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)
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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


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 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.
- `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 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**

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