

Package ‘RegionalConsistency’

May 7, 2026

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](https://doi.org/10.1002/pst.2358)>.

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Imports mvtnorm, stats

Suggests testthat (>= 3.0.0)

Config/testthat/edition 3

Encoding UTF-8

RoxygenNote 7.3.2

NeedsCompilation no

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 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

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

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