Package: midas2 (via r-universe)

October 24, 2026

Type Package

Title Bayesian Platform Design with Subgroup Efficacy Exploration(MIDAS-2)

Version 1.1.0

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Description The rapid screening of effective and optimal therapies from large numbers of candidate combinations, as well as exploring subgroup efficacy, remains challenging, which necessitates innovative, integrated, and efficient trial designs(Yuan, Y., et al. (2016) <doi:10.1002/sim.6971>). MIDAS-2 package enables quick and continuous screening of promising combination strategies and exploration of their subgroup effects within a unified platform design framework. We used a regression model to characterize the efficacy pattern in subgroups. Information borrowing was applied through Bayesian hierarchical model to improve trial efficiency considering the limited sample size in subgroups(Cunanan, K. M., et al. (2019) <doi:10.1177/1740774518812779>). MIDAS-2 provides an adaptive drug screening and subgroup exploring framework to accelerate immunotherapy development in an efficient, accurate, and integrated fashion(Wathen, J. K., & Thall, P. F. (2017) <doi:10.1177/1740774517692302>).

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Encoding UTF-8

Imports MCMCpack,coda,R2jags,stats

RoxygenNote 7.1.2

NeedsCompilation no

Repository https://cran.r-universe.dev

Date/Publication 2023-07-14 13:33:56 UTC

RemoteUrl https://github.com/cran/midas2

RemoteRef HEAD

RemoteSha ba87c1966104c4bf7c3f091604ce388e10e121a7

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`platform_midas2` *An Information borrowing Bayesian platform design with subgroup efficacy exploration(midas-2)*

Description

The rapid screening of effective and optimal therapies from large numbers of candidate combinations, as well as exploring subgroup efficacy, remains challenging, which necessitates innovative, integrated, and efficient trial designs. MIDAS-2 package enables quick and continuous screening of promising combination strategies and exploration of their subgroup effects within a unified platform design framework. We used a regression model to characterize the efficacy pattern in subgroups. Information borrowing was applied through Bayesian hierarchical model to improve trial efficiency considering the limited sample size in subgroups. MIDAS-2 provides an adaptive drug screening and subgroup exploring framework to accelerate immunotherapy development in an efficient, accurate, and integrated fashion.

Usage

```
platform_midas2(
  seed,
  p,
  p_tox,
  n.burnin = 10000,
  n.iter = 20000,
  n.thin = 2,
  C_T = 0.85,
  C_E1 = 0.15,
  C_E2 = 0.999
)
```

Arguments

`seed`	set a random seed to maintain the repeatability of the simulation results.
`p`	a matrix indicating the efficacy. Row number represents the number of candidate drugs.
`p_tox`	a vector indicating the toxicity.
`n.burnin`	the number of iterations in burn-in period, which means the first *n.burnin* iterations are discarded.
`n.iter`	the number of posterior iterations.
`n.thin`	every *n.thin* iterations after the burn-in period is retained for analysis.

C_T early toxicity stopping threshold, which refers to a predefined threshold used to determine when a clinical trial should be stopped early due to unacceptable levels of toxicity or adverse events in the study participants. This threshold is established to ensure the safety and well-being of the trial participants and to prevent further harm.

C_E1 early futility stopping threshold, which refers to a predefined threshold used to determine when a clinical trial should be stopped early due to lack of efficacy or futility. It is established to prevent the continuation of a trial that is unlikely to demonstrate a significant treatment effect, thus saving time, resources, and participant exposure to ineffective treatments.

C_E2 early efficacy stopping threshold, which refers to a predefined threshold used to determine when a clinical trial should be stopped early due to the demonstration of significant efficacy or positive treatment effects. This threshold is established to allow for timely decision-making and saves sample size.

Details

The sample size for a particular subgroup is limited. Therefore, it is difficult to accurately estimate treatment-related effects in each experiment arm separately, and the corresponding subgroup power may also be insufficient. Given that all candidate combination therapies in each arm consist of investigational drugs, it is justifiable to leverage information from specific subgroups across arms. Specifically, we adopt the Bayesian hierarchical model and assign half-cauchy prior distributions to the the standard deviation parameters.

Value

term.tox the indicator of whether early stopping for toxicity

term.fut the indicator of whether early stopping for futility

term.eff the indicator of whether early stopping for efficacy

final.eff a vector of final decision, either efficacy or inefficacy

post.subg subgroup analysis for treatments

post.sign signature analysis for treatments

best selection of best treatment for each subgroup

N sample size, which refers to the number of participants included in a study or experiment.

Examples

```
# Example 1
p0 <- c(0.1,0.1,0.1,0.1)
p1 <- c(0.1,0.1,0.1,0.1)

p <- rbind(p0,p1)
p_tox <- c(0.1,0.4)

# consider 1 candidate drugs with 4 subgroups
result <- platform_midas2(seed=20,p,p_tox,n.burnin=1000,
```

```
          n.iter=2000,n.thin=2,C_T=0.85,C_E1=0.15,C_E2=0.999)
result



# Example 2
p0 <- c(0.05,0.10,0.05,0.10)
p1 <- c(0.24,0.40,0.12,0.22)
p2 <- c(0.24,0.40,0.12,0.22)
p3 <- c(0.12,0.22,0.05,0.10)
p4 <- c(0.24,0.40,0.12,0.22)
p5 <- c(0.28,0.45,0.12,0.22)
p6 <- c(0.24,0.40,0.12,0.22)
p7 <- c(0.12,0.22,0.05,0.10)

p <- rbind(p0, p1, p2, p3, p4, p5, p6, p7)
p_tox <- c(0.10,0.10,0.10,0.10,0.10,0.10,0.15,0.20)

# consider 7 candidate drugs with 4 subgroups
result <- platform_midas2(seed=12,p,p_tox,n.burnin=10000,
          n.iter=20000,n.thin=2,C_T=0.85,C_E1=0.15,C_E2=0.999)
result
```

`platform_midas2s` *An Bayesian platform design without subgroup efficacy exploration(midas-2s), which is the degenerate competing design in the simulation.*

Description

MIDAS-2s is the degenerate competing designs that do not consider subgroups. Beta-binomial model is applied for efficacy in whole population of each arm.

Usage

```
platform_midas2s(seed, p, p_tox, C_T = 0.85, C_E1 = 0.15, C_E2 = 0.999)
```

Arguments

`seed`	set a random seed to maintain the repeatability of the simulation results.
`p`	a matrix indicating the efficacy. Row number represents the number of candidate drugs.
`p_tox`	a vector indicating the toxicity.
`C_T`	early toxicity stopping threshold, which refers to a predefined threshold used to determine when a clinical trial should be stopped early due to unacceptable levels of toxicity or adverse events in the study participants. This threshold is

established to ensure the safety and well-being of the trial participants and to prevent further harm.

C_E1 early futility stopping threshold, which refers to a predefined threshold used to determine when a clinical trial should be stopped early due to lack of efficacy or futility. It is established to prevent the continuation of a trial that is unlikely to demonstrate a significant treatment effect, thus saving time, resources, and participant exposure to ineffective treatments.

C_E2 early efficacy stopping threshold, which refers to a predefined threshold used to determine when a clinical trial should be stopped early due to the demonstration of significant efficacy or positive treatment effects. This threshold is established to allow for timely decision-making and saves sample size.

Value

term.tox the indicator of whether early stopping for toxicity

term.fut the indicator of whether early stopping for futility

term.eff the indicator of whether early stopping for efficacy

final.eff a vector of final decision, either efficacy or inefficacy

N sample size, which refers to the number of participants included in a study or experiment.

Examples

```
# Example 1
p0 <- c(0.1,0.1,0.1,0.1)
p1 <- c(0.1,0.1,0.1,0.1)

p <- rbind(p0,p1)
p_tox <- c(0.1,0.4)

# consider 1 candidate drugs with 4 subgroups
result <- platform_midas2s(seed=20,p,p_tox,C_T=0.85,C_E1=0.15,C_E2=0.999)
result



# Example 2
p0 <- c(0.05,0.10,0.05,0.10)
p1 <- c(0.24,0.40,0.12,0.22)
p2 <- c(0.24,0.40,0.12,0.22)
p3 <- c(0.12,0.22,0.05,0.10)
p4 <- c(0.24,0.40,0.12,0.22)
p5 <- c(0.28,0.45,0.12,0.22)
p6 <- c(0.24,0.40,0.12,0.22)
p7 <- c(0.12,0.22,0.05,0.10)

p <- rbind(p0, p1, p2, p3, p4, p5, p6, p7)
p_tox <- c(0.10,0.10,0.10,0.10,0.10,0.10,0.15,0.20)
```

```
# consider 7 candidate drugs with 4 subgroups
result <- platform_midas2s(seed=12,p,p_tox,C_T=0.85,C_E1=0.15,C_E2=0.999)
result
```

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