Package 'RegionalConsistency'

May 15, 2025

Title Calculate Regional Consistency Probabilities for Multi-Regional
Clinical Trials

Version 1.0.0

Description Provides methods to calculate approximate regional
consistency probabilities using Method 1 and Method 2 proposed by the Japanese
Ministry of Health, Labor and Welfare (2007) <https:
//www.pmda.go.jp/files/000153265.pdf>. These methods
are useful for assessing regional consistency in multi-regional
clinical trials. The package can calculate unconditional, joint, and
conditional regional consistency probabilities. For technical
details, please see Homma (2024) <doi:10.1002/pst.2358>.

License MIT + file LICENSE

Imports mvtnorm, stats

Suggests testthat (>= 3.0.0)

Config/testthat/edition 3

Encoding UTF-8

RoxygenNote 7.3.2

NeedsCompilation no

Author Gosuke Homma [aut, cre]

Maintainer Gosuke Homma <my.name.is.gosuke@gmail.com>

Repository CRAN

Date/Publication 2025-05-15 14:00:06 UTC

Contents

---

regional.consistency.probs

Calculate Regional Consistency Probabilities

Description

This function calculates approximate regional consistency probabilities using Methods 1 and 2 proposed by Japanese MHLW (2007). The function can obtain:

- Unconditional regional consistency probabilities
- Joint regional consistency probabilities
- Conditional regional consistency probabilities

For technical details, please see Homma (2024)

Usage

```
regional.consistency.probs(f.s, PI, alpha, power, seed)
```

Arguments

f.s	A numeric vector representing the proportion of patients in region s(=1,...,S) among patients in the entire trial population. Values must sum to 1.
PI	A numeric value specifying the threshold for Method 1 (typically set at 0.5).
alpha	A numeric value representing the one-sided level of significance.
power	A numeric value representing the target power.
seed	A random number seed.

Value

A list containing the following components:

f.s The input proportion of patients in each region

PI The input threshold value for Method 1

alpha The input one-sided significance level

power The input target power

seed The input seed number

Uncond.Method1 Unconditional regional consistency probability for Method 1

Joint.Method1 Joint regional consistency probability for Method 1

Cond.Method1 Conditional regional consistency probability for Method 1

Uncond.Method2 Unconditional regional consistency probability for Method 2

Joint.Method2 Joint regional consistency probability for Method 2

Cond.Method2 Conditional regional consistency probability for Method 2

Examples

```
regional.consistency.probs(
  f.s = c(0.1, 0.45, 0.45),
  PI = 0.5,
  alpha = 0.025,
  power = 0.8,
  seed = 123
)
```

Index