

Package ‘ewhorm’

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Title Statistical Considerations for Designing e-WHORM Adaptive Trial

Version 1.1

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

URL https://github.com/MartaBofillRoig/ewhorm_sim

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Encoding UTF-8

Imports mvtnorm,

stats,
multcomp,
gMCP,
gtools,
dplyr,
tidyr,
future,
furry

Roxygen list(markdown = TRUE)

RoxygenNote 7.3.2

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sim_trial_pceind_test	<i>Simulate data from a multi-arm multi-stage trial with shared control and two initial doses, where an additional dose could be added after the interim analysis; individual observations are simulated</i>
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Description

Function to simulate trial data (2-stages, with dose selection). The analyses are performed using partial conditional error rates.

Usage

```

sim_trial_pceind_test(
  n_arms = 4,
  N1,
  N2,
  mu_0m,
  mu_6m,
  mu_12m,
  sg,
  alpha1,
  alpha = 0.025,
  sel_scen,
  side = T,
  test,
  dropout,
  rr,
  bound
)

```

Arguments

n_arms	number of arms (including control)
N1	sample size stage 1
N2	sample size stage 2
mu_0m	Baseline value per arm (vector of length n_arm)
mu_6m	6-month value per arm (vector of length n_arm)
mu_12m	12-month value per arm (vector of length n_arm)
sg	sigma covariance matrix between 6- and 12-month mean differences assumed equal across arms (matrix of dim 2x2)
alpha1	significance level for dose selection (futility boundary)
alpha	significance level for selected dose vs control comparison
sel_scen	choose between two different options in case that in interim analysis low dose is promising, but median dose not: 0: do not continue with low dose or median dose; 1: continue with low and median doses
side	TRUE/FALSE referring to the side for 1-side testing (if TRUE then lower = side)
test	defines type of analysis: "t" calculates a t-test, "l" a linear model with baseline values as covariables, "w" Wilcoxon test of differences, and "wl" Wilcoxon test of follow-up values
dropout	dropoutrate, between 0 and 1
rr	responder rate for each dose (vector of length n_arm), which gives the proportion of patients with value 0 at follow-up
bound	lower bound to define total responder in simulation study

Details

eWHORM simulations

Value

A list consisting of pvalues at stage 1, pvalues at stage 2, the decision at stages 1 and 2, the selected dose at stage 1, concordance values, corresponding bias and confidence limits and corresponding values on the multi-armed trials.

Author(s)

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