Package 'ewhorm'

August 8, 2023

Title Statistical Considerations for Designing e-WHORM Adaptive Trial

Version 0.1

Author Marta Bofill Roig [aut, cre] (<https://orcid.org/0000-0002-4400-7541>), Martin Posch [aut], Sonja Zehetmayer [aut]

Maintainer Marta Bofill Roig <marta.bofillroig@meduniwien.ac.at>

Description Data simulation and analysis for the design of e-WHORM trial

License MIT + file LICENSE

Encoding UTF-8

Imports mvtnorm,
stats,
multcomp,
gtools

Roxygen list(markdown = TRUE)

RoxygenNote 7.2.1

Suggests knitr,
rmarkdown

VignetteBuilder knitr

R topics documented:

`get_hyp_mat` *Function to compute the hypotheses to test (closed test)*

Description

Function to compute the hypotheses to test (closed test)

Usage

```
get_hyp_mat(n_hypothesis = 3, selected_hypothesis = 1)
```

Arguments

n_hypothesis	num elementary hypotheses
selected_hypothesis	selected hypothesis for closed test

Details

eWHORM simulations

Value

maximum value in a row

Author(s)

Marta Bofill Roig

---

get_max_col_index *Function to get the column index of the maximum value in a row*

Description

Function to get the column index of the maximum value in a row

Usage

```
get_max_col_index(row)
```

Arguments

row	selected row

Details

eWHORM simulations

Value

maximum value in a row

Author(s)

Marta Bofill Roig

`sim_data` *Simulate data from a multi-arm trial with shared control*

Description

Function to simulate trial data (1-stage, multiple arms)

Usage

```
sim_data(n_arms, N, mu_6m, mu_12m, sigma, rmonth)
```

Arguments

`n_arms`	number of arms (including control)
`N`	total sample size
`mu_6m`	6-month mean response per arm (vector of length `n_arm`)
`mu_12m`	12-month mean response per arm (vector of length `n_arm`)
`sigma`	covariance matrix between 6- and 12-month responses assumed equal across arms (matrix of dim 2x2)
`rmonth`	recruitment per month (recruitment speed assumed constant over time)

Details

eWHORM simulations

Value

simulated data consisting of the responses at 6 and 12 months, treatment arm, and recruitment time for each subject.

Author(s)

Marta Bofill Roig

`sim_trial` *Simulate data from a multi-arm multi-stage trial with shared control and dose selection*

Description

Function to simulate trial data (2-stages, with dose selection)

Usage

```
sim_trial(
  n_arms = 4,
  N1 = 30 * 4,
  N2 = 30 * 2,
  mu_6m,
  mu_12m,
  sigma,
  rmonth,
  alpha1 = 0.5,
  alpha = 0.05,
  p_safety = c(0.9, 0.8, 0.7),
  safety = T
)
```

Arguments

n_arms	number of arms (including control)
N1	sample size stage 1
N2	sample size stage 2
mu_6m	6-month mean response per arm (vector of length n_arm)
mu_12m	12-month mean response per arm (vector of length n_arm)
sigma	covariance matrix between 6- and 12-month responses assumed equal across arms (matrix of dim 2x2)
rmonth	recruitment per month (recruitment speed assumed constant over time)
alpha1	significance level for dose selection
alpha	significance level for selected dose vs control comparison
p_safety	probability of each dose to be safe
safety	indicator - if true, it simulates safety according to p_safety

Details

eWHORM simulations

Value

Combined p-value, selected dose and safety for each dose (if argument safety=TRUE)

Author(s)

Marta Bofill Roig

Index