

Package ‘admiralonco’

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Type Package

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

Version 0.5.0

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/adamig-v1-3-release-package>>). The package is an extension package of the 'admiral' package.

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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 `{admiralonco}` (https://github.com/pharmaverse/admiralonco/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_))
```

call_aval_fun	<i>Creates AVAL from AVALC by Calling User Function</i>
---------------	---

Description**[Deprecated]**

This function is *deprecated*, please use `admiraldev::process_set_values_to()` instead.

Create AVAL from AVALC by calling a function provided by the user. If calling the function fails, the error is caught and a helpful error message provided.

Usage

```
call_aval_fun(dataset, aval_fun)
```

Arguments

dataset	Input dataset The variable AVALC is expected. <i>Permitted Values:</i> a dataframe
aval_fun	Function returning the AVALC values The specified function must expect one argument expecting a character vector and must return a numeric vector. <i>Permitted Values:</i> a function

Details

The new variable AVAL is set to `aval_fun(AVALC)`.

Value

The input dataset with AVAL added

Author(s)

Stefan Bundfuss

`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))
  cat("\n")
}
```

derive_param_bor	<i>Adds a Parameter for Best Overall Response (without confirmation)</i>
------------------	--

Description

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	<p>The input dataframe from which the Best Overall Response will be derived from and added to.</p> <p>The columns PARAMCD, ADT, and AVALC and the columns specified in subject_keys and reference_date are expected.</p> <p>After applying filter_source and/or source_pd the column ADT and the columns specified by subject_keys must be a unique key of the dataframe.</p> <p><i>Permitted Values:</i> a data.frame() object</p>
dataset_adsl	<p>ADSL input dataset.</p> <p>The columns specified in the subject_keys argument are expected. For each subject in the passed dataset a new row is added to the input dataset. Columns in dataset_adsl that also appear in dataset will be populated with the appropriate subject-specific value for these new rows.</p> <p><i>Permitted Values:</i> a data.frame() object</p>
filter_source	Filter to be applied to dataset to derive the Best Overall Response
source_pd	<p>Date of first progressive disease (PD)</p> <p>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.</p> <p><i>Permitted Values:</i> a date_source object (see date_source() for details)</p>

- 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
- ```
pd_date <- date_source(
 dataset_name = "adrs",
 date = ADT,
 filter = PARAMCD == PD
)
```
- 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).  
*Permitted Values:* 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  $ADT \geq reference\_date + ref\_start\_window$ ), see Details section for further information.  
*Permitted Values:* 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\_ads1 without an assessment in the dataset after the filter has been applied. 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** 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  
*Permitted Values:* 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

ADRS Functions for adding Parameters: [derive\\_param\\_clinbenefit\(\)](#), [derive\\_param\\_confirmed\\_bor\(\)](#), [derive\\_param\\_confirmed\\_resp\(\)](#), [derive\\_param\\_response\(\)](#)

## 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

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.<br>The variables PARAMCD, AVALC, ADT, and those specified by the subject_keys parameter and the reference_date parameter are expected.<br>After applying filter_source and/or source_pd the variable ADT and the variables specified by subject_keys must be a unique key of the dataset. |
| dataset_adsl  | ADSL input dataset.<br>The variables specified for subject_keysis expected. For each subject of the specified dataset a new observation is added to the input dataset. Variables in dataset_adsl that also appear in dataset 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. PARAMCD == "OVR" or PARAMCD == "OVRRESP".                                                                                                                                                                                                           |
| source_resp   | A date_source 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.<br>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.<br>Function to map character analysis value (AVALC) to numeric analysis value (AVAL)<br>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

ADRS Functions for adding Parameters: [derive\\_param\\_bor\(\)](#), [derive\\_param\\_confirmed\\_bor\(\)](#), [derive\\_param\\_confirmed\\_resp\(\)](#), [derive\\_param\\_response\(\)](#)

## 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**

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         | <p>Input dataset</p> <p>The PARAMCD, ADT, and AVALC variables and the variables specified by subject_keys and reference_date are expected.</p> <p>After applying filter_source and/or source_pd the variable ADT and the variables specified by subject_keys must be a unique key of the dataset.</p>                                                                                                                                       |
| dataset_adsl    | <p>ADSL input dataset</p> <p>The variables specified for subject_keys are expected. For each subject of the specified dataset a new observation is added to the input dataset.</p>                                                                                                                                                                                                                                                          |
| filter_source   | <p>Source filter</p> <p>All observations in dataset_source fulfilling the specified condition are considered for deriving the confirmed best overall response.</p>                                                                                                                                                                                                                                                                          |
| source_pd       | <p>Date of first progressive disease (PD)</p> <p>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.</p> <p><i>Permitted Values:</i> a date_source object (see admiral::date_source() for details)</p> |
| source_datasets | <p>Source dataset for the first PD date</p> <p>A named list of datasets is expected. It links the dataset_name from source_pd with an existing dataset.</p> <p>For example if source_pd = pd_date with</p>                                                                                                                                                                                                                                  |

```
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   | <p>Reference date</p> <p>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).</p> <p><i>Permitted Values:</i> a numeric date variable</p>                                                                       |
| ref_start_window | <p>Stable disease time window</p> <p>Assessments at least the specified number of days after the reference date (i.e. where ADT &gt;= reference_date + ref_start_window) with response "CR", "PR", "SD", or "NON-CR/NON-PD" are considered for "SD" or "NON-CR/NON-PD" response.</p> <p><i>Permitted Values:</i> a non-negative numeric scalar</p> |
| ref_confirm      | <p>Minimum time period for confirmation</p> <p>The assessment and the confirmatory assessment for "CR" and "PR" have to be at least the specified number of days apart.</p>                                                                                                                                                                        |
| max_nr_ne        | <p>The specified number of "NE" assessments between the assessment and the confirmatory assessment for "CR" and "PR" response is accepted.</p> <p><i>Permitted Values:</i> a non-negative numeric scalar</p>                                                                                                                                       |
| accept_sd        | <p>Accept "SD" for "PR"?</p> <p>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.</p> <p><i>Permitted Values:</i> a logical scalar</p>                                               |
| missing_as_ne    | <p>Consider no assessments as "NE"?</p> <p>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.</p> <p><i>Permitted Values:</i> a logical scalar</p>                                                               |
| aval_fun         | <p><i>Deprecated</i>, please use set_values_to instead.</p> <p>Function to map character analysis value (AVALC) to numeric analysis value (AVAL)</p> <p>The (first) argument of the function must expect a character vector and the function must return a numeric vector.</p>                                                                     |
| set_values_to    | <p>Variables to set</p> <p>A named list returned by exprs() defining the variables to be set for the new parameter, e.g. exprs(PARAMCD = "CBOR", PARAM = "Confirmed Best Overall Response") is expected. The values must be symbols, character strings, numeric values, or NA.</p>                                                                 |



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. 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

ADRS Functions for adding Parameters: [derive\\_param\\_bor\(\)](#), [derive\\_param\\_clinbenefit\(\)](#), [derive\\_param\\_confirmed\\_resp\(\)](#), [derive\\_param\\_response\(\)](#)

### 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 = adrs,
 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**

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         | <p>Input dataset</p> <p>The PARAMCD, ADT, and AVALC variables and the variables specified by subject_keys and reference_date are expected.</p> <p>After applying filter_source and/or source_pd the variable ADT and the variables specified by subject_keys must be a unique key of the dataset.</p>                                                                                                                                       |
| dataset_adsl    | <p>ADSL input dataset</p> <p>The variables specified for subject_keys are expected. For each subject of the specified dataset a new observation is added to the input dataset.</p>                                                                                                                                                                                                                                                          |
| filter_source   | <p>Source filter</p> <p>All observations in dataset_source fulfilling the specified condition are considered for deriving the confirmed response.</p>                                                                                                                                                                                                                                                                                       |
| source_pd       | <p>Date of first progressive disease (PD)</p> <p>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.</p> <p><i>Permitted Values:</i> a date_source object (see admiral::date_source() for details)</p> |
| source_datasets | <p>Source dataset for the first PD date</p> <p>A named list of datasets is expected. It links the dataset_name from source_pd with an existing dataset.</p> <p>For example if source_pd = pd_date with</p> <pre>pd_date &lt;- date_source(</pre>                                                                                                                                                                                            |

```

 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.

|               |                                                                                                                                                                                                                                                                                                      |
|---------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ref_confirm   | <p>Minimum time period for confirmation</p> <p>The assessment and the confirmatory assessment for "CR" and "PR" have to be at least the specified number of days apart.</p>                                                                                                                          |
| max_nr_ne     | <p>The specified number of "NE" assessments between the assessment and the confirmatory assessment for "CR" and "PR" response is accepted.</p> <p><i>Permitted Values:</i> a non-negative numeric scalar</p>                                                                                         |
| accept_sd     | <p>Accept "SD" for "PR"?</p> <p>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.</p> <p><i>Permitted Values:</i> a logical scalar</p> |
| aval_fun      | <p><i>Deprecated</i>, please use set_values_to instead.</p> <p>Function to map character analysis value (AVALC) to numeric analysis value (AVAL)</p> <p>The (first) argument of the function must expect a character vector and the function must return a numeric vector.</p>                       |
| set_values_to | <p>Variables to set</p> <p>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.</p>                                |
| subject_keys  | <p>Variables to uniquely identify a subject</p> <p>A list of symbols created using exprs() is expected.</p>                                                                                                                                                                                          |

## 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

ADRS Functions for adding Parameters: [derive\\_param\\_bor\(\)](#), [derive\\_param\\_clinbenefit\(\)](#), [derive\\_param\\_confirmed\\_bor\(\)](#), [derive\\_param\\_response\(\)](#)

### 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

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         | <p>Input dataset</p> <p>The variables specified by the <code>subject_keys</code> and ADT are expected.</p> <p>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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                  |
| dataset_adsl    | <p>Input dataset</p> <ul style="list-style-type: none"> <li>• The variables specified for <code>subject_keys</code> are expected.</li> <li>• 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.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                      |
| filter_source   | <p>Source filter</p> <p>All observations in the dataset data fulfilling the specified condition are selected.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| source_pd       | <p>Sources and conditions defining the end of the assessment period for the responses.</p> <p>An object of type <code>date_source</code> is expected</p> <p>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>.</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• For all other subjects AVALC is set to "N", AVAL to 0, and ADT to NA.</li> </ul> |
| source_datasets | <p>Source dataset</p> <p>A named list of datasets with one element is expected (e.g. <code>list(adrs= adrs)</code>).</p> <p>The name must match the <code>dataset_name</code> field of the <code>admiral::date_source()</code> object specified for <code>source_pd</code>.</p> <p>The variables specified by the <code>subject_keys</code> argument and the <code>date</code> field of the <code>admiral::date_source()</code> object are expected in the dataset.</p>                                                                                                                                                                                                                                                   |

|               |                                                                                                                                                                                                                                                                                             |
|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| set_values_to | Variables to set<br>A named list returned by <code>exprs()</code> defining the variables to be set for the new parameter, e.g. <code>exprs(PARAMCD = "RSP", PARAM = "Response by investigator")</code> is expected.<br>The values must be symbols, character strings, numeric values or NA. |
| aval_fun      | <i>Deprecated</i> , please use <code>set_values_to</code> instead.<br>Function to map character analysis value (AVALC) to numeric analysis value (AVAL)<br>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<br>A list of symbols created using <code>exprs()</code> 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

ADRS Functions for adding Parameters: [derive\\_param\\_bor\(\)](#), [derive\\_param\\_clinbenefit\(\)](#), [derive\\_param\\_confirmed\\_bor\(\)](#), [derive\\_param\\_confirmed\\_resp\(\)](#)

**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

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<br>The variables ADT and those specified by subject_keys 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<br>For each subject the first date (date field) in the provided dataset (dataset_name field) restricted by filter field is considered as first PD date. |
| source_datasets | A named list of data sets is expected.<br>The name must match the name provided by the dataset_name field of the <code>admiral::date_source()</code> object specified for source_pd.                                                |
| subject_keys    | Variables to uniquely identify a subject<br>A list of symbols created using <code>exprs()</code> 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

**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",
 "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",
 "CDISCPIL01", "01-701-1015", "PD", "Y", "2016-02-22", "Y",
 "CDISCPIL01", "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,
 "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)
)

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 function check that the 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 {admiralonco}
exports <- sort(getNamespaceExports("admiralonco"))
for (obj_name in exports) {
 obj <- getExportedValue("admiralonco", 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<br>A list of symbols created using <code>exprs()</code> is expected.    |
| check_type   | Type of message to issue when detecting PR after CR.<br><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(admiralonacci)
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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