Package 'phase12designs'

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Type Package

Title Comprehensive Tools for Running Model-Assisted Phase I/II Trial Simulations

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Author Angela Cao [aut, cre], Haolun Shi [ctb]

Maintainer Angela Cao <cao.t.angela@gmail.com>

Description Provides a comprehensive set of tools to simulate, evaluate, and compare model-assisted designs for early-phase (Phase I/II) clinical trials. Includes flexible simulation parameters that allow researchers to efficiently compute operating characteristics under various fixed and random trial scenarios and export the results.

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Roxygen list(markdown = TRUE)

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Contents

`decision_plot` *Decision Map Plot*

Description

This function creates a decision plot containing customizable decision zones.

Usage

```
decision_plot(
  filename,
  filetype = c("png", "pdf", "svg"),
  xlab = "Toxicity Probability",
  ylab = "Efficacy Probability",
  x_breaks = c(0, 1),
  y_breaks = c(0, 1),
  x_labels = c(0, 1),
  y_labels = c(0, 1),
  zones = list(),
  legend_info = list(labels = NULL, colors = NULL),
  title = NULL,
  title_pos = c(0.05, 1.1),
  legend_pos = c(0.3, 1.2),
  grid_lines = TRUE,
  plot_size = c(7, 7)
)
```

Arguments

`filename`	File path.
`filetype`	File type.
`xlab`	x-axis label. (Default is "Toxicity Probability")
`ylab`	y-axis label. (Default is "Efficacy Probability")
`x_breaks`	Numeric vector for x-axis major ticks. (Default is 'c(0, 1')
`y_breaks`	Numeric vector for y-axis major ticks. (Default is 'c(0, 1')
`x_labels`	Labels corresponding to `x_breaks`. (Default is 'c(0, 1')
`y_labels`	Labels corresponding to `y_breaks`. (Default is 'c(0, 1')
`zones`	A list of rectangular zones to draw, where each rectangle is a list with elements `xmin`, `xmax`, `ymin`, `ymax`, and `color`.
`legend_info`	A list with two elements: `labels` (character vector) and `colors` (character vector) for the legend.
`title`	Title of plot. (Default is 'NULL')
`title_pos`	A numeric vector (x, y) indicating the position of the title text.
`legend_pos`	A numeric vector (x, y) indicating the position of the legend.
`grid_lines`	Whether to include background grid lines. (Default is TRUE.)
`plot_size`	A numeric vector indicating width and height. (Default is c(7, 7)).

Examples

```
zones <- list(list(xmin = 0.0, xmax = 0.2, ymin = 0, ymax = 1.0, color = "#a8eea8"),
              list(xmin = .2, xmax = .3, ymin = 0, ymax = 0.6, color = "#a8eea8"),
              list(xmin = .2, xmax = .3, ymin = .6, ymax = 1, color = "#a8d5ee"))
tmpfile <- tempfile(fileext = ".png")
decision_plot(tmpfile, filetype = "png", zones = zones, title = "Decision Zones")
```

`oc_boin12` *Compute Operating Characteristics using BOIN12*

Description

`oc_boin12()` uses the BOIN12 design to compute operating charateristics of a user-specificed trial scenario. This design places significance on optimizing utility and the toxicity–efficacy trade-off.

Usage

```
oc_boin12(
  ndose,
  target_t,
  lower_e,
  ncohort = 10,
  cohortsize = 3,
  startdose = 1,
  psafe = 0.95,
  pfutility = 0.95,
  ntrial = 10000,
  utilitytype = 1,
  u1,
  u2,
  prob = NULL
)
```

Arguments

`ndose`	Integer. Number of dose levels. (**Required**)
`target_t`	Numeric. Target toxicity probability. (**Required**)
`lower_e`	Numeric. Minimum acceptable efficacy probability. (**Required**)
`ncohort`	Integer. Number of cohorts. (Default is `10`)
`cohortsize`	Integer. Size of a cohort. (Default is `3`)
`startdose`	Integer. Starting dose level. (Default is `1`)
`psafe`	Numeric. Early stopping cutoff for toxicity. (Default is `0.95`)
`pfutility`	Numeric. Early stopping cutoff for efficacy. (Default is `0.95`)
`ntrial`	Integer. Number of random trial replications. (Default is `10000`)
`utilitytype`	Integer. Type of utility structure. (Default is `1`)

- If set to `1`: Use preset weights (w11 = 0.6, w00 = 0.4)
- If set to `2`: Use (w11 = 1, w00 = 0)
- Other: Use user-specified values from `u1` and `u2`.

u1 Numeric. Utility parameter w_11. (0-100)

u2 Numeric. Utility parameter w_00. (0-100)

prob Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list of the following named elements:

- pE: Numeric vector of efficacy probabilities for each dose level.
- pT: Numeric vector of toxicity probabilities for each dose level.
- obd: Integer indicating the index of the true Optimal Biological Dose (OBD).
- mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).

For example:

```
prob <- list(
  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),
  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),
  obd = 3,
  mtd = 2
)
```

Value

A list containing operating characteristics such as:

bd.sel OBD selection percentage

od.sel Favorable dose selection percentage

bd.pts Average percentage of patients at the OBD

od.pts Average percentage of patients at the favorable doses

earlystop Percentage of early stopped trials

overdose Overdose patients percentage

poorall Poor allocation percentage

ov.sel Overdose selection percentage

---

oc_boinet *Compute Operating Characteristics using BOINET*

Description

oc_boinet() uses the BOINET design to compute operating charateristics of a user-specificed trial scenario. This design uses target toxicity and efficacy rates jointly to form the cutoff intervals within a decision map.

Usage

```
oc_boinet(
  ndose,
  target_t,
  lower_e,
  ncohort = 10,
  cohortsize = 3,
  startdose = 1,
  psafe = 0.95,
  pfutility = 0.95,
  ntrial = 10000,
  utilitytype = 1,
  prob = NULL
)
```

Arguments

`ndose`	Integer. Number of dose levels. (**Required**)
`target_t`	Numeric. Target toxicity probability. (**Required**)
`lower_e`	Numeric. Minimum acceptable efficacy probability. (**Required**)
`ncohort`	Integer. Number of cohorts. (Default is `10`)
`cohortsize`	Integer. Size of a cohort. (Default is `3`)
`startdose`	Integer. Starting dose level. (Default is `1`)
`psafe`	Numeric. Early stopping cutoff for toxicity. (Default is `0.95`)
`pfutility`	Numeric. Early stopping cutoff for efficacy. (Default is `0.95`)
`ntrial`	Integer. Number of random trial replications. (Default is `10000`)
`utilitytype`	Integer. Type of utility structure. (Default is `1`) • If set to `1`: Use preset weights (w11 = 0.6, w00 = 0.4) • If set to `2`: Use (w11 = 1, w00 = 0)

`prob`	Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list with the following named elements:
	• `pE`: Numeric vector of efficacy probabilities for each dose level.
	• `pT`: Numeric vector of toxicity probabilities for each dose level.
	• `obd`: Integer indicating the index of the true Optimal Biological Dose (OBD).
	• `mtd`: Integer indicating the index of the true Maximum Tolerated Dose (MTD).
	For example:
	`prob <- list(`
	`  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),`
	`  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),`
	`  obd = 3,`
	`  mtd = 2`
	`)`

Value

A list containing operating characteristics such as:

bd.sel OBD selection percentage

od.sel Favorable dose selection percentage

bd.pts Average percentage of patients at the OBD

od.pts Average percentage of patients at the favorable doses

earlystop Percentage of early stopped trials

overdose Overdose patients percentage

poorall Poor allocation percentage

ov.sel Overdose selection percentage

`oc_efftox` *Compute Operating Characteristics using EffTox*

Description

`oc_efftox()` uses the EffTox design to compute operating charateristics of a user-specificed trial scenario. This design uses toxicity–efficacy trade-off contours.

Usage

```
oc_efftox(
  ndose,
  target_t,
  lower_e,
  ncohort = 10,
  startdose = 1,
  ntrial = 10000,
  utilitytype = 1,
  prob = NULL
)
```

Arguments

`ndose`	Integer. Number of dose levels. (**Required**)
`target_t`	Numeric. Target toxicity probability. (**Required**)
`lower_e`	Numeric. Minimum acceptable efficacy probability. (**Required**)
`ncohort`	Integer. Number of cohorts. (Default is `10`)
`startdose`	Integer. Starting dose level. (Default is `1`)
`ntrial`	Integer. Number of random trial replications. (Default is `10000`)
`utilitytype`	Integer. Type of utility structure. (Default is `1`) • If set to `1`: Use preset weights (w11 = 0.6, w00 = 0.4) • If set to `2`: Use (w11 = 1, w00 = 0)
`prob`	Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list of the following named elements:

- pE: Numeric vector of efficacy probabilities for each dose level.
- pT: Numeric vector of toxicity probabilities for each dose level.
- obd: Integer indicating the index of the true Optimal Biological Dose (OBD).
- mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).

For example:

```
prob <- list(
  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),
  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),
  obd = 3,
  mtd = 2
)
```

Value

A list containing operating characteristics such as:

bd.sel OBD selection percentage

od.sel Favorable dose selection percentage

bd.pts Average percentage of patients at the OBD

od.pts Average percentage of patients at the favorable doses

earlystop Percentage of early stopped trials

overdose Overdose patients percentage

poorall Poor allocation percentage

ov.sel Overdose selection percentage

---

oc_ji3p3 *Compute Operating Characteristics using Ji3+3*

Description

oc_ji3p3() uses the Ji3+3 design to compute operating charateristics of a user-specificed trial scenario. This design compares observed efficacy and toxicity with predefined target rates.

Usage

```
oc_ji3p3(
  ndose,
  target_t,
  target_e,
  lower_e = 0.2,
  ncohort = 10,
  cohortsize = 3,
  startdose = 1,
  eps1 = 0.05,
  eps2 = 0.05,
  psafe = 0.95,
  pfutility = 0.95,
```

```
  ntrial = 10000,
  utilitytype = 1,
  u1,
  u2,
  prob = NULL
)
```

Arguments

ndose	Integer. Number of dose levels. (**Required**)
target_t	Numeric. Target toxicity probability. (**Required**)
target_e	Numeric. Target efficacy probability. (**Required**)
lower_e	Numeric. Minimum acceptable efficacy probability. (**Required**)
ncohort	Integer. Number of cohorts. (Default is 10)
cohortsize	Integer. Size of a cohort. (Default is 3)
startdose	Integer. Starting dose level. (Default is 1)
eps1	Numerical. Width of the subrectangle.
eps2	Numerical. Width of the subreactangle.
psafe	Numeric. Early stopping cutoff for toxicity. (Default is 0.95)
pfutility	Numeric. Early stopping cutoff for efficacy. (Default is 0.95)
ntrial	Integer. Number of random trial replications. (Default is 10000)
utilitytype	Integer. Type of utility structure. (Default is 1) • If set to 1: Use preset weights (w11 = 0.6, w00 = 0.4) • If set to 2: Use (w11 = 1, w00 = 0) • Other: Use user-specified values from u1 and u2.
u1	Numeric. Utility parameter w_11. (0-100)
u2	Numeric. Utility parameter w_00. (0-100)

prob	Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list of the following named elements:
	• pE: Numeric vector of efficacy probabilities for each dose level.
	• pT: Numeric vector of toxicity probabilities for each dose level.
	• obd: Integer indicating the index of the true Optimal Biological Dose (OBD).
	• mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).
	For example:
	`prob <- list(`
	`  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),`
	`  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),`
	`  obd = 3,`
	`  mtd = 2`
	`)`

Value

A list containing operating characteristics such as:

bd.sel OBD selection percentage

od.sel Favorable dose selection percentage

bd.pts Average percentage of patients at the OBD

od.pts Average percentage of patients at the favorable doses

earlystop Percentage of early stopped trials

overdose Overdose patients percentage

poorall Poor allocation percentage

ov.sel Overdose selection percentage

`oc_pite` *Compute Operating Characteristics using PRINTE*

Description

`oc_pite()` uses the PRINTE design to compute operating charateristics of a user-specificed trial scenario. This design maps toxicity and efficacy intervals onto a decision table, forming 16 equal-area regions.

Usage

```
oc_pite(
  ndose,
  target_t,
  target_e,
  lower_e,
  ncohort = 10,
  cohortsize = 3,
  startdose = 1,
  eps1 = 0.05,
  eps2 = 0.05,
  psafe = 0.95,
  pfutility = 0.95,
  ntrial = 10000,
  utilitytype = 1,
  u1,
  u2,
  prob = NULL
)
```

Arguments

`ndose`	Integer. Number of dose levels. (**Required**)
`target_t`	Numeric. Target toxicity probability. (**Required**)
`target_e`	Numeric. Target efficacy probability. (**Required**)
`lower_e`	Numeric. Minimum acceptable efficacy probability. (**Required**)

ncohort	Integer. Number of cohorts. (Default is 10)
cohortsize	Integer. Size of a cohort. (Default is 3)
startdose	Integer. Starting dose level. (Default is 1)
eps1	Numerical. Width of the subrectangle. (Default is '0.05')
eps2	Numerical. Width of the subreactangle. (Default is '0.05')
psafe	Numeric. Early stopping cutoff for toxicity. (Default is 0.95)
pfutility	Numeric. Early stopping cutoff for efficacy. (Default is 0.95)
ntrial	Integer. Number of random trial replications. (Default is 10000)
utilitytype	Integer. Type of utility structure. (Default is 1) • If set to 1: Use preset weights (w11 = 0.6, w00 = 0.4) • If set to 2: Use (w11 = 1, w00 = 0) • Other: Use user-specified values from u1 and u2.
u1	Numeric. Utility parameter w_11. (0-100)
u2	Numeric. Utility parameter w_00. (0-100)

prob	Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list with the following named elements:
	• pE: Numeric vector of efficacy probabilities for each dose level.
	• pT: Numeric vector of toxicity probabilities for each dose level.
	• obd: Integer indicating the index of the true Optimal Biological Dose (OBD).
	• mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).
	For example:
	`prob <- list(`
	`  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),`
	`  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),`
	`  obd = 3,`
	`  mtd = 2`
	`)`

Value

A list containing operating characteristics such as:

bd.sel OBD selection percentage

od.sel Favorable dose selection percentage

bd.pts Average percentage of patients at the OBD

od.pts Average percentage of patients at the favorable doses

earlystop Percentage of early stopped trials

overdose Overdose patients percentage

poorall Poor allocation percentage

ov.sel Overdose selection percentage

`oc_stein` *Compute Operating Characteristics using STEIN*

Description

`oc_stein()` uses the STEIN design to compute operating charateristics of a user-specificed trial scenario. This design uses target toxicity and efficacy rates separately to form the cutoff intervals within a decision map.

Usage

```
oc_stein(
  ndose,
  target_t,
  lower_e,
  ncohort = 10,
  cohortsize = 3,
  startdose = 1,
  psi1 = 0.2,
  psi2 = 0.6,
  psafe = 0.95,
  pfutility = 0.9,
  ntrial = 10000,
  utilitytype = 1,
  u1,
  u2,
  prob = NULL
)
```

Arguments

`ndose`	Integer. Number of dose levels. (**Required**)
`target_t`	Numeric. Target toxicity probability. (**Required**)
`lower_e`	Numeric. Minimum acceptable efficacy probability. (**Required**)
`ncohort`	Integer. Number of cohorts. (Default is `10`)
`cohortsize`	Integer. Size of a cohort. (Default is `3`)
`startdose`	Integer. Starting dose level. (Default is `1`)
`psi1`	Numerical. Highest inefficacious efficacy probability.
`psi2`	Numerical. Lowest highly-promising efficacy probability.
`psafe`	Numeric. Early stopping cutoff for toxicity. (Default is `0.95`)
`pfutility`	Numeric. Early stopping cutoff for efficacy. (Default is `0.95`)
`ntrial`	Integer. Number of random trial replications. (Default is `10000`)
`utilitytype`	Integer. Type of utility structure. (Default is `1`) • If set to `1`: Use preset weights (w11 = 0.6, w00 = 0.4) • If set to `2`: Use (w11 = 1, w00 = 0) • Other: Use user-specified values from `u1` and `u2`.
`u1`	Numeric. Utility parameter w_11. (0-100)

u2 Numeric. Utility parameter w_00. (0-100)

prob Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list of the following named elements:

- pE: Numeric vector of efficacy probabilities for each dose level.
- pT: Numeric vector of toxicity probabilities for each dose level.
- obd: Integer indicating the index of the true Optimal Biological Dose (OBD).
- mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).

For example:

```
prob <- list(
  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),
  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),
  obd = 3,
  mtd = 2
)
```

Value

A list containing operating characteristics such as:

bd.sel OBD selection percentage

od.sel Favorable dose selection percentage

bd.pts Average percentage of patients at the OBD

od.pts Average percentage of patients at the favorable doses

earlystop Percentage of early stopped trials

overdose Overdose patients percentage

poorall Poor allocation percentage

ov.sel Overdose selection percentage

---

oc_tepi *Compute Operating Characteristics using TEPI*

Description

oc_tepi() uses the TEPI design to compute operating charateristics of a user-specificed trial scenario. This design maps toxicity and efficacy intervals onto a decision table, forming 16 regions.

Usage

```
oc_tepi(
  ndose,
  target_t,
  lower_e,
  ncohort = 10,
  cohortsize = 3,
  startdose = 1,
```

```
  effint_l = c(0, lower_e, lower_e + 0.2, lower_e + 0.4),
  effint_u = c(lower_e, lower_e + 0.2, lower_e + 0.4, 1),
  toxint_l = c(0, 0.15, target_t, target_t + 0.05),
  toxint_u = c(0.15, target_t, target_t + 0.05, 1),
  psafe = 0.95,
  pfutility = 0.95,
  ntrial = 10000,
  utilitytype = 1,
  u1,
  u2,
  prob = NULL
)
```

Arguments

ndose	Integer. Number of dose levels. (**Required**)
target_t	Numeric. Target toxicity probability. (**Required**)
lower_e	Numeric. Minimum acceptable efficacy probability. (**Required**)
ncohort	Integer. Number of cohorts. (Default is 10)
cohortsize	Integer. Size of a cohort. (Default is 3)
startdose	Integer. Starting dose level. (Default is 1)
effint_l	Lower efficacy bounds for dose assignment decision table. (Default is c(0,lower_e,lower_e+0.2,l
effint_u	Lower efficacy bounds for dose assignment decision table. (Default is c(lower_e,lower_e+0.2,low
toxint_l	Lower toxicity bounds for dose assignment decision table. (Default is c(0,0.15,target_t,target_
toxint_u	Lower toxicity bounds for dose assignment decision table. (Default is c(0.15,target_t,target_t+
psafe	Numeric. Early stopping cutoff for toxicity. (Default is 0.95)
pfutility	Numeric. Early stopping cutoff for efficacy. (Default is 0.95)
ntrial	Integer. Number of random trial replications. (Default is 10000)
utilitytype	Integer. Type of utility structure. (Default is 1) • If set to 1: Use preset weights (w11 = 0.6, w00 = 0.4) • If set to 2: Use (w11 = 1, w00 = 0) • Other: Use user-specified values from u1 and u2.
u1	Numeric. Utility parameter w_11. (0-100)
u2	Numeric. Utility parameter w_00. (0-100)

prob	Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list of the following named elements:
	• pE: Numeric vector of efficacy probabilities for each dose level.
	• pT: Numeric vector of toxicity probabilities for each dose level.
	• obd: Integer indicating the index of the true Optimal Biological Dose (OBD).
	• mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).
	For example:
	`prob <- list(`
	`  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),`
	`  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),`
	`  obd = 3,`
	`  mtd = 2`
	`)`

Value

A list containing operating characteristics such as:

bd.sel OBD selection percentage

od.sel Favorable dose selection percentage

bd.pts Average percentage of patients at the OBD

od.pts Average percentage of patients at the favorable doses

earlystop Percentage of early stopped trials

overdose Overdose patients percentage

poorall Poor allocation percentage

ov.sel Overdose selection percentage

`oc_utpi` *Compute Operating Characteristics using uTPI*

Description

`oc_utpi()` uses the uTPI design to compute operating charateristics of a user-specificed trial scenario. This design places significance on optimizing utility using a quasi-binomial likelihood approach.

Usage

```
oc_utpi(
  ndose,
  target_t,
  lower_e,
  ncohort = 10,
  cohortsize = 3,
  startdose = 1,
  psafe = 0.95,
  pfutility = 0.9,
  ntrial = 10000,
  utilitytype = 1,
  u1,
  u2,
  prob = NULL
)
```

Arguments

`ndose`	Integer. Number of dose levels. (**Required**)
`target_t`	Numeric. Target toxicity probability. (**Required**)
`lower_e`	Numeric. Minimum acceptable efficacy probability. (**Required**)
`ncohort`	Integer. Number of cohorts. (Default is `10`)
`cohortsize`	Integer. Size of a cohort. (Default is `3`)
`startdose`	Integer. Starting dose level. (Default is `1`)

`psafe` Numeric. Early stopping cutoff for toxicity. (Default is `0.95`)

`pfutility` Numeric. Early stopping cutoff for efficacy. (Default is `0.95`)

`ntrial` Integer. Number of random trial replications. (Default is `10000`)

`utilitytype` Integer. Type of utility structure. (Default is `1`)

- If set to `1`: Use preset weights (w11 = 0.6, w00 = 0.4)
- If set to `2`: Use (w11 = 1, w00 = 0)
- Other: Use user-specified values from `u1` and `u2`.

`u1` Numeric. Utility parameter w_11. (0-100)

`u2` Numeric. Utility parameter w_00. (0-100)

`prob` Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list with the following named elements:

- `pE`: Numeric vector of efficacy probabilities for each dose level.
- `pT`: Numeric vector of toxicity probabilities for each dose level.
- `obd`: Integer indicating the index of the true Optimal Biological Dose (OBD).
- `mtd`: Integer indicating the index of the true Maximum Tolerated Dose (MTD).

For example:

```
prob <- list(
  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),
  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),
  obd = 3,
  mtd = 2
)
```

Value

A list containing operating characteristics such as:

bd.sel OBD selection percentage

od.sel Favorable dose selection percentage

bd.pts Average percentage of patients at the OBD

od.pts Average percentage of patients at the favorable doses

earlystop Percentage of early stopped trials

overdose Overdose patients percentage

poorall Poor allocation percentage

ov.sel Overdose selection percentage

`simulate_boin12` *Simulate Operating Characteristics using BOIN12.*

Description

This function runs simulations of the BOIN12 design by evaluating operating characteristics over a range of cohort sizes. For each dose level within the user-specified range, it performs multiple trials and saves the results to a corresponding file.

Usage

```
simulate_boin12(
  ndose,
  ssizerange,
  target_t,
  lower_e,
  cohortsize = 3,
  startdose = 1,
  psafe = 0.95,
  pfutility = 0.9,
  ntrial = 10000,
  utilitytype = 1,
  u1,
  u2,
  prob = NULL,
  save_dir = ".",
  save_folder = "boin12_simulations",
  save_file = "boin12_simulation.csv"
)
```

Arguments

`ndose`	Integer. Number of dose levels. (**Required**)
`ssizerange`	Integer vector. Range of number of cohorts to simulate. (**Required**)
`target_t`	Numeric. Target toxicity probability. (**Required**)
`lower_e`	Numeric. Minimum acceptable efficacy probability. (**Required**)
`cohortsize`	Integer. Size of a cohort. (Default is `3`)
`startdose`	Integer. Starting dose level. (Default is `1`)
`psafe`	Numeric. Early stopping cutoff for toxicity. (Default is `0.95`)
`pfutility`	Numeric. Early stopping cutoff for efficacy. (Default is `0.90`)
`ntrial`	Integer. Number of random trial replications. (Default is `10000`)
`utilitytype`	Integer. Type of utility structure. (Default is `1`) • If set to `1`: Use preset weights (w11 = 0.6, w00 = 0.4) • If set to `2`: Use (w11 = 1, w00 = 0) • Other: Use user-specified values from `u1` and `u2`.
`u1`	Numeric. Utility parameter w_11. (0-100)
`u2`	Numeric. Utility parameter w_00. (0-100)

`prob` Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list with the following named elements:

- `pE`: Numeric vector of efficacy probabilities for each dose level.
- `pT`: Numeric vector of toxicity probabilities for each dose level.
- `obd`: Integer indicating the index of the true Optimal Biological Dose (OBD).
- `mtd`: Integer indicating the index of the true Maximum Tolerated Dose (MTD).

For example:

```
prob <- list(
  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),
  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),
  obd = 3,
  mtd = 2
)
```

`save_dir` Directory to save output folders. Default is (".").

`save_folder` Folder name. (Default is "boin12_simulations")

`save_file` File name. (Default is "boin12_simulation.csv")

Value

Results are saved as CSV files organized by OBD within folders.

---

simulate_boinet *Simulate Operating Characteristics using BOINET*

Description

This function runs simulations of the BOINET design by evaluating operating characteristics over a range of cohort sizes. For each dose level within the user-specified range, it performs multiple trials and saves the results to a corresponding file.

Usage

```
simulate_boinet(
  ndose,
  ssizerange,
  target_t,
  lower_e,
  cohortsize = 3,
  startdose = 1,
  psafe = 0.95,
  pfutility = 0.9,
  ntrial = 10000,
  utilitytype = 1,
  prob = NULL,
  save_dir = ".",
  save_folder = "boinet_simulations",
  save_file = "boinet_simulation.csv"
)
```

Arguments

`ndose`	Integer. Number of dose levels. (**Required**)
`ssizerange`	Integer vector. Range of number of cohorts to simulate. (**Required**)
`target_t`	Numeric. Target toxicity probability. (**Required**)
`lower_e`	Numeric. Minimum acceptable efficacy probability. (**Required**)
`cohortsize`	Integer. Size of a cohort. (Default is `3`)
`startdose`	Integer. Starting dose level. (Default is `1`)
`psafe`	Numeric. Early stopping cutoff for toxicity. (Default is `0.95`)
`pfutility`	Numeric. Early stopping cutoff for efficacy. (Default is `0.90`)
`ntrial`	Integer. Number of random trial replications. (Default is `10000`)
`utilitytype`	Integer. Type of utility structure. (Default is `1`) • If set to `1`: Use preset weights (w11 = 0.6, w00 = 0.4) • If set to `2`: Use (w11 = 1, w00 = 0)

`prob`	Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list of the following named elements:
	• `pE`: Numeric vector of efficacy probabilities for each dose level.
	• `pT`: Numeric vector of toxicity probabilities for each dose level.
	• `obd`: Integer indicating the index of the true Optimal Biological Dose (OBD).
	• `mtd`: Integer indicating the index of the true Maximum Tolerated Dose (MTD).
	For example:
	`prob <- list(`
	`  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),`
	`  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),`
	`  obd = 3,`
	`  mtd = 2`
	`)`

`save_dir`	Directory to save output folders. Default is (`"."`).
`save_folder`	Folder name. (Default is "boin12_simulations")
`save_file`	File name. (Default is "boin12_simulation.csv")

Value

Results are saved as CSV files organized by OBD within folders.

`simulate_efftox` *Simulate Operating Characteristics using EffTox*

Description

This function runs simulations of the EffTox design by evaluating operating characteristics over a range of cohort sizes. For each dose level within the user-specified range, it performs multiple trials and saves the results to a corresponding file.

Usage

```
simulate_efftox(
  ndose,
  ssizerange,
  target_t,
  lower_e,
  startdose = 1,
  ntrial = 10000,
  utilitytype = 1,
  prob = NULL,
  save_dir = ".",
  save_folder = "efftox_simulations",
  save_file = "efftox_simulation.csv"
)
```

Arguments

`ndose`	Integer. Number of dose levels. (**Required**)
`ssizerange`	Integer vector. Range of number of cohorts to simulate. (**Required**)
`target_t`	Numeric. Target toxicity probability. (**Required**)
`lower_e`	Numeric. Minimum acceptable efficacy probability. (**Required**)
`startdose`	Integer. Starting dose level. (Default is `1`)
`ntrial`	Integer. Number of random trial replications. (Default is `10000`)
`utilitytype`	Integer. Type of utility structure. (Default is `1`) • If set to `1`: Use preset weights (w11 = 0.6, w00 = 0.4) • If set to `2`: Use (w11 = 1, w00 = 0)
`prob`	Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list of the following named elements: • `pE`: Numeric vector of efficacy probabilities for each dose level. • `pT`: Numeric vector of toxicity probabilities for each dose level. • `obd`: Integer indicating the index of the true Optimal Biological Dose (OBD). • `mtd`: Integer indicating the index of the true Maximum Tolerated Dose (MTD). For example:

```
prob <- list(
  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),
  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),
  obd = 3,
  mtd = 2
)
```

save_dir	Directory to save output folders. Default is (". ").
save_folder	Folder name. (Default is "boin12_simulations")
save_file	File name. (Default is "boin12_simulation.csv")

Value

Results are saved as CSV files organized by OBD within folders.

`simulate_ji3p3` *Simulate Operating Characteristics using Ji3+3*

Description

This function runs simulations of the Ji3+3 design by evaluating operating characteristics over a range of cohort sizes. For each dose level within the user-specified range, it performs multiple trials and saves the results to a corresponding file.

Usage

```
simulate_ji3p3(
  ndose,
  ssizerange,
  target_t,
  target_e,
  lower_e,
  cohortsize = 3,
  startdose = 1,
  eps1 = 0.05,
  eps2 = 0.05,
  psafe = 0.95,
  pfutility = 0.9,
  ntrial = 10000,
  utilitytype = 1,
  u1,
  u2,
  prob = NULL,
  save_dir = ".",
  save_folder = "ji3p3_simulations",
  save_file = "ji3p3_simulation.csv"
)
```

Arguments

ndose	Integer. Number of dose levels. (**Required**)
ssizerange	Integer vector. Range of number of cohorts to simulate. (**Required**)
target_t	Numeric. Target toxicity probability. (**Required**)
target_e	Numeric. Target efficacy probability. (**Required**)
lower_e	Numeric. Minimum acceptable efficacy probability. (**Required**)
cohortsize	Integer. Size of a cohort. (Default is 3)
startdose	Integer. Starting dose level. (Default is 1)
eps1	Numerical. Width of the subrectangle. (Default is '0.05')
eps2	Numerical. Width of the subreactangle. (Default is '0.05')
psafe	Numeric. Early stopping cutoff for toxicity. (Default is 0.95)
pfutility	Numeric. Early stopping cutoff for efficacy. (Default is 0.90)
ntrial	Integer. Number of random trial replications. (Default is 10000)
utilitytype	Integer. Type of utility structure. (Default is 1) • If set to 1: Use preset weights (w11 = 0.6, w00 = 0.4) • If set to 2: Use (w11 = 1, w00 = 0) • Other: Use user-specified values from u1 and u2.
u1	Numeric. Utility parameter w_11. (0-100)
u2	Numeric. Utility parameter w_00. (0-100)

prob	Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list of the following named elements: Use this parameter to provide fixed probability vectors as a list with the following named elements:
	• pE: Numeric vector of efficacy probabilities for each dose level.
	• pT: Numeric vector of toxicity probabilities for each dose level.
	• obd: Integer indicating the index of the true Optimal Biological Dose (OBD).
	• mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).
	For example:
	`prob <- list(`
	`  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),`
	`  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),`
	`  obd = 3,`
	`  mtd = 2`
	`)`

save_dir	Directory to save output folders. Default is ("..").
save_folder	Folder name. (Default is "boin12_simulations")
save_file	File name. (Default is "boin12_simulation.csv")

Value

Results are saved as CSV files organized by OBD within folders.

`simulate_pite` *Simulate Operating Characteristics using PRINTE*

Description

This function runs simulations of the PRINTE design by evaluating operating characteristics over a range of cohort sizes. For each dose level within the user-specified range, it performs multiple trials and saves the results to a corresponding file.

Usage

```
simulate_pite(
  ndose,
  ssizerange,
  target_t,
  target_e,
  lower_e,
  cohortsize = 3,
  startdose = 1,
  eps1 = 0.05,
  eps2 = 0.05,
  psafe = 0.95,
  pfutility = 0.9,
  ntrial = 10000,
  utilitytype = 1,
  u1,
  u2,
  prob = NULL,
  save_dir = ".",
  save_folder = "pite_simulations",
  save_file = "pite_simulation.csv"
)
```

Arguments

`ndose`	Integer. Number of dose levels. (**Required**)
`ssizerange`	Integer vector. Range of number of cohorts to simulate. (**Required**)
`target_t`	Numeric. Target toxicity probability. (**Required**)
`target_e`	Numeric. Target efficacy probability. (**Required**)
`lower_e`	Numeric. Minimum acceptable efficacy probability. (**Required**)
`cohortsize`	Integer. Size of a cohort. (Default is `3`)
`startdose`	Integer. Starting dose level. (Default is `1`)
`eps1`	Numerical. Width of the subrectangle.
`eps2`	Numerical. Width of the subreactangle.
`psafe`	Numeric. Early stopping cutoff for toxicity. (Default is `0.95`)
`pfutility`	Numeric. Early stopping cutoff for efficacy. (Default is `0.90`)
`ntrial`	Integer. Number of random trial replications. (Default is `10000`)

`utilitytype` Integer. Type of utility structure. (Default is 1)

- If set to 1: Use preset weights (w11 = 0.6, w00 = 0.4)
- If set to 2: Use (w11 = 1, w00 = 0)
- Other: Use user-specified values from u1 and u2.

`u1` Numeric. Utility parameter w_11. (0-100)

`u2` Numeric. Utility parameter w_00. (0-100)

`prob` Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list with the following named elements:

- pE: Numeric vector of efficacy probabilities for each dose level.
- pT: Numeric vector of toxicity probabilities for each dose level.
- obd: Integer indicating the index of the true Optimal Biological Dose (OBD).
- mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).

For example:

```
prob <- list(
  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),
  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),
  obd = 3,
  mtd = 2
)
```

`save_dir` Directory to save output folders. Default is (".").

`save_folder` Folder name. (Default is "boin12_simulations")

`save_file` File name. (Default is "boin12_simulation.csv")

Value

Results are saved as CSV files organized by OBD within folders.

---

simulate_stein *Simulate Operating Characteristics using STEIN*

Description

This function runs simulations of the STEIN design by evaluating operating characteristics over a range of cohort sizes. For each dose level within the user-specified range, it performs multiple trials and saves the results to a corresponding file.

Usage

```
simulate_stein(
  ndose,
  ssizerange,
  target_t,
  lower_e,
  cohortsize = 3,
  startdose = 1,
```

```
  psi1 = 0.2,
  psi2 = 0.6,
  psafe = 0.95,
  pfutility = 0.9,
  ntrial = 10000,
  utilitytype = 1,
  u1,
  u2,
  prob = NULL,
  save_dir = ".",
  save_folder = "stein_simulations",
  save_file = "stein_simulation.csv"
)
```

Arguments

ndose	Integer. Number of dose levels. (**Required**)
ssizerange	Integer vector. Range of number of cohorts to simulate. (**Required**)
target_t	Numeric. Target toxicity probability. (**Required**)
lower_e	Numeric. Minimum acceptable efficacy probability. (**Required**)
cohortsize	Integer. Size of a cohort. (Default is 3)
startdose	Integer. Starting dose level. (Default is 1)
psi1	Numerical. Highest inefficacious efficacy probability.
psi2	Numerical. Lowest highly-promising efficacy probability.
psafe	Numeric. Early stopping cutoff for toxicity. (Default is 0.95)
pfutility	Numeric. Early stopping cutoff for efficacy. (Default is 0.90)
ntrial	Integer. Number of random trial replications. (Default is 10000)
utilitytype	Integer. Type of utility structure. (Default is 1) • If set to 1: Use preset weights (w11 = 0.6, w00 = 0.4) • If set to 2: Use (w11 = 1, w00 = 0) • Other: Use user-specified values from u1 and u2.
u1	Numeric. Utility parameter w_11. (0-100)
u2	Numeric. Utility parameter w_00. (0-100)

prob	Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list with the following named elements:
	• pE: Numeric vector of efficacy probabilities for each dose level.
	• pT: Numeric vector of toxicity probabilities for each dose level.
	• obd: Integer indicating the index of the true Optimal Biological Dose (OBD).
	• mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).
	For example:
	`prob <- list(`
	`  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),`
	`  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),`
	`  obd = 3,`
	`  mtd = 2`
	`)`

save_dir	Directory to save output folders. Default is (". ").
save_folder	Folder name. (Default is "boin12_simulations")
save_file	File name. (Default is "boin12_simulation.csv")

Value

Results are saved as CSV files organized by OBD within folders.

`simulate_tepi` *Simulate Operating Characteristics using TEPI*

Description

This function runs simulations of the TEPI design by evaluating operating characteristics over a range of cohort sizes. For each dose level within the user-specified range, it performs multiple trials and saves the results to a corresponding file.

Usage

```
simulate_tepi(
  ndose,
  ssizerange,
  target_t,
  lower_e,
  cohortsize = 3,
  startdose = 1,
  effint_l = c(0, lower_e, lower_e + 0.2, lower_e + 0.4),
  effint_u = c(lower_e, lower_e + 0.2, lower_e + 0.4, 1),
  toxint_l = c(0, 0.15, target_t, target_t + 0.05),
  toxint_u = c(0.15, target_t, target_t + 0.05, 1),
  psafe = 0.95,
  pfutility = 0.9,
  ntrial = 10000,
  utilitytype = 1,
  u1,
  u2,
  prob = NULL,
  save_dir = ".",
  save_folder = "tepi_simulations",
  save_file = "tepi2_simulation.csv"
)
```

Arguments

ndose	Integer. Number of dose levels. (**Required**)
ssizerange	Integer vector. Range of number of cohorts to simulate. (**Required**)
target_t	Numeric. Target toxicity probability. (**Required**)
lower_e	Numeric. Minimum acceptable efficacy probability. (**Required**)
cohortsize	Integer. Size of a cohort. (Default is 3)

`startdose` Integer. Starting dose level. (Default is `1`)

`effint_l` Lower efficacy bounds for dose assignment decision table. (Default is `c(0,lower_e,lower_e+0.2,l`

`effint_u` Lower efficacy bounds for dose assignment decision table. (Default is `c(lower_e,lower_e+0.2,low`

`toxint_l` Lower toxicity bounds for dose assignment decision table. (Default is `c(0,0.15,target_t,target_`

`toxint_u` Lower toxicity bounds for dose assignment decision table. (Default is `c(0.15,target_t,target_t+`

`psafe` Numeric. Early stopping cutoff for toxicity. (Default is `0.95`)

`pfutility` Numeric. Early stopping cutoff for efficacy. (Default is `0.90`)

`ntrial` Integer. Number of random trial replications. (Default is `10000`)

`utilitytype` Integer. Type of utility structure. (Default is `1`)

- If set to `1`: Use preset weights (w11 = 0.6, w00 = 0.4)
- If set to `2`: Use (w11 = 1, w00 = 0)
- Other: Use user-specified values from `u1` and `u2`.

`u1` Numeric. Utility parameter w_11. (0-100)

`u2` Numeric. Utility parameter w_00. (0-100)

`prob` Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list with the following named elements:

- `pE`: Numeric vector of efficacy probabilities for each dose level.
- `pT`: Numeric vector of toxicity probabilities for each dose level.
- `obd`: Integer indicating the index of the true Optimal Biological Dose (OBD).
- `mtd`: Integer indicating the index of the true Maximum Tolerated Dose (MTD).

For example:

```
prob <- list(
  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),
  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),
  obd = 3,
  mtd = 2
)
```

`save_dir` Directory to save output folders. Default is (`"."`).

`save_folder` Folder name. (Default is "boin12_simulations")

`save_file` File name. (Default is "boin12_simulation.csv")

Value

Results are saved as CSV files organized by OBD within folders.

`simulate_utpi` *Simulate Operating Characteristics using uTPI*

Description

This function runs simulations of the uTPI design by evaluating operating characteristics over a range of cohort sizes. For each dose level within the user-specified range, it performs multiple trials and saves the results to a corresponding file.

Usage

```
simulate_utpi(
  ndose,
  ssizerange,
  target_t,
  lower_e,
  cohortsize = 3,
  startdose = 1,
  psafe = 0.95,
  pfutility = 0.9,
  ntrial = 10000,
  utilitytype = 1,
  u1,
  u2,
  prob = NULL,
  save_dir = ".",
  save_folder = "utpi_simulations",
  save_file = "utpi_simulation.csv"
)
```

Arguments

`ndose`	Integer. Number of dose levels. (**Required**)
`ssizerange`	Integer vector. Range of number of cohorts to simulate. (**Required**)
`target_t`	Numeric. Target toxicity probability. (**Required**)
`lower_e`	Numeric. Minimum acceptable efficacy probability. (**Required**)
`cohortsize`	Integer. Size of a cohort. (Default is `3`)
`startdose`	Integer. Starting dose level. (Default is `1`)
`psafe`	Numeric. Early stopping cutoff for toxicity. (Default is `0.95`)
`pfutility`	Numeric. Early stopping cutoff for efficacy. (Default is `0.90`)
`ntrial`	Integer. Number of random trial replications. (Default is `10000`)
`utilitytype`	Integer. Type of utility structure. (Default is `1`) • If set to `1`: Use preset weights (w11 = 0.6, w00 = 0.4) • If set to `2`: Use (w11 = 1, w00 = 0) • Other: Use user-specified values from `u1` and `u2`.
`u1`	Numeric. Utility parameter w_11. (0-100)
`u2`	Numeric. Utility parameter w_00. (0-100)

`prob` Fixed probability vectors. If not specified, a random scenario is used by default. Use this parameter to provide fixed probability vectors as a list with the following named elements:

- `pE`: Numeric vector of efficacy probabilities for each dose level.
- `pT`: Numeric vector of toxicity probabilities for each dose level.
- `obd`: Integer indicating the index of the true Optimal Biological Dose (OBD).
- `mtd`: Integer indicating the index of the true Maximum Tolerated Dose (MTD).

For example:

```
prob <- list(
  pE = c(0.4, 0.5, 0.6, 0.6, 0.6),
  pT = c(0.1, 0.2, 0.3, 0.4, 0.4),
  obd = 3,
  mtd = 2
)
```

`save_dir` Directory to save output folders. Default is (`"."`).

`save_folder` Folder name. (Default is "boin12_simulations")

`save_file` File name. (Default is "boin12_simulation.csv")

Value

Results are saved as CSV files organized by OBD within folders.

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