Package 'BayesDIP'

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Type Package

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>.

License GPL (>= 2)

URL <https://github.com/chenw10/BayesDIP>

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Contents

`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.

Value

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.

Usage

```
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
)
```

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 sample size
nmax	The stop searching 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).
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.

Examples

```
# with traditional Bayesian prior Beta(1,1)
OneSampleBernoulli.Design(list(2,1,1), nmin = 10, nmax=100, p0 = 0.3, p1 = 0.5, d = 0,
                ps = 0.98, pf = 0.02, power = 0.80, t1error=0.05, alternative = "greater",
                   seed = 202210, sim = 10)
# with DIP
OneSampleBernoulli.Design(list(1,0,0), nmin = 10, nmax=100, p0 = 0.3, p1 = 0.5, d = 0,
                ps = 0.98, pf = 0.02, power = 0.80, t1error=0.05, alternative = "greater",
                   seed = 202210, sim = 10)
```

`OneSampleNormal1` *One sample Normal model with one-parameter unknown, given variance*

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.

Value

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.

Usage

```
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
)
```

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.
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.
sim	The number of simulations.

Value

A list of the arguments with method and computed elements.

Examples

```
# with traditional Bayesian prior Beta(1,1)
OneSampleNormal1.Design(list(2,6), nmin = 10, nmax = 100, mu0 = 100, mu1 = 95, var=15, d = 0.05,
                ps = 0.95, pf = 0.05, power = 0.8, t1error = 0.05, alternative = "less",
                 seed = 202210, sim = 10)
# with DIP
OneSampleNormal1.Design(list(1,0), nmin = 10, nmax = 100, mu0 = 100, mu1 = 95, var=15, d = 0.05,
                ps = 0.95, pf = 0.05, power = 0.8, t1error = 0.05, alternative = "less",
                 seed = 202210, sim = 10)
```

`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), var0 = 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.

Value

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.

Usage

```
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
)
```

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), 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.

Examples

```
# with traditional Bayesian prior Beta(1,1)
OneSampleNormal2.Design(list(2,2,1), nmin = 10, nmax = 100, mu0 = 100, mu1 = 95,
                        var0=225, var=225, d = 0, ps = 0.95, pf = 0.05,
                        power = 0.8, t1error = 0.05, alternative = "less",
```

```
                        seed = 202210, sim = 10)
# with DIP
OneSampleNormal2.Design(list(1,0,0), nmin = 10, nmax = 100, mu0 = 100, mu1 = 95,
                        var0=225, var=225, d = 0, ps = 0.95, pf = 0.05,
                        power = 0.8, t1error = 0.05, alternative = "less",
                        seed = 202210, sim = 10)
```

`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

`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 = 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.
sim	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.

Usage

```
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
)
```

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. Gamma(a,b), where a = shape, b = 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.
sim	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.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)
```

`TwoSampleBernoulli` *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`	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 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).
`seed`	The seed for simulations.
`sim`	The number of simulations.

Value

A list of the arguments with method and computed elements

Examples

```
# with traditional Bayesian prior Beta(1,1)
TwoSampleBernoulli(list(2,1,1), N = 200, p1 = 0.5, p2 = 0.3, d = 0,
                   ps = 0.90, pf = 0.05, alternative = "greater",
                   seed = 202210, sim = 5)
# with DIP
TwoSampleBernoulli(list(1,0,0), N = 200, p1 = 0.5, p2 = 0.3, d = 0,
                   ps = 0.90, pf = 0.05, alternative = "greater",
                   seed = 202210, sim = 5)
```

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	The number of simulations.

Value

A list of the arguments with method and computed elements

Examples

```
# with traditional Bayesian prior Beta(1,1)
TwoSampleBernoulli.Design(list(2,1,1), nmin = 100, nmax = 120, p1 = 0.5, p2 = 0.3, d = 0,
                ps = 0.90, pf = 0.05, power = 0.8, t1error = 0.05, alternative = "greater",
                    seed = 202210, sim = 10)
# with DIP
TwoSampleBernoulli.Design(list(1,0,0), nmin = 100, nmax = 120, p1 = 0.5, p2 = 0.3, d = 0,
                ps = 0.90, pf = 0.05, power = 0.8, t1error = 0.05, alternative = "greater",
                    seed = 202210, sim = 10)
```

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