

Package ‘grpseq’

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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](https://doi.org/10.1080/10543406.2014.932285)>).

License GPL (>= 2)

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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:

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

See Also

[fut](#), [print.fut](#), [print.summary.fut](#).

Examples

```
# see example for fut
```

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