

# Package ‘metalite.ae’

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**Title** Adverse Events Analysis Using 'metalite'

**Version** 0.1.3

**Description** Analyzes adverse events in clinical trials using the 'metalite' data structure. The package simplifies the workflow to create production-ready tables, listings, and figures discussed in the adverse events analysis chapters of ```R for Clinical Study Reports and Submission''` by Zhang et al. (2022) <<https://r4csr.org/>>.

**License** GPL-3

**URL** <https://merck.github.io/metalite.ae/>,  
<https://github.com/Merck/metalite.ae>

**BugReports** <https://github.com/Merck/metalite.ae/issues>

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---

`extend_ae_specific_duration`*Add average duration information for AE specific analysis*

---

**Description**

Add average duration information for AE specific analysis

**Usage**

```
extend_ae_specific_duration(outdata, duration_var, duration_unit = "Day")
```

**Arguments**

`outdata` An outdata object created by `prepare_ae_specific()`.  
`duration_var` A character value of variable name for adverse event duration.  
`duration_unit` A character value of adverse event duration unit.

**Value**

A list of analysis raw datasets.

**Examples**

```
meta <- meta_ae_example()
tbl <- prepare_ae_specific(meta,
  population = "apat",
  observation = "wk12",
  parameter = "rel"
) |>
  extend_ae_specific_duration(duration_var = "ADURN") |>
  format_ae_specific(display = c("n", "prop", "dur"))
head(tbl$tbl)
```

---

`extend_ae_specific_events`*Add average number of events information for AE specific analysis*

---

**Description**

Add average number of events information for AE specific analysis

**Usage**

```
extend_ae_specific_events(outdata)
```

**Arguments**

outdata            An outdata object created by `prepare_ae_specific()`.

**Value**

A list of analysis raw datasets.

**Examples**

```
meta <- meta_ae_example()
tbl <- prepare_ae_specific(meta,
  population = "apat",
  observation = "wk12",
  parameter = "rel"
) |>
  extend_ae_specific_events() |>
  format_ae_specific(display = c("n", "prop", "events_avg"))
head(tbl$tbl)
```

---

extend\_ae\_specific\_inference

*Add inference information for AE specific analysis*

---

**Description**

Add inference information for AE specific analysis

**Usage**

```
extend_ae_specific_inference(outdata, ..., ci = 0.95)
```

**Arguments**

outdata            An outdata object created by `prepare_ae_specific()`.  
...                Other options passed on to `rate_compare_sum()`  
ci                 A numeric value for the percentile of confidence interval.

**Value**

A list of analysis raw datasets.

**Examples**

```
meta <- meta_ae_example()
tbl <- prepare_ae_specific(meta,
  population = "apat",
  observation = "wk12",
  parameter = "rel"
) |>
  extend_ae_specific_inference(eps = 1e-6, bisection = 200) |>
  format_ae_specific(display = c("n", "prop", "diff", "diff_ci"))
head(tbl$tbl)
```

---

extend\_ae\_specific\_subgroup

*Add subgroup analysis in AE specific analysis*

---

**Description**

Add subgroup analysis in AE specific analysis

**Usage**

```
extend_ae_specific_subgroup(outdata, subgroup_var)
```

**Arguments**

outdata            An outdata object created by [prepare\\_ae\\_specific\(\)](#).  
subgroup\_var      a character string for subgroup variable name

**Value**

A list of analysis raw datasets.

**Examples**

```
meta <- meta_ae_example()
tbl <- prepare_ae_specific(meta,
  population = "apat",
  observation = "wk12",
  parameter = "rel"
) |>
  extend_ae_specific_subgroup(subgroup_var = "SEX")
```

---

`extend_ae_summary_eaer`*Add exposure-adjusted rate information for AE summary analysis*

---

### Description

Add exposure-adjusted rate information for AE summary analysis

### Usage

```
extend_ae_summary_eaer(  
  outdata,  
  duration_var = "TRTDUR",  
  adj_unit = c("year", "month", "week", "day")  
)
```

### Arguments

<code>outdata</code>	An outdata object created by <a href="#">prepare_ae_summary()</a> .
<code>duration_var</code>	A character value of duration variable name. By default, "TRTDUR" is used.
<code>adj_unit</code>	A character value of exposure adjusted unit. It could be select from "year", "month", "week", and "day".

### Value

A list of analysis raw datasets.

### Examples

```
meta <- meta_ae_example()  
prepare_ae_summary(  
  meta,  
  population = "apat",  
  observation = "wk12",  
  parameter = "any;rel;ser"  
) |>  
extend_ae_summary_eaer()
```

---

fmt_ci	<i>Format confidence interval</i>
--------	-----------------------------------

---

**Description**

Format confidence interval

**Usage**

```
fmt_ci(lower, upper, digits = 2, width = 3 + digits)
```

**Arguments**

lower	A numeric value of lower value of CI.
upper	A numeric value of upper value of CI.
digits	Digits of each column, i.e., format as (x.x, x.x).
width	Width of each column.

**Value**

A numeric vector with the expected format.

**Examples**

```
fmt_ci(0.2356, 0.3871)
```

---

fmt_est	<i>Format model estimator</i>
---------	-------------------------------

---

**Description**

Formats mean sd/se to a format as x.x or x.x (x.xx) if both mean and sd/sd are defined.

**Usage**

```
fmt_est(  
  mean,  
  sd = rep(NA, length(mean)),  
  digits = c(1, 1),  
  width = c(4, 3) + digits  
)
```

**Arguments**

mean	A numeric vector of mean value.
sd	A numeric vector of standard deviation value.
digits	Digits of each column, i.e., format as x.x (x.xx).
width	Width of each column.

**Details**

The function assumes 1 column or 2 columns:

- If there is only 1 column, only represent mean.
- If there are 2 columns, represent mean (sd) or mean(se). Decimals will understand the number will be formatted as x.x (x.xx).

**Value**

The same data frame with additional attributes for page features.

**Specification**

- Check all argument types and possible values.
- Add attributes into tbl.

**Examples**

```
fmt_est(mean(iris$Petal.Length), sd(iris$Petal.Length))
fmt_est(mean(iris$Petal.Length), sd(iris$Petal.Length), digits = c(2, 3))
```

---

fmt_pct	<i>Format percentage</i>
---------	--------------------------

---

**Description**

Format percentage

**Usage**

```
fmt_pct(x, digits = 1, pre = "(", post = ")")
```

**Arguments**

x	A numeric vector.
digits	Number of digits.
pre	Text before the number.
post	Text after the number.

**Value**

A numeric vector with the expected format.

**Examples**

```
fmt_pct(c(1, 1.52, 0.3, 100))
```

---

fmt_pval	<i>Format p-value</i>
----------	-----------------------

---

**Description**

Format p-value

**Usage**

```
fmt_pval(p, digits = 3, width = 3 + digits)
```

**Arguments**

p	A numeric vector of p-values.
digits	Digits of each column, i.e., format as x.xxx.
width	Width of each column.

**Value**

A numeric vector with the expected format.

**Examples**

```
fmt_pval(c(0.1234, 0.00002))
```

---

format_ae_exp_adj	<i>Format exposure-adjusted AE summary</i>
-------------------	--------------------------------------------

---

**Description**

Format exposure-adjusted AE summary

**Usage**

```
format_ae_exp_adj(
  outdata,
  display = c("n", "total_exp", "events", "eaer", "total"),
  digits_total_exp = 2,
  digits_eaer = 2,
  mock = FALSE
)
```

**Arguments**

outdata	An outdata object created by <code>prepare_ae_specific()</code> .
display	A character vector of measurement to be displayed: <ul style="list-style-type: none"> <li>• n: Number of subjects exposed.</li> <li>• total_exp: Total exposure in person-time.</li> <li>• events: Number of AE.</li> <li>• eaer: Exposure adjusted event rate.</li> <li>• total: Total columns.</li> </ul>
digits_total_exp	A numeric value of number of digits for total exposure value.
digits_eaer	A numeric value of number of digits for exposure-adjusted event rate.
mock	A boolean value to display mock table.

**Value**

A list of analysis raw datasets.

**Examples**

```
meta <- meta_ae_example()

outdata <- meta |>
  prepare_ae_summary(
    population = "apat",
    observation = "wk12",
    parameter = "any;ser;rel"
  ) |>
  extend_ae_summary_eaer(adj_unit = "month")
tbl <- outdata |>
  format_ae_exp_adj()
head(tbl$tbl)
```

---

format\_ae\_specific      *Format AE specific analysis*

---

**Description**

Format AE specific analysis

**Usage**

```
format_ae_specific(
  outdata,
  display = c("n", "prop", "total"),
  hide_soc_stats = FALSE,
  digits_prop = 1,
```

```

    digits_ci = 1,
    digits_p = 3,
    digits_dur = c(1, 1),
    digits_events = c(1, 1),
    filter_method = c("percent", "count"),
    filter_criteria = 0,
    sort_order = c("alphabetical", "count_des", "count_asc"),
    sort_column = NULL,
    mock = FALSE
)

```

## Arguments

outdata	An outdata object created by <a href="#">prepare_ae_specific()</a> .
display	A character vector of measurement to be displayed: <ul style="list-style-type: none"> <li>• n: Number of subjects with adverse event.</li> <li>• prop: Proportion of subjects with adverse event.</li> <li>• total: Total columns.</li> <li>• diff: Risk difference.</li> <li>• diff_ci: 95% confidence interval of risk difference using M&amp;N method.</li> <li>• diff_p: p-value of risk difference using M&amp;N method.</li> <li>• dur: Average of adverse event duration.</li> <li>• events_avg: Average number of adverse event per subject.</li> <li>• events_count: Count number of adverse event per subject.</li> </ul>
hide_soc_stats	A boolean value to hide stats for SOC rows.
digits_prop	A numeric value of number of digits for proportion value.
digits_ci	A numeric value of number of digits for confidence interval.
digits_p	A numeric value of number of digits for p-value.
digits_dur	A numeric value of number of digits for average duration of adverse event.
digits_events	A numeric value of number of digits for average of number of adverse events per subject.
filter_method	A character value to specify how to filter rows: <ul style="list-style-type: none"> <li>• count: Filtered based on participant count.</li> <li>• percent: Filtered based percent incidence.</li> </ul>
filter_criteria	A numeric value to display rows where at least one therapy group has a percent incidence or participant count greater than or equal to the specified value. If <code>filter_method</code> is percent, the value should be between 0 and 100. If <code>filter_method</code> is count, the value should be greater than 0.
sort_order	A character value to specify sorting order: <ul style="list-style-type: none"> <li>• alphabetical: Sort by alphabetical order.</li> <li>• count_des: Sort by count in descending order.</li> <li>• count_asc: Sort by count in ascending order.</li> </ul>
sort_column	A character value of group in outdata used to sort a table with.
mock	A boolean value to display mock table.

**Value**

A list of analysis raw datasets.

**Examples**

```
meta <- meta_ae_example()

outdata <- prepare_ae_specific(meta,
  population = "apat",
  observation = "wk12",
  parameter = "rel"
)

# Basic example
tbl <- outdata |>
  format_ae_specific()
head(tbl$tbl)

# Filtering
tbl <- outdata |>
  format_ae_specific(
    filter_method = "percent",
    filter_criteria = 10
  )
head(tbl$tbl)

# Display different measurements
tbl <- outdata |>
  extend_ae_specific_events() |>
  format_ae_specific(display = c("n", "prop", "events_count"))
head(tbl$tbl)
```

---

format\_ae\_specific\_subgroup

*Format AE specific subgroup analysis*

---

**Description**

Format AE specific subgroup analysis

**Usage**

```
format_ae_specific_subgroup(
  outdata,
  display = c("n", "prop"),
  digits_prop = 1,
  digits_ci = 1,
  digits_p = 3,
  digits_dur = c(1, 1),
```

```

  digits_events = c(1, 1),
  mock = FALSE
)

```

### Arguments

outdata	An outdata object created by <code>prepare_ae_specific()</code> .
display	A character vector of measurement to be displayed. <ul style="list-style-type: none"> <li>• n: Number of subjects with adverse event.</li> <li>• prop: Proportion of subjects with adverse event.</li> <li>• total: Total columns.</li> <li>• dur: Average of adverse event duration.</li> <li>• events: Average number of adverse event per subject.</li> </ul>
digits_prop	A numeric value of number of digits for proportion value.
digits_ci	A numeric value of number of digits for confidence interval.
digits_p	A numeric value of number of digits for p-value.
digits_dur	A numeric value of number of digits for average duration of adverse event.
digits_events	A numeric value of number of digits for average of number of adverse event per subjects.
mock	Logical. Display mock table or not.

### Value

A list of analysis raw datasets for subgroup analysis.

### Examples

```

meta <- meta_ae_example()
prepare_ae_specific_subgroup(meta,
  population = "apat",
  observation = "wk12",
  parameter = "rel",
  subgroup_var = "SEX",
  display_subgroup_total = TRUE
) |>
  format_ae_specific_subgroup()

```

---

format\_ae\_summary      *Format AE summary analysis*

---

### Description

Format AE summary analysis

**Usage**

```
format_ae_summary(
  outdata,
  display = c("n", "prop", "total"),
  hide_soc_stats = FALSE,
  digits_prop = 1,
  digits_ci = 1,
  digits_p = 3,
  digits_dur = c(1, 1),
  digits_events = c(1, 1),
  filter_method = c("percent", "count"),
  filter_criteria = 0,
  sort_order = c("alphabetical", "count_des", "count_asc"),
  sort_column = NULL,
  mock = FALSE
)
```

**Arguments**

outdata	An outdata object created by <a href="#">prepare_ae_specific()</a> .
display	A character vector of measurement to be displayed: <ul style="list-style-type: none"> <li>• n: Number of subjects with adverse event.</li> <li>• prop: Proportion of subjects with adverse event.</li> <li>• total: Total columns.</li> <li>• diff: Risk difference.</li> <li>• diff_ci: 95% confidence interval of risk difference using M&amp;N method.</li> <li>• diff_p: p-value of risk difference using M&amp;N method.</li> <li>• dur: Average of adverse event duration.</li> <li>• events_avg: Average number of adverse event per subject.</li> <li>• events_count: Count number of adverse event per subject.</li> </ul>
hide_soc_stats	A boolean value to hide stats for SOC rows.
digits_prop	A numeric value of number of digits for proportion value.
digits_ci	A numeric value of number of digits for confidence interval.
digits_p	A numeric value of number of digits for p-value.
digits_dur	A numeric value of number of digits for average duration of adverse event.
digits_events	A numeric value of number of digits for average of number of adverse events per subject.
filter_method	A character value to specify how to filter rows: <ul style="list-style-type: none"> <li>• count: Filtered based on participant count.</li> <li>• percent: Filtered based percent incidence.</li> </ul>
filter_criteria	A numeric value to display rows where at least one therapy group has a percent incidence or participant count greater than or equal to the specified value. If <code>filter_method</code> is percent, the value should be between 0 and 100. If <code>filter_method</code> is count, the value should be greater than 0.

sort_order	A character value to specify sorting order: <ul style="list-style-type: none"> <li>• alphabetical: Sort by alphabetical order.</li> <li>• count_des: Sort by count in descending order.</li> <li>• count_asc: Sort by count in ascending order.</li> </ul>
sort_column	A character value of group in outdata used to sort a table with.
mock	A boolean value to display mock table.

**Value**

A list of analysis raw datasets.

**Examples**

```
meta <- meta_ae_example()
outdata <- prepare_ae_summary(meta,
  population = "apat",
  observation = "wk12",
  parameter = "any;rel;ser"
)
tbl <- outdata |>
  format_ae_summary()
head(tbl$tbl)
```

---

metalite_ae_adex	<i>ADEX dataset</i>
------------------	---------------------

---

**Description**

A dataset containing exposure details.

**Usage**

```
metalite_ae_adex
```

**Format**

A data frame with 591 rows and 41 variables.

**Value**

An analysis data frame.

**Source**

<https://github.com/phuse-org/phuse-scripts/tree/master/data/sdtm/cdiscpilot01>

---

metalite\_ae\_adexsum     *ADEXSUM dataset*

---

**Description**

A dataset containing exposure details in Basic Data Structure (BDS).

**Usage**

```
metalite_ae_adexsum
```

**Format**

A data frame with 254 rows and 30 variables.

**Value**

An analysis data frame.

**Source**

<https://github.com/phuse-org/phuse-scripts/tree/master/data/sdtm/cdiscpilot01>

---

meta\_ae\_example     *Create an example meta\_adam object*

---

**Description**

This function is only for illustration purpose. r2rtf is required.

**Usage**

```
meta_ae_example()
```

**Value**

A metadata object.

**Examples**

```
meta <- meta_ae_example()
```

---

prepare\_ae\_listing      *Prepare datasets for AE listing*

---

**Description**

Prepare datasets for AE listing

**Usage**

```
prepare_ae_listing(meta, analysis, population, observation, parameter)
```

**Arguments**

meta	A metadata object created by metalite.
analysis	Analysis name from meta.
population	A character value of population term name. The term name is used as key to link information.
observation	A character value of observation term name. The term name is used as key to link information.
parameter	A character value of parameter term name. The term name is used as key to link information.

**Value**

A list of analysis datasets needed for AE listing.

**Examples**

```
meta <- meta_ae_example()
str(prepare_ae_listing(meta, "ae_listing", "apat", "wk12", "ser"))
```

---

prepare\_ae\_specific      *Prepare datasets for AE specific analysis*

---

**Description**

Prepare datasets for AE specific analysis

**Usage**

```
prepare_ae_specific(
  meta,
  population,
  observation,
  parameter,
  components = c("soc", "par"),
  reference_group = NULL
)
```

**Arguments**

meta	A metadata object created by metalite.
population	A character value of population term name. The term name is used as key to link information.
observation	A character value of observation term name. The term name is used as key to link information.
parameter	A character value of parameter term name. The term name is used as key to link information.
components	A character vector of components name.
reference_group	An integer to indicate reference group. Default is 2 if there are 2 groups, otherwise, the default is 1.

**Value**

A list of analysis datasets needed for AE specific analysis.

**Examples**

```
meta <- meta_ae_example()
str(prepare_ae_specific(meta, "apat", "wk12", "rel"))

# Allow to extract each components
prepare_ae_specific(meta, "apat", "wk12", "rel", components = NULL)$data
prepare_ae_specific(meta, "apat", "wk12", "rel", components = "soc")$data
prepare_ae_specific(meta, "apat", "wk12", "rel", components = "par")$data
```

---

```
prepare_ae_specific_subgroup
```

*Prepare datasets for AE specific subgroup analysis*

---

**Description**

Prepare datasets for AE specific subgroup analysis

**Usage**

```
prepare_ae_specific_subgroup(
  meta,
  population,
  observation,
  parameter,
  subgroup_var,
  subgroup_header = c(meta$population[[population]]$group, subgroup_var),
  components = c("soc", "par"),
  display_subgroup_total = TRUE
)
```

**Arguments**

meta	A metadata object created by metalite.
population	A character value of population term name. The term name is used as key to link information.
observation	A character value of observation term name. The term name is used as key to link information.
parameter	A character value of parameter term name. The term name is used as key to link information.
subgroup_var	A character value of subgroup variable name in observation data saved in meta\$data_observation.
subgroup_header	A character vector for column header hierarchy. The first element will be the first level header and the second element will be second level header.
components	A character vector of components name.
display_subgroup_total	Logical. Display total column for subgroup analysis or not.

**Value**

A list of analysis datasets needed for AE specific subgroup analysis.

**Examples**

```
meta <- meta_ae_example()
prepare_ae_specific_subgroup(meta, "apat", "wk12", "rel", subgroup_var = "SEX")$data
```

---

prepare\_ae\_summary      *Prepare datasets for AE summary*

---

**Description**

Prepare datasets for AE summary

**Usage**

```
prepare_ae_summary(meta, population, observation, parameter, ...)
```

**Arguments**

meta	A metadata object created by metalite.
population	A character value of population term name. The term name is used as key to link information.
observation	A character value of observation term name. The term name is used as key to link information.
parameter	A character value of parameter term name. The term name is used as key to link information.
...	Additional arguments passed to <a href="#">prepare_ae_specific()</a> .

**Value**

A list of analysis datasets needed for AE summary.

**Examples**

```
meta <- meta_ae_example()
prepare_ae_summary(
  meta,
  population = "apat",
  observation = "wk12",
  parameter = "any;rel;ser"
)
```

---

rate\_compare

*Unstratified and stratified Miettinen and Nurminen test*


---

**Description**

Unstratified and stratified Miettinen and Nurminen test details can be found in `vignette("rate-compare")`.

**Usage**

```
rate_compare(
  formula,
  strata,
  data,
  delta = 0,
  weight = c("ss", "equal", "cmh"),
  test = c("one.sided", "two.sided"),
  bisection = 100,
  eps = 1e-06,
  alpha = 0.05
)
```

**Arguments**

formula	A symbolic description of the model to be fitted, which has the form $y \sim x$ . Here, $y$ is the numeric vector with values of 0 or 1. $x$ is the group information.
strata	An optional vector of weights to be used in the analysis. If not specified, unstratified MN analysis is used. If specified, stratified MN analysis is conducted.
data	An optional data frame, list, or environment containing the variables in the model. If not found in data, the variables are taken from environment (formula), typically the environment from which rate_compare is called.
delta	A numeric value to set the difference of two group under the null.
weight	Weighting schema used in stratified MN method. Default is "ss": <ul style="list-style-type: none"> <li>• "equal" for equal weighting.</li> <li>• "ss" for sample size weighting.</li> <li>• "cmh" for Cochran–Mantel–Haenszel’s weights.</li> </ul>
test	A character string specifying the side of p-value, must be one of "one.sided", or "two.sided".
bisection	The number of sections in the interval used in bisection method. Default is 100.
eps	The level of precision. Default is 1e-06.
alpha	Pre-defined alpha level for two-sided confidence interval.

**Value**

A data frame with the test results.

**References**

Miettinen, O. and Nurminen, M, Comparative Analysis of Two Rates. *Statistics in Medicine*, 4(2):213–226, 1985.

**Examples**

```
# Conduct the stratified MN analysis with sample size weights
treatment <- c(rep("pbo", 100), rep("exp", 100))
response <- c(rep(0, 80), rep(1, 20), rep(0, 40), rep(1, 60))
stratum <- c(rep(1:4, 12), 1, 3, 3, 1, rep(1:4, 12), rep(1:4, 25))
rate_compare(
  response ~ factor(treatment, levels = c("pbo", "exp")),
  strata = stratum,
  delta = 0,
  weight = "ss",
  test = "one.sided",
  alpha = 0.05
)
```

---

rate_compare_sum	<i>Unstratified and stratified Miettinen and Nurminen test in aggregate data level</i>
------------------	----------------------------------------------------------------------------------------

---

### Description

Unstratified and stratified Miettinen and Nurminen test in aggregate data level

### Usage

```
rate_compare_sum(
  n0,
  n1,
  x0,
  x1,
  strata = NULL,
  delta = 0,
  weight = c("ss", "equal", "cmh"),
  test = c("one.sided", "two.sided"),
  bisection = 100,
  eps = 1e-06,
  alpha = 0.05
)
```

### Arguments

n0, n1	The sample size in the control group and experimental group, separately. The length should be the same as the length for x0/x1 and strata.
x0, x1	The number of events in the control group and experimental group, separately. The length should be the same as the length for n0/n1 and strata.
strata	A vector of stratum indication to be used in the analysis. If NULL or the length of unique values of strata equals to 1, it is unstratified MN analysis. Otherwise, it is stratified MN analysis. The length of strata should be the same as the length for x0/x1 and n0/n1.
delta	A numeric value to set the difference of two groups under the null.
weight	Weighting schema used in stratified MN method. Default is "ss": <ul style="list-style-type: none"> <li>• "equal" for equal weighting.</li> <li>• "ss" for sample size weighting.</li> <li>• "cmh" for Cochran-Mantel-Haenszel's weights.</li> </ul>
test	A character string specifying the side of p-value, must be one of "one.sided", or "two.sided".
bisection	The number of sections in the interval used in bisection method. Default is 100.
eps	The level of precision. Default is 1e-06.
alpha	Pre-defined alpha level for two-sided confidence interval.

**Value**

A data frame with the test results.

**References**

Miettinen, O. and Nurminen, M, Comparative Analysis of Two Rates. *Statistics in Medicine*, 4(2):213–226, 1985.

**Examples**

```
# Conduct the stratified MN analysis with sample size weights
treatment <- c(rep("pbo", 100), rep("exp", 100))
response <- c(rep(0, 80), rep(1, 20), rep(0, 40), rep(1, 60))
stratum <- c(rep(1:4, 12), 1, 3, 3, 1, rep(1:4, 12), rep(1:4, 25))
n0 <- sapply(split(treatment[treatment == "pbo"], stratum[treatment == "pbo"]), length)
n1 <- sapply(split(treatment[treatment == "exp"], stratum[treatment == "exp"]), length)
x0 <- sapply(split(response[treatment == "pbo"], stratum[treatment == "pbo"]), sum)
x1 <- sapply(split(response[treatment == "exp"], stratum[treatment == "exp"]), sum)
strata <- c("a", "b", "c", "d")
rate_compare_sum(
  n0, n1, x0, x1,
  strata,
  delta = 0,
  weight = "ss",
  test = "one.sided",
  alpha = 0.05
)
```

---

tlf\_ae\_exp\_adj

*Exposure-adjusted AE summary table*


---

**Description**

Exposure-adjusted AE summary table

**Usage**

```
tlf_ae_exp_adj(
  outdata,
  source,
  col_rel_width = NULL,
  text_font_size = 9,
  orientation = "portrait",
  title = c("analysis", "observation", "population"),
  footnotes = NULL,
  path_outdata = NULL,
  path_outtable = NULL
)
```

**Arguments**

outdata	An outdata object created by <code>prepare_ae_specific()</code> .
source	A character value of the data source.
col_rel_width	Column relative width in a vector e.g. <code>c(2,1,1)</code> refers to 2:1:1. Default is NULL for equal column width.
text_font_size	Text font size. To vary text font size by column, use numeric vector with length of vector equal to number of columns displayed e.g. <code>c(9,20,40)</code> .
orientation	Orientation in 'portrait' or 'landscape'.
title	Term "analysis", "observation" and "population") for collecting title from meta-data or a character vector of table titles.
footnotes	A character vector of table footnotes.
path_outdata	A character string of the outdata path.
path_outtable	A character string of the outtable path.

**Value**

RTF file and source dataset for exposure-adjusted AE summary table.

**Examples**

```
meta <- meta_ae_example()
outdata <- meta |>
  prepare_ae_summary(
    population = "apat",
    observation = "wk12",
    parameter = "any;rel;ser"
  ) |>
  extend_ae_summary_eaer(adj_unit = "month")
outdata |>
  format_ae_exp_adj() |>
  tlf_ae_exp_adj(
    source = "Source: [CDISCPilot: adam-adsl; adae]",
    path_outdata = tempfile(fileext = ".Rdata"),
    path_outtable = tempfile(fileext = ".rtf")
  )
```

---

tlf\_ae\_listing

*Generate AE listing*


---

**Description**

Generate AE listing

**Usage**

```
tlf_ae_listing(  
  outdata,  
  footnotes = NULL,  
  source = NULL,  
  col_rel_width = NULL,  
  text_font_size = 9,  
  orientation = "landscape",  
  path_outdata = NULL,  
  path_outtable = NULL  
)
```

**Arguments**

outdata	An outdata object created by <a href="#">prepare_ae_listing()</a> .
footnotes	A character vector of table footnotes.
source	A character value of the data source.
col_rel_width	Column relative width in a vector e.g. <code>c(2,1,1)</code> refers to 2:1:1. Default is NULL for equal column width.
text_font_size	Text font size. To vary text font size by column, use numeric vector with length of vector equal to number of columns displayed e.g. <code>c(9,20,40)</code> .
orientation	Orientation in 'portrait' or 'landscape'.
path_outdata	A character string of the outdata path.
path_outtable	A character string of the outtable path.

**Value**

RTF file and the source dataset for AE listing.

**Examples**

```
library(r2rtf)  
library(metalite)  
  
meta <- meta_ae_example()  
prepare_ae_listing(meta, "ae_listing", "apat", "wk12", "ser") |>  
  tlf_ae_listing(  
    footnotes = "footnote1",  
    source = "Source: [CDISCPilot: adam-adsl; adae]",  
    path_outdata = tempfile(fileext = ".Rdata"),  
    path_outtable = tempfile(fileext = ".rtf")  
  )
```

---

tlf_ae_specific	<i>Specific adverse events table</i>
-----------------	--------------------------------------

---

## Description

Specific adverse events table

## Usage

```
tlf_ae_specific(
  outdata,
  meddra_version,
  source,
  col_rel_width = NULL,
  text_font_size = 9,
  orientation = "portrait",
  footnotes = NULL,
  title = c("analysis", "observation", "population"),
  path_outdata = NULL,
  path_outtable = NULL
)
```

## Arguments

outdata	An outdata object created by <code>prepare_ae_specific()</code> .
meddra_version	A character value of the MedDRA version for this dataset.
source	A character value of the data source.
col_rel_width	Column relative width in a vector e.g. <code>c(2,1,1)</code> refers to 2:1:1. Default is NULL for equal column width.
text_font_size	Text font size. To vary text font size by column, use numeric vector with length of vector equal to number of columns displayed e.g. <code>c(9,20,40)</code> .
orientation	Orientation in 'portrait' or 'landscape'.
footnotes	A character vector of table footnotes.
title	Term "analysis", "observation" and "population") for collecting title from meta-data or a character vector of table titles.
path_outdata	A character string of the outdata path.
path_outtable	A character string of the outtable path.

## Value

RTF file and the source dataset for AE specific table.

## Examples

```
meta <- meta_ae_example()

meta |>
  prepare_ae_specific(
    population = "apat",
    observation = "wk12",
    parameter = "rel"
  ) |>
  format_ae_specific() |>
  tlf_ae_specific(
    source = "Source: [CDISCPilot: adam-adsl; adae]",
    meddra_version = "24.0",
    path_outdata = tempfile(fileext = ".Rdata"),
    path_outtable = tempfile(fileext = ".rtf")
  )
```

---

tlf\_ae\_specific\_subgroup

*Specific adverse events table for subgroup analysis*

---

## Description

Specific adverse events table for subgroup analysis

## Usage

```
tlf_ae_specific_subgroup(
  outdata,
  meddra_version,
  source,
  col_rel_width = NULL,
  text_font_size = 9,
  orientation = "landscape",
  footnotes = NULL,
  title = NULL,
  path_outdata = NULL,
  path_outtable = NULL
)
```

## Arguments

outdata	An outdata object created by <a href="#">prepare_ae_specific()</a> .
meddra_version	A character value of the MedDRA version for this dataset.
source	A character value of the data source.
col_rel_width	Column relative width in a vector e.g. <code>c(2,1,1)</code> refers to 2:1:1. Default is NULL for equal column width.

**text\_font\_size** Text font size. To vary text font size by column, use numeric vector with length of vector equal to number of columns displayed e.g. `c(9,20,40)`.  
**orientation** Orientation in 'portrait' or 'landscape'.  
**footnotes** A character vector of table footnotes.  
**title** Term "analysis", "observation" and "population") for collecting title from meta-data or a character vector of table titles.  
**path\_outdata** A character string of the outdata path.  
**path\_outtable** A character string of the outtable path.

### Value

RTF file and the source dataset for AE specific subgroup analysis table.

### Examples

```

meta <- meta_ae_example()
prepare_ae_specific_subgroup(meta,
  population = "apat",
  observation = "wk12",
  parameter = "rel",
  subgroup_var = "SEX",
  display_subgroup_total = TRUE
) |>
format_ae_specific_subgroup() |>
tlf_ae_specific_subgroup(
  meddra_version = "24.0",
  source = "Source: [CDISCPilot: adam-adsl; adae]",
  path_outtable = tempfile(fileext = ".rtf")
)
  
```

---

tlf_ae_summary	<i>AE summary table</i>
----------------	-------------------------

---

### Description

AE summary table

### Usage

```

tlf_ae_summary(
  outdata,
  source,
  col_rel_width = NULL,
  text_font_size = 9,
  orientation = "portrait",
  title = c("analysis", "observation", "population"),
  footnotes = NULL,
  )
  
```

```

    path_outdata = NULL,
    path_outtable = NULL
  )

```

### Arguments

outdata	An outdata object created by <code>prepare_ae_specific()</code> .
source	A character value of the data source.
col_rel_width	Column relative width in a vector e.g. <code>c(2,1,1)</code> refers to 2:1:1. Default is NULL for equal column width.
text_font_size	Text font size. To vary text font size by column, use numeric vector with length of vector equal to number of columns displayed e.g. <code>c(9,20,40)</code> .
orientation	Orientation in 'portrait' or 'landscape'.
title	Term "analysis", "observation" and "population") for collecting title from meta-data or a character vector of table titles.
footnotes	A character vector of table footnotes.
path_outdata	A character string of the outdata path.
path_outtable	A character string of the outtable path.

### Value

RTF file and the source dataset for AE summary table.

### Examples

```

meta <- meta_ae_example()
outdata <- prepare_ae_summary(meta,
  population = "apat",
  observation = "wk12",
  parameter = "any;rel;ser"
)
outdata |>
  format_ae_summary() |>
  tlf_ae_summary(
    source = "Source: [CDISCPilot: adam-adsl; adae]",
    path_outdata = tempfile(fileext = ".Rdata"),
    path_outtable = tempfile(fileext = ".rtf")
  )

```

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