Package 'horizonclaims'

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Type Package

Title Claims About the Risk at a Fixed Time from Censored Data

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Description Rules for demonstrating that the cumulative incidence of an event at a fixed time lies below a threshold, from right-censored follow-up data. The package gives the one-sided upper confidence limit of the beta product confidence procedure of Fay, Brittain and Proschan (2013) <doi:10.1093/biostatistics/kxt016> and of its mid-p version of Fay and Brittain (2016) <doi:10.1002/sim.6905>, the Kaplan-Meier estimate with the log-log limit and the number at risk, and exact binomial limits for patients whose potential follow-up reaches the fixed time, including a limit that counts patients lost to follow-up as having had the event. It also gives the smallest number of patients at risk with which a claim can be demonstrated, the number of patients needed for a given power, and a lower confidence bound for the time during which the risk stays below a threshold, obtained by testing prespecified times in a fixed order.

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Contents

horizonclaims-package 2
bpcp_upper 3

claim_low_risk 4
exact_upper_admin 5
km_at_horizon 7
min_at_risk 8
n_for_power 9
n_potential 10
warranty_lower_bound 11

Index **13**

`horizonclaims-package` *Claims About the Risk at a Fixed Time from Censored Data*

Description

Rules for demonstrating that the cumulative incidence $F(\tau)$ of an event at a fixed time τ lies below a threshold c, from right-censored follow-up data. The claim $F(\tau) < c$ is treated as the one-sided alternative hypothesis, and it is demonstrated at level α when a one-sided $1 - \alpha$ upper confidence limit for $F(\tau)$ lies below c.

Details

`claim_low_risk` reports the Kaplan-Meier estimate, the number at risk, and the upper limits of the beta product confidence procedure (BPCP) and of its mid-p version at a fixed time. `bpcp_upper` gives the BPCP limit alone, and `km_at_horizon` the Kaplan-Meier estimate with the log-log limit.

For planning, `n_potential` counts the patients whose potential follow-up, the time from entry to the data cutoff date, reaches the fixed time; this number is known from the dates before any outcome is observed. `min_at_risk` gives the smallest number of such patients with which the claim can be demonstrated, and `n_for_power` the number needed for a given power when every patient is followed to the fixed time.

`exact_upper_admin` and `exact_upper_losses_as_events` give exact binomial limits for the patients whose potential follow-up reaches the fixed time, the second one counting patients lost to follow-up as having had the event. `warranty_lower_bound` gives a lower confidence bound for the time during which the risk stays below a threshold.

All functions use base R and the package **stats** only.

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References

Clopper, C. J. and Pearson, E. S. (1934). The use of confidence or fiducial limits illustrated in the case of the binomial. *Biometrika*, **26**, 404–413. doi:10.1093/biomet/26.4.404

Fay, M. P., Brittain, E. H. and Proschan, M. A. (2013). Pointwise confidence intervals for a survival distribution with small samples or heavy censoring. *Biostatistics*, **14**, 723–736. doi:10.1093/biostatistics/kxt016

Fay, M. P. and Brittain, E. H. (2016). Finite sample pointwise confidence intervals for a survival distribution with right-censored data. *Statistics in Medicine*, **35**, 2726–2740. doi:10.1002/sim.6905

`bpcp_upper` *Upper Limit of the Beta Product Confidence Procedure at a Fixed Time*

Description

Gives the one-sided $1 - \alpha$ upper confidence limit for the cumulative incidence $F(\tau)$ by the beta product confidence procedure (BPCP) of Fay, Brittain and Proschan (2013), or by its mid-p version of Fay and Brittain (2016).

Usage

```
bpcp_upper(time, status, tau, alpha = 0.05, midp = FALSE)
```

Arguments

`time`	numeric vector of observed times (event or censoring).
`status`	numeric vector, 1 for an event and 0 for censoring.
`tau`	the fixed time, a single positive number.
`alpha`	one-sided level, strictly between 0 and 1.
`midp`	logical; if `TRUE`, the mid-p version is used.

Details

The lower limit of the BPCP for the survival probability $S(\tau)$ is the α quantile of $W^+ = W^- B$, where W^- is the product over the event times $t_j \le \tau$ of independent beta variables with parameters $n_j - d_j + 1$ and d_j, n_j and d_j are the numbers at risk and of events at t_j, and B is an independent beta variable with parameters N^+ and 1, N^+ being the number of patients observed beyond τ. The upper limit for $F(\tau)$ is one minus this lower limit. The product is replaced by the beta distribution with the same first two moments, as in the method of moments version of the package **bpcp** (`nmc = 0`, `Delta = 0`).

With `midp = TRUE`, the lower limit q solves $0.5P(W^- \le q) + 0.5P(W^+ \le q) = \alpha$, each product again replaced by its moment-matched beta distribution.

Without censoring at or before τ, the BPCP limit equals the exact Clopper-Pearson limit and the mid-p limit equals the binomial mid-p limit. When no patient is observed beyond τ, the upper limit is 1.

Value

A number, the one-sided upper limit for $F(\tau)$. `NA` is returned for the mid-p version when the moment-matched beta distribution of W^- does not exist.

References

Fay, M. P., Brittain, E. H. and Proschan, M. A. (2013). Pointwise confidence intervals for a survival distribution with small samples or heavy censoring. *Biostatistics*, **14**, 723–736. doi:10.1093/biostatistics/kxt016

Fay, M. P. and Brittain, E. H. (2016). Finite sample pointwise confidence intervals for a survival distribution with right-censored data. *Statistics in Medicine*, **35**, 2726–2740. doi:10.1002/sim.6905

See Also

claim_low_risk, min_at_risk

Examples

```
set.seed(2)
event <- rexp(300, rate = 0.01)
followup <- runif(300, 1, 10)
time <- pmin(event, followup)
status <- as.numeric(event <= followup)
bpcp_upper(time, status, tau = 5)
bpcp_upper(time, status, tau = 5, midp = TRUE)

## without censoring the limit equals the Clopper-Pearson limit
t0 <- c(runif(3, 0, 5), runif(97, 6, 10))
bpcp_upper(t0, rep(1, 100), tau = 5)
1 - qbeta(0.05, 97, 4)
```

---

claim_low_risk *Demonstrate a Claim of Low Risk at a Fixed Time*

Description

Tests the claim that the cumulative incidence $F(\tau)$ lies below the threshold c, and returns the summaries that a report of the claim should contain.

Usage

```
claim_low_risk(time, status, tau, c, alpha = 0.05)
```

Arguments

time	numeric vector of observed times (event or censoring).
status	numeric vector, 1 for an event and 0 for censoring.
tau	the fixed time, a single positive number.
c	threshold of the claim $F(\tau) < c$, strictly between 0 and 1.
alpha	one-sided level, strictly between 0 and 1.

Details

The claim is demonstrated at level α when the one-sided $1 - \alpha$ upper limit of the beta product confidence procedure (bpcp_upper) lies below c; the decision of the mid-p version is returned as well. The Kaplan-Meier estimate and its log-log limit (km_at_horizon) are returned as descriptions, because the coverage of the log-log limit can fall below the nominal level when few patients remain at risk or many are censored.

Value

A data frame with one row and the columns

tau, c	the fixed time and the threshold.
F_km	Kaplan-Meier estimate of $F(\tau)$.
F_upper_loglog	one-sided log-log upper limit.
n_at_risk	number at risk at τ.
n_beyond	number of patients observed beyond τ.
min_at_risk	smallest number at risk m_c with which the claim can be demonstrated (min_at_risk).
F_upper_bpcp, demonstrated_bpcp	upper limit of the BPCP and whether it lies below c.
F_upper_bpcp_midp, demonstrated_bpcp_midp	the same for the mid-p BPCP.

See Also

warranty_lower_bound

Examples

```
set.seed(2)
event <- rexp(300, rate = 0.01)
followup <- runif(300, 1, 10)
time <- pmin(event, followup)
status <- as.numeric(event <= followup)
claim_low_risk(time, status, tau = 5, c = 0.10)
```

---

exact_upper_admin *Exact Upper Limits for Patients Whose Potential Follow-Up Reaches a Fixed Time*

Description

Exact one-sided $1 - \alpha$ upper confidence limits for the cumulative incidence $F(\tau)$, computed from the patients whose potential follow-up reaches τ. exact_upper_admin applies when censoring before τ is administrative only, and exact_upper_losses_as_events counts patients lost to follow-up before τ as having had the event.

Usage

```
exact_upper_admin(x, m, alpha = 0.05)
exact_upper_losses_as_events(time, status, potential_followup, tau,
                             alpha = 0.05)
```

Arguments

`x`	number of events by τ among the `m` patients.
`m`	number of patients whose potential follow-up reaches τ.
`alpha`	one-sided level, strictly between 0 and 1.
`time`	numeric vector of observed times (event or censoring).
`status`	numeric vector, 1 for an event and 0 for censoring.
`potential_followup`	numeric vector of potential follow-up times, the times from entry to the data cutoff date.
`tau`	the fixed time, a single positive number.

Details

When every patient whose potential follow-up reaches τ is followed to τ, the number of events by τ among them is binomial, and `exact_upper_admin` returns the Clopper-Pearson upper limit `qbeta(1 - alpha, x + 1, m - x)`.

`exact_upper_losses_as_events` counts, among the patients with `potential_followup >= tau`, those with an event by τ and those with an observed time before τ, and applies the same exact limit. Counting a lost patient as an event can only increase the count, so the limit remains valid for any mechanism of loss, provided that entry is independent of the event time.

Value

A number, the one-sided upper limit for $F(\tau)$; it is 1 when `m = 0` or `x = m`.

References

Clopper, C. J. and Pearson, E. S. (1934). The use of confidence or fiducial limits illustrated in the case of the binomial. *Biometrika*, **26**, 404–413. doi:10.1093/biomet/26.4.404

See Also

`n_potential`, `bpcp_upper`

Examples

```
exact_upper_admin(0, 59)
exact_upper_admin(3, 200)

set.seed(3)
potential <- runif(400, 1, 11)
event <- rexp(400, rate = 0.01)
```

```
loss <- rexp(400, rate = 0.05)
time <- pmin(event, potential, loss)
status <- as.numeric(event <= pmin(potential, loss))
exact_upper_losses_as_events(time, status, potential, tau = 5)
```

`km_at_horizon` *Kaplan-Meier Estimate and Log-Log Upper Limit at a Fixed Time*

Description

Gives the Kaplan-Meier estimate of the cumulative incidence $F(\tau)$, the one-sided $1-\alpha$ upper limit based on the log-log transformation and the Greenwood variance, and the number at risk at τ.

Usage

```
km_at_horizon(time, status, tau, alpha = 0.05)
```

Arguments

`time`	numeric vector of observed times (event or censoring).
`status`	numeric vector, 1 for an event and 0 for censoring.
`tau`	the fixed time, a single positive number.
`alpha`	one-sided level, strictly between 0 and 1.

Details

The number at risk at τ counts the patients with `time >= tau`. When no event occurs by τ, the estimate and the upper limit are returned as 0; the log-log limit is then undefined, and `bpcp_upper` gives a limit that uses the number at risk. The coverage of the log-log limit can fall below the nominal level when few patients remain at risk or many are censored (Fay, Brittain and Proschan, 2013), so the limit of `bpcp_upper` is preferable for demonstrating a claim.

Value

A list with components

`F`	Kaplan-Meier estimate of $F(\tau)$.
`upper`	one-sided $1-\alpha$ upper limit for $F(\tau)$ on the log-log scale.
`n_at_risk`	number of patients at risk at τ.
`greenwood`	Greenwood sum $\sum d_j/\{n_j(n_j-d_j)\}$ over the event times up to τ.

References

Fay, M. P., Brittain, E. H. and Proschan, M. A. (2013). Pointwise confidence intervals for a survival distribution with small samples or heavy censoring. *Biostatistics*, **14**, 723–736. doi:10.1093/biostatistics/kxt016

See Also

bpcp_upper, claim_low_risk

Examples

```
set.seed(2)
event <- rexp(300, rate = 0.01)
followup <- runif(300, 1, 10)
time <- pmin(event, followup)
status <- as.numeric(event <= followup)
km_at_horizon(time, status, tau = 5)
```

---

min_at_risk *Smallest Number at Risk That Can Demonstrate a Claim of Low Risk*

Description

Gives the smallest number m_c of patients for which zero events give an exact one-sided $1-\alpha$ upper confidence limit below the threshold c, that is, the smallest m with $1-\alpha^{1/m} < c$.

Usage

```
min_at_risk(c, alpha = 0.05)
```

Arguments

c	threshold of the claim $F(\tau) < c$, strictly between 0 and 1.
alpha	one-sided level, strictly between 0 and 1.

Details

The upper limit of the beta product confidence procedure at τ is at least $1-\alpha^{1/N^+}$, where N^+ is the number of patients observed beyond τ. A claim $F(\tau) < c$ can therefore be demonstrated with bpcp_upper only if at least m_c patients are observed beyond τ. With $\alpha = 0.05$, m_c is 59 for $c = 0.05$ and 299 for $c = 0.01$.

Value

A whole number, the smallest number at risk m_c.

See Also

n_potential, n_for_power

Examples

```
min_at_risk(0.05)
min_at_risk(0.01)
min_at_risk(0.05, alpha = 0.025)
```

`n_for_power` *Power and Sample Size for a Claim of Low Risk*

Description

`power_exact` gives the probability that the exact binomial rule demonstrates $F(\tau) < c$ when `N` patients are followed to τ and the true risk is `F_true`. `n_for_power` gives the smallest `N` for which this power is at least `power` at `N` and at every number up to `N + window`.

Usage

```
power_exact(N, F_true, c, alpha = 0.05)
n_for_power(F_true, c, power = 0.8, alpha = 0.05, window = 100, nmax = 4000)
```

Arguments

`N`	number of patients followed to τ, a positive integer.
`F_true`	true cumulative incidence at τ, between 0 and 1.
`c`	threshold of the claim $F(\tau) < c$, strictly between 0 and 1.
`alpha`	one-sided level, strictly between 0 and 1.
`power`	required power, strictly between 0 and 1.
`window`	number of further sample sizes over which the power must stay at least `power`; the power of an exact test is not monotone in the sample size.
`nmax`	largest sample size searched.

Details

The exact rule demonstrates the claim when the Clopper-Pearson upper limit lies below c. Without censoring at or before τ, the limit of `bpcp_upper` equals this limit, so these numbers apply to a cohort in which every patient is followed to τ. With censoring before τ, the power of the BPCP depends on the whole pattern of follow-up, and these numbers serve as a reference for planning.

Value

`power_exact` returns a number, the power. `n_for_power` returns the sample size, or `NA` if no sample size up to `nmax` qualifies.

See Also

`min_at_risk`

Examples

```
power_exact(434, F_true = 0.025, c = 0.05)
n_for_power(F_true = 0.025, c = 0.05)
```

`n_potential` *Number of Patients Whose Potential Follow-Up Reaches a Fixed Time*

Description

Counts the patients whose potential follow-up, the time from entry to the data cutoff date, is at least τ.

Usage

```
n_potential(potential_followup, tau)
```

Arguments

`potential_followup`	numeric vector of potential follow-up times, in the same unit as `tau`.
`tau`	the fixed time, a single positive number.

Details

The potential follow-up depends only on the dates of entry and data cutoff, so this number is known before any outcome is observed. Comparing it with `min_at_risk` shows at the planning stage whether a claim at τ can be demonstrated at all.

Value

An integer, the number of patients with `potential_followup >= tau`.

See Also

`min_at_risk`

Examples

```
set.seed(1)
entry <- as.Date("2015-01-01") + sort(sample(0:2900, 300))
cutoff <- as.Date("2023-12-31")
potential <- as.numeric(cutoff - entry) / 365.25
n_potential(potential, tau = 5)
n_potential(potential, tau = 5) >= min_at_risk(0.05)
```

`warranty_lower_bound` *Lower Confidence Bound for the Time During Which the Risk Stays Low*

Description

Tests the claims $F(t_k) < c_k$ at prespecified times $t_1 < \cdots < t_K$ in increasing order and stops at the first time at which the claim is not demonstrated. The last time with a demonstrated claim is a lower confidence bound for the time during which the risk stays below the thresholds, often called the warranty period of a negative test.

Usage

```
warranty_lower_bound(time, status, horizons, thresholds, alpha = 0.05,
                     rule = c("bpcp", "bpcp_midp"))
```

Arguments

`time`	numeric vector of observed times (event or censoring).
`status`	numeric vector, 1 for an event and 0 for censoring.
`horizons`	strictly increasing numeric vector of prespecified times.
`thresholds`	numeric vector of thresholds, one for each time.
`alpha`	one-sided level, strictly between 0 and 1.
`rule`	`"bpcp"` for the beta product confidence procedure or `"bpcp_midp"` for its mid-p version.

Details

Each claim is tested with `claim_low_risk` at level α. Testing in a fixed order keeps the probability of any false claim at most α when each test is valid, so no adjustment for the number of times is needed. The times and the thresholds must be chosen before the outcome data are seen.

Value

A list with components

`table`	data frame with one row of `claim_low_risk` for each time.
`lower_bound`	the last time, in the prespecified order, up to which every claim is demonstrated, or 0 if the claim at the first time is not demonstrated.

See Also

`claim_low_risk`

Examples

```
set.seed(2)
event <- rexp(600, rate = 0.005)
followup <- runif(600, 1, 10)
time <- pmin(event, followup)
status <- as.numeric(event <= followup)
warranty_lower_bound(time, status, horizons = 1:5,
                     thresholds = c(0.02, 0.03, 0.04, 0.05, 0.06))$lower_bound
```

Index

∗ **package**
    horizonclaims-package, 2
∗ **survival**
    bpcp_upper, 3
    claim_low_risk, 4
    exact_upper_admin, 5
    horizonclaims-package, 2
    km_at_horizon, 7
    min_at_risk, 8
    n_for_power, 9
    n_potential, 10
    warranty_lower_bound, 11

bpcp_upper, *2*, 3, *5–9*

claim_low_risk, *2*, *4*, 4, *8*, *11*

exact_upper_admin, *2*, 5
exact_upper_losses_as_events, *2*
exact_upper_losses_as_events
        *(*exact_upper_admin*)*, 5

horizonclaims *(*horizonclaims-package*)*, 2
horizonclaims-package, 2

km_at_horizon, *2*, *5*, 7

min_at_risk, *2*, *4, 5*, 8, *9, 10*

n_for_power, *2*, *8*, 9
n_potential, *2*, *6*, *8*, 10

power_exact *(*n_for_power*)*, 9

warranty_lower_bound, *2*, *5*, 11