

How to use R generics with rpact

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```
# Load the package `rpact`  
library(rpact)  
packageVersion("rpact")
```

```
## [1] '2.0.1'
```

Working with objects

Create an example of all available rpact objects

```
design <- getDesignGroupSequential(alpha = 0.05, kMax = 4, sided = 1, typeOfDesign = "WT", deltaWT = 0.1)  
designCharacteristics <- getDesignCharacteristics(design)  
powerAndASN <- getPowerAndAverageSampleNumber(design, theta = 1, nMax = 100)  
designSet <- getDesignSet(design = design, deltaWT = c(0.3, 0.4))  
dataset <- getDataset(  
  n1 = c(22, 11, 22, 11),  
  n2 = c(22, 13, 22, 13),  
  means1 = c(1, 1.1, 1, 1),  
  means2 = c(1.4, 1.5, 3, 2.5),  
  stDevs1 = c(1, 2, 2, 1.3),  
  stDevs2 = c(1, 2, 2, 1.3)  
)  
stageResults <- getStageResults(design, dataset)  
analysisResults <- getAnalysisResults(design, dataset)
```

```
## [PROGRESS] Stage results calculated [0.015 secs]  
## [PROGRESS] Conditional power calculated [0 secs]  
## [PROGRESS] Conditional rejection probabilities (CRP) calculated [0.001 secs]  
## [PROGRESS] Repeated confidence interval of stage 1 calculated [0.2862 secs]  
## [PROGRESS] Repeated confidence interval of stage 2 calculated [0.3271 secs]  
## [PROGRESS] Repeated confidence interval of stage 3 calculated [0.3391 secs]  
## [PROGRESS] Repeated confidence interval of stage 4 calculated [0.375 secs]  
## [PROGRESS] Repeated confidence interval calculated [1.3284 secs]  
## [PROGRESS] Overall repeated p-values of stage 1 calculated [0.4109 secs]  
## [PROGRESS] Overall repeated p-values of stage 2 calculated [0.4079 secs]  
## [PROGRESS] Overall repeated p-values of stage 3 calculated [0.4239 secs]  
## [PROGRESS] Overall repeated p-values of stage 4 calculated [0.4259 secs]  
## [PROGRESS] Repeated p-values calculated [1.6686 secs]  
## [PROGRESS] Final p-value calculated [0.002 secs]  
## [PROGRESS] Final confidence interval calculated [0.0907 secs]
```

```

designPlan <- getSampleSizeMeans(design)

simulationResults <- getSimulationSurvival(design, maxNumberOfSubjects = 100, plannedEvents = c(50, 100)

piecewiseSurvivalTime <- getPiecewiseSurvivalTime(list(
  "0 - <6" = 0.025,
  "6 - <9" = 0.04,
  "9 - <15" = 0.015,
  "15 - <21" = 0.01,
  ">=21" = 0.007), hazardRatio = 0.8)

accrualTime <- getAccrualTime(list(
  "0 - <12" = 15,
  "12 - <13" = 21,
  "13 - <14" = 27,
  "14 - <15" = 33,
  "15 - <16" = 39,
  ">=16" = 45), maxNumberOfSubjects = 1400)

```

How to use R generic functions with rpact objects

Get field names of the object

```
names(design)
```

```

## [1] "kMax"           "alpha"
## [3] "stages"        "informationRates"
## [5] "userAlphaSpending" "criticalValues"
## [7] "stageLevels"   "alphaSpent"
## [9] "bindingFutility" "tolerance"
## [11] "typeOfDesign"  "beta"
## [13] "deltaWT"       "futilityBounds"
## [15] "gammaA"        "gammaB"
## [17] "optimizationCriterion" "sided"
## [19] "betaSpent"     "typeBetaSpending"
## [21] "userBetaSpending" "power"
## [23] "twoSidedPower" "constantBoundsHP"

```

```
names(designCharacteristics)
```

```

## [1] "nFixed"          "shift"
## [3] "inflationFactor" "stages"
## [5] "information"     "power"
## [7] "rejectionProbabilities" "futilityProbabilities"
## [9] "averageSampleNumber1" "averageSampleNumber01"
## [11] "averageSampleNumber0"

```

```
names(powerAndASN)
```

```

## [1] "nMax"           "theta"           "averageSampleNumber"
## [4] "calculatedPower" "overallEarlyStop" "earlyStop"
## [7] "overallReject"  "rejectPerStage"  "overallFutility"
## [10] "futilityPerStage"

```

```
names(designSet)
```

```
## [1] "designs"          "variedParameters"
```

```
names(dataset)
```

```
## [1] "stages"          "groups"          "sampleSizes"  
## [4] "means"           "stDevs"          "overallSampleSizes"  
## [7] "overallMeans"   "overallStDevs"
```

```
names(stageResults)
```

```
## [1] "stages"          "overallTestStatistics"  
## [3] "overallPValues" "overallMeans1"  
## [5] "overallMeans2"  "overallStDevs1"  
## [7] "overallStDevs2" "overallSampleSizes1"  
## [9] "overallSampleSizes2" "testStatistics"  
## [11] "pValues"        "effectSizes"  
## [13] "thetaH0"        "direction"  
## [15] "normalApproximation" "equalVariances"
```

```
names(analysisResults)
```

```
## [1] "stages"  
## [2] "informationRates"  
## [3] "criticalValues"  
## [4] "futilityBounds"  
## [5] "alphaSpent"  
## [6] "stageLevels"  
## [7] "effectSizes"  
## [8] "testStatistics"  
## [9] "pValues"  
## [10] "testActions"  
## [11] "thetaH0"  
## [12] "thetaH1"  
## [13] "assumedStDev"  
## [14] "conditionalRejectionProbabilities"  
## [15] "nPanned"  
## [16] "allocationRatioPlanned"  
## [17] "pi1"  
## [18] "pi2"  
## [19] "conditionalPower"  
## [20] "repeatedConfidenceIntervalLowerBounds"  
## [21] "repeatedConfidenceIntervalUpperBounds"  
## [22] "repeatedPValues"  
## [23] "finalStage"  
## [24] "finalPValues"  
## [25] "finalConfidenceIntervalLowerBounds"  
## [26] "finalConfidenceIntervalUpperBounds"  
## [27] "medianUnbiasedEstimates"  
## [28] "normalApproximation"  
## [29] "equalVariances"  
## [30] "directionUpper"  
## [31] "overallTestStatistics"  
## [32] "overallPValues"
```

```
names(designPlan)
```

```
## [1] "normalApproximation"      "meanRatio"
## [3] "thetaH0"                  "alternative"
## [5] "stDev"                     "groups"
## [7] "allocationRatioPlanned"   "directionUpper"
## [9] "nFixed"                    "nFixed1"
## [11] "nFixed2"                   "informationRates"
## [13] "maxNumberOfSubjects"      "maxNumberOfSubjects1"
## [15] "maxNumberOfSubjects2"     "numberOfSubjects"
## [17] "numberOfSubjects1"        "numberOfSubjects2"
## [19] "expectedNumberOfSubjectsH0" "expectedNumberOfSubjectsH01"
## [21] "expectedNumberOfSubjectsH1" "effect"
## [23] "expectedNumberOfSubjects" "rejectPerStage"
## [25] "overallReject"            "futilityPerStage"
## [27] "futilityStop"             "earlyStop"
## [29] "criticalValuesEffectScale" "criticalValuesEffectScaleLower"
## [31] "criticalValuesEffectScaleUpper" "criticalValuesPValueScale"
## [33] "futilityBoundsEffectScale" "futilityBoundsPValueScale"
```

```
names(simulationResults)
```

```
## [1] "maxNumberOfSubjects"
## [2] "accrualTime"
## [3] "accrualIntensity"
## [4] "plannedEvents"
## [5] "pi1"
## [6] "pi2"
## [7] "median1"
## [8] "median2"
## [9] "directionUpper"
## [10] "dropoutRate1"
## [11] "dropoutRate2"
## [12] "dropoutTime"
## [13] "eventTime"
## [14] "thetaH0"
## [15] "allocation1"
## [16] "allocation2"
## [17] "minNumberOfAdditionalEventsPerStage"
## [18] "maxNumberOfAdditionalEventsPerStage"
## [19] "conditionalPower"
## [20] "thetaH1"
## [21] "maxNumberOfIterations"
## [22] "kappa"
## [23] "piecewiseSurvivalTime"
## [24] "lambda1"
## [25] "lambda2"
## [26] "hazardRatio"
## [27] "iterations"
## [28] "analysisTime"
## [29] "studyDuration"
## [30] "eventsPerStage"
## [31] "expectedNumberOfEvents"
## [32] "eventsNotAchieved"
```

```
## [33] "numberOfSubjects"
## [34] "expectedNumberOfSubjects"
## [35] "rejectPerStage"
## [36] "overallReject"
## [37] "futilityPerStage"
## [38] "futilityStop"
## [39] "earlyStop"
## [40] "conditionalPowerAchieved"
## [41] "seed"
```

```
names(piecewiseSurvivalTime)
```

```
## [1] "piecewiseSurvivalTime" "lambda1"
## [3] "lambda2"              "hazardRatio"
## [5] "pi1"                  "pi2"
## [7] "median1"              "median2"
## [9] "eventTime"           "kappa"
## [11] "piecewiseSurvivalEnabled" "delayedResponseAllowed"
## [13] "delayedResponseEnabled"
```

```
names(accrualTime)
```

```
## [1] "endOfAccrualIsUserDefined"
## [2] "followUpTimeMustBeUserDefined"
## [3] "maxNumberOfSubjectsIsUserDefined"
## [4] "maxNumberOfSubjectsCanBeCalculatedDirectly"
## [5] "absoluteAccrualIntensityEnabled"
## [6] "accrualTime"
## [7] "accrualIntensity"
## [8] "accrualIntensityRelative"
## [9] "maxNumberOfSubjects"
## [10] "remainingTime"
## [11] "piecewiseAccrualEnabled"
```

Access data of a field

```
design$criticalValues
```

```
## [1] 3.069028 2.325888 1.977663 1.762694
```

```
design[["criticalValues"]]
```

```
## [1] 3.069028 2.325888 1.977663 1.762694
```

Print object

```
print(design)
```

```
## Design parameters and output of group sequential design:
##
## User defined parameters:
##   Type of design                : WT
##   Maximum number of stages      : 4
##   Stages                        : 1, 2, 3, 4
##   Information rates              : 0.250, 0.500, 0.750, 1.000
##   Significance level             : 0.0500
```

```
## Delta for Wang & Tsiatis Delta class      : 0.1
##
## Derived from user defined parameters: not available
##
## Default parameters:
## Type II error rate                       : 0.2
## Two-sided power                         : FALSE
## Test                                    : one-sided
## Tolerance                               : 1e-08
##
## Output:
## Cumulative alpha spending                : 0.001074, 0.010527, 0.028206, 0.050000
## Critical values                        : 3.069, 2.326, 1.978, 1.763
## Stage levels                            : 0.001074, 0.010012, 0.023983, 0.038976
```

```
print(designCharacteristics)
```

```
## Group sequential design characteristics:
## Number of subjects fixed                : 6.2
## Shift                                   : 6.4822
## Inflation factor                       : 1.0485
## Informations                            : 1.6205, 3.2411, 4.8616, 6.4822
## Power                                   : 0.03625, 0.30265, 0.60337, 0.80000
## Rejection probabilities                 : 0.03625, 0.26640, 0.30072, 0.19663
## Futility probabilities                  : 0, 0, 0
## Ratio expected vs fixed sample size under H1 : 0.8015
## Ratio expected vs fixed sample size under a value between H0 and H1 : 0.9724
## Ratio expected vs fixed sample size under H0 : 1.0380
```

```
print(powerAndASN)
```

```
## Power and average sample size (ASN):
##
## User defined parameters:
## Effect                                  : 1
##
## Default parameters:
## N_max                                  : 100
##
## Output:
## Average sample sizes (ASN)             : 25.7
## Power                                   : 1.0000
## Overall Early stop                     : 1
## Early stop [1]                         : 9.73e-01
## Early stop [2]                         : 2.67e-02
## Early stop [3]                         : 1.03e-06
## Early stop [4]                         : NA
## Overall reject                          : 1
## Reject per stage [1]                   : 9.73e-01
## Reject per stage [2]                   : 2.67e-02
## Reject per stage [3]                   : 1.02e-06
## Reject per stage [4]                   : 0.00e+00
## Overall futility                       : 0
## Futility stop per stage [1]            : 0
## Futility stop per stage [2]            : 0
```

```
## Futility stop per stage [3] : 0
##
## Legend:
## [k]: values at stage k
print(designSet)

## Trial design set with 3 designs
##
## Design parameters and output of group sequential design:
##
## User defined parameters:
## Type of design : WT
## Maximum number of stages : 4
## Stages : 1, 2, 3, 4
## Information rates : 0.250, 0.500, 0.750, 1.000
## Significance level : 0.0500
## Delta for Wang & Tsiatis Delta class : 0.1
##
## Derived from user defined parameters: not available
##
## Default parameters:
## Type II error rate : 0.2
## Two-sided power : FALSE
## Test : one-sided
## Tolerance : 1e-08
##
## Output:
## Cumulative alpha spending : 0.001074, 0.010527, 0.028206, 0.050000
## Critical values : 3.069, 2.326, 1.978, 1.763
## Stage levels : 0.001074, 0.010012, 0.023983, 0.038976
##
## Design parameters and output of group sequential design:
##
## User defined parameters:
## Type of design : WT
## Stages : 1, 2, 3, 4
## Significance level : 0.0500
## Delta for Wang & Tsiatis Delta class : 0.3
##
## Derived from user defined parameters:
## Maximum number of stages : 4
##
## Default parameters:
## Information rates : 0.250, 0.500, 0.750, 1.000
## Type II error rate : 0.2
## Two-sided power : FALSE
## Test : one-sided
## Tolerance : 1e-08
##
## Output:
## Cumulative alpha spending : 0.006916, 0.020169, 0.035108, 0.050000
## Critical values : 2.462, 2.143, 1.976, 1.866
## Stage levels : 0.006916, 0.016059, 0.024076, 0.031052
##
```

```
## Design parameters and output of group sequential design:
##
## User defined parameters:
##   Type of design           : WT
##   Stages                   : 1, 2, 3, 4
##   Significance level       : 0.0500
##   Delta for Wang & Tsiatis Delta class : 0.4
##
## Derived from user defined parameters:
##   Maximum number of stages : 4
##
## Default parameters:
##   Information rates         : 0.250, 0.500, 0.750, 1.000
##   Type II error rate       : 0.2
##   Two-sided power          : FALSE
##   Test                      : one-sided
##   Tolerance                 : 1e-08
##
## Output:
##   Cumulative alpha spending : 0.01250, 0.02626, 0.03879, 0.05000
##   Critical values           : 2.241, 2.091, 2.008, 1.951
##   Stage levels              : 0.01250, 0.01826, 0.02232, 0.02552
```

```
print(dataset)
```

```
## Dataset of means:
##   Stages                   : 1, 1, 2, 2, 3, 3, 4, 4
##   Treatment groups         : 1, 2, 1, 2, 1, 2, 1, 2
##   Sample sizes             : 22, 22, 11, 13, 22, 22, 11, 13
##   Means                    : 1.0, 1.4, 1.1, 1.5, 1.0, 3.0, 1.0, 2.5
##   Standard deviations      : 1.0, 1.0, 2.0, 2.0, 2.0, 2.0, 1.3, 1.3
##
## Calculated data:
##   Overall sample sizes     : 22, 22, 33, 35, 55, 57, 66, 70
##   Overall means            : 1.000, 1.400, 1.033, 1.437, 1.020, 2.040, 1.017, 2.126
##   Overall standard deviations : 1.00, 1.00, 1.38, 1.43, 1.64, 1.82, 1.58, 1.74
```

```
print(stageResults)
```

```
## Stage results of means:
##   Stages                   : 1, 2, 3, 4
##   Overall test statistics   : -1.327, -1.185, -3.111, -3.887
##   Overall p-values         : 0.9041, 0.8799, 0.9988, 0.9999
##   Overall means (1)        : 1.000, 1.033, 1.020, 1.017
##   Overall means (2)        : 1.400, 1.437, 2.040, 2.126
##   Overall standard deviations (1) : 1.00, 1.38, 1.64, 1.58
##   Overall standard deviations (2) : 1.00, 1.43, 1.82, 1.74
##   Overall sample sizes (1)  : 22, 33, 55, 66
##   Overall sample sizes (2)  : 22, 35, 57, 70
##   Test statistics           : -1.327, -0.488, -3.317, -2.817
##   p-values                  : 0.9041, 0.6849, 0.9991, 0.9950
##   Effect sizes              : -0.4000, -0.4038, -1.0204, -1.1090
##   Theta H0                  : 0
##   Direction                 : upper
##   Normal approximation      : FALSE
```



```

## Equal variances : TRUE
print(analysisResults)

## Analysis results (group sequential design):
## Stages : 1, 2, 3, 4
## Information rates : 0.250, 0.500, 0.750, 1.000
## Critical values : 3.069, 2.326, 1.978, 1.763
## Futility bounds (non-binding) : -Inf, -Inf, -Inf
## Cumulative alpha spending : 0.001074, 0.010527, 0.028206, 0.050000
## Stage levels : 0.001074, 0.010012, 0.023983, 0.038976
## Effect sizes : -0.4000, -0.4038, -1.0204, -1.1090
## Test statistics : -1.327, -0.488, -3.317, -2.817
## p-values : 0.9041, 0.6849, 0.9991, 0.9950
## Overall test statistics : -1.327, -1.185, -3.111, -3.887
## Overall p-values : 0.9041, 0.8799, 0.9988, 0.9999
## Actions : continue, continue, continue, accept
## Theta H0 : 0
## CRP : 2.810e-03, 1.227e-04, 6.661e-16, NA
## Planned sample size : NA, NA, NA, NA
## Planned allocation ratio : 1
## Assumed effect : NA
## Assumed standard deviation : 1.66
## Conditional power : NA, NA, NA, NA
## RCIs (lower) : -1.39, -1.22, -1.68, -1.62
## RCIs (upper) : 0.586, 0.408, -0.364, -0.602
## Repeated p-values : >0.5, >0.5, >0.5, >0.5
## Final stage : 4
## Final p-value : NA, NA, NA, 0.9999
## Final CIs (lower) : NA, NA, NA, -1.55
## Final CIs (upper) : NA, NA, NA, -0.608
## Median unbiased estimate : NA, NA, NA, -1.08
print(designPlan)

## Design plan parameters and output for means:
##
## Design parameters:
## Significance level : 0.0500
## Type II error rate : 0.2
## Test : one-sided
##
## User defined parameters: not available
##
## Default parameters:
## Normal approximation : FALSE
## Mean ratio : FALSE
## Theta H0 : 0
## Alternatives : 0.2, 0.4, 0.6, 0.8, 1
## Standard deviation : 1
## Treatment groups : 2
## Planned allocation ratio : 1
##
## Sample size and output:
## Information rates [1] : 0.250

```

```

## Information rates [2] : 0.500
## Information rates [3] : 0.750
## Information rates [4] : 1.000
## Maximum number of subjects : 649.6, 163.5, 73.5, 42.0, 27.5
## Maximum number of subjects (1) : 324.8, 81.7, 36.7, 21.0, 13.7
## Maximum number of subjects (2) : 324.8, 81.7, 36.7, 21.0, 13.7
## Number of subjects [1] : 162.4, 40.9, 18.4, 10.5, 6.9
## Number of subjects [2] : 324.8, 81.7, 36.7, 21.0, 13.7
## Number of subjects [3] : 487.2, 122.6, 55.1, 31.5, 20.6
## Number of subjects [4] : 649.6, 163.5, 73.5, 42.0, 27.5
## Expected number of subjects under H0 : 643.2, 161.9, 72.8, 41.6, 27.2
## Expected number of subjects under H0/H1 : 602.5, 151.6, 68.2, 39.0, 25.5
## Expected number of subjects under H1 : 496.6, 125.0, 56.2, 32.1, 21.0
## Reject per stage [1] : 0.0362
## Reject per stage [2] : 0.2664
## Reject per stage [3] : 0.3007
## Reject per stage [4] : 0.1966
## Early stop : 0.603
## Critical values (effect scale) [1] : 0.482, 0.960, 1.432, 1.894, 2.342
## Critical values (effect scale) [2] : 0.258, 0.515, 0.767, 1.015, 1.255
## Critical values (effect scale) [3] : 0.179, 0.357, 0.533, 0.705, 0.871
## Critical values (effect scale) [4] : 0.138, 0.276, 0.411, 0.544, 0.673
## Local one-sided significance levels [1] : 0.001074
## Local one-sided significance levels [2] : 0.010012
## Local one-sided significance levels [3] : 0.023983
## Local one-sided significance levels [4] : 0.038976
##
## Legend:
## (i): values of treatment arm i
## [k]: values at stage k

```

```
print(simulationResults)
```

```

## Simulation of survival data (group sequential design):
##
## User defined parameters:
## Maximum number of subjects : 100.0
## Planned events : 50, 100, 150, 200
##
## Default parameters:
## Accrual time : 12
## pi (1) : 0.200, 0.300, 0.400, 0.500
## pi (2) : 0.200
## Direction upper : TRUE
## Drop-out rate (1) : 0.000
## Drop-out rate (2) : 0.000
## Drop-out time : 12
## Event time : 12
## Theta H0 : 1
## Allocation 1 : 1
## Allocation 2 : 1
## Conditional power : NA
## Maximum number of iterations : 1000
## Kappa : 1
## Seed : 458097414

```

```

##
## Results:
##   Accrual intensity           : 8.3
##   Median (1)                 : 37.3, 23.3, 16.3, 12.0
##   Median (2)                 : 37.3
##   Lambda (1)                 : 0.0186, 0.0297, 0.0426, 0.0578
##   Lambda (2)                 : 0.0186
##   Hazard ratio               : 1.000, 1.598, 2.289, 3.106
##   Iterations [1]             : 1000, 1000, 1000, 1000
##   Iterations [2]             : 0, 0, 0, 0
##   Iterations [3]             : 0, 0, 0, 0
##   Iterations [4]             : 0, 0, 0, 0
##   Analysis times [1]         : 43.00, 35.32, 29.97, 26.22
##   Analysis times [2]         : NA, NA, NA, NA
##   Analysis times [3]         : NA, NA, NA, NA
##   Analysis times [4]         : NA, NA, NA, NA
##   Expected study duration    : 0.077, 2.368, 12.238, 21.273
##   Number of events by stage [1] : 50.0, 50.0, 50.0, 50.0
##   Number of events by stage [2] : NA, NA, NA, NA
##   Number of events by stage [3] : NA, NA, NA, NA
##   Number of events by stage [4] : NA, NA, NA, NA
##   Expected number of events  : 0.1, 3.4, 20.1, 40.2
##   Events not achieved [1]     : 0.000, 0.000, 0.000, 0.000
##   Events not achieved [2]     : 0.998, 0.933, 0.599, 0.196
##   Events not achieved [3]     : 0.000, 0.000, 0.000, 0.000
##   Events not achieved [4]     : 0.000, 0.000, 0.000, 0.000
##   Number of subjects [1]     : 100.0, 100.0, 100.0, 100.0
##   Number of subjects [2]     : NA, NA, NA, NA
##   Number of subjects [3]     : NA, NA, NA, NA
##   Number of subjects [4]     : NA, NA, NA, NA
##   Expected number of subjects : 0.2, 6.7, 40.1, 80.4
##   Reject per stage [1]       : 0.002, 0.067, 0.401, 0.804
##   Reject per stage [2]       : 0.000, 0.000, 0.000, 0.000
##   Reject per stage [3]       : 0.000, 0.000, 0.000, 0.000
##   Reject per stage [4]       : 0.000, 0.000, 0.000, 0.000
##   Overall reject             : 0.002, 0.067, 0.401, 0.804
##   Futility stop per stage [1] : 0, 0, 0, 0
##   Futility stop per stage [2] : 0, 0, 0, 0
##   Futility stop per stage [3] : 0, 0, 0, 0
##   Futility stop              : 0, 0, 0, 0
##   Early stop                  : 0.002, 0.067, 0.401, 0.804
##
## Simulated data:
##   Analysis times [1], pi1 = 0.2 : median [range]: 42.69 [28.736 - 66.047]; mean +/-sd
##   Analysis times [1], pi1 = 0.3 : median [range]: 35.167 [25.055 - 49.943]; mean +/-sd
##   Analysis times [1], pi1 = 0.4 : median [range]: 29.719 [20.479 - 44.282]; mean +/-sd
##   Analysis times [1], pi1 = 0.5 : median [range]: 26.042 [18.784 - 35.718]; mean +/-sd
##   Number of subjects [1], pi1 = 0.2 : median [range]: 100 [100 - 100]; mean +/-sd: 100 +/-
##   Number of subjects [1], pi1 = 0.3 : median [range]: 100 [100 - 100]; mean +/-sd: 100 +/-
##   Number of subjects [1], pi1 = 0.4 : median [range]: 100 [100 - 100]; mean +/-sd: 100 +/-
##   Number of subjects [1], pi1 = 0.5 : median [range]: 100 [100 - 100]; mean +/-sd: 100 +/-
##   Observed # events by stage (1) [1], pi1 = 0.2 : median [range]: 25 [19 - 34]; mean +/-sd: 25.13 +/-
##   Observed # events by stage (1) [1], pi1 = 0.3 : median [range]: 29 [22 - 38]; mean +/-sd: 29.001 +/-
##   Observed # events by stage (1) [1], pi1 = 0.4 : median [range]: 32 [26 - 40]; mean +/-sd: 31.972 +/-

```

```
## Observed # events by stage (1) [1], pi1 = 0.5 : median [range]: 34 [27 - 42]; mean +/-sd: 34.459 +
## Observed # events by stage (2) [1], pi1 = 0.2 : median [range]: 25 [16 - 31]; mean +/-sd: 24.87 +/
## Observed # events by stage (2) [1], pi1 = 0.3 : median [range]: 21 [12 - 28]; mean +/-sd: 20.999 +
## Observed # events by stage (2) [1], pi1 = 0.4 : median [range]: 18 [10 - 24]; mean +/-sd: 18.028 +
## Observed # events by stage (2) [1], pi1 = 0.5 : median [range]: 16 [8 - 23]; mean +/-sd: 15.541 +/
## Number of events by stage [1], pi1 = 0.2 : median [range]: 50 [50 - 50]; mean +/-sd: 50 +/-0
## Number of events by stage [1], pi1 = 0.3 : median [range]: 50 [50 - 50]; mean +/-sd: 50 +/-0
## Number of events by stage [1], pi1 = 0.4 : median [range]: 50 [50 - 50]; mean +/-sd: 50 +/-0
## Number of events by stage [1], pi1 = 0.5 : median [range]: 50 [50 - 50]; mean +/-sd: 50 +/-0
## Test statistic [1], pi1 = 0.2 : median [range]: 0.041 [-2.743 - 3.591]; mean +/-sd:
## Test statistic [1], pi1 = 0.3 : median [range]: 1.581 [-1.114 - 5.404]; mean +/-sd:
## Test statistic [1], pi1 = 0.4 : median [range]: 2.843 [-0.217 - 6.08]; mean +/-sd:
## Test statistic [1], pi1 = 0.5 : median [range]: 3.911 [0.455 - 6.962]; mean +/-sd:
## Log-rank statistic [1], pi1 = 0.2 : median [range]: 0.041 [-2.743 - 3.591]; mean +/-sd:
## Log-rank statistic [1], pi1 = 0.3 : median [range]: 1.581 [-1.114 - 5.404]; mean +/-sd:
## Log-rank statistic [1], pi1 = 0.4 : median [range]: 2.843 [-0.217 - 6.08]; mean +/-sd:
## Log-rank statistic [1], pi1 = 0.5 : median [range]: 3.911 [0.455 - 6.962]; mean +/-sd:
## Hazard ratio estimate LR [1], pi1 = 0.2 : median [range]: 1.012 [0.46 - 2.761]; mean +/-sd: 1
## Hazard ratio estimate LR [1], pi1 = 0.3 : median [range]: 1.564 [0.73 - 4.611]; mean +/-sd: 1
## Hazard ratio estimate LR [1], pi1 = 0.4 : median [range]: 2.235 [0.941 - 5.582]; mean +/-sd:
## Hazard ratio estimate LR [1], pi1 = 0.5 : median [range]: 3.023 [1.137 - 7.165]; mean +/-sd:
##
## Legend:
## (i): values of treatment arm i
## [k]: values at stage k
```

```
print(piecewiseSurvivalTime)
```

```
## Piecewise exponential survival times:
## 0 - < 6: 0.025
## 6 - < 9: 0.040
## 9 - <15: 0.015
## 15 - <21: 0.010
## >=21: 0.007
##
## Details:
##
## User defined parameters:
## Piecewise survival times : 0.00, 6.00, 9.00, 15.00, 21.00
## Lambda (2) : 0.025, 0.040, 0.015, 0.010, 0.007
## Hazard ratio : 0.800
##
## Default parameters:
## Event time : 12
## Kappa : 1
## Delayed response allowed : FALSE
##
## Generated parameters:
## Lambda (1) : 0.0200, 0.0320, 0.0120, 0.0080, 0.0056
## Piecewise exponential survival enabled : TRUE
```

```
print(accrualTime)
```

```
## Accrual time and intensity:
## 0.00000 - <12.00000: 15
```

```

## 12.00000 - <13.00000: 21
## 13.00000 - <14.00000: 27
## 14.00000 - <15.00000: 33
## 15.00000 - <16.00000: 39
## 16.00000 - <=40.44444: 45
##
## Formula:
##   maxNumberOfSubjects = 1400 = 12 * 15 + 1 * 21 + 1 * 27 + 1 * 33 + 1 * 39 + 24.4444 * 45
##
## Case (#5):
##   'maxNumberOfSubjects' and absolute accrual intensity are given, end of accrual* and 'followUpTime'.
##   Example: getAccrualTime(accrualTime = c(0, 6), accrualIntensity = c(22, 33), maxNumberOfSubjects =
##
##   (*) Can be calculated directly.
##   (**) Cannot be calculated directly but with 'getSampleSizeSurvival' or 'getPowerSurvival'.
##
## Details:
##
## User defined parameters:
##   Accrual time                : 0.00, 12.00, 13.00, 14.00, 15.00, 16.00, 40.44
##   Accrual intensity           : 15.0, 21.0, 27.0, 33.0, 39.0, 45.0
##   Maximum number of subjects : 1400.0
##
## Default parameters: not available
##
## Generated parameters:
##   End of accrual is user defined      : FALSE
##   Follow-up time must be user defined : FALSE
##   Max number of subjects is user defined : TRUE
##   Max number of subjects can be calculated : TRUE
##   Absolute accrual intensity is enabled : TRUE
##   Remaining time                     : 24.44

```

Show a summary of the object

```
summary(design)
```

```

## This output summarizes the group sequential design specification.
##
## Design parameters and output of group sequential design:
##
## User defined parameters:
##   Type of design                : WT
##   Maximum number of stages      : 4
##   Stages                        : 1, 2, 3, 4
##   Information rates              : 0.250, 0.500, 0.750, 1.000
##   Significance level             : 0.0500
##   Delta for Wang & Tsiatis Delta class : 0.1
##
## Derived from user defined parameters: not available
##
## Default parameters:
##   Type II error rate            : 0.2
##   Two-sided power               : FALSE

```

```

## Test : one-sided
## Tolerance : 1e-08
##
## Output:
## Cumulative alpha spending : 0.001074, 0.010527, 0.028206, 0.050000
## Critical values : 3.069, 2.326, 1.978, 1.763
## Stage levels : 0.001074, 0.010012, 0.023983, 0.038976
##
##
## Technical summary of the trial design object of class "TrialDesignGroupSequential":
##
## [u] Type of design : WT
## [u] Maximum number of stages : 4
## [u] Stages : 1, 2, 3, 4
## [u] Information rates : 0.250, 0.500, 0.750, 1.000
## [u] Significance level : 0.0500
## [d] Type II error rate : 0.2
## [.] Power : NA, NA, NA, NA
## [d] Two-sided power : FALSE
## [u] Delta for Wang & Tsiatis Delta class : 0.1
## [.] Futility bounds (non-binding) : -Inf, -Inf, -Inf
## [.] Binding futility : FALSE
## [.] Haybittle Peto constants : NA
## [.] Parameter for alpha spending function : 1
## [.] Parameter for beta spending function : 1
## [.] Optimization criterion for optimum design within Wang & Tsiatis class : ASNH1
## [d] Test : one-sided
## [d] Tolerance : 1e-08
## [g] Cumulative alpha spending : 0.001074, 0.010527, 0.028206, 0.050000
## [.] User defined alpha spending : NA
## [.] Cumulative beta spending : NA, NA, NA, NA
## [.] Type of beta spending : none
## [.] User defined beta spending : NA
## [g] Critical values : 3.069, 2.326, 1.978, 1.763
## [g] Stage levels : 0.001074, 0.010012, 0.023983, 0.038976
##
## Legend:
## u: user defined
## >: derived value
## d: default value
## g: generated/calculated value
## .: not applicable or hidden
##
## Group sequential design table:
## Information rate Power Futility bound (non-binding)
## Stage 1 0.25 -Inf
## Stage 2 0.50 -Inf
## Stage 3 0.75 -Inf
## Stage 4 1.00
## Cumulative alpha spending Cumulative beta spending
## Stage 1 0.001074
## Stage 2 0.010527
## Stage 3 0.028206
## Stage 4 0.050000

```

```
##           Critical value Stage level
## Stage 1 3.069           0.001074
## Stage 2 2.326           0.010012
## Stage 3 1.978           0.023983
## Stage 4 1.763           0.038976
```

```
summary(designCharacteristics)
```

```
## This output summarizes the group sequential design characteristics specification.
##
```

```
## Group sequential design characteristics:
```

```
## Number of subjects fixed           : 6.2
## Shift                               : 6.4822
## Inflation factor                   : 1.0485
## Informations                        : 1.6205, 3.2411, 4.8616, 6.4822
## Power                               : 0.03625, 0.30265, 0.60337, 0.80000
## Rejection probabilities             : 0.03625, 0.26640, 0.30072, 0.19663
## Futility probabilities              : 0, 0, 0
## Ratio expected vs fixed sample size under H1 : 0.8015
## Ratio expected vs fixed sample size under a value between H0 and H1 : 0.9724
## Ratio expected vs fixed sample size under H0 : 1.0380
```

```
##
```

```
##
```

```
## Technical summary of the design characteristics object of class "TrialDesignCharacteristics":
```

```
## [g] Number of subjects fixed           : 6.2
## [g] Shift                               : 6.4822
## [g] Inflation factor                   : 1.0485
## [u] Stages                             : 1, 2, 3, 4
## [g] Informations                        : 1.6205, 3.2411, 4.8616, 6.4822
## [g] Power                               : 0.03625, 0.30265, 0.60337, 0.80000
## [g] Rejection probabilities             : 0.03625, 0.26640, 0.30072, 0.19663
## [g] Futility probabilities              : 0, 0, 0
## [g] Ratio expected vs fixed sample size under H1 : 0.8015
## [g] Ratio expected vs fixed sample size under a value between H0 and H1 : 0.9724
## [g] Ratio expected vs fixed sample size under H0 : 1.0380
```

```
##
```

```
## Legend:
```

```
## u: user defined
## >: derived value
## d: default value
## g: generated/calculated value
## .: not applicable or hidden
```

```
##
```

```
## Group sequential design characteristics table:
```

	Information	Power	Rejection probability	Futility probability
## Stage 1	1.620541	0.03625	0.03625	0
## Stage 2	3.241081	0.30265	0.26640	0
## Stage 3	4.861622	0.60337	0.30072	0
## Stage 4	6.482163	0.80000	0.19663	

```
summary(powerAndASN)
```

```
## This output summarizes the power and average sample size (ASN) specification.
```

```
##
```

```
## Power and average sample size (ASN):
```

```
##
## User defined parameters:
##   Effect                      : 1
##
## Default parameters:
##   N_max                      : 100
##
## Output:
##   Average sample sizes (ASN)  : 25.7
##   Power                      : 1.0000
##   Overall Early stop          : 1
##   Early stop [1]              : 9.73e-01
##   Early stop [2]              : 2.67e-02
##   Early stop [3]              : 1.03e-06
##   Early stop [4]              : NA
##   Overall reject              : 1
##   Reject per stage [1]        : 9.73e-01
##   Reject per stage [2]        : 2.67e-02
##   Reject per stage [3]        : 1.02e-06
##   Reject per stage [4]        : 0.00e+00
##   Overall futility            : 0
##   Futility stop per stage [1] : 0
##   Futility stop per stage [2] : 0
##   Futility stop per stage [3] : 0
##
## Legend:
##   [k]: values at stage k
##
##
## Technical summary of the power and average sample size (ASN) object:
##   [d] N_max                   : 100
##   [u] Effect                   : 1
##   [g] Average sample sizes (ASN) : 25.7
##   [g] Power                   : 1.0000
##   [g] Overall Early stop       : 1
##   [g] Early stop [1]           : 9.73e-01
##   [g] Early stop [2]           : 2.67e-02
##   [g] Early stop [3]           : 1.03e-06
##   [g] Early stop [4]           : NA
##   [g] Overall reject           : 1
##   [g] Reject per stage [1]     : 9.73e-01
##   [g] Reject per stage [2]     : 2.67e-02
##   [g] Reject per stage [3]     : 1.02e-06
##   [g] Reject per stage [4]     : 0.00e+00
##   [g] Overall futility         : 0
##   [g] Futility stop per stage [1] : 0
##   [g] Futility stop per stage [2] : 0
##   [g] Futility stop per stage [3] : 0
##
## Legend:
##   u: user defined
##   >: derived value
##   d: default value
##   g: generated/calculated value
```



```

##      .: not applicable or hidden
##
## Power and average sample size (ASN) table:
##      Early stop  Reject per stage  Futility stop per stage
## stage = 1 9.732567e-01 9.73e-01      0
## stage = 2 2.674225e-02 2.67e-02      0
## stage = 3 1.025014e-06 1.02e-06      0
## stage = 4 <NA>          0.00e+00
summary(designSet)

##      Length      Class      Mode
##      3 TrialDesignSet      S4
summary(dataset)

## This output summarizes the dataset of means specification.
##
## Dataset of means:
##   Stages           : 1, 1, 2, 2, 3, 3, 4, 4
##   Treatment groups : 1, 2, 1, 2, 1, 2, 1, 2
##   Sample sizes     : 22, 22, 11, 13, 22, 22, 11, 13
##   Means            : 1.0, 1.4, 1.1, 1.5, 1.0, 3.0, 1.0, 2.5
##   Standard deviations : 1.0, 1.0, 2.0, 2.0, 2.0, 2.0, 1.3, 1.3
##
## Calculated data:
##   Overall sample sizes : 22, 22, 33, 35, 55, 57, 66, 70
##   Overall means       : 1.000, 1.400, 1.033, 1.437, 1.020, 2.040, 1.017, 2.040
##   Overall standard deviations : 1.00, 1.00, 1.38, 1.43, 1.64, 1.82, 1.58, 1.74
##
## Technical summary of the dataset object of class"DatasetMeans":
##   [u] Stages           : 1, 1, 2, 2, 3, 3, 4, 4
##   [u] Treatment groups : 1, 2, 1, 2, 1, 2, 1, 2
##   [u] Sample sizes     : 22, 22, 11, 13, 22, 22, 11, 13
##   [u] Means            : 1.0, 1.4, 1.1, 1.5, 1.0, 3.0, 1.0, 2.5
##   [u] Standard deviations : 1.0, 1.0, 2.0, 2.0, 2.0, 2.0, 1.3, 1.3
##   [g] Overall sample sizes : 22, 22, 33, 35, 55, 57, 66, 70
##   [g] Overall means       : 1.000, 1.400, 1.033, 1.437, 1.020, 2.040, 1.017, 2.040
##   [g] Overall standard deviations : 1.00, 1.00, 1.38, 1.43, 1.64, 1.82, 1.58, 1.74
##
## Legend:
##   u: user defined
##   >: derived value
##   d: default value
##   g: generated/calculated value
##   .: not applicable or hidden
##
## Dataset of means table:
##      Treatment group Sample size Mean Standard deviation
## Stage 1 1           22          1.0 1.0
## Stage 2 2           22          1.4 1.0
## Stage 3 1           11          1.1 2.0
## Stage 4 2           13          1.5 2.0
## Stage 5 1           22          1.0 2.0

```

```
## Stage 6 2          22          3.0 2.0
## Stage 7 1          11          1.0 1.3
## Stage 8 2          13          2.5 1.3
## Overall sample size Overall mean Overall standard deviation
## Stage 1 22          1.000          1.00
## Stage 2 22          1.400          1.00
## Stage 3 33          1.033          1.38
## Stage 4 35          1.437          1.43
## Stage 5 55          1.020          1.64
## Stage 6 57          2.040          1.82
## Stage 7 66          1.017          1.58
## Stage 8 70          2.126          1.74
```

```
summary(stageResults)
```

```
## This output summarizes the stage results of means specification.
##
## Stage results of means:
## Stages : 1, 2, 3, 4
## Overall test statistics : -1.327, -1.185, -3.111, -3.887
## Overall p-values : 0.9041, 0.8799, 0.9988, 0.9999
## Overall means (1) : 1.000, 1.033, 1.020, 1.017
## Overall means (2) : 1.400, 1.437, 2.040, 2.126
## Overall standard deviations (1) : 1.00, 1.38, 1.64, 1.58
## Overall standard deviations (2) : 1.00, 1.43, 1.82, 1.74
## Overall sample sizes (1) : 22, 33, 55, 66
## Overall sample sizes (2) : 22, 35, 57, 70
## Test statistics : -1.327, -0.488, -3.317, -2.817
## p-values : 0.9041, 0.6849, 0.9991, 0.9950
## Effect sizes : -0.4000, -0.4038, -1.0204, -1.1090
## Theta H0 : 0
## Direction : upper
## Normal approximation : FALSE
## Equal variances : TRUE
##
##
## Technical summary of the stage results object of class "StageResultsMeans":
##
## [u] Stages : 1, 2, 3, 4
## [?] Overall test statistics : -1.327, -1.185, -3.111, -3.887
## [?] Overall p-values : 0.9041, 0.8799, 0.9988, 0.9999
## [?] Overall means (1) : 1.000, 1.033, 1.020, 1.017
## [?] Overall means (2) : 1.400, 1.437, 2.040, 2.126
## [?] Overall standard deviations (1) : 1.00, 1.38, 1.64, 1.58
## [?] Overall standard deviations (2) : 1.00, 1.43, 1.82, 1.74
## [?] Overall sample sizes (1) : 22, 33, 55, 66
## [?] Overall sample sizes (2) : 22, 35, 57, 70
## [?] Test statistics : -1.327, -0.488, -3.317, -2.817
## [?] p-values : 0.9041, 0.6849, 0.9991, 0.9950
## [?] Effect sizes : -0.4000, -0.4038, -1.0204, -1.1090
## [?] Theta H0 : 0
## [?] Direction : upper
## [?] Normal approximation : FALSE
## [?] Equal variances : TRUE
## [?] Inverse normal combination : -1.305, -1.263, -2.826, -3.734
```

```
##      [?] Fisher combination          : 0.9041, 0.6192, 0.6186, 0.6155
##      [?] Weights Fisher              : 1.000, 1.000, 1.000, 1.000
##      [?] Weights inverse normal     : 0.500, 0.500, 0.500, 0.500
##      [?] Overall means              :
##      [?] Overall standard deviations : 1.00, 1.40, 1.74, 1.66
##      [?] Overall sample sizes       :
```

```
## Legend:
```

```
## u: user defined
## >: derived value
## d: default value
## g: generated/calculated value
## .: not applicable or hidden
##
```

```
## Stage results of means table:
```

```
##      Overall test statistic Overall p-value Overall mean (1)
## Stage 1 -1.326650          0.9041          1.000
## Stage 2 -1.185099          0.8799          1.033
## Stage 3 -3.111238          0.9988          1.020
## Stage 4 -3.886959          0.9999          1.017
##      Overall mean (2) Overall standard deviation (1)
## Stage 1 1.400              1.00
## Stage 2 1.437              1.38
## Stage 3 2.040              1.64
## Stage 4 2.126              1.58
##      Overall standard deviation (2) Overall sample size (1)
## Stage 1 1.00              22
## Stage 2 1.43              33
## Stage 3 1.82              55
## Stage 4 1.74              66
##      Overall sample size (2) Test statistic p-value Effect size
## Stage 1 22                -1.327          0.9041 -0.4000
## Stage 2 35                -0.488          0.6849 -0.4038
## Stage 3 57                -3.317          0.9991 -1.0204
## Stage 4 70                -2.817          0.9950 -1.1090
```

```
summary(analysisResults)
```

```
## This output summarizes the analysis results (group sequential design) specification.
```

```
##
```

```
## Analysis results (group sequential design):
```

```
## Stages                : 1, 2, 3, 4
## Information rates     : 0.250, 0.500, 0.750, 1.000
## Critical values       : 3.069, 2.326, 1.978, 1.763
## Futility bounds (non-binding) : -Inf, -Inf, -Inf
## Cumulative alpha spending : 0.001074, 0.010527, 0.028206, 0.050000
## Stage levels          : 0.001074, 0.010012, 0.023983, 0.038976
## Effect sizes          : -0.4000, -0.4038, -1.0204, -1.1090
## Test statistics       : -1.327, -0.488, -3.317, -2.817
## p-values              : 0.9041, 0.6849, 0.9991, 0.9950
## Overall test statistics : -1.327, -1.185, -3.111, -3.887
## Overall p-values     : 0.9041, 0.8799, 0.9988, 0.9999
## Actions               : continue, continue, continue, accept
## Theta H0              : 0
## CRP                   : 2.810e-03, 1.227e-04, 6.661e-16, NA
```

```
## Planned sample size           : NA, NA, NA, NA
## Planned allocation ratio       : 1
## Assumed effect                 : NA
## Assumed standard deviation     : 1.66
## Conditional power             : NA, NA, NA, NA
## RCI (lower)                   : -1.39, -1.22, -1.68, -1.62
## RCI (upper)                   : 0.586, 0.408, -0.364, -0.602
## Repeated p-values            : >0.5, >0.5, >0.5, >0.5
## Final stage                    : 4
## Final p-value                 : NA, NA, NA, 0.9999
## Final CI (lower)              : NA, NA, NA, -1.55
## Final CI (upper)              : NA, NA, NA, -0.608
## Median unbiased estimate      : NA, NA, NA, -1.08
##
##
## Technical summary of the analysis results object of class "AnalysisResultsGroupSequential":
## [u] Stages                    : 1, 2, 3, 4
## [?] Information rates          : 0.250, 0.500, 0.750, 1.000
## [?] Critical values           : 3.069, 2.326, 1.978, 1.763
## [?] Futility bounds (non-binding) : -Inf, -Inf, -Inf
## [?] Cumulative alpha spending  : 0.001074, 0.010527, 0.028206, 0.050000
## [?] Stage levels              : 0.001074, 0.010012, 0.023983, 0.038976
## [?] Effect sizes              : -0.4000, -0.4038, -1.0204, -1.1090
## [?] Test statistics            : -1.327, -0.488, -3.317, -2.817
## [?] p-values                  : 0.9041, 0.6849, 0.9991, 0.9950
## [?] Overall test statistics    : -1.327, -1.185, -3.111, -3.887
## [?] Overall p-values          : 0.9041, 0.8799, 0.9988, 0.9999
## [?] Actions                   : continue, continue, continue, accept
## [?] Theta H0                  : 0
## [?] CRP                       : 2.810e-03, 1.227e-04, 6.661e-16, NA
## [?] Planned sample size       : NA, NA, NA, NA
## [?] Planned allocation ratio   : 1
## [?] Assumed effect            : NA
## [?] Assumed standard deviation : 1.66
## [?] Conditional power         : NA, NA, NA, NA
## [?] RCI (lower)              : -1.39, -1.22, -1.68, -1.62
## [?] RCI (upper)              : 0.586, 0.408, -0.364, -0.602
## [?] Repeated p-values        : >0.5, >0.5, >0.5, >0.5
## [?] Final stage               : 4
## [?] Final p-value            : NA, NA, NA, 0.9999
## [?] Final CI (lower)         : NA, NA, NA, -1.55
## [?] Final CI (upper)         : NA, NA, NA, -0.608
## [?] Median unbiased estimate  : NA, NA, NA, -1.08
## [?] pi (1)                   :
## [?] pi (2)                   :
## [?] Normal approximation      : FALSE
## [?] Equal variances           : TRUE
## [?] Direction upper           : TRUE
##
## Legend:
## u: user defined
## >: derived value
## d: default value
## g: generated/calculated value
```

```

##      .: not applicable or hidden
##
## Analysis results (group sequential design) table:
##      Information rate Critical value Futility bound (binding)
## Stage 1 0.25          3.069          -Inf
## Stage 2 0.50          2.326          -Inf
## Stage 3 0.75          1.978          -Inf
## Stage 4 1.00          1.763
##      Cumulative alpha spending Stage level Effect size Test statistic
## Stage 1 0.001074          0.001074   -0.4000   -1.327
## Stage 2 0.010527          0.010012   -0.4038   -0.488
## Stage 3 0.028206          0.023983   -1.0204   -3.317
## Stage 4 0.050000          0.038976   -1.1090   -2.817
##      p-value Overall test statistic Overall p-value Action
## Stage 1 0.9041   -1.327          0.9041   continue
## Stage 2 0.6849   -1.185          0.8799   continue
## Stage 3 0.9991   -3.111          0.9988   continue
## Stage 4 0.9950   -3.887          0.9999   accept
##      CRP      Planned sample size Conditional power RCI (lower)
## Stage 1 2.810e-03          -1.39
## Stage 2 1.227e-04          -1.22
## Stage 3 6.661e-16          -1.68
## Stage 4          -1.62
##      RCI (upper) Repeated p-value Final p-value Final CI (lower)
## Stage 1 0.586      >0.5
## Stage 2 0.408      >0.5
## Stage 3 -0.364      >0.5
## Stage 4 -0.602      >0.5          0.9999   -1.55
##      Final CI (upper) Median unbiased estimate
## Stage 1
## Stage 2
## Stage 3
## Stage 4 -0.608          -1.08

```

```
summary(designPlan)
```

```

## This output summarizes the means specification.
##
## Design plan parameters and output for means:
##
## Design parameters:
## Significance level          : 0.0500
## Type II error rate         : 0.2
## Test                        : one-sided
##
## User defined parameters: not available
##
## Default parameters:
## Normal approximation       : FALSE
## Mean ratio                  : FALSE
## Theta H0                    : 0
## Alternatives                 : 0.2, 0.4, 0.6, 0.8, 1
## Standard deviation          : 1
## Treatment groups            : 2
## Planned allocation ratio     : 1

```

```
##
## Sample size and output:
## Information rates [1] : 0.250
## Information rates [2] : 0.500
## Information rates [3] : 0.750
## Information rates [4] : 1.000
## Maximum number of subjects : 649.6, 163.5, 73.5, 42.0, 27.5
## Maximum number of subjects (1) : 324.8, 81.7, 36.7, 21.0, 13.7
## Maximum number of subjects (2) : 324.8, 81.7, 36.7, 21.0, 13.7
## Number of subjects [1] : 162.4, 40.9, 18.4, 10.5, 6.9
## Number of subjects [2] : 324.8, 81.7, 36.7, 21.0, 13.7
## Number of subjects [3] : 487.2, 122.6, 55.1, 31.5, 20.6
## Number of subjects [4] : 649.6, 163.5, 73.5, 42.0, 27.5
## Expected number of subjects under H0 : 643.2, 161.9, 72.8, 41.6, 27.2
## Expected number of subjects under H0/H1 : 602.5, 151.6, 68.2, 39.0, 25.5
## Expected number of subjects under H1 : 496.6, 125.0, 56.2, 32.1, 21.0
## Reject per stage [1] : 0.0362
## Reject per stage [2] : 0.2664
## Reject per stage [3] : 0.3007
## Reject per stage [4] : 0.1966
## Early stop : 0.603
## Critical values (effect scale) [1] : 0.482, 0.960, 1.432, 1.894, 2.342
## Critical values (effect scale) [2] : 0.258, 0.515, 0.767, 1.015, 1.255
## Critical values (effect scale) [3] : 0.179, 0.357, 0.533, 0.705, 0.871
## Critical values (effect scale) [4] : 0.138, 0.276, 0.411, 0.544, 0.673
## Local one-sided significance levels [1] : 0.001074
## Local one-sided significance levels [2] : 0.010012
## Local one-sided significance levels [3] : 0.023983
## Local one-sided significance levels [4] : 0.038976
##
## Legend:
## (i): values of treatment arm i
## [k]: values at stage k
##
##
## Technical summary of the design plan object of class "TrialDesignPlanMeans":
##
## [d] Normal approximation : FALSE
## [d] Mean ratio : FALSE
## [d] Theta H0 : 0
## [d] Alternatives : 0.2, 0.4, 0.6, 0.8, 1
## [d] Standard deviation : 1
## [d] Treatment groups : 2
## [d] Planned allocation ratio : 1
## [.] Direction upper :
## [.] Number of subjects fixed : 619.6, 155.9, 70.1, 40.1, 26.2
## [.] Number of subjects fixed (1) : 309.8, 78.0, 35.0, 20.0, 13.1
## [.] Number of subjects fixed (2) : 309.8, 78.0, 35.0, 20.0, 13.1
## [g] Information rates [1] : 0.250
## [g] Information rates [2] : 0.500
## [g] Information rates [3] : 0.750
## [g] Information rates [4] : 1.000
## [g] Maximum number of subjects : 649.6, 163.5, 73.5, 42.0, 27.5
## [g] Maximum number of subjects (1) : 324.8, 81.7, 36.7, 21.0, 13.7
```

```

## [g] Maximum number of subjects (2) : 324.8, 81.7, 36.7, 21.0, 13.7
## [g] Number of subjects [1] : 162.4, 40.9, 18.4, 10.5, 6.9
## [g] Number of subjects [2] : 324.8, 81.7, 36.7, 21.0, 13.7
## [g] Number of subjects [3] : 487.2, 122.6, 55.1, 31.5, 20.6
## [g] Number of subjects [4] : 649.6, 163.5, 73.5, 42.0, 27.5
## [.] Number of subjects (1) [1] : 81.2, 20.4, 9.2, 5.3, 3.4
## [.] Number of subjects (1) [2] : 162.4, 40.9, 18.4, 10.5, 6.9
## [.] Number of subjects (1) [3] : 243.6, 61.3, 27.6, 15.8, 10.3
## [.] Number of subjects (1) [4] : 324.8, 81.7, 36.7, 21.0, 13.7
## [.] Number of subjects (2) [1] : 81.2, 20.4, 9.2, 5.3, 3.4
## [.] Number of subjects (2) [2] : 162.4, 40.9, 18.4, 10.5, 6.9
## [.] Number of subjects (2) [3] : 243.6, 61.3, 27.6, 15.8, 10.3
## [.] Number of subjects (2) [4] : 324.8, 81.7, 36.7, 21.0, 13.7
## [g] Expected number of subjects under H0 : 643.2, 161.9, 72.8, 41.6, 27.2
## [g] Expected number of subjects under H0/H1 : 602.5, 151.6, 68.2, 39.0, 25.5
## [g] Expected number of subjects under H1 : 496.6, 125.0, 56.2, 32.1, 21.0
## [.] Effect :
## [.] Expected number of subjects :
## [g] Reject per stage [1] : 0.0362
## [g] Reject per stage [2] : 0.2664
## [g] Reject per stage [3] : 0.3007
## [g] Reject per stage [4] : 0.1966
## [.] Overall reject :
## [.] Futility stop :
## [g] Early stop : 0.603
## [g] Critical values (effect scale) [1] : 0.482, 0.960, 1.432, 1.894, 2.342
## [g] Critical values (effect scale) [2] : 0.258, 0.515, 0.767, 1.015, 1.255
## [g] Critical values (effect scale) [3] : 0.179, 0.357, 0.533, 0.705, 0.871
## [g] Critical values (effect scale) [4] : 0.138, 0.276, 0.411, 0.544, 0.673
## [g] Local one-sided significance levels [1] : 0.001074
## [g] Local one-sided significance levels [2] : 0.010012
## [g] Local one-sided significance levels [3] : 0.023983
## [g] Local one-sided significance levels [4] : 0.038976
## [.] Futility bounds (effect scale) [1] : NA
## [.] Futility bounds (effect scale) [2] : NA
## [.] Futility bounds (effect scale) [3] : NA
##
## Legend:
## u: user defined
## >: derived value
## d: default value
## g: generated/calculated value
## .: not applicable or hidden
##
## Means table:
## Normal approximation Mean ratio Theta H0 Alternative
## 1 FALSE FALSE 0 0.2
## 2 <NA> 0.4
## 3 <NA> 0.6
## 4 <NA> 0.8
## 5 <NA> 1
## Standard deviation Treatment group Planned allocation ratio
## 1 1 2 1
## 2

```

```

##      3
##      4
##      5
##      Direction upper # subjects fixed # subjects fixed (1)
##      1          619.6          309.8
##      2          155.9           78.0
##      3           70.1           35.0
##      4           40.1           20.0
##      5           26.2           13.1
##      # subjects fixed (2) Information rate Max # subjects
##      1 309.8          0.250          649.6
##      2  78.0          0.500          163.5
##      3  35.0          0.750           73.5
##      4  20.0          1.000           42.0
##      5  13.1          27.5
##      Max # subjects (1) Max # subjects (2) Expected # subjects under H0
##      1 324.8          324.8          643.2
##      2  81.7           81.7          161.9
##      3  36.7           36.7           72.8
##      4  21.0           21.0           41.6
##      5  13.7           13.7           27.2
##      Expected # subjects under H0/H1 Expected # subjects under H1 Effect
##      1 602.5          496.6
##      2 151.6          125.0
##      3  68.2           56.2
##      4  39.0           32.1
##      5  25.5           21.0
##      Expected # subjects Reject per stage Overall reject Futility stop
##      1          0.0362
##      2          0.2664
##      3          0.3007
##      4          0.1966
##      5
##      Early stop Local one-sided significance level
##      1 0.603      0.001074
##      2          0.010012
##      3          0.023983
##      4          0.038976
##      5
##      Futility bound (effect scale)
##      1
##      2
##      3
##      4
##      5

```

```
summary(simulationResults)
```

```

## This output summarizes the simulation of survival data (group sequential design) specification.
##
## Simulation of survival data (group sequential design):
##
## User defined parameters:
##   Maximum number of subjects          : 100.0
##   Planned events                      : 50, 100, 150, 200

```



```
##
## Default parameters:
##   Accrual time                : 12
##   pi (1)                     : 0.200, 0.300, 0.400, 0.500
##   pi (2)                     : 0.200
##   Direction upper             : TRUE
##   Drop-out rate (1)          : 0.000
##   Drop-out rate (2)          : 0.000
##   Drop-out time              : 12
##   Event time                 : 12
##   Theta H0                   : 1
##   Allocation 1               : 1
##   Allocation 2               : 1
##   Conditional power          : NA
##   Maximum number of iterations : 1000
##   Kappa                      : 1
##   Seed                       : 458097414
##
## Results:
##   Accrual intensity          : 8.3
##   Median (1)                 : 37.3, 23.3, 16.3, 12.0
##   Median (2)                 : 37.3
##   Lambda (1)                 : 0.0186, 0.0297, 0.0426, 0.0578
##   Lambda (2)                 : 0.0186
##   Hazard ratio               : 1.000, 1.598, 2.289, 3.106
##   Iterations [1]             : 1000, 1000, 1000, 1000
##   Iterations [2]             : 0, 0, 0, 0
##   Iterations [3]             : 0, 0, 0, 0
##   Iterations [4]             : 0, 0, 0, 0
##   Analysis times [1]         : 43.00, 35.32, 29.97, 26.22
##   Analysis times [2]         : NA, NA, NA, NA
##   Analysis times [3]         : NA, NA, NA, NA
##   Analysis times [4]         : NA, NA, NA, NA
##   Expected study duration    : 0.077, 2.368, 12.238, 21.273
##   Number of events by stage [1] : 50.0, 50.0, 50.0, 50.0
##   Number of events by stage [2] : NA, NA, NA, NA
##   Number of events by stage [3] : NA, NA, NA, NA
##   Number of events by stage [4] : NA, NA, NA, NA
##   Expected number of events   : 0.1, 3.4, 20.1, 40.2
##   Events not achieved [1]     : 0.000, 0.000, 0.000, 0.000
##   Events not achieved [2]     : 0.998, 0.933, 0.599, 0.196
##   Events not achieved [3]     : 0.000, 0.000, 0.000, 0.000
##   Events not achieved [4]     : 0.000, 0.000, 0.000, 0.000
##   Number of subjects [1]     : 100.0, 100.0, 100.0, 100.0
##   Number of subjects [2]     : NA, NA, NA, NA
##   Number of subjects [3]     : NA, NA, NA, NA
##   Number of subjects [4]     : NA, NA, NA, NA
##   Expected number of subjects : 0.2, 6.7, 40.1, 80.4
##   Reject per stage [1]       : 0.002, 0.067, 0.401, 0.804
##   Reject per stage [2]       : 0.000, 0.000, 0.000, 0.000
##   Reject per stage [3]       : 0.000, 0.000, 0.000, 0.000
##   Reject per stage [4]       : 0.000, 0.000, 0.000, 0.000
##   Overall reject             : 0.002, 0.067, 0.401, 0.804
##   Futility stop per stage [1] : 0, 0, 0, 0
```

```

## Futility stop per stage [2] : 0, 0, 0, 0
## Futility stop per stage [3] : 0, 0, 0, 0
## Futility stop : 0, 0, 0, 0
## Early stop : 0.002, 0.067, 0.401, 0.804
##
## Simulated data:
## Analysis times [1], pi1 = 0.2 : median [range]: 42.69 [28.736 - 66.047]; mean +/-sd
## Analysis times [1], pi1 = 0.3 : median [range]: 35.167 [25.055 - 49.943]; mean +/-sd
## Analysis times [1], pi1 = 0.4 : median [range]: 29.719 [20.479 - 44.282]; mean +/-sd
## Analysis times [1], pi1 = 0.5 : median [range]: 26.042 [18.784 - 35.718]; mean +/-sd
## Number of subjects [1], pi1 = 0.2 : median [range]: 100 [100 - 100]; mean +/-sd: 100 +/-0
## Number of subjects [1], pi1 = 0.3 : median [range]: 100 [100 - 100]; mean +/-sd: 100 +/-0
## Number of subjects [1], pi1 = 0.4 : median [range]: 100 [100 - 100]; mean +/-sd: 100 +/-0
## Number of subjects [1], pi1 = 0.5 : median [range]: 100 [100 - 100]; mean +/-sd: 100 +/-0
## Observed # events by stage (1) [1], pi1 = 0.2 : median [range]: 25 [19 - 34]; mean +/-sd: 25.13 +/-0
## Observed # events by stage (1) [1], pi1 = 0.3 : median [range]: 29 [22 - 38]; mean +/-sd: 29.001 +/-0
## Observed # events by stage (1) [1], pi1 = 0.4 : median [range]: 32 [26 - 40]; mean +/-sd: 31.972 +/-0
## Observed # events by stage (1) [1], pi1 = 0.5 : median [range]: 34 [27 - 42]; mean +/-sd: 34.459 +/-0
## Observed # events by stage (2) [1], pi1 = 0.2 : median [range]: 25 [16 - 31]; mean +/-sd: 24.87 +/-0
## Observed # events by stage (2) [1], pi1 = 0.3 : median [range]: 21 [12 - 28]; mean +/-sd: 20.999 +/-0
## Observed # events by stage (2) [1], pi1 = 0.4 : median [range]: 18 [10 - 24]; mean +/-sd: 18.028 +/-0
## Observed # events by stage (2) [1], pi1 = 0.5 : median [range]: 16 [8 - 23]; mean +/-sd: 15.541 +/-0
## Number of events by stage [1], pi1 = 0.2 : median [range]: 50 [50 - 50]; mean +/-sd: 50 +/-0
## Number of events by stage [1], pi1 = 0.3 : median [range]: 50 [50 - 50]; mean +/-sd: 50 +/-0
## Number of events by stage [1], pi1 = 0.4 : median [range]: 50 [50 - 50]; mean +/-sd: 50 +/-0
## Number of events by stage [1], pi1 = 0.5 : median [range]: 50 [50 - 50]; mean +/-sd: 50 +/-0
## Test statistic [1], pi1 = 0.2 : median [range]: 0.041 [-2.743 - 3.591]; mean +/-sd: 0.041 +/-0
## Test statistic [1], pi1 = 0.3 : median [range]: 1.581 [-1.114 - 5.404]; mean +/-sd: 1.581 +/-0
## Test statistic [1], pi1 = 0.4 : median [range]: 2.843 [-0.217 - 6.08]; mean +/-sd: 2.843 +/-0
## Test statistic [1], pi1 = 0.5 : median [range]: 3.911 [0.455 - 6.962]; mean +/-sd: 3.911 +/-0
## Log-rank statistic [1], pi1 = 0.2 : median [range]: 0.041 [-2.743 - 3.591]; mean +/-sd: 0.041 +/-0
## Log-rank statistic [1], pi1 = 0.3 : median [range]: 1.581 [-1.114 - 5.404]; mean +/-sd: 1.581 +/-0
## Log-rank statistic [1], pi1 = 0.4 : median [range]: 2.843 [-0.217 - 6.08]; mean +/-sd: 2.843 +/-0
## Log-rank statistic [1], pi1 = 0.5 : median [range]: 3.911 [0.455 - 6.962]; mean +/-sd: 3.911 +/-0
## Hazard ratio estimate LR [1], pi1 = 0.2 : median [range]: 1.012 [0.46 - 2.761]; mean +/-sd: 1.012 +/-0
## Hazard ratio estimate LR [1], pi1 = 0.3 : median [range]: 1.564 [0.73 - 4.611]; mean +/-sd: 1.564 +/-0
## Hazard ratio estimate LR [1], pi1 = 0.4 : median [range]: 2.235 [0.941 - 5.582]; mean +/-sd: 2.235 +/-0
## Hazard ratio estimate LR [1], pi1 = 0.5 : median [range]: 3.023 [1.137 - 7.165]; mean +/-sd: 3.023 +/-0
##
## Legend:
## (i): values of treatment arm i
## [k]: values at stage k
##
## Technical summary of the simulation results object of class "SimulationResultsSurvival":
## [u] Maximum number of subjects : 100.0
## [d] Accrual time : 12
## [g] Accrual intensity : 8.3
## [u] Planned events : 50, 100, 150, 200
## [d] pi (1) : 0.200, 0.300, 0.400, 0.500
## [d] pi (2) : 0.200
## [g] Median (1) : 37.3, 23.3, 16.3, 12.0
## [g] Median (2) : 37.3
## [d] Direction upper : TRUE

```

```
## [d] Drop-out rate (1) : 0.000
## [d] Drop-out rate (2) : 0.000
## [d] Drop-out time : 12
## [d] Event time : 12
## [d] Theta H0 : 1
## [d] Allocation 1 : 1
## [d] Allocation 2 : 1
## [.] Minimum number of additional events per stage :
## [.] Maximum number of additional events per stage :
## [d] Conditional power : NA
## [.] Assumed effect : NA
## [d] Maximum number of iterations : 1000
## [d] Kappa : 1
## [.] Piecewise survival times : NA
## [g] Lambda (1) : 0.0186, 0.0297, 0.0426, 0.0578
## [g] Lambda (2) : 0.0186
## [g] Hazard ratio : 1.000, 1.598, 2.289, 3.106
## [g] Iterations [1] : 1000, 1000, 1000, 1000
## [g] Iterations [2] : 0, 0, 0, 0
## [g] Iterations [3] : 0, 0, 0, 0
## [g] Iterations [4] : 0, 0, 0, 0
## [g] Analysis times [1] : 43.00, 35.32, 29.97, 26.22
## [g] Analysis times [2] : NA, NA, NA, NA
## [g] Analysis times [3] : NA, NA, NA, NA
## [g] Analysis times [4] : NA, NA, NA, NA
## [g] Expected study duration : 0.077, 2.368, 12.238, 21.273
## [g] Number of events by stage [1] : 50.0, 50.0, 50.0, 50.0
## [g] Number of events by stage [2] : NA, NA, NA, NA
## [g] Number of events by stage [3] : NA, NA, NA, NA
## [g] Number of events by stage [4] : NA, NA, NA, NA
## [g] Expected number of events : 0.1, 3.4, 20.1, 40.2
## [g] Events not achieved [1] : 0.000, 0.000, 0.000, 0.000
## [g] Events not achieved [2] : 0.998, 0.933, 0.599, 0.196
## [g] Events not achieved [3] : 0.000, 0.000, 0.000, 0.000
## [g] Events not achieved [4] : 0.000, 0.000, 0.000, 0.000
## [g] Number of subjects [1] : 100.0, 100.0, 100.0, 100.0
## [g] Number of subjects [2] : NA, NA, NA, NA
## [g] Number of subjects [3] : NA, NA, NA, NA
## [g] Number of subjects [4] : NA, NA, NA, NA
## [g] Expected number of subjects : 0.2, 6.7, 40.1, 80.4
## [g] Reject per stage [1] : 0.002, 0.067, 0.401, 0.804
## [g] Reject per stage [2] : 0.000, 0.000, 0.000, 0.000
## [g] Reject per stage [3] : 0.000, 0.000, 0.000, 0.000
## [g] Reject per stage [4] : 0.000, 0.000, 0.000, 0.000
## [g] Overall reject : 0.002, 0.067, 0.401, 0.804
## [g] Futility stop per stage [1] : 0, 0, 0, 0
## [g] Futility stop per stage [2] : 0, 0, 0, 0
## [g] Futility stop per stage [3] : 0, 0, 0, 0
## [g] Futility stop : 0, 0, 0, 0
## [g] Early stop : 0.002, 0.067, 0.401, 0.804
## [d] Seed : 458097414
##
## Legend:
## u: user defined
```

```

## >: derived value
## d: default value
## g: generated/calculated value
## .: not applicable or hidden
##
## Simulation of survival data (group sequential design) table:
##   Required planned events pi (1) Median (1)
## [1,] 50                0.200 37.3
## [2,] 100               0.300 23.3
## [3,] 150               0.400 16.3
## [4,] 200               0.500 12.0
##   Minimum # additional events per stage
## [1,]
## [2,]
## [3,]
## [4,]
##   Maximum # additional events per stage Lambda (1) Hazard ratio
## [1,]                0.0186    1.000
## [2,]                0.0297    1.598
## [3,]                0.0426    2.289
## [4,]                0.0578    3.106
##   Expected study duration Expected # events Expected # subjects
## [1,] 0.077                0.1          0.2
## [2,] 2.368                3.4          6.7
## [3,] 12.238               20.1         40.1
## [4,] 21.273               40.2         80.4
##   Overall reject Futility stop Early stop
## [1,] 0.002                0          0.002
## [2,] 0.067                0          0.067
## [3,] 0.401                0          0.401
## [4,] 0.804                0          0.804
summary(piecewiseSurvivalTime)

## This output summarizes the piecewise survival time specification.
##
## Piecewise exponential survival times:
## 0 - < 6: 0.025
## 6 - < 9: 0.040
## 9 - <15: 0.015
## 15 - <21: 0.010
## >=21: 0.007
##
## Details:
##
## User defined parameters:
## Piecewise survival times          : 0.00, 6.00, 9.00, 15.00, 21.00
## Lambda (2)                       : 0.025, 0.040, 0.015, 0.010, 0.007
## Hazard ratio                      : 0.800
##
## Default parameters:
## Event time                        : 12
## Kappa                             : 1
## Delayed response allowed          : FALSE
##

```

```

## Generated parameters:
##   Lambda (1)                : 0.0200, 0.0320, 0.0120, 0.0080, 0.0056
##   Piecewise exponential survival enabled : TRUE
##
##
## Technical summary of the piecewise survival time object of class"PiecewiseSurvivalTime":
##
##   [u] Piecewise survival times      : 0.00, 6.00, 9.00, 15.00, 21.00
##   [g] Lambda (1)                    : 0.0200, 0.0320, 0.0120, 0.0080, 0.0056
##   [u] Lambda (2)                    : 0.025, 0.040, 0.015, 0.010, 0.007
##   [u] Hazard ratio                   : 0.800
##   [.] pi (1)                         : NA
##   [.] pi (2)                         : NA
##   [.] Median (1)                     : NA
##   [.] Median (2)                     : NA
##   [d] Event time                     : 12
##   [d] Kappa                           : 1
##   [g] Piecewise exponential survival enabled : TRUE
##   [d] Delayed response allowed        : FALSE
##   [.] Delayed response enabled        : FALSE
##
## Legend:
##   u: user defined
##   >: derived value
##   d: default value
##   g: generated/calculated value
##   .: not applicable or hidden
##
## Piecewise survival time table:
##   Piecewise survival times Lambda (1) Lambda (2)
## [1,] 0                      0.0200  0.025
## [2,] 6                      0.0320  0.040
## [3,] 9                      0.0120  0.015
## [4,] 15                     0.0080  0.010
## [5,] 21                     0.0056  0.007

```

`summary(accrualTime)`

```

## This output summarizes the accrual time specification.
##
## Accrual time and intensity:
##   0.00000 - <12.00000: 15
##   12.00000 - <13.00000: 21
##   13.00000 - <14.00000: 27
##   14.00000 - <15.00000: 33
##   15.00000 - <16.00000: 39
##   16.00000 - <=40.44444: 45
##
## Formula:
##   maxNumberOfSubjects = 1400 = 12 * 15 + 1 * 21 + 1 * 27 + 1 * 33 + 1 * 39 + 24.4444 * 45
##
## Case (#5):
##   'maxNumberOfSubjects' and absolute accrual intensity are given, end of accrual* and 'followUpTime':
##   Example: getAccrualTime(accrualTime = c(0, 6), accrualIntensity = c(22, 33), maxNumberOfSubjects =
##

```

```

## (*) Can be calculated directly.
## (**) Cannot be calculated directly but with 'getSampleSizeSurvival' or 'getPowerSurvival'.
##
## Details:
##
## User defined parameters:
##   Accrual time                : 0.00, 12.00, 13.00, 14.00, 15.00, 16.00, 40.44
##   Accrual intensity           : 15.0, 21.0, 27.0, 33.0, 39.0, 45.0
##   Maximum number of subjects  : 1400.0
##
## Default parameters: not available
##
## Generated parameters:
##   End of accrual is user defined      : FALSE
##   Follow-up time must be user defined : FALSE
##   Max number of subjects is user defined : TRUE
##   Max number of subjects can be calculated : TRUE
##   Absolute accrual intensity is enabled : TRUE
##   Remaining time                     : 24.44
##
##
## Technical summary of the accrual time object of class"AccrualTime":
##
##   [g] End of accrual is user defined      : FALSE
##   [g] Follow-up time must be user defined : FALSE
##   [g] Max number of subjects is user defined : TRUE
##   [g] Max number of subjects can be calculated : TRUE
##   [g] Absolute accrual intensity is enabled : TRUE
##   [u] Accrual time                : 0.00, 12.00, 13.00, 14.00, 15.00, 16.00, 40.44
##   [u] Accrual intensity           : 15.0, 21.0, 27.0, 33.0, 39.0, 45.0
##   [.] Accrual intensity (relative)      : NA
##   [u] Maximum number of subjects      : 1400.0
##   [g] Remaining time                 : 24.44
##   [?] %piecewiseAccrualEnabled%       : TRUE
##
## Legend:
##   u: user defined
##   >: derived value
##   d: default value
##   g: generated/calculated value
##   .: not applicable or hidden
##
## Accrual time table:
##   Accrual time Accrual intensity
## [1,] 0.00000    15.0
## [2,] 12.00000   21.0
## [3,] 13.00000   27.0
## [4,] 14.00000   33.0
## [5,] 15.00000   39.0
## [6,] 16.00000   45.0
## [7,] 40.44444

```

Coerce object to data.frame: as.data.frame

```
as.data.frame(design)
```

```
##   Type of design Maximum # stages Stage Information rate
## 1           WT           4         1           0.25
## 2          <NA>          NA         2           0.50
## 3          <NA>          NA         3           0.75
## 4          <NA>          NA         4           1.00
##   Significance level Type II error rate Two-sided power
## 1           0.05           0.2           FALSE
## 2           NA           NA           NA
## 3           NA           NA           NA
## 4           NA           NA           NA
##   Delta (Wang & Tsiatis) Futility bound (non-binding) Binding futility
## 1           0.1           -Inf           FALSE
## 2           NA           -Inf           NA
## 3           NA           -Inf           NA
## 4           NA           NA           NA
##   Parameter for alpha spending function
## 1           1
## 2           NA
## 3           NA
## 4           NA
##   Parameter for beta spending function
## 1           1
## 2           NA
## 3           NA
## 4           NA
##   Optimization criterion (Wang & Tsiatis) Test Tolerance
## 1           ASNH1         1         1e-08
## 2           <NA>         NA         NA
## 3           <NA>         NA         NA
## 4           <NA>         NA         NA
##   Cumulative alpha spending Type of beta Critical value Stage level
## 1           0.001073781     none         3.069028 0.001073781
## 2           0.010526914     <NA>         2.325888 0.010012250
## 3           0.028205994     <NA>         1.977663 0.023983344
## 4           0.050000000     <NA>         1.762694 0.038976069
```

```
as.data.frame(designCharacteristics)
```

```
##   Inflation factor Stage Information      Power Rejection probability
## 1           1.04846         1         1.620541 0.03624538         0.03624538
## 2           NA           2         3.241081 0.30264612         0.26640074
## 3           NA           3         4.861622 0.60337036         0.30072424
## 4           NA           4         6.482163 0.80000000         0.19662964
##   Futility probability Ratio expected vs fixed sample size under H1
## 1           9.865876e-10         0.8014789
## 2           9.758407e-10         NA
## 3           9.359906e-10         NA
## 4           NA           NA
##   Ratio expected vs fixed sample size under a value between H0 and H1
## 1           0.9724133
## 2           NA
```

```
## 3 NA
## 4 NA
## Ratio expected vs fixed sample size under H0
## 1 1.038026
## 2 NA
## 3 NA
## 4 NA
```

```
as.data.frame(powerAndASN)
```

```
## Stage Effect Average sample size (ASN) Power Overall Early stop
## 1 1 1 25.66861 1 1
## 2 2 NA NA NA NA
## 3 3 NA NA NA NA
## 4 4 NA NA NA NA
## Early stop Overall reject Reject per stage Overall futility
## 1 9.732567e-01 1 9.732567e-01 2.580925e-09
## 2 2.674225e-02 NA 2.674225e-02 NA
## 3 1.025014e-06 NA 1.024395e-06 NA
## 4 NA NA 0.000000e+00 NA
## Futility stop per stage
## 1 9.865876e-10
## 2 9.755040e-10
## 3 6.188329e-10
## 4 NA
```

```
as.data.frame(designSet)
```

```
## Design number Type of design Maximum # stages Stage Information rate
## 1 1 WT 4 1 0.25
## 2 1 <NA> NA 2 0.50
## 3 1 <NA> NA 3 0.75
## 4 1 <NA> NA 4 1.00
## 5 2 WT 4 1 0.25
## 6 2 <NA> NA 2 0.50
## 7 2 <NA> NA 3 0.75
## 8 2 <NA> NA 4 1.00
## 9 3 WT 4 1 0.25
## 10 3 <NA> NA 2 0.50
## 11 3 <NA> NA 3 0.75
## 12 3 <NA> NA 4 1.00
## Significance level Type II error rate Two-sided power
## 1 0.05 0.2 FALSE
## 2 NA NA NA
## 3 NA NA NA
## 4 NA NA NA
## 5 0.05 0.2 FALSE
## 6 NA NA NA
## 7 NA NA NA
## 8 NA NA NA
## 9 0.05 0.2 FALSE
## 10 NA NA NA
## 11 NA NA NA
## 12 NA NA NA
## Delta (Wang & Tsiatis) Futility bound (non-binding) Binding futility
```



```

## 1          0.1          -Inf          FALSE
## 2          NA          -Inf           NA
## 3          NA          -Inf           NA
## 4          NA           NA           NA
## 5          0.3          -Inf          FALSE
## 6          NA          -Inf           NA
## 7          NA          -Inf           NA
## 8          NA           NA           NA
## 9          0.4          -Inf          FALSE
## 10         NA          -Inf           NA
## 11         NA          -Inf           NA
## 12         NA           NA           NA
##   Parameter for alpha spending function
## 1          1
## 2         NA
## 3         NA
## 4         NA
## 5          1
## 6         NA
## 7         NA
## 8         NA
## 9          1
## 10         NA
## 11         NA
## 12         NA
##   Parameter for beta spending function
## 1          1
## 2         NA
## 3         NA
## 4         NA
## 5          1
## 6         NA
## 7         NA
## 8         NA
## 9          1
## 10         NA
## 11         NA
## 12         NA
##   Optimization criterion (Wang & Tsiatis) Test Tolerance
## 1          ASNH1      1      1e-08
## 2          <NA>      NA      NA
## 3          <NA>      NA      NA
## 4          <NA>      NA      NA
## 5          ASNH1      1      1e-08
## 6          <NA>      NA      NA
## 7          <NA>      NA      NA
## 8          <NA>      NA      NA
## 9          ASNH1      1      1e-08
## 10         <NA>      NA      NA
## 11         <NA>      NA      NA
## 12         <NA>      NA      NA
##   Cumulative alpha spending Type of beta Critical value Stage level
## 1          0.001073781      none      3.069028 0.001073781
## 2          0.010526914      <NA>      2.325888 0.010012250

```

```
## 3          0.028205994      <NA>      1.977663 0.023983344
## 4          0.050000000      <NA>      1.762694 0.038976069
## 5          0.006915859      none      2.461604 0.006915859
## 6          0.020169238      <NA>      2.142951 0.016058517
## 7          0.035108439      <NA>      1.976032 0.024075572
## 8          0.050000000      <NA>      1.865547 0.031052371
## 9          0.012504953      none      2.241250 0.012504953
## 10         0.026260600      <NA>      2.091160 0.018256866
## 11         0.038792487      <NA>      2.008067 0.022318106
## 12         0.050000000      <NA>      1.951121 0.025521316
```

```
as.data.frame(dataset)
```

```
## Stage Treatment group Sample size Mean Standard deviation
## 1 1 1 22 1.0 1.0
## 2 1 2 22 1.4 1.0
## 3 2 1 11 1.1 2.0
## 4 2 2 13 1.5 2.0
## 5 3 1 22 1.0 2.0
## 6 3 2 22 3.0 2.0
## 7 4 1 11 1.0 1.3
## 8 4 2 13 2.5 1.3
## Overall sample size Overall mean Overall standard deviation
## 1 22 1.000000 1.000000
## 2 22 1.400000 1.000000
## 3 33 1.033333 1.381500
## 4 35 1.437143 1.425418
## 5 55 1.020000 1.639151
## 6 57 2.040351 1.822857
## 7 66 1.016667 1.578664
## 8 70 2.125714 1.738706
```

```
as.data.frame(stageResults)
```

```
## Stage Overall test statistic Overall p-value Overall mean (1)
## 1 1 -1.326650 0.9041035 1.000000
## 2 2 -1.185099 0.8798860 1.033333
## 3 3 -3.111238 0.9988132 1.020000
## 4 4 -3.886959 0.9999205 1.016667
## Overall mean (2) Overall standard deviation (1)
## 1 1.400000 1.000000
## 2 1.437143 1.381500
## 3 2.040351 1.639151
## 4 2.125714 1.578664
## Overall standard deviation (2) Overall sample size (1)
## 1 1.000000 22
## 2 1.425418 33
## 3 1.822857 55
## 4 1.738706 66
## Overall sample size (2) Test statistic p-value Effect size Theta H0
## 1 22 -1.326650 0.9041035 -0.4000000 0
## 2 35 -0.488194 0.6848785 -0.4038095 NA
## 3 57 -3.316625 0.9990567 -1.0203509 NA
## 4 70 -2.816504 0.9949743 -1.1090476 NA
## Direction Normal approximation Equal variance
```

```
## 1 upper FALSE TRUE
## 2 <NA> NA NA
## 3 <NA> NA NA
## 4 <NA> NA NA
```

```
as.data.frame(analysisResults)
```

```
## Stage Information rate Critical value Futility bound (non-binding)
## 1 1 0.25 3.069028 -Inf
## 2 2 0.50 2.325888 -Inf
## 3 3 0.75 1.977663 -Inf
## 4 4 1.00 1.762694 NA
## Cumulative alpha spending Stage level Effect size Test statistic
## 1 0.001073781 0.001073781 -0.4000000 -1.326650
## 2 0.010526914 0.010012250 -0.4038095 -0.488194
## 3 0.028205994 0.023983344 -1.0203509 -3.316625
## 4 0.050000000 0.038976069 -1.1090476 -2.816504
## p-value Overall test statistic Overall p-value Action CRP
## 1 0.9041035 -1.326650 0.9041035 continue 2.810091e-03
## 2 0.6848785 -1.185099 0.8798860 continue 1.226756e-04
## 3 0.9990567 -3.111238 0.9988132 continue 6.661338e-16
## 4 0.9949743 -3.886959 0.9999205 accept NA
## Assumed standard deviation RCI (lower) RCI (upper) Repeated p-value
## 1 1.662998 -1.386144 0.5861439 0.499999
## 2 NA -1.216028 0.4084087 0.499999
## 3 NA -1.676258 -0.3644440 0.499999
## 4 NA -1.615872 -0.6022231 0.499999
## Final p-value Final CI (lower) Final CI (upper) Median unbiased estimate
## 1 NA NA NA NA
## 2 NA NA NA NA
## 3 NA NA NA NA
## 4 0.9999205 -1.546886 -0.608249 -1.077568
```

```
as.data.frame(designPlan)
```

```
## Normal approximation Mean ratio Theta H0 Alternative Standard deviation
## 1 FALSE FALSE 0 0.2 1
## 2 NA NA NA 0.4 NA
## 3 NA NA NA 0.6 NA
## 4 NA NA NA 0.8 NA
## 5 NA NA NA 1.0 NA
## Treatment group Planned allocation ratio # subjects fixed
## 1 2 1 619.61294
## 2 NA NA 155.93452
## 3 NA NA 70.08807
## 4 NA NA 40.06552
## 5 NA NA 26.19553
## # subjects fixed (1) # subjects fixed (2) Information rate
## 1 309.80647 309.80647 0.25
## 2 77.96726 77.96726 0.50
## 3 35.04403 35.04403 0.75
## 4 20.03276 20.03276 1.00
## 5 13.09776 13.09776 NA
## Max # subjects Max # subjects (1) Max # subjects (2)
## 1 649.63926 324.81963 324.81963
```

```
## 2      163.49107      81.74554      81.74554
## 3      73.48452      36.74226      36.74226
## 4      42.00708      21.00354      21.00354
## 5      27.46496      13.73248      13.73248
## Expected # subjects under H0 Expected # subjects under H0/H1
## 1      643.17426      602.51988
## 2      161.86406      151.63280
## 3      72.75323      68.15457
## 4      41.58904      38.96024
## 5      27.19163      25.47288
## Expected # subjects under H1 Reject per stage Early stop
## 1      496.60668      0.03624538 0.6033704
## 2      124.97822      0.26640074 NA
## 3      56.17411      0.30072424 NA
## 4      32.11166      0.19662964 NA
## 5      20.99516      NA NA
## Local one-sided significance level
## 1      0.001073781
## 2      0.010012250
## 3      0.023983344
## 4      0.038976069
## 5      NA
as.data.frame(simulationResults)
## Max # subjects Accrual time Accrual intensity Required planned events
## 1      100      12      8.333333      50
## 2      NA      NA      NA      100
## 3      NA      NA      NA      150
## 4      NA      NA      NA      200
## pi (1) pi (2) Median (1) Median (2) Direction upper Drop-out rate (1)
## 1      0.2      0.2      37.27540      37.2754      TRUE      0
## 2      0.3      NA      23.32030      NA      NA      NA
## 3      0.4      NA      16.28299      NA      NA      NA
## 4      0.5      NA      12.00000      NA      NA      NA
## Drop-out rate (2) Drop-out time Event time Theta H0 Allocation 1
## 1      0      12      12      1      1
## 2      NA      NA      NA      NA      NA
## 3      NA      NA      NA      NA      NA
## 4      NA      NA      NA      NA      NA
## Allocation 2 Maximum # iterations Kappa Lambda (1) Lambda (2)
## 1      1      1000      1 0.01859530 0.0185953
## 2      NA      NA      NA 0.02972291 NA
## 3      NA      NA      NA 0.04256880 NA
## 4      NA      NA      NA 0.05776227 NA
## Hazard ratio Expected study duration Expected # events
## 1      1.000000      0.07702965      0.10
## 2      1.598410      2.36765326      3.35
## 3      2.289224      12.23836741      20.05
## 4      3.106284      21.27338467      40.20
## Expected # subjects Overall reject Futility stop Early stop Seed
## 1      0.2      0.002      0      0.002 458097414
## 2      6.7      0.067      0      0.067 NA
## 3      40.1      0.401      0      0.401 NA
## 4      80.4      0.804      0      0.804 NA
```

```
as.data.frame(piecewiseSurvivalTime)
```

```
## Piecewise survival times Lambda (1) Lambda (2) Hazard ratio Event time
## 1 0 0.0200 0.025 0.8 12
## 2 6 0.0320 0.040 NA NA
## 3 9 0.0120 0.015 NA NA
## 4 15 0.0080 0.010 NA NA
## 5 21 0.0056 0.007 NA NA
## Kappa Piecewise exponential survival enabled Delayed response allowed
## 1 1 TRUE FALSE
## 2 NA NA NA
## 3 NA NA NA
## 4 NA NA NA
## 5 NA NA NA
## Delayed response enabled
## 1 FALSE
## 2 NA
## 3 NA
## 4 NA
## 5 NA
```

```
as.data.frame(accrualTime)
```

```
## End of accrual is user defined Follow-up time must be user defined
## 1 FALSE FALSE
## 2 NA NA
## 3 NA NA
## 4 NA NA
## 5 NA NA
## 6 NA NA
## 7 NA NA
## Max number of subjects is user defined
## 1 TRUE
## 2 NA
## 3 NA
## 4 NA
## 5 NA
## 6 NA
## 7 NA
## Max number of subjects can be calculated
## 1 TRUE
## 2 NA
## 3 NA
## 4 NA
## 5 NA
## 6 NA
## 7 NA
## Absolute accrual intensity is enabled Accrual time Accrual intensity
## 1 TRUE 0.00000 15
## 2 NA 12.00000 21
## 3 NA 13.00000 27
## 4 NA 14.00000 33
## 5 NA 15.00000 39
## 6 NA 16.00000 45
```

```
## 7          NA      40.44444          NA
## Max # subjects Remaining time piecewiseAccrualEnabled
## 1      1400      24.44444          TRUE
## 2          NA          NA          NA
## 3          NA          NA          NA
## 4          NA          NA          NA
## 5          NA          NA          NA
## 6          NA          NA          NA
## 7          NA          NA          NA
```

Coerce object to matrix: *as.matrix*

```
as.matrix(design)
```

```
##      Type of design Maximum # stages Stage Information rate
## Stage 1 "WT"          " 4"          "1"  "0.25"
## Stage 2 NA           NA           "2"  "0.50"
## Stage 3 NA           NA           "3"  "0.75"
## Stage 4 NA           NA           "4"  "1.00"
##      Significance level Type II error rate Two-sided power
## Stage 1 "0.05"          "0.2"          "FALSE"
## Stage 2 NA              NA              NA
## Stage 3 NA              NA              NA
## Stage 4 NA              NA              NA
##      Delta (Wang & Tsiatis) Futility bound (non-binding)
## Stage 1 "0.1"          "-Inf"
## Stage 2 NA              "-Inf"
## Stage 3 NA              "-Inf"
## Stage 4 NA              NA
##      Binding futility Parameter for alpha spending function
## Stage 1 "FALSE"        " 1"
## Stage 2 NA              NA
## Stage 3 NA              NA
## Stage 4 NA              NA
##      Parameter for beta spending function
## Stage 1 " 1"
## Stage 2 NA
## Stage 3 NA
## Stage 4 NA
##      Optimization criterion (Wang & Tsiatis) Test Tolerance
## Stage 1 "ASNH1"          " 1" "1e-08"
## Stage 2 NA              NA  NA
## Stage 3 NA              NA  NA
## Stage 4 NA              NA  NA
##      Cumulative alpha spending Type of beta Critical value
## Stage 1 "0.001073781"    "none"  "3.069028"
## Stage 2 "0.010526914"    NA      "2.325888"
## Stage 3 "0.028205994"    NA      "1.977663"
## Stage 4 "0.050000000"    NA      "1.762694"
##      Stage level
## Stage 1 "0.001073781"
## Stage 2 "0.010012250"
## Stage 3 "0.023983344"
## Stage 4 "0.038976069"
```

```
as.matrix(designCharacteristics)
```

```
##           Inflation factor Stage Information      Power
## Stage 1      1.04846      1  1.620541 0.03624538
## Stage 2           NA      2  3.241081 0.30264612
## Stage 3           NA      3  4.861622 0.60337036
## Stage 4           NA      4  6.482163 0.80000000
##           Rejection probability Futility probability
## Stage 1      0.03624538      9.865876e-10
## Stage 2      0.26640074      9.758407e-10
## Stage 3      0.30072424      9.359906e-10
## Stage 4      0.19662964      NA
##           Ratio expected vs fixed sample size under H1
## Stage 1           0.8014789
## Stage 2           NA
## Stage 3           NA
## Stage 4           NA
##           Ratio expected vs fixed sample size under a value between H0 and H1
## Stage 1           0.9724133
## Stage 2           NA
## Stage 3           NA
## Stage 4           NA
##           Ratio expected vs fixed sample size under H0
## Stage 1           1.038026
## Stage 2           NA
## Stage 3           NA
## Stage 4           NA
```

```
as.matrix(powerAndASN)
```

```
##           Stage Effect Average sample size (ASN) Power Overall Early stop
## Stage 1      1      1      25.66861      1      NA      1
## Stage 2      2      NA      NA      NA      NA      NA
## Stage 3      3      NA      NA      NA      NA      NA
## Stage 4      4      NA      NA      NA      NA      NA
##           Early stop Overall reject Reject per stage Overall futility
## Stage 1 9.732567e-01      1      9.732567e-01      2.580925e-09
## Stage 2 2.674225e-02      NA      2.674225e-02      NA
## Stage 3 1.025014e-06      NA      1.024395e-06      NA
## Stage 4      NA      NA      0.000000e+00      NA
##           Futility stop per stage
## Stage 1      9.865876e-10
## Stage 2      9.755040e-10
## Stage 3      6.188329e-10
## Stage 4      NA
```

```
as.matrix(designSet)
```

```
##           Design number Type of design Maximum # stages Stage Information rate
## [1,] "1"      "WT"      " 4"      "1"      "0.25"
## [2,] "1"      NA      NA      "2"      "0.50"
## [3,] "1"      NA      NA      "3"      "0.75"
## [4,] "1"      NA      NA      "4"      "1.00"
## [5,] "2"      "WT"      " 4"      "1"      "0.25"
## [6,] "2"      NA      NA      "2"      "0.50"
```

```

## [7,] "2"          NA          NA          "3"  "0.75"
## [8,] "2"          NA          NA          "4"  "1.00"
## [9,] "3"          "WT"         " 4"        "1"  "0.25"
## [10,] "3"         NA          NA          "2"  "0.50"
## [11,] "3"         NA          NA          "3"  "0.75"
## [12,] "3"         NA          NA          "4"  "1.00"
##      Significance level Type II error rate Two-sided power
## [1,] "0.05"         "0.2"         "FALSE"
## [2,] NA             NA             NA
## [3,] NA             NA             NA
## [4,] NA             NA             NA
## [5,] "0.05"         "0.2"         "FALSE"
## [6,] NA             NA             NA
## [7,] NA             NA             NA
## [8,] NA             NA             NA
## [9,] "0.05"         "0.2"         "FALSE"
## [10,] NA            NA             NA
## [11,] NA            NA             NA
## [12,] NA            NA             NA
##      Delta (Wang & Tsiatis) Futility bound (non-binding) Binding futility
## [1,] "0.1"          "-Inf"         "FALSE"
## [2,] NA             "-Inf"         NA
## [3,] NA             "-Inf"         NA
## [4,] NA             NA             NA
## [5,] "0.3"          "-Inf"         "FALSE"
## [6,] NA             "-Inf"         NA
## [7,] NA             "-Inf"         NA
## [8,] NA             NA             NA
## [9,] "0.4"          "-Inf"         "FALSE"
## [10,] NA            "-Inf"         NA
## [11,] NA            "-Inf"         NA
## [12,] NA            NA             NA
##      Parameter for alpha spending function
## [1,] " 1"
## [2,] NA
## [3,] NA
## [4,] NA
## [5,] " 1"
## [6,] NA
## [7,] NA
## [8,] NA
## [9,] " 1"
## [10,] NA
## [11,] NA
## [12,] NA
##      Parameter for beta spending function
## [1,] " 1"
## [2,] NA
## [3,] NA
## [4,] NA
## [5,] " 1"
## [6,] NA
## [7,] NA
## [8,] NA

```



```
## [9,] " 1"
## [10,] NA
## [11,] NA
## [12,] NA
##      Optimization criterion (Wang & Tsiatis) Test Tolerance
## [1,] "ASNH1"           " 1" "1e-08"
## [2,] NA                NA  NA
## [3,] NA                NA  NA
## [4,] NA                NA  NA
## [5,] "ASNH1"           " 1" "1e-08"
## [6,] NA                NA  NA
## [7,] NA                NA  NA
## [8,] NA                NA  NA
## [9,] "ASNH1"           " 1" "1e-08"
## [10,] NA               NA  NA
## [11,] NA               NA  NA
## [12,] NA               NA  NA
##      Cumulative alpha spending Type of beta Critical value Stage level
## [1,] "0.001073781"           "none" "3.069028" "0.001073781"
## [2,] "0.010526914"           NA     "2.325888" "0.010012250"
## [3,] "0.028205994"           NA     "1.977663" "0.023983344"
## [4,] "0.050000000"           NA     "1.762694" "0.038976069"
## [5,] "0.006915859"           "none" "2.461604" "0.006915859"
## [6,] "0.020169238"           NA     "2.142951" "0.016058517"
## [7,] "0.035108439"           NA     "1.976032" "0.024075572"
## [8,] "0.050000000"           NA     "1.865547" "0.031052371"
## [9,] "0.012504953"           "none" "2.241250" "0.012504953"
## [10,] "0.026260600"          NA     "2.091160" "0.018256866"
## [11,] "0.038792487"          NA     "2.008067" "0.022318106"
## [12,] "0.050000000"          NA     "1.951121" "0.025521316"
```

```
as.matrix(dataset)
```

```
##      Stage Treatment group Sample size Mean Standard deviation
## Stage 1      1           1          22  1.0           1.0
## Stage 2      1           2          22  1.4           1.0
## Stage 3      2           1          11  1.1           2.0
## Stage 4      2           2          13  1.5           2.0
## Stage 5      3           1          22  1.0           2.0
## Stage 6      3           2          22  3.0           2.0
## Stage 7      4           1          11  1.0           1.3
## Stage 8      4           2          13  2.5           1.3
##      Overall sample size Overall mean Overall standard deviation
## Stage 1          22      1.000000      1.000000
## Stage 2          22      1.400000      1.000000
## Stage 3          33      1.033333      1.381500
## Stage 4          35      1.437143      1.425418
## Stage 5          55      1.020000      1.639151
## Stage 6          57      2.040351      1.822857
## Stage 7          66      1.016667      1.578664
## Stage 8          70      2.125714      1.738706
```

```
as.matrix(stageResults)
```

```
##      Stage Overall test statistic Overall p-value Overall mean (1)
```

```
## Stage 1 "1" "-1.326650" "0.9041035" "1.000000"
## Stage 2 "2" "-1.185099" "0.8798860" "1.033333"
## Stage 3 "3" "-3.111238" "0.9988132" "1.020000"
## Stage 4 "4" "-3.886959" "0.9999205" "1.016667"
## Overall mean (2) Overall standard deviation (1)
## Stage 1 "1.400000" "1.000000"
## Stage 2 "1.437143" "1.381500"
## Stage 3 "2.040351" "1.639151"
## Stage 4 "2.125714" "1.578664"
## Overall standard deviation (2) Overall sample size (1)
## Stage 1 "1.000000" "22"
## Stage 2 "1.425418" "33"
## Stage 3 "1.822857" "55"
## Stage 4 "1.738706" "66"
## Overall sample size (2) Test statistic p-value Effect size
## Stage 1 "22" "-1.326650" "0.9041035" "-0.4000000"
## Stage 2 "35" "-0.488194" "0.6848785" "-0.4038095"
## Stage 3 "57" "-3.316625" "0.9990567" "-1.0203509"
## Stage 4 "70" "-2.816504" "0.9949743" "-1.1090476"
## Theta HO Direction Normal approximation Equal variance
## Stage 1 " 0" "upper" "FALSE" "TRUE"
## Stage 2 NA NA NA NA
## Stage 3 NA NA NA NA
## Stage 4 NA NA NA NA
```

```
as.matrix(analysisResults)
```

```
## Stage Information rate Critical value
## Stage 1 "1" "0.25" "3.069028"
## Stage 2 "2" "0.50" "2.325888"
## Stage 3 "3" "0.75" "1.977663"
## Stage 4 "4" "1.00" "1.762694"
## Futility bound (non-binding) Cumulative alpha spending
## Stage 1 "-Inf" "0.001073781"
## Stage 2 "-Inf" "0.010526914"
## Stage 3 "-Inf" "0.028205994"
## Stage 4 NA "0.050000000"
## Stage level Effect size Test statistic p-value
## Stage 1 "0.001073781" "-0.4000000" "-1.326650" "0.9041035"
## Stage 2 "0.010012250" "-0.4038095" "-0.488194" "0.6848785"
## Stage 3 "0.023983344" "-1.0203509" "-3.316625" "0.9990567"
## Stage 4 "0.038976069" "-1.1090476" "-2.816504" "0.9949743"
## Overall test statistic Overall p-value Action CRP
## Stage 1 "-1.326650" "0.9041035" "continue" "2.810091e-03"
## Stage 2 "-1.185099" "0.8798860" "continue" "1.226756e-04"
## Stage 3 "-3.111238" "0.9988132" "continue" "6.661338e-16"
## Stage 4 "-3.886959" "0.9999205" "accept" NA
## Assumed standard deviation RCI (lower) RCI (upper)
## Stage 1 "1.662998" "-1.386144" " 0.5861439"
## Stage 2 NA "-1.216028" " 0.4084087"
## Stage 3 NA "-1.676258" "-0.3644440"
## Stage 4 NA "-1.615872" "-0.6022231"
## Repeated p-value Final p-value Final CI (lower) Final CI (upper)
## Stage 1 "0.499999" NA NA NA
## Stage 2 "0.499999" NA NA NA
```

```
## Stage 3 "0.499999"      NA      NA      NA
## Stage 4 "0.499999"      "0.9999205"  "-1.546886"  "-0.608249"
##      Median unbiased estimate
## Stage 1 NA
## Stage 2 NA
## Stage 3 NA
## Stage 4 "-1.077568"
```

```
as.matrix(designPlan)
```

```
##      Normal approximation Mean ratio Theta H0 Alternative
## 1          0          0          0          0.2
## 2          NA          NA          NA          0.4
## 3          NA          NA          NA          0.6
## 4          NA          NA          NA          0.8
## 5          NA          NA          NA          1.0
##      Standard deviation Treatment group Planned allocation ratio
## 1          1          2          1
## 2          NA          NA          NA
## 3          NA          NA          NA
## 4          NA          NA          NA
## 5          NA          NA          NA
##      # subjects fixed # subjects fixed (1) # subjects fixed (2)
## 1      619.61294      309.80647      309.80647
## 2      155.93452      77.96726      77.96726
## 3       70.08807      35.04403      35.04403
## 4       40.06552      20.03276      20.03276
## 5       26.19553      13.09776      13.09776
##      Information rate Max # subjects Max # subjects (1) Max # subjects (2)
## 1          0.25      649.63926      324.81963      324.81963
## 2          0.50      163.49107      81.74554      81.74554
## 3          0.75      73.48452      36.74226      36.74226
## 4          1.00      42.00708      21.00354      21.00354
## 5          NA       27.46496      13.73248      13.73248
##      Expected # subjects under H0 Expected # subjects under H0/H1
## 1      643.17426      602.51988
## 2      161.86406      151.63280
## 3       72.75323      68.15457
## 4       41.58904      38.96024
## 5       27.19163      25.47288
##      Expected # subjects under H1 Reject per stage Early stop
## 1      496.60668      0.03624538  0.6033704
## 2      124.97822      0.26640074      NA
## 3       56.17411      0.30072424      NA
## 4       32.11166      0.19662964      NA
## 5       20.99516          NA      NA
##      Local one-sided significance level
## 1          0.001073781
## 2          0.010012250
## 3          0.023983344
## 4          0.038976069
## 5          NA
```

```
as.matrix(simulationResults)
```

```
##      Max # subjects Accrual time Accrual intensity Required planned events
## [1,]           100           12           8.333333              50
## [2,]            NA           NA              NA              100
## [3,]            NA           NA              NA              150
## [4,]            NA           NA              NA              200
##      pi (1) pi (2) Median (1) Median (2) Direction upper Drop-out rate (1)
## [1,]   0.2   0.2  37.27540   37.2754         1              0
## [2,]   0.3   NA  23.32030         NA         NA              NA
## [3,]   0.4   NA  16.28299         NA         NA              NA
## [4,]   0.5   NA  12.00000         NA         NA              NA
##      Drop-out rate (2) Drop-out time Event time Theta HO Allocation 1
## [1,]                0           12           12         1          1
## [2,]                NA           NA           NA         NA         NA
## [3,]                NA           NA           NA         NA         NA
## [4,]                NA           NA           NA         NA         NA
##      Allocation 2 Maximum # iterations Kappa Lambda (1) Lambda (2)
## [1,]            1           1000         1 0.01859530 0.0185953
## [2,]            NA           NA         NA 0.02972291         NA
## [3,]            NA           NA         NA 0.04256880         NA
## [4,]            NA           NA         NA 0.05776227         NA
##      Hazard ratio Expected study duration Expected # events
## [1,]   1.000000           0.07702965           0.10
## [2,]   1.598410           2.36765326           3.35
## [3,]   2.289224           12.23836741           20.05
## [4,]   3.106284           21.27338467           40.20
##      Expected # subjects Overall reject Futility stop Early stop      Seed
## [1,]           0.2           0.002           0           0.002 458097414
## [2,]           6.7           0.067           0           0.067         NA
## [3,]          40.1           0.401           0           0.401         NA
## [4,]          80.4           0.804           0           0.804         NA
```

```
as.matrix(piecewiseSurvivalTime)
```

```
##      Piecewise survival times Lambda (1) Lambda (2) Hazard ratio
## [1,]                0   0.0200   0.025           0.8
## [2,]                6   0.0320   0.040           NA
## [3,]                9   0.0120   0.015           NA
## [4,]               15   0.0080   0.010           NA
## [5,]               21   0.0056   0.007           NA
##      Event time Kappa Piecewise exponential survival enabled
## [1,]          12     1              1
## [2,]          NA    NA              NA
## [3,]          NA    NA              NA
## [4,]          NA    NA              NA
## [5,]          NA    NA              NA
##      Delayed response allowed Delayed response enabled
## [1,]                0              0
## [2,]                NA             NA
## [3,]                NA             NA
## [4,]                NA             NA
## [5,]                NA             NA
```

```
as.matrix(accrualTime)
```

```
##      End of accrual is user defined Follow-up time must be user defined
## [1,]                0                      0
## [2,]                NA                     NA
## [3,]                NA                     NA
## [4,]                NA                     NA
## [5,]                NA                     NA
## [6,]                NA                     NA
## [7,]                NA                     NA
##      Max number of subjects is user defined
## [1,]                1
## [2,]                NA
## [3,]                NA
## [4,]                NA
## [5,]                NA
## [6,]                NA
## [7,]                NA
##      Max number of subjects can be calculated
## [1,]                1
## [2,]                NA
## [3,]                NA
## [4,]                NA
## [5,]                NA
## [6,]                NA
## [7,]                NA
##      Absolute accrual intensity is enabled Accrual time Accrual intensity
## [1,]                1      0.00000      15
## [2,]                NA     12.00000      21
## [3,]                NA     13.00000      27
## [4,]                NA     14.00000      33
## [5,]                NA     15.00000      39
## [6,]                NA     16.00000      45
## [7,]                NA     40.44444      NA
##      Max # subjects Remaining time piecewiseAccrualEnabled
## [1,]                1400      24.44444      1
## [2,]                NA      NA          NA
## [3,]                NA      NA          NA
## [4,]                NA      NA          NA
## [5,]                NA      NA          NA
## [6,]                NA      NA          NA
## [7,]                NA      NA          NA
```

System: rpact 2.0.1, R version 3.5.2 (2018-12-20), platform: x86_64-w64-mingw32

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