Package: dtptite (via r-universe)

October 21, 2026

Title Dose Transition Pathways for Time-to-Event Dose-Finding Designs

Version 0.1.0

Description Implements the Dose Transition Pathways (DTP) look-ahead strategy for time-to-event phase I dose-finding clinical trials with delayed or pending toxicity outcomes. Provides a DTP decorator for the 'escalation' framework, supporting both TITE-CRM (model-based) and TITE-BOIN (model-assisted) base designs.

License GPL (>= 3)

URL https://github.com/ICR-EPAT/dtptite

BugReports https://github.com/ICR-EPAT/dtptite/issues

Depends R (>= 4.1.0)

Imports BOIN, dplyr, escalation (>= 0.2.0), stats, tibble

Suggests dfcrm, ggplot2, testthat (>= 3.0.0), TITEgBOIN

Config/testthat/edition 3

Encoding UTF-8

RoxygenNote 7.3.3

NeedsCompilation no

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Repository https://cran.r-universe.dev

Date/Publication 2026-10-21 15:23:33 UTC

RemoteUrl https://github.com/cran/dtptite

RemoteRef HEAD

RemoteSha da91febff1fe9fa71ea703ec49b12c98cb0be1ef

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`apply_dtp` *Apply the DTP look-ahead to a TITE selector factory.*

Description

Wraps a parent TITE selector factory with the Dose Transition Pathways projection engine. At fit time, the decorator checks whether waiting for pending patients' follow-up (up to `t_max`) could change the dose recommendation upward.

Usage

```
apply_dtp(
  parent_selector_factory,
  t_max,
  obswin,
  projection_search = c("binary", "linear"),
  verbose = TRUE
)
```

Arguments

`parent_selector_factory`
: A `selector_factory` (typically from `escalation::get_dfcrm_tite()` or similar TITE model).

`t_max`
: Maximum allowable wait time (numeric >= 0, or `Inf` for unlimited). Must use the same time unit as `obswin`.

`obswin`
: DLT observation window length (e.g. 56 days or 8 weeks). Defines the time-weight mapping: `weight = time_elapsed / obswin`.

`projection_search`
: Strategy used to locate the minimum wait time. `"binary"` (default) screens the top of the candidate range and then bisects, costing `O(log t_max)` model fits. `"linear"` scans every candidate day, costing `O(t_max)` fits. Both return the same answer whenever the projected dose is monotone non-decreasing in wait time, which holds for TITE-CRM and TITE-BOIN; `"linear"` is retained as a verification oracle and an escape hatch for non-monotone parents.

`verbose`
: If `TRUE` (default), emit an informational message when `t_max` covers all remaining follow-up. Set to `FALSE` in simulation, where this fires on nearly every projection. Affects messaging only, never the returned value.

Value

A `dtp_selector_factory` object.

Examples

```
library(escalation)
design <- get_dfcrm_tite(skeleton = c(0.124, 0.25, 0.398, 0.542, 0.666),
                         target = 0.25) |>
  apply_dtp(t_max = 35, obswin = 56)

# Four patients at dose 2: one DLT, and the last patient is only 30% of the
# way through the observation window.
outcomes <- data.frame(dose = c(2, 2, 2, 2), tox = c(0, 1, 0, 0),
                       weight = c(1, 1, 1, 0.3), cohort = 1:4)
x <- fit(design, outcomes)

recommended_dose(x)                # de-escalate now...
dtp_should_wait(x)                 # ...but waiting could change that
dtp_wait_time(x)                   # days to wait
dtp_wait_time(x, type = "weight")  # the same wait as a weight increment
dtp_projected_dose(x)              # recommendation after the wait
```

`dtp_projected_dose` *Projected dose after waiting.*

Description

Projected dose after waiting.

Usage

```
dtp_projected_dose(x, ...)
```

Arguments

`x`
: A `dtp_selector` object.

`...`
: Additional arguments (unused).

Value

Integer dose level, or NA if waiting has no benefit.

Examples

```
library(escalation)
design <- get_dfcrm_tite(skeleton = c(0.124, 0.25, 0.398, 0.542, 0.666),
                         target = 0.25) |>
  apply_dtp(t_max = 35, obswin = 56)

# Four patients at dose 2: one DLT, and the last patient is only 30% of the
# way through the observation window.
outcomes <- data.frame(dose = c(2, 2, 2, 2), tox = c(0, 1, 0, 0),
                       weight = c(1, 1, 1, 0.3), cohort = 1:4)
x <- fit(design, outcomes)

recommended_dose(x)                # de-escalate now...
dtp_should_wait(x)                 # ...but waiting could change that
dtp_wait_time(x)                   # days to wait
dtp_wait_time(x, type = "weight")  # the same wait as a weight increment
dtp_projected_dose(x)              # recommendation after the wait
```

---

dtp_should_wait *Should the trialist wait before dosing the next cohort?*

Description

Returns TRUE if the DTP projection found that waiting could lead to a higher dose recommendation within t_max.

Usage

```
dtp_should_wait(x, ...)
```

Arguments

x	A dtp_selector object.
...	Additional arguments (unused).

Value

Logical scalar.

Examples

```
library(escalation)
design <- get_dfcrm_tite(skeleton = c(0.124, 0.25, 0.398, 0.542, 0.666),
                         target = 0.25) |>
  apply_dtp(t_max = 35, obswin = 56)

# Four patients at dose 2: one DLT, and the last patient is only 30% of the
# way through the observation window.
outcomes <- data.frame(dose = c(2, 2, 2, 2), tox = c(0, 1, 0, 0),
                       weight = c(1, 1, 1, 0.3), cohort = 1:4)
x <- fit(design, outcomes)

recommended_dose(x)                # de-escalate now...
dtp_should_wait(x)                 # ...but waiting could change that
dtp_wait_time(x)                   # days to wait
dtp_wait_time(x, type = "weight")  # the same wait as a weight increment
dtp_projected_dose(x)              # recommendation after the wait
```

`dtp_wait_events` *Raw DTP wait event log from simulated trials.*

Description

Returns a tidy tibble with one row per DTP wait event fired across all simulated replicates. This is the single source of truth from which all DTP wait summaries are derived; users who want metrics not covered by `dtp_wait_summary()` can compute them directly from this table.

Usage

```
dtp_wait_events(x, ...)
```

Arguments

`x`	A `simulations` or `simulations_collection` object.
`...`	Unused.

Details

Replicates with zero waits contribute zero rows (but are still reflected in `dtp_wait_summary()` with explicit `0`s). Replicates from non-DTP designs contribute zero rows and are flagged by the design carrying no event log at all, not by reporting zero waits.

Value

A tibble with columns `replicate` (and `design` for a `simulations_collection`), `cohort_idx`, `dose_before`, `time_in`, `time_out`, `wait_duration`, `projected_dose`, `dose_after`, `ended_by` (factor: `wait_end`/`dtp_decision`/`stopped`), `dose_delta`, `effective`, `num_extensions`, `n_held`, `n_missed`.

wait_duration is the total elapsed time between when the wait was triggered and when it ended, including any extensions caused by in-wait DLT events: each such event prompts a re-fit, and if the updated fit still requests a wait the original wait_end is bumped out. num_extensions records how many times that happened (0 means the wait ran exactly to its initial projection); as a result wait_duration can exceed the design's t_max.

n_held is the number of patients held through the wait and dosed at wait_end, **including** the cohort opener (the patient the wait is for); it is at least 1 for any wait that doses and ranges up to the cohort size. n_missed is the number who arrived while the wait was running to a full waiting room and were never enrolled. See set_dtp_queue_size() for the room capacity that bounds n_held and produces n_missed.

Examples

```
library(escalation)
design <- get_dfcrm_tite(skeleton = c(0.124, 0.25, 0.398, 0.542, 0.666),
                         target = 0.25) |>
  apply_dtp(t_max = 35, obswin = 56, verbose = FALSE) |>
  stop_at_n(n = 9)

set.seed(456)
sims <- simulate_trials(
  design,
  num_sims = 2,
  true_prob_tox = c(0.05, 0.15, 0.25, 0.35, 0.60),
  sample_patient_arrivals = function(df) {
    cohorts_of_n(n = 3, mean_time_delta = 1)
  },
  max_time = 56
)

dtp_wait_events(sims)
dtp_wait_summary(sims)
dtp_wait_summary(sims, by_dose = TRUE)
```

---

dtp_wait_summary *Per-trial DTP wait summary from simulated trials.*

Description

Aggregates the raw event log returned by dtp_wait_events() into a curated per-replicate (or per-replicate × starting dose) summary.

Usage

```
dtp_wait_summary(x, by_dose = FALSE, ...)
```

Arguments

x	A simulations or simulations_collection object.
by_dose	If TRUE, roll up by (replicate, dose_before); otherwise one row per replicate. Default FALSE.
...	Unused.

Details

With the default by_dose = FALSE, one row per replicate with columns:

- num_waits — how often DTP fired in this trial
- total_wait_time — sum of wait durations
- wait_fraction — total_wait_time / trial_duration, a single comparable "DTP overhead" number. The denominator is the full trial calendar time as returned by escalation::trial_duration(), which includes the post-loop "advance to full follow-up" tail. Use the raw event log if you need a decision-phase-only denominator.
- max_wait_time — longest single wait (for slot / IRB conversations). Can exceed t_max when an in-wait DLT triggers an extension; see dtp_wait_events().
- num_effective_waits — number of waits where the post-wait recommendation was strictly higher than the pre-wait recommendation (dose_after > dose_before). Captures both outright escalations and waits that recovered from an otherwise unnecessary de-escalation.
- num_missed — per-trial sum of the event-log n_missed: patients who presented during a wait to a full waiting room and were never enrolled. This is DTP's accrual cost, and is zero whenever no wait ran longer than the room capacity allows.

With by_dose = TRUE, one row per (replicate × dose_before). wait_fraction (needs a whole-trial denominator) is dropped and a mean_wait_time column is added; max_wait_time and num_effective_waits are retained per dose level.

Non-DTP designs — those whose simulation did not attach a wait event log at all — return all-NA metric columns so that users can distinguish "design did not run under DTP" from "ran under DTP and never waited" (num_waits = 0).

On a simulations_collection (e.g. the return value of simulate_compare), both accessors prepend a design column naming the arm.

Value

A tibble. See Details for columns.

Examples

```
library(escalation)
design <- get_dfcrm_tite(skeleton = c(0.124, 0.25, 0.398, 0.542, 0.666),
                         target = 0.25) |>
  apply_dtp(t_max = 35, obswin = 56, verbose = FALSE) |>
  stop_at_n(n = 9)

set.seed(456)
```

```
sims <- simulate_trials(
  design,
  num_sims = 2,
  true_prob_tox = c(0.05, 0.15, 0.25, 0.35, 0.60),
  sample_patient_arrivals = function(df) {
    cohorts_of_n(n = 3, mean_time_delta = 1)
  },
  max_time = 56
)

dtp_wait_events(sims)
dtp_wait_summary(sims)
dtp_wait_summary(sims, by_dose = TRUE)
```

`dtp_wait_time` *Minimum wait time before the dose recommendation changes.*

Description

Minimum wait time before the dose recommendation changes.

Usage

```
dtp_wait_time(x, type = c("time", "weight"), ...)
```

Arguments

`x`	A `dtp_selector` object.
`type`	Character: `"time"` (default) returns wait in the user's time units (same as `t_max` and `obswin`); `"weight"` returns the corresponding weight increment.
`...`	Additional arguments (unused).

Value

Numeric scalar (0 if no benefit from waiting).

Examples

```
library(escalation)
design <- get_dfcrm_tite(skeleton = c(0.124, 0.25, 0.398, 0.542, 0.666),
                         target = 0.25) |>
  apply_dtp(t_max = 35, obswin = 56)

# Four patients at dose 2: one DLT, and the last patient is only 30% of the
# way through the observation window.
outcomes <- data.frame(dose = c(2, 2, 2, 2), tox = c(0, 1, 0, 0),
                       weight = c(1, 1, 1, 0.3), cohort = 1:4)
x <- fit(design, outcomes)
```

```
recommended_dose(x)                # de-escalate now...
dtp_should_wait(x)                 # ...but waiting could change that
dtp_wait_time(x)                   # days to wait
dtp_wait_time(x, type = "weight")  # the same wait as a weight increment
dtp_projected_dose(x)              # recommendation after the wait
```

`get_boin_tite` *Create a TITE-BOIN dose-finding selector.*

Description

Returns a selector factory for the BOIN design with TITE (time-to-event) support via effective sample sizes. This is a barebone selector: stopping, elimination, and overdose control are added via piping (e.g. `stop_for_beta_binomial_toxicity`, `dont_skip_doses`).

Usage

```
get_boin_tite(
  num_doses,
  target,
  p.saf = 0.6 * target,
  p.tox = 1.4 * target,
  ...
)
```

Arguments

`num_doses`	Number of doses under investigation.
`target`	Target toxicity probability.
`p.saf`	Safety boundary parameter (default `0.6 * target`).
`p.tox`	Toxicity boundary parameter (default `1.4 * target`).
`...`	Extra arguments stored for future use.

Value

A `boin_tite_selector_factory` object.

Examples

```
# Barebone — pure dose decision
library(escalation)
get_boin_tite(5, 0.25) %>%
  fit(data.frame(dose = c(1,1,1), tox = c(0,0,0),
                 weight = c(1,1,1), cohort = c(1,1,1)))
```

plot.time_to_first_mtd

Plot the cumulative incidence of reaching the MTD.

Description

Draws, for each design, the proportion of replicates in which a patient had been dosed at the true MTD by a given point. The curve plateaus at `reached_fraction`; replicates that never reached the MTD keep it below 1.

Usage

```
## S3 method for class 'time_to_first_mtd'
plot(x, axis = c("time", "patients"), ci = FALSE, conf = 0.95, ...)
```

Arguments

`x`	A `time_to_first_mtd` object.
`axis`	`"time"` (default) plots calendar time since trial start; `"patients"` plots the number of patients dosed beforehand.
`ci`	If `TRUE`, add pointwise Wilson intervals for Monte Carlo error. Default `FALSE`.
`conf`	Confidence level for the intervals. Default `0.95`.
`...`	Unused.

Value

A `ggplot` object.

Examples

```
library(escalation)
skeleton <- c(0.124, 0.25, 0.398, 0.542, 0.666)
designs <- list(
  `TITE-CRM` = get_dfcrm_tite(skeleton = skeleton, target = 0.25) |>
    stop_at_n(n = 18),
  `DTP + TITE-CRM` = get_dfcrm_tite(skeleton = skeleton, target = 0.25) |>
    apply_dtp(t_max = 35, obswin = 56, verbose = FALSE) |>
    stop_at_n(n = 18)
)

set.seed(456)
sims <- simulate_compare(
  designs,
  num_sims = 10,
  true_prob_tox = c(0.05, 0.15, 0.25, 0.35, 0.60),
  sample_patient_arrivals = function(df) {
    cohorts_of_n(n = 3, mean_time_delta = 1)
```

```
  },
  max_time = 56,
  i_like_big_trials = TRUE
)

ttm <- time_to_first_mtd(sims)
ttm
summary(ttm)
if (requireNamespace("ggplot2", quietly = TRUE)) {
  plot(ttm)
}
```

`scenario_mtd` *True MTD of a simulated scenario.*

Description

Identifies the dose whose true toxicity probability lies within `tol` of the target. When several doses qualify the lowest is returned. When none qualifies the scenario has no MTD and `NA` is returned with a warning.

Usage

```
scenario_mtd(true_prob_tox, target, tol = 0.05)
```

Arguments

`true_prob_tox`	Numeric vector of true toxicity probabilities, one per dose.
`target`	Target toxicity probability.
`tol`	Half-width of the acceptance band. A dose qualifies when `abs(true_prob_tox - target) <= tol`. Default `0.05`.

Value

Integer dose index, or `NA_integer_` when no dose qualifies.

Examples

```
scenario_mtd(c(0.05, 0.15, 0.25, 0.35, 0.60), target = 0.25)

# Two doses inside the band: the lowest is the MTD
scenario_mtd(c(0.05, 0.22, 0.27, 0.50), target = 0.25)
```

`set_dtp_queue_size` *Set the waiting-room capacity for DTP simulation.*

Description

Recruitment onto the trial is shut for the duration of a DTP wait, but the pool of available patients keeps accruing. Patients who present during a wait are held — up to `queue_size` of them — and dosed at the post-wait recommendation the moment the wait ends. Patients who present when the room is already full are **not enrolled**; they are the accrual cost of waiting, reported as the `n_missed` column of `dtp_wait_events()`.

Usage

```
set_dtp_queue_size(dtp_selector_factory, queue_size)
```

Arguments

`dtp_selector_factory`
: A `dtp_selector_factory` created by `apply_dtp()`.

`queue_size`
: Integer >= 0, and no greater than the cohort size. Default (when not set) equals the cohort size, inferred at simulation time from the first `sample_patient_arrivals` call. Values below 1 behave as 1; see Details.

Details

A patient is therefore missed exactly when `wait_duration` > `queue_size` * `accrual_gap`, which concentrates the cost at small cohort sizes.

The patient whose arrival opened the cohort is always held — they are the reason the wait is being taken — so they occupy one slot and values below 1 behave as 1. At cohort size 1 the capacity therefore cannot bind: a single-patient cohort has no room for anyone else whatever this is set to. The knob only does work for cohorts of 2 or more.

Value

The modified `dtp_selector_factory` (invisibly).

Examples

```
library(escalation)
design <- get_dfcrm_tite(skeleton = c(0.124, 0.25, 0.398, 0.542, 0.666),
                         target = 0.25) |>
  apply_dtp(t_max = 35, obswin = 56)

# Hold at most two patients while a wait runs
set_dtp_queue_size(design, 2)
```

stop_for_beta_binomial_toxicity

Stop for excessive toxicity using a Beta-Binomial conjugate posterior.

Description

Creates a stopping decorator that monitors one or more doses and halts the trial when the posterior probability of the true toxicity rate exceeding `tox_threshold` is greater than `confidence`.

Usage

```
stop_for_beta_binomial_toxicity(
  parent_selector_factory,
  dose = 1,
  tox_threshold,
  confidence = 0.88,
  a = NULL,
  b = NULL,
  n_min = 1
)
```

Arguments

`parent_selector_factory`	A `selector_factory` object.
`dose`	Which dose(s) to monitor. A numeric scalar (e.g. `1`), numeric vector (e.g. `c(1, 2)`), `"recommended"`, or `"any"`. Default: `1`.
`tox_threshold`	Toxicity probability threshold. Required.
`confidence`	Posterior exceedance cutoff (default: `0.88`).
`a, b`	Beta prior hyperparameters. When `NULL` (default), resolved at fit time from `tox_target()` of the parent selector: `a = tox_target, b = 1 - tox_target`.
`n_min`	Minimum number of patients at a dose required before the exceedance check fires (default: `1`). Mirrors TITEgBOIN's `Neli` parameter — set to `3` to match TITEgBOIN's default elimination rule.

Value

A `beta_binom_tox_selector_factory` object.

Examples

```
library(escalation)
design <- get_dfcrm_tite(skeleton = c(0.124, 0.25, 0.398, 0.542, 0.666),
                         target = 0.25) |>
  stop_for_beta_binomial_toxicity(dose = 1, tox_threshold = 0.25,
                                  confidence = 0.70)
```

```
# Three DLTs in four patients at the lowest dose stops the trial
outcomes <- data.frame(dose = c(1, 1, 1, 1), tox = c(1, 1, 0, 1),
                       weight = c(1, 1, 1, 1), cohort = 1:4)
x <- fit(design, outcomes)
continue(x)
recommended_dose(x)
```

---

summary.time_to_first_mtd *Summarise time-to-first-MTD across replicates.*

Description

Summarise time-to-first-MTD across replicates.

Usage

```
## S3 method for class 'time_to_first_mtd'
summary(object, probs = NULL, ...)
```

Arguments

object	A time_to_first_mtd object.
probs	Optional numeric vector of probabilities for additional quantile columns. Must be distinct values between 0 and 1. Default NULL adds none.
...	Unused.

Details

Columns:

- num_sims — replicates simulated
- mtd — dose treated as the true MTD
- num_reached — replicates in which a patient was dosed at mtd
- reached_fraction — num_reached / num_sims; NA when the scenario has no MTD
- median_time_to_mtd — median of the cumulative incidence of reaching the MTD. NA unless more than half of replicates reached it, because the quantile is otherwise undefined — including when exactly half did
- median_n_before_mtd — median patients dosed before the MTD, over replicates that reached it

Replicates that never reached the MTD remain in the denominator; they are not dropped. Any probability supplied in probs adds a q<pct>_time_to_mtd column, computed the same way and likewise NA beyond reached_fraction. The percentage is not rounded, so 0.125 gives q12.5_time_to_mtd; distinct probabilities always get distinct columns.

Value

A tibble with one row per design.

Examples

```
library(escalation)
skeleton <- c(0.124, 0.25, 0.398, 0.542, 0.666)
designs <- list(
  `TITE-CRM` = get_dfcrm_tite(skeleton = skeleton, target = 0.25) |>
    stop_at_n(n = 18),
  `DTP + TITE-CRM` = get_dfcrm_tite(skeleton = skeleton, target = 0.25) |>
    apply_dtp(t_max = 35, obswin = 56, verbose = FALSE) |>
    stop_at_n(n = 18)
)

set.seed(456)
sims <- simulate_compare(
  designs,
  num_sims = 10,
  true_prob_tox = c(0.05, 0.15, 0.25, 0.35, 0.60),
  sample_patient_arrivals = function(df) {
    cohorts_of_n(n = 3, mean_time_delta = 1)
  },
  max_time = 56,
  i_like_big_trials = TRUE
)

ttm <- time_to_first_mtd(sims)
ttm
summary(ttm)
if (requireNamespace("ggplot2", quietly = TRUE)) {
  plot(ttm)
}
```

---

time_to_first_mtd *Time until the first patient is dosed at the true MTD.*

Description

Returns one row per simulated replicate recording when, if ever, a patient was first treated at the scenario's true MTD.

Usage

```
time_to_first_mtd(x, mtd = NULL, tol = 0.05, ...)
```

Arguments

x	A simulations or simulations_collection object.
mtd	Dose index to treat as the true MTD. NULL (default) derives it with scenario_mtd(); NA declares the scenario to have no MTD.
tol	Passed to scenario_mtd() when deriving the MTD. Default 0.05.
...	Unused.

Details

Times are dosing times measured from the start of the trial (t = 0). For designs without DTP a patient is dosed on arrival, so dosing time equals recruitment time; for patients held in a DTP queue it is the instant the wait ends and they are dosed.

Columns:

- replicate — index of the simulated trial (and design for a simulations_collection)
- mtd — the dose treated as the true MTD
- time_to_mtd — dosing time of the first patient given mtd, or NA if no patient was given it before the trial ended
- reached — whether any patient was dosed at mtd; NA when the scenario has no MTD
- n_before_mtd — patients dosed strictly earlier than that patient, or NA if the MTD was never given

When the scenario has no MTD (no dose within tol of the target) every row carries mtd = NA and reached = NA, distinguishing "no MTD to reach" from "an MTD existed and was not reached" (reached = FALSE).

The number of replicates is recorded in a num_sims attribute and is used as the denominator by summary.time_to_first_mtd().

Value

A tibble of class time_to_first_mtd. See Details for columns.

Examples

```
library(escalation)
skeleton <- c(0.124, 0.25, 0.398, 0.542, 0.666)
designs <- list(
  `TITE-CRM` = get_dfcrm_tite(skeleton = skeleton, target = 0.25) |>
    stop_at_n(n = 18),
  `DTP + TITE-CRM` = get_dfcrm_tite(skeleton = skeleton, target = 0.25) |>
    apply_dtp(t_max = 35, obswin = 56, verbose = FALSE) |>
    stop_at_n(n = 18)
)

set.seed(456)
sims <- simulate_compare(
  designs,
  num_sims = 10,
```

```
  true_prob_tox = c(0.05, 0.15, 0.25, 0.35, 0.60),
  sample_patient_arrivals = function(df) {
    cohorts_of_n(n = 3, mean_time_delta = 1)
  },
  max_time = 56,
  i_like_big_trials = TRUE
)

ttm <- time_to_first_mtd(sims)
ttm
summary(ttm)
if (requireNamespace("ggplot2", quietly = TRUE)) {
  plot(ttm)
}
```

`tite_patient_samples` *Create patient samples with realistic TITE DLT timing.*

Description

Generates a list of escalation::PatientSample objects whose `tox_time` values are drawn from `U(0, max_time)` instead of the default `U(0, 1)`. Pass the result to `escalation::simulate_compare()` or `escalation::simulate_trials()` via `patient_samples`.

Usage

```
tite_patient_samples(num_sims, max_time, num_patients = 100)
```

Arguments

`num_sims`	Number of simulation replicates.
`max_time`	DLT observation window (e.g. 56 days). Must match the `max_time` argument passed to `simulate_compare` / `simulate_trials`.
`num_patients`	Number of latent patients per sample (default 100).

Value

A list of length `num_sims`, each element a `PatientSample`.

Examples

```
samples <- tite_patient_samples(num_sims = 2, max_time = 56)
length(samples)
```

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