Usage

lab_oor(lab)

Arguments

lab the data returned by [create_lab](#).

Value

a list containg OOR.

listing_ae	<i>list Adverse Envent</i>
------------	----------------------------

Description

list the ae

Usage

listing_ae(aet, type = 1)

Arguments

aet created by create_aet
type an indicator. Should I list ae1 (type = 1), ae2 (type = 2) or ae3 (type = 3)?

Value

a data frame

See Also

[create_aet](#)

listing_concom	<i>list concomitant.</i>
----------------	--------------------------

Description

list concomitant medication data

Usage

```
listing_concom(cm)
```

Arguments

cm the dataset cm read from sas

Value

the data with related columns

listing_dem	<i>demographics listing.</i>
-------------	------------------------------

Description

Summarize the demographic data

Usage

```
listing_dem(dmt)
```

Arguments

dmt the data set created by create_dem.

Value

a data frame

See Also

[create_included](#) and [create_dem](#)

normal_range	<i>Find normal range for lab test</i>
--------------	---------------------------------------

Description

Find the normal range of each test code

Usage

```
normal_range(lab)
```

Arguments

lab the dataset generated by create_lab

Value

a data frame containing test codes and their corresponding normal range

replicate_average	<i>get the averanges of the replicates for vs or eg data.</i>
-------------------	---

Description

Get the averages of the replicates

Usage

```
replicate_average(data_clean, included, digits = NULL, na_rm = TRUE)
```

Arguments

data_clean an object returned from replicate_clean
 included the included data set created by [create_included](#)
 digits should the averages be rounded? Default NO.
 na_rm should missing values be excluded? Default TRUE.

Value

the averages

See Also

[replicate_clean](#)

Examples

```
eg2 <- replicate_data(eg) # find the triplicates
```

replicate_check	<i>check the replicates and issue a message if there's issue</i>
-----------------	--

Description

check data qualities, reporting missing and RECHECKS

Usage

```
replicate_check(data, reps = NULL, printed = TRUE)
```

Arguments

data	currently support eg and vs
reps	the number of replicates planned. (should be tabled by TESTCODE, PERIOD and PHOUR). If NULL, guess_reps will be invoked to guess the number of replicates.
printed	whether to print the observations having issues at the console.

Value

a data frame containing subject and issues at given period and protocol hours

See Also

guess_reps.

Examples

```
d1 <- replicate_check(eg)
```

replicate_clean	<i>get the cleaned replicates by combining the "clean" data and "dirty" data</i>
-----------------	--

Description

get cleaned replicates

Usage

```
replicate_clean(data, rm_row = NULL)
```

Arguments

data	an object returned from replicate_data (works for vs and eg)
rm_row	a vector of integers specifying which rows should be removed from the dirty data.

Value

the cleaned replicates

See Also

[replicate_data](#)

Examples

```
eg2 <- replicate_data(eg) # step 1: find the triplicates
eg_prob <- eg2$data_dirty # need manual check
# the following rows should be removed
rows_removed <- c(2, 4, 7, 13, 14, 15, 19, 25, 28, 32, 37, 40, 44, 52, 57, 59, 64, 65)
eg3 <- replicate_clean(eg2, rows_removed)
```

replicate_data	<i>get the replicates for eg or vs data.</i>
----------------	--

Description

get the replicates for each protocol hour (PHOUR)

Usage

```
replicate_data(data, reps = NULL)
```

Arguments

data	the data set created by create_eg (for ecg data) or by create_vs (for vital signs data).
reps	specifies the structures of reps. If not specified, guess_resp will be invoked. Default set to be NULL.

Value

a list

data_clean	the subjects containing correct number of resplicates
data_dirty	the subjects that have different number of replicates than desired

See Also

[create_eg](#), [guess_resp](#) and [replicate_check](#)

round_df	<i>round data frame</i>
----------	-------------------------

Description

round a data frame if the column is numerical

Usage

```
round_df(df, digits = 3)
```

Arguments

df	the data frame
digits	how many digits you want to keep

Value

a data frame with numerical columns rounded.

summary_ae_rel	<i>Adverse event by relationship to study drug</i>
----------------	--

Description

summarize adverse events by relationship to study drug

Usage

```
summary_ae_rel(data, group = "STUDYNO", var = "EX_TRT_C", by = "subject")
```

Arguments

data	the data set created by create_aet
group	choose a variable that has all values identical (e.g., "STUDYNO").
var	the treatment variable name, "EX_TRT_C" for example
by	has two options, either "event" or "subject". If by = "subject", that means When a subject experienced the same AE at more than one level of drug relationship during a treatment period, each AE was counted separately

Value

a list	
pt	frequency table by preferred term
total	frequency table by treatment

summary_ae_sev	<i>Adverse event by severity</i>
----------------	----------------------------------

Description

summarize adverse events by severity

Usage

```
summary_ae_sev(data, group = "STUDYNO", var = "EX_TRT_C", by = "subject")
```

Arguments

data	the data set created by create_aet
group	choose a variable that has all values identical (e.g., "STUDYNO").
var	the treatment variable name, "EX_TRT_C" for example
by	has two options, either "event" or "subject". If by = "subject", the subject will be counted under the highest severity level.

Value

a list	
pt	frequency table by preferred term
total	frequency table by treatment

summary_dem	<i>demographic summary.</i>
-------------	-----------------------------

Description

Summarize the demographic data

Usage

```
summary_dem(dmt, group = "EX_TRT_C", na.rm = TRUE)
```

Arguments

dmt	the data set created by create_dem .
group	which variable name would be used to calculate summary statistics?
na.rm	should missing values be included? TRUE by default.

Value

a data frame

See Also

[create_included](#) and [create_dem](#)

Examples

```
included <- create_included(ex, dm, cr, ds)
dmt <- create_dem(dm, ex, vs, included)
summary_dem(dmt, group = "SEQ") # the summary by group
summary_dem(dmt, group = "SPONSOR") # to get the overall summary
```

summary_lab

summary statistics for lab shift.

Description

Summarize the lab statistics

Usage

```
summary_lab(lb_clean, digits = 3)
```

Arguments

lb_clean	the dataset returned by clean_lab.
digits	how many digits should be kept for the final data.

Value

the summary statistics by test code, time point and by treatment.

See Also

[clean_lab](#)

Examples

```
included <- create_included(ex, dm, cr, ds)
lab <- create_lab(lb_cq)
lb_clean <- clean_lab(lab, included= included, ex= ex)
s1 <- summary_lab(clean_lab) #not urinalysis
```

summary_labshift	<i>create the lab shift table.</i>
------------------	------------------------------------

Description

Create the lab shift table.

Usage

```
summary_labshift(lb_clean)
```

Arguments

lb_clean the dataset returned by clean_lab.

Value

the shift table

See Also

[clean_lab](#)

Examples

```
included <- create_included(ex, dm, cr, ds)
lab <- create_lab(lb_cq)
lb_clean <- clean_lab(lab, included, ex)
lbshift <- summary_labshift(lb_clean)
```

summary_teae	<i>teae by number of subjects or by number of events</i>
--------------	--

Description

summarize treatment-emergent adverse event

Usage

```
summary_teae(data, group = "STUDYNO", var = "EX_TRT_C", by = "subject")
```

Arguments

data	the data set created by create_aet
group	choose a variable that has all values identical (e.g., "STUDYNO").
var	the treatment variable name, "EX_TRT_C" for example
by	has two options, either "event" or "subject"

Value

a list

ae frequency table for teae

soc summarization by system organ class and by preferred term

summary_vs_eg	<i>summary statistics</i>
---------------	---------------------------

Description

Summary statistics for vital signs or eg

Usage

```
summary_vs_eg(data_clean, included, inter_digit = NULL, final_digits = 3,
               na_rm = TRUE, ischangefrombase = FALSE)
```

Arguments

data_clean the clean data set returned by [replicate_clean](#).

included the included data set created by [create_included](#)

inter_digit if rounding happens for the intermediate averages, what digits should be kept.

na_rm should missing values be excluded? Default set to be TRUE.

ischangefrombase Is this summary for change from baseline? Default set to be FALSE

final_digit what is the digit for final summary?

Value

a data frame with summary statistics by test, time point and treatment.

weight_height_bmi	<i>read BMI Weight and Height info from Screening stage.</i>
-------------------	--

Description

extract BMI, weight and height from vs.sas7bat.

Usage

```
weight_height_bmi(vs)
```

Arguments

vs the vs sas data

Value

a data frame containing BMI, WEIGHT and HEIGHT from admission stage

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