

# Package ‘RegionalConsistency’

July 21, 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](https://doi.org/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

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regional.consistency.probs

*Calculate Regional Consistency Probabilities*


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## 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

<b>f.s</b>	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.
<b>PI</b>	A numeric value specifying the threshold for Method 1 (typically set at 0.5).
<b>alpha</b>	A numeric value representing the one-sided level of significance.
<b>power</b>	A numeric value representing the target power.
<b>seed</b>	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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