Package 'historicalborrow'

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Title Non-Longitudinal Bayesian Historical Borrowing Models **Description** Historical borrowing in clinical trials can improve precision and operating characteristics. This package supports a hierarchical model and a mixture model to borrow historical control data from other studies to better characterize the control response of the current study. It also quantifies the amount of borrowing through benchmark models (independent and pooled). Some of the methods are discussed by Viele et al. (2013) <doi:10.1002/pst.1589>.

```
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2 hb_convergence

R topics documented:

	historicalborrow-package	2
	hb_convergence	2
	hb_data	3
	hb_mcmc_hierarchical	5
	hb_mcmc_independent	7
	hb_mcmc_mixture	9
	hb_mcmc_mixture_hyperparameters	12
	hb_mcmc_pool	14
	hb_metrics	16
	hb_plot_borrow	18
	hb_plot_group	19
	hb_plot_tau	20
	hb_sim_hierarchical	21
	hb_sim_independent	23
	hb_sim_mixture	25
	hb_sim_pool	27
	hb_summary	28
	hb_s_tau	32
Index		33

historicalborrow-package

historicalborrow: Bayesian historical borrowing models for clinical studies.

Description

Bayesian historical borrowing models for clinical studies.

hb_convergence

Check convergence diagnostics

Description

Check the convergence diagnostics on a model.

Usage

hb_convergence(mcmc)

Arguments

mcmc

A wide data frame of posterior samples returned by hb_mcmc_hierarchical() or similar MCMC function.

hb_data 3

Value

A data frame of summarized convergence diagnostics. max_rhat is the maximum univariate Gelman/Rubin potential scale reduction factor over all the parameters of the model, min_ess_bulk is the minimum bulk effective sample size over the parameters, and min_ess_tail is the minimum tail effective sample size. max_rhat should be below 1.01, and the ESS metrics should both be above 100 times the number of MCMC chains. If any of these conditions are not true, the MCMC did not converge, and it is recommended to try running the model for more saved iterations (and if max_rhat is high, possibly more warmup iterations).

See Also

```
Other mcmc: hb_mcmc_hierarchical(), hb_mcmc_independent(), hb_mcmc_mixture_hyperparameters(), hb_mcmc_mixture(), hb_mcmc_pool()
```

Examples

```
data <- hb_sim_pool(n_continuous = 2)$data
mcmc <- hb_mcmc_pool(
    data,
    n_chains = 1,
    n_adapt = 100,
    n_warmup = 200,
    n_iterations = 200
)
hb_convergence(mcmc)</pre>
```

hb_data

Standardize data

Description

Standardize a tidy input dataset.

Usage

```
hb_data(
    data,
    response,
    study,
    study_reference,
    group,
    group_reference,
    patient,
    covariates
)
```

4 hb_data

Arguments

data A tidy data frame or tibble with the data.

response Character of length 1, name of the column in data with the response/outcome

variable. data[[response]] must be a continuous variable, and it *should* be the change from baseline of a clinical endpoint of interest, as opposed to just the raw response. Treatment differences are computed directly from this scale, please supply change from baseline unless you are absolutely certain that treatment differences computed directly from this quantity are clinically meaningful.

study Character of length 1, name of the column in data with the study ID.

study_reference

Atomic of length 1, element of the study column that indicates the current study.

(The other studies are historical studies.)

group Character of length 1, name of the column in data with the group ID.

group_reference

Atomic of length 1, element of the group column that indicates the control

group. (The other groups may be treatment groups.)

patient Character of length 1, name of the column in data with the patient ID.

covariates Character vector of column names in data with the columns with baseline co-

variates. These can be continuous, categorical, or binary. Regardless, historicalborrow

derives the appropriate model matrix.

Details

Users do not normally need to call this function. It mainly serves exposes the indexing behavior of studies and group levels to aid in interpreting summary tables.

Value

A standardized tidy data frame with one row per patient and the following columns:

- response: continuous response/outcome variable. (Should be change from baseline of an outcome of interest.)
- study_label: human-readable label of the study.
- study: integer study index with the max index equal to the current study (at study_reference).
- group_label: human-readable group label (e.g. treatment arm name).
- group: integer group index with an index of 1 equal to the control group (at group_reference).
- patient_label: original patient ID.
- patient: integer patient index.
- covariate_*: baseline covariate columns.

See Also

Other data: hb_s_tau()

hb_mcmc_hierarchical

5

Examples

```
data <- hb_sim_independent(n_continuous = 1, n_study = 2)$data</pre>
data <- dplyr::select(</pre>
  data,
  study,
  group,
  patient,
  response,
  tidyselect::everything()
colnames(data) <- c("trial", "arm", "subject", "change", "cov1", "cov2")</pre>
data$trial <- paste0("trial", data$trial)</pre>
data$arm <- paste0("arm", data$arm)</pre>
hb_data(
  data = data,
  response = "change",
  study = "trial",
  study_reference = "trial1",
  group = "arm",
  group_reference = "arm1",
  patient = "subject",
  covariates = c("cov1", "cov2")
```

hb_mcmc_hierarchical Hierarchical model MCMC

Description

Run the hierarchical model with MCMC.

Usage

```
hb_mcmc_hierarchical(
  data,
  response = "response",
  study = "study",
  study_reference = max(data[[study]]),
  group = "group",
  group_reference = min(data[[group]]),
  patient = "patient",
  covariates = grep("^covariate", colnames(data), value = TRUE),
  s_delta = 30,
  s_beta = 30,
  s_sigma = 30,
  s_mu = 30,
  s_tau = 30,
  n_chains = 4,
```

```
n_adapt = 2000,
n_warmup = 4000,
n_iterations = 20000,
quiet = TRUE
)
```

Arguments

data Tidy data frame with one row per patient, indicator columns for the response

variable, study, group, and patient, and covariates. All columns must be atomic vectors (e.g. not lists). The data for the mixture and simple models should have just one study, and the others should have data from more than one study. The simple model can be used to get the historical data components of m_omega and

s_omega for the mixture model.

response Character of length 1, name of the column in data with the response/outcome

variable. data[[response]] must be a continuous variable, and it *should* be the change from baseline of a clinical endpoint of interest, as opposed to just the raw response. Treatment differences are computed directly from this scale, please supply change from baseline unless you are absolutely certain that treatment

differences computed directly from this quantity are clinically meaningful.

Study Character of length 1, name of the column in data with the study ID.

study_reference

Atomic of length 1, element of the study column that indicates the current study.

(The other studies are historical studies.)

group Character of length 1, name of the column in data with the group ID.

group_reference

Atomic of length 1, element of the group column that indicates the control

group. (The other groups may be treatment groups.)

patient Character of length 1, name of the column in data with the patient ID.

covariates Character vector of column names in data with the columns with baseline co-

variates. These can be continuous, categorical, or binary. Regardless, historicalborrow

derives the appropriate model matrix.

s_delta Numeric of length 1, prior standard deviation of the study-by-group effect pa-

rameters delta.

s_beta Numeric of length 1, prior standard deviation of the fixed effects beta.

s_sigma Numeric of length 1, prior upper bound of the residual standard deviations.

s_mu Positive numeric of length 1, hyperparameter: prior standard deviation of the

mean mu of the study-level control means alpha.

s_tau Positive numeric of length 1, hyperparameter: uniform prior upper bound of the

standard deviation tau of the study-level control means alpha.

n_chains Number of MCMC chains to run.

n_adapt Number of adaptation iterations to run.

n_warmup Number of warmup iterations per chain to run.

n_iterations Number of saved MCMC iterations per chain to run.

quiet Logical of length 1, TRUE to suppress R console output.

Value

A tidy data frame of parameter samples from the posterior distribution. Columns .chain, .iteration, and .draw have the meanings documented in the posterior package.

See Also

```
Other mcmc: hb_convergence(), hb_mcmc_independent(), hb_mcmc_mixture_hyperparameters(), hb_mcmc_mixture(), hb_mcmc_pool()
```

Examples

```
if (!identical(Sys.getenv("HB_TEST", unset = ""), "")) {
data <- hb_sim_hierarchical(n_continuous = 2)$data
hb_mcmc_hierarchical(
    data,
    n_chains = 1,
    n_adapt = 100,
    n_warmup = 50,
    n_iterations = 50
)
}</pre>
```

hb_mcmc_independent

Independent-study model MCMC

Description

Run the independent-study model with MCMC.

Usage

```
hb_mcmc_independent(
  data,
  response = "response",
  study = "study",
  study_reference = max(data[[study]]),
  group = "group",
  group_reference = min(data[[group]]),
  patient = "patient",
  covariates = grep("^covariate", colnames(data), value = TRUE),
  s_alpha = 30,
  s_{delta} = 30,
  s_beta = 30,
  s_sigma = 30,
  n_{chains} = 4,
  n_adapt = 2000,
  n_{warmup} = 4000,
  n_{iterations} = 20000,
```

```
quiet = TRUE
)
```

Arguments

data Tidy data frame with one row per patient, indicator columns for the response

variable, study, group, and patient, and covariates. All columns must be atomic vectors (e.g. not lists). The data for the mixture and simple models should have just one study, and the others should have data from more than one study. The simple model can be used to get the historical data components of m_omega and

s_omega for the mixture model.

response Character of length 1, name of the column in data with the response/outcome

variable. data[[response]] must be a continuous variable, and it *should* be the change from baseline of a clinical endpoint of interest, as opposed to just the raw response. Treatment differences are computed directly from this scale, please supply change from baseline unless you are absolutely certain that treatment differences computed directly from this quantity are clinically meaningful.

study Character of length 1, name of the column in data with the study ID.

study_reference

Atomic of length 1, element of the study column that indicates the current study.

(The other studies are historical studies.)

group Character of length 1, name of the column in data with the group ID.

group_reference

Atomic of length 1, element of the group column that indicates the control

group. (The other groups may be treatment groups.)

patient Character of length 1, name of the column in data with the patient ID.

covariates Character vector of column names in data with the columns with baseline co-

variates. These can be continuous, categorical, or binary. Regardless, historicalborrow

derives the appropriate model matrix.

s_alpha Numeric of length 1, prior standard deviation of the study-specific control group

mean parameters alpha.

s_delta Numeric of length 1, prior standard deviation of the study-by-group effect pa-

rameters delta.

s_beta Numeric of length 1, prior standard deviation of the fixed effects beta.

s_sigma Numeric of length 1, prior upper bound of the residual standard deviations.

n_chains Number of MCMC chains to run.

n_adapt Number of adaptation iterations to run.

n_warmup Number of warmup iterations per chain to run.

quiet Logical of length 1, TRUE to suppress R console output.

Value

A tidy data frame of parameter samples from the posterior distribution. Columns .chain, .iteration, and .draw have the meanings documented in the posterior package.

hb_mcmc_mixture 9

See Also

```
Other mcmc: hb_convergence(), hb_mcmc_hierarchical(), hb_mcmc_mixture_hyperparameters(), hb_mcmc_mixture(), hb_mcmc_pool()
```

Examples

```
if (!identical(Sys.getenv("HB_TEST", unset = ""), "")) {
data <- hb_sim_independent(n_continuous = 2)$data
hb_mcmc_independent(
    data,
    n_chains = 1,
    n_adapt = 100,
    n_warmup = 50,
    n_iterations = 50
)
}</pre>
```

hb_mcmc_mixture

Mixture model MCMC

Description

Run the mixture model with MCMC.

Usage

```
hb_mcmc_mixture(
  data,
  response = "response",
  study = "study",
  study_reference = max(data[[study]]),
  group = "group",
  group_reference = min(data[[group]]),
  patient = "patient",
  covariates = grep("^covariate", colnames(data), value = TRUE),
  s_{delta} = 30,
  s_beta = 30,
  s_sigma = 30,
 m_{omega} = c(0, 0),
  s_{omega} = c(30, 30),
  p_omega = 1/length(m_omega),
  n_{chains} = 4,
  n_adapt = 2000,
  n_{warmup} = 4000,
  n_{iterations} = 20000,
  quiet = TRUE
)
```

10 hb_mcmc_mixture

Arguments

data Tidy data frame with one row per patient, indicator columns for the response

variable, study, group, and patient, and covariates. All columns must be atomic vectors (e.g. not lists). The data for the mixture and simple models should have just one study, and the others should have data from more than one study. The simple model can be used to get the historical data components of m_omega and

s_omega for the mixture model.

response Character of length 1, name of the column in data with the response/outcome

variable. data[[response]] must be a continuous variable, and it *should* be the change from baseline of a clinical endpoint of interest, as opposed to just the raw response. Treatment differences are computed directly from this scale, please supply change from baseline unless you are absolutely certain that treatment

differences computed directly from this quantity are clinically meaningful.

study Character of length 1, name of the column in data with the study ID.

study_reference

Atomic of length 1, element of the study column that indicates the current study.

(The other studies are historical studies.)

group Character of length 1, name of the column in data with the group ID.

group_reference

Atomic of length 1, element of the group column that indicates the control

group. (The other groups may be treatment groups.)

patient Character of length 1, name of the column in data with the patient ID.

covariates Character vector of column names in data with the columns with baseline co-

variates. These can be continuous, categorical, or binary. Regardless, historicalborrow

derives the appropriate model matrix.

s_delta Numeric of length 1, prior standard deviation of the study-by-group effect pa-

rameters delta.

s_beta Numeric of length 1, prior standard deviation of the fixed effects beta.

s_sigma Numeric of length 1, prior upper bound of the residual standard deviations.

m_omega Numeric with length equal to the number of supposed studies (but only the cur-

rent study is in the data). m_omega is the prior control group mean of each study. The last element corresponds to the current study, and the others are for histori-

cal studies.

s_omega Numeric with length equal to the number of supposed studies (but only the cur-

rent study is in the data). s_omega is the prior control group standard deviation of each study. The last element corresponds to the current study, and the others

are for historical studies.

p_omega Numeric with length equal to the number of supposed studies (but only the cur-

rent study is in the data). p_omega is the prior control group mixture proportion of each study. The last element corresponds to the current study, and the others

are for historical studies.

n_chains Number of MCMC chains to run.

n_adapt Number of adaptation iterations to run.

hb_mcmc_mixture 11

```
n_warmup Number of warmup iterations per chain to run.

n_iterations Number of saved MCMC iterations per chain to run.

quiet Logical of length 1, TRUE to suppress R console output.
```

Details

The study-specific components of the mixture prior are all fixed in advance. Mixture components are normal distributions with means in m_omega and standard deviations in s_omega. These vectors are ordered with historical studies first and the current study last. These mixture components can be computed using hb_mcmc_mixture_hyperparameters() on a full set of data (all the historical studies and the current study together). Then the m_omega and s_omega columns of the output can be plugged directly into hb_mcmc_mixture(). See the examples for a demonstration.

Value

A tidy data frame of parameter samples from the posterior distribution. Columns .chain, .iteration, and .draw have the meanings documented in the posterior package.

See Also

```
Other mcmc: hb_convergence(), hb_mcmc_hierarchical(), hb_mcmc_independent(), hb_mcmc_mixture_hyperparamehb_mcmc_pool()
```

Examples

```
data_all_studies <- hb_sim_independent(n_continuous = 2)$data</pre>
data_all_studies$study <- paste0("study", data_all_studies$study)</pre>
hyperparameters <- hb_mcmc_mixture_hyperparameters(</pre>
  data = data_all_studies,
  response = "response",
  study = "study",
  study_reference = "study5",
  group = "group",
  group_reference = 1,
  patient = "patient",
  n_{chains} = 1,
  n_adapt = 100,
  n_{warmup} = 50,
  n_{iterations} = 50
)
print(hyperparameters)
data_current_study <- dplyr::filter(data_all_studies, study == max(study))</pre>
hb_mcmc_mixture(
  data = data_current_study,
  response = "response",
  study = "study",
  study_reference = "study5",
  group = "group",
  group_reference = 1,
  patient = "patient",
  m_omega = hyperparameters$m_omega, # use hyperparams from historical data
```

```
s_omega = hyperparameters$s_omega, # use hyperparams from historical data
p_omega = rep(1 / nrow(hyperparameters), nrow(hyperparameters)),
n_chains = 1,
n_adapt = 100,
n_warmup = 50,
n_iterations = 50
```

hb_mcmc_mixture_hyperparameters

Mixture model MCMC hyperparameters

Description

Run a simple model separately on each historical study control group and compute hyperparameters for hb_mcmc_mixture().

Usage

```
hb_mcmc_mixture_hyperparameters(
  data,
  response = "response",
  study = "study",
  study_reference = max(data[[study]]),
  group = "group",
  group_reference = min(data[[group]]),
  patient = "patient",
  m_mu = 0,
  s_mu = 30,
  s_sigma = 30,
  m_omega_current = 0,
  s_{omega_current} = 30,
  n_{chains} = 4,
  n_adapt = 2000,
  n_{warmup} = 4000,
  n_{iterations} = 20000,
  quiet = TRUE
)
```

Arguments

data

Tidy data frame with one row per patient, indicator columns for the response variable, study, group, and patient, and covariates. All columns must be atomic vectors (e.g. not lists). The data for the mixture and simple models should have just one study, and the others should have data from more than one study. The simple model can be used to get the historical data components of m_omega and s_omega for the mixture model.

response Character of length 1, name of the column in data with the response/outcome

variable. data[[response]] must be a continuous variable, and it *should* be the change from baseline of a clinical endpoint of interest, as opposed to just the raw response. Treatment differences are computed directly from this scale, please supply change from baseline unless you are absolutely certain that treatment differences computed directly from this quantity are clinically meaningful.

study Character of length 1, name of the column in data with the study ID.

study_reference

Atomic of length 1, element of the study column that indicates the current study.

(The other studies are historical studies.)

group Character of length 1, name of the column in data with the group ID.

group_reference

Atomic of length 1, element of the group column that indicates the control

group. (The other groups may be treatment groups.)

patient Character of length 1, name of the column in data with the patient ID.

m_mu Numeric of length 1, prior mean of the mean mu in the simple model.

s_mu Numeric of length 1, prior standard deviation of the mean mu in the simple

model.

s_sigma Numeric of length 1, uniform prior upper bound of the residual standard devia-

tion sigma in the simple model.

m_omega_current

Numeric with length 1, m_omega value of the current study. Inserted as the final

component of the m_omega column in the output.

s_omega_current

Numeric with length 1, s_omega value of the current study. Inserted as the final

component of the s_omega column in the output.

n_chains
 n_adapt
 n_warmup
 n_iterations
 Number of MCMC chains to run.
 Number of adaptation iterations to run.
 Number of warmup iterations per chain to run.
 Number of saved MCMC iterations per chain to run.

quiet Logical of length 1, TRUE to suppress R console output.

Details

The model is a simple Bayesian model with a normal likelihood, an unknown mean mu, and an unknown standard deviation sigma. For each historical study, the posterior mean of mu becomes the corresponding component of m_omega in the output, and the posterior standard deviation of mu becomes the corresponding component of s_omega in the output. See the examples in this help file for a demonstration. m_omega and s_omega define the components of the mixture prior in hb_mcmc_mixture() that act as the contribution of the historical studies to the model.

Value

A tidy data frame of hyperparameter values for hb_mcmc_mixture(). The first several rows are for historical studies, and the last row is for the current study. Studies/rows are sorted in the order hb_mcmc_mixture() sorts them, so you can use columns m_omega and s_omega for the same dataset and same values of other arguments directly in hb_mcmc_mixture().

14 hb_mcmc_pool

See Also

```
Other mcmc: hb_convergence(), hb_mcmc_hierarchical(), hb_mcmc_independent(), hb_mcmc_mixture(), hb_mcmc_pool()
```

Examples

```
data_all_studies <- hb_sim_independent(n_continuous = 2)$data</pre>
data_all_studies$study <- paste0("study", data_all_studies$study)</pre>
hyperparameters <- hb_mcmc_mixture_hyperparameters(</pre>
  data = data_all_studies,
  response = "response",
  study = "study",
  study_reference = "study5",
  group = "group",
  group_reference = 1,
  patient = "patient",
  n_{chains} = 1,
  n_adapt = 100,
  n_{warmup} = 50,
  n_{iterations} = 50
)
print(hyperparameters)
data_current_study <- dplyr::filter(data_all_studies, study == max(study))</pre>
hb_mcmc_mixture(
  data = data_current_study,
  response = "response",
  study = "study",
  study_reference = "study5",
  group = "group",
  group_reference = 1,
  patient = "patient",
  m_omega = hyperparameters$m_omega, # use hyperparams from historical data
  s_omega = hyperparameters$s_omega, # use hyperparams from historical data
  p_omega = rep(1 / nrow(hyperparameters), nrow(hyperparameters)),
  n_{chains} = 1,
  n_adapt = 100,
  n_{warmup} = 50,
  n_{iterations} = 50
)
```

hb_mcmc_pool

Non-longitudinal pooled MCMC

Description

Run the non-longitudinal pooled model with MCMC.

hb_mcmc_pool 15

Usage

```
hb_mcmc_pool(
  data,
  response = "response",
  study = "study",
  study_reference = max(data[[study]]),
  group = "group",
  group_reference = min(data[[group]]),
  patient = "patient",
  covariates = grep("^covariate", colnames(data), value = TRUE),
  s_alpha = 30,
  s_{delta} = 30,
  s_beta = 30,
  s\_sigma = 30,
  n_{chains} = 4,
  n_adapt = 2000,
  n_{warmup} = 4000,
  n_{iterations} = 20000,
  quiet = TRUE
)
```

Arguments

data

Tidy data frame with one row per patient, indicator columns for the response variable, study, group, and patient, and covariates. All columns must be atomic vectors (e.g. not lists). The data for the mixture and simple models should have just one study, and the others should have data from more than one study. The simple model can be used to get the historical data components of m_omega and s_omega for the mixture model.

response

Character of length 1, name of the column in data with the response/outcome variable. data[[response]] must be a continuous variable, and it *should* be the change from baseline of a clinical endpoint of interest, as opposed to just the raw response. Treatment differences are computed directly from this scale, please supply change from baseline unless you are absolutely certain that treatment differences computed directly from this quantity are clinically meaningful.

study

Character of length 1, name of the column in data with the study ID.

study_reference

Atomic of length 1, element of the study column that indicates the current study. (The other studies are historical studies.)

group

Character of length 1, name of the column in data with the group ID.

group_reference

Atomic of length 1, element of the group column that indicates the control group. (The other groups may be treatment groups.)

patient

Character of length 1, name of the column in data with the patient ID.

covariates

Character vector of column names in data with the columns with baseline covariates. These can be continuous, categorical, or binary. Regardless, historicalborrow derives the appropriate model matrix.

16 hb_metrics

s_alpha	Numeric of length 1, prior standard deviation of the study-specific control group mean parameters alpha.
s_delta	Numeric of length 1, prior standard deviation of the study-by-group effect parameters delta.
s_beta	Numeric of length 1, prior standard deviation of the fixed effects beta.
s_sigma	Numeric of length 1, prior upper bound of the residual standard deviations.
n_chains	Number of MCMC chains to run.
n_adapt	Number of adaptation iterations to run.
n_warmup	Number of warmup iterations per chain to run.
n_iterations	Number of saved MCMC iterations per chain to run.
quiet	Logical of length 1, TRUE to suppress R console output.

Value

A tidy data frame of parameter samples from the posterior distribution. Columns .chain, .iteration, and .draw have the meanings documented in the posterior package.

See Also

```
Other mcmc: hb_convergence(), hb_mcmc_hierarchical(), hb_mcmc_independent(), hb_mcmc_mixture_hyperparamehb_mcmc_mixture()
```

Examples

```
if (!identical(Sys.getenv("HB_TEST", unset = ""), "")) {
  data <- hb_sim_pool(n_continuous = 2)$data
  hb_mcmc_pool(
    data,
    n_chains = 1,
    n_adapt = 100,
    n_warmup = 50,
    n_iterations = 50
)
}</pre>
```

hb_metrics

Borrowing metrics

Description

Calculate historical borrowing metrics using summary output from a fitted borrowing model and analogous summaries from the benchmark models.

Usage

```
hb_metrics(borrow, pool, independent)
```

hb_metrics 17

Arguments

borrow A data frame returned by hb_summary() for a borrowing model, either the hier-

archical model or the mixture model.

pool A data frame returned by hb_summary() for the pooled model.

independent A data frame returned by hb_summary() for the independent model.

Value

A data frame with borrowing metrics.

See Also

```
Other summary: hb_summary()
```

Examples

```
if (!identical(Sys.getenv("HB_TEST", unset = ""), "")) {
data <- hb_sim_independent(n_continuous = 2)$data</pre>
mcmc_borrow <- hb_mcmc_hierarchical(</pre>
  data,
  n_{chains} = 1,
  n_adapt = 100,
  n_{warmup} = 100,
  n_{iterations} = 200
)
mcmc_pool <- hb_mcmc_pool(</pre>
  data,
  n_{chains} = 1,
  n_adapt = 100,
  n_{warmup} = 50,
  n_{iterations} = 50
mcmc_independent <- hb_mcmc_independent(</pre>
  data,
  n_{chains} = 1,
  n_adapt = 100,
  n_{warmup} = 50,
  n_{iterations} = 50
)
borrow <- hb_summary(mcmc_borrow, data)</pre>
pool <- hb_summary(mcmc_pool, data)</pre>
independent <- hb_summary(mcmc_independent, data)</pre>
hb_metrics(
  borrow = borrow,
  pool = pool,
  independent = independent
)
}
```

18 hb_plot_borrow

hb_plot_borrow

Plot a borrowing model response against the benchmark models.

Description

Plot the response from a borrowing model (hierarchical or mixture) against the independent and pooled benchmark models.

Usage

```
hb_plot_borrow(borrow, pool, independent, outcome = c("response", "diff"))
```

Arguments

borrow A data frame returned by hb_summary() for a borrowing model, either the hier-

archical model or the mixture model.

pool A data frame returned by hb_summary() for the pooled model.

independent A data frame returned by hb_summary() for the independent model.

outcome Character of length 1, either "response" or "diff", the quantity to plot on the

vertical axis.

Value

A ggplot object

See Also

```
Other plot: hb_plot_group(), hb_plot_tau()
```

Examples

```
if (!identical(Sys.getenv("HB_TEST", unset = ""), "")) {
data <- hb_sim_independent(n_continuous = 2)$data</pre>
mcmc_borrow <- hb_mcmc_hierarchical(</pre>
  data,
  n_{chains} = 1,
  n_adapt = 100,
  n_{warmup} = 100,
  n_{iterations} = 200
)
mcmc_pool <- hb_mcmc_pool(</pre>
  data,
  n_{chains} = 1,
  n_adapt = 100,
  n_{warmup} = 200,
  n_{iterations} = 200
mcmc_independent <- hb_mcmc_independent(</pre>
```

hb_plot_group 19

```
data,
  n_chains = 1,
  n_adapt = 100,
  n_warmup = 200,
  n_iterations = 200
)
borrow <- hb_summary(mcmc_borrow, data)
pool <- hb_summary(mcmc_pool, data)
independent <- hb_summary(mcmc_independent, data)
hb_plot_borrow(
  borrow = borrow,
  pool = pool,
  independent = independent
)
}</pre>
```

hb_plot_group

Plot the groups of a borrowing model and its benchmark models.

Description

Plot the groups against one another for a borrowing model (hierarchical or mixture) and the independent and pooled benchmark models.

Usage

```
hb_plot_group(borrow, pool, independent, outcome = c("response", "diff"))
```

Arguments

borrow A data frame returned by hb_summary() for a borrowing model, either the hier-

archical model or the mixture model.

pool A data frame returned by hb_summary() for the pooled model.

independent A data frame returned by hb_summary() for the independent model.

outcome Character of length 1, either "response" or "diff", the quantity to plot on the

vertical axis.

Value

A ggplot object

See Also

```
Other plot: hb_plot_borrow(), hb_plot_tau()
```

20 hb_plot_tau

Examples

```
if (!identical(Sys.getenv("HB_TEST", unset = ""), "")) {
data <- hb_sim_independent(n_continuous = 2)$data</pre>
mcmc_borrow <- hb_mcmc_hierarchical(</pre>
  data,
  n_{chains} = 1,
  n_adapt = 100,
  n_{warmup} = 100,
  n_{iterations} = 200
)
mcmc_pool <- hb_mcmc_pool(</pre>
  data,
  n_{chains} = 1,
  n_adapt = 100,
  n_{warmup} = 200,
  n_{iterations} = 200
)
mcmc_independent <- hb_mcmc_independent(</pre>
  data,
  n_{chains} = 1,
  n_adapt = 100,
  n_{warmup} = 200,
  n_{iterations} = 200
)
borrow <- hb_summary(mcmc_borrow, data)</pre>
pool <- hb_summary(mcmc_pool, data)</pre>
independent <- hb_summary(mcmc_independent, data)</pre>
hb_plot_group(
  borrow = borrow,
  pool = pool,
  independent = independent
)
}
```

hb_plot_tau

Plot tau

Description

Plot the tau parameter of a fitted hierarchical model.

Usage

```
hb_plot_tau(mcmc)
```

Arguments

 mcmc

Data frame of posterior samples generated by hb_mcmc_hierarchical().

hb_sim_hierarchical 21

Value

```
A ggplot object
```

See Also

```
Other plot: hb_plot_borrow(), hb_plot_group()
```

Examples

```
data <- hb_sim_independent(n_continuous = 2)$data
mcmc <- hb_mcmc_hierarchical(
   data,
   n_chains = 1,
   n_adapt = 100,
   n_warmup = 100,
   n_iterations = 200
)
hb_plot_tau(mcmc = mcmc)</pre>
```

hb_sim_hierarchical

Non-longitudinal hierarchical simulations.

Description

Simulate from the non-longitudinal hierarchical model.

Usage

```
hb_sim_hierarchical(
  n_study = 5,
  n_{group} = 3,
  n_patient = 100,
  n_{continuous} = 0,
  n_binary = 0,
  s_{delta} = 1,
  s_beta = 1,
  s_sigma = 1,
  s_mu = 1,
  s_tau = 1,
  alpha = stats::rnorm(n = n_study, mean = mu, sd = tau),
  delta = stats::rnorm(n = n_group - 1, mean = 0, sd = s_delta),
 beta = stats::rnorm(n = n_study * (n_continuous + n_binary), mean = 0, sd = s_delta),
  sigma = stats::runif(n = n_study, min = 0, max = s_sigma),
 mu = stats::rnorm(n = 1, mean = 0, sd = s_mu),
  tau = stats::runif(n = 1, min = 0, max = s_tau)
)
```

22 hb_sim_hierarchical

Arguments

n_study	Number of studies to simulate.
n_group	Number of groups (e.g. study arms) to simulate per study.
n_patient	Number of patients to simulate per study per group.
n_continuous	Number of continuous covariates to simulate (all from independent standard normal distributions).
n_binary	Number of binary covariates to simulate (all from independent Bernoulli distributions with $p = 0.5$).
s_delta	Numeric of length 1, prior standard deviation of the study-by-group effect parameters delta.
s_beta	Numeric of length 1, prior standard deviation of the fixed effects beta.
s_sigma	Numeric of length 1, prior upper bound of the residual standard deviations.
s_mu	Numeric of length 1, prior standard deviation of mu.
s_tau	Numeric of length 1, Upper bound on tau.
alpha	Numeric vector of length 1 for the pooled and mixture models and length n_study for the independent and hierarchical models. alpha is the vector of control group mean parameters. alpha enters the model by multiplying with \$matrices\$x_alpha (see the return value). The control group in the data is the one with the group column equal to 1.
delta	Numeric vector of length n_group - 1 of treatment effect parameters. delta enters the model by multiplying with \$matrices\$x_delta (see the return value). The control (non-treatment) group in the data is the one with the group column equal to 1.
beta	Numeric vector of n_study * (n_continuous + n_binary) fixed effect parameters. Within each study, the first n_continuous betas are for the continuous covariates, and the rest are for the binary covariates. All the betas for one study appear before all the betas for the next study, and studies are arranged in increasing order of the sorted unique values in \$data\$study in the output. betas enters the model by multiplying with \$matrices\$x_alpha (see the return value).
sigma	Numeric vector of n_study study-specific residual standard deviations.
mu	Numeric of length 1, mean of the control group means alpha.
tau	Numeric of length 1, standard deviation of the control group means alpha.

Value

A list with the following elements:

• data: tidy long-form dataset with the patient-level data. one row per patient and indicator columns for the study, group (e.g. treatment arm), and patient ID. The response columns is the patient response. The other columns are baseline covariates. The control group is the one with the group column equal to 1, and the current study (non-historical) is the one with the maximum value of the study column. Only the current study has any non-control-group patients, the historical studies have only the control group.

hb_sim_independent 23

 parameters: named list of model parameter values. See the model specification vignette for details.

• matrices: A named list of model matrices. See the model specification vignette for details.

See Also

```
Other simulate: hb_sim_independent(), hb_sim_mixture(), hb_sim_pool()
```

Examples

```
hb_sim_hierarchical()$data
```

hb_sim_independent

Non-longitudinal independent simulations.

Description

Simulate from the non-longitudinal independent model.

Usage

```
hb_sim_independent(
    n_study = 5,
    n_group = 3,
    n_patient = 100,
    n_continuous = 0,
    n_binary = 0,
    s_alpha = 1,
    s_delta = 1,
    s_beta = 1,
    s_sigma = 1,
    alpha = stats::rnorm(n = n_study, mean = 0, sd = s_alpha),
    delta = stats::rnorm(n = n_group - 1, mean = 0, sd = s_delta),
    beta = stats::rnorm(n = n_study * (n_continuous + n_binary), mean = 0, sd = s_delta),
    sigma = stats::runif(n = n_study, min = 0, max = s_sigma)
)
```

Arguments

n_study	Number of studies to simulate.
n_group	Number of groups (e.g. study arms) to simulate per study.
n_patient	Number of patients to simulate per study per group.
n_continuous	Number of continuous covariates to simulate (all from independent standard normal distributions).
n_binary	Number of binary covariates to simulate (all from independent Bernoulli distributions with $p = 0.5$).

24 hb_sim_independent

s_alpha	Numeric of length 1, prior standard deviation of the study-specific control group mean parameters alpha.
s_delta	Numeric of length 1, prior standard deviation of the study-by-group effect parameters delta.
s_beta	Numeric of length 1, prior standard deviation of the fixed effects beta.
s_sigma	Numeric of length 1, prior upper bound of the residual standard deviations.
alpha	Numeric vector of length 1 for the pooled and mixture models and length n_study for the independent and hierarchical models. alpha is the vector of control group mean parameters. alpha enters the model by multiplying with \$matrices\$x_alpha (see the return value). The control group in the data is the one with the group column equal to 1.
delta	Numeric vector of length n_group - 1 of treatment effect parameters. delta enters the model by multiplying with \$matrices\$x_delta (see the return value). The control (non-treatment) group in the data is the one with the group column equal to 1.
beta	Numeric vector of n_study * (n_continuous + n_binary) fixed effect parameters. Within each study, the first n_continuous betas are for the continuous covariates, and the rest are for the binary covariates. All the betas for one study appear before all the betas for the next study, and studies are arranged in increasing order of the sorted unique values in \$data\$study in the output. betas enters the model by multiplying with \$matrices\$x_alpha (see the return value).
sigma	Numeric vector of n_study study-specific residual standard deviations.

Value

A list with the following elements:

- data: tidy long-form dataset with the patient-level data. one row per patient and indicator columns for the study, group (e.g. treatment arm), and patient ID. The response columns is the patient response. The other columns are baseline covariates. The control group is the one with the group column equal to 1, and the current study (non-historical) is the one with the maximum value of the study column. Only the current study has any non-control-group patients, the historical studies have only the control group.
- parameters: named list of model parameter values. See the model specification vignette for details.
- matrices: A named list of model matrices. See the model specification vignette for details.

See Also

Other simulate: hb_sim_hierarchical(), hb_sim_mixture(), hb_sim_pool()

Examples

hb_sim_independent()\$data

hb_sim_mixture 25

hb_sim_mixture

Non-longitudinal mixture simulations.

Description

Simulate from the non-longitudinal mixture model.

Usage

```
hb_sim_mixture(
  n_study = 5,
  n_{group} = 3,
 n_patient = 100,
  n_{continuous} = 0,
  n_binary = 0,
  s_{delta} = 1,
  s_beta = 1,
  s_sigma = 1,
 m_{omega} = 0,
  s_{omega} = 1,
  p_{omega} = 1/n_{study}
  alpha = omega[pi],
  delta = stats::rnorm(n = n_group - 1, mean = 0, sd = s_delta),
  beta = stats::rnorm(n = n_continuous + n_binary, mean = 0, sd = s_delta),
  sigma = stats::runif(n = 1, min = 0, max = s_sigma),
 pi = sample.int(n = n_study, size = 1, prob = p_omega),
  omega = stats::rnorm(n = n_study, mean = m_omega, sd = s_omega)
)
```

Arguments

n_study	Number of studies to simulate.
n_group	Number of groups (e.g. study arms) to simulate per study.
n_patient	Number of patients to simulate per study per group.
n_continuous	Number of continuous covariates to simulate (all from independent standard normal distributions).
n_binary	Number of binary covariates to simulate (all from independent Bernoulli distributions with $p=0.5$).
s_delta	Numeric of length 1, prior standard deviation of the study-by-group effect parameters delta.
s_beta	Numeric of length 1, prior standard deviation of the fixed effects beta.
s_sigma	Numeric of length 1, prior upper bound of the residual standard deviations.
m_omega	Numeric of length 1 or n_study, prior control group mean of each study. If length n_study, then the last element corresponds to the current study, and the others are for historical studies.

26 hb_sim_mixture

s_omega	Numeric of length 1 or n_study, prior control group standard deviation of each study. If length n_study, the the last element corresponds to the current study, and the others are for historical studies.
p_omega	Numeric of length n_study, prior mixture proportion of each study. If length n_study, then the last element corresponds to the current study, and the others are for historical studies.
alpha	Numeric vector of length 1 for the pooled and mixture models and length n_study for the independent and hierarchical models. alpha is the vector of control group mean parameters. alpha enters the model by multiplying with \$matrices\$x_alpha (see the return value). The control group in the data is the one with the group column equal to 1.
delta	Numeric vector of length n_group - 1 of treatment effect parameters. delta enters the model by multiplying with \$matrices\$x_delta (see the return value). The control (non-treatment) group in the data is the one with the group column equal to 1.
beta	Numeric vector of n_continuous + n_binary fixed effect parameters. The first n_continuous betas are for the continuous covariates, and the rest are for the binary covariates. betas enters the model by multiplying with matricesx_alpha (see the return value).
sigma	Numeric vector of n_study study-specific residual standard deviations.
pi	Integer of length 1, index of the mixture component randomly chosen for alpha.
omega	Numeric of length n_study, Candidate placebo mean parameters drawn from each of the mixture components.

Value

A list with the following elements:

- data: tidy long-form dataset with the patient-level data. one row per patient and indicator columns for the study, group (e.g. treatment arm), and patient ID. The response columns is the patient response. The other columns are baseline covariates. The control group is the one with the group column equal to 1, and the current study (non-historical) is the one with the maximum value of the study column. Only the current study has any non-control-group patients, the historical studies have only the control group.
- parameters: named list of model parameter values. See the model specification vignette for details.
- matrices: A named list of model matrices. See the model specification vignette for details.

See Also

Other simulate: hb_sim_hierarchical(), hb_sim_independent(), hb_sim_pool()

Examples

hb_sim_mixture()\$data

hb_sim_pool 27

hb_sim_pool

Non-longitudinal pooled simulations.

Description

Simulate from the non-longitudinal pooled model.

Usage

```
hb_sim_pool(
    n_study = 5,
    n_group = 3,
    n_patient = 100,
    n_continuous = 0,
    n_binary = 0,
    s_alpha = 1,
    s_delta = 1,
    s_beta = 1,
    s_sigma = 1,
    alpha = stats::rnorm(n = 1, mean = 0, sd = s_alpha),
    delta = stats::rnorm(n = n_group - 1, mean = 0, sd = s_delta),
    beta = stats::rnorm(n = n_study * (n_continuous + n_binary), mean = 0, sd = s_delta),
    sigma = stats::runif(n = n_study, min = 0, max = s_sigma)
)
```

Arguments

n_study	Number of studies to simulate.
n_group	Number of groups (e.g. study arms) to simulate per study.
n_patient	Number of patients to simulate per study per group.
n_continuous	Number of continuous covariates to simulate (all from independent standard normal distributions).
n_binary	Number of binary covariates to simulate (all from independent Bernoulli distributions with $p = 0.5$).
s_alpha	Numeric of length 1, prior standard deviation of the study-specific control group mean parameters alpha.
s_delta	Numeric of length 1, prior standard deviation of the study-by-group effect parameters delta.
s_beta	Numeric of length 1, prior standard deviation of the fixed effects beta.
s_sigma	Numeric of length 1, prior upper bound of the residual standard deviations.
alpha	Numeric vector of length 1 for the pooled and mixture models and length n_study for the independent and hierarchical models. alpha is the vector of control group mean parameters. alpha enters the model by multiplying with \$matrices\$x_alpha (see the return value). The control group in the data is the one with the group column equal to 1.

delta Numeric vector of length n_group - 1 of treatment effect parameters. delta enters the model by multiplying with \$matrices\$x_delta (see the return value).

The control (non-treatment) group in the data is the one with the group column

equal to 1.

beta Numeric vector of n_study * (n_continuous + n_binary) fixed effect param-

eters. Within each study, the first n_continuous betas are for the continuous covariates, and the rest are for the binary covariates. All the betas for one study appear before all the betas for the next study, and studies are arranged in increasing order of the sorted unique values in \$data\$study in the output. betas enters the model by multiplying with \$matrices\$x_alpha (see the re-

turn value).

sigma Numeric vector of n_study study-specific residual standard deviations.

Value

A list with the following elements:

- data: tidy long-form dataset with the patient-level data. one row per patient and indicator columns for the study, group (e.g. treatment arm), and patient ID. The response columns is the patient response. The other columns are baseline covariates. The control group is the one with the group column equal to 1, and the current study (non-historical) is the one with the maximum value of the study column. Only the current study has any non-control-group patients, the historical studies have only the control group.
- parameters: named list of model parameter values. See the model specification vignette for details.
- matrices: A named list of model matrices. See the model specification vignette for details.

See Also

Other simulate: hb_sim_hierarchical(), hb_sim_independent(), hb_sim_mixture()

Examples

 $hb_sim_pool(n_continuous = 1)$ \$data

hb_summary

Model summary

Description

Summarize a fitted model in a table.

Usage

```
hb_summary(
  mcmc,
  data,
  response = "response",
  study = "study",
  study_reference = max(data[[study]]),
  group = "group",
  group_reference = min(data[[group]]),
  patient = "patient",
  covariates = grep("^covariate", colnames(data), value = TRUE),
  eoi = 0,
  direction = "<"
)</pre>
```

Arguments

mcmc A wide data frame of posterior samples returned by hb_mcmc_hierarchical()

or similar MCMC function.

data Tidy data frame with one row per patient, indicator columns for the response

variable, study, group, and patient, and covariates. All columns must be atomic vectors (e.g. not lists). The data for the mixture and simple models should have just one study, and the others should have data from more than one study. The simple model can be used to get the historical data components of m_omega and

s_omega for the mixture model.

response Character of length 1, name of the column in data with the response/outcome

variable. data[[response]] must be a continuous variable, and it *should* be the change from baseline of a clinical endpoint of interest, as opposed to just the raw response. Treatment differences are computed directly from this scale, please supply change from baseline unless you are absolutely certain that treatment differences computed directly from this quantity are clinically meaningful.

study Character of length 1, name of the column in data with the study ID.

study_reference

Atomic of length 1, element of the study column that indicates the current study.

(The other studies are historical studies.)

group Character of length 1, name of the column in data with the group ID.

group_reference

Atomic of length 1, element of the group column that indicates the control

group. (The other groups may be treatment groups.)

patient Character of length 1, name of the column in data with the patient ID.

covariates Character vector of column names in data with the columns with baseline co-

 $variates. \ These \ can \ be \ continuous, \ categorical, \ or \ binary. \ Regardless, \ historical borrown \ and \ historical borrown \ be \ continuous, \ categorical, \ or \ binary.$

derives the appropriate model matrix.

eoi Numeric of length at least 1, vector of effects of interest (EOIs) for critical suc-

cess factors (CSFs).

direction

Character of length length(eoi) indicating how to compare the treatment effect to each EOI. ">" means Prob(treatment effect > EOI), and "<" means Prob(treatment effect < EOI). All elements of direction must be either ">" or "<".

Details

The hb_summary() function post-processes the results from the model. It accepts MCMC samples of parameters and returns interpretable group-level posterior summaries such as change from baseline response and treatment effect. To arrive at these summaries, hb_summary() computes marginal posteriors of transformed parameters. The transformations derive patient-level fitted values from model parameters, then derive group-level responses as averages of fitted values. We refer to this style of estimation as "unconditional estimation", as opposed to "conditional estimation", which takes each group mean to be the appropriate linear combination of the relevant alpha and delta parameters, without using beta components or going through fitted values. If the baseline covariates are balanced across studies, unconditional and conditional estimation should produce similar estimates of placebo and treatment effects.

Value

A tidy data frame with one row per group (e.g. treatment arm) and the columns in the following list. Unless otherwise specified, the quantities are calculated at the group level. Some are calculated for the current (non-historical) study only, while others pertain to the combined dataset which includes all historical studies. The mixture model is an exception because the data argument only includes the current study, so other quantities that include historical information will need to borrow from an hb_summary() call on one of the other models.

- group: group label.
- data_mean: observed mean response specific to the current study.
- data_sd: observed standard deviation of the response specific to the current study.
- data_lower: lower bound of a simple frequentist 95% confidence interval of the observed mean specific to the current study.
- data_upper: upper bound of a simple frequentist 95% confidence interval of the observed mean specific to the current study.
- data_n: number of non-missing observations in the combined dataset with all studies.
- data_N: total number of observations (missing and non-missing) in the combined dataset with all studies.
- data_n_study_*: number of non-missing observations separately for each study. The suffixes
 of these column names are integer study indexes. Call dplyr::distinct(hb_data(your_data),
 study, study_label) to see which study labels correspond to these integer indexes. Note:
 the combined dataset for the mixture model is just the current study. If all the data_n_study_*
 results across all studies are desired, then call hb_summary() on a different model (e.g. pooled).
- data_N_study_*: same as data_n_study_* except both missing and non-missing observations are counted (total number of observations).
- response_mean: Estimated posterior mean of the response from the model specific to the current study. Typically, the raw response is change from baseline, in which case response_mean is estimating change from baseline.

• response_sd: Estimated posterior standard deviation of the mean response from the model specific to the current study.

- response_variance: Estimated posterior variance of the mean response from the model specific to the current study.
- response_lower: Lower bound of a 95% posterior interval on the mean response from the model specific to the current study.
- response_upper: Upper bound of a 95% posterior interval on the mean response from the model specific to the current study.
- response_mean_mcse: Monte Carlo standard error of response_mean.
- response_sd_mcse: Monte Carlo standard error of response_sd.
- response_lower_mcse: Monte Carlo standard error of response_lower.
- response_upper_mcse: Monte Carlo standard error of response_upper.
- diff_mean: Estimated treatment effect from the model specific to the current study.
- diff_lower: Lower bound of a 95% posterior interval on the treatment effect from the model specific to the current study..
- diff_upper: Upper bound of a 95% posterior interval on the treatment effect from the model specific to the current study..
- diff_mean_mcse: Monte Carlo standard error of diff_mean.
- diff_lower_mcse: Monte Carlo standard error of diff_lower.
- diff_upper_mcse: Monte Carlo standard error of diff_upper.
- P(diff > E0I), P(diff < E0I): CSF probabilities on the treatment effect specified with the eoi and direction arguments. Specific to the current study.
- effect_mean: Estimated posterior mean of effect size (treatment difference divided by residual standard deviation). Specific to the current study.
- effect_lower: Lower bound of a 95% posterior interval of effect size from the model. Specific to the current study.
- effect_upper: Upper bound of a 95% posterior interval of effect size from the model. Specific to the current study.
- precision_ratio: For the hierarchical model only, a model-based mean of the precision ratio. Specific to the current study.
- precision_ratio_lower: For the hierarchical model only, lower bound of a model-based 95% posterior interval of the precision ratio. Specific to the current study.
- precision_ratio_upper: For the hierarchical model only, upper bound of a model-based 95% posterior interval of the precision ratio. Specific to the current study.
- mix_prop_*: For the mixture model only, posterior mixture proportions of each of the mixture components. The last one is for the current study and the first ones are for the historical studies. The suffixes of these column names are the integer study indexes. Call dplyr::distinct(hb_data(your_data), study, study_label) to see which study labels correspond to these integer indexes.

See Also

Other summary: hb_metrics()

32 hb_s_tau

Examples

```
if (!identical(Sys.getenv("HB_TEST", unset = ""), "")) {
  data <- hb_sim_pool(n_continuous = 2)$data
  data$group <- sprintf("group%s", data$group)

mcmc <- hb_mcmc_pool(
  data,
  n_chains = 1,
  n_adapt = 100,
  n_warmup = 50,
  n_iterations = 50
)
hb_summary(mcmc, data)
}</pre>
```

hb_s_tau

Suggest s_tau

Description

Suggest a value of the s_tau hyperparameter to achieve a given amount of borrowing in the hierarchical model. Only use if a diffuse prior on tau is not feasible.

Usage

```
hb_s_tau(precision_ratio = 0.5, sigma = 1, n = 100)
```

Arguments

precision_ratio

Positive numeric vector of elements between 0 and 1 with target precision ratios.

sigma

Positive numeric vector of residual standard deviations.

n

Number of non-missing patients.

Details

See the hierarchical model section of the methods vignette for details.

Value

Numeric of length equal to length(precision_ratio) and length(sigma), suggested values of s_tau for each element of precision_ratio and sigma.

See Also

```
Other data: hb_data()
```

Examples

```
hb_s_tau(precision_ratio = 0.5, sigma = 1, n = 100)
```

Index

```
* data
                                                  hb_plot_tau, 18, 19, 20
    hb_data, 3
                                                  hb_s_tau, 4, 32
    hb_s_tau, 32
                                                  hb_sim_hierarchical, 21, 24, 26, 28
* help
                                                  hb_sim_independent, 23, 23, 26, 28
    historicalborrow-package, 2
                                                  hb_sim_mixture, 23, 24, 25, 28
* mcmc
                                                  hb_sim_pool, 23, 24, 26, 27
    hb_convergence, 2
                                                  hb_summary, 17, 28
    hb_mcmc_hierarchical, 5
                                                  hb_summary(), 17–19
                                                  historicalborrow-package, 2
    hb_mcmc_independent, 7
    hb_mcmc_mixture, 9
    hb_mcmc_mixture_hyperparameters,
         12
    hb_mcmc_pool, 14
* plot
    hb_plot_borrow, 18
    hb_plot_group, 19
    hb_plot_tau, 20
* simulate
    hb_sim_hierarchical, 21
    hb_sim_independent, 23
    hb_sim_mixture, 25
    hb_sim_pool, 27
* summary
    hb_metrics, 16
    hb_summary, 28
hb_convergence, 2, 7, 9, 11, 14, 16
hb_data, 3, 32
hb_mcmc_hierarchical, 3, 5, 9, 11, 14, 16
hb_mcmc_hierarchical(), 2, 20, 29
hb_mcmc_independent, 3, 7, 7, 11, 14, 16
hb_mcmc_mixture, 3, 7, 9, 9, 14, 16
hb_mcmc_mixture(), 11-13
hb_mcmc_mixture_hyperparameters, 3, 7, 9,
         11, 12, 16
hb_mcmc_mixture_hyperparameters(), 11
hb_mcmc_pool, 3, 7, 9, 11, 14, 14
hb_metrics, 16, 31
hb_plot_borrow, 18, 19, 21
hb_plot_group, 18, 19, 21
```