Package 'phase12designs'

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

Type Package

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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. 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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2 decision_plot

decision_plot Decision Map Plot

Description

This function creates a decision plot containing customizable decision zones.

Usage

```
decision_plot(
  filename,
  filetype = c("png", "pdf", "svg"),
  xlab = "Toxicity Probability",
  ylab = "Efficacy Probability",
  x_breaks = c(0, 1),
  y_breaks = c(0, 1),
  x_{labels} = c(0, 1),
  y_{abels} = 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)
)
```

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 $c(7, 7)$).

oc_boin12

Examples

oc_boin12

Compute Operating Characteristics using BOIN12

Description

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

Usage

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

```
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)
                   Numeric. Early stopping cutoff for toxicity. (Default is 0.95)
psafe
pfutility
                   Numeric. Early stopping cutoff for efficacy. (Default is 0.95)
ntrial
                   Integer. Number of random trial replications. (Default is 10000)
                   Integer. Type of utility structure. (Default is 1)
utilitytype
                     • 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.
```

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

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

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
)</pre>
```

Value

prob

A list containing operating characteristics such as:

bd.sel OBD selection percentage

od.sel Favorable dose selection percentage

bd.pts Average percentage of patients at the OBD

od.pts Average percentage of patients at the favorable doses

earlystop Percentage of early stopped trials

overdose Overdose patients percentage

poorall Poor allocation percentage

ov.sel Overdose selection percentage

oc_boinet

Compute Operating Characteristics using BOINET

Description

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

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Usage

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

Arguments

```
ndose
                   Integer. Number of dose levels. (Required)
                   Numeric. Target toxicity probability. (Required)
target_t
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)
                   Numeric. Early stopping cutoff for toxicity. (Default is 0.95)
psafe
pfutility
                   Numeric. Early stopping cutoff for efficacy. (Default is 0.95)
ntrial
                   Integer. Number of random trial replications. (Default is 10000)
                   Integer. Type of utility structure. (Default is 1)
utilitytype
                     • If set to 1: Use preset weights (w11 = 0.6, w00 = 0.4)
                     • If set to 2: Use (w11 = 1, w00 = 0)
prob
```

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

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

For example:

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

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Value

A list containing operating characteristics such as:

```
bd.sel OBD selection percentage
od.sel Favorable dose selection percentage
bd.pts Average percentage of patients at the OBD
od.pts Average percentage of patients at the favorable doses
earlystop Percentage of early stopped trials
overdose Overdose patients percentage
poorall Poor allocation percentage
ov.sel Overdose selection percentage
```

oc_efftox

Compute Operating Characteristics using EffTox

Description

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

Usage

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

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

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- 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
)</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

oc_ji3p3

Compute Operating Characteristics using Ji3+3

Description

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

Usage

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

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

Arguments

```
ndose
                   Integer. Number of dose levels. (Required)
                   Numeric. Target toxicity probability. (Required)
target_t
                   Numeric. Target efficacy probability. (Required)
target_e
lower e
                   Numeric. Minimum acceptable efficacy probability. (Required)
                   Integer. Number of cohorts. (Default is 10)
ncohort
                   Integer. Size of a cohort. (Default is 3)
cohortsize
startdose
                   Integer. Starting dose level. (Default is 1)
eps1
                   Numerical. Width of the subrectangle.
                   Numerical. Width of the subreactangle.
eps2
psafe
                   Numeric. Early stopping cutoff for toxicity. (Default is 0.95)
pfutility
                   Numeric. Early stopping cutoff for efficacy. (Default is 0.95)
                   Integer. Number of random trial replications. (Default is 10000)
ntrial
                   Integer. Type of utility structure. (Default is 1)
utilitytype
                     • 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)
                   Numeric. Utility parameter w_00. (0-100)
u2
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
)</pre>
```

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Value

A list containing operating characteristics such as:

```
bd.sel OBD selection percentage
od.sel Favorable dose selection percentage
bd.pts Average percentage of patients at the OBD
od.pts Average percentage of patients at the favorable doses
earlystop Percentage of early stopped trials
overdose Overdose patients percentage
poorall Poor allocation percentage
ov.sel Overdose selection percentage
```

oc_pite

Compute Operating Characteristics using PRINTE

Description

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

Usage

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

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

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ncohort Integer. Number of cohorts. (Default is 10) cohortsize Integer. Size of a cohort. (Default is 3) Integer. Starting dose level. (Default is 1) startdose Numerical. Width of the subrectangle. (Default is '0.05') eps1 eps2 Numerical. Width of the subreactangle. (Default is '0.05') Numeric. Early stopping cutoff for toxicity. (Default is 0.95) psafe Numeric. Early stopping cutoff for efficacy. (Default is 0.95) pfutility ntrial Integer. Number of random trial replications. (Default is 10000) Integer. Type of utility structure. (Default is 1) utilitytype • 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. Numeric. Utility parameter w_11. (0-100) u1 Numeric. Utility parameter w_00. (0-100) u2 Fixed probability vectors. If not specified, a random scenario is used by deprob

- 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).

fault. Use this parameter to provide fixed probability vectors as a list with the

• mtd: Integer indicating the index of the true Maximum Tolerated Dose (MTD).

For example:

following named elements:

```
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>
```

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

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oc_stein Compute Operating Characteristics using STEIN

Description

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

Usage

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

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

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

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
)</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

oc_tepi

Compute Operating Characteristics using TEPI

Description

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

Usage

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

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```
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

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

)

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Value

```
A list containing operating characteristics such as:
```

```
bd.sel OBD selection percentage
od.sel Favorable dose selection percentage
bd.pts Average percentage of patients at the OBD
od.pts Average percentage of patients at the favorable doses
earlystop Percentage of early stopped trials
overdose Overdose patients percentage
poorall Poor allocation percentage
ov.sel Overdose selection percentage
```

oc_utpi

Compute Operating Characteristics using uTPI

Description

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

Usage

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

```
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)
```

oc_utpi

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

Pfutility

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

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

utilitytype

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

• If set to 1: Use preset weights (w11 = 0.6, w00 = 0.4)

• If set to 2: Use (w11 = 1, w00 = 0)

• Other: Use user-specified values from u1 and u2.

u1 Numeric. Utility parameter w_11. (0-100)
u2 Numeric. Utility parameter w_00. (0-100)

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

following named elements:

• pE: Numeric vector of efficacy probabilities for each dose level.

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

For example:

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

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simulate_boin12

Simulate Operating Characteristics using BOIN12.

Description

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

Usage

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

```
Integer. Number of dose levels. (Required)
ndose
ssizerange
                   Integer vector. Range of number of cohorts to simulate. (Required)
                   Numeric. Target toxicity probability. (Required)
target_t
lower e
                   Numeric. Minimum acceptable efficacy probability. (Required)
                   Integer. Size of a cohort. (Default is 3)
cohortsize
startdose
                   Integer. Starting dose level. (Default is 1)
psafe
                   Numeric. Early stopping cutoff for toxicity. (Default is 0.95)
                   Numeric. Early stopping cutoff for efficacy. (Default is 0.90)
pfutility
ntrial
                   Integer. Number of random trial replications. (Default is 10000)
                   Integer. Type of utility structure. (Default is 1)
utilitytype
                     • 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.
                   Numeric. Utility parameter w_11. (0-100)
u1
                   Numeric. Utility parameter w_00. (0-100)
u2
```

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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:

Value

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

simulate_boinet

Simulate Operating Characteristics using BOINET

Description

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

Usage

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

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Arguments

```
ndose
                   Integer. Number of dose levels. (Required)
                   Integer vector. Range of number of cohorts to simulate. (Required)
ssizerange
                   Numeric. Target toxicity probability. (Required)
target_t
lower_e
                   Numeric. Minimum acceptable efficacy probability. (Required)
                   Integer. Size of a cohort. (Default is 3)
cohortsize
startdose
                   Integer. Starting dose level. (Default is 1)
psafe
                   Numeric. Early stopping cutoff for toxicity. (Default is 0.95)
                   Numeric. Early stopping cutoff for efficacy. (Default is 0.90)
pfutility
                   Integer. Number of random trial replications. (Default is 10000)
ntrial
                   Integer. Type of utility structure. (Default is 1)
utilitytype
                     • If set to 1: Use preset weights (w11 = 0.6, w00 = 0.4)
                     • If set to 2: Use (w11 = 1, w00 = 0)
                   Fixed probability vectors. If not specified, a random scenario is used by default.
prob
                   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(</pre>
                     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
                   )
                   Directory to save output folders. Default is (".").
save_dir
```

Value

save_folder

save_file

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

Folder name. (Default is "boin12_simulations")

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

simulate_efftox 19

simulate_efftox

Simulate Operating Characteristics using EffTox

Description

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

Usage

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

Arguments

ndose Integer. Number of dose levels. (Required) Integer vector. Range of number of cohorts to simulate. (Required) ssizerange Numeric. Target toxicity probability. (Required) target_t Numeric. Minimum acceptable efficacy probability. (Required) lower_e Integer. Starting dose level. (Default is 1) startdose Integer. Number of random trial replications. (Default is 10000) ntrial utilitytype Integer. Type of utility structure. (Default is 1) • If set to 1: Use preset weights (w11 = 0.6, w00 = 0.4) • If set to 2: Use (w11 = 1, w00 = 0)Fixed probability vectors. If not specified, a random scenario is used by default. prob 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:

20 simulate_ji3p3

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

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

Value

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

simulate_ji3p3

Simulate Operating Characteristics using Ji3+3

Description

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

Usage

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

simulate_ji3p3 21

Arguments

```
Integer. Number of dose levels. (Required)
ndose
                   Integer vector. Range of number of cohorts to simulate. (Required)
ssizerange
target_t
                   Numeric. Target toxicity probability. (Required)
                   Numeric. Target efficacy probability. (Required)
target_e
                   Numeric. Minimum acceptable efficacy probability. (Required)
lower_e
                   Integer. Size of a cohort. (Default is 3)
cohortsize
                   Integer. Starting dose level. (Default is 1)
startdose
                   Numerical. Width of the subrectangle. (Default is '0.05')
eps1
                   Numerical. Width of the subreactangle. (Default is '0.05')
eps2
psafe
                   Numeric. Early stopping cutoff for toxicity. (Default is 0.95)
                   Numeric. Early stopping cutoff for efficacy. (Default is 0.90)
pfutility
ntrial
                   Integer. Number of random trial replications. (Default is 10000)
                   Integer. Type of utility structure. (Default is 1)
utilitytype
                     • 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.
                   Numeric. Utility parameter w_11. (0-100)
u1
                   Numeric. Utility parameter w 00. (0-100)
u2
                   Fixed probability vectors. If not specified, a random scenario is used by default.
prob
                   Use this parameter to provide fixed probability vectors as a list of the following
                   named elements: Use this parameter to provide fixed probability vectors as a list
                   with the following named elements:
                     • pE: Numeric vector of efficacy probabilities for each dose level.
                     • pT: Numeric vector of toxicity probabilities for each dose level.
                     • obd: Integer indicating the index of the true Optimal Biological Dose (OBD).
                     • mtd: Integer indicating the index of the true Maximum Tolerated Dose
                        (MTD).
                   For example:
                   prob <- list(</pre>
                     pE = c(0.4, 0.5, 0.6, 0.6, 0.6),
                     pT = c(0.1, 0.2, 0.3, 0.4, 0.4),
                     obd = 3.
                     mtd = 2
                   )
save_dir
                   Directory to save output folders. Default is (".").
save_folder
                   Folder name. (Default is "boin12_simulations")
```

Value

save file

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

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

22 simulate_pite

simulate_pite

Simulate Operating Characteristics using PRINTE

Description

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

Usage

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

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

simulate_stein 23

```
utilitytype
                  Integer. Type of utility structure. (Default is 1)
                     • If set to 1: Use preset weights (w11 = 0.6, w00 = 0.4)
                     • If set to 2: Use (w11 = 1, w00 = 0)
                     • Other: Use user-specified values from u1 and u2.
                  Numeric. Utility parameter w_11. (0-100)
u1
                  Numeric. Utility parameter w_00. (0-100)
u2
                  Fixed probability vectors. If not specified, a random scenario is used by de-
prob
                  fault. 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(</pre>
                     pE = c(0.4, 0.5, 0.6, 0.6, 0.6),
                     pT = c(0.1, 0.2, 0.3, 0.4, 0.4),
                     obd = 3,
                     mtd = 2
                  )
save_dir
                  Directory to save output folders. Default is (".").
save_folder
                  Folder name. (Default is "boin12_simulations")
save_file
                  File name. (Default is "boin12_simulation.csv")
```

Value

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

simulate_stein

Simulate Operating Characteristics using STEIN

Description

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

Usage

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

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

Arguments

```
ndose
                   Integer. Number of dose levels. (Required)
                   Integer vector. Range of number of cohorts to simulate. (Required)
ssizerange
                   Numeric. Target toxicity probability. (Required)
target_t
                   Numeric. Minimum acceptable efficacy probability. (Required)
lower_e
cohortsize
                   Integer. Size of a cohort. (Default is 3)
startdose
                   Integer. Starting dose level. (Default is 1)
                   Numerical. Highest inefficacious efficacy probability.
psi1
psi2
                   Numerical. Lowest highly-promising efficacy probability.
                   Numeric. Early stopping cutoff for toxicity. (Default is 0.95)
psafe
pfutility
                   Numeric. Early stopping cutoff for efficacy. (Default is 0.90)
ntrial
                   Integer. Number of random trial replications. (Default is 10000)
utilitytype
                   Integer. Type of utility structure. (Default is 1)
                     • If set to 1: Use preset weights (w11 = 0.6, w00 = 0.4)
                     • If set to 2: Use (w11 = 1, w00 = 0)
                     • Other: Use user-specified values from u1 and u2.
u1
                   Numeric. Utility parameter w_11. (0-100)
u2
                   Numeric. Utility parameter w 00. (0-100)
                   Fixed probability vectors. If not specified, a random scenario is used by de-
prob
                   fault. 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(</pre>
  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_tepi 25

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

Value

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

simulate_tepi Simulate Operating Characteristics using TEPI

Description

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

Usage

```
simulate_tepi(
 ndose,
  ssizerange,
  target_t,
  lower_e,
 cohortsize = 3,
  startdose = 1,
 effint_1 = c(0, lower_e, lower_e + 0.2, lower_e + 0.4),
 effint_u = c(lower_e, lower_e + 0.2, lower_e + 0.4, 1),
  toxint_l = c(0, 0.15, target_t, target_t + 0.05),
  toxint_u = c(0.15, target_t, target_t + 0.05, 1),
 psafe = 0.95,
 pfutility = 0.9,
 ntrial = 10000,
 utilitytype = 1,
 u1,
 u2,
 prob = NULL,
  save_dir = ".",
  save_folder = "tepi_simulations",
  save_file = "tepi2_simulation.csv"
)
```

```
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)
```

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```
startdose
                  Integer. Starting dose level. (Default is 1)
                  Lower efficacy bounds for dose assignment decision table. (Default is c(0,lower_e,lower_e+0.2,1
effint_1
                  Lower efficacy bounds for dose assignment decision table. (Default is c(lower_e,lower_e+0.2,low
effint_u
toxint_1
                  Lower toxicity bounds for dose assignment decision table. (Default is c(0,0.15, target_t, target_
toxint_u
                  Lower toxicity bounds for dose assignment decision table. (Default is c(0.15, target_t, target_t+
                  Numeric. Early stopping cutoff for toxicity. (Default is 0.95)
psafe
                  Numeric. Early stopping cutoff for efficacy. (Default is 0.90)
pfutility
ntrial
                  Integer. Number of random trial replications. (Default is 10000)
                  Integer. Type of utility structure. (Default is 1)
utilitytype
                     • 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.
                  Numeric. Utility parameter w_11. (0-100)
u1
                  Numeric. Utility parameter w_00. (0-100)
u2
                  Fixed probability vectors. If not specified, a random scenario is used by de-
prob
                  fault. 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(</pre>
                     pE = c(0.4, 0.5, 0.6, 0.6, 0.6),
                     pT = c(0.1, 0.2, 0.3, 0.4, 0.4),
                     obd = 3,
                     mtd = 2
                  )
save_dir
                  Directory to save output folders. Default is (".").
save_folder
                  Folder name. (Default is "boin12_simulations")
                  File name. (Default is "boin12_simulation.csv")
save_file
```

Value

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

simulate_utpi 27

simulate_utpi

Simulate Operating Characteristics using uTPI

Description

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

Usage

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

```
Integer. Number of dose levels. (Required)
ndose
ssizerange
                   Integer vector. Range of number of cohorts to simulate. (Required)
                   Numeric. Target toxicity probability. (Required)
target_t
lower e
                   Numeric. Minimum acceptable efficacy probability. (Required)
                   Integer. Size of a cohort. (Default is 3)
cohortsize
startdose
                   Integer. Starting dose level. (Default is 1)
psafe
                   Numeric. Early stopping cutoff for toxicity. (Default is 0.95)
                   Numeric. Early stopping cutoff for efficacy. (Default is 0.90)
pfutility
ntrial
                   Integer. Number of random trial replications. (Default is 10000)
                   Integer. Type of utility structure. (Default is 1)
utilitytype
                     • 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.
                   Numeric. Utility parameter w_11. (0-100)
u1
                   Numeric. Utility parameter w_00. (0-100)
u2
```

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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
)</pre>
```

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

Value

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

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