

Package ‘ewhorm’

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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 What the package does (one paragraph).

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Encoding UTF-8

Imports mvtnorm,
stats

Roxygen list(markdown = TRUE)

RoxygenNote 7.2.1

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sim_data	<i>Simulate data from a multi-arm trial with shared control</i>
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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	<i>Simulate data from a multi-arm multi-stage trial with shared control and dose selection</i>
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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)
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

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