Package ‘SEARS’

Type Package

Title Seamless Dose Escalation/Expansion with Adaptive Randomization Scheme

Version 0.1.0

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Description A seamless design that combines phase I dose escalation based on toxicity with phase II dose expansion and dose comparison based on efficacy.

License GPL-2

Encoding UTF-8

Depends BOIN

Suggests knitr, rmarkdown

VignetteBuilder knitr

NeedsCompilation no

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SEARS

A randomized distributed phase I-II seamless dose escalation/expansion schema for dose optimization and selection in early oncology clinical development

Description

Implements seamless randomized phase I-II SEARS design for finding the optimal design. Practitioners can use a rich set of parameters to explore various real scenarios for their studies. The function can generate operating characteristics via simulation for practitioners to examine the design’s properties

Usage

SEARS(p.p, p.d, p.tox, k1, k2, pi_t, pi_e, pT, eff_a = 0.5, eff_b = 0.5, plac_a = 0.5, plac_b = 0.5, tox_a = 1, tox_b = 1, csize, csize2, p.star = 0.2, q.star = 0.6, f.star = 0.06, p.star2 = 0.2, q.star2 = 0.98, d.cs, p.cs, phase1_size, n_earlystop, extrasafe_BOIN = FALSE, offset_BOIN = 0.05, Nsim, n_catchup, control_arm = "", power_c = 0.5, lower_bound = 0.05, weight1, weight2, seed = 100)

Arguments

- **p.p**  
  the true placebo response rate
- **p.d**  
  the true dose response rate vector
- **p.tox**  
  the true dose toxicity rate vector
- **k1**  
  the safety rule cutoff value in phase I
- **k2**  
  the safety rule cutoff value in phase II
- **pi_t**  
  the physician-specified upper toxicity rate threshold
- **pi_e**  
  the physician-specified lower response rate threshold
- **pT**  
  the target toxicity rate
- **eff_a**  
  the hyperparameter "a" for priors of the response rate for experimental doses. The default value is eff_a = 0.5
- **eff_b**  
  the hyperparameter "b" for priors of the response rate for experimental doses. The default value is eff_b = 0.5
- **plac_a**  
  the hyperparameter "a" for prior of the response rate for the control arm. The default value is plac_a = 0.5
- **plac_b**  
  the hyperparameter "b" for prior of the response rate for the control arm. The default value is plac_b = 0.5
- **tox_a**  
  the hyperparameter "a" for priors of the toxicity rates. The default value is tox_a = 1
SEARS returns a list with following elements (1) type I error (2) average sample size for the trial (3) average sample size for each dose (4) average sample size for placebo (5) selection percentage for each dose (6) average toxicity events for each dose
Author(s)

Chia-Wei Hsu, Haitao Pan

Examples

SEARS(p.p = 0.2, p.d = c(0.2, 0.2, 0.2, 0.2, 0.2), p.tox = c(0.03, 0.06, 0.17, 0.3, 0.5),
    k1 = 0.95, k2 = 0.8, pi_t = 0.17, pi_e = 0.2, pT = 0.17, eff_a = 0.5, eff_b = 0.5,
    plac_a = 0.5, plac_b = 0.5, tox_a = 1, tox_b = 1, csize = 3, csize2 = 3,
    p.star = 0.2, q.star = 0.6, f.star = 0.06, p.star2 = 0.2, q.star2 = 0.98,
    d.cs = 36, p.cs = 36, phase1_size = 30, n_earlystop = 100, extrasafe_BOIN = FALSE,
    offset_BOIN = 0.05, Nsim = 10, n_catchup = 3, control_arm = "fixed", power_c = 0.5,
    lower_bound = 0.05, weight1 = 0.5, weight2 = 0.5, seed = 100)
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