Package 'survmixer'

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

survmixture_f

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

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Usage

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

Mixture survival function

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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

survw_effectsize

Effect size calculation for mixture survival distributions

Description

The function 'survw_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

```
survw_effectsize(
   ascale0_r,
   ascale0_nr,
   delta_p,
   p0,
   bshape0,
   bshape1,
   ascale1_r,
   ascale1_nr,
   tau,
   Delta_r = 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 event rate for the response shape parameter for the Weibull distribution in the control group

survw_samplesize 3

bshape1 shape parameter for the Weibull distribution in the intervention group scale parameter for the Weibull distribution in the intervention group for responascale1_r scale parameter for the Weibull distribution in the intervention group for nonascale1_nr 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 RMST difference between intervention and control groups for non-responders Delta_nr

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

Effect size for overall survival

Author(s)

Marta Bofill Roig

survw_samplesize

Sample size calculation for mixture survival distributions

Description

The function 'survw_samplesize' calculates the sample size according to the distributional parameters of the responders and non-responders.

Usage

```
survw_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,
```

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```
Delta_r,
Delta_nr,
ascale_cens,
tau,
bshape0 = 1,
bshape1 = 1,
alpha = 0.025,
beta = 0.2,
ss_strategy = 0
```

Arguments

ascale0_r scale parameter for the Weibull distribution in the control group for responders scale parameter for the Weibull distribution in the control group for non-responders ascale0_nr ascale1_r scale parameter for the Weibull distribution in the intervention group for responders scale parameter for the Weibull distribution in the intervention group for nonascale1_nr responders delta_p effect size for the response rate event rate for the response **0**q survival mean for responders in the control group m0_r survival mean for non-responders in the control group m0_nr diffm_r difference in survival means between groups for responders diffm_nr difference in survival means between groups for 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 restricted mean survival times (RMST) difference between intervention and con-Delta_r trol groups for responders Delta_nr RMST difference between intervention and control groups for non-responders distributional parameter for the exponential distribution for the censoring ascale_cens tau bshape0 shape parameter for the Weibull distribution in the control group shape parameter for the Weibull distribution in the intervention group bshape1 alpha type I error beta type II error ss_strategy Sample size strategy to be used.

Value

Sample size for overall survival

Author(s)

Marta Bofill Roig

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```