

Package ‘survmixer’

July 31, 2020

Title Design of clinical trials with survival endpoints based on binary response.

Version 0.0.0.9000

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Description Sample size and effect size calculations for survival endpoints based on mixture survival-by-response model.

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Encoding UTF-8

LazyData true

RoxygenNote 7.1.0

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survmixture_f	<i>Mixture survival function</i>
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Description

The function ‘survmixture_f’ computes the survival distribution as a mixture of responders and non-responders. The responders and non-responders distributions are assumed to be Weibull distributions.

Usage

```
survmixture_f(t, ascale_r, ascale_nr, bshape = 1, p)
```

Arguments

t	time at which the survival distribution is evaluated
ascale_r	scale parameter for the Weibull distribution for responders
ascale_nr	scale parameter for the Weibull distribution for non-responders
bshape	shape parameter for the Weibull distribution
p	event rate for the response

Value

Mixture survival function evaluated at t

Author(s)

Marta Bofill Roig

survm_effectsize	<i>Effect size calculation for mixture survival distributions</i>
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Description

The function 'survm_effectsize' calculates the effect size in terms of the difference of restricted mean survival times (RMST) according to the information on responders and non-responders.

Usage

```
survm_effectsize(
  ascale0_r,
  ascale0_nr,
  delta_p,
  p0,
  bshape0 = 1,
  bshape1 = 1,
  ascale1_r,
  ascale1_nr,
  tau,
  Delta_r = NULL,
  Delta_0 = NULL,
  Delta_nr = NULL,
  anticipated_effects = FALSE
)
```

Arguments

ascale0_r	scale parameter for the Weibull distribution in the control group for responders
ascale0_nr	scale parameter for the Weibull distribution in the control group for non-responders
delta_p	effect size for the response rate
p0	event rate for the response
bshape0	shape parameter for the Weibull distribution in the control group

bshape1	shape parameter for the Weibull distribution in the intervention group
ascale1_r	scale parameter for the Weibull distribution in the intervention group for responders
ascale1_nr	scale parameter for the Weibull distribution in the intervention group for non-responders
tau	follow-up
Delta_r	RMST difference between intervention and control groups for responders
Delta_0	RMST difference between responders and non-responders in the control group
Delta_nr	RMST difference between intervention and control groups for non-responders
anticipated_effects	Logical parameter. If it is TRUE then the effect size is computed based on previous information on the effect sizes on response rate and survival-by-responses (that is, based on Delta_r, Delta_0, Delta_nr); otherwise is based on the distributional parameters (ascale0_r, ascale0_nr, ascale1_r, ascale1_nr, bshape0, bshape1).

Value

This function returns the overall mean survival improvement (RMST difference between groups) and it also includes the mean survival improvement that would be assumed for each responders and non-responders

Author(s)

Marta Bofill Roig

survm_samplesize	<i>Sample size calculation for mixture survival distributions</i>
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Description

The function ‘survm_samplesize’ calculates the sample size according to the distributional parameters of the responders and non-responders.

Usage

```
survm_samplesize(
  ascale0_r,
  ascale0_nr,
  ascale1_r,
  ascale1_nr,
  delta_p,
  p0,
  m0_r,
  m0_nr,
  diffm_r,
  diffm_nr,
  S0_r,
  S0_nr,
```

```

diffS_r,
diffS_nr,
Delta_r,
Delta_nr,
ascale_cens,
tau,
bshape0 = 1,
bshape1 = 1,
alpha = 0.025,
beta = 0.2,
set_param = 0
)

```

Arguments

ascale0_r	scale parameter for the Weibull distribution in the control group for responders
ascale0_nr	scale parameter for the Weibull distribution in the control group for non-responders
ascale1_r	scale parameter for the Weibull distribution in the intervention group for responders
ascale1_nr	scale parameter for the Weibull distribution in the intervention group for non-responders
delta_p	effect size for the response rate
p0	event rate for the response
m0_r	survival mean for responders in the control group
m0_nr	survival mean for non-responders in the control group
diffm_r	difference in survival means between groups for responders
diffm_nr	difference in survival means between groups for non-responders
S0_r	tau-year survival rates for responders in the control group
S0_nr	tau-year survival rates for non-responders in the control group
diffS_r	difference in tau-year survival rates for responders
diffS_nr	difference in tau-year survival rates for non-responders
Delta_r	restricted mean survival times (RMST) difference between intervention and control groups for responders
Delta_nr	RMST difference between intervention and control groups for non-responders
ascale_cens	distributional parameter for the exponential distribution for the censoring
tau	follow-up
bshape0	shape parameter for the Weibull distribution in the control group
bshape1	shape parameter for the Weibull distribution in the intervention group
alpha	type I error
beta	type II error
set_param	Set of parameters to be used.

Value

This function returns the total sample size needed and the expected effect size for overall survival (RMST difference between groups).

Author(s)

Marta Bofill Roig

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