How to create admirable plots with rpact

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Summary

This R Markdown document provides many different examples for creating plots with rpact and ggplot2, e.g. the plot arguments type and showSource will be illustrated.

1 Design plots

First, load the rpact package

```r
library(rpact)
packageVersion("rpact") # version should be version 2.0.5 or later
```

```evaluating
[1] "2.0.6"
```

1.1 One-sided design with futility bounds

```r
design <- getDesignGroupSequential(kMax = 3,
  typeOfWorkDesign = "OF", sided = 1,
  futilityBounds = c(0, 0.1))

plot(design, type = 1, showSource = TRUE)
```

```evaluating
## 
## Source data of the plot:
## x-axis: design$informationRates
## y-axes:
## y1: design$futilityBounds
## y2: design$criticalValues
```
1.1 One-sided design with futility bounds

\[ qnorm(1 - 0.025) = 1.96 \]

---

```
plot(design, type = 3, showSource = TRUE)
```

```
## Source data of the plot:
## x-axis: design$informationRates
## y-axis: design$stageLevels
```
1.1 One-sided design with futility bounds

---

plot(design, type = 4, showSource = TRUE)

## Source data of the plot:
## x-axis: design$informationRates
## y-axis: design$alphaSpent
1.1 One-sided design with futility bounds

Type One Error Spending

plot(design, type = 5, nMax = 10, showSource = TRUE)

## Source data of the plot:
## x-axis: design$theta
## y-axes:
##   y1: design$overallEarlyStop
##   y2: design$calculatedPower
1.1 One-sided design with futility bounds

Power and Early Stopping

\((N_{\text{max}}=10)\)

---

```r
plot(design, type = 6, nMax = 10, showSource = TRUE)
```

---

## Source data of the plot:
## x-axis: design\$theta
## y-axes:
## y1: design\$averageSampleNumber
## y2: design\$overallEarlyStop
## y3: design\$calculatedPower

---
Average Sample Size and Power / Early Stop

(*N_{max}=10*)

plot(design, type = 7, nMax = 10, showSource = TRUE)

## Source data of the plot:

## x-axis: design$theta
## y-axis: design$calculatedPower
1.1 One-sided design with futility bounds

plot(design, type = 8, nMax = 10, showSource = TRUE)

## Source data of the plot:
## x-axis: design$theta
## y-axis: design$overallEarlyStop
1.1 One-sided design with futility bounds

```
plot(design, type = 9, nMax = 10, showSource = TRUE)
```

## Source data of the plot:
```
## x-axis: design$theta
## y-axis: design$averageSampleNumber
```
1.2 Two-sided design

```r
design <- getDesignGroupSequential(
  kMax = 4, typeOfDesign = "OF", sided = 2, twoSidedPower = TRUE)

plot(design, type = 1)
```
1.2 Two-sided design

\[ qnorm(1 - 0.0125) = 2.2414 \]

\begin{verbatim}
plot(design, type = 3)
\end{verbatim}
1.2 Two-sided design

```
plot(design, type = 4)
```
1.2 Two-sided design

```
plot(design, type = 5, nMax = 10)
```
Power and Early Stopping

\( (N_{\text{max}}=10) \)

\begin{verbatim}
plot(design, type = 6, nMax = 10)
\end{verbatim}
Average Sample Size and Power / Early Stop

\((N_{\text{max}}=10)\)

- **Average sample size (ASN)**
- **Overall Early stop**
- **Power**

\[\text{plot}(\text{design, type = 7, nMax = 10})\]
1.2 Two-sided design

Power

\( (N_{\text{max}}=10) \)

\texttt{plot(design, type = 8, nMax = 10)}
Early Stopping

\( (N_{\text{max}}=10) \)

\texttt{plot(design, type = 9, nMax = 10)}
2 Sample size plots

2.1 Sample size means (continuous endpoint)

2.1.1 Sample size means for a one-sided design with futility bounds

```r
sampleSizeMeans1 <- getSampleSizeMeans(
    getDesignGroupSequential(sided = 1,
                            futilityBounds = c(0, 0.2)))
```

## Design plan parameters and output for means:

```
## Design parameters:
## ### Significance level : 0.0250
## ### 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
```
## 2.1 Sample size means (continuous endpoint)

### Treatment groups
- 2

### Planned allocation ratio
- 1

### Sample size and output:

- **Information rates [1]**: 0.333
- **Information rates [2]**: 0.667
- **Information rates [3]**: 1.000

- **Maximum number of subjects**: 836.7, 210.7, 94.8, 54.3, 35.5
- **Maximum number of subjects (1)**: 418.4, 105.4, 47.4, 27.1, 17.8
- **Maximum number of subjects (2)**: 418.4, 105.4, 47.4, 27.1, 17.8
- **Number of subjects [1]**: 278.9, 70.2, 31.6, 18.1, 11.8
- **Number of subjects [2]**: 557.8, 140.5, 63.2, 36.2, 23.7
- **Number of subjects [3]**: 836.7, 210.7, 94.8, 54.3, 35.5
- **Expected number of subjects under H0**: 509.0, 128.2, 57.7, 33.0, 21.6
- **Expected number of subjects under H0/H1**: 676.9, 170.5, 76.7, 43.9, 28.8
- **Expected number of subjects under H1**: 669.4, 168.6, 75.9, 43.4, 28.4

- **Reject per stage [1]**: 0.0357
- **Reject per stage [2]**: 0.4263
- **Reject per stage [3]**: 0.3380

- **Futility stop per stage [1]**: 0.04766
- **Futility stop per stage [2]**: 0.00685
- **Futility stop**: 0.0545

- **Early stop**: 0.516

- **Critical values (effect scale) [1]**: 0.421, 0.870, 1.385, 2.032, 2.938
- **Critical values (effect scale) [2]**: 0.209, 0.419, 0.636, 0.860, 1.097
- **Critical values (effect scale) [3]**: 0.139, 0.278, 0.417, 0.557, 0.698

- **Local one-sided significance levels [1]**: 0.0002592
- **Local one-sided significance levels [2]**: 0.0070554
- **Local one-sided significance levels [3]**: 0.0225331

- **Futility bounds (effect scale) [1]**: 0.0000, 0.0000, 0.0000, 0.0000, 0.0000
- **Futility bounds (effect scale) [2]**: 0.0169, 0.0338, 0.0505, 0.0670, 0.0832

- **Futility bounds (1-sided p-value scale) [1]**: 0.5000
- **Futility bounds (1-sided p-value scale) [2]**: 0.4207

### Legend:

- **(i)**: values of treatment arm i
- **[k]**: values at stage k

```r
plot(sampleSizeMeans1, type = 1, showSource = TRUE)
```
2.1 Sample size means (continuous endpoint)

\[
qnorm(1 - 0.025) = 1.96
\]

```
plot(sampleSizeMeans1, type = 2, showSource = TRUE)
```

## Warning: Only the first 'alternative' (0.2) was used for plotting

## Source data of the plot:
## x-axis: sampleSizeMeans1$informationRates * 836.7166
## y-axes:
## y1: sampleSizeMeans1$criticalValuesEffectScaleUpper[, 1]
## y2: sampleSizeMeans1$futilityBoundsEffectScale[, 1]
Sample size means (continuous endpoint) 2 SAMPLE SIZE PLOTS

\[ N_{\text{max}} = 836.7, \text{ standard deviation } = 1, \, H_0: \text{mean difference } = 0, \, \text{allocation ratio } = 1 \]

- **Sample Size**
- **Mean Difference**
- **Critical value**
- **Futility bound (non-binding)**

```
plot(sampleSizeMeans1, type = 3, showSource = TRUE)
```

## Source data of the plot:
- x-axis: sampleSizeMeans1$.design$informationRates
- y-axis: sampleSizeMeans1$.design$stageLevels
2.1 Sample size means (continuous endpoint) 2 SAMPLE SIZE PLOTS

```
plot(sampleSizeMeans1, type = 4, showSource = TRUE)

## Source data of the plot:
## x-axis: sampleSizeMeans1$.design$informationRates
## y-axis: sampleSizeMeans1$.design$alphaSpent
```
2.1 Sample size means (continuous endpoint)

```r
plot(sampleSizeMeans1, type = 5, showSource = TRUE)
```

---

```
## Source data of the plot:
## x-axis: sampleSizeMeans1$alternative
## y-axes:
## y1: sampleSizeMeans1$nFixed
## y2: sampleSizeMeans1$maxNumberOfSubjects
## y3: sampleSizeMeans1$expectedNumberOfSubjectsH1
```
2.1 Sample size means (continuous endpoint)

Sample Size

Standard deviation = 1, H0: mean difference = 0, allocation ratio = 1

![Sample Size Plot]

2.1.2 Sample size means for a two-sided design

```r
sampleSizeMeans2 <- getSampleSizeMeans(
  getDesignGroupSequential(sided = 2))
sampleSizeMeans2
```

## Design plan parameters and output for means:

### Design parameters:

- Significance level: 0.0250
- Type II error rate: 0.2
- Two-sided power: FALSE
- Test: two-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
- Rates: 0.333, 0.667, 1.000

### Maximum number of subjects
- Stage 1: 964.0, 242.9, 109.4, 62.7, 41.1
- Stage 2: 482.0, 121.5, 54.7, 31.4, 20.6
- Stage 3: 482.0, 121.5, 54.7, 31.4, 20.6
- Stage 4: 482.0, 121.5, 54.7, 31.4, 20.6

### Number of subjects
- Stage 1: 321.3, 81.0, 36.5, 20.9, 13.7
- Stage 2: 642.7, 162.0, 72.9, 41.8, 27.4
- Stage 3: 964.0, 242.9, 109.4, 62.7, 41.1

### Expected number of subjects
- Under H0: 962.3, 242.5, 109.2, 62.6, 41.0
- Under H0/H1: 942.8, 237.6, 107.0, 61.3, 40.2
- Under H1: 830.0, 209.1, 94.2, 54.0, 35.4

### Reject per stage
- Stage 1: 0.016
- Stage 2: 0.385
- Stage 3: 0.399
- Early stop: 0.401

### Lower critical values (effect scale)
- Stage 1: -0.445, -0.922, -1.477, -2.181, -3.175
- Stage 2: -0.220, -0.443, -0.672, -0.911, -1.162
- Stage 3: -0.147, -0.293, -0.441, -0.589, -0.738

### Upper critical values (effect scale)
- Stage 1: 0.445, 0.922, 1.477, 2.181, 3.175
- Stage 2: 0.220, 0.443, 0.672, 0.911, 1.162
- Stage 3: 0.147, 0.293, 0.441, 0.589, 0.738

### Local two-sided significance levels
- Stage 1: 0.00008313
- Stage 2: 0.00539247
- Stage 3: 0.02308736

---

## Legend:

- (i): values of treatment arm i
- [k]: values at stage k

```r
plot(sampleSizeMeans2, type = 1)
```
2.1 Sample size means (continuous endpoint)

qnorm(1 − 0.0125) = 2.2414

plot(sampleSizeMeans2, type = 2)

## Warning: Only the first 'alternative' (0.2) was used for plotting
2.1 Sample size means (continuous endpoint)

\begin{itemize}
\item \textbf{Boundary Effect Scale}:
\begin{align*}
N_{\text{max}} &= 964, \quad \text{standard deviation} = 1, \quad H_0: \text{mean difference} = 0, \quad \text{allocation ratio} = 1
\end{align*}
\end{itemize}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{plot}
\caption{Sample Size Means Plot}
\end{figure}

\texttt{plot(sampleSizeMeans2, type = 3)
2.1 Sample size means (continuous endpoint)

![Sample Size Means Plot]

\[ \alpha = 0.0125 \]

\[
\begin{array}{cccc}
0.000 & 0.004 & 0.008 & 0.012 \\
321.346 & 642.693 & 964.039 & \\
\end{array}
\]

\[ \text{plot(sampleSizeMeans2, type = 4)} \]
2.1 Sample size means (continuous endpoint)

```
plot(sampleSizeMeans2, type = 5)
```
2.2 Sample size rates (binary endpoint)

2.2.1 Sample size rates for a one-sided design with futility bounds

```r
sampleSizeRates1 <- getSampleSizeRates(
    getDesignGroupSequential(sided = 1,
        futilityBounds = c(0, 0.1))
)
```

---

### Design plan parameters and output for rates:

#### Design parameters:

- Significance level: 0.0250
- Type II error rate: 0.2
- Test: one-sided

#### User defined parameters: not available

#### Default parameters:

- Normal approximation: TRUE
- Risk ratio: FALSE
- Theta H0: 0
- \( \pi (1) \): 0.400, 0.500, 0.600
- \( \pi (2) \): 0.200
- Treatment groups: 2
- Planned allocation ratio: 1
## Sample size rates (binary endpoint)

### Sample size and output:

- **Direction upper**: TRUE, TRUE, TRUE
- **Information rates [1]**: 0.333
- **Information rates [2]**: 0.667
- **Information rates [3]**: 1.000
- **Maximum number of subjects**: 172.7, 81.8, 47.5
- **Maximum number of subjects (1)**: 86.4, 40.9, 23.7
- **Maximum number of subjects (2)**: 86.4, 40.9, 23.7
- **Number of subjects [1]**: 57.6, 27.3, 15.8
- **Number of subjects [2]**: 115.1, 54.5, 31.7
- **Number of subjects [3]**: 172.7, 81.8, 47.5
- **Expected number of subjects under H0**: 106.3, 50.4, 29.2
- **Expected number of subjects under H0/H1**: 140.5, 66.5, 38.6
- **Expected number of subjects under H1**: 138.3, 65.5, 38.0
- **Reject per stage [1]**: 0.0357
- **Reject per stage [2]**: 0.4262
- **Reject per stage [3]**: 0.3381
- **Futility stop per stage [1]**: 0.0477
- **Futility stop per stage [2]**: 0.0049
- **Futility stop**: 0.0526
- **Early stop**: 0.514
- **Critical values (effect scale) [1]**: 0.452, 0.663, NA
- **Critical values (effect scale) [2]**: 0.211, 0.319, 0.430
- **Critical values (effect scale) [3]**: 0.135, 0.203, 0.275
- **Local one-sided significance levels [1]**: 0.0002592
- **Local one-sided significance levels [2]**: 0.0070554
- **Local one-sided significance levels [3]**: 0.0225331
- **Futility bounds (effect scale) [1]**: 0.00000, 0.00000, 0.00000
- **Futility bounds (effect scale) [2]**: 0.00751, 0.01094, 0.01441
- **Futility bounds (1-sided p-value scale) [1]**: 0.5000
- **Futility bounds (1-sided p-value scale) [2]**: 0.4602

### Legend:

- **(i)**: values of treatment arm i
- **[k]**: values at stage k

```r
plot(sampleSizeRates1, type = 1, showSource = TRUE)
```
2.2 Sample size rates (binary endpoint)

\[ qnorm(1 - 0.025) = 1.96 \]

```
plot(sampleSizeRates1, type = 2, showSource = TRUE)
```

### Warning: Only the first 'pi1' (0.4) was used for plotting

### Source data of the plot:

- x-axis: sampleSizeRates1$informationRates * 172.7029
- y-axes:
  - y1: sampleSizeRates1$criticalValuesEffectScaleUpper[, 1]
  - y2: sampleSizeRates1$futilityBoundsEffectScale[, 1]
**Boundaries Effect Scale**

\[ N_{\text{max}} = 172.7, \ \pi_2 = 0.2, \ H_0: \text{risk difference} = 0, \ \text{allocation ratio} = 1 \]

plot(sampleSizeRates1, type = 3, showSource = TRUE)

## Source data of the plot:
## x-axis: sampleSizeRates1$.design$informationRates
## y-axis: sampleSizeRates1$.design$stageLevels
Sample size rates (binary endpoint)

\[ \alpha = 0.025 \]

---

```r
plot(sampleSizeRates1, type = 4, showSource = TRUE)
```

---

```
## Source data of the plot:
## x-axis: sampleSizeRates1$.design$informationRates
## y-axis: sampleSizeRates1$.design$alphaSpent
```
2.2 Sample size rates (binary endpoint)
2.2 Sample size rates (binary endpoint)

Sample size rates for a two-sided design

```r
sampleSizeRates2 <- getSampleSizeRates(
  getDesignGroupSequential(sided = 2))
```

## Design plan parameters and output for rates:

### Design parameters:
### - Significance level: 0.0250
### - Type II error rate: 0.2
### - Two-sided power: FALSE
### - Test: two-sided

### User defined parameters: not available

### Default parameters:
### - Normal approximation: TRUE
### - Risk ratio: FALSE
### - Theta H0: 0
### - $\pi (1)$: $0.400, 0.500, 0.600$
### - $\pi (2)$: 0.200
### - Treatment groups: 2
### - Planned allocation ratio: 1

### Sample size and output:
## Direction upper : TRUE, TRUE, TRUE
## Information rates [1] : 0.333
## Information rates [2] : 0.667
## Information rates [3] : 1.000
## Maximum number of subjects : 199.3, 94.5, 55.0
## Maximum number of subjects (1) : 99.6, 47.3, 27.5
## Maximum number of subjects (2) : 99.6, 47.3, 27.5
## Number of subjects [1] : 66.4, 31.5, 18.3
## Number of subjects [2] : 132.8, 63.0, 36.7
## Number of subjects [3] : 199.3, 94.5, 55.0
## Expected number of subjects under H0 : 198.9, 94.4, 54.9
## Expected number of subjects under H0/H1 : 194.9, 92.5, 53.8
## Expected number of subjects under H1 : 171.5, 81.4, 47.3
## Reject per stage [1] : 0.016
## Reject per stage [2] : 0.385
## Reject per stage [3] : 0.399
## Early stop : 0.401
## Lower critical values (effect scale) [1] : NA, NA, NA
## Lower critical values (effect scale) [2] : -0.158, NA, NA
## Lower critical values (effect scale) [3] : -0.113, -0.154, -0.188
## Upper critical values (effect scale) [1] : 0.479, 0.698, NA
## Upper critical values (effect scale) [2] : 0.224, 0.338, 0.455
## Upper critical values (effect scale) [3] : 0.143, 0.216, 0.291
## Local two-sided significance levels [1] : 0.00008313
## Local two-sided significance levels [2] : 0.00539247
## Local two-sided significance levels [3] : 0.02308736

## Legend:
## (i): values of treatment arm i
## [k]: values at stage k

plot(sampleSizeRates2, type = 1)
2.2 Sample size rates (binary endpoint)

\[ qnorm(1 - 0.0125) = 2.2414 \]

```
plot(sampleSizeRates2, type = 2)
```

## Warning: Only the first 'pi1' (0.4) was used for plotting
2.2 Sample size rates (binary endpoint)

Boundaries Effect Scale

\[ N_{\text{max}} = 199.3, \ pi_2 = 0.2, \ H_0: \text{risk difference} = 0, \ \text{allocation ratio} = 1 \]

```r
plot(sampleSizeRates2, type = 3)
```
2.2 Sample size rates (binary endpoint)
2.2 Sample size rates (binary endpoint)

plot(sampleSizeRates2, type = 5)
2.3 Sample size survival (survival endpoint)

2.3.1 Sample size survival for a one-sided design with futility bounds

design <- getDesignGroupSequential(
  kMax = 3, typeOfDesign = "OF", sided = 1,
  futilityBounds = c(-1, 0.5))

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

sampleSizeSurvival1 <- getSampleSizeSurvival(design = design,
  typeOfComputation = "Schoenfeld",
  thetaH0 = 1, allocationRatioPlanned = 1, kappa = 1,
  piecewiseSurvivalTime = piecewiseSurvivalTime,
  hazardRatio = c(0.5, 0.9))

## Design plan parameters and output for survival data:
##
## Design parameters:
##  Significance level : 0.0250
## Sample size survival (survival endpoint)

### User defined parameters:
- **lambda (2)**: 0.025, 0.040, 0.015, 0.010, 0.007
- **Hazard ratio**: 0.500, 0.900
- **Piecewise survival times**: 0.00, 6.00, 9.00, 15.00, 21.00

### Default parameters:
- **Type of computation**: Schoenfeld
- **Theta H0**: 1
- **Planned allocation ratio**: 1
- **Accrual time**: 12
- **kappa**: 1
- **Follow up time**: 6
- **Drop-out rate (1)**: 0.000
- **Drop-out rate (2)**: 0.000
- **Drop-out time**: 12

### Sample size and output:
- **Direction upper**: FALSE, FALSE
- **Maximum number of subjects**: 334.0, 11628.4
- **Maximum number of subjects (1)**: 167.0, 5814.2
- **Maximum number of subjects (2)**: 167.0, 5814.2
- **Maximum number of events**: 66.9, 2897.1
- **Accrual intensity**: 27.8, 969.0
- **Calculate follow up time**: FALSE
- **Information rates [1]**: 0.333
- **Information rates [2]**: 0.667
- **Information rates [3]**: 1.000
- **Analysis times [1]**: 9.25, 9.21
- **Analysis times [2]**: 13.30, 13.27
- **Analysis times [3]**: 18.00, 18.00
- **Expected study duration under H1**: 15.58, 15.57
- **Maximal study duration**: 18.00, 18.00
- **Number of events by stage [1]**: 22.3, 965.7
- **Number of events by stage [2]**: 44.6, 1931.4
- **Number of events by stage [3]**: 66.9, 2897.1
- **Expected number of events under H0**: 47.7, 2066.1
- **Expected number of events under H0/H1**: 58.1, 2515.0
- **Number of subjects [1]**: 257.4, 8924.2
- **Number of subjects [2]**: 334.0, 11628.4
- **Number of subjects [3]**: 334.0, 11628.4
- **Expected number of subjects under H1**: 331.1, 11527.0
- **Reject per stage [1]**: 0.0333
- **Reject per stage [2]**: 0.4122
- **Reject per stage [3]**: 0.3545
- **Futility stop per stage [1]**: 0.00418
- **Futility stop per stage [2]**: 0.03207
- **Futility stop**: 0.0362
- **Early stop**: 0.482
- **Critical values (effect scale) [1]**: 0.230, 0.800
- **Critical values (effect scale) [2]**: 0.480, 0.894
2.3 Sample size survival (survival endpoint)  

---

```r
## Critical values (effect scale) [3]: 0.613, 0.928
## Local one-sided significance levels [1]: 0.0002592
## Local one-sided significance levels [2]: 0.0070554
## Local one-sided significance levels [3]: 0.0225331
## Futility bounds (effect scale) [1]: 1.527, 1.066
## Futility bounds (effect scale) [2]: 0.861, 0.978
## Futility bounds (1-sided p-value scale) [1]: 0.8413
## Futility bounds (1-sided p-value scale) [2]: 0.3085
##
## Legend:
## (i): values of treatment arm i
## [k]: values at stage k

plot(sampleSizeSurvival1, type = 1, showSource = TRUE)

## Source data of the plot:
## x-axis: sampleSizeSurvival1$eventsPerStage
## y-axes:
## y1: sampleSizeSurvival1$futilityBounds
## y2: sampleSizeSurvival1$criticalValues

# Events By Stage
Futility Bound (non-binding) and Critical Value

Boundaries Z Scale

plot(sampleSizeSurvival1, type = 2, showSource = TRUE)

## Warning: Only the first 'hazardRatio' (0.5) was used for plotting
## Source data of the plot:
## x-axis: sampleSizeSurvival1$eventsPerStage
## y-axes:
```

---

qnorm(1 - 0.025) = 1.96

```

---

www.rpact.com
## Boundaries Effect Scale

H0: hazard ratio = 1, allocation ratio = 1, hazardRatio = 0.5

```
## y1: sampleSizeSurvival1$criticalValuesEffectScaleUpper[, 1]
## y2: sampleSizeSurvival1$futilityBoundsEffectScale[, 1]
```

```
plot(sampleSizeSurvival1, type = 3, showSource = TRUE)
```

```
## Source data of the plot:
## x-axis: sampleSizeSurvival1$eventsPerStage[, 1]
## y-axis: sampleSizeSurvival1$.design$stageLevels
```
2.3 Sample size survival (survival endpoint)

\[ \alpha = 0.025 \]

<table>
<thead>
<tr>
<th>Boundaries</th>
<th>p Values</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.010</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.015</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.020</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.025</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

# Events By Stage

plot(sampleSizeSurvival1, type = 4, showSource = TRUE)

## Source data of the plot:
## x-axis: sampleSizeSurvival1$eventsPerStage[, 1]
## y-axis: sampleSizeSurvival1$.design$alphaSpent
2.3 Sample size survival (survival endpoint)

```r
plot(sampleSizeSurvival1, type = 5, showSource = TRUE)
```

## Source data of the plot:
## x-axis: sampleSizeSurvival1$hazardRatio
## y-axes:
## y1: sampleSizeSurvival1$eventsFixed
## y2: sampleSizeSurvival1$eventsPerStage[3, ]
## y3: sampleSizeSurvival1$expectedEventsH1

## Note: interim values between 0.5 and 0.9 were calculated to get smoother lines; use, e.g., 'hazardRatio = seq(0.5, 0.9, 0.013333)'
Sample Size

H0: hazard ratio = 1, allocation ratio = 1

```
plot(sampleSizeSurvival1, type = 13, legendPosition = 1)
```

## Warning: Only the first 'hazardRatio' (0.5) was used for plotting
plot(sampleSizeSurvival1, type = 14)

## Warning: Only the first 'hazardRatio' (0.5) was used for plotting
2.3 Sample size survival (survival endpoint)

### 2.3.2 Sample size survival for a two-sided design

```r
design <- getDesignGroupSequential(kMax = 3, typeOfDesign = "OF", sided = 2, twoSidedPower = TRUE)
piecewiseSurvivalTime <- list(
  "0 - <14" = 0.015,
  "14 - <24" = 0.01,
  "24 - <44" = 0.005,
  ">=44" = 0.0025
)
sampleSizeSurvival2 <- getSampleSizeSurvival(design = design,
  typeOfComputation = "Schoenfeld",
  thetaH0 = 1,
  allocationRatioPlanned = 1, kappa = 1,
  piecewiseSurvivalTime = piecewiseSurvivalTime,
  maxNumberOfSubjects = 0, hazardRatio = c(0.1, 0.2, 0.5, 0.6))
sampleSizeSurvival2
```

## Design plan parameters and output for survival data:

## Design parameters:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significance level</td>
<td>0.0250</td>
</tr>
<tr>
<td>Type II error rate</td>
<td>0.2</td>
</tr>
<tr>
<td>Two-sided power</td>
<td>TRUE</td>
</tr>
<tr>
<td>Test</td>
<td>two-sided</td>
</tr>
</tbody>
</table>
## User defined parameters:
## lambda (2) : 0.0150, 0.0100, 0.0050, 0.0025
## Hazard ratio : 0.100, 0.200, 0.500, 0.600
## Piecewise survival times : 0.00, 14.00, 24.00, 44.00
##
## Default parameters:
## Type of computation : Schoenfeld
## Theta H0 : 1
## Planned allocation ratio : 1
## Accrual time : 12
## kappa : 1
## Follow up time : 6
## Drop-out rate (1) : 0.000
## Drop-out rate (2) : 0.000
## Drop-out time : 12
##
## Sample size and output:
## Direction upper : FALSE, FALSE, FALSE, FALSE
## Maximum number of subjects : 81.3, 151.8, 652.7, 1128.6
## Maximum number of subjects (1) : 40.6, 75.9, 326.4, 564.3
## Maximum number of subjects (2) : 40.6, 75.9, 326.4, 564.3
## Maximum number of events : 7.3, 14.8, 80.0, 147.4
## Accrual intensity : 6.8, 12.6, 54.4, 94.0
## Calculate follow up time : FALSE
## Information rates [1] : 0.333
## Information rates [2] : 0.667
## Information rates [3] : 1.000
## Analysis times [3] : 18.00, 18.00, 18.00, 18.00
## Expected study duration under H1 : 16.20, 16.20, 16.20, 16.20
## Maximal study duration : 18.00, 18.00, 18.00, 18.00
## Number of events by stage [1] : 2.4, 4.9, 26.7, 49.1
## Number of events by stage [2] : 4.8, 9.9, 53.4, 98.3
## Number of events by stage [3] : 7.3, 14.8, 80.0, 147.4
## Expected number of events under H0 : 7.2, 14.8, 79.9, 147.4
## Expected number of events under H0/H1 : 7.1, 14.5, 78.3, 144.1
## Expected number of events under H1 : 6.2, 12.8, 68.9, 126.9
## Number of subjects [1] : 64.4, 120.4, 518.0, 895.3
## Number of subjects [2] : 81.3, 151.8, 652.7, 1128.6
## Number of subjects [3] : 81.3, 151.8, 652.7, 1128.6
## Expected number of subjects under H1 : 81.0, 151.3, 650.6, 1124.8
## Reject per stage [1] : 0.016
## Reject per stage [2] : 0.385
## Reject per stage [3] : 0.399
## Early stop : 0.401
## Lower critical values (effect scale) [1] : 0.00634, 0.02908, 0.21792, 0.32535
## Lower critical values (effect scale) [2] : 0.07960, 0.17052, 0.46682, 0.57039
## Lower critical values (effect scale) [3] : 0.18505, 0.30751, 0.60177, 0.68778
## Upper critical values (effect scale) [1] : 157.809, 34.390, 4.589, 3.074
## Upper critical values (effect scale) [2] : 12.562, 5.864, 2.142, 1.753
## Upper critical values (effect scale) [3] : 5.404, 3.252, 1.662, 1.454
## Local two-sided significance levels [1] : 0.00008313
## Local two-sided significance levels [2] : 0.00539247
Local two-sided significance levels [3] : 0.02308736

Legend:
(i): values of treatment arm i
[k]: values at stage k

plot(sampleSizeSurvival2, type = 1)

plot(sampleSizeSurvival2, type = 2)

## Warning: Only the first 'hazardRatio' (0.1) was used for plotting
2.3 Sample size survival (survival endpoint)

Boundaries Effect Scale

H0: hazard ratio = 1, allocation ratio = 1, hazardRatio = 0.1

plot(sampleSizeSurvival2, type = 3)
2.3 Sample size survival (survival endpoint)  

![Type One Error Spending](#)

```
plot(sampleSizeSurvival2, type = 5)
```
Sample Size

H0: hazard ratio = 1, allocation ratio = 1

plot(sampleSizeSurvival2, type = 13, legendPosition = 1)

## Warning: Only the first 'hazardRatio' (0.1) was used for plotting
2.3 Sample size survival (survival endpoint)

```
plot(sampleSizeSurvival2, type = 14)

## Warning: Only the first 'hazardRatio' (0.1) was used for plotting
```
3 Power plots

3.1 Power means (continuous endpoint)

3.1.1 Power means for a one-sided design with futility bounds

```r
design <- getDesignGroupSequential(
  typeOfDesign = "OF", sided = 1,
  futilityBounds = c(0, 0.5))

powerMeans1 <- getPowerMeans(design,
  groups = 1, meanRatio = FALSE,
  thetaH0 = 0, alternative = c(-1, 4),
  stDev = 2, normalApproximation = FALSE,
  maxNumberOfSubjects = 40)

powerMeans1
```

```r
## Design plan parameters and output for means:
##
## Design parameters:
##  Significance level : 0.0250
##  Test : one-sided
##
## User defined parameters:
##  Alternatives : -1, 4
##  Standard deviation : 2
```
## Treatment groups

### Maximum number of subjects

### Default parameters:
- Normal approximation: FALSE
- Theta H0: 0
- Direction upper: TRUE

### Sample size and output:
- Number of subjects [1]: 13.3
- Number of subjects [2]: 26.7
- Number of subjects [3]: 40.0
- Effect: -1, 4
- Expected number of subjects: 13.8, 13.3
- Reject per stage [1]: 0.0000000755, 0.9998629684
- Reject per stage [2]: 0.0000003253, 0.0001370298
- Reject per stage [3]: 0.0000001446, 0.0000000000
- Overall reject: 0.000000545, 0.999999998
- Futility stop per stage [1]: 0.9625, 0.0000
- Futility stop per stage [2]: 0.0365, 0.0000
- Futility stop: 0.999, 0.000
- Early stop: 0.999, 1.000
- Critical values (effect scale) [1]: 2.549
- Critical values (effect scale) [2]: 1.020
- Critical values (effect scale) [3]: 0.655
- Local one-sided significance levels [1]: 0.0002592
- Local one-sided significance levels [2]: 0.0070554
- Local one-sided significance levels [3]: 0.0225331
- Futility bounds (effect scale) [1]: 0.000
- Futility bounds (effect scale) [2]: 0.196
- Futility bounds (1-sided p-value scale) [1]: 0.5000
- Futility bounds (1-sided p-value scale) [2]: 0.3085

### Legend:
- [k]: values at stage k

```r
plot(powerMeans1, type = 1, showSource = TRUE)
```
3.1 Power means (continuous endpoint)

$qnorm(1 - 0.025) = 1.96$

Sample Size

Futility Bound (non-binding) and Critical Value

Critical value
Futility bound (non-binding)

plot(powerMeans1, type = 2, showSource = TRUE)

## Source data of the plot:
## x-axis: powerMeans1$informationRates * 40
## y-axes:
## y1: powerMeans1$criticalValuesEffectScaleUpper[, 1]
## y2: powerMeans1$futilityBoundsEffectScale[, 1]
3.1 Power means (continuous endpoint)  

**Boundaries Effect Scale**

\[ N_{\text{max}} = 40, \ \text{standard deviation} = 2, \ \text{H0: mu = 0}, \ \text{allocation ratio} = 1 \]

---

```r
plot(powerMeans1, type = 3, showSource = TRUE)

## Source data of the plot:
## x-axis: powerMeans1$.design$informationRates
## y-axis: powerMeans1$.design$stageLevels
```
3.1 Power means (continuous endpoint)

```r
plot(powerMeans1, type = 4, showSource = TRUE)
```

## Source data of the plot:
## x-axis: powerMeans1$.design$informationRates
## y-axis: powerMeans1$.design$alphaSpent
3.1 Power means (continuous endpoint)
3.1 Power means (continuous endpoint)  

**Overall Power and Early Stopping**  

$N_{\text{max}}=40$, standard deviation =2, H0: $\mu =0$, allocation ratio =1

---

```r
plot(powerMeans1, type = 6, showSource = TRUE)
```

---

## Source data of the plot:

---

### x-axis: `powerMeans1$effect`

### y-axes:

- `y1`: `powerMeans1$expectedNumberOfSubjects`
- `y2`: `powerMeans1$overallReject`
- `y3`: `powerMeans1$earlyStop`

### Note: interim values between -1 and 4 were calculated to get smoother lines; use, e.g., `alternative`
3.1 Power means (continuous endpoint)

Expected Sample Size and Power / Early Stop

\( N_{\text{max}} = 40, \) standard deviation = 2, \( H_0: \mu = 0, \) allocation ratio = 1

\[
\frac{\text{Expected # Subjects}}{\text{Effect}}
\]

- Red: Overall reject
- Blue: Expected # subjects
- Green: Early stop

```
plot(powerMeans1, type = 7, showSource = TRUE)
```

## Source data of the plot:

### x-axis: powerMeans1$effect
### y-axis: powerMeans1$overallReject

## Note: interim values between -1 and 4 were calculated to get smoother lines; use, e.g., 'alternative
3.1 Power means (continuous endpoint) 3 POWER PLOTS

Overall Power

\[ N_{\text{max}} = 40, \ \text{standard deviation} = 2, \ H_0: \mu = 0, \ \text{allocation ratio} = 1 \]

plot(powerMeans1, type = 8, showSource = TRUE)

## Source data of the plot:
## x-axis: powerMeans1$effect
## y-axes:
## y1: powerMeans1$earlyStop
## y2: powerMeans1$futilityStop
## Note: interim values between -1 and 4 were calculated to get smoother lines; use, e.g., 'alternative
Overall Early Stopping

\( N_{\text{max}} = 40 \), standard deviation = 2, \( H_0: \mu = 0 \), allocation ratio = 1

---

```
plot(powerMeans1, type = 9, showSource = TRUE)
```

### Source data of the plot:
- **x-axis**: powerMeans1$effect
- **y-axis**: powerMeans1$expectedNumberOfSubjects

### Note:
- Interim values between -1 and 4 were calculated to get smoother lines; use, e.g., `alternative`
3.1 Power means (continuous endpoint)

3.1.2 Power means for a two-sided design

```r
powerMeans2 <- getPowerMeans(getDesignGroupSequential(
  typeOfDesign = "OF", sided = 2, twoSidedPower = TRUE), maxNumberOfSubjects = 120)
powerMeans2
```

```yaml
## Design plan parameters and output for means:
##
## Design parameters:
##  Significance level : 0.0250
##  Test : two-sided
##
## User defined parameters:
##  Direction upper : NA
##  Maximum number of subjects : 120.0
##
## Default parameters:
##  Normal approximation : FALSE
##  Mean ratio : FALSE
##  Theta H0 : 0
##  Alternatives : 0, 0.2, 0.4, 0.6, 0.8, 1
##  Standard deviation : 1
##  Treatment groups : 2
##  Planned allocation ratio : 1
##
## Sample size and output:
```
## Number of subjects

- **[1]**: 40.0
- **[2]**: 80.0
- **[3]**: 120.0

## Effect

- 0.0, 0.2, 0.4, 0.6, 0.8, 1.0

## Expected number of subjects

- **[1]**: 119.8, 118.8, 113.6, 101.2, 85.9, 73.6
- **[2]**: 119.8, 118.8, 113.6, 101.2, 85.9, 73.6
- **[3]**: 119.8, 118.8, 113.6, 101.2, 85.9, 73.6

## Reject per stage

- **[1]**: 0.0000831, 0.0004699, 0.0036402, 0.0197905, 0.0760023, 0.2098551
- **[2]**: 0.0053436, 0.0286152, 0.1521829, 0.4296001, 0.6995911, 0.7398469
- **[3]**: 0.0195732, 0.0929896, 0.3088675, 0.3899312, 0.2053212, 0.0494953

## Overall reject

- 0.025, 0.122, 0.465, 0.839, 0.981, 0.999

## Early stop

- 0.00543, 0.02909, 0.15582, 0.44939, 0.77559, 0.94970

## Lower critical values (effect scale)

- **[1]**: -1.393
- **[2]**: -0.640
- **[3]**: -0.420

## Upper critical values (effect scale)

- **[1]**: 1.393
- **[2]**: 0.640
- **[3]**: 0.420

## Local two-sided significance levels

- **[1]**: 0.00008313
- **[2]**: 0.00539247
- **[3]**: 0.02308736

---

**Legend:**

- (i): values of treatment arm i
- [k]: values at stage k

```r
dget(powerMeans2, type = 1)
```

---

**Diagram:**

- **Boundaries**
- **Critical Value**
- **Sample Size**

---

qnorm(1 - 0.0125) = 2.2414

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3.1 Power means (continuous endpoint)

$$\text{plot}(\text{powerMeans2, type = 2})$$

**Boundaries Effect Scale**

$N_{\text{max}} = 120$, standard deviation = 1, $H_0$: mean difference = 0, allocation ratio = 1

$$\text{plot}(\text{powerMeans2, type = 3})$$
3.1 Power means (continuous endpoint)
3.1 Power means (continuous endpoint)

```r
plot(powerMeans2, type = 5)
```
Overall Power and Early Stopping

\( N_{\text{max}} = 120, \)  standard deviation = 1,  \( H_0: \) mean difference = 0,  allocation ratio = 1

```r
plot(powerMeans2, type = 6)
```
3.1 Power means (continuous endpoint)

Expected Sample Size and Power / Early Stop

$N_{\text{max}}=120$, standard deviation = 1, $H_0$: mean difference = 0, allocation ratio = 1

plot(powerMeans2, type = 7)
Overall Power

\[ N_{\text{max}} = 120, \ \text{standard deviation} = 1, \ \text{H0: mean difference} = 0, \ \text{allocation ratio} = 1 \]

\[
\text{plot}(\text{powerMeans2, type} = 8)
\]
Overall Early Stopping

\[ N_{\text{max}} = 120, \text{ standard deviation} = 1, \ H_0: \text{mean difference} = 0, \ \text{allocation ratio} = 1 \]
3.2 Power rates (binary endpoint)

3.2.1 Power rates for a one-sided design with futility bounds

design <- getDesignGroupSequential(
  kMax = 3,
  typeOfDesign = "OF",
  sided = 1,
  futilityBounds = c(-1, 0.5))

powerRates1 <- getPowerRates(design,
  groups = 2, riskRatio = TRUE,
  thetaH0 = 0.2, allocationRatioPlanned = 1,
  pi1 = c(0.1, 0.4), pi2 = 0.2,
  normalApproximation = TRUE,
  maxNumberOfSubjects = 80)

## Warning: Argument unknown in getPowerRates(...): 'normalApproximation' = TRUE
## will be ignored

powerRates1

## Design plan parameters and output for rates:
##
## Design parameters:
##
## Significance level : 0.0250
## Test : one-sided
## User defined parameters:
## Risk ratio : TRUE
## Theta H0 : 0.2
## $\pi (1)$ : 0.100, 0.400
## Maximum number of subjects : 80.0
##
## Default parameters:
## Normal approximation : TRUE
## $\pi (2)$ : 0.200
## Treatment groups : 2
## Planned allocation ratio : 1
## Direction upper : TRUE
##
## Sample size and output:
## Number of subjects [1] : 26.7
## Number of subjects [2] : 53.3
## Number of subjects [3] : 80.0
## Effect : 0.3, 1.8
## Expected number of subjects : 70.3, 44.3
## Reject per stage [1] : 0.00666, 0.36203
## Reject per stage [2] : 0.14190, 0.61277
## Reject per stage [3] : 0.24893, 0.02484
## Overall reject : 0.397, 1.000
## Futility stop per stage [1] : 0.0229539, 0.0000191
## Futility stop per stage [2] : 0.1622267, 0.0000439
## Futility stop : 0.185181, 0.000063
## Early stop : 0.334, 0.975
## Critical values (effect scale) [1] : 1.509
## Critical values (effect scale) [2] : 0.784
## Critical values (effect scale) [3] : 0.572
## Local one-sided significance levels [1] : 0.0002592
## Local one-sided significance levels [2] : 0.0070554
## Local one-sided significance levels [3] : 0.0225331
## Futility bounds (effect scale) [1] : NA
## Futility bounds (effect scale) [2] : 0.306
## Futility bounds (1-sided p-value scale) [1] : 0.8413
## Futility bounds (1-sided p-value scale) [2] : 0.3085
##
## Legend:
## (i): values of treatment arm i
## [k]: values at stage k

```r
plot(powerRates1, type = 1, showSource = TRUE)
```
3.2 Power rates (binary endpoint)

\[ qnorm \left( 1 - 0.025 \right) = 1.96 \]

Sample Size

Critical value
Futility bound (non-binding)

plot(powerRates1, type = 2, showSource = TRUE)

## Source data of the plot:
## x-axis: powerRates1$informationRates * 80
## y-axes:
## y1: powerRates1$criticalValuesEffectScaleUpper[, 1]
## y2: powerRates1$futilityBoundsEffectScale[, 1]
3.2 Power rates (binary endpoint)

### Boundaries Effect Scale

\[ N_{\text{max}} = 80, \ \pi_2 = 0.2, \ H_0: \text{risk ratio} = 0.2, \ \text{allocation ratio} = 1 \]

```
plot(powerRates1, type = 3, showSource = TRUE)
```

## Source data of the plot:

```
## x-axis: powerRates1$design$informationRates
## y-axis: powerRates1$design$stageLevels
```
3.2 Power rates (binary endpoint)

```r
plot(powerRates1, type = 4, showSource = TRUE)
```

## Source data of the plot:

```
## x-axis: powerRates1$.design$informationRates
## y-axis: powerRates1$.design$alphaSpent
```
3.2 Power rates (binary endpoint)
3.2 Power rates (binary endpoint)

Overall Power and Early Stopping

$N_{\text{max}} = 80$, $\pi_2 = 0.2$, $H_0$: risk ratio = 0.2, allocation ratio = 1

`plot(powerRates1, type = 6, showSource = TRUE)`

## Source data of the plot:
## x-axis: powerRates1$effect
## y-axes:
## y1: powerRates1$expectedNumberOfSubjects
## y2: powerRates1$overallReject
## y3: powerRates1$earlyStop
## Note: interim values between 0.1 and 0.4 were calculated to get smoother lines; use, e.g., 'pi1 = seq(0.1, 0.4, 0.01)' to get all interim values.
Expected Sample Size and Power / Early Stop

\[ N_{\text{max}} = 80, \quad \pi_2 = 0.2, \quad H_0: \text{risk ratio} = 0.2, \quad \text{allocation ratio} = 1 \]

```
plot(powerRates1, type = 7, showSource = TRUE)
```

## Source data of the plot:

- x-axis: `powerRates1$effect`
- y-axis: `powerRates1$overallReject`

## Note: interim values between 0.1 and 0.4 were calculated to get smoother lines; use, e.g., `pi1 = seq(0.1, 0.4, 0.01)`
3.2 Power rates (binary endpoint)

Overall Power

\[ N_{\text{max}} = 80, \quad \pi_2 = 0.2, \quad H_0: \text{risk ratio} = 0.2, \quad \text{allocation ratio} = 1 \]

```
plot(powerRates1, type = 8, showSource = TRUE)
```

## Source data of the plot:
## x-axis: powerRates1$effect
## y-axes:
## y1: powerRates1$earlyStop
## y2: powerRates1$futilityStop
## Note: interim values between 0.1 and 0.4 were calculated to get smoother lines; use, e.g., 'pi1 = seq(0.1, 0.4, 0.01)'

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3.2 Power rates (binary endpoint)

Overall Early Stopping

$N_{\text{max}} = 80$, $\pi_2 = 0.2$, $H_0$: risk ratio $= 0.2$, allocation ratio $= 1$

```
plot(powerRates1, type = 9, showSource = TRUE)
```

## Source data of the plot:
## x-axis: powerRates1$effect
## y-axis: powerRates1$expectedNumberOfSubjects

## Note: interim values between 0.1 and 0.4 were calculated to get smoother lines; use, e.g., 'pi1 = seq(0.1, 0.4, 0.01)' to get all interim values
### 3.2.2 Power rates for a two-sided design

```r
cmpowerRates2 <- getPowerRates(getDesignGroupSequential(
  typeOfDesign = "OF", sided = 2, twoSidedPower = TRUE),
  maxNumberOfSubjects = 120)

cmpowerRates2
```

```
## Design plan parameters and output for rates:
##
## Design parameters:
## Significance level : 0.0250
## Test : two-sided
##
## User defined parameters:
## Direction upper : NA
## Maximum number of subjects : 120.0
##
## Default parameters:
## Normal approximation : TRUE
## Risk ratio : FALSE
## Theta H0 : 0
## pi (1) : 0.200, 0.300, 0.400, 0.500
## pi (2) : 0.200
## Treatment groups : 2
## Planned allocation ratio : 1
```
3.2 Power rates (binary endpoint) 3 POWER PLOTS

## Sample size and output:

Number of subjects [1] : 40.0  
Number of subjects [2] : 80.0  
Number of subjects [3] : 120.0  
Effect : 0.0, 0.1, 0.2, 0.3  
Expected number of subjects : 119.8, 118.4, 111.6, 97.5  
Reject per stage [1] : 0.0000831, 0.0006683, 0.0053410, 0.0281264  
Reject per stage [2] : 0.0053436, 0.0391283, 0.1988217, 0.5051498  
Reject per stage [3] : 0.0195732, 0.1206744, 0.3503647, 0.3609235  
Overall reject : 0.025, 0.160, 0.555, 0.894  
Early stop : 0.00543, 0.03980, 0.20416, 0.53328  
Lower critical values (effect scale) [1] : NA  
Lower critical values (effect scale) [2] : -0.191  
Lower critical values (effect scale) [3] : -0.140  
Upper critical values (effect scale) [1] : 0.622  
Upper critical values (effect scale) [2] : 0.296  
Upper critical values (effect scale) [3] : 0.189  
Local two-sided significance levels [1] : 0.00008313  
Local two-sided significance levels [2] : 0.00539247  
Local two-sided significance levels [3] : 0.02308736  

## Legend:

(i): values of treatment arm i  
[k]: values at stage k

plot(powerRates2, type = 1)
3.2 Power rates (binary endpoint)  

\[
\text{plot(powerRates2, type = 2)}
\]

### Boundaries Effect Scale

\[N_{\max} = 120, \ p_{i2} = 0.2, \ H_0: \text{risk difference} = 0, \ \text{allocation ratio} = 1\]

\[
\text{plot(powerRates2, type = 3)}
\]
3.2 Power rates (binary endpoint)  

$\alpha = 0.0125$

<table>
<thead>
<tr>
<th>Sample Size</th>
<th>Boundaries p Values Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td></td>
</tr>
<tr>
<td>80</td>
<td></td>
</tr>
<tr>
<td>120</td>
<td></td>
</tr>
</tbody>
</table>

plot(powerRates2, type = 4)
3.2 Power rates (binary endpoint)

Type One Error Spending

```
plot(powerRates2, type = 5)
```
3.2 Power rates (binary endpoint)

Overall Power and Early Stopping

\[ N_{\text{max}} = 120, \ \pi_2 = 0.2, \ H_0: \text{risk difference} = 0, \ \text{allocation ratio} = 1 \]

plot(powerRates2, type = 6)

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3.2 Power rates (binary endpoint)

Expected Sample Size and Power / Early Stop

\( N_{\text{max}} = 120, \ \pi_2 = 0.2, \ H_0: \text{risk difference} = 0, \ \text{allocation ratio} = 1 \)

```r
plot(powerRates2, type = 7)
```
3.2 Power rates (binary endpoint)

Overall Power

\[ N_{\text{max}} = 120, \ \pi_2 = 0.2, \ H_0: \text{risk difference} = 0, \ \text{allocation ratio} = 1 \]

\[
\begin{align*}
\text{Effect} & \quad \text{Overall Reject} \\
0.0 & \quad 0.00 \\
0.1 & \quad 0.25 \\
0.2 & \quad 0.50 \\
0.3 & \quad 0.75
\end{align*}
\]

\text{plot(powerRates2, type = 8)}
3.2 Power rates (binary endpoint)

Overall Early Stopping

\( N_{\text{max}} = 120, \ p_2 = 0.2, \ H_0: \text{risk difference} = 0, \ \text{allocation ratio} = 1 \)

```r
plot(powerRates2, type = 9)
```
3.3 Power survival (survival endpoint)

### 3.3.1 Power survival for a one-sided design with futility bounds

```r
design <- getDesignGroupSequential(kMax = 3,
                                  typeOfDesign = "OF", sided = 1,
                                  futilityBounds = c(0, 0))
design
```

## Design parameters and output of group sequential design:

### User defined parameters:

- Futility bounds (non-binding): 0.000, 0.000

### Derived from user defined parameters:

- Maximum number of stages: 3

### Default parameters:

- Type of design: OF
- Information rates: 0.333, 0.667, 1.000
- Significance level: 0.0250
- Type II error rate: 0.2
- Two-sided power: FALSE
- Binding futility: FALSE
- Test: one-sided
- Tolerance: 0.00000001
### Output:

```
Cumulative alpha spending : 0.0002592, 0.0071601, 0.0250000
Critical values : 3.471, 2.454, 2.004
Stage levels : 0.0002592, 0.0070554, 0.0225331
```

### ISSUES (parameters with undefined type):

```
Stages : 1, 2, 3
```

```r
powerSurvival <- getPowerSurvival(design = design,
  typeOfComputation = "Schoenfeld", thetaH0 = 1,
  allocationRatioPlanned = 1, kappa = 1,
  maxNumberOfSubjects = 2480,
  maxNumberOfEvents = 70)
```

### Design plan parameters and output for survival data:

```
Design parameters:
Significance level : 0.0250
Test : one-sided

User defined parameters:
Maximum number of subjects : 2480.0
Maximum number of events : 70.0

Default parameters:
Type of computation : Schoenfeld
Theta H0 : 1
Direction upper : TRUE
pi (1) : 0.200, 0.300, 0.400, 0.500
pi (2) : 0.200
Planned allocation ratio : 1
Event time : 12
Accrual time : 12
kappa : 1
Drop-out rate (1) : 0.000
Drop-out rate (2) : 0.000
Drop-out time : 12

Sample size and output:
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
Accrual intensity : 206.7
Follow up time : -5.85, -6.58, -7.16, -7.64
Analysis times [1] : 3.52, 3.10, 2.76, 2.48
Analysis times [2] : 5.00, 4.40, 3.93, 3.54
Expected study duration : 4.68, 4.89, 4.12, 3.35
Maximal study duration : 6.15, 5.42, 4.84, 4.36
Number of events by stage [1] : 23.3
Number of events by stage [2] : 46.7
```
## Number of events by stage [3]: 70.0
## Expected number of events: 43.6, 58.7, 52.2, 42.9
## Number of subjects [1]: 728.0, 640.1, 570.7, 512.6
## Number of subjects [2]: 1034.3, 910.2, 812.5, 730.9
## Number of subjects [3]: 1271.2, 1119.4, 1000.2, 900.8
## Expected number of subjects: 968.2, 1009.9, 852.0, 692.5
## Reject per stage [1]: 0.000259, 0.009685, 0.070677, 0.231595
## Reject per stage [2]: 0.006876, 0.187578, 0.575128, 0.689890
## Reject per stage [3]: 0.016709, 0.279572, 0.272079, 0.072816
## Overall reject: 0.0238, 0.4768, 0.9179, 0.9943
## Futility stop per stage [1]: 0.5000000, 0.1286563, 0.0227326, 0.0030955
## Futility stop per stage [2]: 0.1250000, 0.0190142, 0.0009094, 0.0000223
## Futility stop: 0.62500, 0.14767, 0.02364, 0.00312
## Early stop: 0.632, 0.345, 0.669, 0.925
## Critical values (effect scale) [1]: 4.209
## Critical values (effect scale) [2]: 2.052
## Critical values (effect scale) [3]: 1.615
## Local one-sided significance levels [1]: 0.0002592
## Local one-sided significance levels [2]: 0.0070554
## Local one-sided significance levels [3]: 0.0225331
## Futility bounds (effect scale) [1]: 1.000
## Futility bounds (effect scale) [2]: 1.000
## Futility bounds (1-sided p-value scale) [1]: 0.5000
## Futility bounds (1-sided p-value scale) [2]: 0.5000
## Legend:
## (i): values of treatment arm i
## [k]: values at stage k

```r
plot(powerSurvival, type = 1, showSource = TRUE)
```

## Source data of the plot:
## x-axis: powerSurvival$eventsPerStage
## y-axes:
## y1: powerSurvival$futilityBounds
## y2: powerSurvival$criticalValues

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### Boundaries Z Scale

- **Critical value**
- **Futility bound (non-binding)**

$qnorm(1-0.025) = 1.96$

```r
plot(powerSurvival, type = 2, showSource = TRUE)

## Source data of the plot:
## x-axis: powerSurvival$eventsPerStage
## y-axes:
##   y1: powerSurvival$criticalValuesEffectScaleUpper[, 1]
##   y2: powerSurvival$futilityBoundsEffectScale[, 1]
```
3.3 Power survival (survival endpoint)

**Boundaries Effect Scale**

Maximum number of events = 70, H0: hazard ratio = 1, allocation ratio = 1

![Graph showing boundaries effect scale with critical value and futility bound.]

```r
plot(powerSurvival, type = 3, showSource = TRUE)
```

## Source data of the plot:

- **x-axis:** powerSurvival$eventsPerStage[, 1]
- **y-axis:** powerSurvival$.design$stageLevels
### Boundaries p Values Scale

<table>
<thead>
<tr>
<th>Stage Level</th>
<th>Boundaries</th>
<th>p Values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.005</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.010</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.015</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.020</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.025</td>
<td></td>
</tr>
</tbody>
</table>

```r
plot(powerSurvival, type = 4, showSource = TRUE)
```

---

```r
# Source data of the plot:
# x-axis: powerSurvival$eventsPerStage[, 1]
# y-axis: powerSurvival$.design$alphaSpent
```
Type One Error Spending

```
plot(powerSurvival, type = 5, legendPosition = 5,
     showSource = TRUE)
```
### Overall Power and Early Stopping

Maximum number of events = 70, H0: hazard ratio = 1, allocation ratio = 1

#### Source data of the plot:
- **x-axis:** `powerSurvival$hazardRatio`
- **y-axes:**
  - **y1:** `powerSurvival$expectedNumberOfEvents`
  - **y2:** `powerSurvival$overallReject`
  - **y3:** `powerSurvival$earlyStop`
Expected Number of Events and Power / Early Stop

Maximum number of events = 70, H0: hazard ratio = 1, allocation ratio = 1

```
plot(powerSurvival, type = 7, showSource = TRUE)

## Source data of the plot:
## x-axis: powerSurvival$hazardRatio
## y-axis: powerSurvival$overallReject
```
3.3 Power survival (survival endpoint)

### Overall Power

Maximum number of events = 70, H0: hazard ratio = 1, allocation ratio = 1

```r
plot(powerSurvival, type = 8, showSource = TRUE)
```

---

**Source data of the plot:**
- **x-axis:** `powerSurvival$hazardRatio`
- **y-axes:**
  - `y1`: `powerSurvival$earlyStop`
  - `y2`: `powerSurvival$futilityStop`
3.3 Power survival (survival endpoint)

Overall Early Stopping

Maximum number of events = 70, H0: hazard ratio = 1, allocation ratio = 1

plot(powerSurvival, type = 9, showSource = TRUE)

# Source data of the plot:
# x-axis: powerSurvival$hazardRatio
# y-axis: powerSurvival$expectedNumberOfEvents
Expected Number of Events

Maximum number of events = 70, H0: hazard ratio = 1, allocation ratio = 1

plot(powerSurvival, type = 10, showSource = TRUE)

## Source data of the plot:
## x-axis: powerSurvival$hazardRatio
## y-axis: powerSurvival$studyDuration
3.3 Power survival (survival endpoint) 3 POWER PLOTS

Study Duration

Maximum number of events = 70, maximum number of subjects = 2480, H0: hazard ratio = 1, allocation ratio

```
plot(powerSurvival, type = 11, showSource = TRUE)
```

## Source data of the plot:
## x-axis: powerSurvival$hazardRatio
## y-axis: powerSurvival$expectedNumberOfSubjects
Expected Number of Subjects

Maximum number of events = 70, maximum number of subjects = 2480, H0: hazard ratio = 1, allocation

```
plot(powerSurvival, type = 12, showSource = TRUE)
```

## Source data of the plot:
## x-axis: powerSurvival$hazardRatio
## y-axis: powerSurvival$analysisTime
3.3 Power survival (survival endpoint)

Analysis Times

maximum number of events = 70, maximum number of subjects = 2480, H0: hazard ratio = 1, allocation ratio = 1

3.3.2 Power for a piecewise exponential survival distribution

design <- getDesignGroupSequential(kMax = 3, typeOfDesign = "OF", sided = 2, twoSidedPower = TRUE)
design

## Design parameters and output of group sequential design:
##
## User defined parameters:
##   Two-sided power: TRUE
##   Test: two-sided
##
## Derived from user defined parameters: not available
##
## Default parameters:
##   Type of design: OF
##   Maximum number of stages: 3
##   Information rates: 0.333, 0.667, 1.000
##   Significance level: 0.0250
##   Type II error rate: 0.2
##   Tolerance: 0.0000001
##
## Output:
##   Cumulative alpha spending: 0.00008313, 0.00542677, 0.02500000
##   Critical values: 3.935, 2.783, 2.272
##   Stage levels: 0.00004156, 0.00269624, 0.01154368
## ISSUES (parameters with undefined type):
## Stages : 1, 2, 3

```r
piecewiseSurvivalTime <- list(
  "<5" = 0.04,
  "5 - <10" = 0.02,
  ">=10" = 0.008)
```

```r
powerSurvival1 <- getPowerSurvival(design = design, typeOfComputation = "Schoenfeld",
                                   thetaH0 = 1,
                                   allocationRatioPlanned = 1, kappa = 1,
                                   piecewiseSurvivalTime = piecewiseSurvivalTime,
                                   maxNumberOfSubjects = 2480, maxNumberOfEvents = 70,
                                   hazardRatio = c(0.5, 2))
```

## Design plan parameters and output for survival data:
##
## Design parameters:
## Significance level : 0.0250
## Test : two-sided

## User defined parameters:
## Direction upper : NA
## lambda (2) : 0.040, 0.020, 0.008
## Hazard ratio : 0.500, 2.000
## Maximum number of subjects : 2480.0
## Maximum number of events : 70.0
## Piecewise survival times : 0.00, 5.00, 10.00

## Default parameters:
## Type of computation : Schoenfeld
## Theta H0 : 1
## Planned allocation ratio : 1
## Accrual time : 12
## kappa : 1
## Drop-out rate (1) : 0.000
## Drop-out rate (2) : 0.000
## Drop-out time : 12

## Sample size and output:
## Accrual intensity : 206.7
## Follow up time : -7.12, -8.51
## Analysis times [1] : 2.79, 1.98
## Analysis times [2] : 3.97, 2.83
## Expected study duration : 4.56, 3.26
## Maximal study duration : 4.88, 3.49
## Number of events by stage [1] : 23.3
## Number of events by stage [2] : 46.7
## Number of events by stage [3] : 70.0
## Expected number of events : 61.8, 61.8
## Number of subjects [1] : 575.8, 409.7
## Number of subjects [2] : 819.5, 584.7
## Number of subjects [3] : 1008.6, 721.2
### 3.3 Power survival (survival endpoint)

---

```r
## Expected number of subjects : 941.5, 672.8
## Reject per stage [1] : 0.0119, 0.0119
## Reject per stage [2] : 0.3275, 0.3275
## Reject per stage [3] : 0.3999, 0.3999
## Overall reject : 0.739, 0.739
## Early stop : 0.339, 0.339
## Lower critical values (effect scale) [1] : 0.196
## Lower critical values (effect scale) [2] : 0.443
## Lower critical values (effect scale) [3] : 0.581
## Upper critical values (effect scale) [1] : 5.100
## Upper critical values (effect scale) [2] : 2.258
## Upper critical values (effect scale) [3] : 1.721
## Local two-sided significance levels [1] : 0.00008313
## Local two-sided significance levels [2] : 0.00539247
## Local two-sided significance levels [3] : 0.02308736

plot(powerSurvival1, type = 1)

plot(powerSurvival1, type = 2)
```

---

---
Boundaries Effect Scale

Maximum number of events = 70, H0: hazard ratio = 1, allocation ratio = 1

plot(powerSurvival1, type = 3)
3.3 Power survival (survival endpoint)

```
plot(powerSurvival1, type = 4)
```
Type One Error Spending

Cumulative Error (Cumulative Alpha Spending)

plot(powerSurvival1, type = 5, legendPosition = 1)
3.3 Power survival (survival endpoint)

Overall Power and Early Stopping

Maximum number of events = 70, H0: hazard ratio = 1, allocation ratio = 1

plot(powerSurvival1, type = 6)
3.3 Power survival (survival endpoint)

Expected Number of Events and Power / Early Stop

Maximum number of events = 70, H0: hazard ratio = 1, allocation ratio = 1

plot(powerSurvival1, type = 7)
3.3 Power survival (survival endpoint)

Overall Power

Maximum number of events = 70, H0: hazard ratio = 1, allocation ratio = 1

plot(powerSurvival1, type = 8)
3.3 Power survival (survival endpoint)

Overall Early Stopping

Maximum number of events = 70, H0: hazard ratio = 1, allocation ratio = 1

plot(powerSurvival1, type = 9)
3.3 Power survival (survival endpoint) 3 POWER PLOTS

Expected Number of Events

Maximum number of events = 70, H0: hazard ratio = 1, allocation ratio = 1

plot(powerSurvival1, type = 10)
3.3 Power survival (survival endpoint) 3 POWER PLOTS

\[ \text{Maximum number of events } = 70, \text{ maximum number of subjects } = 2480, \ H_0: \text{hazard ratio } = 1, \ \text{allocation ratio} \]

\[
\text{Expected Study Duration} = \frac{\text{Maximum number of events}}{\text{Hazard Ratio}} \\
\text{Study Duration} = \frac{\text{Maximum number of subjects}}{\text{Hazard Ratio}} \\
\]

\[
\text{plot}(\text{powerSurvival1, type = 11})
\]
3.3 Power survival (survival endpoint)

Expected Number of Subjects

Maximum number of events = 70, maximum number of subjects = 2480, H0: hazard ratio = 1, allocation

plot(powerSurvival1, type = 12)
Analysis Times

Maximum number of events = 70, maximum number of subjects = 2480, H0: hazard ratio = 1, allocation ratio = 1

```r
plot(powerSurvival1, type = 13, legendPosition = 1)
```

## Warning: Only the first 'hazardRatio' (0.5) was used for plotting
3.3 Power survival (survival endpoint)

```
plot(powerSurvival1, type = 14, legendPosition = 5)
```

## Warning: Only the first 'hazardRatio' (0.5) was used for plotting
3.3 Power survival (survival endpoint)

3.3.3 Power for a piecewise exponential survival distribution and a design with futility bounds

design <- getDesignGroupSequential(typeOfDesign = "OF", sided = 1, futilityBounds = c(0, 0.1))

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

powerSurvival2 <- getPowerSurvival(design = design, typeOfComputation = "Schoenfeld",
                                     thetaH0 = 1,
                                     allocationRatioPlanned = 1, kappa = 1,
                                     piecewiseSurvivalTime = piecewiseSurvivalTime,
                                     maxNumberOfSubjects = 2480, maxNumberOfEvents = 70,
                                     hazardRatio = 0.8)

powerSurvival2

## Design plan parameters and output for survival data:
##
## Design parameters:
##  Significance level : 0.0250
##  Test : one-sided
##
## User defined parameters:
---

### 3.3 Power survival (survival endpoint)

| **## lambda (2)** | : 0.025, 0.040, 0.015, 0.010, 0.007 |
| **Hazard ratio** | : 0.800 |
| **Maximum number of subjects** | : 2480.0 |
| **Maximum number of events** | : 70.0 |
| **Piecewise survival times** | : 0.00, 6.00, 9.00, 15.00, 21.00 |

### Default parameters:

| **Type of computation** | : Schoenfeld |
| **Theta H0** | : 1 |
| **Direction upper** | : TRUE |
| **Planned allocation ratio** | : 1 |
| **Accrual time** | : 12 |
| **kappa** | : 1 |
| **Drop-out rate (1)** | : 0.000 |
| **Drop-out rate (2)** | : 0.000 |
| **Drop-out time** | : 12 |

### Sample size and output:

| **lambda (1)** | : 0.0200, 0.0320, 0.0120, 0.0080, 0.0056 |
| **Accrual intensity** | : 206.7 |
| **Follow up time** | : -6.40 |
| **Analysis times [1]** | : 3.21 |
| **Analysis times [2]** | : 4.56 |
| **Analysis times [3]** | : 5.60 |
| **Expected study duration** | : 3.75 |
| **Maximal study duration** | : 5.60 |
| **Number of events by stage [1]** | : 23.3 |
| **Number of events by stage [2]** | : 46.7 |
| **Number of events by stage [3]** | : 70.0 |
| **Expected number of events** | : 33.5 |
| **Number of subjects [1]** | : 662.7 |
| **Number of subjects [2]** | : 941.9 |
| **Number of subjects [3]** | : 1158.1 |
| **Expected number of subjects** | : 775.2 |
| **Reject per stage [1]** | : 0.0000304 |
| **Reject per stage [2]** | : 0.0006345 |
| **Reject per stage [3]** | : 0.0012773 |
| **Overall reject** | : 0.00194 |
| **Futility stop per stage [1]** | : 0.705 |
| **Futility stop per stage [2]** | : 0.155 |
| **Futility stop** | : 0.86 |
| **Early stop** | : 0.861 |
| **Critical values (effect scale) [1]** | : 4.209 |
| **Critical values (effect scale) [2]** | : 2.052 |
| **Critical values (effect scale) [3]** | : 1.615 |
| **Local one-sided significance levels [1]** | : 0.0002592 |
| **Local one-sided significance levels [2]** | : 0.0070554 |
| **Local one-sided significance levels [3]** | : 0.0225331 |
| **Futility bounds (effect scale) [1]** | : 1.000 |
| **Futility bounds (effect scale) [2]** | : 1.030 |
| **Futility bounds (1-sided p-value scale) [1]** | : 0.5000 |
| **Futility bounds (1-sided p-value scale) [2]** | : 0.4602 |

### Legend:
3.3 Power survival (survival endpoint)

```r
# (i): values of treatment arm i  
# [k]: values at stage k  
plot(powerSurvival2, type = 1)
```

![Boundaries Z Scale](image)

```r
plot(powerSurvival2, type = 2)
```
Boundaries Effect Scale

Maximum number of events = 70, H0: hazard ratio = 1, allocation ratio = 1

- Critical value
- Futility bound (non-binding)

plot(powerSurvival2, type = 3)
3.3 Power survival (survival endpoint)  

```
plot(powerSurvival2, type = 4)
```
Type One Error Spending

Cumulative Error (Cumulative Alpha Spending)

# Events By Stage

plot(powerSurvival2, type = 13, legendPosition = 1)
3.3 Power survival (survival endpoint) 3 POWER PLOTS

Cumulative Distribution Function

Hazard Ratio = 0.8

plot(powerSurvival2, type = 14)
3.3 Power survival (survival endpoint)

\[ \text{Survival Function} \]

Hazard Ratio = 0.8

\begin{center}
\begin{tikzpicture}
\begin{axis}[
    title = \text{Survival Function},
    xlabel = \text{Time},
    ylabel = \text{Survival Function},
    xmin = 0, xmax = 30,
    ymin = 0, ymax = 1,
    xtick = {0, 10, 20, 30},
    ytick = {0.25, 0.50, 0.75, 1.00},
    legend style = {at = {(0.5, 0.97)}, anchor = north west},
    legend entries = {Control piecew. exp., Control piecew. lambda, Treatm. piecew. exp., Treatm. piecew. lambda}
]\end{axis}\end{tikzpicture}
\end{center}

\begin{verbatim}
design <- getDesignGroupSequential(typeOfDesign = "OF", sided = 1, futilityBounds = c(0, 0.1))

powerSurvival3 <- getPowerSurvival(design = design, typeOfComputation = "Schoenfeld",
    thetaH0 = 1,
    allocationRatioPlanned = 1, kappa = 1,
    piecewiseSurvivalTime = c(0, 5, 10),
    lambda2 = c(0.025, 0.04, 0.015),
    lambda1 = c(0.02, 0.032, 0.012),
    maxNumberOfSubjects = 2480, maxNumberOfEvents = 70,
    hazardRatio = 0.8)

## Warning: 'hazardRatio' (0.8) will be ignored because it will be calculated

powerSurvival3

## Design plan parameters and output for survival data:
##
## Design parameters:
## Significance level : 0.0250
## Test : one-sided
##
## User defined parameters:
## lambda (2) : 0.025, 0.040, 0.015
## Maximum number of subjects : 2480.0
## Maximum number of events : 70.0
## Piecewise survival times : 0.00, 5.00, 10.00
##
\end{verbatim}
3.3 Power survival (survival endpoint)

## Default parameters:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of computation</td>
<td>Schoenfeld</td>
</tr>
<tr>
<td>Theta H0</td>
<td>1</td>
</tr>
<tr>
<td>Direction upper</td>
<td>TRUE</td>
</tr>
<tr>
<td>Planned allocation ratio</td>
<td>1</td>
</tr>
<tr>
<td>Accrual time</td>
<td>12</td>
</tr>
<tr>
<td>kappa</td>
<td>1</td>
</tr>
<tr>
<td>Drop-out rate (1)</td>
<td>0.000</td>
</tr>
<tr>
<td>Drop-out rate (2)</td>
<td>0.000</td>
</tr>
<tr>
<td>Drop-out time</td>
<td>12</td>
</tr>
</tbody>
</table>

## Sample size and output:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>lambda (1)</td>
<td>0.020, 0.032, 0.012</td>
</tr>
<tr>
<td>Hazard ratio</td>
<td>0.800</td>
</tr>
<tr>
<td>Accrual intensity</td>
<td>206.7</td>
</tr>
<tr>
<td>Follow up time</td>
<td>-6.41</td>
</tr>
<tr>
<td>Analysis times [1]</td>
<td>3.21</td>
</tr>
<tr>
<td>Analysis times [2]</td>
<td>4.56</td>
</tr>
<tr>
<td>Analysis times [3]</td>
<td>5.59</td>
</tr>
<tr>
<td>Expected study duration</td>
<td>3.75</td>
</tr>
<tr>
<td>Maximal study duration</td>
<td>5.59</td>
</tr>
<tr>
<td>Number of events by stage [1]</td>
<td>23.3</td>
</tr>
<tr>
<td>Number of events by stage [2]</td>
<td>46.7</td>
</tr>
<tr>
<td>Number of events by stage [3]</td>
<td>70.0</td>
</tr>
<tr>
<td>Expected number of events</td>
<td>33.5</td>
</tr>
<tr>
<td>Number of subjects [1]</td>
<td>662.7</td>
</tr>
<tr>
<td>Number of subjects [2]</td>
<td>941.9</td>
</tr>
<tr>
<td>Number of subjects [3]</td>
<td>1154.5</td>
</tr>
<tr>
<td>Expected number of subjects</td>
<td>774.7</td>
</tr>
<tr>
<td>Reject per stage [1]</td>
<td>0.000304</td>
</tr>
<tr>
<td>Reject per stage [2]</td>
<td>0.0006345</td>
</tr>
<tr>
<td>Reject per stage [3]</td>
<td>0.0012773</td>
</tr>
<tr>
<td>Overall reject</td>
<td>0.00194</td>
</tr>
<tr>
<td>Futility stop per stage [1]</td>
<td>0.705</td>
</tr>
<tr>
<td>Futility stop per stage [2]</td>
<td>0.155</td>
</tr>
<tr>
<td>Futility stop</td>
<td>0.86</td>
</tr>
<tr>
<td>Early stop</td>
<td>0.861</td>
</tr>
<tr>
<td>Critical values (effect scale) [1]</td>
<td>4.209</td>
</tr>
<tr>
<td>Critical values (effect scale) [2]</td>
<td>2.052</td>
</tr>
<tr>
<td>Critical values (effect scale) [3]</td>
<td>1.615</td>
</tr>
<tr>
<td>Local one-sided significance levels [1]</td>
<td>0.0002592</td>
</tr>
<tr>
<td>Local one-sided significance levels [2]</td>
<td>0.0070554</td>
</tr>
<tr>
<td>Local one-sided significance levels [3]</td>
<td>0.0225331</td>
</tr>
<tr>
<td>Futility bounds (effect scale) [1]</td>
<td>1.000</td>
</tr>
<tr>
<td>Futility bounds (effect scale) [2]</td>
<td>1.030</td>
</tr>
<tr>
<td>Futility bounds (1-sided p-value scale) [1]</td>
<td>0.5000</td>
</tr>
<tr>
<td>Futility bounds (1-sided p-value scale) [2]</td>
<td>0.4602</td>
</tr>
</tbody>
</table>

## Legend:

- (i): values of treatment arm i
- [k]: values at stage k

plot(powerSurvival3, type = 1)
3.3 Power survival (survival endpoint) 3 POWER PLOTS

![Boundaries Z Scale](image)

- **Critical value**
- **Futility bound (non-binding)**

\[ qnorm(1 - 0.025) = 1.96 \]

\[ \text{# Events By Stage} \]

```
plot(powerSurvival3, type = 2)
```
3.3 Power survival (survival endpoint)  

**Boundaries Effect Scale**

Maximum number of events = 70, H0: hazard ratio = 1, allocation ratio = 1

- Critical value
- Futility bound (non-binding)

```r
plot(powerSurvival3, type = 3)
```
3.3 Power survival (survival endpoint)

![Boundary p Values Scale](image)

```r
plot(powerSurvival3, type = 4)
```
3.3 Power survival (survival endpoint)  

Type One Error Spending

```r
plot(powerSurvival3, type = 13, legendPosition = 1)
```
Cumulative Distribution Function

Hazard Ratio = 0.8

- Control piecew. exp.
- Control piecew. lambda
- Treatm. piecew. exp.
- Treatm. piecew. lambda

plot(powerSurvival2, type = 14)
3.3 Power survival (survival endpoint)

### 3.3.4 Power survival for one lambda

```r
powerSurvival4 <- getPowerSurvival(
  accrualTime = 12,
  lambda2 = 0.04,
  hazardRatio = 0.6,
  maxNumberOfSubjects = 1400,
  maxNumberOfEvents = 300)
```

```r
powerSurvival4
```

```r
## Design plan parameters and output for survival data:
##
## Design parameters:
## Significance level : 0.0250
## Test : one-sided
##
## User defined parameters:
## lambda (2) : 0.040
## Hazard ratio : 0.600
## Maximum number of subjects : 1400.0
## Number of events : 300.0
##
## Default parameters:
## Type of computation : Schoenfeld
## Theta H0 : 1
## Direction upper : TRUE
```
## Planned allocation ratio : 1
## Event time : 12
## Accrual time : 12.00
## kappa : 1
## Piecewise survival times : 0.00
## Drop-out rate (1) : 0.000
## Drop-out rate (2) : 0.000
## Drop-out time : 12
## Sample size and output:
## pi (1) : 0.250
## pi (2) : 0.381
## median (1) : 28.9
## median (2) : 17.3
## lambda (1) : 0.024
## Accrual intensity : 116.7
## Follow up time : 1.79
## Analysis times : 13.79
## Study duration : 13.79
## Expected number of events : 300.0
## Expected number of subjects : 1400.0
## Overall reject : 0
## Critical values (effect scale) : 1.254
## Local one-sided significance levels : 0.0250
## Legend:
## (i): values of treatment arm i

plot(powerSurvival4, type = 13, legendPosition = 1)
Cumulative Distribution Function

\[ \Lambda_1 = 0.024, \; \Lambda_2 = 0.04 \]

- Control piecew. exp.
- Control piecew. lambda
- Treatm. piecew. exp.
- Treatm. piecew. lambda

plot(powerSurvival4, type = 14, legendPosition = 5)
3.3 Power survival (survival endpoint)

3.3.5 Power survival for default \( \pi_1 \) and \( \pi_2 \)

```r
powerSurvival5 <- getPowerSurvival(
  maxNumberOfSubjects = 1400,
  maxNumberOfEvents = 300)
```

```
## Design plan parameters and output for survival data:
##
## Design parameters:
## Significance level : 0.0250
## Test : one-sided
##
## User defined parameters:
## Maximum number of subjects : 1400.0
## Number of events : 300.0
##
## Default parameters:
## Type of computation : Schoenfeld
## Theta H0 : 1
## Direction upper : TRUE
## \pi (1) : 0.200, 0.300, 0.400, 0.500
## \pi (2) : 0.200
## Planned allocation ratio : 1
## Event time : 12
## Accrual time : 12
```
3.3 Power survival (survival endpoint) 3 POWER PLOTS

## kappa
: 1
## Drop-out rate (1)
: 0.000
## Drop-out rate (2)
: 0.000
## Drop-out time
: 12

## Sample size and output:
## 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
## Accrual intensity
: 116.7
## Follow up time
: 7.08, 4.20, 2.24, 0.81
## Analysis times
: 19.08, 16.20, 14.24, 12.81
## Study duration
: 19.08, 16.20, 14.24, 12.81
## Expected number of events
: 300.0, 300.0, 300.0, 300.0
## Expected number of subjects
: 1400.0, 1400.0, 1400.0, 1400.0
## Overall reject
: 0.025, 0.982, 1.000, 1.000
## Critical values (effect scale)
: 1.254
## Local one-sided significance levels
: 0.0250

## Legend:
## (i): values of treatment arm i

```
plot(powerSurvival5, type = 13, legendPosition = 1)
```

## Warning: Only the first 'pi1' (0.2) was used for plotting
### Simulation plots

```r
simulationResults1 <- getSimulationSurvival(
  accrualTime = 12,
  maxNumberOfSubjects = 1405,
  plannedEvents = 300, maxNumberOfIterations = 1000,
  seed = 12345)
simulationResults1
```

## Simulation of survival data (group sequential design):

## User defined parameters:

## Maximum number of subjects : 1405.0
## Planned events : 300
## Seed : 12345

## Default parameters:

## Accrual time : 12.00
## pi (1) : 0.200, 0.300, 0.400, 0.500
## pi (2) : 0.200
## Planned allocation ratio : 1
### 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

### Results:
### Accrual intensity : 117.1
### median (1) : 37.3, 23.3, 16.3, 12.0
### median (2) : 0.0186, 0.0297, 0.0426, 0.0578
### lambda (1) : 0.0186
### lambda (2) : 0.0186
### Hazard ratio : 1.000, 1.598, 2.289, 3.106
### Iterations : 1000, 1000, 1000, 1000
### Analysis times : 18.99, 16.15, 14.20, 12.78
### Expected study duration : 18.99, 16.15, 14.20, 12.78
### Expected number of events : 300.0, 300.0, 300.0, 300.0
### Expected number of subjects : 1405.0, 1405.0, 1405.0, 1404.9
### Overall reject : 0.021, 0.982, 1.000, 1.000
### Futility stop : 0, 0, 0, 0
### Early stop : 0, 0, 0, 0

### Simulated data:
### Analysis times [1], pi1 = 0.2 : median [range]: 18.993 [16.687 - 21.531]; mean +/-sd: 18.992 +/-0.744
### Analysis times [1], pi1 = 0.3 : median [range]: 16.111 [14.772 - 18.612]; mean +/-sd: 16.145 +/-0.548
### Analysis times [1], pi1 = 0.4 : median [range]: 14.184 [12.933 - 16.137]; mean +/-sd: 14.195 +/-0.463
### Analysis times [1], pi1 = 0.5 : median [range]: 12.77 [11.6 - 13.831]; mean +/-sd: 12.782 +/-0.344
### Number of subjects [1], pi1 = 0.2 : median [range]: 1405 [1405 - 1405]; mean +/-sd: 1405 +/-0
### Number of subjects [1], pi1 = 0.3 : median [range]: 1405 [1405 - 1405]; mean +/-sd: 1405 +/-0
### Number of subjects [1], pi1 = 0.4 : median [range]: 1405 [1405 - 1405]; mean +/-sd: 1405 +/-0
### Number of subjects [1], pi1 = 0.5 : median [range]: 1405 [1358 - 1405]; mean +/-sd: 1404.88 +/-1.778
### Observed # events by stage (1) [1], pi1 = 0.2 : median [range]: 151 [125 - 175]; mean +/-sd: 150.17 +/-7.641
### Observed # events by stage (1) [1], pi1 = 0.3 : median [range]: 181 [153 - 206]; mean +/-sd: 180.688 +/-7.482
### Observed # events by stage (1) [1], pi1 = 0.4 : median [range]: 202 [179 - 224]; mean +/-sd: 201.754 +/-7.446
### Observed # events by stage (1) [1], pi1 = 0.5 : median [range]: 219 [195 - 241]; mean +/-sd: 218.536 +/-6.953
### Observed # events by stage (1) [1], pi1 = 0.6 : median [range]: 238 [214 - 261]; mean +/-sd: 237.464 +/-6.491
### Observed # events by stage (1) [1], pi1 = 0.7 : median [range]: 252 [229 - 274]; mean +/-sd: 251.526 +/-6.463
### Observed # events by stage (1) [1], pi1 = 0.8 : median [range]: 266 [243 - 287]; mean +/-sd: 265.469 +/-6.435
### Observed # events by stage (1) [1], pi1 = 0.9 : median [range]: 278 [255 - 297]; mean +/-sd: 277.526 +/-6.408
### Observed # events by stage (1) [1], pi1 = 1.0 : median [range]: 290 [266 - 311]; mean +/-sd: 289.526 +/-6.381
### Number of events by stage [1], pi1 = 0.2 : median [range]: 300 [300 - 301]; mean +/-sd: 300.001 +/-0.032
### Number of events by stage [1], pi1 = 0.3 : median [range]: 300 [300 - 300]; mean +/-sd: 300 +/-0
### Number of events by stage [1], pi1 = 0.4 : median [range]: 300 [300 - 300]; mean +/-sd: 300 +/-0
### Number of events by stage [1], pi1 = 0.5 : median [range]: 300 [300 - 300]; mean +/-sd: 300 +/-0
### Number of events by stage [1], pi1 = 0.6 : median [range]: 300 [300 - 300]; mean +/-sd: 300 +/-0
### Number of events by stage [1], pi1 = 0.7 : median [range]: 300 [300 - 300]; mean +/-sd: 300 +/-0
### Number of events by stage [1], pi1 = 0.8 : median [range]: 300 [300 - 300]; mean +/-sd: 300 +/-0
### Number of events by stage [1], pi1 = 0.9 : median [range]: 300 [300 - 300]; mean +/-sd: 300 +/-0
### Number of events by stage [1], pi1 = 1.0 : median [range]: 300 [300 - 300]; mean +/-sd: 300 +/-0
### Test statistic [1], pi1 = 0.2 : median [range]: 0.055 [-3.288 - 3.32]; mean +/-sd: 0.011 +/-1.001
### Test statistic [1], pi1 = 0.3 : median [range]: 4.036 [0.42 - 7.244]; mean +/-sd: 4.048 +/-0.993
### Test statistic [1], pi1 = 0.4 : median [range]: 6.913 [3.854 - 9.992]; mean +/-sd: 6.901 +/-0.987
### Test statistic [1], pi1 = 0.5 : median [range]: 9.249 [5.979 - 12.189]; mean +/-sd: 9.245 +/-0.934
## Simulation Plots

### Log-rank statistic [1], \( \pi_1 = 0.2 \)
- Median [range]: \(0.055 \, [\, -3.288 \, - 3.32\,]\)
- Mean +/-SD: \(0.011 +/- 1.001\)

### Log-rank statistic [1], \( \pi_1 = 0.3 \)
- Median [range]: \(4.036 \, [\, 0.42 \, - 7.244\,]\)
- Mean +/-SD: \(4.048 +/- 0.993\)

### Log-rank statistic [1], \( \pi_1 = 0.4 \)
- Median [range]: \(6.913 \, [\, 3.854 \, - 9.992\,]\)
- Mean +/-SD: \(6.901 +/- 0.987\)

### Log-rank statistic [1], \( \pi_1 = 0.5 \)
- Median [range]: \(9.249 \, [\, 5.979 \, - 12.189\,]\)
- Mean +/-SD: \(9.245 +/- 0.934\)

### Hazard ratio estimate LR [1], \( \pi_1 = 0.2 \)
- Median [range]: \(1.006 \, [\, 0.684 \, - 1.467\,]\)
- Mean +/-SD: \(1.008 +/- 0.116\)

### Hazard ratio estimate LR [1], \( \pi_1 = 0.3 \)
- Median [range]: \(1.594 \, [\, 1.05 \, - 2.308\,]\)
- Mean +/-SD: \(1.606 +/- 0.185\)

### Hazard ratio estimate LR [1], \( \pi_1 = 0.4 \)
- Median [range]: \(2.222 \, [\, 1.56 \, - 3.17\,]\)
- Mean +/-SD: \(2.233 +/- 0.253\)

### Hazard ratio estimate LR [1], \( \pi_1 = 0.5 \)
- Median [range]: \(2.909 \, [\, 1.994 \, - 4.086\,]\)
- Mean +/-SD: \(2.925 +/- 0.316\)

### Legend:
- \((i)\): values of treatment arm \(i\)

```r
plot(simulationResults1, type = 5, showSource = TRUE)
```

### Overall Power and Early Stopping

#### Source data of the plot:
- **x-axis:** `simulationResults1$hazardRatio`
- **y-axes:**
  - `simulationResults1$expectedNumberOfEvents`
  - `simulationResults1$overallReject`
  - `simulationResults1$earlyStop`

```r
plot(simulationResults1, type = 6, showSource = TRUE)
```
Expected Number of Events and Power / Early Stop

**Plot**

```r
plot(simulationResults1, type = 7, showSource = TRUE)
```

**Source data of the plot:**

- **x-axis**: `simulationResults1$hazardRatio`
- **y-axis**: `simulationResults1$overallReject`
plot(simulationResults1, type = 8, showSource = TRUE)

## Source data of the plot:
## x-axis: simulationResults1$hazardRatio
## y-axes:
## y1: simulationResults1$earlyStop
## y2: simulationResults1$futilityStop
plot(simulationResults1, type = 9, showSource = TRUE)

## Source data of the plot:
## x-axis: simulationResults1$hazardRatio
## y-axis: simulationResults1$expectedNumberOfEvents
plot(simulationResults1, type = 10, showSource = TRUE)

## Source data of the plot:
## x-axis: simulationResults1$hazardRatio
## y-axis: simulationResults1$studyDuration
plot(simulationResults1, type = 11, showSource = TRUE)

## Source data of the plot:
## x-axis: simulationResults1$hazardRatio
## y-axis: simulationResults1$expectedNumberOfSubjects
plot(simulationResults1, type = 12, showSource = TRUE)

## Source data of the plot:
## x-axis: simulationResults1$hazardRatio
## y-axis: simulationResults1$analysisTime
plot(simulationResults1, type = 13)

## Warning: Only the first 'pi1' (0.2) was used for plotting
Cumulative Distribution Function

$P_{i1} = 0.2, \, P_{i2} = 0.2$

plot(simulationResults1, type = 14)

## Warning: Only the first 'pi1' (0.2) was used for plotting
Survival Function

\[ \pi_1 = 0.2, \pi_2 = 0.2 \]

Simulation Results 2

```r
simulationResults2 <- getSimulationSurvival(
    accrualTime = 12,
    lambda2 = 0.03,
    hazardRatio = 0.8,
    maxNumberOfSubjects = 1405,
    plannedEvents = 300,
    maxNumberOfIterations = 1000,
    seed = 23456)
```

## Simulation of survival data (group sequential design):

## User defined parameters:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum number of subjects</td>
<td>1405.0</td>
</tr>
<tr>
<td>Planned events</td>
<td>300</td>
</tr>
<tr>
<td>lambda (2)</td>
<td>0.030</td>
</tr>
<tr>
<td>Hazard ratio</td>
<td>0.800</td>
</tr>
<tr>
<td>Seed</td>
<td>23456</td>
</tr>
</tbody>
</table>

## Default parameters:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accrual time</td>
<td>12.00</td>
</tr>
<tr>
<td>Planned allocation ratio</td>
<td>1</td>
</tr>
<tr>
<td>Direction upper</td>
<td>TRUE</td>
</tr>
<tr>
<td>Drop-out rate (1)</td>
<td>0.000</td>
</tr>
<tr>
<td>Drop-out rate (2)</td>
<td>0.000</td>
</tr>
<tr>
<td>Drop-out time</td>
<td>12</td>
</tr>
<tr>
<td>Event time</td>
<td>12</td>
</tr>
<tr>
<td>Theta H0</td>
<td>1</td>
</tr>
</tbody>
</table>
## Allocation 1 : 1
## Allocation 2 : 1
## Conditional power : NA
## Maximum number of iterations : 1000
## kappa : 1

## Results:
## Accrual intensity : 117.1
## pi (1) : 0.250
## pi (2) : 0.302
## median (1) : 28.9
## median (2) : 23.1
## lambda (1) : 0.024
## Iterations : 1000
## Analysis times : 15.09
## Expected study duration : 15.09
## Expected number of events : 300.0
## Events not achieved : 0
## Expected number of subjects : 1405.0
## Overall reject : 0
## Futility stop : 0
## Early stop : 0

## Simulated data:
## Analysis times [1] : median [range]: 15.071 [13.563 - 16.825]; mean +/-sd: 15.087 +/-0.52
## Number of subjects [1] : median [range]: 1405 [1405 - 1405]; mean +/-sd: 1405 +/-0
## Observed # events by stage (1) [1] : median [range]: 136 [111 - 158]; mean +/-sd: 135.774 +/-7.536
## Observed # events by stage (2) [1] : median [range]: 164 [142 - 189]; mean +/-sd: 164.227 +/-7.536
## Number of events by stage [1] : median [range]: 300 [300 - 301]; mean +/-sd: 300.001 +/-0.032
## Test statistic [1] : median [range]: -1.862 [-5.082 - 1.207]; mean +/-sd: -1.903 +/-0.998
## Log-rank statistic [1] : median [range]: -1.862 [-5.082 - 1.207]; mean +/-sd: -1.903 +/-0.998
## Hazard ratio estimate LR [1] : median [range]: 0.807 [0.556 - 1.15]; mean +/-sd: 0.808 +/-0.093

## Legend:
## (i): values of treatment arm i

```R
plot(simulationResults2, type = 13)
```
Cumulative Distribution Function

\[ \lambda_1 = 0.024, \quad \lambda_2 = 0.03 \]

plot(simulationResults2, type = 14)
Survival Function

Lambda\(_1\) = 0.024, \(\lambda_2 = 0.03\)

design <- getDesignGroupSequential(
  sided = 1, alpha = 0.025, beta = 0.2,
  informationRates = c(0.33, 0.7, 1),
  typeOfDesign="asOF")

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

simulationResults3 <- getSimulationSurvival(
  design = design,
  thetaH0 = 1,
  dropoutRate1 = 0.2, dropoutRate2 = 0.2, dropoutTime = 12,
  allocation1 = 1,
  allocation2 = 1,
  accrualTime = accrualTime,
  hazardRatio = c(0.5, 0.6, 0.7, 0.75),
  directionUpper = FALSE,
  maxNumberOfSubjects = 1405,
  plannedEvents = c(99, 210, 300),
  maxNumberOfIterations = 1000,
  conditionalPower = 0.8,
minNumberOfEventsPerStage = c(99, 210, 300),
maxNumberOfEventsPerStage = c(200, 300, 400),
seed = 34567)

## Warning
## in .assertIsValidMinNumberOfSubjectsPerStage(maxNumberOfEventsPerStage, : First
## value of 'maxNumberOfEventsPerStage' (200) will be ignored

plot(simulationResults3, type = 5)

plot(simulationResults3, type = 6)
Expected Number of Events and Power / Early Stop

- **Early stop**
- **Expected # events**
- **Overall reject**

plot(simulationResults3, type = 7)
plot(simulationResults3, type = 8)
Overall Early Stopping

plot(simulationResults3, type = 9)
Expected Number of Events

plot(simulationResults3, type = 10)
plot(simulationResults3, type = 11)
plot(simulationResults3, type = 12)
plot(simulationResults3, type = 13)

## Warning: Only the first 'pi1' (0.106) was used for plotting
Cumulative Distribution Function

\[ \pi_1 = 0.106, \; \pi_2 = 0.2 \]

plot(simulationResults3, type = 14)

## Warning: Only the first 'pi1' (0.106) was used for plotting
System: rpact 2.0.6, R version 3.6.1 (2019-07-05), platform: x86_64-w64-mingw32

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To cite package ‘rpact’ in publications use:


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