Package ‘randomizeR’

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Type Package

Title Randomization for Clinical Trials

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Description This tool enables the user to choose a randomization procedure based on sound scientific criteria. It comprises the generation of randomization sequences as well the assessment of randomization procedures based on carefully selected criteria. Furthermore, ‘randomizeR’ provides a function for the comparison of randomization procedures.

License GPL (>= 3)

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Collate 'getDesign.R' 'randPar.R' 'pbrPar.R' 'rarPar.R' 'POC.R' 'OBF.R' 'GSD.R' 'abcdPar.R' 'randSeq.R' 'abcdSeq.R'
'getParameters.R' 'getExpectation.R' 'survEndp.R' 'expEndp.R'
'normEndp.R' 'endpoint.R' 'util.R' 'getStat.R' 'power.R'
'imbalance.R' 'corGuess.R' 'logRankDistribution.R' 'doublyF.R'
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'bsdPar.R' 'bsdSeq.R' 'chenPar.R' 'chenSeq.R'
'chronBiasStepT.R' 'combinedBias.R' 'compare.R' 'crPar.R'
'crSeq.R' 'createParam.R' 'derFunc.R' 'desFunc.R'
'getDesFunc.R' 'derringerLs.R' 'derringerRs.R' 'derringerTs.R'
'desScores.R' 'desirability.R' 'ebcSeq.R' 'evaluate.R'
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'mpPar.R' 'mpSeq.R' 'pbrSeq.R' 'probUnDes.R' 'rtbdSeq.R'
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'rtbdPar.R' 'saveAssess.R' 'saveRand.R' 'stratifiedAnalysis.R'
'tbdSeq.R' 'udPar.R' 'udSeq.R'

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Description

This tool enables the user to choose a randomization procedure based on sound scientific criteria. It comprises the generation of randomization sequences as well the assessment of randomization procedures based on carefully selected criteria. Furthermore, randomizeR provides a function for the comparison of randomization procedures.

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References


See Also

For functionality for randomization procedures, see randPar and genSeq. For the criteria for the assessment of randomization procedures, see issues. For the assessment and comparison of randomization procedures, see assess and compare.
Function returning the adjusting parameter \( a \) slot of an S4 object

### Description

Function returning the adjusting parameter \( a \) slot of an S4 object

### Usage

\( a(obj) \)

### Arguments

- \( obj \)
  - object of class \texttt{randPar}

### Value

the value of the adjusting parameter \( a \) of an S4 object

---

Representing Accelerated Biased Coin Design

### Description

Represents the randomization procedure Accelerated Biased Coin Design.

### Usage

\( \texttt{abcdPar}(N, a, \texttt{groups} = \texttt{LETTERS}[1:2]) \)

### Arguments

- \( N \)
  - integer for the total sample size of the trial.
- \( a \)
  - nonnegative parameter which controls the degree of randomness: For decreasing \( a \) the allocations become deterministic, while for increasing \( a \) the randomization procedure tends to complete randomization.
- \( \texttt{groups} \)
  - character vector of labels for the different treatments.

### Details

This is a class of 'biased coins' where the probability of selecting the under-represented treatment is dependent from the absolute difference between the two treatment allocations up to the current step.
Value

S4 object of the class abcdPar.

References


See Also

Other randomization procedures: bbcdPar, bsdPar, chenPar, crPar, createParam(), ebcPar, gbcdPar, hadaPar, mpPar, pbrPar, rarPar, rpbrPar, rtbdPar, tbdPar, udPar

Analyse

Creates stratified sequences Compares stratified sequences to their respective non-stratified version under the influence of bias.

Description

Creates stratified sequences Compares stratified sequences to their respective non-stratified version under the influence of bias.

Arguments

- **endp**: object of class endpoint.
- **pr**: at least one object of class randPar or just a list of objects of class randPar

Details

Stratified and Non-stratified versions of a randomization sequence behave differently with respect to issues like selection bias, chronological bias or combined bias. The analyse function creates both versions of a sequence for each of the specified randomization procedures and analyses them in relation to the bias created according to the theta and eta values. The first argument should specify the total sample size of patients. The second argument should be one of class normEndp describing a normally distributed endpoint. The third argument should be the allocation ratio for the different strata. The fourth argument should be the number of strata in the clinical trial. The fifth and sixth arguments should be the selection bias effect eta and the time trend theta. The seventh argument should be a vector of strings representing different randomization procedures. The strings should be given as described by the getDesign function. Any additional parameters should be given after the design name of the procedure encapsulated in parenthesis.

Value

The function returns a matrix that summarizes the performance of the randomization procedures. The values for each randomization procedure represent the percentage of sequences that kept the 5
assess

Assessing randomization sequences

Description

Assesses randomization sequences based on specified issues in clinical trials.

Usage

assess(randSeq, ..., endp)

## S4 method for signature 'randSeq,missing'
assess(randSeq, ..., endp)

## S4 method for signature 'randSeq,endpoint'
assess(randSeq, ..., endp)

Arguments

randSeq object of class randSeq.
...
endp object of class endpoint, or missing.

Details

Randomization sequences behave differently with respect to issues like selection bias, chronological bias, or loss in power estimation. The assess function evaluates the behavior of randomization sequences with respect to these issues. The first argument should be a result of one of the functions genSeq or getAllSeq. The second argument should be any number of issues arising in a clinical trial. The last argument endp may be provided if the assessment should take the distribution of the treatment groups into account, e.g. for power evaluation.

Value

S4 object of class assessment summarizing the assessment of the randomization procedure.

See Also

Representation of randomization procedures: randPar
Generation of randomization sequences: genSeq
issues for the assessment of randomization sequences
Examples

# assess the full set of Random Allocation Rule for N=4 patients
sequences <- getAllSeq(rarPar(4))
issue1 <- corGuess("CS")
issue2 <- corGuess("DS")
issue3 <- imbal("imb")
issue4 <- imbal("maxImb")
assess(sequences, issue1, issue2, issue3, issue4)

# assess one sequence of the Big Stick Design with respect to correct guesses
sequence <- genSeq(bsdPar(10, 2), seed = 1909)
assess(sequence, issue1)

# assess the same sequence with respect to selection bias and power for a normal endpoint
endp <- normEndp(c(2, 2), c(1, 1))
issue5 <- selBias("CS", 4, "exact")
issue6 <- setPower(2, 'exact')
assess(sequence, issue1, issue5, issue6, endp = endp)

# assess the same sequence with respect to selection bias for an exponential endpoint
endp <- expEndp(lambda = c(0.5, 0.5), cenRate=0.1, accrualTime=1, cenTime=5)
issue7 <- selBias("CS", 0.1, "exact")
assess(sequence, issue1, issue7, endp = endp)

# recommended plot for the assessment of rejection probabilities
RP <- getAllSeq(crvPar(6))
cB <- chronBias(type = "linT", theta = 1/6, method = "exact")
sB <- selBias(type= "CS", eta = 1/4, method = "exact")
normEndp <- normEndp(c(0, 0), c(1, 1))
A <- assess(RP, cB, sB, endp = normEndp)
D <- A$D
desiredSeq <- round(sum(D[,2][D[,3] <= 0.05 & D[,4] <= 0.05]), digits = 4)
colnames(D) <- c("Seq", "Prob", "SB", "linT")
g <- ggplot(D, aes(x = SB, y = linT))
g <- g + annotate("rect", xmin = 0, xmax = 0.05, ymin = 0, ymax = 0.05,
alpha=0.2, fill="green")
g <- g + geom_point(alpha = 1/10, size = 3, col = "orange")
g <- g + geom_hline(yintercept = 0.05, col = "red")
g <- g + geom_text(data = NULL, x = 0, y = 0,
label = paste("Proportion:", desiredSeq), hjust=0, vjust=0, size = 7)
g

bbcdPar

Representing Bayesian Biased Coin Design

Description

Represents the randomization procedure Bayesian Biased Coin Design.
Usage

bbcdPar(N, a, groups = LETTERS[1:2])

Arguments

N integer for the total sample size of the trial.
a nonnegative parameter which controls the degree of randomness: For decreasing
a the allocations become deterministic, while for increasing a the randomization
procedure tends to complete randomization.
groups character vector of labels for the different treatments.

Details

Extension of Efron’s biased coin design.

Value

S4 object of the class bbcdPar.

References

A. B. Antognini and Maroussa Zagoraiou (2014) Balance and randomness in sequential clinical
trials: the dominant biased coin design. Pharmaceutical Statistics 13(2), 119-127

See Also

Other randomization procedures: abcdPar, bsdPar, chenPar, crPar, createParam(), ebcPar,
gbcdPar, hadaPar, mpPar, pbrPar, rarPar, rpbrPar, rtbdPar, tbdPar, udPar

blocks

Function returning the block slot of an S4 object

Description

Function returning the block slot of an S4 object

Usage

blocks(obj)

Arguments

obj object of class pbrPar

Value

a vector with the lengths of each block of a pbrPar object
bsdPar

*Representing Big Stick Design*

**Description**

Represents the randomization procedure Big Stick Design.

**Usage**

```r
bsdPar(N, mti, groups = LETTERS[1:2])
```

**Arguments**

- **N** integer for the total sample size of the trial.
- **mti** maximum tolerated imbalance in patient numbers during the trial.
- **groups** character vector of labels for the different treatments.

**Details**

Tossing a fair coin as long as the difference in group sizes does not exceed the `mti`. If the `mti` is reached a deterministic allocation is done, so that the difference in group sizes is reduced.

**Value**

S4 object of the class `bsdPar`.

**References**


**See Also**

Other randomization procedures: `abcdPar`, `bbcdPar`, `chenPar`, `crPar`, `createParam()`, `ebcPar`, `gbcdPar`, `hadaPar`, `mpPar`, `pbrPar`, `rarPar`, `rpbrPar`, `rtbdPar`, `tbdPar`, `udPar`
Description

Represents the randomization procedure Chen’s Design.

Usage

```r
chenPar(N, mti = N, p = 0.5, groups = LETTERS[1:2])
```

Arguments

- **N**: integer for the total sample size of the trial.
- **mti**: maximum tolerated imbalance in patient numbers during the trial.
- **p**: success probability of the biased coin (e.g. in Efron’s Biased Coin Design).
- **groups**: character vector of labels for the different treatments.

Details

Flip a biased coin with probability \( p \) in favor of the treatment which is allocated less frequently as long as the difference in group sizes does not exceed the \( mti \). If the \( mti \) is reached a deterministic allocation is done, so that the difference in group sizes is reduced. If both treatments have been assigned equally often a fair coin is tossed.

Value

S4 object of the class `chenPar`.

References


See Also

Other randomization procedures: `abcdPar`, `bbcdPar`, `bsdPar`, `crPar`, `createParam()`, `ebcPar`, `gbcdPar`, `hadaPar`, `mpPar`, `pbrPar`, `rarPar`, `rpbrPar`, `rtbdPar`, `tbdPar`, `udPar`
**Description**

Represents the issue of chronological bias in a clinical trial.

**Usage**

```r
chronBias(type, theta, method, saltus, alpha = 0.05)
```

**Arguments**

- `type` character string, should be one of "linT", "logT", or "stepT", see Details.
- `theta` factor of the time trend for further details see `type`.
- `method` character string, should be one of "sim" or "exact", see Description.
- `saltus` integer or missing specifying the patient index (i.e. position) of the step in case of step time trend.
- `alpha` significance level

**Details**

Chronological bias can be an issue in the design of a clinical trial. The `chronBias` function is a constructor function for an S4 object of the class `chronBias` representing the issue of chronological bias, s.a. time trends, in a clinical trial. It supports two possible modes, `method="sim"` and `method="exact"`, and three different types of trend.

If `method="sim"`, the object represents the simulated type-I-error rate given the level `alpha`, the selection effect `eta` and the biasing strategy `type`. When calling `assess` for a `chronBias` object with `method="sim"`, one test decision is computed for each sequence of `randSeq`. The type-I-error rate (power) is the proportion of falsely (correctly) rejected null hypotheses.

If `method="exact"`, the object represents the exact type-I-error probability given the level `alpha`, the selection effect `eta` and the biasing strategy `type`. When calling `assess` for a `chronBias` object with `method="exact"`, the $p$-value of each randomization sequence is computed. For normal endpoints and two treatment groups these $p$-values are exact values which can be calculated from the sum of the corresponding quantiles of the doubly noncentral t-distribution. For more than two treatment groups, exact $p$-values are computed using a doubly noncentral F distribution. For exponential endpoints the $p$-values are obtained using an approximation formula.

**Types of chronological bias:**

- `type = "linT"` Represents linear time trend. Linear time trend means that the time trend function of the patients, i.e. expected response for normal endpoints, increases evenly by $\theta/(N-1)$ with every patient included in the study, until reaching $\theta$ after $N$ patients. Linear time trend may occur as a result of gradually relaxing in- or exclusion criteria throughout the trial. It can be represented by the formula:

  \[ f(i) = (i - 1)/(N - 1)\theta \]
type = "logT" Represents logarithmic time trend. Logarithmic time trend means that the time trend function of the patients, i.e. expected response for normal endpoints, increases logarithmically in the patient index by \(\theta/\log(N)\) with every patient included in the study, until reaching \(\theta\) after \(N\) patients. Logarithmic time trend may occur as a result of a learning curve, i.e. in a surgical trial. It can be represented by the formula:

\[
\log(i)/\log(N)\theta
\]

\(\text{type} = "\text{stepT}\) Represents step trend. Step trend means that the expected response of the patients increases by \(\theta\) after a given point ("saltus") in the allocation process. Step trend may occur if a new device is used after the point \(c = "\text{saltus}\)", or if the medical personal changes after this point. Step time trend can be represented by the formula:

\[
f(i) = 1_{c<i\leq N}\theta
\]

Value

S4 object of class chronBias, a formal representation of the issue of chronological bias in a clinical trial.

References


See Also

Other issues: combineBias(), corGuess, imbal, issue, selBias, setPower()

Examples

```r
# create a linear time trend with theta = 0.5 for which the exact rejection probabilities
# are calculated
cbias <- chronBias("linT", 0.5, "exact")

# create a stepwise time trend with theta = 1 after 10 allocations for which the test
# decision is simulated
cbias <- chronBias("stepT", 1, "sim", 10)
```

Function returning the coin slot of an S4 object

Description

Function returning the coin slot of an S4 object
Usage

coin(obj)

Arguments

obj object extending class randPar or randSeq

Value

The success probability of the biased coin

---

combineBias      Combined bias criterion

Description

This class combines a selBias object and a chronBias object to a new object. In the analysis within the new object the two types of bias are treated as additive effect for normal endpoints and as multiplicative effect for exponential endpoints.

Usage

combineBias(selBias, chronBias)

Arguments

selBias object of class selBias
chronBias object of class chronBias

Value

A combined bias object that combines a selBias and a chronBias object

See Also

Other issues: chronBias, corGuess, imbal, issue, selBias, setPower()

Examples

chronBias <- chronBias(type="linT", theta=1, method="sim")
selBias <- selBias(type="CS", eta=1, method="sim")
combineBias(selBias, chronBias)
comparison of randomization procedures

Description

Compares randomization procedures based on a specified issue in clinical trials.

Usage

```r
compare(issue, ..., endp)
```

## S4 method for signature 'issue,missing'
```r
compare(issue, ..., endp)
```

## S4 method for signature 'issue,endpoint'
```r
compare(issue, ..., endp)
```

Arguments

- `issue`: object of class `issue`.
- `...`: at least one object of class `randSeq` or a list of objects of class `randSeq`.
- `endp`: object of class `endpoint`, or `missing`.

Details

Randomization procedures behave differently with respect to issues like selection bias, chronological bias, or loss in power estimation. The `compare` function evaluates the behavior of randomization procedures with respect to one issue. Its first argument should represent one of the implemented issues. The second argument should be any number of objects of the class `randSeq`. These objects represent the randomization procedures for the planned comparison. The last argument `endp` may be provided if the assessment should take the distribution of the treatment groups into account, e.g. for power evaluation.

Value

S4 object of class `comparison` summarizing the comparison of the randomization procedures.

See Also

- Representation of randomization procedures: `randPar`
- Generation of randomization sequences: `genSeq`
- `issues` for the assessment of randomization sequences
Examples

# compare Random Allocation Rule and Big Stick for N = 4 with respect to
correct guesses
RAR <- getAllSeq(rarPar(4))
BSD <- getAllSeq(bsdPar(4, mti = 2))
corGuess <- corGuess("CS")
(comp <- compare(corGuess, RAR, BSD))
plot(comp)

# compare the same procedures with respect to selection bias for a normal endpoint
endp <- normEndp(c(2, 2), c(1, 1))
selBias <- selBias("CS", 4, "exact")
(comp <- compare(selBias, RAR, BSD, endp = endp))
plot(comp)

# compare the same procedures with respect to selection bias for an exponential endpoint
endp <- expEndp(lambda = c(0.5, 0.5), cenRate=0.1, accrualTime=1, cenTime=5)
selBias <- selBias("CS", 0.1, "exact")
(comp <- compare(selBias, RAR, BSD, endp = endp))
plot(comp)

---

corGuess

Representing the expected number of correct guesses

Description

Represents the expected number of correct guesses of randomization sequences.

Usage

corGuess(type)

Arguments

- type: character string, should be one of "CS" or "DS", see Details.

Details

Selection bias can be an issue in the design of a clinical trial. The expected number of correct guesses is one measure for selection bias. The corGuess function is a constructor function for an S4 object of the class corGuess representing the issue of correct guesses in a clinical trial. The parameter type takes the following values:

"CS" refers to "convergence strategy", i.e. the investigator predicts the treatment which has hitherto occurred less often.

"DS" refers to "divergence strategy", i.e. the investigator predicts the treatment which has hitherto occurred more often.
createParam

Value

S4 object of class corGuess, a formal representation of the issue of correct guesses in a clinical trial.

References


See Also

Other issues: chronBias, combineBias(), imbal, issue, selBias, setPower()

createParam

Representing any randomization procedure

Description

Represents any randomization procedure for a two-armed clinical trial.

Usage

createParam(method, N, mti, bc, rb, p, ini, add, filledBlock)

Arguments

<table>
<thead>
<tr>
<th>Argument</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>method</td>
<td>method that is used to generate the (random) allocation sequence. It can take values PBR, RAR, HAD, PWR, EBC, BSD, CR, TBD, UD, and MP.</td>
</tr>
<tr>
<td>N</td>
<td>integer for the total sample size of the trial.</td>
</tr>
<tr>
<td>mti</td>
<td>maximum tolerated imbalance in patient numbers during the trial.</td>
</tr>
<tr>
<td>bc</td>
<td>vector which contains the lengths $k_1, \ldots, k_l$ of each block. This means that the vector bc will have one entry for each block.</td>
</tr>
<tr>
<td>rb</td>
<td>block lengths of the blocks that can be selected equiprobable at random.</td>
</tr>
<tr>
<td>p</td>
<td>success probability of the biased coin (e.g. in Efron’s Biased Coin Design).</td>
</tr>
<tr>
<td>ini</td>
<td>integer representing the initial urn composition.</td>
</tr>
<tr>
<td>add</td>
<td>integer representing the number of balls that are added to the urn in each step.</td>
</tr>
<tr>
<td>filledBlock</td>
<td>logical whether the last block should be filled or not.</td>
</tr>
</tbody>
</table>

Details

Depending on the input of the user, createParam creates an object representing a randomization procedures for a two-armed clinical trial (see also randPar).

Value

S4 object of the corresponding randomization procedure class.
See Also

Other randomization procedures: abcdPar, bbcdPar, bsdPar, chenPar, crPar, ebcPar, gbcdPar, hadaPar, mpPar, pbrPar, rarPar, rpbrPar, rtbdPar, tbdPar, udPar

createSeq

Query to create a randomization sequence of a particular randomization procedure

Description

This function is a query to create an corresponding randomization sequence for a two-armed clinical trial. If file is defined, the generated sequence is automatically saved to the corresponding path.

Usage

createSeq(file)

Arguments

file

A connection, or a character string naming the file to write to.

Value

an object Param, which is available

crPar

Representing Complete Randomization

Description

Represents the randomization procedure Complete Randomization.

Usage

crPar(N, K = 2, ratio = rep(1, K), groups = LETTERS[1:K])

Arguments

N

integer for the total sample size of the trial.

K

number of treatment groups (e.g. K=2 if we compare one experimental against one control treatment).

ratio

vector of length K. The total sample number N and all used block lengths (bc) have to be divisible by sum(ratio).

groups

character vector of labels for the different treatments.
**Details**

Toss a fair coin \(N\) times in case \(K=2\) and assign the treatments according to the result of the coin. In case of \(K>2\), replace the coin by a die with \(K\) sides.

**Value**

S4 object of the class `crPar`.

**References**


**See Also**

Other randomization procedures: `abcdPar`, `bbcdPar`, `bsdPar`, `chenPar`, `createParam()`, `ebcPar`, `gbcdPar`, `hadaPar`, `mpPar`, `pbrPar`, `rarPar`, `rpbrPar`, `rtbdPar`, `tbdPar`, `udPar`

---

### derFunc

**Representing Derringer-Suich desirability functions**

**Description**

Represents the Derringer-Suich desirability approach.

**Usage**

```r
derFunc(TV, SLs, b)
```

**Arguments**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>TV</td>
<td>numeric specifying the optimal desired value called the target value.</td>
</tr>
<tr>
<td>SLs</td>
<td>numeric vector of length at most 2 specifying the lower and/or upper specified border.</td>
</tr>
<tr>
<td>b</td>
<td>numeric vector of length at most 2 specifying the weight(s) for the punishment of deviations from the target value.</td>
</tr>
</tbody>
</table>

**Details**

derFunc represents the framework for left, right and two-sided desirability functions introduced by Derringer and Suich (1980). For all three different kinds of desirability functions the parameter `TV` must be specified. If the parameter `SLs` has length 1, either the left- or right-sided desirability function is created depending from whether the value is smaller (left-sided) or greater (right-sided) than the target value. By specifying `SLs` as a vector of length 2 a two-sided desirability function is created where the lower specified border is determined as the smaller value of `SLs` and thus the upper specified border is determined as the greater value. If there are no values specified for the weights, then they are automatically set to 1 (linear loss).
Value

S4 object of class `derFunc`, a formal representation of desirability functions introduced by Derringer and Suich.

References


See Also

Other desirability topics: `evaluate()`, `getDesScores()`, `plotDes()`, `plotEv()`, `probUnDes()`

Examples

```r
# create an object of a left-sided desirability function
dLeft <- derFunc(0.5, 0.3, 2)

# create an object of a right-sided desirability function
dRight <- derFunc(0.5, 0.8, 1)

# create an object of a two-sided desirability function
dLR <- derFunc(0.5, c(0.3, 0.9), c(3, 1))
```

---

**desirability**

*Desirability functions within the scope of clinical trials*

Description

Illustrates the interplay between functions related to desirability indices.

Details

Currently, `randomizeR` encompasses the class of desirability functions introduced by Derringer and Suich (1980) and corresponding functions to evaluate and compare randomization sequences which have been assessed on the basis of desirability indices of specific issues:

- `derFunc` represents the class of desirability functions according to Derringer-Suich (1980).
- `getDesScores` can be applied to an object of class `assessment` together with prespecified desirability functions to compare the behavior of randomization sequences (on a common scale \([0,1]\)).
- `plotDes` plots a `desScores` object on a radar chart.
- `evaluate` performs a comparison of sequences from different randomization sequences on the basis of object of the class `desScores`.
- `plotEv` plots an evaluation object on a radar chart.
- `probUnDes` computes the probability of undesired randomization sequences with respect to certain issues and desirability functions.
**ebcPar**

**Representing Efron’s Biased Coin Design**

**Description**

Represents the randomization procedure Efron’s Biased Coin Design.

**Usage**

```r
ebcPar(N, p, groups = LETTERS[1:2])
```
evaluate

Arguments

- **N**: integer for the total sample size of the trial.
- **p**: success probability of the biased coin (e.g. in Efron’s Biased Coin Design).
- **groups**: character vector of labels for the different treatments.

Details

Flip a biased coin with probability $p$ in favor of the treatment which is allocated less frequently. If both treatments have been assigned equally often a fair coin is tossed.

Value

S4 object of the class `ebcPar`.

References


See Also

Other randomization procedures: `abcdPar`, `bbcdPar`, `bsdPar`, `chenPar`, `crPar`, `createParam()`, `gbcdPar`, `hadaPar`, `mpPar`, `pbrPar`, `rarPar`, `rpbrPar`, `rtbdPar`, `tbdPar`, `udPar`

Description

Evaluation of several randomization procedures with respect to certain desirability functions applied to specified issues.

Usage

```r
evaluate(..., statistic)
```

## S4 method for signature 'missing'
```r
evaluate(..., statistic)
```

## S4 method for signature 'character'
```r
evaluate(..., statistic)
```

Arguments

- **...**: at least one object of the class `desScores` or a list of objects of the class `desScores`.
- **statistic**: character string that specifies on the basis of which statistic the `evaluate` function should be applied. The statistic can be chosen from "mean", "median", "min" or "max".
**Details**

The `evaluate` function allows the user to compare and evaluate different randomization procedures. It expects a number of objects that result when applying the `getDesScores` function to an `assess` object and specified desirability functions. The `evaluate` function summarizes the desirability scores of each randomization procedure on the basis of a prespecified statistic and incorporates them into a data frame. If no statistic is specified then it is automatically set to `mean`. If the function is applied to only one object it corresponds simply to `summary(getDesScores(...))`.

**Value**

S4 object of class `evaluation` Comparison of randomization procedures with respect to desirability functions applied to specified issues, summarized by a prespecified statistic.

**References**


**See Also**

Representation of randomization procedures: `randPar`

Generation of randomization sequences: `genSeq`

`issues` for the desirability of randomization sequences

Other desirability topics: `derFunc`, `getDesScores()`, `plotDes()`, `plotEv()`, `probUnDes()`

**Examples**

```r
# compare Random Allocation Rule to Big Stick Design with respect to different issues
# and their corresponding desirability functions
issue1 <- corGuess("CS")
issue2 <- corGuess("DS")
RAR <- getAllSeq(rarPar(4))
BSD <- getAllSeq(bsdPar(4, mti = 2))
A1 <- assess(RAR, issue1, issue2)
A2 <- assess(BSD, issue1, issue2)

d1 <- derFunc(TV = 0.1, 0.7, 2)
d2 <- derFunc(0.5, c(0.3, 0.8), c(1, 1))
DesScore <- getDesScores(A1, d1, d2, weights = c(5/6, 1/6))
DesScore2 <- getDesScores(A2, d1, d2, weights = c(5/6, 1/6))

evaluate(DesScore, DesScore2)
evaluate(DesScore, DesScore2, statistic = "max")
```
expEndp

Representation of exponentially distributed endpoints

Description

Represents exponentially distributed endpoints in clinical trials.

Usage

expEndp(lambda, cenRate, accrualTime = 0, cenTime)

Arguments

- lambda: vector of the exponential rate parameters in each treatment group.
- cenRate: exponential censoring rate in a survival study.
- accrualTime: duration of the accrual period in a survival study.
- cenTime: total duration of a survival study (maximum length of followup).

Details

The `expEndp` function is a constructor function for an S4 object of the class `expEndp` representing an exponentially distributed endpoint in a clinical trial. In conjunction with the `assess` function, exponential endpoints admit the calculation of the 'exact' type-I-error probability and power using an approximation formula.

Value

A S4 object representing an exponentially distributed endpoint in a clinical trial.

See Also

Compute exact or simulated type-I-error: `assess`.

Other endpoint types: `normEndp, survEndp`

Examples

# set the parameters of two exponentially distributed endpoints
dep <- expEndp(lambda = c(1, 2), cenTime = 10, cenRate = 0.01)
gbcdPar

Representing Generalized Biased Coin Design

Description

Represents the randomization procedure Generalized Biased Coin Design.

Usage

gbcdPar(N, rho, groups = LETTERS[1:2])

Arguments

N  integer for the total sample size of the trial.
rho nonnegative parameter which may be adjusted according to how strongly it is desired to balance the experiment. If rho = 1, we have Wei’s urn design with alpha = 0. If rho = 0, we have complete randomization.
groups character vector of labels for the different treatments.

Details

Generalization of Wei’s urn and Efron’s biased coin design.

Value

S4 object of the class gbcdPar.

References


See Also

Other randomization procedures: abcdPar, bbcdPar, bsdPar, chenPar, crPar, createParam(), ebcPar, hadaPar, mpPar, pbrPar, rarPar, rpbrPar, rtbdPar, tbdPar, udPar
**generateAllSequences**

*Complete set of randomization sequences*

**Description**

Computes all randomization sequences for the given randomization procedure, and stores them in an object along with the parameters belonging to the randomization procedure.

**Usage**

```
getAllSeq(obj)
```

```r
## S4 method for signature 'pbrPar'
geAllSeq(obj)

## S4 method for signature 'rarPar'
geAllSeq(obj)

## S4 method for signature 'abcdPar'
geAllSeq(obj)

## S4 method for signature 'bbcdPar'
geAllSeq(obj)

## S4 method for signature 'ebcPar'
geAllSeq(obj)

## S4 method for signature 'bsdPar'
geAllSeq(obj)

## S4 method for signature 'chenPar'
geAllSeq(obj)

## S4 method for signature 'crPar'
geAllSeq(obj)

## S4 method for signature 'gbcdPar'
geAllSeq(obj)

## S4 method for signature 'hadaPar'
geAllSeq(obj)

## S4 method for signature 'mpPar'
geAllSeq(obj)

## S4 method for signature 'tbdPar'
geAllSeq(obj)
```
## S4 method for signature 'udPar'

getAllSeq(obj)

### Arguments

- **obj**: object specifying the randomization procedure, see `randPar` or `createParam`.

### Details

getAllSeq is a generic function which dispatches different methods depending on the type of input. The set of sequences of a procedure is computed by enumerating all possible sequences and eliminating those that are not possible in the randomization procedure specified by `obj`. The parameters of the randomization procedure are saved along with the sequences to ensure reproducibility of the results.

### Value

An object inheriting from `randSeq`, representing the set of randomization sequences for the given parameters. The output consists of the parameters used for the generation of the randomization sequences (see `createParam`) and the matrix M that stores the randomization sequences in its rows.

### See Also

- `createParam`

### Examples

```r
# all randomization sequences of Efron's Biased Coin Design with p = 0.667 for N = 6
myPar <- ebcPar(6, 0.667)
getchPar(myPar)

# all randomization sequences of Big Stick Design with mti = 2 for N = 6
myPar <- bsdPar(6, 2)
getchPar(myPar)

# all randomization sequences of Permuted Block Randomization with block sizes 4 and 2
myPar <- pbrPar(c(4, 2))
getchPar(myPar)
```
generateRandomSequences

Generate random sequences

Description
Generates randomization sequences from a given randomization procedure.

Usage

```r
genSeq(obj, r, seed)
```

## S4 method for signature 'pbrPar,missing,numeric'

```r
genSeq(obj, r, seed)
```

## S4 method for signature 'pbrPar,numeric,numeric'

```r
genSeq(obj, r, seed)
```

## S4 method for signature 'pbrPar,missing,missing'

```r
genSeq(obj, r, seed)
```

## S4 method for signature 'rarPar,numeric,numeric'

```r
genSeq(obj, r, seed)
```

## S4 method for signature 'rarPar,missing,numeric'

```r
genSeq(obj, r, seed)
```

## S4 method for signature 'rarPar,numeric,missing'

```r
genSeq(obj, r, seed)
```

## S4 method for signature 'rarPar,missing,missing'

```r
genSeq(obj, r, seed)
```

## S4 method for signature 'abcdPar,numeric,numeric'

```r
genSeq(obj, r, seed)
```

## S4 method for signature 'abcdPar,numeric,missing'

```r
genSeq(obj, r, seed)
```

## S4 method for signature 'abcdPar,missing,numeric'

```r
genSeq(obj, r, seed)
```

## S4 method for signature 'abcdPar,missing,missing'

```r
genSeq(obj, r, seed)
```
generateRandomSequences

## S4 method for signature 'bbcdPar,numeric,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'bbcdPar,numeric,missing'
genSeq(obj, r, seed)

## S4 method for signature 'bbcdPar,missing,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'bbcdPar,missing,missing'
genSeq(obj, r, seed)

## S4 method for signature 'ebcPar,numeric,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'ebcPar,numeric,missing'
genSeq(obj, r, seed)

## S4 method for signature 'ebcPar,missing,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'ebcPar,missing,missing'
genSeq(obj, r, seed)

## S4 method for signature 'bsdPar,numeric,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'bsdPar,numeric,missing'
genSeq(obj, r, seed)

## S4 method for signature 'bsdPar,missing,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'bsdPar,missing,missing'
genSeq(obj, r, seed)

## S4 method for signature 'chenPar,numeric,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'chenPar,numeric,missing'
genSeq(obj, r, seed)

## S4 method for signature 'chenPar,missing,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'chenPar,missing,missing'
genSeq(obj, r, seed)
## S4 method for signature 'crPar,numeric,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'crPar,missing,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'crPar,numeric,missing'
genSeq(obj, r, seed)

## S4 method for signature 'crPar,missing,missing'
genSeq(obj, r, seed)

## S4 method for signature 'gbcdPar,numeric,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'gbcdPar,numeric,missing'
genSeq(obj, r, seed)

## S4 method for signature 'gbcdPar,missing,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'gbcdPar,missing,missing'
genSeq(obj, r, seed)

## S4 method for signature 'hadaPar,numeric,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'hadaPar,missing,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'hadaPar,numeric,missing'
genSeq(obj, r, seed)

## S4 method for signature 'hadaPar,missing,missing'
genSeq(obj, r, seed)

## S4 method for signature 'mpPar,numeric,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'mpPar,missing,numeric'
genSeq(obj, r, seed)

## S4 method for signature 'mpPar,numeric,missing'
genSeq(obj, r, seed)

## S4 method for signature 'mpPar,missing,missing'
genSeq(obj, r, seed)
# S4 method for signature 'rpbrPar,missing,numeric'
genSeq(obj, r, seed)

# S4 method for signature 'rpbrPar,numERIC,numERIC'
genSeq(obj, r, seed)

# S4 method for signature 'rpbrPar,missing,missing'
genSeq(obj, r, seed)

# S4 method for signature 'rpbrPar,numERIC,missing'
genSeq(obj, r, seed)

# S4 method for signature 'tbdPar,numERIC,numERIC'
genSeq(obj, r, seed)

# S4 method for signature 'tbdPar,missing,numERIC'
genSeq(obj, r, seed)

# S4 method for signature 'tbdPar,numERIC,missing'
genSeq(obj, r, seed)

# S4 method for signature 'tbdPar,missing,missing'
genSeq(obj, r, seed)

# S4 method for signature 'tbdPar,numERIC,missing'
genSeq(obj, r, seed)

# S4 method for signature 'rtbdPar,numERIC,numERIC'
genSeq(obj, r, seed)

# S4 method for signature 'rtbdPar,missing,numERIC'
genSeq(obj, r, seed)

# S4 method for signature 'rtbdPar,numERIC,missing'
genSeq(obj, r, seed)

# S4 method for signature 'rtbdPar,missing,missing'
genSeq(obj, r, seed)

# S4 method for signature 'udPar,numERIC,numERIC'
genSeq(obj, r, seed)

# S4 method for signature 'udPar,missing,numERIC'
genSeq(obj, r, seed)

# S4 method for signature 'udPar,numERIC,missing'
genSeq(obj, r, seed)

# S4 method for signature 'udPar,missing,missing'
genSeq(obj, r, seed)
Arguments

obj object specifying the randomization procedure, see `randPar` or `createParam`.

r numeric indicating the number of random sequences to be generated at random, or missing.

seed a single value, interpreted as an integer, that specifies the seed for the random number generation.

Details

genSeq generates randomization sequences for a randomization procedure as defined by the input parameters. genSeq has two modes, according to the input.

1. genSeq(obj, r): gives r random sequences from the design specified by obj, along with the parameters stored in obj.
2. genSeq(obj): gives one random sequences from the design specified by obj, along with the parameters stored in obj.

The sequences are generated by using the Monte-Carlo sampling technique to sample from the true distribution of the sequences according to the randomization procedure specified by obj. The parameters of the randomization procedure are saved along with the sequences to ensure reproducibility of the results.

Value

An object inheriting from `randSeq`, representing the r randomization sequences generated at random for the specified randomization procedure. The output consists of the parameters used for the generation of the randomization sequences (see `createParam`) and the matrix M that stores the randomization sequences in its r rows. If r is missing, one sequence is generated by default.

Examples

```r
# generate randomization sequences using Complete Randomization for N = 10
myPar <- crPar(10)
genSeq(myPar, 4)
genSeq(myPar)

# generate randomization sequences using the Random Allocation Rule for N = 10
myPar <- rarPar(10)
genSeq(myPar, 4)
genSeq(myPar)

# generate randomization sequences using the Maximal Procedure with mti = 2 and N = 10
myPar <- mpPar(10, 2)
genSeq(myPar, 4)
genSeq(myPar)
```
**Description**

Computes the noncentrality parameters delta and lambda for the doubly noncentral t-distribution of each randomization sequence.

**Usage**

```r
genNcps_new(randSeq, bias, endp, weight = FALSE)
```

**Arguments**

- `randSeq`: a list of randSeq(rCrSeq or others) with possible varying N’s.
- `bias`: a list of biases - corresponding to the different randSeq’s.
- `endp`: object of the class endpoint.
- `weight`: if set to TRUE the weight will be set to 1, according to the paper.

**Value**

A list containing the noncentrality parameters delta and lambda of all randomization sequences.

---

**Description**

Calculates the guesses of the investigator of a randomization list following the specified guessing strategy.

**Usage**

```r
corGuesses(randSeq, guessing)
```

**Arguments**

- `randSeq`: object of the class randSeq.
- `guessing`: object of the class corGuess.

**Value**

Matrix of the guesses of the investigator following the specified guessing strategy. No guess is abbreviated with "nG".
### getDesFunc

**Type of Desirability function**

---

**Description**

Generates a character vector which specifies the used desirability function and its parameters

**Usage**

```r
getDesFunc(obj)
```

`## S4 method for signature 'derringerLs'
getDesFunc(obj)`

`## S4 method for signature 'derringerRs'
getDesFunc(obj)`

`## S4 method for signature 'derringerTs'
getDesFunc(obj)`

**Arguments**

- `obj` object of the class desFunc.

**Value**

A character vector which specifies the used desirability function and its parameters

---

### getDesign

**Design of a randomization procedure**

---

**Description**

Generates a character vector which specifies the used randomization method
Usage

getDesign(obj)

## S4 method for signature 'pbrPar'
getDesign(obj)

## S4 method for signature 'rarPar'
getDesign(obj)

## S4 method for signature 'abcdPar'
getDesign(obj)

## S4 method for signature 'abcdSeq'
getDesign(obj)

## S4 method for signature 'bbcdPar'
getDesign(obj)

## S4 method for signature 'bbcdSeq'
getDesign(obj)

## S4 method for signature 'ebcPar'
getDesign(obj)

## S4 method for signature 'bsdPar'
getDesign(obj)

## S4 method for signature 'bsdSeq'
getDesign(obj)

## S4 method for signature 'chenPar'
getDesign(obj)

## S4 method for signature 'chenSeq'
getDesign(obj)

## S4 method for signature 'crPar'
getDesign(obj)

## S4 method for signature 'crSeq'
getDesign(obj)

## S4 method for signature 'ebcSeq'
getDesign(obj)

## S4 method for signature 'gbcdPar'
getDesign(obj)
## S4 method for signature 'gbcdSeq'
getDesign(obj)

## S4 method for signature 'hadaPar'
getDesign(obj)

## S4 method for signature 'hadaSeq'
getDesign(obj)

## S4 method for signature 'mpPar'
getDesign(obj)

## S4 method for signature 'mpSeq'
getDesign(obj)

## S4 method for signature 'pbrSeq'
getDesign(obj)

## S4 method for signature 'rRtbdSeq'
getDesign(obj)

## S4 method for signature 'rRpbrSeq'
getDesign(obj)

## S4 method for signature 'rarSeq'
getDesign(obj)

## S4 method for signature 'rpbrPar'
getDesign(obj)

## S4 method for signature 'tbdPar'
getDesign(obj)

## S4 method for signature 'rtbdPar'
getDesign(obj)

## S4 method for signature 'tbdSeq'
getDesign(obj)

## S4 method for signature 'udPar'
getDesign(obj)

## S4 method for signature 'udSeq'
getDesign(obj)

### Arguments

obj object of the class randSeq or randPar.
getDesScores

Value
the name of the randomization procedure used

---

getDesScores  Applying desirability functions on issues of individual randomization sequences

Description
Applying desirability function on issues of individual randomization sequences.

Usage
getDesScores(assess, ..., weights)

## S4 method for signature 'assessment,missing'
getDesScores(assess, ..., weights)

## S4 method for signature 'assessment,numeric'
getDesScores(assess, ..., weights)

Arguments
assess  object of class assessment.
...  at least one object of class derFunc or a list of objects of the class derFunc.
weights  weights for computing the geometric mean of several desirability scores. If missing, the issues are automatically equally weighted.

Details
Randomization sequences behave differently with respect to issues like selection bias, chronological bias, or loss in power estimation. The getDesScores function evaluates the behavior of randomization sequences with respect to these issues. The difference to the assess function is that it scales them to \( [0,1] \) and makes them easier interpretable. The first argument should be a result of the assess function. The second argument should be any number of derFunc objects that represent the desirability functions. The last argument weights may be provided if the desirability functions should be weighted differently.

Value
S4 object of class desirability summarizing the desirability of the randomization procedure.

See Also
Representation of randomization procedures: randPar
Generation of randomization sequences: genSeq
issues for the desirability of randomization sequences
Other desirability topics: derFunc, evaluate(), plotDes(), plotEv(), probUnDes()
Examples

```r
# compute the desire-function for the full set of Random Allocation Rule for N = 4
sequences <- getAllSeq(rarPar(4))
issue1 <- corGuess("CS")
issue2 <- chronBias("linT", 0.25, "exact")
endp <- normEndp(mu = c(0,0), sigma = c(1,1))
A <- assess(sequences, issue1, issue2, endp = endp)
d1 <- derFunc(0.5, 0.75, 1)
d2 <- derFunc(0.05, 0.1, 1)

D1 <- getDesScores(A, d1, d2)
summary(D1)

D2 <- getDesScores(A, d1, d2, weights = c(3/4, 1/4))
summary(D2)
```

getDistributionPars  
*Get distribution parameters of a randomization list*

**Description**

Generates a matrix of the distribution parameters of the included patients in the clinical trial.

**Usage**

```r
getDistributionPars(randSeq, issue, endp)
```

## S4 method for signature 'randSeq,missing,survEndp'

```r
getDistributionPars(randSeq, endp)
```

## S4 method for signature 'randSeq,chronBias,survEndp'

```r
getDistributionPars(randSeq, issue, endp)
```

## S4 method for signature 'randSeq,selBias,survEndp'

```r
getDistributionPars(randSeq, issue, endp)
```

## S4 method for signature 'randSeq,combinedBias,survEndp'

```r
getDistributionPars(randSeq, issue, endp)
```

## S4 method for signature 'randSeq,combinedBiasStepTrend,survEndp'

```r
getDistributionPars(randSeq, issue, endp)
```

**Arguments**

<table>
<thead>
<tr>
<th>Argument</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>randSeq</td>
<td>object of the class randSeq.</td>
</tr>
<tr>
<td>issue</td>
<td>object of the class issue (optional).</td>
</tr>
<tr>
<td>endp</td>
<td>object of the class endpoint.</td>
</tr>
</tbody>
</table>
getExpectation

Value

a matrix of the distribution parameters of the included patients in the clinical trial.

Examples

# return the shape and scale parameters of a Weibull distribution
endp <- survEndp(shape = c(1,1), scale = c(0.5,1), cenTime = 10, cenRate = 0.01)
biasSB <- selBias("CS", log(2), "exact")
randSeq <- genSeq(rpbrPar(rb = 2, N = 12))
getDistributionPars(randSeq,biasSB,endp)

Description

Generates a matrix of the expectations of the included patients in the clinical trial.

Usage

getExpectation(randSeq, issue, endp)

## S4 method for signature 'randSeq,missing,survEndp'
getExpectation(randSeq, endp)

## S4 method for signature 'randSeq,missing,expEndp'
getExpectation(randSeq, endp)

## S4 method for signature 'randSeq,missing,normEndp'
getExpectation(randSeq, endp)

## S4 method for signature 'randSeq,power,normEndp'
getExpectation(randSeq, issue, endp)

## S4 method for signature 'randSeq,chronBias,normEndp'
getExpectation(randSeq, issue, endp)

## S4 method for signature 'randSeq,chronBias,expEndp'
getExpectation(randSeq, issue, endp)

## S4 method for signature 'randSeq,chronBias,survEndp'
getExpectation(randSeq, issue, endp)

## S4 method for signature 'randSeq,chronBias,missing'
getExpectation(randSeq, issue)

## S4 method for signature 'randSeq,selBias,normEndp'
getExpectation(randSeq, issue, endp)

## S4 method for signature 'randSeq,selBias,expEndp'
getExpectation(randSeq, issue, endp)

## S4 method for signature 'randSeq,selBias,survEndp'
getExpectation(randSeq, issue, endp)

## S4 method for signature 'randSeq,selBias,missing'
getExpectation(randSeq, issue)

## S4 method for signature 'randSeq,combinedBias,normEndp'
getExpectation(randSeq, issue, endp)

## S4 method for signature 'randSeq,combinedBias,expEndp'
getExpectation(randSeq, issue, endp)

## S4 method for signature 'randSeq,combinedBias,survEndp'
getExpectation(randSeq, issue, endp)

## S4 method for signature 'randSeq,combinedBiasStepTrend,normEndp'
getExpectation(randSeq, issue, endp)

## S4 method for signature 'randSeq,combinedBiasStepTrend,expEndp'
getExpectation(randSeq, issue, endp)

## S4 method for signature 'randSeq,combinedBiasStepTrend,survEndp'
getExpectation(randSeq, issue, endp)

Arguments

- randSeq: object of the class randSeq.
- issue: object of the class issue (optional).
- endp: object of the class endpoint (optional).

Details

It is assumed that the expectations of the included patients in a clinical trial can be influenced in three different ways:

- The strength of selection bias and the guessing strategy of the investigator (see selBias).
- The strength of a linear time trend, which is described by an object of the class chronBias.
- The expectations of the investigated treatment groups can be different (see e.g. normEndp).

Value

A matrix of the expectations of the included patients in the clinical trial.
Examples

# get Expectation for a normal endpoint
myPar <- bsdPar(10, 2)
M <- genSeq(myPar, 2)
cs <- selBias("CS", 2, "sim")
endp <- normEndp(mu = c(2, 2), sigma = c(1, 1))
getExpectation(M, cs, endp)

# get Expectation for an exponential endpoint
endp <- expEndp(lambda = c(0.5, 1), cenTime = 10, cenRate = 0.01)
getExpectation(M, cs, endp)

getProbabilities

Theoretical probability for randomization sequences

Description

Calculate theoretical probability for observed randomization sequences

Usage

getProb(obj)

## S4 method for signature 'abcdSeq'
getProb(obj)

## S4 method for signature 'bbcdSeq'
getProb(obj)

## S4 method for signature 'bsdSeq'
getProb(obj)

## S4 method for signature 'chenSeq'
getProb(obj)

## S4 method for signature 'crSeq'
getProb(obj)

## S4 method for signature 'ebcSeq'
getProb(obj)

## S4 method for signature 'gbcdSeq'
getProb(obj)

## S4 method for signature 'hadaSeq'
getRandomizationList

getProb(obj)

## S4 method for signature 'mpSeq'
getProb(obj)

## S4 method for signature 'pbrSeq'
getProb(obj)

## S4 method for signature 'rarSeq'
getProb(obj)

## S4 method for signature 'tbdSeq'
getProb(obj)

## S4 method for signature 'udSeq'
getProb(obj)

Arguments

obj object of a class inheriting from randSeq. Formal representation of a randomization sequences together with the parameters that belong to the procedure that generated the sequences.

Value

a matrix with theoretical probabilities for observed randomization sequences

Examples

myPar <- bsdPar(10, 2)
M <- genSeq(myPar, 2)
getProb(M)

# all Sequences
par <- pbrPar(bc=c(2,2))
refSet <- getAllSeq(myPar)
probs <- getProb(refSet)

# sequences with probabilities
cbind(probs, refSet$M)

getRandomizationList  Accessor function for the randomization list

Description

Get the randomization list coded in its groups.
Usage

getRandList(obj)

Arguments

obj object specifying the randomization procedure, see randPar or createParam.

Value

A matrix with all randomization sequences of a S4 object

Examples

myPar <- bsdPar(10, 2)
M <- genSeq(myPar, 2)
getRandList(M)


get_p_values_new Calculating p values

Description

Computes the p values based on the noncentrality parameters delta and lambda for the doubly noncentral t-distribution

Usage

get_p_values_new(delta, lambda, N, alpha = 0.05, df = sum(N - 2))

Arguments

delta The first noncentrality parameter
lambda The second noncentrality parameter
N the amount of patients in the trial
alpha significance level
df degrees of freedom

Value

a p value
**GSD_OBF**  
*Simulate Group Sequential Design according to O'Brien and Fleming*

**Description**
Calculates the mean type-I-error and go-no-go value for each stage of a group sequential design study according to O'Brien and Fleming’s design.

**Usage**

```
GSD_OBF(n, norep, K, RP, approach)
```

**Arguments**
- `n`: total sample size
- `norep`: number of simulations to be conducted
- `K`: number of stages. (Currently available: 2, 3 and 4)
- `RP`: the randomization procedure used. (Currently available: 'RAR', 'PBD2', 'BSD' - BSD(3), BSD(5) and BSD(10), 'EBC' - EBC(0.5), EBC(2/3) and EBC(0.8), 'CHEN' - CHEN(2/3, 3), CHEN(2/3, 5) and CHEN(2/3, 10))
- `approach`: the approach used, where 1 corresponds to allocating all patients at the beginning of the trial and 2 corresponds to allocating patients for each stage separately (Only needed for 'RAR', 'BSD' and 'CHEN')

**Value**
A Dataframe with the mean type-I-error and go-no-go values for each stage of a group sequential design study according to O'Brien and Fleming’s design

**Examples**
```
# Simulate a GSD according to O'Brien and Fleming's design with 30 patients, 10 simulation runs, # 3 Stages using Random Allocation Rule as a randomization procedure and applying it to # all patients at the beginning
GSD_OBF(30, 10, 2, 'RAR', 1)
```

---

---

**GSD_POC**  
*Simulate Group Sequential Design according to Pocock*

**Description**
Calculates the mean type-I-error and go-no-go value for each stage of a group sequential design study according to Pocock’s design.
Usage

GSD_POC(n, norep, K, RP, approach)

Arguments

n  
total sample size

norep  
number of simulations to be conducted

K  
number of stages. (Currently available: 2, 3 and 4)

RP  
the randomization procedure used. (Currently available: ‘RAR’, ‘PBD2’, ‘BSD’ - BSD(3), BSD(5) and BSD(10), ‘EBC’ - EBC(0.5), EBC(2/3) and EBC(0.8), ‘CHEN’ - CHEN(2/3,3), CHEN(2/3,5) and CHEN(2/3,10))

approach  
the approach used, where 1 corresponds to allocating all patients at the beginning of the trial and 2 corresponds to allocating patients for each stage separately (Only needed for ‘RAR’, ‘BSD’ and ‘CHEN’)

Value

A Dataframe with the mean type-I-error and go-no-go values for each stage of a group sequential design study according to Pocock’s design/

Examples

# Simulate a GSD according to Pocock’s design with 30 patients, 10 simulation runs, # 2 Stages using Random Allocation Rule as a randomization procedure and applying it to # all patients at the beginning
GSD_POC(30, 10, 2, 'RAR', 1)

hadaPar  
Representing Hadamard Randomization

Description

Represents the randomization procedure Hadamard Randomization.

Usage

hadaPar(N, groups = LETTERS[1:2])

Arguments

N  
integer for the total sample size of the trial.

groups  
character vector of labels for the different treatments.
Details
Hadamard randomization has been proposed by R.A. Bailey. The key idea is to use the columns of a special Hadamard Matrix as a randomization scheme. The implemented algorithm uses the Hadamard Matrix with \( N=12 \) columns proposed in the paper, see references.

Value
S4 object of the class hadaPar.

Note
getProb and getAllSeq are currently only supported for hadaPar with total sample size \( N=12 \).

References

See Also
Other randomization procedures: abcdPar, bbcdPar, bsdPar, chenPar, crPar, createParam(), ebcPar, gbcPar, mpPar, pbrPar, rarPar, rpbrPar, rtbdPar, tbdPar, udPar

Description
Represents the imbalance of the treatment assignments of patients in a clinical trial.

Usage
`imbal(type)`

Arguments
type character string, should be one of "imb", "absImb", "loss", or "maxImb", see Details.

Details
Balance of the treatment assignment of patients can be an issue in the design of a clinical trial. The `imbal` function is a constructor function for an S4 object of class `imbal` representing the issue of imbalance of a clinical trial. The parameter `type` can take the following values: The type

- "imb" the final imbalance, i.e. difference in group sizes at the end of a trial
- "absImb" the absolute value of the final imbalance
- "loss" the loss in power estimation, i.e. \( \text{imb}^2/N \)
- "maxImb" the maximal attained imbalance during the trial
Value

S4 object of class imbal, a formal representation of the issue of imbalance in a clinical trial.

References


See Also

Other issues: chronBias, combineBias(), corGuess, issue, selBias, setPower()
See Also

Representation of randomization procedures: \texttt{randPar}

Generation of randomization sequences: \texttt{genSeq}

Assessment of randomization sequences: \texttt{assess}

Comparison of randomization sequences: \texttt{compare}

Other issues: \texttt{chronBias,combineBias()}, \texttt{corGuess}, \texttt{imbal}, \texttt{selBias}, \texttt{setPower()}

---

\textbf{K} \hspace{1cm} \textit{Function returning the number of trial arms slot of an S4 object}

**Description**

Function returning the number of trial arms slot of an S4 object

**Usage**

\texttt{K(obj)}

**Arguments**

\begin{itemize}
  \item \texttt{obj} \hspace{1cm} object of class \texttt{randPar}
\end{itemize}

**Value**

The number of trial arms

---

\textbf{lambda} \hspace{1cm} \textit{Method returning the rate parameter of an expEndp S4 object}

**Description**

Method returning the rate parameter of an expEndp S4 object

**Usage**

\texttt{lambda(obj)}

**Arguments**

\begin{itemize}
  \item \texttt{obj} \hspace{1cm} object of class \texttt{expEndp}
\end{itemize}
**method**

Function returning the method of an S4 object

**Description**

Function returning the method of an S4 object

**Usage**

```r
method(obj)
```

**Arguments**

- `obj` object inheriting from `randPar`

**Value**

The method of an S4 object

---

**mpPar**

*Representing Maximal Procedure*

**Description**

Represents the Maximal Procedure.

**Usage**

```r
mpPar(N, mti, ratio = c(1, 1), groups = LETTERS[1:2])
```

**Arguments**

- `N` integer for the total sample size of the trial.
- `mti` maximum tolerated imbalance in patient numbers during the trial.
- `ratio` vector of length K. The total sample number N and all used block lengths (bc) have to be divisible by `sum(ratio)`.
- `groups` character vector of labels for the different treatments.

**Details**

Fix the total sample size N and the mti. Afterwards, the patients are assigned to each treatment arm according to the ratio. All randomization sequences are equiprobable.

**Value**

S4 object of the class `mpPar`.
References


See Also

Other randomization procedures: `abcdPar`, `bbcdPar`, `bsdPar`, `chenPar`, `crPar`, `createParam()`, `ebcPar`, `gbcdPar`, `hadaPar`, `pbrPar`, `rarPar`, `rpbrPar`, `rtbdPar`, `tbdPar`, `udPar`

---

### `mti`

*Function returning the MTI slot of an S4 object*

#### Description

Function returning the MTI slot of an S4 object

#### Usage

```r
mti(obj)
```

#### Arguments

- `obj` object of class `bsdPar` or `mpPar`

---

### `mu`

*Access the expectation value slot of a normEndp S4 object*

#### Description

Access the expectation value slot of a normEndp S4 object

#### Usage

```r
mu(obj)
```

#### Arguments

- `obj` object of class `normEndp`
Function returning the sample size slot of an S4 object

**Description**
Function returning the sample size slot of an S4 object

**Usage**
\[ N(obj) \]

**Arguments**
- `obj` object inheriting from `randPar`

**Value**
the sample size slot of an S4 object

---

Representation of normally distributed endpoints

**Description**
Represents normally distributed endpoints in clinical trials.

**Usage**
\[ \text{normEndp}(\mu, \sigma) \]

**Arguments**
- `\mu` vector of the expected responses of the treatment groups, should have length K (i.e. one entry for each treatment group).
- `\sigma` vector of the standard deviations in each treatment group, should have length K (i.e. one entry for each treatment group).

**Details**
The `normEndp` function is a constructor function for an S4 object of the class `normEndp` representing a normally distributed endpoint in a clinical trial. In conjunction with the `assess` function, normal endpoints admit the calculation of the exact type-I-error probability and power.

**Value**
A S4 object that represents a normally distributed endpoint in a clinical trial
See Also

Compute exact or simulated type-I-error: `assess`.
Other endpoint types: `expEndp`, `survEndp`

Examples

```r
# set the parameters of two normally distributed endpoints
derp <- normEndp(mu = c(1, 2), sigma = c(1, 1))
```

Description

This list of parameters yields a comprehensive overview of the parameters used in the `randomizeR` package.

Arguments

- `a` nonnegative parameter which controls the degree of randomness: For decreasing `a` the allocations become deterministic, while for increasing `a` the randomization procedure tends to complete randomization.
- `accrualTime` duration of the accrual period in a survival study.
- `add` integer representing the number of balls that are added to the urn in each step.
- `alpha` the significance level of the test in each simulation.
- `bc` vector which contains the lengths `k_1, \ldots, k_l` of each block. This means that the vector `bc` will have one entry for each block.
- `b` numeric vector of length at most 2 specifying the weight(s) for the punishment of deviations from the target value.
- `cenRate` exponential censoring rate in a survival study.
- `cenTime` total duration of a survival study (maximum length of followup).
- `d` effect size.
- `df` degrees of freedom (i.a. `N-2`).
- `eta` numeric specifying the magnitude of selection bias.
- `file` A connection, or a character string naming the file to write to.
- `filledBlock` logical whether the last block should be filled or not.
- `FTI` final tolerated imbalance. This is the difference in number of patients of groups A and B that is permitted at the end of a trial. Usually this is set to zero.
- `groups` character vector of labels for the different treatments.
- `ini` integer representing the initial urn composition.
length of the block to be permuted. \( k \) should be divisible by the number of treatment arms.

\( K \)
number of treatment groups (e.g. \( K=2 \) if we compare one experimental against one control treatment).

\( \lambda_b \)
lower bound for the starting value of the poisson distribution.

\( \lambda \)
vector of the exponential rate parameters in each treatment group.

\( \text{method} \)
method that is used to generate the (random) allocation sequence. It can take values \( \text{PBR} \), \( \text{RAR} \), \( \text{HAD} \), \( \text{PWR} \), \( \text{EBC} \), \( \text{BSD} \), \( \text{CR} \), \( \text{TBD} \), \( \text{UD} \), and \( \text{MP} \).

\( \text{mti} \)
maximum tolerated imbalance in patient numbers during the trial.

\( \mu \)
vector of the expected responses of the treatment groups, should have length \( K \) (i.e. one entry for each treatment group).

\( N \)
integer for the total sample size of the trial.

\( \text{name} \)
name of a variable.

\( \text{obj} \)
object specifying the randomization procedure, see \( \text{randPar} \) or \( \text{createParam} \).

\( \text{object} \)
any R object.

\( p \)
success probability of the biased coin (e.g. in Efron’s Biased Coin Design).

\( \text{pr} \)
vector with patient responses, i.e. each patients resulting value after the treatment.

\( q \)
"cut-off" value in \([0.5,1]\). This is the ratio of patients up from which the experimenter imposes selection bias on the data.

\( r \)
numeric indicating the number of random sequences to be generated at random, or missing.

\( \text{ratio} \)
vector of length \( K \). The total sample number \( N \) and all used block lengths (\( \text{bc} \)) have to be divisible by \( \text{sum(ratio)} \).

\( \text{rb} \)
block lengths of the blocks that can be selected equiprobable at random.

\( \rho \)
nonnegative parameter which my be adjusted according to how strongly it is desired to balance the experiment. If \( \rho = 1 \), we have Wei’s urn design with \( \alpha = 0 \). If \( \rho = 0 \), we have complete randomization.

\( \text{rsob} \)
randomization sequence (of one block).

\( \text{rs} \)
randomization sequence (of all blocks).

\( S \)
matrix for the computation of the probabilities in the maximal procedure.

\( \text{saltus} \)
integer or missing specifying the patient index (i.e. position) of the step in case of step time trend.

\( \text{seed} \)
a single value, interpreted as an integer, that specifies the seed for the random number generation.

\( \sigma \)
vector of the standard deviations in each treatment group, should have length \( K \) (i.e. one entry for each treatment group).

\( \text{SLs} \)
numeric vector of length at most 2 specifying the lower and/or upper specified border.

\( \theta \)
factor of the time trend for further details see \( \text{type} \).
type character vector indicating which biasing strategy the experimenter is using (selection bias) and which other bias is present in the clinical trial (e.g. time trend). All biases included in the vector are combined (i.e. added up) to form the total bias. Possible values are "none" (if no bias occurs), "CS" (resp. "DS") (if the experimenter uses the convergence (resp. divergence) strategy to invoke selection bias), LinT for linear time trend, LogT for log-linear time trend, StepT for step time trend, SigT for sigmoid time trend, PWR for knowledge of all up to the first observation in each block, MTI the next observation after reaching the maximal tolerated imbalance is reached will be known to the physician.

TV numeric specifying the optimal desired value called the target value.

ub upper bound for the last value of the poisson distribution.

varEq logical parameter for the t.test: Shall the variances be treated as equal (TRUE= t.test) or different (FALSE= Welch.test).

x a variable x.

allocRatio numerical vector that represents the allocation ratio for the different strata in a clinical trial

strata numeric specifying the number of strata in a clinical trial

maxcombo logical specifying if the maxcombo test is used

weights numeric specifying the weights used for the test. Unless specified an unweighted test is conducted.

---

pbrPar Representing Permuted Block Randomization

Description

Represents the randomization procedure Permuted Block Randomization.

Usage

pbrPar(bc, K = 2, ratio = rep(1, K), groups = LETTERS[1:K])

Arguments

bc vector which contains the lengths k_1,...,k_l of each block. This means that the vector bc will have one entry for each block.

K number of treatment groups (e.g. K=2 if we compare one experimental against one control treatment).

ratio vector of length K. The total sample number N and all used block lengths (bc) have to be divisible by sum(ratio).

groups character vector of labels for the different treatments.
Details

Fix the block constellation bc, the number of treatment groups K, and the vector of the ratio. Afterwards, in each block the patients are assigned according to the ratio to the corresponding treatment groups. All generated randomization sequences are equiprobable.

Value

S4 object of the class pbrPar.

References


See Also

Other randomization procedures: abcdPar, bbcdPar, bsdPar, chenPar, crPar, createParam(), ebcPar, gbcdPar, hadaPar, mpPar, rarPar, rpbrPar, rtbdPar, tbdPar, udPar

plot

Generic plotting of comparison objects

Description

Generic plotting of comparison objects

Usage

plot(x, y, ...)

## S4 method for signature 'comparison,character'
plot(x, y)

## S4 method for signature 'comparison,missing'
plot(x, y)

Arguments

x  
object of class comparison.

y  
character "boxplot", or "violin", or "missing".

...  
"missing"

Details

Creates a box- or violinplot of an object x of the class comparison.

Value

A plot created with the additional package ggplot2.
Function: `plotDes`

Description:

Plot of a desScore object.

Usage:

```r
plotDes(desScore, labels, colAv = "red", quantiles = FALSE)
```

Arguments:

- `desScore`: object of type `desScore`.
- `labels`: labels used in the plot. Can be `NULL`.
- `colAv`: color of the line representing the average of the desirability scores in the plot.
- `quantiles`: logical whether the quantiles should be depicted in the plot.

Value:

- a plot of an `desScore` object

See Also:

- Other desirability topics: `derFunc`, `evaluate()`, `getDesScores()`, `plotEv()`, `probUnDes()`
Examples

# compute the desirability scores of the full set of PBR(4)
sequences <- getAllSeq(rarPar(4))
issue1 <- corGuess("CS")
issue2 <- chronBias("linT", 1/4, "exact")
endp <- normEndp(mu = c(0,0), sigma = c(1,1))
A <- assess(sequences, issue1, issue2, endp = endp)
d1 <- derFunc(0.5, 0.75, 1)
d2 <- derFunc(0.05, 0.1, 1)

D <- getDesScores(A, d1, d2)
summary(D)
plotDes(D)
plotDes(D, quantiles = TRUE)

plotEv

Evaluation plotting

Description

Plot of an evaluation object.

Usage

plotEv(evaluation, labels, cols)

Arguments

evaluation object of type evaluation.
labels labels used in the plot. Can be NULL.
cols colors of the lines representing the desirability scores in the plot. Can be NULL.

Value

A plot of an evaluation object

See Also

Other desirability topics: derFunc, evaluate, getDesScores, plotDes, probUnDes

Examples

# compare Random Allocation Rule to Big Stick Design with respect to different issues
# and their corresponding desirability functions
issue1 <- corGuess("CS")
issue2 <- chronBias(type = "linT", theta = 1/4, method = "exact")
RAR <- getAllSeq(rarPar(4))
BSD <- getAllSeq(bsdPar(4, mti = 2))
A1 <- assess(RAR, issue1, issue2, endp = normEndp(c(0,0), c(1,1)))
A2 <- assess(BSD, issue1, issue2, endp = normEndp(c(0,0), c(1,1)))

d1 <- derFunc(TV = 0.5, 0.75, 2)
d2 <- derFunc(0.05, c(0, 0.1), c(1, 1))
DesScore <- getDesScores(A1, d1, d2, weights = c(5/6, 1/6))
DesScore2 <- getDesScores(A2, d1, d2, weights = c(5/6, 1/6))

E <- evaluate(DesScore, DesScore2)
plotEv(E)

---

plotSeq

Sequence plotting

Description

Plot all randomization sequences of a randSeq object

Usage

plotSeq(sequences, plotAllSeq = FALSE, emph = NA, rs = NA)

Arguments

- **sequences**: object of type randSeq
- **plotAllSeq**: logical. If plotAllSeq=TRUE, the complete set of randomization sequences will be plotted in light gray.
- **emph**: integer indicating which sequence should be highlighted in blue.
- **rs**: vector of a randomization sequence that should be highlighted.

Value

A plot of all randomization sequences of a randSeq object.

---

probUnDes

Computing the probability of having desirability scores of zero

Description

Computing the probability of having desirability scores of zero for each desirability function applied to an issue.
Usage
probUnDes(desScore)

## S4 method for signature 'desScores'
probUnDes(desScore)

Arguments

- desScore: an object of the class desScores, i.e. an object resulting from applying the function `getDesScores`.

Details

The function `probUnDes` expects an object that results from the `getDesScores` function. For each issue it computes the probability that it achieves an undesirable score, i.e. a desirability score of 0. In doing so, it weights the zero desirability scores with the probability that the sequence occurs.

Value

S4 object of class `probUnDesirable` computing the probability of getting undesirable scores, i.e. desirability scores of 0.

See Also

- Representation of randomization procedures: `randPar`
- Generation of randomization sequences: `genSeq`
- `issues` for the desirability of randomization sequences
- Other desirability topics: `derFunc`, `evaluate()`, `getDesScores()`, `plotDes()`, `plotEv()`

Examples

```r
# compare Random Allocation Rule to Big Stick Design with respect to different issues
# and their corresponding desirability functions
RAR <- getAllSeq(rarPar(4))
issue1 <- corGuess("CS")
issue2 <- corGuess("DS")
A1 <- assess(RAR, issue1, issue2)
d1 <- derFunc(TV = 0.1, 0.7, 2)
d2 <- derFunc(0.5, c(0.3, 0.8), c(1, 1))
DesScore <- getDesScores(A1, d1, d2, weights = c(5/6, 1/6))
probUnDes(DesScore)
```
**randBlocks**

*Function returning the block slot of an S4 object*

**Description**

Function returning the block slot of an S4 object

**Usage**

`randBlocks(obj)`

**Arguments**

- **obj**
  object of class `pbrPar`

**Value**

a vector with the lengths of each random block of a `pbrPar` object

---

**randPar**

*Settings for randomization procedures*

**Description**

Randomization procedures in randomizeR are represented by objects that inherit from `randPar`. The representation can then be used in order to generate randomization sequences. In order generate a representation of a randomization procedure, call `createParam` or one of the following functions.

**Supported randomization procedures**

- Complete Randomization (`crPar`)
- Random Allocation Rule (`rarPar`)
- Permutted Block Randomization (`pbrPar`)
- Permutted Block Randomization with random block length (`rpbrPar`)
- Truncated Binomial Design (`tbdPar`)
- Truncated Binomial Design with random block length (`rtbdPar`)
- Efron's Biased Coin Design (`ebcPar`)
- Big Stick Design (`bsdPar`)
- Maximal Procedure (`mpPar`)
- Wei's Urn Design (`udPar`)
- Chen's Design (`chenPar`)
- Generalized Biased Coin Design (`gbcdPar`)
- Accelerated Biased Coin Design (`abcdPar`)
- Bayesian Biased Coin Design (`bbcdPar`)
- Hadamard Randomization (`hadaPar`)
See Also

Generate randomization sequences \texttt{genSeq}. Calculate the complete set of randomization sequences of a randomization procedure. \texttt{getAllSeq}.

\begin{itemize}
  \item \texttt{randSeq-class}
\end{itemize}

\textit{An S4 Class for the representation of randomization sequences}

\section*{Description}

This set of classes provides functionality of storing randomization sequences of different randomization procedures along with the parameters representing the design.

\section*{Slots}

- \texttt{N} total number of patients included in the trial
- \texttt{M} matrix containing randomization sequences of length \texttt{N} in its rows.
- \texttt{K} number of treatment groups
- \texttt{groups} character string of length \texttt{K} defining the names of the treatment groups
- \texttt{ratio} ratio of patients between the different groups

\begin{itemize}
  \item \texttt{rarPar}
\end{itemize}

\textit{Representing Random Allocation Rule}

\section*{Description}

Represents the randomization procedure Random Allocation Rule.

\section*{Usage}

\begin{verbatim}
rarPar(N, K = 2, ratio = rep(1, K), groups = LETTERS[1:K])
\end{verbatim}

\section*{Arguments}

- \texttt{N} integer for the total sample size of the trial.
- \texttt{K} number of treatment groups (e.g. \texttt{K=2} if we compare one experimental against one control treatment).
- \texttt{ratio} vector of length \texttt{K}. The total sample number \texttt{N} and all used block lengths (bc) have to be divisible by \texttt{sum(ratio)}.
- \texttt{groups} character vector of labels for the different treatments.
Details

Fix a total sample size $N$ the number of treatment groups $K$, and the vector of the ratio. Afterwards, all patients are assigned according to the ratio to the corresponding treatment groups. All randomization sequences are equiprobable.

Value

S4 object of the class `rarPar`.

References


See Also

Other randomization procedures: `abcdPar`, `bbcdPar`, `bsdPar`, `chenPar`, `crPar`, `createParam()`, `ebcPar`, `gbcdPar`, `hadaPar`, `mpPar`, `pbrPar`, `rpbrPar`, `rtbdPar`, `tbdPar`, `udPar`

<table>
<thead>
<tr>
<th>ratio</th>
<th>Function returning the allocation ratio slot of an S4 object</th>
</tr>
</thead>
</table>

Description

Function returning the allocation ratio slot of an S4 object

Usage

```r
ratio(obj)
```

Arguments

- `obj` object of class `randPar`

Value

A vector containing the allocation ratio of an S4 object
rho

Function returning the adjusting parameter rho slot of an S4 object

Description
Function returning the adjusting parameter rho slot of an S4 object

Usage
rho(obj)

Arguments
obj object of class randPar

Value
the value of the rho parameter of an S4 object

rpbrPar
Representing Randomized Permuted Block Randomization

Description
Represents the randomization procedure Randomized Permuted Block Randomization.

Usage
rpbrPar(
  N,
  rb,
  K = 2,
  ratio = rep(1, K),
  groups = LETTERS[1:K],
  filledBlock = FALSE
)

Arguments
N integer for the total sample size of the trial.
rb block lengths of the blocks that can be selected equiprobable at random.
K number of treatment groups (e.g. K=2 if we compare one experimental against one control treatment).
ratio vector of length K. The total sample number N and all used block lengths (bc) have to be divisible by sum(ratio).
groups character vector of labels for the different treatments.
filledBlock logical whether the last block should be filled or not.
Details

Fix the possible random block lengths \( rb \), the number of treatment groups \( K \), the sample size \( N \) and the vector of the ratio. Afterwards, one block length is randomly selected of the random block lengths. The patients are assigned according to the ratio to the corresponding treatment groups. This procedure is repeated until \( N \) patients are assigned. Within each block all possible randomization sequences are equiprobable.

Value

S4 object of the class `rpbrPar`.

References


See Also

Other randomization procedures: `abcdPar`, `bbcdPar`, `bsdPar`, `chenPar`, `crPar`, `createParam()`, `ebcPar`, `gbcdPar`, `hadaPar`, `mpPar`, `pbrPar`, `rarPar`, `rtbdPar`, `tbdPar`, `udPar`
saveAssess

Value

S4 object of the class `rtbdPar`.

References


See Also

Other randomization procedures: `abcdPar`, `bbcdPar`, `bsdPar`, `chenPar`, `crPar`, `createParam()`, `ebcPar`, `gbcdPar`, `hadaPar`, `mpPar`, `pbrPar`, `rarPar`, `rpbrPar`, `tbdPar`, `udPar`

---

saveAssess  Saving an assess object

Description

Saves the full information of an assess object in a .csv data sheet.

Usage

```r
saveAssess(obj, file = "assessObject.csv")
```

Arguments

- `obj` object of class assessment, e.g. the output of the `assess` function.
- `file` A connection, or a character string naming the file to write to.

Value

Creates a .csv data in the home folder.

See Also

Other saving functions: `saveRand()`
saveRand  Saving a randomization lists

Description

Saves the parameters of a randSeq object in a .csv data sheet.

Usage

saveRand(obj, file = "randList.csv")

Arguments

obj  object of class randSeq containing a single randomization sequence.
file  A connection, or a character string naming the file to write to.

Value

Creates a .csv data in the home folder and saves the randomization list as a column vector.

See Also

Other saving functions: saveAssess()

scale  Method returning the scale parameter of an survEndp S4 object

Description

Method returning the scale parameter of an survEndp S4 object

Usage

scale(obj)

Arguments

obj  object of class survEndp
seed

Function returning the allocation seed slot of an object

Description

Returns the seed that was either generated at random or user specified. The seed can be specified for any random operation e.g. genSeq.

Usage

seed(obj)

Arguments

obj object specifying the randomization procedure, see randPar or createParam.

selBias

Representing selection bias

Description

Represents the issue of selection bias in a clinical trial.

Usage

selBias(type, eta, method, alpha = 0.05, delta = 0)

Arguments

type character string, should be one of "CS", "CS2" or "DS", see Details.
etatype numeric specifying the magnitude of selection bias.
method character string, should be one of "sim" or "exact", see Details.
alphasignificance level.
deltaparameter of selection bias used for calculating shape and scale of the Weibull distribution with exponential endpoints

Details

Selection bias can be an issue in the design of a clinical trial. The selBias function is a constructor function for an S4 object of the class selBias representing the issue of third order selection bias in a clinical trial. It supports two possible modes, method="sim" and method="exact". This representation is particularly useful in interaction with the assess function.
method="sim" Represents the simulated type-I-error rate given the level alpha, the selection effect eta and the biasing strategy type. When calling assess for a selBias object with method="sim", one test decision is computed for each sequence of randSeq. The type-I-error rate (power) is the proportion of falsely (correctly) rejected null hypotheses.

method="exact" Represents the exact type-I-error probability given the level alpha, the selection effect eta and the biasing strategy type. When calling assess for a selBias object with method="exact", the p-value of each randomization sequence is computed. For normal endpoints and two treatment groups these p-values are exact values which can be calculated from the sum of the corresponding quantiles of the doubly noncentral t-distribution. For more than two treatment groups, exact p-values are computed using a doubly noncentral F distribution. For exponential endpoints the p-values are obtained using an approximation formula.

It also supports three types of selection bias:

type="DS" Refers to the divergence strategy according to Blackwell and Hodges (1957). Under this guessing strategy, the investigator guesses that the upcoming treatment is the one that has so far been allocated *more* frequently.

type="CS" Refers to the convergence strategy according to Blackwell and Hodges (1957). Under this guessing strategy, the investigator guesses that the upcoming treatment is the one that has so far been allocated *less* frequently. In multi-arm trials, type="CS" refers to the first generalization of the convergence strategy according to Uschner et al (2018). The investigator guesses the treatment that had been allocated less frequently whenever all the treatments of the opposite group are larger than the smallest of the present group.

type="CS2" In trials with two treatment arms, type="CS2" is equivalent to type="CS". In multi-arm trials, type="CS2" refers to the second generalization of convergence strategy according to Uschner et al (2018). The investigator guesses the treatment that had been allocated less frequently whenever all the treatments of the opposite group are larger than the smallest of the present group.

Value

S4 object of class selBias, a formal representation of the issue of selection bias in a clinical trial.

References


See Also

Compute exact or simulated rejection probability: assess.

Other issues: chronBias, combineBias(), corGuess, imbal, issue, setPower()
Examples

# create a selection bias of the convergency strategy type with eta = 0.25 for which
# the exact rejection probabilities are calculated
sbias <- selBias("CS", 0.25, "exact")

setPower

### Representing the power

#### Description

Represents the expected power of the individual randomization sequences.

#### Usage

```
setPower(d, method, alpha = 0.05)
```

#### Arguments

- **d**: effect size.
- **method**: character string, should be one of "sim" or "exact", see Description.
- **alpha**: significance level.

#### Details

The attained power of an individual randomization sequence can be an issue in the design of a clinical trial. The power of a randomization sequence is computed depending on the effect size \( d \) and the difference in group sizes.

- If method="sim", the object represents the simulated power of an individual randomization sequence. When calling assess for a power object with method="sim", one test decision is computed for each randomization sequence of randSeq. The power is the proportion of falsely (correctly) rejected null hypotheses.

- If method="exact", the object represents the exact power of an individual randomization sequence. When calling assess for a power object with method="exact", the exact \( p \)-value of each randomization sequence is computed. So far, this is only supported for normal endpoints. Then the power is the sum of the corresponding quantiles of the noncentral t-distribution.

#### Value

S4 object of class power, a formal representation of the issue of power in a clinical trial.

#### See Also

Other issues: chronBias, combineBias(), corGuess, imbal, issue, selBias
**shape**

*Method returning the shape parameter of an survEndp S4 object*

**Description**

Method returning the shape parameter of an survEndp S4 object

**Usage**

`shape(obj)`

**Arguments**

- `obj` object of class survEndp

---

**sigma**

*Function returning the standard deviation slot of a normEndp S4 object*

**Description**

Function returning the standard deviation slot of a normEndp S4 object

**Usage**

`sigma(obj)`

**Arguments**

- `obj` object of class normEndp

---

**summary**

*Summary of assessments of a randomization procedure*

**Description**

Summary of assessments of a randomization procedure

Summary of desirability scores of a randomization procedure
Usage

summary(object, ...)

## S4 method for signature 'assessment'
summary(object)

summary(object, ...)

## S4 method for signature 'desScores'
summary(object)

Arguments

object assessment object.
... additional arguments affecting the summary that will be produced.

Details

For each issue the assessment of the sequences is summarized to permit a design-based assessment of the randomization procedure. This approach uses the sequence-wise values of the assessment and the probabilities in order to give an overall summary.

For each issue the desirability score of the sequences is summarized to permit a design-based desirability score of the randomization procedure. This approach uses the sequence-wise values of the desirability and the probabilities in order to give an overall summary.

Value

Data frame with a summary of the assessment object.

Data frame with a summary of the desirability scores object.

Examples

# assess the full set of PBR(4)
seq <- getAllSeq(pbrPar(4))
issue <- corGuess("CS")
A <- assess(seq, issue)
summary(A)

# compute the desirability scores of the full set of PBR(4)
seq <- getAllSeq(pbrPar(4))
issue1 <- corGuess("CS")
issue2 <- corGuess("DS")
A <- assess(seq, issue1, issue2)
d1 <- derFunc(0.5, c(0.1, 0.8), c(1, 1))
d2 <- derFunc(0.1, 0.7, 2)
D <- getDesScores(A, d1, d2, weights = c(5/6, 1/6))
summary(D)
survEndp  

**Representation of survival endpoints**

---

**Description**

Represents survival endpoints in clinical trials.

**Usage**

```r
survEndp(
  cenRate,
  accrualTime = 0,
  cenTime,
  shape,
  scale,
  weights = c(0, 0),
  maxcombo = FALSE
)
```

**Arguments**

- `cenRate`: exponential censoring rate in a survival study.
- `accrualTime`: duration of the accrual period in a survival study.
- `cenTime`: total duration of a survival study (maximum length of followup).
- `shape`: parameter of the Weibull distribution (must be positive)
- `scale`: parameter of the Weibull distribution (must be positive)
- `weights`: numeric specifying the weights used for the test. Unless specified an unweighted test is conducted.
- `maxcombo`: logical specifying if the maxcombo test is used

**Details**

The `survEndp` function is a constructor function for an S4 object of the class `survEnd` representing a survival endpoint in a clinical trial.

**Value**

A S4 object representing a survival endpoint in a clinical trial.

**See Also**

- Compute exact or simulated type-I-error: `assess`
- Other endpoint types: `expEndp`, `normEndp`
tbdPar

**Representing Truncated Binomial Design**

### Description

Represents the Truncated Binomial Design.

### Usage

```r
tbdPar(bc = N, groups = LETTERS[1:2])
```

### Arguments

- **bc**: vector which contains the lengths $k_1, \ldots, k_l$ of each block. This means that the vector `bc` will have one entry for each block.
- **groups**: character vector of labels for the different treatments.

### Details

A fair coin is tossed until half of the patients have been assigned to one of the treatment arms. Afterwards, the randomization list is filled with the other treatment.

### Value

S4 object of the class `tbdPar`.

### References


### See Also

Other randomization procedures: `abcdPar`, `bbcdPar`, `bsdPar`, `chenPar`, `crPar`, `createParam()`, `ebcPar`, `gbcdPar`, `hadaPar`, `mpPar`, `pbrPar`, `rarPar`, `rpbrPar`, `rtbdPar`, `udPar`

---

**TV**

*Function returning the target value slot of an S4 object*

### Description

Function returning the target value slot of an S4 object

### Usage

```r
TV(obj)
```
Arguments

\textbf{obj} \hspace{1cm} \text{object inheriting from \texttt{derFunc}}

\underline{type} \hspace{1cm} \emph{Get type of an object}

\textbf{Description}

Accesses the type slot of an S4 object

\textbf{Usage}

\texttt{type(obj)}

\textbf{Arguments}

\textbf{obj} \hspace{1cm} \text{a bias object (i.e. S4 object inheriting from \texttt{bias})}

\textbf{Value}

Character string specifying the type of bias \texttt{obj} represents, e.g. "\texttt{linT}" in case of chronological bias.

\underline{udPar} \hspace{1cm} \emph{Representing Wei’s Urn Design}

\textbf{Description}

Represents Wei’s Urn Design.

\textbf{Usage}

\texttt{udPar(N, ini, add, groups = LETTERS[1:2])}

\textbf{Arguments}

\textbf{N} \hspace{1cm} \text{integer for the total sample size of the trial.}

\textbf{ini} \hspace{1cm} \text{integer representing the initial urn composition.}

\textbf{add} \hspace{1cm} \text{integer representing the number of balls that are added to the urn in each step.}

\textbf{groups} \hspace{1cm} \text{character vector of labels for the different treatments.}

\textbf{Details}

An urn is filled with a number of \texttt{ini} balls of both of the treatments. Afterwards, a ball is drawn randomly from the urn. Finally, \texttt{add} balls are added to the urn from the opposite treatment. This procedure is repeated until \texttt{N} patients are assigned.
Value

S4 object of the class udPar.

References


See Also

Other randomization procedures: `abcdPar`, `bbcdPar`, `bsdPar`, `chenPar`, `crPar`, `createParam()`, `ebcPar`, `gbcdPar`, `hadaPar`, `mpPar`, `pbrPar`, `rarPar`, `rpbrPar`, `rtbdPar`, `tbdPar`
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