Package 'STARTdesign'

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Type Package

Title Single to Double Arm Transition Design for Phase II Clinical Trials

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Description The package is used for calibrating the design parameters for single-to-double arm transition design proposed by Shi and Yin (2017). The calibration is performed via numerical enumeration to find the optimal design that satisfies the constraints on the type I and II error rates.

License GPL (>= 2)

Imports Rcpp (>= 0.12.7)

LinkingTo Rcpp

NeedsCompilation yes

Repository CRAN

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Contents

`findparameter` *Parameter Calibration*

Description

Calibrate the design parameters for the Single-to-double Arm Transition Design

Usage

```
findparameter(p0,p1,alpha1,beta1,alpha2,beta2)
```

Arguments

p0	The minimally required level for the response rate to be clinically meaningful.
p1	The desirable target rate.
alpha1	The type I error rate in the first stage.
beta1	The type II error rate in the first stage.
alpha2	The type I error rate in the second stage.
beta2	The type II error rate in the second stage.

Value

n1	The number of subjects in the experimental arm in the single-arm stage.
n2	The number of subjects in each arm in the double-arm stage.
r1	The minimum number of responses to achieve in the single-arm stage in order for the trial to proceed into the next stage.The number of responses observed at the end of single-arm stage should be greater than or equal to $r1$ for the trial to proceed.
ess0	The expected sample size under the null hypothesis.
ess1	The expected sample size under the alternative hypothesis.
asn	The average sample number taken as the average of $ess0$ and $ess1$.

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References

Shi H., Yin G. (2017), START: Single-to-double Arm Transition Design for Phase II Clinical Trials. Submitted.

Examples

```
findparameter(p0=0.2,p1=0.5,alpha1=0.25,beta1=0.05,alpha2=0.2,beta2=0.25)
```

`rejectprob` *Rejection Probability Calculation*

Description

Calculate the probability of rejecting the null hypothesis at the end of the second stage in the Single-to-double Arm Transition Design

Usage

```
rejectprob(pe,ps,n1,n2,r1,z)
```

Arguments

`pe`	The response rate of the experimental arm.
`ps`	The response rate of the standard arm.
`n1`	The number of subjects in the experiemntal arm in the single-arm stage.
`n2`	The number of subjects in each arm in the double-arm stage.
`r1`	The minimum number of responses to achieve in the single-arm stage in order for the trial to proceed into the next stage.
`z`	The threshold value for the Z test, i.e., the Z statistic should be greater than z in order to reject the null hypothesis at the end of the second stage.

Value

`n1`	The number of subjects in the experiemntal arm in the single-arm stage.
`n2`	The number of subjects in each arm in the double-arm stage.
`r1`	The minimum number of responses to achieve in the single-arm stage in order for the trial to proceed into the next stage.The number of responses observed at the end of single-arm stage should be greater than or equal to $r1$ for the trial to proceed.
`ess0`	The expected sample size under the null hypothesis.
`ess1`	The expected sample size under the alternative hypothesis.
`asn`	The average sample number taken as the average of $ess0$ and $ess1$.

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References

Shi H., Yin G. (2017), START: Single-to-double Arm Transition Design for Phase II Clinical Trials.

Examples

```
rejectprob(pe=0.2,ps=0.4,n1=20,n2=40,r1=10,z=qnorm(0.9))
```

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