

# Package ‘ph2rand’

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**Type** Package

**Title** Randomized Phase II Oncology Trials with Bernoulli Outcomes

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**Description** Provides functions to assist with the design of randomized comparative phase II oncology trials that assume their primary outcome variable is Bernoulli distributed. Specifically, support is provided to (a) perform a sample size calculation when using one of several published designs, (b) evaluate the operating characteristics of a given design (both analytically and via simulation), and (c) produce informative plots.

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**Imports** dplyr, ggplot2, Rcpp, scales, stats, tibble, tidyr

**LinkingTo** Rcpp

**RoxygenNote** 7.1.1

**URL** <https://github.com/mjg211/ph2rand>

**BugReports** <https://github.com/mjg211/ph2rand/issues>

**Encoding** UTF-8

**Suggests** knitr, rmarkdown

**VignetteBuilder** knitr

**SystemRequirements** C++11

**NeedsCompilation** yes

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des_one_stage	<i>Design a one-stage two-arm randomised clinical trial assuming a Bernoulli distributed primary outcome variable</i>
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### Description

des\_one\_stage determines one-stage two-arm randomised clinical trial designs, assuming the primary outcome variable is Bernoulli distributed. It supports a flexible framework for specifying which scenarios to control the type-I and type-II error-rates for, and allows for design determination assuming a variety of test statistics. In all instances, des\_one\_stage computes the optimal required sample size in each arm, the associated optimal stopping boundaries, and returns information on key operating characteristics.

### Usage

```
des_one_stage(
  type = "binomial",
  alpha = 0.1,
  beta = 0.2,
  delta = 0.2,
  ratio = 1,
  Pi0 = 0.1,
  Pi1 = Pi0[1],
  nCmax = 50L,
  summary = FALSE
)
```

### Arguments

type	A <a href="#">character</a> string indicating the chosen design framework/test statistic to assume. Must be one of "barnard", "binomial", "fisher", or "sat". Defaults to "binomial".
------	---

alpha	A <b>numeric</b> indicating the chosen value for $\alpha$ , the significance level (i.e., the type-I error-rate). Defaults to 0.1.
beta	A <b>numeric</b> indicating the chosen value for $\beta$ , used in the definition of the desired power (i.e., the type-II error-rate). Defaults to 0.2.
delta	A <b>numeric</b> indicating the chosen value for $\delta$ , the treatment effect assumed in the power calculation. Defaults to 0.2.
ratio	A <b>numeric</b> indicating the chosen value for $r$ , the allocation ratio to the experimental arm, relative to the control arm. Defaults to 1.
Pi0	A <b>numeric vector</b> indicating the chosen value for $\Pi_0$ , the control arm response rates to control the type-I error-rate to level $\alpha$ for. Must either be of <b>length</b> one, indicating a single point, or of <b>length</b> two. In this case, the elements indicate the range of possible response rates to allow for. Defaults to 0.1.
Pi1	A <b>numeric vector</b> indicating the chosen value for $\Pi_1$ , the control arm response rates to allow for in the power calculations. Must either be of <b>length</b> one, indicating a single point, or of <b>length</b> two. In this case, the elements indicate the range of possible response rates to allow for. Defaults to Pi0[1].
nCmax	A <b>numeric</b> indicating the maximum value of the sample size in the control arm to consider in the search procedure. Defaults to 50L.
summary	A <b>logical</b> variable indicating whether a summary of the function's progress should be printed to the console. Defaults to FALSE.

### Value

A **list** with additional class "ph2rand\_des", containing each of the input parameters along with several additional variables, including

- A **list** in the slot \$boundaries giving the rejection boundary/boundaries of the optimal design. The names of these elements depends on the value of type.
- A **tibble** in the slot \$feasible summarising the operating characteristics of the feasible designs.
- A **numeric** in the slot \$nC giving the sample size in the control arm for the optimal design.
- A **numeric** in the slot \$nE giving the sample size in the experimental arm for the optimal design.
- A **tibble** in the slot \$opchar summarising the operating characteristics of the optimal design.

### See Also

[des\\_two\\_stage](#), [opchar](#), [pmf](#), [sim](#), [terminal](#), [plot.ph2rand\\_des](#), [summary.ph2rand\\_des](#).

### Examples

```
# The design for the default parameters
des <- des_one_stage()
# Controlling the type-I/II error-rates over a range of possible response
# rates
des_range <- des_one_stage(Pi0 = c(0, 1),
                          Pi1 = c(0, 0.8))
```

---

des_two_stage	<i>Design a two-stage two-arm randomised clinical trial assuming a Bernoulli distributed primary outcome variable</i>
---------------	---

---

### Description

des\_two\_stage determines two-stage two-arm randomised clinical trial designs, assuming the primary outcome variable is Bernoulli distributed. It supports a flexible framework for specifying which scenarios to control the type-I and type-II error-rates for, and allows for design determination assuming a variety of test statistics. In all instances, des\_two\_stage computes the optimal required sample size in each arm in each stage, the associated optimal stopping boundaries, and returns information on key operating characteristics.

### Usage

```
des_two_stage(
  type = "binomial",
  alpha = 0.1,
  beta = 0.2,
  delta = 0.2,
  ratio = 1,
  Pi0 = 0.1,
  Pi1 = Pi0[1],
  nCmax = 50L,
  equal = T,
  w = c(1, 0, 0, 0, 0),
  pi0 = Pi0[1],
  efficacy = FALSE,
  futility = TRUE,
  efficacy_type = 0L,
  efficacy_param = NULL,
  futility_type = 1L,
  futility_param = 0L,
  summary = FALSE
)
```

### Arguments

type	A <a href="#">character</a> string indicating the chosen design framework/test statistic to assume. Must be one of "barnard", "binomial", "fisher", or "sat". Defaults to "binomial".
alpha	A <a href="#">numeric</a> indicating the chosen value for $\alpha$ , the significance level (i.e., the type-I error-rate). Defaults to 0.1.
beta	A <a href="#">numeric</a> indicating the chosen value for $\beta$ , used in the definition of the desired power (i.e., the type-II error-rate). Defaults to 0.2.

delta	A <b>numeric</b> indicating the chosen value for $\delta$ , the treatment effect assumed in the power calculation. Defaults to 0.2.
ratio	A <b>numeric</b> indicating the chosen value for $r$ , the allocation ratio to the experimental arm, relative to the control arm. Defaults to 1.
Pi0	A <b>numeric vector</b> indicating the chosen values of the control arm response rate to control the type-I error-rate to level $\alpha$ for. Must either be of <b>length</b> one, indicating a single point, or of <b>length</b> two. In this case, the elements indicate the range of possible response rates to allow for. Defaults to 0.1.
Pi1	A <b>numeric vector</b> indicating the chosen values of the control arm response rate to allow for in the power calculations. Must either be of <b>length</b> one, indicating a single point, or of <b>length</b> two. In this case, the elements indicate the range of possible response rates to allow for. Defaults to Pi0[1].
nCmax	A <b>numeric</b> indicating the maximum value of the sample size in the control arm (across both stages) to consider in the search procedure. Defaults to 50L.
equal	A <b>logical</b> variable indicating whether the sample size of the two stages should be equal. Defaults to TRUE.
w	A <b>numeric vector</b> indicating the weights to use in the optimality criteria. Must be of <b>length</b> five, with all elements greater than or equal to zero, and at least one of the first four elements strictly positive. Defaults to c(1, 0, 0, 0, 0).
pi0	A <b>numeric</b> indicating the value of the control arm response rate to assume in the optimality criteria. Defaults to Pi0[1].
efficacy	Only used if type is one of "barnard", "binomial", or "sat". Then, it is a <b>logical</b> variable indicating whether to include early stopping for efficacy in the design. Defaults to FALSE.
futility	Only used if type is one of "barnard", "binomial", or "sat". Then, it is a <b>logical</b> variable indicating whether to include early stopping for futility in the design. Defaults to TRUE.
efficacy_type	Only used if type is "fisher". Then, it is a <b>numeric</b> indicating whether, and which type of, early stopping for efficacy to include in the design. See the vignette for details. Defaults to 0L.
efficacy_param	Only used if type is "fisher" and efficacy_type is not equal to 0L. Then, it is a <b>numeric</b> that influences the precise way in which an efficacy boundary is specified. See the vignette for details. Defaults to NULL.
futility_type	Only used if type is "fisher". Then, it is a <b>numeric</b> indicating whether, and which type of, early stopping for futility to include in the design. See the vignette for details. Defaults to 1L.
futility_param	Only used if type is "fisher" and futility_type is not equal to 0L. Then, it is a <b>numeric</b> that influences the precise way in which a futility boundary is specified. See the vignette for details. Defaults to 1L.
summary	A <b>logical</b> variable indicating whether a summary of the function's progress should be printed to the console. Defaults to FALSE.

**Value**

A **list** with additional class "ph2rand\_des", containing each of the input parameters along with several additional variables, including

- A **list** in the slot `$boundaries` giving the rejection boundaries of the optimal design. The names of these elements depends on the value of `type`.
- A **tibble** in the slot `$feasible` summarising the operating characteristics of the feasible designs.
- A **numeric vector** in the slot `$nC` giving the sample sizes in the control arm in each stage for the optimal design.
- A **numeric vector** in the slot `$nE` giving the sample sizes in the experimental arm in each stage for the optimal design.
- A **tibble** in the slot `$opchar` summarising the operating characteristics of the optimal design.

**See Also**

[des\\_one\\_stage](#), [opchar](#), [pmf](#), [terminal](#), [plot.ph2rand\\_des](#), [summary.ph2rand\\_des](#).

**Examples**

```
# The design for the default parameters
des      <- des_two_stage()
# Controlling the type-I/II error-rates over a range of possible response
# rates
des_range <- des_two_stage(Pi0 = c(0, 1),
                          Pi1 = c(0, 0.8))
```

---

opchar

*Determine operating characteristics of a randomised clinical trial design that assumes a Bernoulli distributed primary outcome variable*

---

**Description**

`opchar` determines the operating characteristics (analytically) of a design returned by [des\\_one\\_stage](#) or [des\\_two\\_stage](#), under given response rate scenarios (see `pi`).

**Usage**

```
opchar(
  des = ph2rand::des_one_stage(),
  pi = des$opchar[, 1:2],
  k = 1:des$J,
  summary = FALSE
)
```

**Arguments**

des	An object of class <code>ph2rand_des</code> , as returned by <code>des_one_stage</code> or <code>des_two_stage</code> . Defaults to <code>ph2rand::des_one_stage()</code> .
pi	A <b>numeric vector</b> with two elements, or a <b>numeric matrix</b> or <b>data.frame</b> with two columns, giving the response rate scenarios to consider. The first element/column should correspond to the control arm and the second element/column to the experimental arm. Defaults to <code>des\$opchar[, 1:2]</code> .
k	A <b>numeric vector</b> indicating which stages to consider in determining the operating characteristics. That is, it will condition the calculations on the trial ending in the stages given in <code>k</code> . Defaults to <code>1:des\$J</code> (i.e., to all stages of the given design).
summary	A <b>logical</b> variable indicating whether a summary of the function's progress should be printed to the console. Defaults to <code>FALSE</code> .

**Value**

A **list** with additional class `"ph2rand_opchar"`, containing each of the input parameters along with a tibble in the slot `$opchar`, which gives the determined operating characteristics.

**See Also**

[des\\_one\\_stage](#), [des\\_two\\_stage](#).

**Examples**

```
# The default two-stage design
des <- des_two_stage()
# Its operating characteristics under the uninteresting and interesting
# scenarios
opchar <- opchar(des)
# The same operating characteristics, conditioning on the trial ending in
# stage 2
opchar <- opchar(des, k = 2)
```

---

ph2rand

*ph2rand: Randomized Phase II Oncology Trials with Bernoulli Outcomes*

---

**Description**

**ph2rand** provides functions to assist with the design of randomized comparative phase II oncology trials that assume their primary outcome variable is Bernoulli distributed. Specifically, support is provided to (a) perform a sample size calculation when using one of several published designs, (b) evaluate the operating characteristics of a given design (both analytically and via simulation), and (c) produce informative plots.

## Getting started

You can install the latest development version of **ph2rand** from [Github](#) with:

```
devtools::install_github("mjg211/ph2rand")
```

An introductory example of how to make use of the package's core functionality can be found [here](#). For further help, please see the package vignettes or email <[michael.grayling@newcastle.ac.uk](mailto:michael.grayling@newcastle.ac.uk)>.

## Details

Currently, the following functions are available (exported)

- [des\\_one\\_stage](#): Determine a one-stage randomized comparative phase II oncology trial design, assuming a Bernoulli primary outcome variable.
- [des\\_two\\_stage](#): Determine a two-stage randomized comparative phase II oncology trial design, assuming a Bernoulli primary outcome variable.
- [opchar](#): Evaluate the operating characteristics (analytically) of a randomized comparative phase II oncology trial design that assumes a Bernoulli primary outcome variable.
- [plot.ph2rand\\_des](#): Plot the operating characteristics of a randomized comparative phase II oncology trial design that assumes a Bernoulli primary outcome variable.
- [plot.ph2rand\\_pmf](#): Plot the probability mass function of a randomized comparative phase II oncology trial design that assumes a Bernoulli primary outcome variable.
- [plot.ph2rand\\_terminal](#): Plot the terminal points of a randomized comparative phase II oncology trial design that assumes a Bernoulli primary outcome variable.
- [pmf](#): Find the probability mass function of a randomized comparative phase II oncology trial design that assumes a Bernoulli primary outcome variable.
- [sim](#): Evaluate the operating characteristics (via simulation) of a randomized comparative phase II oncology trial design that assumes a Bernoulli primary outcome variable.
- [summary.ph2rand\\_des](#): Display a summary of a randomized comparative phase II oncology trial design that assumes a Bernoulli primary outcome variable.
- [terminal](#): Find the terminal points of a randomized comparative phase II oncology trial design that assumes a Bernoulli primary outcome variable.

## References

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---

plot.ph2rand_des	<i>Plot the operating characteristics of a randomised clinical trial design that assumes a Bernoulli distributed primary outcome variable</i>
------------------	---

---

## Description

plot.ph2rand\_des plots the operating characteristics of a design returned by [des\\_one\\_stage](#) or [des\\_two\\_stage](#), under a range of key response rate scenarios. For convenience, it also calls [plot.ph2rand\\_terminal](#) to plot the terminal points of the design.

## Usage

```
## S3 method for class 'ph2rand_des'  
plot(x, k = 1:x$J, output = FALSE, ...)
```

## Arguments

x	An object of class ph2rand_des, as returned by <a href="#">des_one_stage</a> or <a href="#">des_two_stage</a> .
k	A <a href="#">numeric vector</a> indicating which stages to consider in determining the probability mass function. That is, it will condition the calculations on the trial ending in the stages given in k. Defaults to 1:des\$J (i.e., to all stages of the given design).
output	A <a href="#">logical</a> variable indicating whether available outputs should be returned by the function.
...	Not currently used.

## Value

If output = TRUE, a [list](#) containing each of the input parameters along with a [list](#) in the slot \$plots, which gives all of the available produced plots.

## See Also

[des\\_one\\_stage](#), [des\\_two\\_stage](#), [plot.ph2rand\\_terminal](#).

## Examples

```
# The default two-stage design  
des <- des_two_stage()  
# Print several key plots  
plot(des)  
# Determine and store all available plots  
plots <- plot(des, output = TRUE)
```

---

plot.ph2rand_pmf	<i>Plot probability mass functions of a randomised clinical trial design that assumes a Bernoulli distributed primary outcome variable</i>
------------------	--

---

## Description

plot.ph2rand\_pmf plots the terminal points of a design returned by [pmf](#).

## Usage

```
## S3 method for class 'ph2rand_pmf'  
plot(x, output = FALSE, ...)
```

## Arguments

x	An object of class ph2rand_pmf, as returned by <a href="#">pmf</a> .
output	A <a href="#">logical</a> variable indicating whether outputs should be returned by the function.
...	Not currently used.

## Value

If output = TRUE, a [list](#) containing each of the input parameters along with a plot in the slot \$plot, which gives the produced plot of the terminal points.

## See Also

[des\\_one\\_stage](#), [des\\_two\\_stage](#), [pmf](#), [plot.ph2rand\\_des](#).

## Examples

```
# The default two-stage design  
des <- des_two_stage()  
# Its probability mass function under the uninteresting and interesting  
# scenarios  
pmf <- pmf(des)  
# The plot of them  
plot(pmf)  
# The same probability mass functions, conditioning on the trial ending in  
# stage 2  
pmf <- pmf(des, k = 2)  
# The plot of them  
plot(pmf)
```

---

plot.ph2rand\_terminal *Plot the terminal points of a randomised clinical trial design that assumes a Bernoulli distributed primary outcome variable*

---

## Description

plot.ph2rand\_terminal plots the terminal points of a design returned by [terminal](#).

## Usage

```
## S3 method for class 'ph2rand_terminal'  
plot(x, output = FALSE, ...)
```

## Arguments

x	An object of class <code>ph2rand_terminal</code> , as returned by <a href="#">terminal</a> .
output	A <a href="#">logical</a> variable indicating whether outputs should be returned by the function.
...	Not currently used.

## Value

If `output = TRUE`, a [list](#) containing each of the input parameters along with `plot(s)` in the slot `$plots`, which gives the produced `plot(s)` of the terminal points.

## See Also

[des\\_one\\_stage](#), [des\\_two\\_stage](#), [terminal](#), [plot.ph2rand\\_des](#).

## Examples

```
# The default two-stage design  
des <- des_two_stage()  
# Its terminal points across stages 1 and 2  
term <- terminal(des)  
# The plot of them  
plot(term)  
# Its terminal points from stage 2 only  
term <- terminal(des, 2)  
# The plot of them  
plot(term)
```

---

pmf	<i>Probability mass functions of a randomised clinical trial design that assumes a Bernoulli distributed primary outcome variable</i>
-----	---

---

### Description

pmf determines probability mass functions of a design returned by [des\\_one\\_stage](#) or [des\\_two\\_stage](#), under given response rate scenarios (see [pi](#)).

### Usage

```
pmf(
  des = ph2rand::des_one_stage(),
  pi = des$opchar[, 1:2],
  k = 1:des$J,
  summary = FALSE
)
```

### Arguments

des	An object of class <code>ph2rand_des</code> , as returned by <a href="#">des_one_stage</a> or <a href="#">des_two_stage</a> . Defaults to <code>ph2rand::des_one_stage()</code> .
pi	A <a href="#">numeric vector</a> with two elements, or a <a href="#">numeric matrix</a> or <a href="#">data.frame</a> with two columns, giving the response rate scenarios to consider. The first element/column should correspond to the control arm and the second element/column to the experimental arm. Defaults to <code>des\$opchar[, 1:2]</code> .
k	A <a href="#">numeric vector</a> indicating which stages to consider in determining the probability mass functions. That is, it will condition the calculations on the trial ending in the stages given in <code>k</code> . Defaults to <code>1:des\$J</code> (i.e., to all stages of the given design).
summary	A <a href="#">logical</a> variable indicating whether a summary of the function's progress should be printed to the console. Defaults to <code>FALSE</code> .

### Value

A [list](#) with additional class `"ph2rand_pmf"`, containing each of the input parameters along with a tibble in the slot `$pmf`, which gives the determined probability mass functions.

### See Also

[des\\_one\\_stage](#), [des\\_two\\_stage](#), [plot.ph2rand\\_terminal](#).

## Examples

```
# The default two-stage design
des <- des_two_stage()
# Its probability mass function under the uninteresting and interesting
# scenarios
pmf <- pmf(des)
# The same probability mass functions, conditioning on the trial ending in
# stage 2
pmf <- pmf(des, k = 2)
```

---

sim	<i>Estimate operating characteristics of a randomised clinical trial design that assumes a Bernoulli distributed primary outcome variable</i>
-----	---

---

## Description

sim estimated the operating characteristics (via simulation) of a design returned by [des\\_one\\_stage](#) or [des\\_two\\_stage](#), under given response rate scenarios (see pi).

## Usage

```
sim(
  des = ph2rand::des_one_stage(),
  pi = des$opchar[, 1:2],
  k = 1:des$J,
  replicates = 10000,
  summary = FALSE
)
```

## Arguments

des	An object of class ph2rand_des, as returned by <a href="#">des_one_stage</a> or <a href="#">des_two_stage</a> . Defaults to ph2rand::des_one_stage().
pi	A <a href="#">numeric vector</a> with two elements, or a <a href="#">numeric matrix</a> or <a href="#">data.frame</a> with two columns, giving the response rate scenarios to consider. The first element/column should correspond to the control arm and the second element/column to the experimental arm. Defaults to des\$opchar[, 1:2].
k	A <a href="#">numeric vector</a> indicating which stages to consider in determining the operating characteristics. That is, it will condition the calculations on the trial ending in the stages given in k. Defaults to 1:des\$J (i.e., to all stages of the given design).
replicates	A <a href="#">numeric</a> indicating the number of replicate simulations to use for each value of $\pi$ . Defaults to 1e4.
summary	A <a href="#">logical</a> variable indicating whether a summary of the function's progress should be printed to the console. Defaults to FALSE.

**Value**

A `list` with additional class "ph2rand\_sim", containing each of the input parameters along with a tibble in the slot `$sim`, which gives the estimated operating characteristics.

**See Also**

[des\\_one\\_stage](#), [des\\_two\\_stage](#).

**Examples**

```
# The default two-stage design
des <- des_two_stage()
# Its operating characteristics under the uninteresting and interesting
# scenarios
sim <- sim(des)
# The same operating characteristics, conditioning on the trial ending in
# stage 2
sim <- sim(des, k = 2)
```

---

summary.ph2rand_des	<i>Summarise a randomised clinical trial design that assumes a Bernoulli distributed primary outcome variable</i>
---------------------	---

---

**Description**

`summary.ph2rand_des` prints a summary of a design returned by [des\\_one\\_stage](#) or [des\\_two\\_stage](#).

**Usage**

```
## S3 method for class 'ph2rand_des'
summary(object, ...)
```

**Arguments**

object	An object of class <code>ph2rand_des</code> , as returned by <a href="#">des_one_stage</a> or <a href="#">des_two_stage</a> .
...	Not currently used.

**Value**

Currently not used.

**See Also**

[des\\_one\\_stage](#), [des\\_two\\_stage](#), [plot.ph2rand\\_des](#).

## Examples

```
# The default two-stage design
des <- des_two_stage()
# Print a summary
summary(des)
```

---

terminal	<i>Terminal points of a randomised clinical trial design that assumes a Bernoulli distributed primary outcome variable</i>
----------	--

---

## Description

terminal determines the 'terminal' points of a design returned by [des\\_one\\_stage](#) or [des\\_two\\_stage](#).

## Usage

```
terminal(des = ph2rand::des_one_stage(), k = 1:des$J, summary = FALSE)
```

## Arguments

des	An object of class <code>ph2rand_des</code> , as returned by <a href="#">des_one_stage</a> or <a href="#">des_two_stage</a> . Defaults to <code>ph2rand::des_one_stage()</code> .
k	A <a href="#">numeric vector</a> indicating which stages to consider when determining the terminal points. Defaults to <code>1:des\$J</code> (i.e., to all stages of the given design).
summary	A <a href="#">logical</a> variable indicating whether a summary of the function's progress should be printed to the console. Defaults to <code>FALSE</code> .

## Value

A [list](#) with additional class `"ph2rand_terminal"`, containing each of the input parameters along with a tibble in the slot `$terminal`, which gives the determined terminal points.

## See Also

[des\\_one\\_stage](#), [des\\_two\\_stage](#), [plot.ph2rand\\_terminal](#).

## Examples

```
# The default two-stage design
des <- des_two_stage()
# Its terminal points across stages 1 and 2
term_12 <- terminal(des)
# Its terminal points from stage 2 only
term_2 <- terminal(des, 2)
# A plot of these points
plot(term_2)
```

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