Package: BayesDIP (via r-universe)

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Title Bayesian Decreasingly Informative Priors for Early Termination Phase II Trials
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Description Provide early termination phase II trial designs with a decreasingly informative prior (DIP) or a regular Bayesian prior chosen by the user. The program can determine the minimum planned sample size necessary to achieve the user-specified admissible designs. The program can also perform power and expected sample size calculations for the tests in early termination Phase II trials. See Wang C and Sabo RT (2022) <doi:10.18203 2349-3259.ijct20221110="">; Sabo RT (2014) <doi:10.1080 10543406.2014.888441="">.</doi:10.1080></doi:10.18203>
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Contents
OneSampleBernoulli

2 OneSampleBernoulli

	OneSampleNormal1.Design	6
	OneSampleNormal2	8
	OneSampleNormal2.Design	9
	OneSamplePoisson	11
	OneSamplePoisson.Design	12
	TwoSampleBernoulli	14
	TwoSampleBernoulli.Design	15
Index		17

OneSampleBernoulli

One sample Bernoulli model

Description

For a given planned sample size, the efficacy and futility boundaries, return the power, the type I error, the expected sample size and its standard deviation, the probability of reaching the efficacy and futility boundaries.

Usage

```
OneSampleBernoulli(
   prior,
   N = 100,
   p0,
   p1,
   d = 0,
   ps = 0.95,
   pf = 0.05,
   alternative = c("less", "greater"),
   seed = 202209,
   sim = 5000
)
```

Arguments

prior A list of length 3 containing the distributional information of the prior. The first element is a number specifying the type of prior. Options are

1. DIP;

2. Beta(a,b), where a = shape, b = scale

The second and third elements of the list are the parameters a and b, respectively.

N The planned sample size.

p0 The null response rate, which could be taken as the standard or historical rate.

p1 The response rate of the new treatment.

d The target improvement (minimal clinically meaningful difference).

ps The efficacy boundary (upper boundary).

pf	The futility boundary (lower boundary).
alternative	less (lower values imply greater efficacy) or greater (larger values imply greater efficacy).
seed	The seed for simulations.
sim	The number of simulations.

A list of the arguments with method and computed elements

Examples

```
# with traditional Bayesian prior Beta(1,1)  
OneSampleBernoulli(list(2,1,1), N = 100, p0 = 0.3, p1 = 0.5, d = 0.05, ps = 0.98, pf = 0.05, alternative = "greater", seed = 202210, sim = 10)  
# with DIP  
OneSampleBernoulli(list(1,0,0), N = 100, p0 = 0.3, p1 = 0.5, d = 0.05, ps = 0.98, pf = 0.05, alternative = "greater", seed = 202210, sim = 10)
```

OneSampleBernoulli.Design

One sample Bernoulli model - Trial Design

Description

Calculate the minimum planned sample size under an admissible design. The users decide the power and type-I-error, and pick the efficacy and futility boundaries. If there are no admissible design based on controlled type-I-error, then default to output the designs with the lowest type-I-error and at least the user-defined (e.g. 80%) power.

```
OneSampleBernoulli.Design(
    prior,
    nmin = 10,
    nmax = 100,
    p0,
    p1,
    d = 0,
    ps,
    pf,
    power = 0.8,
    t1error = 0.05,
    alternative = c("less", "greater"),
    seed = 202209,
    sim = 1000
)
```

prior A list of length 3 containing the distributional information of the prior. The first element is a number specifying the type of prior. Options are 1. DIP; 2. Beta(a,b), where a = shape, b = scaleThe second and third elements of the list are the parameters a and b, respectively. nmin The start searching sample size The stop searching sample size nmax The null response rate, which could be taken as the standard or historical rate. p0 The response rate of the new treatment. **p1** The target improvement (minimal clinically meaningful difference). The efficacy boundary (upper boundary). ps The futility boundary (lower boundary). pf The power to achieve. power

t1error The controlled type-I-error.

alternative less (lower values imply greater efficacy) or greater (larger values imply greater

efficacy).

seed The seed for simulations.

sim The number of simulations.

Value

A list of the arguments with method and computed elements.

OneSampleNormal1 5

OneSampleNormal1	One sample Normal model with one-parameter unknown, given vari-
	ance

Description

For a given planned sample size, the efficacy and futility boundaries, return the power, the type I error, the expected sample size and its standard deviation, the probability of reaching the efficacy and futility boundaries.

Usage

```
OneSampleNormal1(
    prior,
    N = 100,
    mu0,
    mu1,
    var,
    d = 0,
    ps = 0.95,
    pf = 0.05,
    alternative = c("less", "greater"),
    seed = 202209,
    sim = 5000
)
```

Arguments

prior	A list of length 2 containing the distributional information of the prior. The first element is a number specifying the type of prior. Options are
	1. DIP;
	2. Normal($mu0$, $var/n0$), where $mu0$ = prior mean, var = the known variance
	The second elements of the list is the parameter n0.
N	The planned sample size.
mu0	The null mean value, which could be taken as the standard or current mean.
mu1	The mean value of the new treatment.
var	The variance
d	The target improvement (minimal clinically meaningful difference).
ps	The efficacy boundary (upper boundary).
pf	The futility boundary (lower boundary).
alternative	less (lower values imply greater efficacy) or greater (larger values imply greater efficacy).
seed	The seed for simulations.
sim	The number of simulations.

A list of the arguments with method and computed elements.

Examples

```
# with traditional Bayesian prior Beta(1,1)  
OneSampleNormal1(list(2,6), N = 100, mu0 = 100, mu1 = 95, var=15, d = 0.05, ps = 0.95, pf = 0.05, alternative = "less", seed = 202210, sim = 10)  
OneSampleNormal1(list(1,0), N = 100, mu0 = 100, mu1 = 95, var=15, d = 0.05, ps = 0.95, pf = 0.05, alternative = "less", seed = 202210, sim = 10)
```

OneSampleNormal1.Design

One sample Normal model with one-parameter unknown, given variance

Description

#' Calculate the minimum planned sample size under an admissible design. The users decide the power and type-I-error, and pick the efficacy and futility boundaries. If there are no admissible design based on controlled type-I-error, then default to output the designs with the lowest type-I-error and at least the user-defined (e.g. 80%) power.

```
OneSampleNormal1.Design(
 prior,
 nmin = 10,
 nmax = 100,
 mu0,
 mu1,
  var,
  d = 0,
  ps,
 pf,
  power = 0.8,
  t1error = 0.05,
  alternative = c("less", "greater"),
  seed = 202209,
  sim = 1000
)
```

prior	A list of length 2 containing the distributional information of the prior. The first element is a number specifying the type of prior. Options are
	1. DIP;
	2. Normal($mu0$, $var/n0$), where $mu0$ = prior mean, var = the known variance
	The second elements of the list is the parameter n0.
nmin	The start searching sample size
nmax	The stop searching sample size
mu0	The null mean value, which could be taken as the standard or current mean.
mu1	The mean value of the new treatment.
var	The variance
d	The target improvement (minimal clinically meaningful difference).
ps	The efficacy boundary (upper boundary).
pf	The futility boundary (lower boundary).
power	The power to achieve.
t1error	The controlled type-I-error.
alternative	less (lower values imply greater efficacy) or greater (larger values imply greater efficacy).
seed	The seed for simulations.

Value

sim

A list of the arguments with method and computed elements.

The number of simulations.

8 OneSampleNormal2

One Sample Normal model with two-parameter unknown - both mean and variance unknown

Description

For a given planned sample size, the efficacy and futility boundaries, return the power, the type I error, the expected sample size and its standard deviation, the probability of reaching the efficacy and futility boundaries.

Usage

```
OneSampleNormal2(
    prior,
    N = 100,
    mu0,
    mu1,
    var0,
    var,
    d = 0,
    ps = 0.95,
    pf = 0.05,
    alternative = c("less", "greater"),
    seed = 202209,
    sim = 5000
)
```

Arguments

prior

A list of length 3 containing the distributional information of the prior. The first element is a number specifying the type of prior. Options are

- 1. DIP;
- 2. Normal(mu0,var/k) and var ~ Inverse-Gamma(v/2, v*var0/2) where mu0 = prior mean, k = sample size of prior observations (Normal prior),

 $v = sample \ size \ of \ prior \ observations \ (Gamma \ prior), \ var 0 = prior \ sample \ variance$

The second and third elements of the list are the parameters k and v, respectively.

N The planned sample size.

mu0 The null mean value, which could be taken as the standard or current mean.

mu1 The mean value of the new treatment.

var0 The prior sample variance

var The variance

d The target improvement (minimal clinically meaningful difference).

ps	The efficacy boundary (upper boundary).
pf	The futility boundary (lower boundary).
alternative	less (lower values imply greater efficacy) or greater (larger values imply greater efficacy).
seed	The seed for simulations.
sim	The number of simulations.

A list of the arguments with method and computed elements.

Examples

```
# with traditional Bayesian prior Beta(1,1)  
OneSampleNormal2(list(2,2,1), N = 100, mu0 = 100, mu1 = 95, var0=225, var=225, d = 0, ps = 0.95, pf = 0.05, alternative = "less", seed = 202210, sim = 10)  
# with DIP  
OneSampleNormal2(list(1,0,0), N = 100, mu0 = 100, mu1 = 95, var0=225, var=225, d = 0, ps = 0.95, pf = 0.05, alternative = "less", seed = 202210, sim = 10)
```

OneSampleNormal2.Design

One sample Normal model with two-parameter unknown - both mean and variance unknown

Description

Calculate the minimum planned sample size under an admissible design. The users decide the power and type-I-error, and pick the efficacy and futility boundaries. If there are no admissible design based on controlled type-I-error, then default to output the designs with the lowest type-I-error and at least the user-defined (e.g. 80%) power.

```
OneSampleNormal2.Design(
   prior,
   nmin = 10,
   nmax = 100,
   mu0,
   mu1,
   var0,
   var,
   d = 0,
   ps,
   pf,
```

```
power = 0.8,
    t1error = 0.05,
    alternative = c("less", "greater"),
    seed = 202209,
    sim = 1000
)
```

prior

A list of length 3 containing the distributional information of the prior. The first element is a number specifying the type of prior. Options are

- 1. DIP;
- 2. Normal(mu0,var/k) and var ~ Inverse-Gamma(v/2, v*var0/2) where mu0 = prior mean, k = sample size of prior observations (Normal prior),

v = sample size of prior observations (Gamma prior), var0 = prior sample variance

The second and third elements of the list are the parameters k and v, respectively.

nmin The start searching sample size
nmax The stop searching sample size

mu0 The null mean value, which could be taken as the standard or current mean.

mu1 The mean value of the new treatment.

var0 The prior sample variance

var The variance

d The target improvement (minimal clinically meaningful difference).

ps The efficacy boundary (upper boundary).
pf The futility boundary (lower boundary).

power The power to achieve.

t1error The controlled type-I-error.

alternative less (lower values imply greater efficacy) or greater (larger values imply greater

efficacy).

seed The seed for simulations.

sim The number of simulations.

Value

A list of the arguments with method and computed elements.

OneSamplePoisson 11

OneSamplePoisson

One sample Poisson model

Description

For a given planned sample size, the efficacy and futility boundaries, return the power, the type I error, the expected sample size and its standard deviation, the probability of reaching the efficacy and futility boundaries.

Usage

```
OneSamplePoisson(
   prior,
   N = 100,
   m0,
   m1,
   d = 0,
   ps = 0.95,
   pf = 0.05,
   alternative = c("less", "greater"),
   seed = 202209,
   sim = 5000
)
```

Arguments

A list of length 3 containing the distributional information of the prior. The first element is a number specifying the type of prior. Options are
DIP;
Gamma(a,b), where a = shape, b = rate

The second and third elements of the list are the parameters a and b, respectively.

N The planned sample size.

m0 The null event rate, which could be taken as the standard or current event rate.

m1 The event rate of the new treatment.

d The target improvement (minimal clinically meaningful difference).

ps The efficacy boundary (upper boundary).

pf The futility boundary (lower boundary).

alternative less (lower values imply greater efficacy) or greater (larger values imply greater efficacy).

seed The seed for simulations.

The number of simulations.

Value

A list of the arguments with method and computed elements

Examples

```
# with traditional Bayesian prior Gamma(0.5,0.001)  
OneSamplePoisson(list(2,0.5,0.001), N = 100, m0 = 0.5, m1 = 0.4, d = 0.05, ps = 0.95, pf = 0.05, alternative = "less", seed = 202210, sim = 10)  
# with DIP  
OneSamplePoisson(list(1,0,0), N = 100, m0 = 0.5, m1 = 0.4, d = 0.05, ps = 0.95, pf = 0.05, alternative = "less", seed = 202210, sim = 10)
```

OneSamplePoisson.Design

One sample Poisson model - Trial Design

Description

Calculate the minimum planned sample size under an admissible design. The users decide the power and type-I-error, and pick the efficacy and futility boundaries. If there are no admissible design based on controlled type-I-error, then default to output the designs with the lowest type-I-error and at least the user-defined (e.g. 80%) power.

```
OneSamplePoisson.Design(
    prior,
    nmin = 10,
    nmax = 100,
    m0,
    m1,
    d = 0,
    ps,
    pf,
    power = 0.8,
    t1error = 0.05,
    alternative = c("less", "greater"),
    seed = 202209,
    sim = 1000
)
```

prior	A list of length 3 containing the distributional information of the prior. The first element is a number specifying the type of prior. Options are
	1. DIP;
	2. Gamma (a,b) , where $a = \text{shape}$, $b = \text{rate}$
	The second and third elements of the list are the parameters a and b, respectively.
nmin	The start searching sample size
nmax	The stop searching sample size
m0	The null event rate, which could be taken as the standard or current event rate.
m1	The event rate of the new treatment.
d	The target improvement (minimal clinically meaningful difference).
ps	The efficacy boundary (upper boundary).
pf	The futility boundary (lower boundary).
power	The expected power to achieve.
t1error	The controlled type-I-error.
alternative	less (lower values imply greater efficacy) or greater (larger values imply greater efficacy).
seed	The seed for simulations.

Value

sim

A list of the arguments with method and computed elements

The number of simulations.

```
# with traditional Bayesian prior Gamma(0.5,0.001)  
OneSamplePoisson.Design(list(2,0.5,0.001), nmin = 10, nmax=100, m0 = 5, m1 = 4, d = 0, ps = 0.95, pf = 0.05, power = 0.80, t1error=0.05, alternative = "less", seed = 202210, sim = 10)  
# with DIP  
OneSamplePoisson.Design(list(1,0,0), nmin = 10, nmax=100, m0 = 5, m1 = 4, d = 0, ps = 0.95, pf = 0.05, power = 0.80, t1error=0.05, alternative = "less", seed = 202210, sim = 10)
```

14 TwoSampleBernoulli

TwoSampleBernoulli Two

Two sample Bernoulli model

Description

For a given planned sample size, the efficacy and futility boundaries, return the power, the type I error, the expected sample size and its standard deviation, the probability of reaching the efficacy and futility boundaries. Equal allocation between two treatment groups.

Usage

```
TwoSampleBernoulli(
   prior,
   N = 200,
   p1,
   p2,
   d = 0,
   ps = 0.95,
   pf = 0.05,
   alternative = c("less", "greater"),
   seed = 202209,
   sim = 5000
)
```

Arguments

prior

	element is a number specifying the type of prior. Options are
	1. DIP;
	2. Beta(a,b), where $a = \text{shape}$, $b = \text{scale}$
	The second and third elements of the list are the parameters a and b, respectively.
N	The total planned sample size for two treatment groups.
p1	The response rate of the new treatment.
p2	The response rate of the compared treatment.
d	The target improvement (minimal clinically meaningful difference).
ps	The efficacy boundary (upper boundary).
pf	The futility boundary (lower boundary).
alternative	less (lower values imply greater efficacy) or greater (larger values imply greater efficacy).

A list of length 3 containing the distributional information of the prior. The first

Value

seed

sim

A list of the arguments with method and computed elements

The seed for simulations.

The number of simulations.

Examples

TwoSampleBernoulli.Design

Two sample Bernoulli model - Trial Design

Description

Calculate the minimum planned sample size under an admissible design. The users decide the power and type-I-error, and pick the efficacy and futility boundaries. If there are no admissible design based on controlled type-I-error, then default to output the designs with the lowest type-I-error and at least the user-defined (e.g. 80%) power.

Usage

```
TwoSampleBernoulli.Design(
   prior,
   nmin = 10,
   nmax = 200,
   p1,
   p2,
   d = 0,
   ps = 0.95,
   pf = 0.05,
   power = 0.8,
   t1error = 0.05,
   alternative = c("less", "greater"),
   seed = 202209,
   sim = 500
)
```

Arguments

prior

A list of length 3 containing the distributional information of the prior. The first element is a number specifying the type of prior. Options are

- 1. DIP:
- 2. Beta(a,b), where a = shape, b = scale

The second and third elements of the list are the parameters a and b, respectively.

nmin	The start searching total sample size for two treatment groups.
nmax	The stop searching total sample size for two treatment groups.
p1	The response rate of the new treatment.
p2	The response rate of the compared treatment.
d	The target improvement (minimal clinically meaningful difference).
ps	The efficacy boundary (upper boundary).
pf	The futility boundary (lower boundary).
power	The power to achieve.
t1error	The controlled type-I-error.
alternative	less (lower values imply greater efficacy) or greater (larger values imply greater efficacy).
seed	The seed for simulations.

sim

A list of the arguments with method and computed elements

The number of simulations.

Index

```
OneSampleBernoulli, 2
OneSampleBernoulli.Design, 3
OneSampleNormal1, 5
OneSampleNormal1.Design, 6
OneSampleNormal2, 8
OneSampleNormal2.Design, 9
OneSamplePoisson, 11
OneSamplePoisson.Design, 12
TwoSampleBernoulli, 14
TwoSampleBernoulli.Design, 15
```