

Package ‘ph2bayes’

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Type Package

Title Bayesian Single-Arm Phase II Designs

Version 0.0.2

Description An implementation of Bayesian single-arm phase II design methods for binary outcome based on posterior probability (Thall and Simon (1994) <[doi:10.2307/2533377](https://doi.org/10.2307/2533377)>) and predictive probability (Lee and Liu (2008) <[doi:10.1177/1740774508089279](https://doi.org/10.1177/1740774508089279)>).

License GPL-3

Imports stats, Rcpp (>= 0.12.15)

LinkingTo Rcpp

RoxygenNote 6.0.1

NeedsCompilation yes

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ph2bayes-package *The 'ph2bayes' package*

Description

An implementation of Bayesian single-arm phase II design methods for binary outcome based on posterior probability and predictive probability: Thall and Simon (Biometrics 1994), Lee and Liu (Clinical Trials 2008).

postprob *The posterior probability criterion function*

Description

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

Usage

```
postprob(y, n, alpha_e, beta_e, alpha_s, beta_s, delta)
```

Arguments

y	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.
alpha_e	the hyperparameter (shape1) of the Beta prior for the experimental drug.
beta_e	the hyperparameter (shape2) of the Beta prior for the experimental drug.
alpha_s	the hyperparameter (shape1) of the Beta prior for the standard drug.
beta_s	the hyperparameter (shape2) of the Beta prior for the standard drug.
delta	the minimally acceptable increment of the response rate for the experimental drug compared with the standard drug.

Value

prob	the posterior probability: $\Pr(p_E > p_S + \delta y)$
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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.

predprob *The predictive probability criterion function*

Description

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

Usage

```
predprob(y, n, nmax, alpha_e, beta_e, p_s, theta_t)
```

Arguments

y	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.
alpha_e	the hyperparameter (shape1) of the Beta prior for the experimental drug.
beta_e	the hyperparameter (shape2) of the Beta prior for the experimental drug.
p_s	the the response rate for the standard drug.
theta_t	the prespecified target probability; typically, $\theta_T = [0.85, 0.95]$.

Value

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

```
# p. 97, PP = 0.5656
predprob(16, 23, 40, 0.6, 0.4, 0.6, 0.9)
```

stopbound_post	<i>The stopping boundaries based on Thall and Simon's criterion</i>
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Description

The stopping boundaries based on Thall and Simon's criterion.

Usage

```
stopbound_post(theta, type, nmax, alpha_e, beta_e, alpha_s, beta_s, delta)
```

Arguments

theta	the cutoff probability: typically, $\theta = [0.95, 0.99]$ for superiority, $\theta = [0.01, 0.05]$ for futility.
type	type of boundaries: "superiority" or "futility".
nmax	the maximum number of patients treated by the experimental drug.
alpha_e	the hyperparameter (shape1) of the Beta prior for the experimental drug.
beta_e	the hyperparameter (shape2) of the Beta prior for the experimental drug.
alpha_s	the hyperparameter (shape1) of the Beta prior for the standard drug.
beta_s	the hyperparameter (shape2) of the Beta prior for the standard drug.
delta	the minimally acceptable increment of the response rate for the experimental drug compared with the standard drug. Note: if type = "superiority", then delta is set to 0.

Value

boundset	the boundaries set; U_n or L_n
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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

```
stopbound_post(0.05, "futility", 40, 0.6, 1.4, 15, 35, 0)
stopbound_post(0.05, "futility", 30, 0.4, 1.6, 10, 40, 0)
stopbound_post(0.95, "superiority", 40, 0.6, 1.4, 15, 35, 0)
```

stopbound_pred	<i>The stopping boundaries based on Lee and Liu's criterion</i>
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Description

The stopping boundaries based on Lee and Liu's criterion.

Usage

```
stopbound_pred(theta, type, nmax, alpha_e, beta_e, p_s, theta_t)
```

Arguments

theta	the cutoff probability: typically, $\theta = [0.95, 0.99]$ for superiority, $\theta = [0.01, 0.05]$ for futility.
type	type of boundaries: "superiority" or "futility".
nmax	the maximum number of patients treated by the experimental drug.
alpha_e	the hyperparameter (shape1) of the Beta prior for the experimental drug.
beta_e	the hyperparameter (shape2) of the Beta prior for the experimental drug.
p_s	the the response rate for the standard drug.
theta_t	the prespecified target probability; typically, $\theta_T = [0.85, 0.95]$.

Value

boundset	the boundaries set: U_n or L_n
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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

```
stopbound_pred(0.05, "futility", 40, 0.6, 1.4, 0.3, 0.85)
stopbound_pred(0.05, "futility", 30, 0.4, 1.6, 0.2, 0.85)
stopbound_pred(0.95, "superiority", 40, 0.6, 1.4, 0.3, 0.85)
```

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