

Package ‘admiralonco’

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Type Package

Title Oncology Extension Package for ADaM in 'R' Asset Library

Version 1.3.0

Description Programming oncology specific Clinical Data Interchange Standards Consortium (CDISC) compliant 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>>).
The package is an extension package of the 'admiral' package.

Language en-US

License Apache License (>= 2)

BugReports <https://github.com/pharmaverse/admiralonco/issues>

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<https://github.com/pharmaverse/admiralonco>

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admiral_adrs	<i>Response Analysis Dataset</i>
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Description

An example response analysis dataset

Usage

admiral_adrs

Format

An object of class `tbl_df` (inherits from `tbl`, `data.frame`) with 3694 rows and 75 columns.

Source

Derived from the `adsl`, `rs` and `tu` datasets using `{admiral}` (https://github.com/pharmaverse/admiral/blob/main/inst/templates/ad_adrs.R)

aval_resp	<i>Map Character Response Values to Numeric Values</i>
-----------	--

Description

Map character response values like "PR" or "SD" to numeric values.

Usage

```
aval_resp(arg)
```

Arguments

arg	Character vector
-----	------------------

Value

- 1 if arg equals "CR",
- 2 if arg equals "PR",
- 3 if arg equals "SD",
- 4 if arg equals "NON-CR/NON-PD",
- 5 if arg equals "PD",
- 6 if arg equals "NE",
- 7 if arg equals "MISSING",
- NA_real_ otherwise

Author(s)

Stefan Bundfuss

Examples

```
aval_resp(c("CR", "PR", "SD", "NON-CR/NON-PD", "PD", "NE", "MISSING", "ND", NA_character_))
```

death_event

Pre-Defined Time-to-Event Source Objects

Description

These pre-defined `tte_source` objects can be used as input to `admiral::derive_param_tte()`.

Usage

```
death_event
lastalive_censor
pd_event
lasta_censor
rand_censor
trts_censor
```

Details

To see the definition of the various objects simply print the object in the R console, e.g. `print(death_event)`. For details of how to use these objects please refer to [admiral::derive_param_tte\(\)](#).

Printing an object will display input `dataset_name`, filter (if applicable), date variable, and appropriate values for `EVNTDESC`, `CNSDTDSC`, `SRCDOM`, `SRCVAR`, and `SRCSEQ`.

See Also

[admiral::derive_param_tte\(\)](#), [admiral::tte_source\(\)](#), [admiral::event_source\(\)](#), [admiral::censor_source\(\)](#)

Examples

```
# This shows the definition of all pre-defined `tte_source` objects that ship
# with {admiralonco}
for (obj in admiral::list_tte_source_objects(package = "admiralonco")$object) {
  cat(obj, "\n")
  print(get(obj, envir = getNamespace("admiralonco")))
  cat("\n")
}
```

derive_param_bor	Adds a Parameter for Best Overall Response (without confirmation)
------------------	---

Description

[Superseded] The `derive_param_bor()` function has been superseded in favor of `derive_extreme_event()`.

Adds a parameter for best overall response, without confirmation, optionally up to first progressive disease

Usage

```
derive_param_bor(
  dataset,
  dataset_adsl,
  filter_source,
  source_pd = NULL,
  source_datasets = NULL,
  reference_date,
  ref_start_window,
  missing_as_ne = FALSE,
  aval_fun,
  set_values_to,
  subject_keys = get_admiral_option("subject_keys")
)
```

Arguments

dataset	The input dataframe from which the Best Overall Response will be derived from and added to. The columns PARAMCD, ADT, and AVALC and the columns specified in <code>subject_keys</code> and <code>reference_date</code> are expected. After applying <code>filter_source</code> and/or <code>source_pd</code> the column ADT and the columns specified by <code>subject_keys</code> must be a unique key of the dataframe. <i>Permitted Values:</i> a <code>data.frame()</code> object
dataset_adsl	ADSL input dataset. The columns specified in the <code>subject_keys</code> argument are expected. For each subject in the passed dataset a new row is added to the input dataset. Columns in <code>dataset_adsl</code> that also appear in <code>dataset</code> will be populated with the appropriate subject-specific value for these new rows. <i>Permitted Values:</i> a <code>data.frame()</code> object
filter_source	Filter to be applied to dataset to derive the Best Overall Response
source_pd	Date of first progressive disease (PD) If the parameter is specified, the observations of the input dataset for deriving the new parameter are restricted to observations up to the specified date. Observations at the specified date are included. For subjects without first PD date all observations are take into account.

	<i>Permitted Values:</i> a date_source object (see date_source() for details)
source_datasets	Source dataframe to be used to calculate the first PD date A named list of dataframes is expected (although for BOR) only one dataframe is needed. It links the dataset_name from source_pd with an existing dataframe. For example if source_pd = pd_date with <pre>pd_date <- date_source(dataset_name = "adrs", date = ADT, filter = PARAMCD == PD)</pre> and the actual response dataframe in the script is myadrs, source_datasets = list(adrs = myadrs) should be specified.
reference_date	Reference date The reference date is used along with ref_start_window to determine those records that occur before and after ADT (see Details section for further information). Usually it is treatment start date (TRTSDT) or randomization date (RANDDT). <i>Permitted Values:</i> a numeric date column
ref_start_window	Stable disease time window The ref_start_window is used along with reference_date to determine those records that occur before and after ADT (i.e. for a record determine whether ADT >= reference_date + ref_start_window), see Details section for further information. <i>Permitted Values:</i> a non-negative numeric scalar
missing_as_ne	Consider no assessments as "NE"? If the argument is set to TRUE, the response is set to "NE" for subjects in dataset_adsl without an assessment in the dataset after the filter has been applied. Otherwise, the response is set to "MISSING" for these subjects. <i>Permitted Values:</i> a logical scalar
aval_fun	<i>Deprecated</i>, please use set_values_to instead. Function to map character analysis value (AVALC) to numeric analysis value (AVAL) The (first) argument of the function must expect a character vector and the function must return a numeric vector.
set_values_to	New columns to set A named list returned by exprs() defining the columns to be set for the new parameter, e.g. exprs(PARAMCD = "BOR", PARAM = "Best Overall Response") is expected. The values must be symbols, character strings, numeric values, or NA.
subject_keys	Columns to uniquely identify a subject <i>Permitted Values:</i> A list of symbols created using exprs().

Details

Calculates the best overall response (BOR) parameter, as detailed below.

Records after PD can be removed using the `source_pd` and `source_datasets` arguments.

Note:

1. All CR, PR and PD response records are considered for Best Overall Response.
2. All SD or NON-CR/NON-PD records where $ADT \geq reference_date + ref_start_window$ are also considered for Best Overall Response.
3. Subjects with **ONLY** an SD or NON-CR/NON-PD records where $ADT < reference_date + ref_start_window$ are assigned a Best Overall Response of NE.
4. The Best Response, from the records in steps 1 to 3, is then selected in the following order of preference: CR, PR, SD, NON-CR/NON-PD, PD, NE, MISSING
5. The AVAL column is added and set using the `aval_fun(AVALC)` function
6. The columns specified by the `set_values_to` parameter and records are added to the dataframe passed into the `dataset` argument

Note: Any responses of SD or NON-CR/NON-PD that occur before $reference_date + ref_start_window$ are ignored in the calculation of BOR. All other responses are included in the calculation of BOR, irrespective of the number of days from the reference date.

Also Note: All columns from the input dataset are kept. For subjects with no records in the input dataset (after the filter is applied) all columns are kept from ADSL which are also in the input dataset. Columns which are not to be populated for the new parameter or populated differently (e.g. RSSTRESC, VISIT, PARCATy, ANLzzFL, ...) should be overwritten using the `set_values_to` parameter.

Value

The dataframe passed in the `dataset` argument with additional columns and/or rows as set in the `set_values_to` argument.

Author(s)

Stephen Gormley

See Also

Other superseded: [derive_param_clinbenefit\(\)](#), [derive_param_confirmed_bor\(\)](#), [derive_param_confirmed_resp\(\)](#), [derive_param_response\(\)](#), [filter_pd\(\)](#)

Examples

```
library(magrittr)
library(dplyr)
library(tibble)
library(lubridate)
library(admiral)

# Create ADSL dataset
```

```

adsl <- tribble(
  ~USUBJID, ~TRTSDTC,
  "1", "2020-01-01",
  "2", "2019-12-12",
  "3", "2019-11-11",
  "4", "2019-12-30",
  "5", "2020-01-01",
  "6", "2020-02-02",
  "7", "2020-02-02",
  "8", "2020-04-01"
) %>%
  mutate(
    TRTSDT = ymd(TRTSDTC),
    STUDYID = "XX1234"
  )

# Create ADRS dataset
ovr_obs <- tribble(
  ~USUBJID, ~ADTC, ~AVALC, ~ANL01FL,
  "1", "2020-01-01", "PR", "Y",
  "1", "2020-02-01", "CR", "Y",
  "1", "2020-02-16", "NE", "Y",
  "1", "2020-03-01", "CR", "Y",
  "1", "2020-04-01", "SD", "Y",
  "2", "2020-01-01", "SD", "Y",
  "2", "2020-02-01", "PR", "Y",
  "2", "2020-03-01", "SD", "Y",
  "2", "2020-03-13", "CR", "Y",
  "3", "2019-11-12", "CR", "Y",
  "3", "2019-12-02", "CR", "Y",
  "3", "2020-01-01", "SD", "Y",
  "4", "2020-01-01", "PR", "Y",
  "4", "2020-03-01", "SD", "N",
  "4", "2020-04-01", "SD", "Y",
  "4", "2020-05-01", "PR", "Y",
  "4", "2020-05-15", "NON-CR/NON-PD", "Y",
  "5", "2020-01-01", "PR", "Y",
  "5", "2020-01-10", "SD", "Y",
  "5", "2020-01-20", "PR", "Y",
  "5", "2020-05-15", "NON-CR/NON-PD", "Y",
  "6", "2020-02-06", "PR", "Y",
  "6", "2020-02-16", "CR", "Y",
  "6", "2020-03-30", "PR", "Y",
  "6", "2020-04-12", "PD", "Y",
  "6", "2020-05-01", "CR", "Y",
  "6", "2020-06-01", "CR", "Y",
  "7", "2020-02-06", "PR", "Y",
  "7", "2020-02-16", "CR", "Y",
  "7", "2020-04-01", "NE", "N"
) %>%
  mutate(PARAMCD = "OVR")

pd_obs <-

```

```

    bind_rows(tribble(
      ~USUBJID, ~ADTC,      ~AVALC,
      "2",      "2020-03-01", "Y",
      "4",      "2020-02-01", "Y"
    ) %>%
      mutate(PARAMCD = "PD"))

adrs <- bind_rows(ovr_obs, pd_obs) %>%
  mutate(
    ADT = ymd(ADTC),
    STUDYID = "XX1234"
  ) %>%
  select(-ADTC) %>%
  derive_vars_merged(
    dataset_add = adsl,
    by_vars     = exprs(STUDYID, USUBJID),
    new_vars    = exprs(TRTSDT)
  )

pd_date <- date_source(
  dataset_name = "adrs",
  date         = ADT,
  filter       = PARAMCD == "PD"
)

aval_fun_pass <- function(arg) {
  case_when(
    arg == "CR" ~ 11,
    arg == "PR" ~ 22,
    arg == "SD" ~ 33,
    arg == "NON-CR/NON-PD" ~ 44,
    arg == "PD" ~ 55,
    arg == "NE" ~ 66,
    arg == "MISSING" ~ 77,
    TRUE ~ NA_real_
  )
}

# Derive best overall response parameter
derive_param_bor(
  adrs,
  dataset_adsl = adsl,
  filter_source = PARAMCD == "OVR" & ANL01FL == "Y",
  source_pd = pd_date,
  source_datasets = list(adrs = adrs),
  aval_fun = aval_fun_pass,
  reference_date = TRTSDT,
  ref_start_window = 28,
  set_values_to = exprs(
    PARAMCD = "BOR",
    PARAM = "Best Overall Response"
  )
) %>%

```

```
filter(PARAMCD == "BOR")
```

```
derive_param_clinbenefit
```

Adds a Parameter for Clinical Benefit

Description

[Superseded] The `derive_param_clinbenefit()` function has been superseded in favor of `derive_extreme_event()`.

Adds a parameter for clinical benefit/disease control

Usage

```
derive_param_clinbenefit(
  dataset,
  dataset_adsl,
  filter_source,
  source_resp,
  source_pd = NULL,
  source_datasets,
  reference_date,
  ref_start_window,
  aval_fun,
  clinben_vals = c("CR", "PR", "SD", "NON-CR/NON-PD"),
  set_values_to,
  subject_keys = get_admiral_option("subject_keys")
)
```

Arguments

dataset	Input dataset. This is the dataset to which the clinical benefit rate parameter will be added. The variables PARAMCD, AVALC, ADT, and those specified by the <code>subject_keys</code> parameter and the <code>reference_date</code> parameter are expected. After applying <code>filter_source</code> and/or <code>source_pd</code> the variable ADT and the variables specified by <code>subject_keys</code> must be a unique key of the dataset.
dataset_adsl	ADSL input dataset. The variables specified for <code>subject_keys</code> is expected. For each subject of the specified dataset a new observation is added to the input dataset. Variables in <code>dataset_adsl</code> that also appear in <code>dataset</code> will be populated with the appropriate subject-specific value for these new observations.
filter_source	Filter condition in dataset that represents records for overall disease response assessment for a subject at a given timepoint, e.g. <code>PARAMCD == "OVR"</code> or <code>PARAMCD == "OVRRESP"</code>.
source_resp	A <code>date_source</code> object specifying the dataset, date variable, and filter condition used to identify response status.

source_pd	A date_source object specifying the dataset, date variable, and filter condition used to identify disease progression.
source_datasets	A named list of data sets is expected. The list must contain the names provided by the dataset_name field of the date_source() objects specified for source_pd and source_resp.
reference_date	Name of variable representing the index date for ref_start_window. A variable providing a date. An unquoted symbol is expected.
ref_start_window	Integer representing number of days from reference_date that must elapse before an evaluable non-PD assessment counts toward determining clinical benefit.
aval_fun	<i>Deprecated</i> , please use set_values_to instead. Function to map character analysis value (AVALC) to numeric analysis value (AVAL) The (first) argument of the function must expect a character vector and the function must return a numeric vector.
clinben_vals	A vector of response values to be considered when determining clinical benefit.
set_values_to	A named list returned by exprs() containing new variables and their static value to be populated for the clinical benefit rate parameter records, e.g. exprs(PARAMCD = "CBR", PARAM = "Clinical Benefit Rate").
subject_keys	A named list returned by exprs() containing variables used to uniquely identify subjects.

Details

Clinical benefit/disease control is first identified by looking for subjects having response status, and then derived for subjects that have at least one evaluable non-PD response assessment prior to first PD (Progressive Disease) (i.e., responses inclusive of CR, PR, SD, and NON-CR/NON-PD) and after a specified amount of time from a reference date (ref_start_window).

Note: The user input values they wish to include when determining clinical benefit using the argument clinben_vals. The default values for this are CR, PR, SD, and NON-CR/NON-PD, as listed above. In the below example, eligible values be limited to CR and PR.

Example: `clinben_vals <- c("CR", "PR")`

1. The input dataset (dataset) is restricted to the observations matching filter_source and to observations before or at the date specified by source_pd.
2. This dataset is further restricted to include user-generated response assessments from clinben_vals or include response assessments of CR, PR, SD, and NON-CR/NON-PD, exclude missing response assessments, and exclude those less than ref_start_window after reference_date. The earliest assessment by ADT is then selected.
3. The dataset identified by dataset in source_resp is restricted according to its filter argument. The variable corresponding to the date parameter of source_resp is considered together with ADT from the previous step.
4. For the observations being added to dataset, ADT is set to the earlier of the first assessment date representing an evaluable non-PD assessment prior to first PD, or the date representing the start of response.

5. For the observations being added to dataset, AVALC is set to
 - Y for those subjects in the dataset meeting the criteria for clinical benefit above
 - N for subjects not meeting the clinical benefit criteria in dataset or the dataset identified in source_resp
 - N for subjects present in dataset_adsl but not present in dataset or the dataset identified in source_resp.
6. AVAL is derived using AVALC as input to the function specified in aval_fun.
7. The variables specified by set_values_to are added to the new observations with values equal to the values specified in the same.
8. The new observations are added to dataset. Variables held in common between dataset and dataset_adsl are kept for the new observations, and are populated with their values from dataset_adsl.

Value

The input dataset with a new parameter for clinical benefit

Author(s)

Andrew Smith

See Also

Other superseded: [derive_param_bor\(\)](#), [derive_param_confirmed_bor\(\)](#), [derive_param_confirmed_resp\(\)](#), [derive_param_response\(\)](#), [filter_pd\(\)](#)

Examples

```
library(lubridate)
library(dplyr)
library(admiral)

adsl <- tibble::tribble(
  ~USUBJID, ~TRTSDT,
  "01",     ymd("2020-01-14"),
  "02",     ymd("2021-02-16"),
  "03",     ymd("2021-03-09"),
  "04",     ymd("2021-04-21")
) %>%
  mutate(STUDYID = "AB42")

adrs <- tibble::tribble(
  ~USUBJID, ~PARAMCD, ~AVALC, ~ADT,
  "01",     "RSP",     "Y",     ymd("2021-03-14"),
  "02",     "RSP",     "N",     ymd("2021-05-07"),
  "03",     "RSP",     "N",     NA,
  "04",     "RSP",     "N",     NA,
  "01",     "PD",      "N",     NA,
  "02",     "PD",      "Y",     ymd("2021-05-07"),
  "03",     "PD",      "N",     NA,
```

```

      "04",      "PD",      "N",      NA,
      "01",      "OVR",     "SD",     ymd("2020-03-14"),
      "01",      "OVR",     "PR",     ymd("2021-04-13"),
      "02",      "OVR",     "PR",     ymd("2021-04-08"),
      "02",      "OVR",     "PD",     ymd("2021-05-07"),
      "02",      "OVR",     "CR",     ymd("2021-06-20"),
      "03",      "OVR",     "SD",     ymd("2021-03-30"),
      "04",      "OVR",     "NE",     ymd("2021-05-21"),
      "04",      "OVR",     "NA",     ymd("2021-06-30"),
      "04",      "OVR",     "NE",     ymd("2021-07-24"),
      "04",      "OVR",     "ND",     ymd("2021-09-04"),
    ) %>%
    mutate(STUDYID = "AB42", ANL01FL = "Y") %>%
    derive_vars_merged(
      dataset_add = adsl,
      by_vars = exprs(STUDYID, USUBJID),
      new_vars = exprs(TRTSDT)
    )

pd <- date_source(
  dataset_name = "adrs",
  date = ADT,
  filter = PARAMCD == "PD" & AVALC == "Y" & ANL01FL == "Y"
)

resp <- date_source(
  dataset_name = "adrs",
  date = ADT,
  filter = PARAMCD == "RSP" & AVALC == "Y" & ANL01FL == "Y"
)

derive_param_clinbenefit(
  dataset = adrs,
  dataset_adsl = adsl,
  filter_source = PARAMCD == "OVR" & ANL01FL == "Y",
  source_resp = resp,
  source_pd = pd,
  source_datasets = list(adrs = adrs),
  reference_date = TRTSDT,
  ref_start_window = 28,
  set_values_to = exprs(
    PARAMCD = "CBR"
  )
) %>%
  filter(PARAMCD == "CBR")

```

derive_param_confirmed_bor

Adds a Parameter for Confirmed Best Overall Response

Description

[Superseded] The `derive_param_confirmed_bor()` function has been superseded in favor of `derive_extreme_event()`.

Adds a parameter for confirmed best overall response (BOR)

Usage

```
derive_param_confirmed_bor(
  dataset,
  dataset_adsl,
  filter_source,
  source_pd = NULL,
  source_datasets = NULL,
  reference_date,
  ref_start_window,
  ref_confirm,
  max_nr_ne = 1,
  accept_sd = FALSE,
  missing_as_ne = FALSE,
  aval_fun,
  set_values_to,
  subject_keys = get_admiral_option("subject_keys")
)
```

Arguments

dataset	Input dataset The PARAMCD, ADT, and AVALC variables and the variables specified by <code>subject_keys</code> and <code>reference_date</code> are expected. After applying <code>filter_source</code> and/or <code>source_pd</code> the variable ADT and the variables specified by <code>subject_keys</code> must be a unique key of the dataset.
dataset_adsl	ADSL input dataset The variables specified for <code>subject_keys</code> are expected. For each subject of the specified dataset a new observation is added to the input dataset.
filter_source	Source filter All observations in <code>dataset_source</code> fulfilling the specified condition are considered for deriving the confirmed best overall response.
source_pd	Date of first progressive disease (PD) If the parameter is specified, the observations of the input dataset for deriving the new parameter are restricted to observations up to the specified date. Observations at the specified date are included. For subjects without first PD date all observations are take into account. <i>Permitted Values:</i> a <code>date_source</code> object (see <code>admiral::date_source()</code> for details)
source_datasets	Source dataset for the first PD date

A named list of datasets is expected. It links the dataset_name from source_pd with an existing dataset.

For example if source_pd = pd_date with

```
pd_date <- date_source(
  dataset_name = "adrs",
  date = ADT,
  filter = PARAMCD == PD
)
```

and the actual response dataset in the script is myadrs, source_datasets = list(adrs = myadrs) should be specified.

reference_date Reference date

The reference date is used for the derivation of "SD" and "NON-CR/NON-PD" response (see "Details" section). Usually it is treatment start date (TRTSDT) or randomization date (RANDDT).

Permitted Values: a numeric date variable

ref_start_window

Stable disease time window

Assessments at least the specified number of days after the reference date (i.e. where $ADT \geq \text{reference_date} + \text{ref_start_window}$) with response "CR", "PR", "SD", or "NON-CR/NON-PD" are considered for "SD" or "NON-CR/NON-PD" response.

Permitted Values: a non-negative numeric scalar

ref_confirm Minimum time period for confirmation

The assessment and the confirmatory assessment for "CR" and "PR" have to be at least the specified number of days apart.

max_nr_ne

The specified number of "NE" assessments between the assessment and the confirmatory assessment for "CR" and "PR" response is accepted.

Permitted Values: a non-negative numeric scalar

accept_sd

Accept "SD" for "PR"?

If the argument is set to TRUE, one "SD" assessment between the assessment and the confirmatory assessment for "PR" response is accepted. Otherwise, no "SD" assessment must occur between the two assessments.

Permitted Values: a logical scalar

missing_as_ne Consider no assessments as "NE"?

If the argument is set to TRUE, the response is set to "NE" for subjects without an assessment in the input dataset. Otherwise, the response is set to "MISSING" for these subjects.

Permitted Values: a logical scalar

aval_fun

Deprecated, please use set_values_to instead.

Function to map character analysis value (AVALC) to numeric analysis value (AVAL)

The (first) argument of the function must expect a character vector and the function must return a numeric vector.

set_values_to	Variables to set A named list returned by <code>exprs()</code> defining the variables to be set for the new parameter, e.g. <code>exprs(PARAMCD = "CBOR", PARAM = "Confirmed Best Overall Response")</code> is expected. The values must be symbols, character strings, numeric values, or NA.
subject_keys	Variables to uniquely identify a subject A list of symbols created using <code>exprs()</code> is expected.

Details

1. The input dataset (`dataset`) is restricted to the observations matching `filter_source` and to observations before or at the date specified by `source_pd`.
2. The following potential confirmed responses are selected from the restricted input dataset:
 - "CR": An assessment is considered as complete response (CR) if
 - `AVALC == "CR"`,
 - there is a confirmatory assessment with `AVALC == "CR"` at least `ref_confirm` days after the assessment,
 - all assessments between the assessment and the confirmatory assessment are "CR" or "NE", and
 - there are at most `max_nr_ne` "NE" assessments between the assessment and the confirmatory assessment.
 - "PR": An assessment is considered as partial response (PR) if
 - `AVALC == "PR"`,
 - there is a confirmatory assessment with `AVALC %in% c("CR", "PR")` at least `ref_confirm` days after the assessment,
 - all assessments between the assessment and the confirmatory assessment are "CR", "PR", "SD", or "NE",
 - there is no "PR" assessment after a "CR" assessment in the confirmation period,
 - there are at most `max_nr_ne` "NE" assessments between the assessment and the confirmatory assessment, and
 - if the `accept_sd` argument is set to TRUE, one "SD" assessment in the confirmation period is accepted. Otherwise, no "SD" assessment must occur within the confirmation period.
 - "SD": An assessment is considered as stable disease (SD) if
 - `AVALC %in% c("CR", "PR", "SD")` and
 - the assessment is at least `ref_start_window` days after `reference_date`.
 - "NON-CR/NON-PD": An assessment is considered as NON-CR/NON-PD if
 - `AVALC = "NON-CR/NON-PD"` and
 - the assessment is at least `ref_start_window` days after `reference_date`.
 - "PD": An assessment is considered as progressive disease (PD) if `AVALC == "PD"`.
 - "NE": An assessment is considered as not estimable (NE) if
 - `AVALC == "NE"` or
 - `AVALC %in% c("CR", "PR", "SD", "NON-CR/NON-PD")` and the assessment is less than `ref_start_window` days after `reference_date`.

- "ND": An assessment is considered as not done (ND) if AVALC == "ND".
 - "MISSING": An assessment is considered as missing (MISSING) if a subject has no observation in the input dataset.
If the missing_as_ne argument is set to TRUE, AVALC is set to "NE" for these subjects.
3. For each subject the best response as derived in the previous step is selected, where "CR" is best and "MISSING" is worst in the order above. If the best response is not unique, the first one (with respect to ADT) is selected. If the selected record is from the input dataset, all variables are kept. If the selected record is from dataset_ads1, all variables which are in both dataset and dataset_ads1 are kept.
 4. The AVAL variable is added and set to aval_fun(AVALC).
 5. The variables specified by the set_values_to parameter are added to the new observations.
 6. The new observations are added to input dataset.

Value

The input dataset with a new parameter for confirmed best overall response

Author(s)

Stefan Bundfuss

See Also

Other superseded: [derive_param_bor\(\)](#), [derive_param_clinbenefit\(\)](#), [derive_param_confirmed_resp\(\)](#), [derive_param_response\(\)](#), [filter_pd\(\)](#)

Examples

```
library(dplyr)
library(lubridate)
library(admiral)

# Create ADSL dataset
adsl <- tibble::tribble(
  ~USUBJID, ~TRTSDTC,
  "1",      "2020-01-01",
  "2",      "2019-12-12",
  "3",      "2019-11-11",
  "4",      "2019-12-30",
  "5",      "2020-01-01",
  "6",      "2020-02-02",
  "7",      "2020-02-02",
  "8",      "2020-04-01",
  "9",      "2020-03-01"
) %>%
  mutate(
    TRTSDT = ymd(TRTSDTC),
    STUDYID = "XX1234"
  )
```

```

# Create ADRS dataset
ovr_obs <- tibble::tribble(
  ~USUBJID, ~ADTC,      ~AVALC,
  "1",      "2020-01-01", "PR",
  "1",      "2020-02-01", "CR",
  "1",      "2020-02-16", "NE",
  "1",      "2020-03-01", "CR",
  "1",      "2020-04-01", "SD",
  "2",      "2020-01-01", "SD",
  "2",      "2020-02-01", "PR",
  "2",      "2020-03-01", "SD",
  "2",      "2020-03-13", "CR",
  "3",      "2019-11-12", "CR",
  "3",      "2019-12-02", "CR",
  "3",      "2020-01-01", "SD",
  "4",      "2020-01-01", "PR",
  "4",      "2020-03-01", "SD",
  "4",      "2020-04-01", "SD",
  "4",      "2020-05-01", "PR",
  "4",      "2020-05-15", "NON-CR/NON-PD",
  "5",      "2020-01-01", "PR",
  "5",      "2020-01-10", "SD",
  "5",      "2020-01-20", "PR",
  "5",      "2020-05-15", "NON-CR/NON-PD",
  "6",      "2020-02-06", "PR",
  "6",      "2020-02-16", "CR",
  "6",      "2020-03-30", "PR",
  "6",      "2020-04-12", "PD",
  "6",      "2020-05-01", "CR",
  "6",      "2020-06-01", "CR",
  "7",      "2020-02-06", "PR",
  "7",      "2020-02-16", "CR",
  "7",      "2020-04-01", "NE",
  "9",      "2020-03-16", "CR",
  "9",      "2020-04-01", "NE",
  "9",      "2020-04-16", "NE",
  "9",      "2020-05-01", "CR"
) %>%
  mutate(PARAMCD = "OVR", ANL01FL = "Y")

pd_obs <-
  bind_rows(tibble::tribble(
    ~USUBJID, ~ADTC,      ~AVALC,
    "6",      "2020-04-12", "Y"
  ) %>%
    mutate(PARAMCD = "PD", ANL01FL = "Y"))

adrs <- bind_rows(ovr_obs, pd_obs) %>%
  mutate(
    ADT = ymd(ADTC),
    STUDYID = "XX1234"
  ) %>%
  select(-ADTC) %>%

```

```

    derive_vars_merged(
      dataset_add = adsl,
      by_vars = exprs(STUDYID, USUBJID),
      new_vars = exprs(TRTSDT)
    )

pd_date <- date_source(
  dataset_name = "adrs",
  date = ADT,
  filter = PARAMCD == "PD" & ANL01FL == "Y"
)

# Derive confirmed best overall response parameter
derive_param_confirmed_bor(
  adrs,
  dataset_adsl = adsl,
  filter_source = PARAMCD == "OVR" & ANL01FL == "Y",
  source_pd = pd_date,
  source_datasets = list(adrs = adrs),
  reference_date = TRTSDT,
  ref_start_window = 28,
  ref_confirm = 28,
  set_values_to = exprs(
    PARAMCD = "CBOR",
    PARAM = "Best Confirmed Overall Response by Investigator"
  )
) %>%
  filter(PARAMCD == "CBOR")

# Derive confirmed best overall response parameter (accepting SD for PR,
# accept two NEs, and considering missings as NE)
derive_param_confirmed_bor(
  adrs,
  dataset_adsl = adsl,
  filter_source = PARAMCD == "OVR" & ANL01FL == "Y",
  source_pd = pd_date,
  source_datasets = list(adrs = adrs),
  reference_date = TRTSDT,
  ref_start_window = 28,
  ref_confirm = 28,
  max_nr_ne = 2,
  accept_sd = TRUE,
  missing_as_ne = TRUE,
  set_values_to = exprs(
    PARAMCD = "CBOR",
    PARAM = "Best Confirmed Overall Response by Investigator"
  )
) %>%
  filter(PARAMCD == "CBOR")

```

derive_param_confirmed_resp

Adds a Parameter for Confirmed Response

Description

[Superseded] The `derive_param_confirmed_resp()` function has been superseded in favor of `derive_extreme_event()`.

Adds a parameter for confirmed response

Usage

```
derive_param_confirmed_resp(
  dataset,
  dataset_adsl,
  filter_source,
  source_pd = NULL,
  source_datasets = NULL,
  ref_confirm,
  max_nr_ne = 1,
  accept_sd = FALSE,
  aval_fun,
  set_values_to,
  subject_keys = get_admiral_option("subject_keys")
)
```

Arguments

dataset	Input dataset The PARAMCD, ADT, and AVALC variables and the variables specified by <code>subject_keys</code> and <code>reference_date</code> are expected. After applying <code>filter_source</code> and/or <code>source_pd</code> the variable ADT and the variables specified by <code>subject_keys</code> must be a unique key of the dataset.
dataset_adsl	ADSL input dataset The variables specified for <code>subject_keys</code> are expected. For each subject of the specified dataset a new observation is added to the input dataset.
filter_source	Source filter All observations in <code>dataset_source</code> fulfilling the specified condition are considered for deriving the confirmed response.
source_pd	Date of first progressive disease (PD) If the parameter is specified, the observations of the input dataset for deriving the new parameter are restricted to observations up to the specified date. Observations at the specified date are included. For subjects without first PD date all observations are take into account. <i>Permitted Values:</i> a <code>date_source</code> object (see <code>admiral::date_source()</code> for details)

source_datasets	Source dataset for the first PD date A named list of datasets is expected. It links the dataset_name from source_pd with an existing dataset. For example if source_pd = pd_date with <pre>pd_date <- date_source(dataset_name = "adrs", date = ADT, filter = PARAMCD == PD)</pre> and the actual response dataset in the script is myadrs, source_datasets = list(adrs = myadrs) should be specified.
ref_confirm	Minimum time period for confirmation The assessment and the confirmatory assessment for "CR" and "PR" have to be at least the specified number of days apart.
max_nr_ne	The specified number of "NE" assessments between the assessment and the confirmatory assessment for "CR" and "PR" response is accepted. <i>Permitted Values:</i> a non-negative numeric scalar
accept_sd	Accept "SD" for "PR"? If the argument is set to TRUE, one "SD" assessment between the assessment and the confirmatory assessment for "PR" response is accepted. Otherwise, no "SD" assessment must occur between the two assessments. <i>Permitted Values:</i> a logical scalar
aval_fun	<i>Deprecated</i>, please use set_values_to instead. Function to map character analysis value (AVALC) to numeric analysis value (AVAL) The (first) argument of the function must expect a character vector and the function must return a numeric vector.
set_values_to	Variables to set A named list returned by exprs() defining the variables to be set for the new parameter, e.g. exprs(PARAMCD = "CRSP", PARAM = "Confirmed Response") is expected. The values must be symbols, character strings, numeric values, or NA.
subject_keys	Variables to uniquely identify a subject A list of symbols created using exprs() is expected.

Details

1. The input dataset (dataset) is restricted to the observations matching filter_source and to observations before or at the date specified by source_pd.
2. A subject is considered as responder if there is at least one observation in the restricted dataset with
 - AVALC == "CR",

- there is a confirmatory assessment with AVALC == "CR" at least ref_confirm days after the assessment,
- all assessments between the assessment and the confirmatory assessment are "CR" or "NE", and
- there are at most max_nr_ne "NE" assessments between the assessment and the confirmatory assessment.

or at least one observation with

- AVALC == "PR",
 - there is a confirmatory assessment with AVALC %in% c("CR", "PR") at least ref_confirm days after the assessment,
 - all assessments between the assessment and the confirmatory assessment are "CR", "PR", "SD", or "NE",
 - there is no "PR" assessment after a "CR" assessment in the confirmation period,
 - there are at most max_nr_ne "NE" assessments between the assessment and the confirmatory assessment,
 - if the accept_sd argument is set to TRUE, one "SD" assessment in the confirmation period is accepted. Otherwise, no "SD" assessment must occur within the confirmation period.
3. For responders AVALC is set to "Y" and ADT to the first date where the response criteria are fulfilled. For all other subjects in dataset_adsl AVALC is set to "N" and ADT to NA.
 4. The AVAL variable is added and set to aval_fun(AVALC).
 5. The variables specified by the set_values_to parameter are added to the new observations.
 6. The new observations are added to input dataset.

Value

The input dataset with a new parameter for confirmed response

Author(s)

Stefan Bundfuss

See Also

Other superseded: [derive_param_bor\(\)](#), [derive_param_clinbenefit\(\)](#), [derive_param_confirmed_bor\(\)](#), [derive_param_response\(\)](#), [filter_pd\(\)](#)

Examples

```
library(dplyr)
library(admiral)

# Create ADSL dataset
adsl <- tibble::tribble(
  ~USUBJID, ~TRTSDTC,
  "1",      "2020-01-01",
  "2",      "2019-12-12",
  "3",      "2019-11-11",
```

```

      "4",      "2019-12-30",
      "5",      "2020-01-01",
      "6",      "2020-02-02",
      "7",      "2020-02-02",
      "8",      "2020-04-01",
      "9",      "2020-03-01"
    ) %>%
      mutate(
        STUDYID = "XX1234"
      )

# Create ADRS dataset
ovr_obs <- tibble::tribble(
  ~USUBJID, ~ADTC,      ~AVALC,
  "1",      "2020-01-01", "PR",
  "1",      "2020-02-01", "CR",
  "1",      "2020-02-16", "NE",
  "1",      "2020-03-01", "CR",
  "1",      "2020-04-01", "SD",
  "2",      "2020-01-01", "SD",
  "2",      "2020-02-01", "PR",
  "2",      "2020-03-01", "SD",
  "2",      "2020-03-13", "CR",
  "3",      "2019-11-12", "CR",
  "3",      "2019-12-02", "CR",
  "3",      "2020-01-01", "SD",
  "4",      "2020-01-01", "PR",
  "4",      "2020-03-01", "SD",
  "4",      "2020-04-01", "SD",
  "4",      "2020-05-01", "PR",
  "4",      "2020-05-15", "NON-CR/NON-PD",
  "5",      "2020-01-01", "PR",
  "5",      "2020-01-10", "SD",
  "5",      "2020-01-20", "PR",
  "5",      "2020-05-15", "NON-CR/NON-PD",
  "6",      "2020-02-06", "PR",
  "6",      "2020-02-16", "CR",
  "6",      "2020-03-30", "PR",
  "6",      "2020-04-12", "PD",
  "6",      "2020-05-01", "CR",
  "6",      "2020-06-01", "CR",
  "7",      "2020-02-06", "PR",
  "7",      "2020-02-16", "CR",
  "7",      "2020-04-01", "NE",
  "9",      "2020-03-16", "CR",
  "9",      "2020-04-01", "NE",
  "9",      "2020-04-16", "NE",
  "9",      "2020-05-01", "CR"
) %>%
  mutate(PARAMCD = "OVR", ANL01FL = "Y")

pd_obs <-
  bind_rows(tibble::tribble(

```

```

      ~USUBJID, ~ADTC,      ~AVALC,
      "6",      "2020-04-12", "Y"
    ) %>%
      mutate(PARAMCD = "PD", ANL01FL = "Y"))

adrs <- bind_rows(ovr_obs, pd_obs) %>%
  mutate(
    ADT = lubridate::ymd(ADTC),
    STUDYID = "XX1234"
  ) %>%
  select(-ADTC)

pd_date <- date_source(
  dataset_name = "adrs",
  date = ADT,
  filter = PARAMCD == "PD" & ANL01FL == "Y"
)

# Derive confirmed response parameter
derive_param_confirmed_resp(
  adrs,
  dataset_adsl = adsl,
  filter_source = PARAMCD == "OVR" & ANL01FL == "Y",
  source_pd = pd_date,
  source_datasets = list(adrs = adrs),
  ref_confirm = 28,
  set_values_to = exprs(
    PARAMCD = "CRSP",
    PARAM = "Confirmed Response by Investigator"
  )
) %>%
  filter(PARAMCD == "CRSP")

# Derive confirmed response parameter (accepting SD for PR and two NEs)
derive_param_confirmed_resp(
  adrs,
  dataset_adsl = adsl,
  filter_source = PARAMCD == "OVR" & ANL01FL == "Y",
  source_pd = pd_date,
  source_datasets = list(adrs = adrs),
  ref_confirm = 28,
  max_nr_ne = 2,
  accept_sd = TRUE,
  set_values_to = exprs(
    PARAMCD = "CRSP",
    PARAM = "Confirmed Response by Investigator"
  )
) %>%
  filter(PARAMCD == "CRSP")

```

derive_param_response *Adds a Parameter Indicating If a Subject Had a Response before Progressive Disease*

Description

[Superseded] The `derive_param_response()` function has been superseded in favor of `derive_extreme_event()`.

Adds a parameter indicating if a response has been observed. If a response has been observed, AVALC is set to "Y", AVAL to 1 and ADT is set to the first date when a response has been observed. If a response has not been observed, AVALC is set to "N", AVAL to 0 and ADT is set NA.

Usage

```
derive_param_response(
  dataset,
  dataset_adsl,
  filter_source,
  source_pd = NULL,
  source_datasets = NULL,
  set_values_to,
  aval_fun,
  subject_keys = get_admiral_option("subject_keys")
)
```

Arguments

dataset	Input dataset The variables specified by the <code>subject_keys</code> and ADT are expected. After applying <code>filter_source</code> and/or <code>source_pd</code> the variable ADT and the variables specified by <code>subject_keys</code> must be a unique key of the dataset.
dataset_adsl	Input dataset • The variables specified for <code>subject_keys</code> are expected. • For each observation of the specified dataset a new observation is added to the input dataset. This is to capture those patients that may never have had a tumor assessment.
filter_source	Source filter All observations in the dataset data fulfilling the specified condition are selected.
source_pd	Sources and conditions defining the end of the assessment period for the responses. An object of type <code>date_source</code> is expected All observations in <code>dataset</code> defining the response data fulfilling the <code>filter_source</code> condition are considered as response if they fall before the end of the assessment period as defined by <code>source_pd</code>.

- For subjects with at least one response before the end of the assessment period, AVALC is set to "Y", AVAL to 1, and ADT to the first date when the response occurred.
- For all other subjects AVALC is set to "N", AVAL to 0, and ADT to NA.

source_datasets

Source dataset

A named list of datasets with one element is expected (e.g. `list(adrs= adrs)`). The name must match the `dataset_name` field of the `admiral::date_source()` object specified for `source_pd`.

The variables specified by the `subject_keys` argument and the date field of the `admiral::date_source()` object are expected in the dataset.

set_values_to

Variables to set

A named list returned by `exprs()` defining the variables to be set for the new parameter, e.g. `exprs(PARAMCD = "RSP", PARAM = "Response by investigator")` is expected.

The values must be symbols, character strings, numeric values or NA.

aval_fun

Deprecated, please use `set_values_to` instead.

Function to map character analysis value (AVALC) to numeric analysis value (AVAL)

The (first) argument of the function must expect a character vector and the function must return a numeric vector.

subject_keys

Variables to uniquely identify a subject

A list of symbols created using `exprs()` is expected.

Details

1. The Date of the end of the assessment period (e.g. Progressive disease, as defined by `pd_source`) is added to the response dataset.
2. The response dataset is restricted to observations occurring before **or on** the date of progressive disease.
3. For each subject (with respect to the variables specified for the `subject_keys` parameter), the first observation (with respect to ADT) where the response condition (`filter_source` parameter) is fulfilled is selected.
4. For each observation in `dataset_ads1` a new observation is created.
 - For subjects with a response AVALC is set to "Y", AVAL to 1, and ADT to the first date (ADT) where the response condition is fulfilled.
 - For all other subjects AVALC is set to "N", AVAL to 0 and ADT to NA.
5. The variables specified by the `set_values_to` parameter are added to the new observations.
6. The new observations are added to input dataset.

Value

The input dataset with a new parameter indicating if and when a response occurred

Author(s)

Samia Kabi

See Also

Other superseded: [derive_param_bor\(\)](#), [derive_param_clinbenefit\(\)](#), [derive_param_confirmed_bor\(\)](#), [derive_param_confirmed_resp\(\)](#), [filter_pd\(\)](#)

Examples

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

adsl <- tribble(
  ~USUBJID,
  "1",
  "2",
  "3",
  "4"
) %>%
  mutate(STUDYID = "XX1234")

adrs <- tribble(
  ~USUBJID, ~PARAMCD, ~ADTC, ~AVALC, ~ANL01FL,
  "1", "OVR", "2020-01-02", "PR", "Y",
  "1", "OVR", "2020-02-01", "CR", "Y",
  "1", "OVR", "2020-03-01", "CR", "Y",
  "1", "OVR", "2020-04-01", "SD", "Y",
  "1", "PD", NA_character_, "N", "Y",
  "2", "OVR", "2021-06-15", "SD", "Y",
  "2", "OVR", "2021-07-16", "PD", "Y",
  "2", "OVR", "2021-09-14", "PD", "Y",
  "2", "PD", "2021-09-14", "Y", "Y",
  "3", "OVR", "2021-09-14", "SD", "Y",
  "3", "OVR", "2021-10-30", "PD", "Y",
  "3", "OVR", "2021-12-25", "CR", "Y",
  "3", "PD", "2021-10-30", "Y", "Y"
) %>%
  mutate(
    STUDYID = "XX1234",
    ADT = ymd(ADTC),
    ANL01FL = "Y"
  ) %>%
  select(-ADTC)

# Define the end of the assessment period for responses:
# all responses before or on the first PD will be used.
pd <- date_source(
  dataset_name = "adrs",
  date = ADT,
```

```

    filter = PARAMCD == "PD" & AVALC == "Y"
  )
  # Derive the response parameter
  derive_param_response(
    dataset = adrs,
    dataset_adsl = adsl,
    filter_source = PARAMCD == "OVR" & AVALC %in% c("CR", "PR") & ANL01FL == "Y",
    source_pd = pd,
    source_datasets = list(adrs = adrs),
    set_values_to = exprs(
      AVAL = yn_to_numeric(AVALC),
      PARAMCD = "RSP",
      PARAM = "Response by investigator"
    ),
    subject_keys = get_admiral_option("subject_keys")
  ) %>%
  arrange(USUBJID, PARAMCD, ADT)

```

filter_pd

Filter up to First PD (Progressive Disease) Date

Description

[Superseded] The `filter_pd()` function has been superseded in favor of `filter_relative()`.

Filter a dataset to only include the source parameter records up to and including the first PD (progressive disease). These records are passed to downstream derivations regarding responses such as BOR (best overall response).

Usage

```

filter_pd(
  dataset,
  filter,
  source_pd,
  source_datasets,
  subject_keys = get_admiral_option("subject_keys")
)

```

Arguments

dataset	Input dataset The variables ADT and those specified by <code>subject_keys</code> are expected.
filter	Filter condition for restricting the input dataset
source_pd	A <code>admiral::date_source()</code> object providing the date of first PD For each subject the first date (date field) in the provided dataset (<code>dataset_name</code> field) restricted by <code>filter</code> field is considered as first PD date.

source_datasets	A named list of data sets is expected. The name must match the name provided by the dataset_name field of the admiral::date_source() object specified for source_pd.
subject_keys	Variables to uniquely identify a subject A list of symbols created using exprs() is expected.

Details

1. The input dataset (dataset) is restricted by filter.
2. For each subject the first PD date is derived as the first date (source_pd\$date) in the source pd dataset (source_datasets[[source_pd\$dataset_name]]) restricted by source_pd\$filter.
3. The restricted input dataset is restricted to records up to first PD date. Records matching first PD date are included. For subject without any first PD date, all records are included.

Value

A subset of the input dataset

Author(s)

Teckla Akinyi, Stefan Bundfuss

See Also

Other superseded: [derive_param_bor\(\)](#), [derive_param_clinbenefit\(\)](#), [derive_param_confirmed_bor\(\)](#), [derive_param_confirmed_resp\(\)](#), [derive_param_response\(\)](#)

Examples

```
library(dplyr)
library(lubridate)
library(admiral)
library(admiralonco)

# Filter OVR records up to first PD, first PD date provided in separate BDS dataset (adevent)
adrs <- tibble::tribble(
  ~STUDYID, ~USUBJID, ~PARAMCD, ~AVALC, ~ADT, ~ANL01FL,
  "CDISCPIL01", "01-701-1015", "OVR", "CR", "2016-01-25", "Y",
  "CDISCPIL01", "01-701-1015", "OVR", "SD", "2016-02-22", NA_character_,
  "CDISCPIL01", "01-701-1015", "OVR", "PD", "2016-02-22", "Y",
  "CDISCPIL01", "01-701-1015", "BOR", "CR", "2016-01-25", "Y",
  "CDISCPIL01", "01-701-1034", "OVR", "SD", "2015-12-07", "Y",
  "CDISCPIL01", "01-701-1034", "OVR", "PD", "2016-04-25", "Y",
  "CDISCPIL01", "01-701-1034", "OVR", "PD", "2016-06-25", "Y",
  "CDISCPIL01", "01-701-1034", "BOR", "SD", "2015-12-07", "Y",
  "CDISCPIL01", "01-701-1035", "OVR", "SD", "2016-04-25", "Y",
  "CDISCPIL01", "01-701-1035", "OVR", "PR", "2016-06-25", "Y",
  "CDISCPIL01", "01-701-1035", "BOR", "PR", "2016-06-25", "Y"
) %>% mutate(
```

```

    ADT = as_date(ADT)
  )

adevent <- tibble::tribble(
  ~STUDYID, ~USUBJID, ~PARAMCD, ~AVALC, ~ADT,
  "CDISCPIL01", "01-701-1015", "PD", "Y", "2016-02-22",
  "CDISCPIL01", "01-701-1034", "PD", "Y", "2016-04-25"
) %>% mutate(
  ADT = as_date(ADT)
)

pd <- date_source(
  dataset_name = "adevent",
  date = ADT,
  filter = PARAMCD == "PD"
)

filter_pd(
  dataset = adrs,
  filter = PARAMCD == "OVR" & ANL01FL == "Y",
  source_pd = pd,
  source_datasets = list(adevent = adevent)
)

# Filter OVR records up to first PD, first PD date provided in ADSL dataset
adsl <- tibble::tribble(
  ~STUDYID, ~USUBJID, ~PDDT,
  "CDISCPIL01", "01-701-1015", "2016-02-22",
  "CDISCPIL01", "01-701-1034", "2016-04-25",
  "CDISCPIL01", "01-701-1035", ""
) %>% mutate(
  PDDT = as_date(PDDT)
)

pd <- date_source(
  dataset_name = "adsl",
  date = PDDT
)

filter_pd(
  dataset = adrs,
  filter = PARAMCD == "OVR" & ANL01FL == "Y",
  source_pd = pd,
  source_datasets = list(adsl = adsl)
)

# Filter OVR records up to first PD, first PD date provided in input dataset (PD parameter)
adrs <- tibble::tribble(
  ~STUDYID, ~USUBJID, ~PARAMCD, ~AVALC, ~ADT, ~ANL01FL,
  "CDISCPIL01", "01-701-1015", "OVR", "CR", "2016-01-25", "Y",
  "CDISCPIL01", "01-701-1015", "OVR", "SD", "2016-02-22", NA_character_,
  "CDISCPIL01", "01-701-1015", "OVR", "PD", "2016-02-22", "Y",
  "CDISCPIL01", "01-701-1015", "BOR", "CR", "2016-01-25", "Y",

```

```

      "CDISCPILLOT01", "01-701-1034", "OVR", "SD", "2015-12-07", "Y",
      "CDISCPILLOT01", "01-701-1034", "OVR", "PD", "2016-04-25", "Y",
      "CDISCPILLOT01", "01-701-1034", "OVR", "PD", "2016-06-25", "Y",
      "CDISCPILLOT01", "01-701-1034", "BOR", "SD", "2015-12-07", "Y",
      "CDISCPILLOT01", "01-701-1035", "OVR", "SD", "2016-04-25", "Y",
      "CDISCPILLOT01", "01-701-1035", "OVR", "PR", "2016-06-25", "Y",
      "CDISCPILLOT01", "01-701-1035", "BOR", "PR", "2016-06-25", "Y",
      "CDISCPILLOT01", "01-701-1015", "PD", "Y", "2016-02-22", "Y",
      "CDISCPILLOT01", "01-701-1034", "PD", "Y", "2016-04-25", "Y"
    ) %>% mutate(
      ADT = as_date(ADT)
    )

pd <- date_source(
  dataset_name = "adrs",
  date = ADT,
  filter = PARAMCD == "PD"
)

filter_pd(
  dataset = adrs,
  filter = PARAMCD == "OVR" & ANL01FL == "Y",
  source_pd = pd,
  source_datasets = list(adrs = adrs)
)

# Filter OVR records up to first PD, first PD date derived from OVR records
adrs <- tibble::tribble(
  ~STUDYID, ~USUBJID, ~PARAMCD, ~AVALC, ~ADT, ~ANL01FL,
  "CDISCPILLOT01", "01-701-1015", "OVR", "CR", "2016-01-25", "Y",
  "CDISCPILLOT01", "01-701-1015", "OVR", "SD", "2016-02-22", NA_character_,
  "CDISCPILLOT01", "01-701-1015", "OVR", "PD", "2016-02-22", "Y",
  "CDISCPILLOT01", "01-701-1015", "BOR", "CR", "2016-01-25", "Y",
  "CDISCPILLOT01", "01-701-1034", "OVR", "SD", "2015-12-07", "Y",
  "CDISCPILLOT01", "01-701-1034", "OVR", "PD", "2016-04-25", "Y",
  "CDISCPILLOT01", "01-701-1034", "OVR", "PD", "2016-06-25", "Y",
  "CDISCPILLOT01", "01-701-1034", "BOR", "SD", "2015-12-07", "Y",
  "CDISCPILLOT01", "01-701-1035", "OVR", "SD", "2016-04-25", "Y",
  "CDISCPILLOT01", "01-701-1035", "OVR", "PR", "2016-06-25", "Y",
  "CDISCPILLOT01", "01-701-1035", "BOR", "PR", "2016-06-25", "Y"
) %>% mutate(
  ADT = as_date(ADT)
)

pd <- date_source(
  dataset_name = "adrs",
  date = ADT,
  filter = PARAMCD == "OVR" & ANL01FL == "Y" & AVALC == "PD"
)

filter_pd(
  dataset = adrs,
  filter = PARAMCD == "OVR" & ANL01FL == "Y",

```

```

    source_pd = pd,
    source_datasets = list(adrs = adrs)
  )

```

get_crpr_dataset

Get CR Records Followed by PR That Lead to a Prior Error

Description

Get CR Records Followed by PR That Lead to a Prior Error

Usage

```
get_crpr_dataset()
```

Details

Some {admiralonco} functions check that in the source records CR is not followed by PR and throw an error otherwise. The `get_crpr_dataset()` function allows one to retrieve the duplicate records that lead to an error.

Note that the function always returns the dataset of duplicates from the last error that has been thrown in the current R session. Thus, after restarting the R sessions `get_crpr_dataset()` will return NULL and after a second error has been thrown, the dataset of the first error can no longer be accessed (unless it has been saved in a variable).

Value

A data.frame or NULL

Author(s)

Stefan Bundfuss

See Also

[signal_crpr\(\)](#)

Utilities for Dataset Checking: [signal_crpr\(\)](#)

Examples

```

library(tibble)
library(dplyr)
library(lubridate)
library(admiralonco)
library(rlang)

adrs <- tribble(
  ~USUBJID, ~ADTC,      ~AVALC,

```

```

      "1",      "2020-01-01", "PR",
      "1",      "2020-02-01", "CR",
      "1",      "2020-02-16", "NE",
      "1",      "2020-03-01", "CR",
      "2",      "2020-02-06", "PR",
      "2",      "2020-02-16", "CR",
      "2",      "2020-03-30", "PR",
    ) %>%
      mutate(
        ADT = ymd(ADTC),
        STUDYID = "XX1234"
      )

    signal_crpr(adrs, order = exprs(ADT))

    get_crpr_dataset()

```

 rsp_y

Pre-Defined Response Event Objects

Description

These pre-defined event() and event_joined() objects can be used as input to `admiral::derive_extreme_event()`.

Usage

rsp_y

no_data_n

cb_y

bor_cr

bor_pr

bor_sd

bor_non_crpd

bor_pd

bor_ne

no_data_missing

crsp_y_cr

```
crsp_y_pr
```

```
cbor_cr
```

```
cbor_pr
```

Details

To see the definition of the various objects simply print the object in the R console, e.g. `bor_sd`. For details of how to use these objects please refer to `admiral::derive_extreme_event()`.

It is assumed that `dataset_name = "ovr"` refers to the dataset of the only overall response assessments at each visit which should be considered for the parameter derivations. For example the dataset should include only post-baseline assessments up to first PD and before start of anti-cancer therapy.

See Also

`admiral::derive_extreme_event()`, `admiral::event()`, `admiral::event_joined()`

Examples

```
# This shows the definition of all pre-defined `event` objects that ship
# with {admiral}
exports <- sort(getNamespaceExports("admiral"))
for (obj_name in exports) {
  obj <- getExportedValue("admiral", obj_name)
  if (inherits(obj, "event_def")) {
    cat("\n", obj_name, ":\n", sep = "")
    print(obj, indent = 2)
  }
}
```

signal_crpr

Signal CR Records Followed by PR

Description

Signal CR Records Followed by PR

Usage

```
signal_crpr(
  dataset,
  order,
  msg = "Dataset contains CR records followed by PR.",
  subject_keys = get_admiral_option("subject_keys"),
  check_type = "warning"
)
```

Arguments

dataset	A data frame
order	A list of variables created using <code>exprs()</code> determining the order or the records
msg	The condition message
subject_keys	Variables to uniquely identify a subject A list of symbols created using <code>exprs()</code> is expected.
check_type	Type of message to issue when detecting PR after CR. <i>Permitted Values:</i> "message", "warning" or "error"

Value

No return value, called for side effects

Author(s)

Stefan Bundfuss

See Also

[get_crpr_dataset\(\)](#)

Utilities for Dataset Checking: [get_crpr_dataset\(\)](#)

Examples

```
library(tibble)
library(dplyr)
library(lubridate)
library(admiralonco)
library(rlang)

adrs <- tribble(
  ~USUBJID, ~ADTC,      ~AVALC,
  "1",      "2020-01-01", "PR",
  "1",      "2020-02-01", "CR",
  "1",      "2020-02-16", "NE",
  "1",      "2020-03-01", "CR",
  "2",      "2020-02-06", "PR",
  "2",      "2020-02-16", "CR",
  "2",      "2020-03-30", "PR",
) %>%
  mutate(
    ADT = ymd(ADTC),
    STUDYID = "XX1234"
  )

signal_crpr(adrs, order = exprs(ADT))
```

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