

Package ‘titeIR’

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Type Package

Title Isotonic Designs for Phase 1 Trials with Late-Onset Toxicities

Version 0.1.0

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Description Functions to design phase 1 trials using an isotonic regression based design incorporating time-to-event information. Simulation and design functions are available, which incorporate information about followup and DLTs, and apply isotonic regression to devise estimates of DLT probability.

License GPL-3

Imports Iso

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NeedsCompilation no

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Contents

isotitedose	2
isotitesim	3

Index	4
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`isotitedose`*Dose assignment for TITE-IR designs*

Description

Calculate the next dose assignment for a TITE-IR design.

Usage

```
isotitedose(followup, DLT, assignment, obswin, doses, target = 1/3,  
            safety = 0.05)
```

Arguments

<code>followup</code>	A vector of followup times
<code>DLT</code>	A vector of DLT results. FALSE or 0 is interpreted as no observed DLT and TRUE or 1 is interpreted as observed DLT.
<code>assignment</code>	a vector of dose assignments. Doses should be labeled in consecutive integers from 1 to number of dose levels.
<code>obswin</code>	The observation window with respect to which the MTD is defined.
<code>doses</code>	An integer providing the number of doses.
<code>target</code>	Target DLT rate
<code>safety</code>	The safety factor to prevent overly aggressive escalation

Value

an integer specifying the recommended dose level

See Also

[isotitesim](#) for simulations

Examples

```
isotitedose(followup = c(6, 5, 4, 3, 2, 1), DLT = c(0, 0, 0, 0, 0, 0),  
            assignment = c(1, 1, 1, 2, 2, 2), obswin = 6, doses = 6)
```

`isotitesim`*Simulate TITE-IR designs*

Description

Simulates trials based on the TITE-IR design.

Usage

```
isotitesim(PI, target, n, nsim, obswin = 1, rate = 1, safety = 0.05,  
  accrual = "poisson", restrict = TRUE)
```

Arguments

<code>PI</code>	A vector of true toxicity probabilities at each dose
<code>target</code>	Target DLT rate
<code>n</code>	Sample size of the trial
<code>nsim</code>	Number of trial replicates
<code>obswin</code>	The observation window with respect to which the MTD is defined
<code>rate</code>	Patient arrival rate: expected number of arrivals per observation window
<code>safety</code>	The safety factor to prevent overly aggressive escalation
<code>accrual</code>	Specify the accrual distribution. Can be either "poisson" or "fixed". Partial strings are also acceptable.
<code>restrict</code>	If TRUE, do not allow escalation immediately after a toxic outcome (require coherent escalation)

Value

Object of type `isotite` which provides results from TITE-IR simulations

See Also

[isotitedose](#) for dose recommendation

Examples

```
isotitesim(PI = c(0.05, 0.10, 0.20, 0.30, 0.50, 0.70),  
  target = 1/3, n = 24, nsim = 10, obswin = 6, rate = 12)
```

Index

isotitedose, 2, 3

isotitesim, 2, 3

titeIR(isotitesim), 3