Package ‘IAbin’

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Type Package
Title Plotting N-T Plane for Decision on Performing an Interim Analysis
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Description In randomized-controlled trials, interim analyses are often planned for possible early trial termination to claim superiority or futility of a new therapy. Blinded data also have information about the potential treatment difference between the groups. We developed a blinded data monitoring tool that enables investigators to predict whether they observe such an unblinded interim analysis results that supports early termination of the trial. Investigators may skip some of the planned interim analyses if an early termination is unlikely. This tool will provide reference information about N: Sample size at interim analysis, and T: Total number of responders at interim analysis for decision on performing an interim analysis.
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R topics documented:

 plotNT.fut .......................................................... 2
 plotNT.sup ........................................................ 3

Index 6
Description

The package plots N-T plane for decision for conducting an interim analysis in a randomized control trial. The functions for interim analysis expecting early stopping for superiority and futility are prepared respectively.

Usage

\[
\text{plotNT.fut}(p0, M, q, alpha1, cp1, \\
xlab = "N: Number of patients at interim analysis", \\
ylab = "T: Number of responders at interim analysis", \\
col = "blue", \\
main = "N-T plot", \\
lty = 2,...)
\]

Arguments

- \( p0 \): Expected response rate for the control arm: scalar or vector. the value between 0 to 1.
- \( M \): Total number of patients: expected number of patients until last time.
- \( q \): Allocation ratio of the treatment arm: the value between 0 to 1.
- \( alpha1 \): Critical alpha at an interim analysis.
- \( cp1 \): Critical conditional power at an interim analysis.
- \( xlab \): Label name for x-axis in N-T plot.
- \( ylab \): Label name for y-axis in N-T plot.
- \( col \): Line color. Default is "blue". For multiple p0, set the same length of color with p0.
- \( main \): Main title in N-T plot.
- \( lty \): Line type. The default is 2 for early stopping for futility.
- \( ... \): Other graphics parameters

Details

For more details, please refer to the vignette: \text{browseVignettes(package = "IAbin")}

Value

A matrix or list with variable names N, T, Z_score and CP.

Draw N-T plot for early stopping for futility

\[
\begin{align*}
\text{x axis:} & \quad \text{N (Total number of patients at interim analysis)} \\
\text{y axis:} & \quad \text{T (Total number of responders at interim analysis)}
\end{align*}
\]
plotNT.sup

References

Decision on Performing Interim Analysis for Comparative Clinical Trials

Examples

--- Settings ---
--- With an expected parameter for control therapy ---
\( p_0 = 0.5 \)
\( M = 135 \)
\( q = 2/3 \)
\( \alpha_1 = 0.01 \)
\( c_{p1} = 0.2 \)

--- N-T plot for early stopping for superiority and futility ---
\( N_{T_f} = \text{plotNT.fut}(p_0, M, q, \alpha_1, c_{p1}) \)
\( \text{print}(N_{T_f}) \)

--- Settings ---
--- With several expected parameters for control therapy ---
\( p_0 = c(0.2, 0.4, 0.6) \)
\( M = 135 \)
\( q = 2/3 \)
\( \alpha_1 = 0.01 \)
\( \text{col} = c(1, 2, 3) \)
\( c_{p1} = 0.2 \)

--- N-T plot for early stopping for superiority and futility ---
\( N_{T_{f3}} = \text{plotNT.fut}(p_0, M, q, \alpha_1, c_{p1}, \text{col}=\text{col}) \)
\( \text{print}(N_{T_{f3}}) \)

plotNT.sup  Plotting N-T Plane for Decision on Performing an Interim Analysis

Description

The package plots N-T plane for decision for conducting an interim analysis in a randomized control trial. The functions for interim analysis expecting early stopping for superiority and futility are prepared respectively.

Usage

\[
\text{plotNT.sup}(p_0, M, q, \alpha_1, \\
\text{xlab} = "N: Number of patients at interim analysis", \\
\text{ylab} = "T: Number of responders at interim analysis", \\
\text{col} = "blue", \\
\text{main} = "N-T plot", \\
\text{lty} = 1,...)
\]
Arguments

- `p0` Expected response rate for the control arm: scalar or vector. the value between 0 to 1.
- `M` Total number of patients: expected number of patients until last time.
- `q` Allocation ratio of the treatment arm: the value between 0 to 1.
- `alpha1` Critical alpha at an interim analysis.
- `xlab` Label name for x-axis in N-T plot.
- `ylab` Label name for y-axis in N-T plot.
- `col` Line color. Default is "blue". For multiple p0, set the same length of color with p0.
- `main` Main title in N-T plot.
- `lty` Line type. The default is 1 for early stopping for superiority.
- `...` Other graphics parameters

Details

For more details, please refer to the vignette: `browseVignettes(package = "iabin")`

Value

A matrix or list with variable names `N`, `T`, `Z_score` and `p_val`.

Draw N-T plot for early stopping for futility

- **x axis**: N (Total number of patients at interim analysis)
- **y axis**: T (Total number of responders at interim analysis)

References

Decision on Performing Interim Analysis for Comparative Clinical Trials

Examples

```r
#--- Settings ---#
#--- With an expected parameter for control therapy ---#
p0  = 0.5
M   = 135
q   = 2/3
alpha1 = 0.01

#--- N-T plot for early stopping for superiority ---#
NT_s = plotNT.sup(p0, M, q, alpha1)
print(NT_s)

#--- Settings ---#
#--- With several expected parameters for control therapy ---#
p0  = c(0.2, 0.4, 0.6)
M   = 135
```
```r
q = 2/3
col = c(1, 2, 3)

#--- N-T plot for early stopping for superiority ---#
NT_s3 = plotNT.sup(p0, M, q, alpha1, col=col)
print(NT_s3)
```
Index

plotNT.fut, 2
plotNT.sup, 3