Package 'smartDesign'

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Type Package

Title Sequential Multiple Assignment Randomized Trial Design

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Description SMART trial design, as described by He, J., McClish, D., Sabo, R. (2021) <doi:10.1080/19466315.2021.1883472>, includes multiple stages of randomization, where participants are randomized to an initial treatment in the first stage and then subsequently re-randomized between treatments in the following stage.

License GPL (>= 3)

Depends R (>= 4.1.0), methods, graphics, stats

Imports knitr

NeedsCompilation no

RoxygenNote 7.1.0

VignetteBuilder knitr

URL https://cran.r-project.org/package=smartDesign

Suggests testthat, rmarkdown

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powerDTR *Power Dynamic Treatment Regimen (DTR) Trial design clinical trial calculations*

Description

Power Calculations Comparing two Dynamic Treatment Regimen (DTR) Trial design clinical trial calculations

Usage

```
powerDTR(dtr1, dtr2, pG_A1 = 0.8, pG_A2 = 0.8, alpha=0.05)
```

Arguments

dtr1	an object of smartDTR class, created by function of the same name
dtr2	an object of smartDTR class, created by function of the same name
pG_A1	probability of response to therapy given assignment to A1
pG_A2	probability of response to therapy given assignment to A2
alpha	accepted type-I error rate for power calculations

Details

more details on power DTR

Value

An object of the powerDTR S3 class, with the following elements:

powerdat:	data.frame with sens, spec, mu, sigsq and sample size, power

Author(s)

Jun (Jessie) He, Aberaham Eyman-Casey, Jason P. Sinnwell, Mayo Clinic

Examples

```
mumat13 <- cbind(G1=c(30,35), G0=c(20,28))
varmat13 <- cbind(G1=c(100,100),G0=c(100,100))

dtr13 <- smartDTR(mu_Barm=mumat13, sigsq_Barm=varmat13,
                  Barm=c(1,3), nsubject=252, pG_A1=0.8)

mumat24 <- cbind(G1=c(25,32), G0=c(18,23))
varmat24 <- cbind(G1=c(100,100),G0=c(100,100))

dtr24 <- smartDTR(mu_Barm=mumat24, sigsq_Barm=varmat24,
                  Barm=c(2,4), nsubject=252, pG_A1=0.8, pG_A2=0.8)
```

```
pdtr13vs24 <- powerDTR(dtr13, dtr24)
print(pdtr13vs24)  ## plot(pdtr13vs24)
```

---

powerSST *Power for Single Sequential Treatment (SST) Trial design clinical trial calculations*

Description

Power Calculations Comparing two Single Sequential Treatment Treatment (SST) Trial design clinical trial calculations

Usage

```
powerSST(sst1, sst2, pG_A1 = 0.8, pG_A2 = 0.8, alpha=0.05)
```

Arguments

sst1	an object of smartSST class, created by function of the same name
sst2	an object of smartSST class, created by function of the same name
pG_A1	probability of response to therapy given assignment to A1
pG_A2	probability of response to therapy given assignment to A2
alpha	accepted type-I error rate for power calculations

Details

more details to come

Value

An object of the powerSST S3 class, with the following elements:

powerdat:	data.frame with sens, spec, mu, sigsq and sample size, power

Author(s)

Jun (Jessie) He, Aberaham Eyman-Casey, Jason P. Sinnwell, Mayo Clinic

Examples

```
sst1 <- smartSST(mu_Barm=c(G1=30, G0=20), sigsq_Barm=c(G1=16,G0=16),
       Barm=1, sens=seq(.6, 1, by=.1),  spec=seq(.6, 1, by=.1),
       nsubject=252)
sst2 <- smartSST(mu_Barm=c(G1=20, G0=30), sigsq_Barm=c(G1=16,G0=16),
       Barm=2, sens=seq(.6, 1, by=.1),  spec=seq(.6, 1, by=.1),
       nsubject=252)
```

```
psst12 <- powerSST(sst1, sst2)
print(psst12) ## plot(psst12)
```

`smartDTR` *Dynamic Treatment Regimen (DTR) Trial design clinical trial calculations*

Description

Dynamic Treatment Regimen (DTR) Trial design clinical trial calculations

Usage

```
smartDTR(mu_Barm=cbind(G1=c(30,25), G0=c(20,20)),
                     sigsq_Barm=cbind(G1=c(100,100), G0=c(100,100)),
                     nsubject=500,  Barm=c(1,3), type="continuous",
                     sens=seq(0.5,1, by=0.1), spec=seq(0.5, 1, by=0.1),
                     pG_A1 = 0.8, pG_A2 = 0.8, pran_A1 = 0.5,
                     pran_Barm = c(0.5, 0.5))
```

Arguments

`mu_Barm`	matrix of two named vectors of the means for the two B arms (columns) for the smart DTR trial, with rows as 'G1' and 'G0'
`sigsq_Barm`	matrix of two named vectors of the variances (sigma-squared) for the two Blevels (columns) for the smart DTR trial, with rows as 'G1' and 'G0'
`nsubject`	total sample size for the trial
`Barm`	for the second phase of the trial, the 'B' levels for which the DTR means/variances apply
`type`	trial response variable type; only continuous is implemented currently
`sens`	range of sensitivity for smart SST calculations; (0,1]
`spec`	range of specificity for smart SST calculations; (0,1]
`pG_A1`	probability of response to therapy given assignment to A1
`pG_A2`	probability of response to therapy given assignment to A2
`pran_A1`	probability of random assignment to A1
`pran_Barm`	probability of assignment to Barms

Details

see details in the reference

Value

An object of the smartDTR S3 class, with the following elements:

`dtrdat:` data.frame with sens, spec, mu, sigsq and sample size (n)

`sst1:` smartSST object from the first Barm

`sst2:` smartSST object from the second Barm

`true_mumix:` true mu mixture

`true_sigmix:` true sigma mixture

`mu_Barm, sigsq_Barm, Barm:` input B-arm, mu, and sigsq for DTR

Author(s)

Jun (Jessie) He, Aberaham Eyman-Casey, Jason P. Sinnwell, Mayo Clinic

References

Jun He, Donna K. McClish & Roy T. Sabo (2021) Evaluating Misclassification Effects on Single Sequential Treatment in Sequential Multiple Assignment Randomized Trial (SMART) Designs, Statistics in Biopharmaceutical Research, DOI: 10.1080/19466315.2021.1883472

Examples

```
mumat13 <- cbind(G1=c(30,35), G0=c(20,28))
varmat13 <- cbind(G1=c(100,100),G0=c(100,100))

dtr13 <- smartDTR(mu_Barm=mumat13, sigsq_Barm=varmat13,
                  Barm=c(1,3), nsubject=252, pG_A1=0.8)

print(dtr13)
```

---

smartSST *Single Sequential Trial design clinical trial calculations*

Description

Single Sequential Trial design clinical trial calculations

Usage

```
smartSST(mu_Barm=c(G1=30, G0=20), sigsq_Barm=c(G1=100, G0=100),
                      nsubject=500,
                      Barm=1, type="continuous",
                      sens=seq(0.5,1, by=0.1), spec=seq(0.5, 1, by=0.1),
                      pG_A1 = 0.8, pG_A2=0.8, pran_A1 = 0.5, pran_Barm = 0.5)
```

Arguments

mu_Barm	named vector of the means for the Barm for the smart SST trial, with names 'G1' and 'G0'
sigsq_Barm	named vector of the variances (sigma-squared) for the Barm for the smart SST trial, with names 'G1' and 'G0'
nsubject	total sample size for the trial
Barm	for the second phase of the trial, the 'B' level for which the means/variances apply
type	trial response variable type; only continuous is implemented currently
sens	range of sensitivity for smart SST calculations; (0,1]
spec	range of specificity for smart SST calculations; (0,1]
pG_A1	probability of response to therapy given assignment to A1
pG_A2	probability of response to therapy given assignment to A2
pran_A1	probability of random assignment to A1
pran_Barm	probability of assignment to Barm

Details

more details on smart SST

Value

An object of the smartSST S3 class, with the following elements:

sstdat:	data.frame with sens, spec, mu, sigsq and sample size (n)
mu_Barm:	The value of mu_Barm passed to the function
sigsq_Barm:	The value of sigsq_Barm passed to the function

Author(s)

Jun (Jessie) He, Aberaham Eyman-Casey, Jason P. Sinnwell, Mayo Clinic

References

Jun He, Donna K. McClish & Roy T. Sabo (2021) Evaluating Misclassification Effects on Single Sequential Treatment in Sequential Multiple Assignment Randomized Trial (SMART) Designs, Statistics in Biopharmaceutical Research, DOI: 10.1080/19466315.2021.1883472

Examples

```
sst1 <- smartSST(mu_Barm=c(G1=30, G0=20), sigsq_Barm=c(G1=16,G0=16),
        Barm=1, sens=seq(.6, 1, by=.1),  spec=seq(.6, 1, by=.1),
        nsubject=252)
print(sst1$sstdat, digits=2)
```

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