Package: SingleArmMRCT (via r-universe)

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Type Package

Title Regional Consistency Probability for Single-Arm Multi-Regional Clinical Trials

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Description Provides functions to calculate and visualise the Regional Consistency Probability (RCP) for single-arm multi-regional clinical trials (MRCTs) using the Effect Retention Approach (ERA). Six endpoint types are supported: continuous, binary, count (negative binomial), time-to-event via hazard ratio, milestone survival, and restricted mean survival time (RMST). For each endpoint, both a closed-form (or semi-analytical) solution and a Monte Carlo simulation approach are implemented. Two consistency evaluation methods are available: Method 1 (effect retention in Region 1 relative to the overall population) and Method 2 (simultaneous positive effect across all regions). Plotting functions generate faceted visualisations of RCP as a function of the regional allocation proportion, overlaying formula and simulation results for direct comparison. The methodology follows the Japanese MHLW guidelines for MRCTs. Abbreviations used: RCP (Regional Consistency Probability), MRCT (Multi-Regional Clinical Trial), RMST (Restricted Mean Survival Time), MHLW (Ministry of Health, Labour and Welfare).

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`plot_rcp1armBinary` *Plot Regional Consistency Probability for Single-Arm MRCT (Binary Endpoint)*

Description

Generate a faceted plot of Regional Consistency Probability (RCP) as a function of the regional allocation proportion f_1 for binary endpoints. Formula and simulation results are shown together for both Method 1 and Method 2. Facet columns correspond to total sample sizes specified in `N_vec`.

Regional sample sizes are allocated as: $N_{j1} = \lfloor N \times f_1 \rfloor$ and $N_{j2} = \cdots = N_{jJ} = (N - N_{j1})/(J - 1)$.

Usage

```
plot_rcp1armBinary(
  p = 0.5,
  p0 = 0.2,
  PI = 0.5,
  N_vec = c(20, 40, 100),
  J = 3,
  f1_seq = seq(0.1, 0.9, by = 0.1),
  nsim = 10000,
  seed = 1,
  base_size = 28
)
```

Arguments

p	Numeric scalar. True response rate under the alternative hypothesis. Must be in $(0, 1)$. Default is 0.5.
p0	Numeric scalar. Null hypothesis response rate. Must be in $[0, 1)$. Default is 0.2.
PI	Numeric scalar. Effect retention threshold for Method 1. Must be in $[0, 1]$. Default is 0.5.
N_vec	Integer vector. Total sample sizes for each facet column. Default is c(20, 40, 100).
J	Positive integer (>= 2). Number of regions. Default is 3.
f1_seq	Numeric vector. Sequence of Region 1 allocation proportions. Each value must be in $(0, 1)$. Default is seq(0.1, 0.9, by = 0.1).
nsim	Positive integer. Number of Monte Carlo iterations for simulation. Default is 10000.
seed	Non-negative integer. Random seed for simulation. Default is 1.
base_size	Positive numeric. Base font size in points passed to theme. Use larger values (e.g., 28) for presentation slides and smaller values (e.g., 11) for vignettes or reports. Default is 28.

Value

A ggplot2 object.

Examples

```
p <- plot_rcp1armBinary(
  p     = 0.5,
  p0    = 0.2,
  PI    = 0.5,
  N_vec = c(20, 40, 100),
  J     = 3
)
print(p)
```

`plot_rcp1armContinuous` *Plot Regional Consistency Probability for Single-Arm MRCT (Continuous Endpoint)*

Description

Generate a faceted plot of Regional Consistency Probability (RCP) as a function of the regional allocation proportion f_1 for continuous endpoints. Formula and simulation results are shown together for both Method 1 and Method 2. Facet columns correspond to total sample sizes specified in `N_vec`.

Regional sample sizes are allocated as: $N_{j1} = \lfloor N \times f_1 \rfloor$ and $N_{j2} = \cdots = N_{jJ} = (N - N_{j1})/(J - 1)$.

Usage

```
plot_rcp1armContinuous(
  mu = 0.5,
  mu0 = 0.1,
  sd = 1,
  PI = 0.5,
  N_vec = c(20, 40, 100),
  J = 3,
  f1_seq = seq(0.1, 0.9, by = 0.1),
  nsim = 10000,
  seed = 1,
  base_size = 28
)
```

Arguments

`mu`	Numeric scalar. True mean under the alternative hypothesis. Default is `0.5`.
`mu0`	Numeric scalar. Null hypothesis mean. Default is `0.1`.
`sd`	Numeric scalar. True standard deviation. Must be positive. Default is `1`.
`PI`	Numeric scalar. Effect retention threshold for Method 1. Must be in $[0, 1]$. Default is `0.5`.
`N_vec`	Integer vector. Total sample sizes for each facet column. Default is `c(20, 40, 100)`.
`J`	Positive integer (>= 2). Number of regions. Default is `3`.
`f1_seq`	Numeric vector. Sequence of Region 1 allocation proportions. Each value must be in $(0, 1)$. Default is `seq(0.1, 0.9, by = 0.1)`.
`nsim`	Positive integer. Number of Monte Carlo iterations for simulation. Default is `10000`.
`seed`	Non-negative integer. Random seed for simulation. Default is `1`.

base_size — Positive numeric. Base font size in points passed to theme. Use larger values (e.g., 28) for presentation slides and smaller values (e.g., 11) for vignettes or reports. Default is 28.

Value

A ggplot2 object.

Examples

```
p <- plot_rcp1armContinuous(
  mu  = 0.5,
  mu0 = 0.1,
  sd  = 1,
  PI  = 0.5,
  N_vec = c(20, 40, 100),
  J   = 3
)
print(p)
```

---

plot_rcp1armCount *Plot Regional Consistency Probability for Single-Arm MRCT (Count Endpoint)*

Description

Generate a faceted plot of Regional Consistency Probability (RCP) as a function of the regional allocation proportion f_1 for count endpoints (negative binomial model). Formula and simulation results are shown for Method 1 (log-RR and linear-RR scales) and Method 2. Facet rows correspond to the two Method 1 scales ($\log(RR)$ and $1 - RR$), and facet columns correspond to total sample sizes specified in N_vec.

Regional sample sizes are allocated as: $N_{j1} = \lfloor N \times f_1 \rfloor$ and $N_{j2} = \cdots = N_{jJ} = (N - N_{j1})/(J - 1)$.

Usage

```
plot_rcp1armCount(
  lambda = 2,
  lambda0 = 3,
  dispersion = 1,
  PI = 0.5,
  N_vec = c(20, 40, 100),
  J = 3,
  f1_seq = seq(0.1, 0.9, by = 0.1),
  nsim = 10000,
  seed = 1,
  base_size = 28
)
```

Arguments

lambda	Numeric scalar. Expected count per patient under the alternative hypothesis. Must be positive. Default is 2.
lambda0	Numeric scalar. Expected count per patient under the historical control. Must be positive. Default is 3.
dispersion	Numeric scalar. Dispersion parameter of the negative binomial distribution. Must be positive. Default is 1.
PI	Numeric scalar. Effect retention threshold for Method 1. Must be in $[0, 1]$. Default is 0.5.
N_vec	Integer vector. Total sample sizes for each facet column. Default is c(20, 40, 100).
J	Positive integer (>= 2). Number of regions. Default is 3.
f1_seq	Numeric vector. Sequence of Region 1 allocation proportions. Each value must be in $(0, 1)$. Default is seq(0.1, 0.9, by = 0.1).
nsim	Positive integer. Number of Monte Carlo iterations for simulation. Default is 10000.
seed	Non-negative integer. Random seed for simulation. Default is 1.
base_size	Positive numeric. Base font size in points passed to theme. Use larger values (e.g., 28) for presentation slides and smaller values (e.g., 11) for vignettes or reports. Default is 28.

Value

A ggplot2 object.

Examples

```
p <- plot_rcp1armCount(
  lambda     = 2,
  lambda0    = 3,
  dispersion = 1,
  PI         = 0.5,
  N_vec      = c(20, 40, 100),
  J          = 3
)
print(p)
```

---

plot_rcp1armHazardRatio

Plot Regional Consistency Probability for Single-Arm MRCT (Hazard Ratio Endpoint)

Description

Generate a faceted plot of Regional Consistency Probability (RCP) as a function of the regional allocation proportion f_1 for hazard ratio endpoints. Formula and simulation results are shown for Method 1 (log-HR and linear-HR scales) and Method 2. Facet rows correspond to the two Method 1 scales ($\log(HR)$ and $1 - HR$), and facet columns correspond to total sample sizes specified in `N_vec`.

Regional sample sizes are allocated as: $N_{j1} = \lfloor N \times f_1 \rfloor$ and $N_{j2} = \cdots = N_{jJ} = (N - N_{j1})/(J - 1)$.

Usage

```
plot_rcp1armHazardRatio(
  lambda = log(2)/10,
  lambda0 = log(2)/5,
  t_a = 3,
  t_f = 10,
  lambda_dropout = NULL,
  PI = 0.5,
  N_vec = c(20, 40, 100),
  J = 3,
  f1_seq = seq(0.1, 0.9, by = 0.1),
  nsim = 10000,
  seed = 1,
  base_size = 28
)
```

Arguments

`lambda`	Numeric scalar. True hazard rate under the alternative hypothesis. Must be positive. Default is `log(2) / 10`.
`lambda0`	Numeric scalar. Historical control hazard rate. Must be positive. Default is `log(2) / 5`.
`t_a`	Numeric scalar. Accrual period. Must be positive. Default is `3`.
`t_f`	Numeric scalar. Follow-up period. Must be positive. Default is `10`.
`lambda_dropout`	Numeric scalar or `NULL`. Dropout hazard rate. If `NULL` (default), no dropout is assumed.
`PI`	Numeric scalar. Effect retention threshold for Method 1. Must be in $[0, 1]$. Default is `0.5`.
`N_vec`	Integer vector. Total sample sizes for each facet column. Default is `c(20, 40, 100)`.
`J`	Positive integer (>= 2). Number of regions. Default is `3`.
`f1_seq`	Numeric vector. Sequence of Region 1 allocation proportions. Each value must be in $(0, 1)$. Default is `seq(0.1, 0.9, by = 0.1)`.
`nsim`	Positive integer. Number of Monte Carlo iterations for simulation. Default is `10000`.

seed	Non-negative integer. Random seed for simulation. Default is 1.
base_size	Positive numeric. Base font size in points passed to theme. Use larger values (e.g., 28) for presentation slides and smaller values (e.g., 11) for vignettes or reports. Default is 28.

Value

A ggplot2 object.

Examples

```
p <- plot_rcp1armHazardRatio(
  lambda  = log(2) / 10,
  lambda0 = log(2) / 5,
  t_a     = 3,
  t_f     = 10,
  PI      = 0.5,
  N_vec   = c(20, 40, 100),
  J       = 3
)
print(p)
```

---

plot_rcp1armMilestoneSurvival

Plot Regional Consistency Probability for Single-Arm MRCT (Milestone Survival Endpoint)

Description

Generate a faceted plot of Regional Consistency Probability (RCP) as a function of the regional allocation proportion f_1 for milestone survival endpoints. Formula and simulation results are shown together for both Method 1 and Method 2. Facet columns correspond to total sample sizes specified in N_vec.

Regional sample sizes are allocated as: $N_{j1} = \lfloor N \times f_1 \rfloor$ and $N_{j2} = \cdots = N_{jJ} = (N - N_{j1})/(J - 1)$.

Usage

```
plot_rcp1armMilestoneSurvival(
  lambda = log(2)/10,
  t_eval = 8,
  S0 = exp(-log(2) * 8/5),
  t_a = 3,
  t_f = 10,
  lambda_dropout = NULL,
  PI = 0.5,
  N_vec = c(20, 40, 100),
```

```
  J = 3,
  f1_seq = seq(0.1, 0.9, by = 0.1),
  nsim = 10000,
  seed = 1,
  base_size = 28
)
```

Arguments

lambda	Numeric scalar. True hazard rate under the alternative hypothesis. Must be positive. Default is log(2) / 10.
t_eval	Numeric scalar. Milestone evaluation time point. Must be positive. Default is 8.
S0	Numeric scalar. Historical control survival rate at t_eval. Must be in $(0, 1)$. Default is exp(-log(2) * 8 / 5).
t_a	Numeric scalar. Accrual period. Must be positive. Default is 3.
t_f	Numeric scalar. Follow-up period. Must be positive. Default is 10.
lambda_dropout	Numeric scalar or NULL. Dropout hazard rate. If NULL (default), no dropout is assumed.
PI	Numeric scalar. Effect retention threshold for Method 1. Must be in $[0, 1]$. Default is 0.5.
N_vec	Integer vector. Total sample sizes for each facet column. Default is c(20, 40, 100).
J	Positive integer (>= 2). Number of regions. Default is 3.
f1_seq	Numeric vector. Sequence of Region 1 allocation proportions. Each value must be in $(0, 1)$. Default is seq(0.1, 0.9, by = 0.1).
nsim	Positive integer. Number of Monte Carlo iterations for simulation. Default is 10000.
seed	Non-negative integer. Random seed for simulation. Default is 1.
base_size	Positive numeric. Base font size in points passed to theme. Use larger values (e.g., 28) for presentation slides and smaller values (e.g., 11) for vignettes or reports. Default is 28.

Value

A ggplot2 object.

Examples

```
p <- plot_rcp1armMilestoneSurvival(
  lambda = log(2) / 10,
  t_eval = 8,
  S0     = exp(-log(2) * 8 / 5),
  t_a    = 3,
  t_f    = 10,
  PI     = 0.5,
  N_vec  = c(20, 40, 100),
```

```
  J      = 3
)
print(p)
```

`plot_rcp1armRMST` *Plot Regional Consistency Probability for Single-Arm MRCT (RMST Endpoint)*

Description

Generate a faceted plot of Regional Consistency Probability (RCP) as a function of the regional allocation proportion f_1 for restricted mean survival time (RMST) endpoints. Formula and simulation results are shown together for both Method 1 and Method 2. Facet columns correspond to total sample sizes specified in `N_vec`.

Regional sample sizes are allocated as: $N_{j1} = \lfloor N \times f_1 \rfloor$ and $N_{j2} = \cdots = N_{jJ} = (N - N_{j1})/(J - 1)$.

Usage

```
plot_rcp1armRMST(
  lambda = log(2)/10,
  tau_star = 8,
  mu0 = (1 - exp(-log(2)/5 * 8))/(log(2)/5),
  t_a = 3,
  t_f = 10,
  lambda_dropout = NULL,
  PI = 0.5,
  N_vec = c(20, 40, 100),
  J = 3,
  f1_seq = seq(0.1, 0.9, by = 0.1),
  nsim = 10000,
  seed = 1,
  base_size = 28
)
```

Arguments

`lambda`	Numeric scalar. True hazard rate under the alternative hypothesis. Must be positive. Default is `log(2) / 10`.
`tau_star`	Numeric scalar. Truncation time for RMST calculation. Must be positive and no greater than the total study duration $\tau = t_a + t_f$. Default is `8`.
`mu0`	Numeric scalar. Historical control RMST at `tau_star`, i.e., $\mu_0(\tau^*) = \int_0^{\tau^*} S_0(t)\,dt$. Must be positive and less than `tau_star`. Default is `(1 - exp(-log(2) / 5 * 8)) / (log(2) / 5)`.

t_a	Numeric scalar. Accrual period. Must be positive. Default is 3.
t_f	Numeric scalar. Follow-up period. Must be positive. Default is 10.
lambda_dropout	Numeric scalar or NULL. Dropout hazard rate. If NULL (default), no dropout is assumed.
PI	Numeric scalar. Effect retention threshold for Method 1. Must be in $[0, 1]$. Default is 0.5.
N_vec	Integer vector. Total sample sizes for each facet column. Default is c(20, 40, 100).
J	Positive integer (>= 2). Number of regions. Default is 3.
f1_seq	Numeric vector. Sequence of Region 1 allocation proportions. Each value must be in $(0, 1)$. Default is seq(0.1, 0.9, by = 0.1).
nsim	Positive integer. Number of Monte Carlo iterations for simulation. Default is 10000.
seed	Non-negative integer. Random seed for simulation. Default is 1.
base_size	Positive numeric. Base font size in points passed to theme. Use larger values (e.g., 28) for presentation slides and smaller values (e.g., 11) for vignettes or reports. Default is 28.

Value

A ggplot2 object.

Examples

```
lam0    <- log(2) / 5
tstar   <- 8
mu0_val <- (1 - exp(-lam0 * tstar)) / lam0

p <- plot_rcp1armRMST(
  lambda   = log(2) / 10,
  tau_star = tstar,
  mu0      = mu0_val,
  t_a      = 3,
  t_f      = 10,
  PI       = 0.5,
  N_vec    = c(20, 40, 100),
  J        = 3
)
print(p)
```

print.rcp1armBinary *Print Method for rcp1armBinary Objects*

Description

Print Method for rcp1armBinary Objects

Usage

```
## S3 method for class 'rcp1armBinary'
print(x, ...)
```

Arguments

x	An object of class "rcp1armBinary".
...	Additional arguments (not used).

Value

Invisibly returns the input object x.

print.rcp1armContinuous *Print Method for rcp1armContinuous Objects*

Description

Print Method for rcp1armContinuous Objects

Usage

```
## S3 method for class 'rcp1armContinuous'
print(x, ...)
```

Arguments

x	An object of class "rcp1armContinuous".
...	Additional arguments (not used).

Value

Invisibly returns the input object x.

print.rcp1armCount *Print Method for rcp1armCount Objects*

Description

Print Method for rcp1armCount Objects

Usage

```
## S3 method for class 'rcp1armCount'
print(x, ...)
```

Arguments

x	An object of class "rcp1armCount".
...	Additional arguments (not used).

Value

Invisibly returns the input object x.

print.rcp1armHazardRatio *Print Method for rcp1armHazardRatio Objects*

Description

Print Method for rcp1armHazardRatio Objects

Usage

```
## S3 method for class 'rcp1armHazardRatio'
print(x, ...)
```

Arguments

x	An object of class "rcp1armHazardRatio".
...	Additional arguments (not used).

Value

Invisibly returns the input object x.

print.rcp1armMilestoneSurvival *Print Method for rcp1armMilestoneSurvival Objects*

Description

Print Method for rcp1armMilestoneSurvival Objects

Usage

```
## S3 method for class 'rcp1armMilestoneSurvival'
print(x, ...)
```

Arguments

x	An object of class "rcp1armMilestoneSurvival".
...	Additional arguments (not used).

Value

Invisibly returns the input object x.

print.rcp1armRMST *Print Method for rcp1armRMST Objects*

Description

Print Method for rcp1armRMST Objects

Usage

```
## S3 method for class 'rcp1armRMST'
print(x, ...)
```

Arguments

x	An object of class "rcp1armRMST".
...	Additional arguments (not used).

Value

Invisibly returns the input object x.

`rcp1armBinary` *Regional Consistency Probability for Single-Arm MRCT (Binary Endpoint)*

Description

Calculate the regional consistency probability (RCP) for binary endpoints in single-arm multi-regional clinical trials (MRCTs) using the Effect Retention Approach (ERA).

Two evaluation methods are supported:

- Method 1: Effect retention approach. Evaluates whether Region 1 retains at least a fraction PI of the overall treatment effect: $Pr[(\hat{p}_1 - p_0) > \pi \times (\hat{p} - p_0)]$.
- Method 2: Simultaneous positivity across all regions. Evaluates whether all regional response rates exceed the null value: $Pr[\hat{p}_j > p_0$ for all $j]$.

Two calculation approaches are available:

- `"formula"`: Exact closed-form solution via full enumeration of the binomial joint distribution. Method 1 uses a two-block decomposition (Region 1 vs regions 2..J combined), which is valid for $J \geq 2$. Method 2 supports $J \geq 2$ regions.
- `"simulation"`: Monte Carlo simulation. Supports $J \geq 2$ regions.

Usage

```
rcp1armBinary(
  p,
  p0,
  Nj,
  PI = 0.5,
  approach = "formula",
  nsim = 10000,
  seed = 1
)
```

Arguments

`p`	Numeric scalar. True response rate under the alternative hypothesis. Must be in $(0, 1)$.
`p0`	Numeric scalar. Null hypothesis response rate (baseline or historical control). Must be in $[0, 1)$.
`Nj`	Integer vector. Sample sizes for each region. For example, `c(10, 90)` indicates Region 1 has 10 subjects and Region 2 has 90 subjects. All elements must be positive integers.
`PI`	Numeric scalar. Prespecified effect retention threshold for Method 1. Typically $\pi \geq 0.5$. Must be in $[0, 1]$. Default is `0.5`.

approach	Character scalar. Calculation approach: "formula" for the exact solution or "simulation" for Monte Carlo simulation. Default is "formula".
nsim	Positive integer. Number of Monte Carlo iterations. Used only when approach = "simulation". Default is 10000.
seed	Non-negative integer. Random seed for reproducibility. Used only when approach = "simulation". Default is 1.

Value

An object of class "rcp1armBinary", which is a list containing:

approach Calculation approach used ("formula" or "simulation").

nsim Number of Monte Carlo iterations (NULL for "formula" approach).

p True response rate under the alternative hypothesis.

p0 Null hypothesis response rate.

Nj Sample sizes for each region.

PI Effect retention threshold.

Method1 RCP using Method 1 (effect retention).

Method2 RCP using Method 2 (all regions positive).

Examples

```
# Example 1: Exact solution with N = 100, Region 1 has 10 subjects
result1 <- rcp1armBinary(
  p  = 0.5,
  p0 = 0.2,
  Nj = c(10, 90),
  PI = 0.5,
  approach = "formula"
)
print(result1)

# Example 2: Monte Carlo simulation with N = 100, Region 1 has 10 subjects
result2 <- rcp1armBinary(
  p    = 0.5,
  p0   = 0.2,
  Nj   = c(10, 90),
  PI   = 0.5,
  approach = "simulation",
  nsim = 10000,
  seed = 1
)
print(result2)
```

`rcp1armContinuous` *Regional Consistency Probability for Single-Arm MRCT (Continuous Endpoint)*

Description

Calculate the regional consistency probability (RCP) for continuous endpoints in single-arm multi-regional clinical trials (MRCTs) using the Effect Retention Approach (ERA).

Two evaluation methods are supported:

- Method 1: Effect retention approach. Evaluates whether Region 1 retains at least a fraction PI of the overall treatment effect: $Pr[(\hat{\mu}_1 - \mu_0) > \pi \times (\hat{\mu} - \mu_0)]$.
- Method 2: Simultaneous positivity across all regions. Evaluates whether all regional estimates exceed the null value: $Pr[\hat{\mu}_j > \mu_0$ for all $j]$.

Two calculation approaches are available:

- `"formula"`: Closed-form analytical solution based on normal approximation. Method 1 uses a two-block decomposition (Region 1 vs regions 2..J combined), which is valid for $J \geq 2$. Method 2 supports $J \geq 2$ regions.
- `"simulation"`: Monte Carlo simulation. Supports $J \geq 2$ regions.

Usage

```
rcp1armContinuous(
  mu,
  mu0,
  sd,
  Nj,
  PI = 0.5,
  approach = "formula",
  nsim = 10000,
  seed = 1
)
```

Arguments

`mu`	Numeric scalar. True mean under the alternative hypothesis.
`mu0`	Numeric scalar. Null hypothesis mean (baseline or historical control). The treatment effect is defined as $\delta = \mu - \mu_0$.
`sd`	Numeric scalar. True standard deviation, assumed common across all regions. Must be positive.
`Nj`	Integer vector. Sample sizes for each region. For example, `c(10, 90)` indicates Region 1 has 10 subjects and Region 2 has 90 subjects. All elements must be positive integers.

PI	Numeric scalar. Prespecified effect retention threshold for Method 1. Typically $\pi \geq 0.5$. Must be in $[0, 1]$. Default is 0.5.
approach	Character scalar. Calculation approach: "formula" for the closed-form solution or "simulation" for Monte Carlo simulation. Default is "formula".
nsim	Positive integer. Number of Monte Carlo iterations. Used only when approach = "simulation". Default is 10000.
seed	Non-negative integer. Random seed for reproducibility. Used only when approach = "simulation". Default is 1.

Value

An object of class "rcp1armContinuous", which is a list containing:

approach Calculation approach used ("formula" or "simulation").

nsim Number of Monte Carlo iterations (NULL for "formula" approach).

mu True mean under the alternative hypothesis.

mu0 Null hypothesis mean.

sd Standard deviation.

Nj Sample sizes for each region.

PI Effect retention threshold.

Method1 RCP using Method 1 (effect retention).

Method2 RCP using Method 2 (all regions positive).

Examples

```
# Example 1: Closed-form solution with N = 100, Region 1 has 10 subjects
result1 <- rcp1armContinuous(
  mu  = 0.5,
  mu0 = 0.1,
  sd  = 1,
  Nj  = c(10, 90),
  PI  = 0.5,
  approach = "formula"
)
print(result1)

# Example 2: Monte Carlo simulation with N = 100, Region 1 has 10 subjects
result2 <- rcp1armContinuous(
  mu   = 0.5,
  mu0  = 0.1,
  sd   = 1,
  Nj   = c(10, 90),
  PI   = 0.5,
  approach = "simulation",
  nsim = 10000,
  seed = 1
)
print(result2)
```

`rcp1armCount` *Regional Consistency Probability for Single-Arm MRCT (Count Endpoint)*

Description

Calculate the regional consistency probability (RCP) for count (overdispersed) endpoints in single-arm multi-regional clinical trials (MRCTs) using the Effect Retention Approach (ERA).

Count data are modelled by the negative binomial distribution, and the treatment effect is expressed as a rate ratio (RR) relative to a historical control rate λ_0. Two effect scales are considered:

- Log-RR scale: $\log(\widehat{RR}_j) = \log(\hat{\lambda}_j/\lambda_0)$.
- Linear-RR scale: $1 - \widehat{RR}_j = 1 - \hat{\lambda}_j/\lambda_0$.

Two evaluation methods are supported (for each scale):

- Method 1: Effect retention approach. Evaluates whether Region 1 retains at least a fraction PI of the overall treatment effect. Log-RR: $\log(\widehat{RR}_1) < \pi \times \log(\widehat{RR})$; Linear-RR: $(1 - \widehat{RR}_1) > \pi \times (1 - \widehat{RR})$.
- Method 2: Simultaneous benefit across all regions. Evaluates whether all regional rate ratios are below 1: $\widehat{RR}_j < 1$ for all j. (Equivalent for both log-RR and linear-RR scales.)

Two calculation approaches are available:

- `"formula"`: Exact closed-form solution via full enumeration of the negative binomial joint distribution. Method 1 uses a two-block decomposition (Region 1 vs regions 2..J combined), which is valid for $J \geq 2$. Method 2 supports $J \geq 2$ regions.
- `"simulation"`: Monte Carlo simulation. Supports $J \geq 2$ regions.

Usage

```
rcp1armCount(
  lambda,
  lambda0,
  dispersion,
  Nj,
  PI = 0.5,
  approach = "formula",
  nsim = 10000,
  seed = 1
)
```

Arguments

`lambda`	Numeric scalar. Expected count per patient under the alternative hypothesis. Must be positive.

lambda0	Numeric scalar. Expected count per patient under the historical control (null hypothesis reference value). Must be positive.
dispersion	Numeric scalar. Dispersion parameter (size) of the negative binomial distribution, assumed common across all regions. Smaller values indicate greater overdispersion. Must be positive.
Nj	Integer vector. Sample sizes for each region. For example, c(10, 90) indicates Region 1 has 10 subjects and Region 2 has 90 subjects. All elements must be positive integers.
PI	Numeric scalar. Prespecified effect retention threshold for Method 1. Typically $\pi \geq 0.5$. Must be in $[0, 1]$. Default is 0.5.
approach	Character scalar. Calculation approach: "formula" for the exact solution or "simulation" for Monte Carlo simulation. Default is "formula".
nsim	Positive integer. Number of Monte Carlo iterations. Used only when approach = "simulation". Default is 10000.
seed	Non-negative integer. Random seed for reproducibility. Used only when approach = "simulation". Default is 1.

Value

An object of class "rcp1armCount", which is a list containing:

approach Calculation approach used ("formula" or "simulation").

nsim Number of Monte Carlo iterations (NULL for "formula" approach).

lambda Expected count per patient under the alternative hypothesis.

lambda0 Expected count per patient under the historical control.

dispersion Dispersion parameter.

Nj Sample sizes for each region.

PI Effect retention threshold.

Method1_logRR RCP using Method 1 (log-RR scale).

Method1_linearRR RCP using Method 1 (linear-RR scale).

Method2 RCP using Method 2 (all regions show benefit; identical for log-RR and linear-RR scales).

Examples

```
# Example 1: Exact solution with N = 100, Region 1 has 10 subjects
result1 <- rcp1armCount(
  lambda     = 2,
  lambda0    = 3,
  dispersion = 1,
  Nj         = c(10, 90),
  PI         = 0.5,
  approach   = "formula"
)
print(result1)

# Example 2: Monte Carlo simulation with N = 100, Region 1 has 10 subjects
```

```
result2 <- rcp1armCount(
  lambda     = 2,
  lambda0    = 3,
  dispersion = 1,
  Nj         = c(10, 90),
  PI         = 0.5,
  approach   = "simulation",
  nsim       = 10000,
  seed       = 1
)
print(result2)
```

`rcp1armHazardRatio` *Regional Consistency Probability for Single-Arm MRCT (Time-to-Event Endpoint)*

Description

Calculate the regional consistency probability (RCP) for time-to-event endpoints using the hazard ratio (HR) in single-arm multi-regional clinical trials (MRCTs) using the Effect Retention Approach (ERA).

Event times are modelled by the exponential distribution with hazard rate λ (treatment) relative to a known historical control hazard λ_0. The treatment effect is expressed as a hazard ratio: $HR = \lambda/\lambda_0 < 1$ (benefit). Two effect scales are considered:

- Log-HR scale: $\log(\widehat{HR}_j) = \log(\hat{\lambda}_j/\lambda_0)$.
- Linear-HR scale: $1 - \widehat{HR}_j = 1 - \hat{\lambda}_j/\lambda_0$.

Two evaluation methods are supported (for each scale):

- Method 1: Effect retention approach. Evaluates whether Region 1 retains at least a fraction PI of the overall treatment effect. Log-HR: $\log(\widehat{HR}_1) < \pi \times \log(\widehat{HR})$; Linear-HR: $(1-\widehat{HR}_1) > \pi \times (1 - \widehat{HR})$.
- Method 2: Simultaneous benefit across all regions. Evaluates whether all regional hazard ratios are below 1: $\widehat{HR}_j < 1$ for all j. (Equivalent for both log-HR and linear-HR scales.)

Two calculation approaches are available:

- `"formula"`: Closed-form solution based on normal approximation for $\log(\widehat{HR})$ and the delta method for the linear-HR scale (Hayashi and Itoh 2018). Method 1 uses a two-block decomposition (Region 1 vs regions 2..J combined), which is valid for $J \geq 2$. Method 2 supports $J \geq 2$ regions.
- `"simulation"`: Monte Carlo simulation using individual patient data with person-years estimation of the hazard rate. Supports $J \geq 2$ regions.

Usage

```
rcp1armHazardRatio(
  lambda,
  lambda0,
  Nj,
  t_a,
  t_f,
  lambda_dropout = NULL,
  PI = 0.5,
  approach = "formula",
  nsim = 10000,
  seed = 1
)
```

Arguments

lambda	Numeric scalar. True hazard rate under the alternative hypothesis. Must be positive. Under exponential distribution, median survival = $\log(2)/\lambda$.
lambda0	Numeric scalar. Known hazard rate for the historical control (null hypothesis reference value). Must be positive.
Nj	Integer vector. Sample sizes for each region. For example, c(10, 90) indicates Region 1 has 10 subjects and Region 2 has 90 subjects. All elements must be positive integers.
t_a	Numeric scalar. Accrual period (patient enrolment duration). Must be positive.
t_f	Numeric scalar. Follow-up period (additional follow-up after accrual ends). Must be positive.
lambda_dropout	Numeric scalar or NULL. Dropout hazard rate. If NULL (default), no dropout is assumed. If specified, dropout times follow an exponential distribution with rate lambda_dropout.
PI	Numeric scalar. Prespecified effect retention threshold for Method 1. Typically $\pi \geq 0.5$. Must be in $[0, 1]$. Default is 0.5.
approach	Character scalar. Calculation approach: "formula" for the closed-form solution or "simulation" for Monte Carlo simulation. Default is "formula".
nsim	Positive integer. Number of Monte Carlo iterations. Used only when approach = "simulation". Default is 10000.
seed	Non-negative integer. Random seed for reproducibility. Used only when approach = "simulation". Default is 1.

Value

An object of class "rcp1armHazardRatio", which is a list containing:

approach Calculation approach used ("formula" or "simulation").

nsim Number of Monte Carlo iterations (NULL for "formula" approach).

lambda True hazard rate under the alternative hypothesis.

`lambda0` Historical control hazard rate.

`Nj` Sample sizes for each region.

`t_a` Accrual period.

`t_f` Follow-up period.

`tau` Total study duration ($\tau = t_a + t_f$).

`lambda_dropout` Dropout hazard rate (`NA` if `NULL`).

`PI` Effect retention threshold.

`Method1_logHR` RCP using Method 1 (log-HR scale).

`Method1_linearHR` RCP using Method 1 (linear-HR scale).

`Method2` RCP using Method 2 (all regions show benefit; identical for log-HR and linear-HR scales).

References

Hayashi N, Itoh Y (2017). A re-examination of Japanese sample size calculation for multi-regional clinical trial evaluating survival endpoint. *Japanese Journal of Biometrics*, 38(2): 79–92.

Wu J (2015). Sample size calculation for the one-sample log-rank test. *Pharmaceutical Statistics*, 14(1): 26–33.

Examples

```
# Example 1: Closed-form solution with N = 100, Region 1 has 10 subjects
result1 <- rcp1armHazardRatio(
  lambda         = log(2) / 10,
  lambda0        = log(2) / 5,
  Nj             = c(10, 90),
  t_a            = 3,
  t_f            = 10,
  lambda_dropout = NULL,
  PI             = 0.5,
  approach       = "formula"
)
print(result1)

# Example 2: Monte Carlo simulation with N = 100, Region 1 has 10 subjects
result2 <- rcp1armHazardRatio(
  lambda         = log(2) / 10,
  lambda0        = log(2) / 5,
  Nj             = c(10, 90),
  t_a            = 3,
  t_f            = 10,
  lambda_dropout = NULL,
  PI             = 0.5,
  approach       = "simulation",
  nsim           = 10000,
  seed           = 1
)
print(result2)
```

`rcp1armMilestoneSurvival` *Regional Consistency Probability for Single-Arm MRCT (Milestone Survival Endpoint)*

Description

Calculate the regional consistency probability (RCP) for milestone survival endpoints in single-arm multi-regional clinical trials (MRCTs) using the Effect Retention Approach (ERA).

Event times are modelled by the exponential distribution with hazard rate λ (treatment). The treatment effect at a prespecified evaluation time t_{eval} is expressed as the difference in survival rates: $\delta = S(t_{\text{eval}}) - S_0(t_{\text{eval}})$, where S_0 is the historical control survival rate at t_{eval}.

Two evaluation methods are supported:

- Method 1: Effect retention approach. Evaluates whether Region 1 retains at least a fraction PI of the overall treatment effect: $Pr[(\hat{S}_1(t) - S_0(t)) > \pi \times (\hat{S}(t) - S_0(t))]$.
- Method 2: Simultaneous benefit across all regions. Evaluates whether all regional Kaplan-Meier estimates exceed the historical control: $Pr[\hat{S}_j(t) > S_0(t)$ for all $j]$.

Two calculation approaches are available:

- `"formula"`: Closed-form or semi-analytical solution based on the asymptotic variance of the Kaplan-Meier estimator derived from Greenwood's formula. When $t_{\text{eval}} \leq t_f$, the administrative censoring survival function $G_a(t) = 1$ and the variance integral has a closed-form solution. When $t_{\text{eval}} > t_f$, the integral is evaluated numerically via `integrate`. Method 1 uses a two-block decomposition (Region 1 vs regions 2..J combined). Method 2 supports $J \geq 2$ regions.
- `"simulation"`: Monte Carlo simulation with vectorized Kaplan-Meier estimation. Supports $J \geq 2$ regions.

Usage

```
rcp1armMilestoneSurvival(
  lambda,
  t_eval,
  S0,
  Nj,
  t_a,
  t_f,
  lambda_dropout = NULL,
  PI = 0.5,
  approach = "formula",
  nsim = 10000,
  seed = 1
)
```

Arguments

`lambda`	Numeric scalar. True hazard rate under the alternative hypothesis. Must be positive.
`t_eval`	Numeric scalar. Evaluation time point for the milestone survival probability. Must be positive.
`S0`	Numeric scalar. Historical control survival rate at `t_eval`. Must be in $(0, 1]$.
`Nj`	Integer vector. Sample sizes for each region. For example, `c(10, 90)` indicates Region 1 has 10 subjects and Region 2 has 90 subjects. All elements must be positive integers.
`t_a`	Numeric scalar. Accrual period (patient enrolment duration). Must be positive.
`t_f`	Numeric scalar. Follow-up period (additional follow-up after accrual ends). Must be positive.
`lambda_dropout`	Numeric scalar or `NULL`. Dropout hazard rate. If `NULL` (default), no dropout is assumed. If specified, dropout times follow an exponential distribution with rate `lambda_dropout`.
`PI`	Numeric scalar. Prespecified effect retention threshold for Method 1. Typically $\pi \geq 0.5$. Must be in $[0, 1]$. Default is `0.5`.
`approach`	Character scalar. Calculation approach: `"formula"` for the closed-form (or semi-analytical) solution or `"simulation"` for Monte Carlo simulation. Default is `"formula"`.
`nsim`	Positive integer. Number of Monte Carlo iterations. Used only when `approach = "simulation"`. Default is `10000`.
`seed`	Non-negative integer. Random seed for reproducibility. Used only when `approach = "simulation"`. Default is `1`.

Details

Variance formula. The asymptotic variance of the Kaplan-Meier estimator $\hat{S}_j(t)$ for a single arm with N_j subjects is derived from Greenwood's formula:

$$\mathrm{Var}[\hat{S}_j(t)] \approx \frac{S^2(t)}{N_j} \int_0^t \frac{\lambda(u)}{S(u) \cdot G(u)}\, du,$$

where $G(u) = e^{-\lambda_d u} \cdot G_a(u)$ is the overall censoring survival function, and

$$G_a(u) = \begin{cases} 1 & 0 \leq u \leq t_f, \\ (\tau - u)/t_a & t_f < u \leq \tau. \end{cases}$$

Under the exponential model $S(u) = e^{-\lambda u}$, this simplifies to:

$$\mathrm{Var}[\hat{S}_j(t)] \approx \frac{e^{-2\lambda t}}{N_j} \int_0^t \frac{\lambda\, e^{(\lambda+\lambda_d)u}}{G_a(u)}\, du.$$

Closed-form solution ($t_{\mathrm{eval}} \leq t_f$). When $t_{\mathrm{eval}} \leq t_f$, $G_a(u) = 1$ throughout $[0, t_{\mathrm{eval}}]$, and the integral reduces to:

$$\int_0^t \lambda\, e^{(\lambda+\lambda_d)u}\, du = \frac{\lambda}{\lambda + \lambda_d}\big(e^{(\lambda+\lambda_d)t} - 1\big).$$

Therefore:

$$\mathrm{Var}[\hat{S}_j(t)] = \frac{e^{-2\lambda t}}{N_j} \cdot \frac{\lambda}{\lambda + \lambda_d}\big(e^{(\lambda+\lambda_d)t} - 1\big).$$

When there is no dropout ($\lambda_d = 0$), this further simplifies to the binomial variance:

$$\mathrm{Var}[\hat{S}_j(t)] = \frac{S(t)(1 - S(t))}{N_j}.$$

Value

An object of class `"rcp1armMilestoneSurvival"`, which is a list containing:

`approach` Calculation approach used (`"formula"` or `"simulation"`).

`formula_type` For `approach = "formula"`: either `"closed-form"` (when $t_{\text{eval}} \leq t_f$) or `"numerical-integration"` (when $t_{\text{eval}} > t_f$). `NULL` for simulation.

`nsim` Number of Monte Carlo iterations (`NULL` for `"formula"` approach).

`lambda` True hazard rate under the alternative hypothesis.

`Nj` Sample sizes for each region.

`t_a` Accrual period.

`t_f` Follow-up period.

`tau` Total study duration ($\tau = t_a + t_f$).

`lambda_dropout` Dropout hazard rate (`NA` if `NULL`).

`PI` Effect retention threshold.

`eval_time` Milestone evaluation time point.

`S0` Historical control survival rate at `eval_time`.

`S_est` True survival rate under the alternative at `eval_time`: $S(t) = e^{-\lambda t}$.

`Method1` RCP using Method 1 (effect retention).

`Method2` RCP using Method 2 (all regions positive).

References

Wu J (2015). Sample size calculation for the one-sample log-rank test. *Pharmaceutical Statistics*, 14(1): 26–33.

Examples

```
# Example 1: Closed-form solution (t_eval <= t_f) with N = 100
result1 <- rcp1armMilestoneSurvival(
  lambda         = log(2) / 10,
  t_eval         = 8,
  S0             = exp(-log(2) * 8 / 5),
  Nj             = c(10, 90),
  t_a            = 3,
  t_f            = 10,
  lambda_dropout = NULL,
  PI             = 0.5,
```

```
  approach       = "formula"
)
print(result1)

# Example 2: Monte Carlo simulation with N = 100
result2 <- rcp1armMilestoneSurvival(
  lambda         = log(2) / 10,
  t_eval         = 8,
  S0             = exp(-log(2) * 8 / 5),
  Nj             = c(10, 90),
  t_a            = 3,
  t_f            = 10,
  lambda_dropout = NULL,
  PI             = 0.5,
  approach       = "simulation",
  nsim           = 10000,
  seed           = 1
)
print(result2)
```

`rcp1armRMST` *Regional Consistency Probability for Single-Arm MRCT (RMST Endpoint)*

Description

Calculate the regional consistency probability (RCP) for restricted mean survival time (RMST) endpoints in single-arm multi-regional clinical trials (MRCTs) using the Effect Retention Approach (ERA).

Event times are modelled by the exponential distribution with hazard rate λ (treatment). The treatment effect is expressed as the difference in RMST at a prespecified truncation time τ^*: $\delta = \mu(\tau^*) - \mu_0(\tau^*)$, where $\mu_0(\tau^*)$ is the historical control RMST at τ^*.

The regional RMST estimator is defined as the area under the Kaplan-Meier curve up to τ^*: $\hat{\mu}_j(\tau^*) = \int_0^{\tau^*} \hat{S}_j(t)\, dt$.

Two evaluation methods are supported:

- Method 1: Effect retention approach. Evaluates whether Region 1 retains at least a fraction PI of the overall treatment effect: $Pr[(\hat{\mu}_1 - \mu_0) > \pi \times (\hat{\mu} - \mu_0)]$.
- Method 2: Simultaneous benefit across all regions. Evaluates whether all regional RMST estimates exceed the historical control RMST: $Pr[\hat{\mu}_j > \mu_0 \text{ for all } j]$.

Two calculation approaches are available:

- `"formula"`: Normal approximation based on exponential event times and exponential dropout. When $\tau^* \leq t_f$ (the most common setting in practice), the administrative censoring survival function equals 1 on $[0, \tau^*]$ and the variance integral has a closed-form solution. When $\tau^* > t_f$, the integral is evaluated numerically via `integrate`. Method 1 uses a two-block

decomposition (Region 1 vs regions 2..J combined), valid for $J \geq 2$. Method 2 supports $J \geq 2$ regions.

- `"simulation"`: Monte Carlo simulation. The RMST for each simulation replicate is computed as the exact area under the Kaplan-Meier step function (sum of rectangles). Supports $J \geq 2$ regions.

Usage

```
rcp1armRMST(
  lambda,
  tau_star,
  mu0,
  Nj,
  t_a,
  t_f,
  lambda_dropout = NULL,
  PI = 0.5,
  approach = "formula",
  nsim = 10000,
  seed = 1
)
```

Arguments

`lambda`	Numeric scalar. True hazard rate under the alternative hypothesis. Must be positive.
`tau_star`	Numeric scalar. Truncation time for RMST calculation. Must be positive and no greater than the total study duration $\tau = t_a + t_f$.
`mu0`	Numeric scalar. Historical control RMST at `tau_star`, i.e., $\mu_0(\tau^*) = \int_0^{\tau^*} S_0(t)\,dt$. Must be positive and less than `tau_star`.
`Nj`	Integer vector. Sample sizes for each region. For example, `c(10, 90)` indicates Region 1 has 10 subjects and Region 2 has 90 subjects. All elements must be positive integers.
`t_a`	Numeric scalar. Accrual period (patient enrolment duration). Must be positive.
`t_f`	Numeric scalar. Follow-up period (additional follow-up after accrual ends). Must be positive.
`lambda_dropout`	Numeric scalar or `NULL`. Dropout hazard rate. If `NULL` (default), no dropout is assumed. If specified, dropout times follow an exponential distribution with rate `lambda_dropout`.
`PI`	Numeric scalar. Prespecified effect retention threshold for Method 1. Typically $\pi \geq 0.5$. Must be in $[0, 1]$. Default is `0.5`.
`approach`	Character scalar. Calculation approach: `"formula"` for the normal approximation or `"simulation"` for Monte Carlo simulation. Default is `"formula"`.
`nsim`	Positive integer. Number of Monte Carlo iterations. Used only when `approach = "simulation"`. Default is `10000`.
`seed`	Non-negative integer. Random seed for reproducibility. Used only when `approach = "simulation"`. Default is `1`.

Details

Variance formula. The asymptotic variance of the RMST estimator $\hat{\mu}_j(\tau^*)$ for a single arm with n subjects is:

$$\mathrm{Var}(\hat{\mu}_j(\tau^*)) \approx \frac{1}{n}\int_0^{\tau^*} \frac{\left(e^{-\lambda t} - e^{-\lambda\tau^*}\right)^2}{\lambda \cdot e^{-\lambda t} \cdot G(t)}\, dt,$$

where $G(t) = P(\text{observed time} \geq t)$ is the overall censoring survival function:

$$G(t) = e^{-\lambda_d t} \times G_a(t), \quad G_a(t) = \begin{cases} 1 & 0 \leq t \leq t_f, \\ (\tau - t)/t_a & t_f < t \leq \tau. \end{cases}$$

Closed-form variance ($\tau^* \leq t_f$). When $\tau^* \leq t_f$, $G_a(t) = 1$ on $[0, \tau^*]$ and the integrand reduces to $e^{\lambda_d t}(1 - e^{-\lambda(\tau^* - t)})^2/\lambda$. Expanding and integrating term by term:

$$v(\tau^*) = \frac{1}{\lambda}\Big[A(\lambda_d) - 2e^{-\lambda\tau^*}A(\lambda_d + \lambda) + e^{-2\lambda\tau^*}A(\lambda_d + 2\lambda)\Big],$$

where $A(r) = (e^{r\tau^*} - 1)/r$ for $r > 0$ and $A(0) = \tau^*$. When there is no dropout ($\lambda_d = 0$) this further reduces to:

$$v(\tau^*) = \tau^* - \frac{2(1 - e^{-\lambda\tau^*})}{\lambda} + \frac{1 - e^{-2\lambda\tau^*}}{2\lambda}.$$

Value

An object of class `"rcp1armRMST"`, which is a list containing:

`approach` Calculation approach used (`"formula"` or `"simulation"`).

`formula_type` For `approach = "formula"`: either `"closed-form"` (when $\tau^* \leq t_f$) or `"numerical-integration"` (when $\tau^* > t_f$). `NULL` for simulation.

`nsim` Number of Monte Carlo iterations (`NULL` for `"formula"` approach).

`lambda` True hazard rate under the alternative hypothesis.

`Nj` Sample sizes for each region.

`t_a` Accrual period.

`t_f` Follow-up period.

`tau` Total study duration ($\tau = t_a + t_f$).

`lambda_dropout` Dropout hazard rate (`NA` if `NULL`).

`PI` Effect retention threshold.

`tau_star` Truncation time for RMST.

`mu0` Historical control RMST at `tau_star`.

`mu_est` True RMST under the alternative: $\mu(\tau^*) = (1 - e^{-\lambda\tau^*})/\lambda$.

`Method1` RCP using Method 1 (effect retention).

`Method2` RCP using Method 2 (all regions positive).

References

Wu J (2015). Sample size calculation for the one-sample log-rank test. *Pharmaceutical Statistics*, 14(1): 26–33.

Examples

```
# Example 1: Closed-form solution (tau_star <= t_f) with N = 100
lam   <- log(2) / 10
lam0  <- log(2) / 5
tstar <- 8
mu0_val <- (1 - exp(-lam0 * tstar)) / lam0

result1 <- rcp1armRMST(
  lambda         = lam,
  tau_star       = tstar,
  mu0            = mu0_val,
  Nj             = c(10, 90),
  t_a            = 3,
  t_f            = 10,
  lambda_dropout = NULL,
  PI             = 0.5,
  approach       = "formula"
)
print(result1)

# Example 2: Monte Carlo simulation with N = 100
result2 <- rcp1armRMST(
  lambda         = lam,
  tau_star       = tstar,
  mu0            = mu0_val,
  Nj             = c(10, 90),
  t_a            = 3,
  t_f            = 10,
  lambda_dropout = NULL,
  PI             = 0.5,
  approach       = "simulation",
  nsim           = 10000,
  seed           = 1
)
print(result2)
```

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