Package 'tm.ttni'

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Title 'teal' Module for Time-to-Next-Intervention and Time-to-Event Tables

Version 0.1.0

Description Provides an open-source 'teal' module and a reusable table builder for time to next intervention and related time-to-event endpoints. Kaplan-Meier summaries are produced with 'tern' and 'rtables' for both multi-arm (dose-level) and two-arm designs. Hazard ratio, Wald confidence interval, and log-rank p-value are calculated only when exactly two treatment arms are present. The builder can be called without launching 'shiny'.

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URL https://github.com/ygma-bitc/tm.ttni, https://ygma-bitc.github.io/tm.ttni/

BugReports https://github.com/ygma-bitc/tm.ttni/issues

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`build_ttni_table` *Build a TTE / TTNI summary table*

Description

Uses `tern` Kaplan-Meier layout functions for both multi-arm (dose-level) and two-arm designs. Hazard ratio, 95% CI, and log-rank p-value are added only when exactly two arms are present.

Usage

```
build_ttni_table(
  adsl = NULL,
  adtte = NULL,
  arm_var = "TRT01A",
  ref_arm = NULL,
  paramcd = "TTNI",
  timepoints = c(3, 6, 12, 18, 24),
  show_total = NULL,
  include_followup = TRUE,
  surv_stats = NULL,
  landmark_style = c("detailed", "rate_only"),
  conf_type = c("log-log", "log", "plain"),
  conf_level = 0.95,
  compute_hr = NULL,
  title = NULL,
  footnotes = NULL,
  prepped = NULL,
  ...
)
```

Arguments

adsl	ADSL or combined TTE data. Ignored when prepped is supplied.
adtte	Optional ADTTE data frame.
arm_var	Treatment / grouping variable.
ref_arm	Reference arm used for two-arm HR calculations.
paramcd	Analysis parameter code.
timepoints	Landmark months.
show_total	Whether to add a Total column. Defaults to TRUE for multi-arm designs and FALSE for two-arm designs.
include_followup	Whether to include reverse KM follow-up time.
surv_stats	Time-to-event statistics from ttni_surv_time_choices(). NULL uses default_ttni_surv_stats(). mean_sd is a descriptive Mean (SD) of AVAL; the rest are tern::surv_time() statistics. Legacy median / median_ci requests are folded into one median_ci_3d row. The same selection is used for follow-up time when include_followup is TRUE.
landmark_style	"detailed" includes patients remaining at risk; "rate_only" shows rate (95% CI) only.
conf_type	KM CI type passed to tern::control_surv_time().
conf_level	Confidence level.
compute_hr	NULL to auto-detect (two-arm only), or a flag. A request of TRUE on a multi-arm data set is ignored with a warning.
title	Table title. NULL derives a title from paramcd.
footnotes	Optional method footnotes. NULL (default) omits them so the interactive table stays compact; definitions live in the README. Pass default_ttni_footnotes() when a TFL-style footer is required.
prepped	Optional list from prep_ttni_data(). When supplied, raw adsl / adtte are not re-prepared.
...	Passed to prep_ttni_data() when prepped is NULL.

Details

Pass either raw adsl / adtte or a list returned by prep_ttni_data() via prepped so the teal server can prepare data once.

Value

An rtables VTableTree.

Examples

```
two_arm <- make_synthetic_ttni_data("two_arm", seed = 1L)
build_ttni_table(two_arm$ADSL, two_arm$ADTTE, ref_arm = "Placebo")

multi <- make_synthetic_ttni_data("multi_arm", seed = 1L)
build_ttni_table(multi$ADSL, multi$ADTTE, show_total = TRUE)
```

---

default_ttni_censor_levels

Default TTE censor-reason labels

Description

Default TTE censor-reason labels

Usage

```
default_ttni_censor_levels()
```

Value

Character vector of preferred censoring descriptions.

---

default_ttni_event_levels

Default TTE event-reason labels

Description

Generic labels used when `EVNTDESC` is missing or to order known reasons. Study-specific wording (for example a named investigational product) should be supplied by the caller, not baked into the package defaults.

Usage

```
default_ttni_event_levels()
```

Value

Character vector of preferred event descriptions.

default_ttni_footnotes

Default TTE footnotes

Description

Default TTE footnotes

Usage

```
default_ttni_footnotes(compute_hr = FALSE, conf_type = "log-log")
```

Arguments

compute_hr	logical(1) Whether inferential statistics are shown.
conf_type	character(1) KM confidence-interval type.

Value

Character vector of footer notes.

default_ttni_surv_stats

Default time-to-event statistics shown in the module

Description

Includes descriptive Mean (SD) of AVAL plus Kaplan-Meier median (95% CI), quartiles, and range.

Usage

```
default_ttni_surv_stats()
```

Value

Character vector of statistic names from ttni_surv_time_choices().

derive_mock_adtte *Derive a simple OS-style ADTTE from ADSL death / last-alive dates*

Description

Used when a local CDISC Pilot checkout has ADSL but no ADTTE, or when a demo needs a second PARAMCD alongside a native TTE dataset.

Usage

```
derive_mock_adtte(adsl, paramcd = "OS", param = "Overall Survival")
```

Arguments

adsl	Standardized ADSL with TRTSDT and either DTHDT / DTHFL or LSTALVDT.
paramcd	Parameter code to assign.
param	Parameter label.

Value

An ADTTE-like data frame.

detect_arm_design *Detect whether a TTE table should use two-arm inferential statistics*

Description

TTNI can appear in a multi-dose Phase 1/2 study or a two-arm randomized trial. Hazard ratio, Wald CI, and log-rank p-value are only appropriate when exactly two treatment arms are present.

Usage

```
detect_arm_design(data, arm_var, ref_arm = NULL)
```

Arguments

data	A data frame containing the treatment variable.
arm_var	character(1) Treatment / grouping variable name.
ref_arm	character(1) or NULL Reference arm. Defaults to the first factor level (or first unique value).

Value

A list with n_arms, arms, ref_arm, comp_arms, design (single_arm, two_arm, or multi_arm), and compute_hr.

Examples

```
detect_arm_design(
  data.frame(TRT01A = c("Placebo", "Drug")),
  arm_var = "TRT01A",
  ref_arm = "Placebo"
)
```

`make_synthetic_ttni_data` *Build synthetic ADSL / ADTTE fixtures for TTE demos and tests*

Description

Returns a subject-level ADSL and a BDS-style ADTTE with two parameters: `TTNI` (time to next intervention) and `OS` (overall survival). The two data frames are distinct objects.

Usage

```
make_synthetic_ttni_data(
  design = c("two_arm", "multi_arm"),
  n_per_arm = 40L,
  seed = 20260823L
)
```

Arguments

`design`	`character(1)` Either `"two_arm"` (randomized comparison) or `"multi_arm"` (three generic arms; no study-specific dose labels).
`n_per_arm`	`integer(1)` Subjects per arm.
`seed`	`integer(1)` Random seed.

Value

A list with `ADSL` and `ADTTE`.

Examples

```
data <- make_synthetic_ttni_data(design = "two_arm", seed = 1L)
names(data)
unique(data$ADTTE$PARAMCD)
```

`prep_ttni_data` *Prepare ADSL / ADTTE records for a TTE table*

Description

Accepts either a single ADSL-like data frame that already contains TTE variables (`PARAMCD`, `AVAL`, `CNSR`, `EVNTDESC`) or a separate ADTTE data frame joined to ADSL by subject. An empty result after filtering is returned as a structured list (`empty = TRUE`) rather than an error so the teal module can show a no-data message.

Usage

```
prep_ttni_data(
  adsl,
  adtte = NULL,
  arm_var = "TRT01A",
  ref_arm = NULL,
  paramcd = "TTNI",
  subject_var = "USUBJID",
  paramcd_var = "PARAMCD",
  aval_var = "AVAL",
  cnsr_var = "CNSR",
  evntdesc_var = "EVNTDESC",
  population_var = "SAFFL",
  population_value = "Y"
)
```

Arguments

`adsl`	ADSL or combined subject-level TTE data.
`adtte`	Optional ADTTE data frame. If `NULL`, `adsl` is used as the TTE source.
`arm_var`	Treatment / grouping variable.
`ref_arm`	Optional reference arm for two-arm comparisons.
`paramcd`	Analysis parameter code.
`subject_var`	Subject identifier.
`paramcd_var`	PARAMCD variable name.
`aval_var`	Analysis value variable.
`cnsr_var`	Censor variable (`0` = event).
`evntdesc_var`	Event / censor description variable.
`population_var`	Optional population flag variable.
`population_value`	Population flag value to keep.

Value

A list with analysis data, design metadata, description levels, and `empty` (`TRUE` when no records remain).

`standardize_adsl` *Standardize an ADSL-like data frame for TTE tables*

Description

Harmonizes common CDISC Pilot / `random.cdisc.data` column variants so `prep_ttni_data()` can join treatment and population flags.

Usage

```
standardize_adsl(adsl)
```

Arguments

`adsl`	A data frame with at least `USUBJID`.

Value

A standardized ADSL data frame.

`standardize_adtte` *Standardize an ADTTE-like data frame*

Description

Ensures `PARAMCD` / `PARAM` / `AVAL` / `CNSR` exist and converts day-valued `AVAL` to months when `AVALU` is `DAYS`.

Usage

```
standardize_adtte(adtte, adsl = NULL, default_avalu = NULL)
```

Arguments

`adtte`	A data frame with at least `USUBJID` and a time-to-event value.
`adsl`	Optional standardized ADSL used to back-fill `TRT01A`.
`default_avalu`	Unit used when `AVALU` is missing. `NULL` infers `DAYS` when the maximum `AVAL` exceeds 60, otherwise `MONTHS`.

Value

A standardized ADTTE data frame.

tm_t_ttni *teal Module: Time to Next Intervention and related TTE tables*

Description

Interactive TTE table. Kaplan-Meier summaries are always shown. Hazard ratio, 95% CI, and log-rank p-value appear only when the selected grouping variable has exactly two arms. PARAMCD, the grouping variable, and the population flag are selected with `teal.picks`.

Usage

```
tm_t_ttni(
  label = "Time to Next Intervention (TTNI)",
  cat = NULL,
  adsl_name = "ADSL",
  tte_name = "ADTTE",
  paramcd = "TTNI",
  group_vars = NULL,
  population_var = NULL,
  population_value = "Y",
  population_choices = NULL,
  timepoints = c(3, 6, 12, 18, 24),
  landmark_style = c("detailed", "rate_only"),
  surv_stats = default_ttni_surv_stats(),
  include_followup = TRUE,
  show_total = NULL,
  compute_hr = NULL,
  conf_type = c("log-log", "log", "plain"),
  title = NULL
)
```

Arguments

`label`	Module label.
`cat`	(`picks` or legacy `choices_selected`) PARAMCD selector. When `NULL`, a `teal.picks::picks()` object is built: `datasets` is `tte_name`, `variables` is fixed to `PARAMCD` with `multiple = FALSE`, and `values` selects `paramcd` with `multiple = FALSE`. A `teal.transform::choices_` object is still accepted, with a deprecation warning, and converted to that picks shape.
`adsl_name`	ADSL dataset name in `teal_data`.
`tte_name`	ADTTE dataset name.
`paramcd`	Default PARAMCD stored in `values$selected` when `cat` is `NULL`.
`group_vars`	(`picks` or legacy character) grouping column. When `NULL`, `datasets` is `adsl_name` and `variables` is `TRT01A` (`multiple = FALSE`). A character vector of column names is still accepted, with a deprecation warning. Names on that vector were display labels and are dropped.

`population_var` (`picks` or legacy character) population-flag column. When `NULL` and `population_choices` is `NULL`, `datasets` is `adsl_name` and `variables` offers `SAFFL` and `ITTFL`, with `SAFFL` selected (`multiple = FALSE`).

`population_value` Population flag value to keep.

`population_choices` Legacy character vector of flag columns. Ignored when `population_var` is a `picks` object. Passing either this or a character `population_var` signals a deprecation warning.

`timepoints` Default landmark months.

`landmark_style` `"detailed"` or `"rate_only"`.

`surv_stats` Initial time-to-event statistics from `ttni_surv_time_choices()`.

`include_followup` Whether reverse KM follow-up is shown.

`show_total` Initial Total-column setting. `NULL` follows design.

`compute_hr` Leave `NULL` to auto-detect two-arm only.

`conf_type` KM CI type.

`title` Table title. `NULL` derives a title from the selected PARAMCD.

Value

A `teal` module object.

Examples

```
if (interactive()) {
  data <- make_synthetic_ttni_data("two_arm")
  app_data <- teal.data::teal_data(ADSL = data$ADSL, ADTTE = data$ADTTE)
  paramcd_choices <- unique(as.character(data$ADTTE$PARAMCD))
  app <- teal::init(
    data = app_data,
    modules = teal::modules(
      tm_t_ttni(
        label = "TTNI",
        cat = teal.picks::picks(
          teal.picks::datasets(choices = "ADTTE", selected = "ADTTE"),
          teal.picks::variables(
            choices = "PARAMCD",
            selected = "PARAMCD",
            multiple = FALSE,
            fixed = TRUE
          ),
          teal.picks::values(
            choices = paramcd_choices,
            selected = "TTNI",
            multiple = FALSE
          )
        ),
```

```
        group_vars = teal.picks::picks(
          teal.picks::datasets(choices = "ADSL", selected = "ADSL"),
          teal.picks::variables(
            choices = c("TRT01A", "SEX"),
            selected = "TRT01A",
            multiple = FALSE
          )
        ),
        population_var = teal.picks::picks(
          teal.picks::datasets(choices = "ADSL", selected = "ADSL"),
          teal.picks::variables(
            choices = c("SAFFL", "ITTFL"),
            selected = "SAFFL",
            multiple = FALSE
          )
        )
      )
    )
  )
  shiny::shinyApp(app$ui, app$server)
}
```

`ttni_surv_time_choices`

Time-to-event statistics offered in the module

Description

`mean_sd` is a descriptive summary of `AVAL` (one row). The remaining names are `tern::surv_time()` statistics, shown in tern's native order. `quantiles` and `range` are labeled `Q1, Q3` and `Min, Max`. Separate `median` / `median_ci` rows are not offered; use `median_ci_3d` so median and 95% CI stay on one line.

Usage

```
ttni_surv_time_choices()
```

Value

A named character vector (`label = stat`).

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