

Package ‘BACCT’

July 21, 2025

Type Package

Title Bayesian Augmented Control for Clinical Trials

Version 1.0

Date 2016-06-24

Description Implements the Bayesian Augmented Control (BAC, a.k.a. Bayesian historical data borrowing) method under clinical trial setting by calling 'Just Another Gibbs Sampler' ('JAGS') software. In addition, the 'BACCT' package evaluates user-specified decision rules by computing the type-I error/power, or probability of correct go/no-go decision at interim look. The evaluation can be presented numerically or graphically. Users need to have 'JAGS' 4.0.0 or newer installed due to a compatibility issue with 'rjags' package. Currently, the package implements the BAC method for binary outcome only. Support for continuous and survival endpoints will be added in future releases. We would like to thank AbbVie's Statistical Innovation group and Clinical Statistics group for their support in developing the 'BACCT' package.

Depends R (>= 2.10)

Imports rjags, ggplot2, reshape2

License GPL (>= 3)

LazyData TRUE

RoxygenNote 5.0.1

NeedsCompilation no

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Repository CRAN

Date/Publication 2016-06-25 19:07:22

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Description

Implements the Bayesian Augmented Control (BAC, a.k.a. Bayesian historical data borrowing) method under clinical trial setting by calling 'Just Another Gibbs Sampler' ('JAGS') software. In addition, the 'BACCT' package evaluates user-specified decision rules by computing the type-I error/power, or probability of correct go/no-go decision at interim look. The evaluation can be presented numerically or graphically. Users need to have 'JAGS' 4.0.0 or newer installed due to a compatibility issue with 'rjags' package. Currently, the package implements the BAC method for binary outcome only. Support for continuous and survival endpoints will be added in future releases. We would like to thank AbbVie's Statistical Innovation group and Clinical Statistics group for their support in developing the 'BACCT' package.

Details

JAGS software can be downloaded from <http://mcmc-jags.sourceforge.net/>.

References

Viele, et al., "Use of historical control data for assessing treatment effects in clinical trials." Pharmaceutical statistics 13(1) (2014): 41-54.

Examples

```
## Not run:
library(BACCT)

#####
#Example for binary response#
#####

#specify historical data
yh = c(11,305,52);nh = c(45,874,120)
#specify subjects
n1 = 20;n2 = 30
#implement BAC and wait patiently
post = BAC_binom(yh=yh,nh=nh,n1=n1,n2=n2,n.chain=5,
  criterion.type="diff",sim.mode="express")
#evaluate the decision
rule1 = decision_eval(object=post,decision.rule=c(0.05,0.05),
  control.range=seq(0.3,0.5,0.01),es=c(0,0.1,0.15),csv.name="rule1.csv")
#plot the decision evaluation
(fig1 = plot(rule1))
#continue polishing the figure
#add data points
fig1 + geom_point(size=4)
```

```
#replace the title
fig1 + ggtitle("replace title")
#add reference lines
fig1 + geom_hline(aes(yintercept=0.05)) +
      geom_vline(aes(xintercept=0.42),color="black",type="dashed")

## End(Not run)
```

BAC_binom

Bayesian Augmented Control for Binary Responses

Description

Calling JAGS to implement BAC for binary responses

Usage

```
BAC_binom(yh, nh, n1, n2, y1.range = 0:n1, y2.range = 0:n2, n.chain = 5,
  tau.alpha = 0.001, tau.beta = 0.001, prior.type = "nonmixture",
  criterion.type = c("diff", "prob"), prob.threshold, sim.mode = c("full",
  "express"))
```

Arguments

yh, nh	Vector of the numbers of events (subjects) in the historical trial(s). Must be of equal length.
n1, n2	Number of subjects in the control or treatment arm of the current trial.
y1.range, y2.range	Number of events in control or treatment arm of the current trial. See "Details".
n.chain	Controls the number of posterior samples. Each chain contains 20,000 samples.
tau.alpha, tau.beta	Hyperparameters of the inverse gamma distribution controlling the extent of borrowing.
prior.type	Type of prior on control groups. Currently, only the inverse-gamma prior is implemented.
criterion.type	Type of posterior quantities to be monitored. See "Details."
prob.threshold	For criterion.type="prob" only. See "Details".
sim.mode	Simulation duration reduces greatly in "express" mode, if treatment and control arms are independent. See "Details".

Details

There are two types of posterior quantities for `criterion.type` argument. With "diff" option, the quantity computed is $p_T - p_C$; with "prob," such quantity is $pr(p_T - p_C > \Delta)$, where Δ is specified by `prob.threshold` argument.

By default, `y1.range` and `y2.range` cover all possible outcomes and should be left unspecified in most cases. However, when `n1` and/or `n2` is fairly large, it is acceptable to use a reduced range that covers the outcomes that are most likely (e.g., within 95% CI) to be observed. This may help shorten the time to run MCMC.

Another way that can greatly shorten the MCMC running time is to specify "express" mode in `sim.mode` argument. Express mode reduces the number of simulations from `length(y1.range)*length(y2.range)` to `length(y1.range)+length(y2.range)`. Express mode is proper when the treatment arm rate is independent of control arm rate.

Value

An object of class "BAC".

Author(s)

Hongtao Zhang

Examples

```
## Not run:
library(BACCT)
#borrow from 3 historical trials#
yh = c(11,300,52);nh = c(45,877,128)
#specify current trial sample sizes#
n1 = 20;n2 = 30

#Difference criterion type in full simulation mode#
obj1 = BAC_binom(yh=yh,nh=nh,n1=n1,n2=n2,n.chain=5,
criterion.type="diff",sim.mode="full")

#Probability criterion type in express simulation mode#
obj2 = BAC_binom(yh=yh,nh=nh,n1=n1,n2=n2,n.chain=5,
criterion.type="prob",prob.threshold=0.1,sim.mode="express")

#S3 method for class "BAC"
summary(obj1)

## End(Not run)
```

decision_eval	<i>Evaluating a Decision Rule</i>
---------------	-----------------------------------

Description

Applies a decision rule to a "BAC" class object and provides rule evaluation

Usage

```
decision_eval(object, decision.rule, control.range, es, csv.name = NULL)
```

Arguments

object	An object of class "BAC".
decision.rule	A vector of $c(a,b)$ specifying the thresholds for claiming significance (or probabilities of making correct go/no-go decisions at interim look). See "Details".
control.range	A vector of control rates at which the decision rule is evaluated.
es	A vector of treatment arm effect sizes, compared to control arm.
csv.name	If a name is specified, the output data set is exported in CSV format.

Details

The decision rules specified in $c(a,b)$ may be in the context of either interim or final analysis. At the interim, a "go" decision is made if the criterion in the "BAC" object exceeds b and a "no go" decision if such criterion is below a . Otherwise, the decision falls in the gray zone.

For the final analysis, the decision rule should satisfy $a=b$. Significance is claimed if the criterion in the "BAC" object exceeds a . Specifying an a larger than b will lead to an error.

For interim analysis, specified decision rule is evaluated by the probability of making a correct go or no go decision. For final analysis, power or type-I error is computed.

Negative es values are allowed if a lower rate is desirable.

Value

An object of class "BACdecision".

Author(s)

Hongtao Zhang

Examples

```
## Not run:
#borrow from 3 historical trials#
yh = c(11,300,52);nh = c(45,877,128)
#specify current trial sample sizes#
n1 = 20;n2 = 30
obj = BAC_binom(yh=yh,nh=nh,n1=n1,n2=n2,n.chain=5,
criterion.type="prob",prob.threshold=0.1,sim.mode="express")

rule = decision_eval(obj,decision.rule=c(0.05,0.15),
control.range=seq(0.3,0.5,0.01),es=c(0,0.1,0.2),csv.name="result.csv")

#S3 method for class "BACdecision"
plot(rule,interim=T)

## End(Not run)
```

heatmap_decision	<i>Heatmap for Decision Rules</i>
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Description

Visualizing a decision rule for binary endpoint using heatmap plots

Usage

```
heatmap_decision(object, decision.rule, y1.display = NA, y2.display = NA)
```

Arguments

object	An object of "BAC" class.
decision.rule	A vector of c(a,b) specifying the decision rule. See help for decision_eval function.
y1.display, y2.display	A subset of control/treatment number of events to be displayed.

Author(s)

Hongtao Zhang

Examples

```
## Not run:
#borrow from 3 historical trials#
yh = c(11,300,52);nh = c(45,877,128)
#specify current trial sample sizes#
n1 = 20;n2 = 30
obj = BAC_binom(yh=yh,nh=nh,n1=n1,n2=n2,n.chain=5,
```

```

criterion.type="prob",prob.threshold=0.1,sim.mode="express")

#generate full heatmap
heatmap_decision(obj,decision.rule=c(0.05,0.15))
#generate partial heatmap
heatmap_decision(obj,decision.rule=c(0.05,0.15),y1.display=5:15,y2.display=10:25)

## End(Not run)

```

plot.BACdecision	<i>Generateing Plot(s) Used for Decision Rule Evaluation</i>
------------------	--

Description

plot method for class "BACdecision"

Usage

```

## S3 method for class 'BACdecision'
plot(x, es.null = 0, es.null.side, interim = F, ...)

```

Arguments

x	An object of "BACdecision" class.
es.null	Effect size under the null hypothesis. Default is 0.
es.null.side	"=" is the only option now.
interim	Logical indicator of interim analysis (versus final analysis). Figures will differ in legends and titles.
...	Argument to be passed to or from other methods

Details

If interim=F, only one power/type I error figure will be generated. Otherwise, two figures will be generated correponding to "No Go" and "Go" decisions respectively.

Value

An object of "ggplot" class. Certain further edits are still allowed, such as changing title and adding reference lines.

Author(s)

Hongtao Zhang

`summary.BAC`*Summarizing BAC*

Description

summary method for class "BAC"

Usage

```
## S3 method for class 'BAC'  
summary(object, ...)
```

Arguments

<code>object</code>	An object of class "BAC"
<code>...</code>	Argument to be passed to or from other methods

Author(s)

Hongtao Zhang

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