Package 'ph2bye'

July 22, 2016

Type Package

Title Phase II Clinical Trial Design Using Bayesian Methods

Version 0.1.1

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Description Calculate the Bayesian posterior/predictive probability and
determine the sample size and stopping boundaries for single-arm Phase II design

License GPL (>= 2)

LazyData TRUE

Imports base,
ph2bayes

Suggests clinfun,
gsDesign,
survival

RoxygenNote 5.0.1

R topics documented:

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ph2bye *ph2bye: A package for Phase II single-arm Bayesian design.*

Description

The ph2bye package provides two categories of important functions: PostP.design and PredP.design.

Posterior probability criterion functions

The posterior probability criterion functions include PostP and PostP.design functions.

Predictive probability criterion functions

The predictive probability criterion functions include PredP and PredP.design functions.

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`PostP` *The posterior probability criterion function for Phase II single-arm design*

Description

Thall and Simon's criterion function for determining the trial decision boundaries based on the posterior probability.

Usage

```
PostP(x, n, a, b, p0)
```

Arguments

`x`	the number of responses among n patients treated by the experimental drug at a certain stage of the trial.
`n`	the number of patients treated by the experimental drug at a certain stage of the trial.
`a`	the hyperparameter (shape1) of the Beta prior for the experimental drug.
`b`	the hyperparameter (shape2) of the Beta prior for the experimental drug.
`p0`	the prespecified reseponse rate.

Value

`prob`	the posterior probability: $Pr(p > p_0 \| X = x)$

References

Berry, S. M., Carlin, B. P., Lee, J. J., & Muller, P. (2010). *Bayesian adaptive methods for clinical trials.* CRC press.

Thall, P. F., Simon, R. (1994). Practical Bayesian guidelines for phase IIB clinical trials. *Biometrics* **50**: 337-349.

Yin, G. (2013). *Clinical Trial Design: Bayesian and Frequentist Adaptive Methods.* New York: Wiley.

Examples

```
PostP(8,15,1,1,0.8)
```

PostP.design *The stopping boundaries based on the posterior probability criterion*

Description

The design function to sequentially monitor sample size and boundary based on Thall and Simon's criterion.

Usage

```
PostP.design(type, nmax, a, b, p0, delta, theta)
```

Arguments

type	type of boundaries: "superiority" or "futility".
nmax	the maximum number of patients treated by the experimental drug.
a	the hyperparameter (shape1) of the Beta prior for the experimental drug.
b	the hyperparameter (shape2) of the Beta prior for the experimental drug.
p0	the pre-specified reseponse rate.
delta	the minimally acceptable increment of the response rate for the experimental drug compared with the standard drug.
theta	the cutoff probability: typically, $\theta = [0.95, 0.99]$ for efficacy, $\theta = [0.01, 0.05]$ for futility.

Value

boundset	the boundaries set; U_n or L_n

References

Thall, P. F., Simon, R. (1994). Practical Bayesian guidelines for phase IIB clinical trials. *Biometrics* **50**: 337-349.

Yin, G. (2012). *Clinical Trial Design: Bayesian and Frequentist Adaptive Methods.* New York: Wiley.

Examples

```
## Using vague prior Unif(0,1)
PostP.design(type = "futility", nmax=100, a=1, b=1, p0=0.15, delta=0.15, theta=0.05)
PostP.design(type = "efficacy", nmax=100, a=1, b=1, p0=0.15, delta=0.15, theta=0.9)
## Or using Jeffery prior with Beta(0.5,0.5)
PostP.design(type = "futility", nmax=100, a=0.5, b=0.5, p0=0.15, delta=0.15, theta=0.05)
PostP.design(type = "efficacy", nmax=100, a=0.5, b=0.5, p0=0.15, delta=0.15, theta=0.9)
```

PredP *The predictive probability criterion function for Phase II single-arm design*

Description

Lee and Liu's criterion function for determining the trial decision cutoffs based on the predictive probability.

Usage

```
PredP(x, n, nmax, a, b, p0, theta_t)
```

Arguments

x	the number of responses among n patients treated by the experimental drug at a certain stage of the trial.
n	the number of patients treated by the experimental drug at a certain stage of the trial.
nmax	the maximum number of patients treated by the experimental drug.
a	the hyperparameter (shape1) of the Beta prior for the experimental drug.
b	the hyperparameter (shape2) of the Beta prior for the experimental drug.
p0	the the response rate for the standard drug.
theta_t	the prespecified target probability; tipically, $\theta_T = [0.85, 0.95]$.

Value

prob	the predictive probability: $PP = \sum_{y=0}^{n_{max}-n} Pr(Y = y\|x) I(\Pr(p > p_0\|Y = y, x) \geq \theta_T)$

References

Lee, J. J., Liu, D. D. (2008). A predictive probability design for phase II cancer clinical trials. *Clinical Trials* **5**: 93-106.

Yin, G. (2012). *Clinical Trial Design: Bayesian and Frequentist Adaptive Methods.* New York: Wiley.

Examples

```
# Using vague prior Uniform(0,1), i.e. Beta(1,1)
PredP(16, 23, 40, 1, 1, 0.15, 0.9)
```

PredP.design *The stopping boundaries based on the predictive probability criterion*

Description

The design function to sequentially monitor sample size and boundary based on Lee and Liu's criterion.

Usage

```
PredP.design(type, nmax, a, b, p0, theta_t, delta, theta)
```

Arguments

type	type of boundaries: "superiority" or "futility".
nmax	the maximum number of patients treated by the experimental drug.
a	the hyperparameter (shape1) of the Beta prior for the experimental drug.
b	the hyperparameter (shape2) of the Beta prior for the experimental drug.
p0	the the response rate for the standard drug.
theta_t	the prespecified target probability; tipically, $\theta_T = [0.85, 0.95]$.
delta	the minimally acceptable increment of the response rate for the experimental drug compared with the standard drug
theta	the cutoff probability: typically, $\theta = [0.95, 0.99]$ for efficacy, $\theta = [0.01, 0.05]$ for futility.

Value

boundset	the boundaries set: U_n or L_n

References

Lee, J. J., Liu, D. D. (2008). A predictive probability design for phase II cancer clinical trials. *Clinical Trials* **5**: 93-106.

Yin, G. (2012). *Clinical Trial Design: Bayesian and Frequentist Adaptive Methods.* New York: Wiley.

Examples

```
PredP.design(type = "futility", nmax=40, a=1, b=1, p0=0.15, delta=0.15, theta=0.05)
PredP.design(type = "efficacy", nmax=40, a=1, b=1, p0=0.15, delta=0.15, theta=0.9)
```

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