Package 'OptOTrials'

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Title Optimal Two-Stage Designs for Ordered Categorical Outcomes

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Description Functions to design and simulate optimal two-stage randomized controlled trials (RCTs) with ordered categorical outcomes, supporting rank-based tests and group-sequential decision rules. Methods build on classical and modern rank tests and two-stage/Group-Sequential designs, e.g., Park (2025) <doi:10.1371/journal.pone.0318211>. Please see the package reference manual and vignettes for details.

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Author Yeonhee Park [aut, cre],
Yudi Wang [aut],
Zhanpeng Xu [aut]

Maintainer Yeonhee Park <yeonheepark@skku.edu>

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Contents

`OptOTrials-package` *Optimal Two-Stage Designs for Ordered Categorical Outcomes*

Description

Functions to design and simulate optimal two-stage randomized controlled trials (RCTs) with ordered categorical outcomes, supporting rank-based tests and group-sequential decision rules. Methods build on classical and modern rank tests and two-stage/Group-Sequential designs, e.g., Park (2025) <doi: 10.1371/journal.pone.0318211>. Please see the package reference manual and vignettes for details.

Details

There are several main functoins. `Decision_rule_S_1stage`, `Decision_rule_M_1stage`, `Decision_rule_W_1stage`, `ruleF`, and `ruleFS` determine the decision rule for clinical trials. `op.1stage`, `op.F`, and `op.FS` calculate the operating characteristics for clinical trial designs, including type I error, power, and expected sample size, to investigate the performance of the designs.

Author(s)

Yeonhee Park [aut, cre], Yudi Wang [aut], Zhanpeng Xu [aut]

Maintainer: Yeonhee Park <yeonheepark@skku.edu>

References

Park, Y. (2025). Optimal two-stage group sequential designs based on Mann-Whitney-Wilcoxon test. PloS one, 20(2), e0318211.

`Decision_rule_M.F` *Decision fule for the F design based on the Mann-Whitney-Wilcoxon test with specified values of alpha1 and beta1*

Description

This is to determine the decision rule for a two-stage design based on the Mann-Whitney-Wilcoxon test with the specified values of alpha1 and beta1.

Usage

```
Decision_rule_M.F(p1, p2, alpha1, beta1, alpha, beta, lambda = 1)
```

Arguments

`p1`	A vector containing the probabilities of the outcome falling into each level of the control arm.
`p2`	A vector containging the probabilities of the outcome falling into each level of the control arm.
`alpha1`	The parameter used to define futility monitoring. Under the null hypothesis, 1 - alpha1 corresponds to the probability of stopping for futility at the interim analysis.
`beta1`	The probability of stopping for futility at the interim analysis when the alternative hypothesis is true.
`alpha`	Target type I error rate.
`beta`	Target type II error rate.
`lambda`	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

`n1`	The total sample size of the control and experimental groups required at the 1st analysis.
`t1`	The threshold of the test statistic at the 1st analysis.
`n2`	The cumulative total sample size of the control and experimental groups required at the 2nd analysis.
`t2`	The threshold of the test statistic at the 2nd analysis.

References

Park, Y. (2025). Optimal two-stage group sequential designs based on Mann-Whitney-Wilcoxon test. PloS one, 20(2), e0318211.

Examples

```
alpha = 0.05; beta = 0.2;
p1 = c(0.2, 0.5, 0.2, 0.1)
p2 = c(0.4, 0.3, 0.2, 0.1)
alpha1 <- 0.2
beta1 <- 0.1
Decision_rule_M.F(p1, p2, alpha1, beta1, alpha, beta, lambda = 1)
```

`Decision_rule_M.FS` *Decision rule for the FS design based on the Mann-Whitney-Wilcoxon test with the specified values of alpha1, alpha2, and beta1*

Description

This is the function to determine the decision rule for the FS design based on the Mann-Whitney-Wilcoxon test with the specified values of alpha1, alpha2, and beta1.

Usage

```
Decision_rule_M.FS(p1, p2, alpha1, alpha2, beta1, alpha, beta, lambda = 1)
```

Arguments

`p1`	A vector containing the probabilities of the outcome falling into each level of the control arm.
`p2`	A vector containging the probabilities of the outcome falling into each level of the control arm.
`alpha1`	The parameter used to define futility monitoring. Under the null hypothesis, 1 - alpha1 corresponds to the probability of stopping for futility at the interim analysis.
`alpha2`	The probability of stopping for superiority at the interim analysis when the null hypothesis is true.
`beta1`	The probability of stopping for futility at the interim analysis when the alternative hypothesis is true.
`alpha`	Target type I error rate.
`beta`	Target type II error rate.
`lambda`	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

n1	The total sample size of the control and experimental groups required at the 1st analysis.
t1l	The lower threshold of the test statistic at the 1st analysis.
t1u	The upper threshold of the test statistic at the 1st analysis.
n2	The cumulative total sample size of the control and experimental groups required at the 2nd analysis.
t2	The threshold of the test statistic at the 2nd analysis.
beta2	Under the null hypothesis, 1 - beta2 denotes the probability of stopping for superiority at the interim analysis.

References

Park, Y. (2025). Optimal two-stage group sequential designs based on Mann-Whitney-Wilcoxon test. PloS one, 20(2), e0318211.

Examples

```
alpha = 0.05; beta = 0.2;
p1 = c(0.2, 0.5, 0.2, 0.1)
p2 = c(0.4, 0.3, 0.2, 0.1)
alpha1 <- 0.2
alpha2 <- 0.025
beta1 <- 0.1
Decision_rule_M.FS(p1, p2, alpha1, alpha2, beta1, alpha, beta, lambda = 1)
```

Decision_rule_M_1stage

One-stage clinical trial design based on the Mann-Whitney-Wilcoxon test

---

Description

This is the function to determine the decision rule for a one-stage clinical trial designs based on the Mann-Whitney-Wilcoxon test.

Usage

```
Decision_rule_M_1stage(p1, p2, alpha, beta, lambda = 1)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.

alpha	Target type I error rate.
beta	Target type II error rate.
lambda	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

n2	The total sample size at the final analysis including both the control and experimental groups.
t2	The threshold of the test statistic at the analysis.

References

Park, Y. (2025). Optimal two-stage group sequential designs based on Mann-Whitney-Wilcoxon test. PloS one, 20(2), e0318211.

Examples

```
alpha = 0.05; beta = 0.2;
p1 = c(0.2, 0.5, 0.2, 0.1)
p2 = c(0.4, 0.3, 0.2, 0.1)
Decision_rule_M_1stage(p1, p2, alpha, beta, lambda = 1)
```

Decision_rule_S.F *Decision rule for the F design based on the score test with the specified values of alpha1 and beta1*

Description

This is to determine the decision rule for a two-stage design based on the score test with the specified values of alpha1 and beta1.

Usage

```
Decision_rule_S.F(p1, p2, alpha1, beta1, alpha, beta, lambda = 1)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.
alpha1	The parameter used to define futility monitoring. Under the null hypothesis, 1 - alpha1 corresponds to the probability of stopping for futility at the interim analysis.

beta1	The probability of stopping for futility at the interim analysis when the alternative hypothesis is true.
alpha	Target type I error rate.
beta	Target type II error rate.
lambda	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

n1	The total sample size of the control and experimental groups required at the 1st analysis.
t1	The threshold of the test statistic at the 1st analysis.
n2	The cumulative total sample size of the control and experimental groups required at the 2nd analysis.
t2	The threshold of the test statistic at the 2nd analysis.

Examples

```
alpha = 0.05; beta = 0.2; or = 3.06
p1 = c(0.075, 0.182, 0.319, 0.243, 0.015, 0.166)  # control prob
p2 = p2_fun(p1, log(or))  # experimental prob
p2
alpha1 <- 0.2
beta1 <- 0.1
Decision_rule_S.F(p1, p2, alpha1, beta1, alpha, beta, lambda = 1)
```

Decision_rule_S.FS *Decision rule of the FS design based on the score test with the specified values of alpha1, alpha2, and beta1*

Description

This is the function to determine the decision rule for the FS design based on the score test with the specified values of alpha1, alpha2, and beta1.

Usage

```
Decision_rule_S.FS(p1, p2, alpha1, alpha2, beta1, alpha, beta, lambda = 1)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.

alpha1	The parameter used to define futility monitoring. Under the null hypothesis, 1 - alpha1 corresponds to the probability of stopping for futility at the interim analysis.
alpha2	The probability of stopping for superiority at the interim analysis when the null hypothesis is true.
beta1	The probability of stopping for futility at the interim analysis when the alternative hypothesis is true.
alpha	Target type I error rate.
beta	Target type II error rate.
lambda	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

n1	The total sample size of the control and experimental groups required at the 1st analysis.
t1l	The lower threshold of the test statistic at the 1st analysis.
t1u	The upper threshold of the test statistic at the 1st analysis.
n2	The cumulative total sample size of the control and experimental groups required at the 2nd analysis.
t2	The threshold of the test statistic at the 2nd analysis.
beta2	Under the null hypothesis, 1 - beta2 denotes the probability of stopping for superiority at the interim analysis.

Examples

```
alpha = 0.05; beta = 0.2; or = 3.06
p1 = c(0.075, 0.182, 0.319, 0.243, 0.015, 0.166)  # control prob
p2 = p2_fun(p1, log(or))  # experimental prob
p2
alpha1 <- 0.2
alpha2 <- 0.025
beta1 <- 0.1
Decision_rule_S.FS(p1, p2, alpha1, alpha2, beta1, alpha, beta, lambda = 1)
```

Decision_rule_S_1stage

One-stage clinical trial design based on the score test

Description

This is the function to determine the decision rule for a one-stage clinical trial designs based on the score test.

Usage

```
Decision_rule_S_1stage(p1, p2, alpha, beta, lambda = 1)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.
alpha	Target type I error rate.
beta	Target type II error rate.
lambda	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

n2	The total sample size at the final analysis including both the control and experimental groups.
t2	The threshold of the test statistic at the analysis.

References

Park, Y. (2025). Optimal two-stage group sequential designs based on Mann-Whitney-Wilcoxon test. PloS one, 20(2), e0318211.

Examples

```
alpha = 0.05; beta = 0.2; or = 3.06
p1 = c(0.075, 0.182, 0.319, 0.243, 0.015, 0.166)  # control prob
p2 = p2_fun(p1, log(or))  # experimental prob
p2
Decision_rule_S_1stage(p1, p2, alpha, beta, lambda = 1)
```

Decision_rule_W.F *Decision rule of the F design based on the Win Odds test with the specified values of alpha1 and beta1*

Description

This is to determine the decision rule for a two-stage design based on the Win Odds test with the specified values of alpha1 and beta1.

Usage

```
Decision_rule_W.F(p1, p2, alpha1, beta1, alpha, beta, lambda = 1)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.
alpha1	The parameter used to define futility monitoring. Under the null hypothesis, 1 - alpha1 corresponds to the probability of stopping for futility at the interim analysis.
beta1	The probability of stopping for futility at the interim analysis when the alternative hypothesis is true.
alpha	Target type I error rate.
beta	Target type II error rate.
lambda	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

n1	The total sample size of the control and experimental groups required at the 1st analysis.
t1	The threshold of the test statistic at the 1st analysis.
n2	The cumulative total sample size of the control and experimental groups required at the 2nd analysis.
t2	The threshold of the test statistic at the 2nd analysis.

Examples

```
alpha = 0.05; beta = 0.2;
p1 = c(0.2, 0.5, 0.2, 0.1)
p2 = c(0.4, 0.3, 0.2, 0.1)
alpha1 <- 0.2
beta1 <- 0.1
Decision_rule_W.F(p1, p2, alpha1, beta1, alpha, beta, lambda = 1)
```

Decision_rule_W.FS *Decision rule of the FS design based on the Win Odds test with the specified values of alpha1, alpha2, and beta1*

Description

This is the function to determine the decision rule for the FS design based on the Win Odds test with the specified values of alpha1, alpha2, and beta1.

Usage

```
Decision_rule_W.FS(p1, p2, alpha1, alpha2, beta1, alpha, beta, lambda = 1)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.
alpha1	The parameter used to define futility monitoring. Under the null hypothesis, 1 - alpha1 corresponds to the probability of stopping for futility at the interim analysis.
alpha2	The probability of stopping for superiority at the interim analysis when the null hypothesis is true.
beta1	The probability of stopping for futility at the interim analysis when the alternative hypothesis is true.
alpha	Target type I error rate.
beta	Target type II error rate.
lambda	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

n1	The total sample size of the control and experimental groups required at the 1st analysis.
t1l	The lower threshold of the test statistic at the 1st analysis.
t1u	The upper threshold of the test statistic at the 1st analysis.
n2	The cumulative total sample size of the control and experimental groups required at the 2nd analysis.
t2	The threshold of the test statistic at the 2nd analysis.
beta2	Under the null hypothesis, 1 - beta2 denotes the probability of stopping for superiority at the interim analysis.

Examples

```
alpha = 0.05; beta = 0.2;
p1 = c(0.2, 0.5, 0.2, 0.1)
p2 = c(0.4, 0.3, 0.2, 0.1)
alpha1 <- 0.2
alpha2 <- 0.025
beta1 <- 0.1
Decision_rule_W.FS(p1, p2, alpha1, alpha2, beta1, alpha, beta, lambda = 1)
```

`Decision_rule_W_1stage` *One-stage clinical trial design based on the Win Odds test*

Description

This is the function to determine the decision rule for a one-stage clinical trial designs based on the Win Odds test.

Usage

```
Decision_rule_W_1stage(p1, p2, alpha, beta, lambda = 1)
```

Arguments

`p1`	A vector containing the probabilities of the outcome falling into each level of the control arm.
`p2`	A vector containging the probabilities of the outcome falling into each level of the control arm.
`alpha`	Target type I error rate.
`beta`	Target type II error rate.
`lambda`	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

`n2`	The total sample size at the final analysis including both the control and experimental groups.
`t2`	The threshold of the test statistic at the analysis.

Examples

```
alpha = 0.05; beta = 0.2;
p1 = c(0.2, 0.5, 0.2, 0.1)
p2 = c(0.4, 0.3, 0.2, 0.1)
Decision_rule_W_1stage(p1, p2, alpha, beta, lambda = 1)
```

`op.1stage` *Performance evaluation of a one-stage design*

Description

This is the function to calculate the operating characteristics for a one-stage design, including type I error, power, and expected sample size.

Usage

```
op.1stage(alpha, beta, p1, p2, method, n2, t2, nsim = 10000, lambda = 1)
```

Arguments

`alpha`	Target type I error rate.
`beta`	Target type II error rate.
`p1`	A vector containing the probabilities of the outcome falling into each level of the control arm.
`p2`	A vector containging the probabilities of the outcome falling into each level of the control arm.
`method`	"S", "M" or "W", denotes score test, Mann-Whitney-Wilcoxon test and wi n odds test respectively.
`n2`	The cumulative total sample size of the control and experimental groups required at the 2nd analysis.
`t2`	The threshold of the test statistic at the 2nd analysis.
`nsim`	The number of simulations. nsim = 10000 by default
`lambda`	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

The probability of wrong decision and the expected total sample size under the true hypothesis.

Examples

```
set.seed(1234)
alpha = 0.05; beta = 0.2;
p1 = c(0.2, 0.5, 0.2, 0.1)
p2 = c(0.4, 0.3, 0.2, 0.1)
out <- Decision_rule_W_1stage(p1, p2, alpha, beta, lambda = 1)
# report the power and EN_a
op.1stage(alpha, beta, p1, p2, method="W", n2=out[1], t2=out[2], nsim = 1000, lambda = 1)
# report the overall type I error rate and EN_0
op.1stage(alpha, beta, p1, p1, method="W", n2=out[1], t2=out[2], nsim = 1000, lambda = 1)
```

op.F *Performance evaluation of the F design*

Description

This is the function to calculate the operating characteristics for the F design, including type I error, power, and expected sample size.

Usage

```
op.F(alpha, beta, p1, p2, method, n1, t1, n2, t2, nsim = 10000, lambda = 1)
```

Arguments

alpha	Target type I error rate.
beta	Target type II error rate.
p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.
method	"S", "M" or "W", denotes score test, Mann-Whitney-Wilcoxon test and wi n odds test respectively.
n1	The total sample size of the control and experimental groups required at the 1st analysis.
t1	The threshold of the test statistic at the 1st analysis.
n2	The cumulative total sample size of the control and experimental groups required at the 2nd analysis.
t2	The threshold of the test statistic at the 2nd analysis.
nsim	The number of simulations. nsim = 10000 by default
lambda	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

The probability of wrong decision and the expected total sample size under the true hypothesis.

Examples

```
set.seed(1234)
alpha = 0.05; beta = 0.2;
p1 = c(0.2, 0.5, 0.2, 0.1)
p2 = c(0.4, 0.3, 0.2, 0.1)
alpha1 <- 0.2
beta1 <- 0.1
```

```
out <- Decision_rule_W.F(p1, p2, alpha1, beta1, alpha, beta, lambda = 1)


# heavier example for illustration (skipped on CRAN timing checkes)
# report the power and EN_a
op.F(alpha, beta, p1, p2, method="W", n1=out[1], t1=out[2], n2=out[3],
 t2=out[4], nsim = 10000, lambda = 1)
# report the overall type I error rate and EN_0
op.F(alpha, beta, p1, p1, method="W", n1=out[1], t1=out[2], n2=out[3],
 t2=out[4], nsim = 10000, lambda = 1)
```

`op.FS` *Performance evaluation of the FS design*

Description

This is the function to calculate the operating characteristics for the FS design, including type I error, power, and expected sample size.

Usage

```
op.FS(alpha, beta, p1, p2, method, n1, t1l, t1u, n2, t2, nsim = 10000, lambda = 1)
```

Arguments

`alpha`	Target type I error rate.
`beta`	Target type II error rate.
`p1`	A vector containing the probabilities of the outcome falling into each level of the control arm.
`p2`	A vector containging the probabilities of the outcome falling into each level of the control arm.
`method`	"S", "M" or "W", denotes score test, Mann-Whitney-Wilcoxon test and win odds test respectively.
`n1`	The total sample size of the control and experimental groups required at the 1st analysis.
`t1l`	The lower threshold of the test statistic at the 1st analysis.
`t1u`	The upper threshold of the test statistic at the 1st analysis.
`n2`	The cumulative total sample size of the control and experimental groups required at the 2nd analysis.
`t2`	The threshold of the test statistic at the 2nd analysis.
`nsim`	The number of simulations. nsim = 10000 by default
`lambda`	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

The probability of wrong decision and the expected total sample size under the true hypothesis.

Examples

```
set.seed(1234)
alpha = 0.05; beta = 0.2;
p1 = c(0.2, 0.5, 0.2, 0.1)
p2 = c(0.4, 0.3, 0.2, 0.1)
alpha1 <- 0.2
alpha2 <- 0.025
beta1 <- 0.1
out <- Decision_rule_W.FS(p1, p2, alpha1, alpha2, beta1, alpha, beta, lambda = 1)


# heavier example for illustration (skipped on CRAN timing checkes)
# report the power and EN_a
op.FS(alpha, beta, p1, p2, method="W", n1=out[1], t1l=out[2],
t1u=out[3], n2=out[4], t2=out[5], nsim = 10000, lambda = 1)
# report the overall type I error rate and EN_0
op.FS(alpha, beta, p1, p1, method="W", n1=out[1], t1l=out[2],
t1u=out[3], n2=out[4], t2=out[5], nsim = 10000, lambda = 1)
```

---

p2_fun *p2*

Description

This is the function to calculate the probability p2 when p1 and odds ratio are given.

Usage

```
p2_fun(p1, theta)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
theta	The log odds ratio according to expected effect of the experimental treatment.

Value

A numeric vector representing the expected probability distribution of outcomes across levels for the experimental group.

pq_fun *Calculation of pq*

Description

This is the function to compute p_{jk} and q_{ik}, which are required for the Win Odds test.

Usage

```
pq_fun(p1, p2)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.

Value

The value of p_{jk} and q_{ik}.

Proportional_odds_assumption
Checking proportional odds assumption

Description

This is the function to check the proportional odds assumption for the score test.

Usage

```
Proportional_odds_assumption(p1, p2)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.

Value

Indicates whether the proportional odds assumption holds. If the assumption holds, the function returns the log-odds ratio from the score test. If the assumption does not hold, the function returns NA.

p_minus *p_minus*

Description

This is the function to comupute p-, which is required for the Mann-Whitney-Wilcoxon test.

Usage

```
p_minus(p1, p2)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.

Value

The value of p-.

p_plus *p_plus*

Description

This is the function to comupute p+, which is required for the Mann-Whitney-Wilcoxon test.

Usage

```
p_plus(p1, p2)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.

Value

The value of p+.

QR_fun *Calculateion of Q or R*

Description

This is the function to compute Q or R, which is required for the Mann-Whitney-Wilcoxon test.

Usage

```
QR_fun(p1, p2)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.

Value

The value of Q or R.

ruleF *Decision fule of the F design*

Description

This is the function to determine the decision rule for the F design.

Usage

```
ruleF(alpha, beta, p1, p2, method, criterion, lambda = 1)
```

Arguments

alpha	Target type I error rate.
beta	Target type II error rate.
p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.
method	"S", "M" or "W", denotes score test, Mann-Whitney-Wilcoxon test and win odds test respectively.

criterion	1: minimizing the expected total sample size under the null hypothesis, 2: minimizing the expected total sample size under the alternative hypothesis, 3: minimizing the expected total sample size assuming that Pr(H0) = Pr(Ha), 4: balancing sample sizes of the two stages prioritizing EN0, 5: balancing sample sizes of the two stages prioritizing maximum sample size n2.
lambda	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

method	Statistical test chosen.
criterion	Criterion chosen.
n1	The total sample size of the control and experimental groups required at the 1st analysis.
t1	The threshold of the test statistic at the 1st analysis.
n2	The cumulative total sample size of the control and experimental groups required at the 2nd analysis.
t2	The threshold of the test statistic at the 2nd analysis.

Examples

```
alpha = 0.05; beta = 0.2;
p1 = c(0.2, 0.5, 0.2, 0.1)
p2 = c(0.4, 0.3, 0.2, 0.1)
ruleF(alpha, beta, p1, p2, method="M", criterion="1", lambda = 1)
```

---

ruleFS *Decision fule of the FS design*

Description

This is the function to determine the decision rule for the FS design.

Usage

```
ruleFS(alpha, beta, p1, p2, method, criterion, lambda = 1)
```

Arguments

alpha	Target type I error rate.
beta	Target type II error rate.
p1	A vector containing the probabilities of the outcome falling into each level of the control arm.

p2	A vector containging the probabilities of the outcome falling into each level of the control arm.
method	"S", "M" or "W", denotes score test, Mann-Whitney-Wilcoxon test and win odds test respectively.
criterion	1: minimizing the expected total sample size under the null hypothesis, 2: minimizing the expected total sample size under the alternative hypothesis, 3: minimizing the expected total sample size assuming that Pr(H0) = Pr(Ha), 4: balancing sample sizes of the two stages prioritizing EN0, 5: balancing sample sizes of the two stages prioritizing maximum sample size n2.
lambda	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

method	Statistical test chosen.
criterion	Criterion chosen.
n1	The total sample size of the control and experimental groups required at the 1st analysis.
t1l	The lower threshold of the test statistic at the 1st analysis.
t1u	The upper threshold of the test statistic at the 1st analysis.
n2	The cumulative total sample size of the control and experimental groups required at the 2nd analysis.
t2	The threshold of the test statistic at the 2nd analysis.

Examples

```
alpha = 0.05; beta = 0.2;
p1 = c(0.2, 0.5, 0.2, 0.1)
p2 = c(0.4, 0.3, 0.2, 0.1)
ruleFS(alpha, beta, p1, p2, method="M", criterion="1", lambda = 1)
```

---

theta *Calculation of theta*

Description

This is the function to compute theta (i.e., the expectation of T), which is required for the Win Odds test.

Usage

```
theta(p1, p2)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.

Value

The value of theta

V_S.over.nk *Calcualtion of V*

Description

This is the function to compute the value of V over $n_{..k}$, which is requited for the score test, where $n_{..k}$ denotes the total sample size at the kth analysis.

Usage

```
V_S.over.nk(p1, p2, lambda = 1)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.
lambda	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

The value of V over $n_{..k}$.

W_W *Calculation of W*

Description

This is the function to compute W, which is required for the Win Odds test.

Usage

```
W_W(p1, p2, lambda = 1)
```

Arguments

p1	A vector containing the probabilities of the outcome falling into each level of the control arm.
p2	A vector containging the probabilities of the outcome falling into each level of the control arm.
lambda	The ratio of sample sizes between the experimental and control groups, defined as sample size (experimental): sample size (control) = lambda:1. The default value is 1.

Value

The value of W.

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