Package ‘ph2hetero’

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\[
\begin{array}{ll}
\text{design.jones} & \text{Jones 2-stage Phase II design} \\
\end{array}
\]

Description

Calculates Optimal 2-stage Phase II designs given by Cheryl L. Jones (2007).

Usage

\[
\text{design.jones(alpha=0.05,beta=0.2,p0,p1n,p1p,nmax=100,Ppos=0.5,NumThreads=1)}
\]

Arguments

- \text{alpha}\ : Type I error.
- \text{beta}\ : Type II error.
- \text{p0}\ : Max unacceptable response rate.
- \text{p1n}\ : Min acceptable response rate for "negative" subgroup.
- \text{p1p}\ : Min acceptable response rate for "positive" subgroup.
- \text{nmax}\ : Maximum sample size.
- \text{Ppos}\ : Prevalence of "biomarker-positive" subjects.
- \text{NumThreads}\ : Number of threads used for parallel compilation.

Value

Returns a data.frame object which components are:

- \text{alpha}\ : Type I error probability of the optimal design.
- \text{power}\ : Power of the optimal design.
- \text{p0}\ : Max unacceptable response rate.
- \text{p1n}\ : Min acceptable response rate for "negative" subgroup.
- \text{p1p}\ : Min acceptable response rate for "positive" subgroup.
- \text{PET}\ : Overall probability of early termination.
- \text{EN}\ : Expected sample size.
- \text{k1n}\ : Minimum number of responses in marker negative subjects to go into the unselected population during stage 2.
- \text{k1p}\ : Minimum number of responses in the marker positive subjects.
- \text{N1n}\ : Number of marker negative subjects enrolled during the first stage.
- \text{N1p}\ : Number of marker positive subjects enrolled during the first stage.
- \text{k2p}\ : Total number of response required during stage 1 and stage 2 combined in the amplified when preliminary efficacy is in the amplified subgroup.
**N2p**  
Number of amplified subjects enrolled during the second stage if preliminary evidence of efficacy leads to this path.

**kn**  
Total number of response required during stage 1 and stage 2 combined in the negative sample to conclude efficacy in the unselected population.

**kp**  
Total number of response required during stage 1 and stage 2 combined in the amplified sample to conclude efficacy in this population when preliminary efficacy is unselected.

**N2un**  
Number of unselected subjects enrolled during the second stage if preliminary evidence of efficacy leads to this path.

**Author(s)**  
Patrick Sfumato and Bastien Cabarrou.

**References**  

**Examples**

```r
outJones<-designJones(alpha=0.05,
                        beta=0.2,
                        pP=0.03,
                        p1n=0.10,
                        p1p=0.15,
                        Nmax=150,
                        Ppos=0.40)
```

---

**design.parashar**  
*Parashar’s 2-stage Phase II design*

**Description**  
Calculates Optimal 2-stage Phase II designs given by Deepak Parashar (2016).

**Usage**

```r
design.parashar(alpha=0.05,beta=0.2,p0,p1n,p1p,Nmax=100,NumThreads=1)
```

**Arguments**

- **alpha**  
  Type I error.

- **beta**  
  Type II error.

- **p0**  
  Max unacceptable response rate.

- **p1n**  
  Min acceptable response rate for "negative" subgroup.
p1p Min acceptable response rate for "positive" subgroup.
Nmax Maximum sample size.
NumThreads Number of threads used for parallel compilation.

Value

Returns a data.frame object which components are:

alpha Type I error probability of the optimal design.
power Power of the optimal design.
p0 Max unacceptable response rate.
p1n Min acceptable response rate for "negative" subgroup.
p1p Min acceptable response rate for "positive" subgroup.
PET Overall probability of early termination.
EN Expected sample size.
k1n Minimum number of responses in marker negative subjects to go into the unselected population during stage 2.
k1p Minimum number of responses in the marker positive subjects.
N1n Number of marker negative subjects enrolled during the first stage.
N1p Number of marker positive subjects enrolled during the first stage.
kep Minimum number of responses in the enrichment population.
Nep Number of subjects in the enrichment population.
kn Total number of response required during stage 1 and stage 2 combined in the negative sample to conclude efficacy in the unselected population.
kp Total number of response required during stage 1 and stage 2 combined in the amplified sample to conclude efficacy in this population when preliminary efficacy is unselected.
Nn Number of marker negative subjects enrolled during the first stage and the second stage.
N2p Number of marker positive subjects enrolled during the first stage and the second stage.

Author(s)

Patrick Sfumato and Bastien Cabarrou.

References

Examples

```r
out.parashar<-design.parashar(alpha=0.05, 
beta=0.2, 
p0=0.03, 
p1n=0.25, 
p1p=0.40, 
Nmax=30)
```

**design.tournoux**

*Tournoux 2-stage Phase II design*

Description

Calculates Optimal 2-stage Phase II designs given by Caroline Tournoux-Facon (2011).

Usage

```r
design.tournoux(alpha=0.05,beta=0.2,p0n,p0p,p1n,p1p,w=1,gamma=0.6)
```

Arguments

- **alpha**: Type I error.
- **beta**: Type II error.
- **p0n**: Max unacceptable response rate for "negative" subgroup.
- **p0p**: Max unacceptable response rate for "positive" subgroup.
- **p1n**: Min acceptable response rate for "negative" subgroup.
- **p1p**: Min acceptable response rate for "positive" subgroup.
- **w**: Ratio between the two subgroups $\frac{N_{pos}}{N_{neg}}$.
- **gamma**: Level of the heterogeneity test.

Value

Returns a data.frame object which components are number of patients, error-rates and power-levels for each stage. The first line of the data.frame corresponds to the arguments for an One-stage Fleming design and the others are two-stages Fleming designs with :
- Non-stratified heterogeneous Fleming two-stage design when psi=0.
- Stratified adaptive Fleming two-stage with identification of heterogeneity of responses in favour of "negative" subgroup when psi=1.
- Stratified adaptive Fleming two-stage with identification of heterogeneity of responses in favour of "positive" subgroup when psi=2.

Author(s)

Patrick Sfumato and Bastien Cabarrou.
References


Examples

```r
out.tournoux<-design.tournoux(p0n=0.15, 
   p0p=0.15, 
   p1n=0.30, 
   p1p=0.25, 
   w=2, 
   gamma=0.6, 
   alpha=0.05, 
   beta=0.1)
```
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