Package: grpseq (via r-universe)

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Type Package

Title Group Sequential Analysis of Clinical Trials

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Description Design of group sequential trials, including non-binding futility analysis at multiple time points (Gallo, Mao, and Shih, 2014, <doi:10.1080/10543406.2014.932285>).

License GPL (>= 2)

Encoding UTF-8

RoxygenNote 7.1.1

VignetteBuilder knitr

Depends R (>= 2.10)

Imports mvtnorm

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`fut` *Design of non-binding futility analysis at multiple points*

Description

Design of non-binding futility looks at multiple information times based on conditional power (CP), predictive power (PP), or condition power under current estimate (CPd) (Gallo, Mao, and Shih, 2014).

Usage

```
fut(
  alpha,
  beta,
  t,
  gamma,
  side = 2,
  increment = 1e-04,
  si = 0,
  scale = "CP",
  seed = 12345
)
```

Arguments

`alpha`	Type I error.
`beta`	Type II error (1 - power).
`t`	A numeric vector of information times in $(0, 1)$ for futility looks.
`gamma`	A numeric vector of probabilities (whose meaning depends on `scale`) at information times `t`.
`side`	1- or 2-sided test.
`increment`	Error for the numerical solution of the sample size inflation factor.
`si`	`0`: without sample size inflation; `1`: with sample size inflation.
`scale`	Character string specifying the scaled used: `"CP"`, conditional power; `"PP"`, predictive power; `"CPd"`: condition power under current estimate.
`seed`	Seed number for the randomized evaluation of multivariate normal distribution.

Value

An object of class `fut` with the following components. `gamma1`: conditional power at information times `t` converted from the supplied `gamma` and `scale`; `theta`: local alternative associated with the actual power when the futility rules of enforced; `IF`: sample size inflation factor if `si=1`; `loss`: power loss if `si=0`.

References

Gallo, P., Mao, L., and Shih, V.H. (2014). Alternative views on setting clinical trial futility criteria. Journal of Biopharmaceutical Statistics, 24, 976-993.

See Also

print.fut, summary.fut, plot.fut, powerplot

Examples

```
## load the package
library(grpseq)
## two-sided level 0.05 test with 80% power;
## evenly spaced three futility looks with predictive power 20%;
## inflate sample size to recoup power.
obj1 <- fut(alpha=0.05,beta=0.2,t=(1:3)/4,gamma=0.2*rep(1,3),side=2,scale="PP",si=1)
obj1
## print the summary results
summary(obj1)

## do the same thing without sample size inflation
obj2 <- fut(alpha=0.05,beta=0.2,t=(1:3)/4,gamma=0.2*rep(1,3),side=2,scale="PP",si=0)
obj2
## print the summary results
summary(obj2)
oldpar <- par(mfrow = par("mfrow"))
par(mfrow=c(1,2))
## plot the futility boundaries by z-value
plot(obj2,scale='z',lwd=2,main="")
## plot the futility boundaries by B-value
plot(obj2,scale='b',lwd=2,main="")
par(oldpar)
## plot the power curve as a function of the (local)
## effect size in units of the hypothesized effect size
## ref=TRUE requests the power curve for the original one-time analysis
powerplot(obj2,lwd=2, ref=TRUE)
```

---

plot.fut *Plot the planned futility boundaries*

Description

Plot the planned futility boundaries in B- or z-values as a function of information time.

Usage

```
## S3 method for class 'fut'
plot(
  x,
```

```
  scale = "z",
  add = FALSE,
  lty = 8,
  xlab = "Info Time",
  ylab = "z score",
  type = "b",
  pch = 1,
  cex = 1,
  main = "Futility Boundary for the Planned Test",
  xlim = c(0, 1.1),
  ylim = NULL,
  ...
)
```

Arguments

x	An object returned by fut.
scale	"z": plot z-values; "b": plot B-values.
add	If TRUE, the curve will be overlaid on an existing plot; otherwise, a separate plot will be constructed.
lty	Line type for the segments connecting the z-/B-value points.
xlab	A label for the x axis, defaults to a description of x.
ylab	A label for the y axis, defaults to a description of y.
type	Plot type. "l": only line segments; "p": only z-/B-value points; "b": both.
pch	Point types for the z-/B-values.
cex	Point size.
main	A main title for the plot.
xlim	The x limits of the plot.
ylim	The y limits of the plot.
...	Other arguments that can be passed to the underlying plot method.

Value

No return value, called for side effects.

See Also

fut, summary.fut, powerplot.

Examples

```
# see example for fut
```

`powerplot` *Plot the power function of the planned analysis*

Description

Plot the power curve of the planned futility analysis as a function of the effect size (in units of the hypothesized effect size).

Usage

```
powerplot(
  x,
  ref = FALSE,
  add = FALSE,
  lty = 1,
  ref.lty = 2,
  lwd = 1,
  xlab = expression(delta),
  ylab = "Power",
  main = "Power curve of the planned futility analysis",
  xlim = c(0, 1.5),
  ylim = c(0, 1),
  ...
)
```

Arguments

`x`	An object returned by `fut`.
`ref`	If TRUE, power curve of the reference test (one that ignores the futility boundaries) will be overlaid.
`add`	If TRUE, the curve will be overlaid on an existing plot; otherwise, a separate plot will be constructed.
`lty`	Line type for the power curve of the futility analysis.
`ref.lty`	Line type for the power curve of the reference if `ref=TRUE`.
`lwd`	Line width.
`xlab`	A label for the x axis, defaults to a description of x.
`ylab`	A label for the y axis, defaults to a description of y.
`main`	A main title for the plot.
`xlim`	The x limits of the plot.
`ylim`	The y limits of the plot.
`...`	Other arguments that can be passed to the underlying `plot` method.

Value

No return value, called for side effects.

See Also

fut, summary.fut, plot.fut.

Examples

```
# see example for fut
```

---

print.fut *Print basic information about the futility design*

Description

Print the power loss or sample size inflation factor due to the planned futility analysis.

Usage

```
## S3 method for class 'fut'
print(x, ...)
```

Arguments

x	An object of class fut.
...	Further arguments passed to or from other methods.

Value

Print the results of fut object.

See Also

fut, summary.fut

Examples

```
# see example for fut
```

print.summary.fut *Print method for summary.fut objects*

Description

Print the detailed summary of the futility design.

Usage

```
## S3 method for class 'summary.fut'
print(x, ...)
```

Arguments

x	An object returned by summary.fut.
...	Further arguments passed to or from other methods

Value

No return value, called for side effects.

See Also

fut, summary.fut.

summary.fut *Detailed summary of the futility design*

Description

Provide key information about the futility design, including B-/z-values, beta (type II error) spent, and power loss at each futility look as well the the sample size distribution under the null hypothesis.

Usage

```
## S3 method for class 'fut'
summary(object, ...)
```

Arguments

object	An object returned by fut.
...	further arguments passed to or from other methods.

Value

An object of class `summary.fut` with components:

`t`	A K-dimensional vector of information times.
`b`	A K-dimensional vector of B-values at `t`.
`z`	A K-dimensional vector of z-values at `t`.
`type2`	A K-dimensional vector of beta spent at `t`.
`loss`	A K-dimensional vector of power loss at `t`.
`ess`	Expected sample size at H_0.
`...`	

See Also

`fut`, `print.fut`, `print.summary.fut`.

Examples

```
# see example for fut
```

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