Package ‘eventPred’

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Title Event Prediction
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Description
Predicts enrollment and events at the design or analysis stage using specified enrollment and time-
to-event models through simulations.
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Author Kaifeng Lu [aut, cre] (<https://orcid.org/0000-0002-6160-7119>)
Maintainer Kaifeng Lu <kaifenglu@gmail.com>
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Description

Predicts enrollment and events at the design stage using assumed enrollment and treatment-specific time-to-event models, or at the analysis stage using blinded or unblinded data and specified enrollment and time-to-event models through simulations.

Details

Accurately predicting the date at which a target number of subjects or events will be achieved is critical for the planning, monitoring, and execution of clinical trials. The eventPred package provides enrollment and event prediction capabilities using assumed enrollment and treatment-specific time-to-event models at the design stage, using blinded or unblinded data and specified enrollment and time-to-event models at the analysis stage.

At the design stage, enrollment is often specified using a piecewise Poisson process with a constant enrollment rate during each specified time interval. At the analysis stage, before enrollment completion, the eventPred package considers several models, including the homogeneous Poisson model, the time-decay model with an enrollment rate function \( \lambda(t) = \mu/\delta(1 - \exp(-\delta t)) \), the B-spline model with the daily enrollment rate \( \lambda(t) = \exp(B(t)\theta) \), and the piecewise Poisson model. If prior information exists on the model parameters, it can be combined with the likelihood to yield the posterior distribution.

The eventPred package also offers several time-to-event models, including exponential, Weibull, log-normal, piecewise exponential, model-averaging of Weibull and log-normal, and spline. For time to dropout, exponential, Weibull, log-normal, and piecewise exponential distributions are considered. If enrollment is complete, ongoing subjects who have not had the event of interest or dropped out of the study before the data cut contribute additional events in the future. Their event times are generated from the conditional distribution given that they have survived at the data cut. For new subjects that need to be enrolled, their enrollment time and event time can be generated from the specified enrollment and time-to-event models with parameters drawn from the posterior distribution. Time-to-dropout can be generated in a similar fashion.

The eventPred package displays the Bayesian Information Criterion (BIC) and a fitted curve overlaid with observed data to help users select the most appropriate model for enrollment and event prediction. Prediction intervals in the prediction plot can be used to measure prediction uncertainty, and the simulated enrollment and event data can be used for further data exploration.

The most useful function in the eventPred package is getPrediction, which combines model fitting, data simulation, and a summary of simulation results. Other functions perform individual tasks and can be used to select an appropriate prediction model.
The `eventPred` package implements a model parameterization that enhances the asymptotic normality of parameter estimates. Specifically, the package utilizes the following parameterization to achieve this goal:

- **Enrollment models**
  - Poisson: \( \theta = \log(\text{rate}) \)
  - Time-decay: \( \theta = (\log(\mu), \log(\delta)) \)
  - B-spline: no reparametrization is needed. The knots as considered fixed.
  - Piecewise Poisson: \( \theta = \log(\text{rates}) \). The left endpoints of time intervals, denoted as \( \text{accrualTime} \), are considered fixed.

- **Event or dropout models**
  - Exponential: \( \theta = \log(\text{rate}) \)
  - Weibull: \( \theta = (\log(\text{shape}), \log(\text{scale})) \)
  - Log-normal: \( \theta = (\text{meanlog}, \log(\text{sdlog})) \)
  - Piecewise exponential: \( \theta = \log(\text{rates}) \). The left endpoints of time intervals, denoted as \( \text{piecewiseSurvivalTime} \) for event model and \( \text{piecewiseDropoutTime} \) for dropout model, are considered fixed.
  - Model averaging: \( \theta = (\log(\text{weibull$\text{shape}$}), \log(\text{weibull$\text{scale}$}), \text{lnorm$\text{meanlog}$}, \log(\text{lnorm$\text{sdlog}$})) \). The covariance matrix for \( \theta \) is structured as a block diagonal matrix, with the upper-left block corresponding to the Weibull component and the lower-right block corresponding to the log-normal component. In other words, the covariance matrix is partitioned into two distinct blocks, with no off-diagonal elements connecting the two components. The weight assigned to the Weibull component, denoted as \( w_1 \), is considered fixed.
  - Spline: \( \theta \) corresponds to the coefficients of basis vectors. The knots and scale are considered fixed. The scale can be hazard, odds, or normal, corresponding to extensions of Weibull, log-logistic, and log-normal distributions, respectively.

The `eventPred` package uses days as its primary time unit. If you need to convert enrollment or event rates per month to rates per day, simply divide by 30.4375.

**Author(s)**

Kaifeng Lu, <kaifenglu@gmail.com>

**References**


fitDropout

### finalData

*Final enrollment and event data after achieving the target number of events*

A data frame with 300 rows and 7 columns:

- **trialsdt**: The trial start date
- **randdt**: The randomization date
- **cutoffdt**: The cutoff date
- **treatment**: The treatment group
- **time**: The day of event or censoring since randomization
- **event**: The event indicator: 1 for event, 0 for non-event
- **dropout**: The dropout indicator: 1 for dropout, 0 for non-dropout

For ongoing subjects, both `event` and `dropout` are equal to 0.

### Usage

```r
finalData
```

### Format

An object of class `tbl_df` (inherits from `tbl, data.frame`) with 300 rows and 7 columns.

---

### fitDropout

*Fit time-to-dropout model*

Fits a specified time-to-dropout model to the dropout data.

### Usage

```r
fitDropout(
  df,
  dropout_model = "exponential",
  piecewiseDropoutTime = 0,
  showplot = TRUE,
  by_treatment = FALSE
)
```
Arguments

- **df**: The subject-level dropout data, including time and dropout. The data should also include treatment coded as 1, 2, and so on, for fitting the dropout model by treatment.
- **dropout_model**: The dropout model used to analyze the dropout data which can be set to one of the following options: "exponential", "Weibull", "log-normal", or "piecewise exponential". By default, it is set to "exponential".
- **piecewiseDropoutTime**: A vector that specifies the time intervals for the piecewise exponential dropout distribution. Must start with 0, e.g., c(0, 60) breaks the time axis into 2 event intervals: [0, 60) and [60, Inf). By default, it is set to 0.
- **showplot**: A Boolean variable to control whether or not to show the fitted time-to-dropout survival curve. By default, it is set to TRUE.
- **by_treatment**: A Boolean variable to control whether or not to fit the time-to-dropout data by treatment group. By default, it is set to FALSE.

Value

A list of results from the model fit including key information such as the dropout model, model, the estimated model parameters, theta, the covariance matrix, vtheta, as well as the Bayesian Information Criterion, bic.

If the piecewise exponential model is used, the location of knots used in the model, piecewiseDropoutTime, will be included in the list of results.

When fitting the dropout model by treatment, the outcome is presented as a list of lists, where each list element corresponds to a specific treatment group.

The fitted time-to-dropout survival curve is also returned.

Examples

```r
dropout_fit <- fitDropout(df = interimData2, dropout_model = "exponential")
```

**fitEnrollment**

*Fit enrollment model*

Description

Fits a specified enrollment model to the enrollment data.
Usage

```r
fitEnrollment(
  df, 
  enroll_model = "b-spline",
  nknots = 0,
  accrualTime = 0,
  showplot = TRUE
)
```

Arguments

- **df**  
The subject-level enrollment data, including `trialsdt`, `randdt` and `cutoffdt`.

- **enroll_model**  
The enrollment model which can be specified as "Poisson", "Time-decay", "B-spline", or "Piecewise Poisson". By default, it is set to "B-spline".

- **nknots**  
The number of inner knots for the B-spline enrollment model. By default, it is set to 0.

- **accrualTime**  
The accrual time intervals for the piecewise Poisson model. Must start with 0, e.g., c(0, 30) breaks the time axis into 2 accrual intervals: [0, 30) and [30, Inf). By default, it is set to 0.

- **showplot**  
A Boolean variable to control whether or not to show the fitted enrollment curve. By default, it is set to `TRUE`.

Details

For the time-decay model, the mean function is \( \mu(t) = \frac{\mu}{\delta}(1 - \exp(-\delta t)) \) and the rate function is \( \lambda(t) = \frac{\mu}{\delta}(1 - \exp(-\delta t)) \). For the B-spline model, the daily enrollment rate is approximated as \( \lambda(t) = \exp(B(t)\theta) \), where \( B(t) \) represents the B-spline basis functions.

Value

A list of results from the model fit including key information such as the enrollment model, model, the estimated model parameters, \( \theta \), the covariance matrix, \( \Omega \), and the Bayesian Information Criterion, \( \text{bic} \), as well as the design matrix \( x \) for the B-spline enrollment model, and accrualTime for the piecewise Poisson enrollment model.

The fitted enrollment curve is also returned.

Examples

```r
enroll_fit <- fitEnrollment(df = interimData1, enroll_model = "b-spline",
                           nknots = 1)
```
Description

Fits a specified time-to-event model to the event data.

Usage

```r
fitEvent(
  df,
  event_model = "model averaging",
  piecewiseSurvivalTime = 0,
  k = 0,
  scale = "hazard",
  showplot = TRUE,
  by_treatment = FALSE
)
```

Arguments

- `df` The subject-level event data, including `time` and `event`. The data should also include `treatment` coded as 1, 2, and so on, for fitting the event model by treatment.
- `event_model` The event model used to analyze the event data which can be set to one of the following options: "exponential", "Weibull", "log-normal", "piecewise exponential", "model averaging", or "spline". The model averaging uses the \( \exp(-\text{bic}/2) \) weighting and combines Weibull and log-normal models. The spline model of Royston and Parmar (2002) assumes that a transformation of the survival function is modeled as a natural cubic spline function of log time. By default, it is set to "model averaging".
- `piecewiseSurvivalTime` A vector that specifies the time intervals for the piecewise exponential survival distribution. Must start with 0, e.g., \( c(0, 60) \) breaks the time axis into 2 event intervals: \( [0, 60) \) and \( [60, \text{Inf}) \). By default, it is set to 0.
- `k` The number of inner knots of the spline. The default \( k=0 \) gives a Weibull, log-logistic or log-normal model, if `scale` is "hazard", "odds", or "normal", respectively. The knots are chosen as equally-spaced quantiles of the log uncensored survival times. The boundary knots are chosen as the minimum and maximum log uncensored survival times.
- `scale` If "hazard", the log cumulative hazard is modeled as a spline function. If "odds", the log cumulative odds is modeled as a spline function. If "normal", \(-\text{qnorm(S(t))}\) is modeled as a spline function.
- `showplot` A Boolean variable to control whether or not to show the fitted time-to-event survival curve. By default, it is set to `TRUE`.
- `by_treatment` A Boolean variable to control whether or not to fit the time-to-event data by treatment group. By default, it is set to `FALSE`.
**getPrediction**

Value

A list of results from the model fit including key information such as the event model, model, the estimated model parameters, \( \theta \), the covariance matrix, \( \nabla_\theta \), as well as the Bayesian Information Criterion, \( \text{bic} \).

If the piecewise exponential model is used, the location of knots used in the model, piecewiseSurvivalTime, will be included in the list of results.

If the model averaging option is chosen, the weight assigned to the Weibull component is indicated by the \( w_1 \) variable.

If the spline option is chosen, the knots and scale will be included in the list of results.

When fitting the event model by treatment, the outcome is presented as a list of lists, where each list element corresponds to a specific treatment group.

The fitted time-to-event survival curve is also returned.

Examples

```r
event_fit <- fitEvent(df = interimData2,
  event_model = "piecewise exponential",
  piecewiseSurvivalTime = c(0, 180))
```

**Description**

Performs enrollment and event prediction by utilizing observed data and specified enrollment and event models.

**Usage**

```r
getCode

df = NULL,
to_predict = "enrollment and event",
target_n = NA,
target_d = NA,
enroll_model = "b-spline",
nknots = 0,
lags = 30,
accrualTime = 0,
enroll_prior = NULL,
enroll_model = "model averaging",
piecewiseSurvivalTime = 0,
k = 0,
scale = "hazard",
```
event_prior = NULL,
dropout_model = "exponential",
piecewiseDropoutTime = 0,
dropout_prior = NULL,
fixedFollowup = FALSE,
followupTime = 365,
pilevel = 0.9,
nyears = 4,
nreps = 500,
showEnrollment = TRUE,
showEvent = TRUE,
showDropout = FALSE,
showOngoing = FALSE,
showsummary = TRUE,
showplot = TRUE,
by_treatment = FALSE,
ngroups = 1,
alloc = NULL)

Arguments

df The subject-level enrollment and event data, including trialsdt, randdt, and
cutoffdt for enrollment prediction, and, additionally, time, event, and dropout
for event prediction. The data should also include treatment coded as 1, 2, and
so on, for enrollment and event prediction by treatment. By default, it is set to
NULL for enrollment and event prediction at the design stage.
to_predict Specifies what to predict: "enrollment only", "event only", or "enrollment and
event". By default, it is set to "enrollment and event".
target_n The target number of subjects to enroll in the study.
target_d The target number of events to reach in the study.
enroll_model The enrollment model which can be specified as "Poisson", "Time-decay", "B-
spline", or "Piecewise Poisson". By default, it is set to "B-spline".
nknots The number of inner knots for the B-spline enrollment model. By default, it is
set to 0.
lags The day lags to compute the average enrollment rate to carry forward for the
B-spline enrollment model. By default, it is set to 30.
accrualTime The accrual time intervals for the piecewise Poisson model. Must start with 0,
e.g., c(0, 30) breaks the time axis into 2 accrual intervals: [0, 30) and [30, Inf).
By default, it is set to 0.
enroll_prior The prior of enrollment model parameters.
event_model The event model used to analyze the event data which can be set to one of
the following options: "exponential", "Weibull", "log-normal", "piecewise ex-
ponential", or "model averaging". The model averaging uses the \( \exp(-\text{bic}/2) \)
weighting and combines Weibull and log-normal models. By default, it is set to
"model averaging".
**getPrediction**

**piecewiseSurvivalTime**
A vector that specifies the time intervals for the piecewise exponential survival distribution. Must start with 0, e.g., \(c(0, 60)\) breaks the time axis into 2 event intervals: \([0, 60)\) and \([60, \infty)\). By default, it is set to 0.

**k**
The number of inner knots of the spline event model of Royston and Parmar (2002). The default \(k=0\) gives a Weibull, log-logistic or log-normal model, if `scale` is "hazard", "odds", or "normal", respectively. The knots are chosen as equally-spaced quantiles of the log uncensored survival times. The boundary knots are chosen as the minimum and maximum log uncensored survival times.

**scale**
If "hazard", the log cumulative hazard is modeled as a spline function. If "odds", the log cumulative odds is modeled as a spline function. If "normal", \(-\text{qnorm}(S(t))\) is modeled as a spline function.

**event_prior**
The prior of event model parameters.

**dropout_model**
The dropout model used to analyze the dropout data which can be set to one of the following options: "exponential", "Weibull", "log-normal", or "piecewise exponential". By default, it is set to "exponential".

**piecewiseDropoutTime**
A vector that specifies the time intervals for the piecewise exponential dropout distribution. Must start with 0, e.g., \(c(0, 60)\) breaks the time axis into 2 event intervals: \([0, 60)\) and \([60, \infty)\). By default, it is set to 0.

**dropout_prior**
The prior of dropout model parameters.

**fixedFollowup**
A Boolean variable indicating whether a fixed follow-up design is used. By default, it is set to FALSE for a variable follow-up design.

**followupTime**
The follow-up time for a fixed follow-up design, in days. By default, it is set to 365.

**pilevel**
The prediction interval level. By default, it is set to 0.90.

**nyears**
The number of years after the data cut for prediction. By default, it is set to 4.

**nreps**
The number of replications for simulation. By default, it is set to 500.

**showEnrollment**
A Boolean variable to control whether or not to show the number of enrolled subjects. By default, it is set to TRUE.

**showEvent**
A Boolean variable to control whether or not to show the number of events. By default, it is set to TRUE.

**showDropout**
A Boolean variable to control whether or not to show the number of dropouts. By default, it is set to FALSE.

**showOngoing**
A Boolean variable to control whether or not to show the number of ongoing subjects. By default, it is set to FALSE.

**showsummary**
A Boolean variable to control whether or not to show the prediction summary. By default, it is set to TRUE.

**showplot**
A Boolean variable to control whether or not to show the plots. By default, it is set to TRUE.

**by_treatment**
A Boolean variable to control whether or not to predict by treatment group. By default, it is set to FALSE.
getPrediction

**ngroups**
The number of treatment groups for enrollment prediction at the design stage. By default, it is set to 1. It is replaced with the actual number of treatment groups in the observed data if `df` is not NULL.

**alloc**
The treatment allocation in a randomization block. By default, it is set to NULL, which yields equal allocation among the treatment groups.

**Details**

For the time-decay model, the mean function is \( \mu(t) = \frac{\mu}{\delta}(t - 1/\delta * (1 - \exp(-\delta * t))) \) and the rate function is \( \lambda(t) = \frac{\mu}{\delta}(1 - \exp(-\delta * t)) \). For the B-spline model, the daily enrollment rate is approximated as \( \lambda(t) = \exp(B(t) \theta) \), where \( B(t) \) represents the B-spline basis functions.

The `enroll_prior` variable should be a list that includes `model` to specify the enrollment model (poisson, time-decay, or piecewise poisson), `theta` and `vtheta` to indicate the parameter values and the covariance matrix. One can use a very small value of `vtheta` to fix the parameter values. For the piecewise Poisson enrollment model, the list should also include `accrualTime`. It should be noted that the B-spline model is not appropriate for use as prior.

The `event_prior` variable should be a list with one element per treatment. For each treatment, the element should include `w` to specify the weight of the treatment in a randomization block, `model` to specify the event model (exponential, weibull, log-normal, or piecewise exponential), `theta` and `vtheta` to indicate the parameter values and the covariance matrix. For the piecewise exponential event model, the list should also include `piecewiseSurvivalTime` to indicate the location of knots. It should be noted that the model averaging and spline options are not appropriate for use as prior.

The `dropout_prior` should be a list with one element per treatment. For each treatment, the element should include `w` to specify the weight of the treatment in a randomization block, `model` to specify the dropout model (exponential, weibull, log-normal, or piecewise exponential), `theta` and `vtheta` to indicate the parameter values and the covariance matrix. For the piecewise exponential dropout model, the list should also include `piecewiseDropoutTime` to indicate the location of knots.

For analysis-stage enrollment and event prediction, the `enroll_prior`, `event_prior`, and `dropout_prior` are either set to NULL to use the observed data only, or specify the prior distribution of model parameters to be combined with observed data likelihood for enhanced modeling flexibility.

**Value**

A list that includes the fits of observed data models, as well as simulated enrollment data for new subjects and simulated event data for ongoing and new subjects.

**Examples**

```r
# Event prediction after enrollment completion
pred <- getPrediction(
  df = interimData2, to_predict = "event only",
  target_d = 200,
  event_model = "weibull",
  dropout_model = "exponential",
  pilevel = 0.90, nreps = 100)
```
**interimData1**  
*Interim enrollment and event data before enrollment completion*

**Description**

A data frame with 225 rows and 7 columns:

- **trialsdt**  The trial start date
- **randdt**   The randomization date
- **cutoffdt** The cutoff date
- **treatment** The treatment group
- **time**     The day of event or censoring since randomization
- **event**    The event indicator: 1 for event, 0 for non-event
- **dropout**  The dropout indicator: 1 for dropout, 0 for non-dropout

For ongoing subjects, both event and dropout are equal to 0.

**Usage**

```r
interimData1
```

**Format**

An object of class `tbl_df` (inherits from `tbl, data.frame`) with 223 rows and 7 columns.

---

**interimData2**  
*Interim enrollment and event data after enrollment completion*

**Description**

A data frame with 300 rows and 7 columns:

- **trialsdt**  The trial start date
- **randdt**   The randomization date
- **cutoffdt** The cutoff date
- **treatment** The treatment group
- **time**     The day of event or censoring since randomization
- **event**    The event indicator: 1 for event, 0 for non-event
- **dropout**  The dropout indicator: 1 for dropout, 0 for non-dropout

For ongoing subjects, both event and dropout are equal to 0.
predictEnrollment

Usage

interimData2

Format

An object of class tbl_df (inherits from tbl, data.frame) with 300 rows and 7 columns.

predictEnrollment  Predict enrollment

Description

Utilizes a pre-fitted enrollment model to generate enrollment times for new subjects and provide a prediction interval for the expected time to reach the enrollment target.

Usage

predictEnrollment(
  df = NULL,
  target_n,
  enroll_fit,
  lags = 30,
  pilevel = 0.9,
  nyears = 4,
  nreps = 500,
  showsummary = TRUE,
  showplot = TRUE,
  by_treatment = FALSE,
  ngroups = 1,
  alloc = NULL
)

Arguments

df  The subject-level enrollment data, including trialsdt, randdt and cutoffdt. The data should also include treatment for prediction by treatment group. By default, it is set to NULL for enrollment prediction at the design stage.
target_n  The target number of subjects to enroll in the study.
enroll_fit  The pre-fitted enrollment model used to generate predictions.
lags  The day lags to compute the average enrollment rate to carry forward for the B-spline enrollment model. By default, it is set to 30.
pilevel  The prediction interval level. By default, it is set to 0.90.
nyears  The number of years after the data cut for prediction. By default, it is set to 4.
nreps  The number of replications for simulation. By default, it is set to 500.
showsummary  A Boolean variable to control whether or not to show the prediction summary. By default, it is set to TRUE.

showplot    A Boolean variable to control whether or not to show the prediction plot. By default, it is set to TRUE.

by_treatment A Boolean variable to control whether or not to predict enrollment by treatment group. By default, it is set to FALSE.

ngroups     The number of treatment groups for enrollment prediction at the design stage. By default, it is set to 1. It is replaced with the actual number of treatment groups in the observed data if df is not NULL.

alloc       The treatment allocation in a randomization block. By default, it is set to NULL, which yields equal allocation among the treatment groups.

Details

The enroll_fit variable can be used for enrollment prediction at the design stage. A piecewise Poisson model can be parameterized through the time intervals, accrualTime, which is treated as fixed, and the enrollment rates in the intervals, accrualIntensity, the log of which is used as the model parameter. For the homogeneous Poisson, time-decay, and piecewise Poisson models, enroll_fit is used to specify the prior distribution of model parameters, with a very small variance being used to fix the parameter values. It should be noted that the B-spline model is not appropriate for use during the design stage.

During the enrollment stage, enroll_fit is the enrollment model fit based on the observed data. The fitted enrollment model is used to generate enrollment times for new subjects.

Value

A list of prediction results, which includes important information such as the median, lower and upper percentiles for the estimated time to reach the target number of subjects, as well as simulated enrollment data for new subjects. The data for the prediction plot is also included within the list.

Examples

# Enrollment prediction at the design stage

enroll_pred <- predictEnrollment(
  target_n = 300,
  enroll_fit = list(model = "piecewise poisson",
                    theta = log(26/9*seq(1, 9)/30.4375),
                    vtheta = diag(9)*1e-8,
                    accrualTime = seq(0, 8)*30.4375),
  pilevel = 0.90, nreps = 100)
**predictEvent**

<table>
<thead>
<tr>
<th>predictEvent</th>
<th>Predict event</th>
</tr>
</thead>
</table>

**Description**

Utilizes pre-fitted time-to-event and time-to-dropout models to generate event and dropout times for ongoing subjects and new subjects. It also provides a prediction interval for the expected time to reach the target number of events.

**Usage**

```r
predictEvent(
  df = NULL,
  target_d, 
  newSubjects = NULL, 
  event_fit, 
  dropout_fit = NULL, 
  fixedFollowup = FALSE, 
  followupTime = 365, 
  pilevel = 0.9, 
  nyears = 4, 
  nreps = 500, 
  showEnrollment = TRUE, 
  showEvent = TRUE, 
  showDropout = FALSE, 
  showOngoing = FALSE, 
  showsummary = TRUE, 
  showplot = TRUE, 
  by_treatment = FALSE
)
```

**Arguments**

<table>
<thead>
<tr>
<th>df</th>
<th>The subject-level enrollment and event data, including trialsdt, randdt, cutoffdt, time, event, and dropout. The data should also include treatment for by-treatment prediction. By default, it is set to NULL for event prediction at the design stage.</th>
</tr>
</thead>
<tbody>
<tr>
<td>target_d</td>
<td>The target number of events to reach in the study.</td>
</tr>
<tr>
<td>newSubjects</td>
<td>The enrollment data for new subjects including draw and arrivalTime. The data should also include treatment for prediction by treatment. By default, it is set to NULL, indicating the completion of subject enrollment.</td>
</tr>
<tr>
<td>event_fit</td>
<td>The pre-fitted event model used to generate predictions.</td>
</tr>
<tr>
<td>dropout_fit</td>
<td>The pre-fitted dropout model used to generate predictions. By default, it is set to NULL, indicating no dropout.</td>
</tr>
<tr>
<td>fixedFollowup</td>
<td>A Boolean variable indicating whether a fixed follow-up design is used. By default, it is set to FALSE for a variable follow-up design.</td>
</tr>
<tr>
<td>Parameter</td>
<td>Description</td>
</tr>
<tr>
<td>-----------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>followupTime</td>
<td>The follow-up time for a fixed follow-up design, in days. By default, it is set to 365.</td>
</tr>
<tr>
<td>pilevel</td>
<td>The prediction interval level. By default, it is set to 0.90.</td>
</tr>
<tr>
<td>nyears</td>
<td>The number of years after the data cut for prediction. By default, it is set to 4.</td>
</tr>
<tr>
<td>nreps</td>
<td>The number of replications for simulation. By default, it is set to 500. If newSubjects is not NULL, the number of draws in newSubjects should be nreps.</td>
</tr>
<tr>
<td>showEnrollment</td>
<td>A Boolean variable to control whether or not to show the number of enrolled subjects. By default, it is set to TRUE.</td>
</tr>
<tr>
<td>showEvent</td>
<td>A Boolean variable to control whether or not to show the number of events. By default, it is set to TRUE.</td>
</tr>
<tr>
<td>showDropout</td>
<td>A Boolean variable to control whether or not to show the number of dropouts. By default, it is set to FALSE.</td>
</tr>
<tr>
<td>showOngoing</td>
<td>A Boolean variable to control whether or not to show the number of ongoing subjects. By default, it is set to FALSE.</td>
</tr>
<tr>
<td>showSummary</td>
<td>A Boolean variable to control whether or not to show the prediction summary. By default, it is set to TRUE.</td>
</tr>
<tr>
<td>showPlot</td>
<td>A Boolean variable to control whether or not to show the prediction plot. By default, it is set to TRUE.</td>
</tr>
<tr>
<td>by_treatment</td>
<td>A Boolean variable to control whether or not to predict event by treatment group. By default, it is set to FALSE.</td>
</tr>
</tbody>
</table>

**Details**

To ensure successful event prediction at the design stage, it is important to provide the newSubjects data set.

To specify the event model used during the design-stage event prediction, the event_fit be a list with one element per treatment. For each treatment, the element should include w to specify the weight of the treatment in a randomization block, model to specify the event model (exponential, weibull, log-normal, or piecewise exponential), theta and vtheta to indicate the parameter values and the covariance matrix. For the piecewise exponential event model, the list should also include piecewiseSurvivalTime to indicate the location of knots. It should be noted that the model averaging and spline options are not appropriate for use during the design stage.

To specify the dropout model used during the design stage event prediction, the dropout_fit should be a list with one element per treatment. For each treatment, the element should include w to specify the weight of the treatment in a randomization block, model to specify the dropout model (exponential, weibull, log-normal, or piecewise exponential), theta and vtheta to indicate the parameter values and the covariance matrix. For the piecewise exponential dropout model, the list should also include piecewiseDropoutTime to indicate the location of knots.

Following the commencement of the trial, we obtain the event model fit and the dropout model fit based on the observed data, denoted as event_fit and dropout_fit, respectively. These fitted models are subsequently utilized to generate event and dropout times for both ongoing and new subjects in the trial.
Value

A list of prediction results which includes important information such as the median, lower and upper percentiles for the estimated day and date to reach the target number of events, as well as simulated event data for both ongoing and new subjects. The data for the prediction plot is also included within this list.

Examples

```
# Event prediction after enrollment completion

event_fit <- fitEvent(df = interimData2,
                      event_model = "piecewise exponential",
                      piecewiseSurvivalTime = c(0, 140, 352))

dropout_fit <- fitDropout(df = interimData2,
                          dropout_model = "exponential")

event_pred <- predictEvent(df = interimData2, target_d = 200,
                           event_fit = event_fit$event_fit,
                           dropout_fit = dropout_fit$dropout_fit,
                           pilevel = 0.90, nreps = 100)
```

summarizeObserved  Summary of observed data

Description

Provides an overview of the observed data, including the trial start date, data cutoff date, enrollment duration, number of subjects enrolled, number of events and dropouts, number of subjects at risk, cumulative enrollment and event data, daily enrollment rates, and Kaplan-Meier plots for time to event and time to dropout.

Usage

```
summarizeObserved(
  df,
  to_predict = "event only",
  showplot = TRUE,
  by_treatment = FALSE
)
```

Arguments

df  The subject-level data, including trialsdt, randdt, and cutoffdt for enrollment prediction, as well as time, event and dropout for event prediction, and treatment for prediction by treatment group.
`summarizeObserved`

- **to_predict**: Specifies what to predict: "enrollment only", "event only", or "enrollment and event". By default, it is set to "event only".

- **showplot**: A Boolean variable to control whether or not to show the observed data plots. By default, it is set to `TRUE`.

- **by_treatment**: A Boolean variable to control whether or not to summarize observed data by treatment group. By default, it is set to `FALSE`.

**Value**

A list that includes a range of summary statistics, data sets, and plots depending on the value of `to_predict`.

**Examples**

```r
observed1 <- summarizeObserved(df = interimData1,
                                to_predict = "enrollment and event")
observed2 <- summarizeObserved(df = interimData2,
                                to_predict = "event only")
```
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