

Package: phase12designs (via r-universe)

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Type Package

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

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Description Provides a comprehensive set of tools to simulate, evaluate, and compare model-assisted designs for early-phase (Phase I/II) clinical trials, including: - BOIN12 (Bayesian optimal interval phase 1/11 trial design; Lin et al. (2020) <doi:10.1200/PO.20.00257>), - BOIN-ET (Takeda, K., Taguri, M., & Morita, S. (2018) <doi:10.1002/pst.1864>), - EffTox (Thall, P. F., & Cook, J. D. (2004) <doi:10.1111/j.0006-341X.2004.00218.x>), - Ji3+3 (Joint i3+3 design; Lin, X., & Ji, Y. (2020) <doi:10.1080/10543406.2020.1818250>), - PRINTE (probability intervals of toxicity and efficacy design; Lin, X., & Ji, Y. (2021) <doi:10.1177/0962280220977009>), - STEIN (simple toxicity and efficacy interval design; Lin, R., & Yin, G. (2017) <doi:10.1002/sim.7428>), - TEPI (toxicity and efficacy probability interval design; Li, D. H., Whitmore, J. B., Guo, W., & Ji, Y. (2017) <doi:10.1158/1078-0432.CCR-16-1125>), - uTPI (utility-based toxicity Probability interval design; Shi, H., Lin, R., & Lin, X. (2024) <doi:10.1002/sim.8922>). 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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decision_plot	<i>Decision map plot</i>
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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)).

Value

No return value, called for side effects.

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 characteristics of a user-specified 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,
  OBD = 0,
  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)
OBD	Integer. True index of the Optimal Biological Dose (OBD) for the trial scenario. (Default is 0) <ul style="list-style-type: none"> • If set to 0: Random OBD will be selected. • Other: Treat this argument as the true OBD.
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 ($w_{11} = 0.6$, $w_{00} = 0.4$)
 - If set to 2: Use ($w_{11} = 1$, $w_{00} = 0$)
 - 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

## Examples

```
oc_boin12(
 ndose = 5,
 target_t = 0.3,
 lower_e = 0.4,
 ntrial = 10,
)
```

---

 oc\_boinet

---

*Compute operating characteristics using BOINET*


---

### Description

oc\_boinet() uses the BOINET design to compute operating characteristics of a user-specified 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,
 OBD = 0,
 psafe = 0.95,
 pfutility = 0.95,
 ntrial = 10000,
 utilitytype = 1,
 prob = NULL
)
```

### Arguments

|             |                                                                                                                                                                                                                                                      |
|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ndose       | Integer. Number of dose levels. <b>(Required)</b>                                                                                                                                                                                                    |
| target_t    | Numeric. Target toxicity probability. <b>(Required)</b>                                                                                                                                                                                              |
| lower_e     | Numeric. Minimum acceptable efficacy probability. <b>(Required)</b>                                                                                                                                                                                  |
| 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)                                                                                                                                                                                                         |
| OBD         | Integer. True index of the Optimal Biological Dose (OBD) for the trial scenario. (Default is 0) <ul style="list-style-type: none"> <li>• If set to 0: Random OBD will be selected.</li> <li>• Other: Treat this argument as the true OBD.</li> </ul> |
| 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) <ul style="list-style-type: none"> <li>• If set to 1: Use preset weights (w11 = 0.6, w00 = 0.4)</li> </ul>                                                                                        |

- If set to 2: Use ( $w_{11} = 1$ ,  $w_{00} = 0$ )
- 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

## Examples

```
oc_boinet(
 ndose = 5,
 target_t = 0.3,
 lower_e = 0.4,
 ntrial = 10,
)
```

oc\_efftox

*Compute operating characteristics using EffTox***Description**

oc\_efftox() uses the EffTox design to compute operating characteristics of a user-specified trial scenario. This design uses toxicity–efficacy trade-off contours.

**Usage**

```
oc_efftox(
 ndose,
 target_t,
 lower_e,
 ncohort = 10,
 startdose = 1,
 OBD = 0,
 ntrial = 10000,
 utilitytype = 1,
 prob = NULL
)
```

**Arguments**

|             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ndose       | Integer. Number of dose levels. <b>(Required)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                |
| target_t    | Numeric. Target toxicity probability. <b>(Required)</b>                                                                                                                                                                                                                                                                                                                                                                                                                          |
| lower_e     | Numeric. Minimum acceptable efficacy probability. <b>(Required)</b>                                                                                                                                                                                                                                                                                                                                                                                                              |
| ncohort     | Integer. Number of cohorts. (Default is 10)                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| startdose   | Integer. Starting dose level. (Default is 1)                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| OBD         | Integer. True index of the Optimal Biological Dose (OBD) for the trial scenario. (Default is 0) <ul style="list-style-type: none"> <li>• If set to 0: Random OBD will be selected.</li> <li>• Other: Treat this argument as the true OBD.</li> </ul>                                                                                                                                                                                                                             |
| ntrial      | Integer. Number of random trial replications. (Default is 10000)                                                                                                                                                                                                                                                                                                                                                                                                                 |
| utilitytype | Integer. Type of utility structure. (Default is 1) <ul style="list-style-type: none"> <li>• If set to 1: Use preset weights (<math>w_{11} = 0.6</math>, <math>w_{00} = 0.4</math>)</li> <li>• If set to 2: Use (<math>w_{11} = 1</math>, <math>w_{00} = 0</math>)</li> </ul>                                                                                                                                                                                                     |
| 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: <ul style="list-style-type: none"> <li>• pE: Numeric vector of efficacy probabilities for each dose level.</li> <li>• pT: Numeric vector of toxicity probabilities for each dose level.</li> <li>• obd: Integer indicating the index of the true Optimal Biological Dose (OBD).</li> </ul> |

- **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

### Examples

```
oc_efftox(
 ndose = 2,
 target_t = 0.3,
 lower_e = 0.4,
 ntrial = 1,
)
```

### Description

oc\_ji3p3() uses the Ji3+3 design to compute operating characteristics of a user-specified 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,
 OBD = 0,
 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. <b>(Required)</b>                                                                                                                                                                                                                                                                                        |
| target_t    | Numeric. Target toxicity probability. <b>(Required)</b>                                                                                                                                                                                                                                                                                  |
| target_e    | Numeric. Target efficacy probability. <b>(Required)</b>                                                                                                                                                                                                                                                                                  |
| lower_e     | Numeric. Minimum acceptable efficacy probability. <b>(Required)</b>                                                                                                                                                                                                                                                                      |
| 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)                                                                                                                                                                                                                                                                                             |
| OBD         | Integer. True index of the Optimal Biological Dose (OBD) for the trial scenario. (Default is 0) <ul style="list-style-type: none"> <li>• If set to 0: Random OBD will be selected.</li> <li>• Other: Treat this argument as the true OBD.</li> </ul>                                                                                     |
| eps1        | Numerical. Width of the subrectangle.                                                                                                                                                                                                                                                                                                    |
| eps2        | Numerical. Width of the subrectangle.                                                                                                                                                                                                                                                                                                    |
| 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) <ul style="list-style-type: none"> <li>• If set to 1: Use preset weights (<math>w_{11} = 0.6</math>, <math>w_{00} = 0.4</math>)</li> <li>• If set to 2: Use (<math>w_{11} = 1</math>, <math>w_{00} = 0</math>)</li> <li>• Other: Use user-specified values from u1 and u2.</li> </ul> |

|      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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: <ul style="list-style-type: none"> <li>• pE: Numeric vector of efficacy probabilities for each dose level.</li> <li>• pT: Numeric vector of toxicity probabilities for each dose level.</li> <li>• obd: Integer indicating the index of the true Optimal Biological Dose (OBD).</li> <li>• mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).</li> </ul> |

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

## Examples

```
oc_ji3p3(
 ndose = 5,
 target_t = 0.3,
 target_e = 0.35,
 lower_e = 0.4,
 ntrial = 10,
)
```

---

 oc\_pite

---

*Compute operating characteristics using PRINTE*


---

### Description

oc\_pite() uses the PRINTE design to compute operating characteristics of a user-specified 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,
 OBD = 0,
 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. <b>(Required)</b>                                                                                                                                                                                                    |
| target_t   | Numeric. Target toxicity probability. <b>(Required)</b>                                                                                                                                                                                              |
| target_e   | Numeric. Target efficacy probability. <b>(Required)</b>                                                                                                                                                                                              |
| lower_e    | Numeric. Minimum acceptable efficacy probability. <b>(Required)</b>                                                                                                                                                                                  |
| 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)                                                                                                                                                                                                         |
| OBD        | Integer. True index of the Optimal Biological Dose (OBD) for the trial scenario. (Default is 0) <ul style="list-style-type: none"> <li>• If set to 0: Random OBD will be selected.</li> <li>• Other: Treat this argument as the true OBD.</li> </ul> |

|             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| eps1        | Numerical. Width of the subrectangle. (Default is '0.05')                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| eps2        | Numerical. Width of the subrectangle. (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) <ul style="list-style-type: none"> <li>• If set to 1: Use preset weights (w11 = 0.6, w00 = 0.4)</li> <li>• If set to 2: Use (w11 = 1, w00 = 0)</li> <li>• Other: Use user-specified values from u1 and u2.</li> </ul>                                                                                                                                                                                                                                                                                                  |
| 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: <ul style="list-style-type: none"> <li>• pE: Numeric vector of efficacy probabilities for each dose level.</li> <li>• pT: Numeric vector of toxicity probabilities for each dose level.</li> <li>• obd: Integer indicating the index of the true Optimal Biological Dose (OBD).</li> <li>• mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).</li> </ul> |

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

**Examples**

```
oc_pite(
 ndose = 5,
 target_t = 0.3,
 target_e = 0.35,
 lower_e = 0.4,
 ntrial = 10,
)
```

oc\_stein

*Compute operating characteristics using STEIN***Description**

oc\_stein() uses the STEIN design to compute operating characteristics of a user-specified 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,
 OBD = 0,
 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. <b>(Required)</b>                   |
| target_t   | Numeric. Target toxicity probability. <b>(Required)</b>             |
| lower_e    | Numeric. Minimum acceptable efficacy probability. <b>(Required)</b> |
| 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)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| OBD         | Integer. True index of the Optimal Biological Dose (OBD) for the trial scenario. (Default is 0) <ul style="list-style-type: none"> <li>• If set to 0: Random OBD will be selected.</li> <li>• Other: Treat this argument as the true OBD.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 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) <ul style="list-style-type: none"> <li>• If set to 1: Use preset weights (<math>w_{11} = 0.6</math>, <math>w_{00} = 0.4</math>)</li> <li>• If set to 2: Use (<math>w_{11} = 1</math>, <math>w_{00} = 0</math>)</li> <li>• Other: Use user-specified values from <math>u_1</math> and <math>u_2</math>.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                |
| 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: <ul style="list-style-type: none"> <li>• <math>p_E</math>: Numeric vector of efficacy probabilities for each dose level.</li> <li>• <math>p_T</math>: Numeric vector of toxicity probabilities for each dose level.</li> <li>• <math>obd</math>: Integer indicating the index of the true Optimal Biological Dose (OBD).</li> <li>• <math>mtd</math>: Integer indicating the index of the true Maximum Tolerated Dose (MTD).</li> </ul> For example: <pre>prob &lt;- 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 )</pre> |

## 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

**Examples**

```
oc_stein(
 ndose = 5,
 target_t = 0.3,
 lower_e = 0.4,
 ntrial = 10,
)
```

---

 oc\_tepi
 

---



---

*Compute operating characteristics using TEPI*


---

**Description**

oc\_tepi() uses the TEPI design to compute operating characteristics of a user-specified 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,
 OBD = 0,
 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. <b>(Required)</b>                   |
| target_t   | Numeric. Target toxicity probability. <b>(Required)</b>             |
| lower_e    | Numeric. Minimum acceptable efficacy probability. <b>(Required)</b> |
| 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)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| OBD         | Integer. True index of the Optimal Biological Dose (OBD) for the trial scenario. (Default is 0) <ul style="list-style-type: none"> <li>• If set to 0: Random OBD will be selected.</li> <li>• Other: Treat this argument as the true OBD.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| effint_l    | Lower efficacy bounds for dose assignment decision table. (Default is $c(0, lower\_e, lower\_e+0.2, lower\_e+0.4)$ )                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| effint_u    | Upper efficacy bounds for dose assignment decision table. (Default is $c(lower\_e, lower\_e+0.2, lower\_e+0.4, lower\_e+0.6)$ )                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| toxint_l    | Lower toxicity bounds for dose assignment decision table. (Default is $c(0, 0.15, target\_t, target\_t+0.05)$ )                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| toxint_u    | Upper toxicity bounds for dose assignment decision table. (Default is $c(0.15, target\_t, target\_t+0.05, target\_t+0.1)$ )                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 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) <ul style="list-style-type: none"> <li>• If set to 1: Use preset weights (<math>w_{11} = 0.6, w_{00} = 0.4</math>)</li> <li>• If set to 2: Use (<math>w_{11} = 1, w_{00} = 0</math>)</li> <li>• Other: Use user-specified values from u1 and u2.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                |
| 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: <ul style="list-style-type: none"> <li>• pE: Numeric vector of efficacy probabilities for each dose level.</li> <li>• pT: Numeric vector of toxicity probabilities for each dose level.</li> <li>• obd: Integer indicating the index of the true Optimal Biological Dose (OBD).</li> <li>• mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).</li> </ul> For example: <pre>prob &lt;- 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 )</pre> |

## 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

### Examples

```
oc_tepi(
 ndose = 5,
 target_t = 0.3,
 lower_e = 0.4,
 ntrial = 10,
)
```

---

oc\_utpi

*Compute operating characteristics using uTPI*

---

### Description

oc\_utpi() uses the uTPI design to compute operating characteristics of a user-specified 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,
 OBD = 0,
 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. <b>(Required)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| ncohort     | Integer. Number of cohorts. (Default is 10)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| cohortsizes | Integer. Size of a cohort. (Default is 3)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| startdose   | Integer. Starting dose level. (Default is 1)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| OBD         | Integer. True index of the Optimal Biological Dose (OBD) for the trial scenario. (Default is 0) <ul style="list-style-type: none"> <li>• If set to 0: Random OBD will be selected.</li> <li>• Other: Treat this argument as the true OBD.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 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) <ul style="list-style-type: none"> <li>• If set to 1: Use preset weights (<math>w_{11} = 0.6</math>, <math>w_{00} = 0.4</math>)</li> <li>• If set to 2: Use (<math>w_{11} = 1</math>, <math>w_{00} = 0</math>)</li> <li>• Other: Use user-specified values from <math>u_1</math> and <math>u_2</math>.</li> </ul>                                                                                                                                                                                                                                                                                                                                            |
| 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: <ul style="list-style-type: none"> <li>• pE: Numeric vector of efficacy probabilities for each dose level.</li> <li>• pT: Numeric vector of toxicity probabilities for each dose level.</li> <li>• obd: Integer indicating the index of the true Optimal Biological Dose (OBD).</li> <li>• mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).</li> </ul> For example: <pre>prob &lt;- 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 )</pre> |

## 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

**Examples**

```
oc_utpi(
 ndose = 5,
 target_t = 0.3,
 lower_e = 0.4,
 ntrial = 10,
)
```

---

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

**Arguments**

|             |                                                                           |
|-------------|---------------------------------------------------------------------------|
| ndose       | Integer. Number of dose levels. <b>(Required)</b>                         |
| ssize_range | Integer vector. Range of number of cohorts to simulate. <b>(Required)</b> |
| target_t    | Numeric. Target toxicity probability. <b>(Required)</b>                   |
| lower_e     | Numeric. Minimum acceptable efficacy probability. <b>(Required)</b>       |
| 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) <ul style="list-style-type: none"> <li>• If set to 1: Use preset weights (<math>w_{11} = 0.6</math>, <math>w_{00} = 0.4</math>)</li> <li>• If set to 2: Use (<math>w_{11} = 1</math>, <math>w_{00} = 0</math>)</li> <li>• Other: Use user-specified values from <math>u_1</math> and <math>u_2</math>.</li> </ul>                                                                                                                                                                                                                                                                                                                                            |
| 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: <ul style="list-style-type: none"> <li>• pE: Numeric vector of efficacy probabilities for each dose level.</li> <li>• pT: Numeric vector of toxicity probabilities for each dose level.</li> <li>• obd: Integer indicating the index of the true Optimal Biological Dose (OBD).</li> <li>• mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).</li> </ul> For example: <pre>prob &lt;- 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 )</pre> |
| save_dir    | Directory to save output folders. Default is tempdir().                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| save_folder | Folder name. (Default is "boin12_simulations")                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| save_file   | File name. (Default is "boin12_simulation.csv")                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

**Value**

No return value, called for side effects

**Examples**

```
prob <- list(
 pE = c(0.4, 0.5, 0.6),
 pT = c(0.1, 0.2, 0.3),
 obd = 2,
 mtd = 2
)
simulate_boin12(
 ndose = 3,
 ssizerange = c(3, 5),
 target_t = 0.3,
```

```

 lower_e = 0.2,
 ntrial = 10,
 prob = prob,
)

```

---

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

```

### Arguments

|             |                                                                           |
|-------------|---------------------------------------------------------------------------|
| ndose       | Integer. Number of dose levels. <b>(Required)</b>                         |
| ssize_range | Integer vector. Range of number of cohorts to simulate. <b>(Required)</b> |
| target_t    | Numeric. Target toxicity probability. <b>(Required)</b>                   |
| lower_e     | Numeric. Minimum acceptable efficacy probability. <b>(Required)</b>       |
| 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 ( $w_{11} = 0.6$ ,  $w_{00} = 0.4$ )
  - If set to 2: Use ( $w_{11} = 1$ ,  $w_{00} = 0$ )
- 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 `tempdir()`.
- save_folder** Folder name. (Default is "boin12_simulations")
- save_file** File name. (Default is "boin12_simulation.csv")

Value

No return value, called for side effects

Examples

```
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
)
simulate_boinet(
  ndose = 5,
  ssizerange = 1:2,
  target_t = 0.3,
  lower_e = 0.4,
  ntrial = 10,
  prob = prob,
)
```

simulate_efftox	<i>Simulate operating characteristics using EffTox</i>
-----------------	--

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

Arguments

ndose	Integer. Number of dose levels. (Required)
ssize_range	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) <ul style="list-style-type: none"> • If set to 1: Use preset weights ($w_{11} = 0.6$, $w_{00} = 0.4$) • If set to 2: Use ($w_{11} = 1$, $w_{00} = 0$)
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: <ul style="list-style-type: none"> • 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 `tempdir()`.
`save_folder` Folder name. (Default is "boin12_simulations")
`save_file` File name. (Default is "boin12_simulation.csv")

Value

No return value, called for side effects

Examples

```
prob <- list(  
  pE = c(0.4, 0.5),  
  pT = c(0.1, 0.2),  
  obd = 2,  
  mtd = 2  
)  
simulate_efftox(  
  ndose = 2,  
  ssizerange = 1,  
  target_t = 0.3,  
  lower_e = 0.4,  
  ntrial = 2,  
  prob = prob,  
)
```

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 = tempdir(),
  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 subrectangle. (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) <ul style="list-style-type: none"> • If set to 1: Use preset weights ($w_{11} = 0.6$, $w_{00} = 0.4$) • If set to 2: Use ($w_{11} = 1$, $w_{00} = 0$) • 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	<p>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:</p> <ul style="list-style-type: none"> • 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). <p>For example:</p> <pre>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)</pre>
save_dir	Directory to save output folders. Default is tempdir().
save_folder	Folder name. (Default is "boin12_simulations")
save_file	File name. (Default is "boin12_simulation.csv")

Value

No return value, called for side effects

Examples

```
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
)
simulate_ji3p3(
  ndose = 5,
  ssizerange = 1:2,
  target_t = 0.3,
  target_e = 0.5,
  lower_e = 0.4,
  ntrial = 10,
  prob = prob,
)
```

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 = tempdir(),
  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 subrectangle.

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) <ul style="list-style-type: none"> • If set to 1: Use preset weights ($w_{11} = 0.6$, $w_{00} = 0.4$) • If set to 2: Use ($w_{11} = 1$, $w_{00} = 0$) • Other: Use user-specified values from <code>u1</code> and <code>u2</code>.
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: <ul style="list-style-type: none"> • <code>pE</code>: Numeric vector of efficacy probabilities for each dose level. • <code>pT</code>: Numeric vector of toxicity probabilities for each dose level. • <code>obd</code>: Integer indicating the index of the true Optimal Biological Dose (OBD). • <code>mtd</code>: Integer indicating the index of the true Maximum Tolerated Dose (MTD). For example: <pre>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)</pre>
save_dir	Directory to save output folders. Default is <code>tempdir()</code> .
save_folder	Folder name. (Default is "boin12_simulations")
save_file	File name. (Default is "boin12_simulation.csv")

Value

No return value, called for side effects

Examples

```
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
)
simulate_pite(
  ndose = 5,
  ssizerange = 1:2,
  target_t = 0.3,
```

```

    target_e = 0.5,
    lower_e = 0.4,
    ntrial = 10,
    prob = prob,
)

```

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 = tempdir(),
  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) <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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). <p>For example:</p> <pre>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)</pre>
save_dir	Directory to save output folders. Default is tempdir().
save_folder	Folder name. (Default is "boin12_simulations")
save_file	File name. (Default is "boin12_simulation.csv")

Value

No return value, called for side effects

Examples

```
simulate_stein(
  ndose = 5,
  ssizerange = 1:2,
  target_t = 0.3,
  lower_e = 0.4,
  ntrial = 10,
)
```

 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 = tempdir(),
  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 $c(0, \text{lower_e}, \text{lower_e} + 0.2, \text{lower_e} + 0.4)$)
effint_u	Upper efficacy bounds for dose assignment decision table. (Default is $c(\text{lower_e}, \text{lower_e} + 0.2, \text{lower_e} + 0.4, 1)$)
toxint_l	Lower toxicity bounds for dose assignment decision table. (Default is $c(0, 0.15, \text{target_t}, \text{target_t} + 0.05)$)
toxint_u	Upper toxicity bounds for dose assignment decision table. (Default is $c(0.15, \text{target_t}, \text{target_t} + 0.05, 1)$)

toxint_u	Lower toxicity bounds for dose assignment decision table. (Default is $c(0.15, \text{target}_t, \text{target}_t + 0.05)$)
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) <ul style="list-style-type: none"> • If set to 1: Use preset weights ($w_{11} = 0.6, w_{00} = 0.4$) • If set to 2: Use ($w_{11} = 1, w_{00} = 0$) • Other: Use user-specified values from u_1 and u_2.
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: <ul style="list-style-type: none"> • 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). <p>For example:</p> <pre>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)</pre>
save_dir	Directory to save output folders. Default is <code>tempdir()</code> .
save_folder	Folder name. (Default is "boin12_simulations")
save_file	File name. (Default is "boin12_simulation.csv")

Value

No return value, called for side effects

Examples

```
simulate_tepi(
  ndose = 5,
  ssizerange = 1:2,
  target_t = 0.3,
  lower_e = 0.4,
  ntrial = 10,
)
```

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 = tempdir(),
  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) <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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). <p>For example:</p> <pre>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)</pre>
save_dir	Directory to save output folders. Default is tempdir().
save_folder	Folder name. (Default is "boin12_simulations")
save_file	File name. (Default is "boin12_simulation.csv")

Value

No return value, called for side effects

Examples

```
simulate_utpi(
  ndose = 5,
  ssize_range = 1:2,
  target_t = 0.3,
  lower_e = 0.4,
  ntrial = 10,
)
```

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