Package 'futility'

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Type Package

Title Interim Analysis of Operational Futility in Randomized Trials
with Time-to-Event Endpoints and Fixed Follow-Up

Version 0.5

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BugReports https://github.com/mjuraska/futility/issues

Description Randomized clinical trials commonly follow participants for a time-to-event efficacy end-
point for a fixed period of time. Consequently, at the time when the last enrolled participant com-
pletes their follow-up, the number of observed endpoints is a random variable. Assum-
ing data collected through an interim timepoint, simulation-based estimation and inferential pro-
cedures in the standard right-censored failure time analysis framework are conducted for the dis-
tribution of the number of endpoints--in total as well as by treatment arm--at the end of the fol-
low-up period. The future (i.e., yet unobserved) enrollment, endpoint, and dropout times are gen-
erated according to mechanisms specified in the simTrial() function in the 'seqDesign' pack-
age. A Bayesian model for the endpoint rate, offering the option to specify a robust mix-
ture prior distribution, is used for generating future data (see the vignette for details). Infer-
ence can be restricted to participants who received treatment according to the proto-
col and are observed to be at risk for the endpoint at a specified timepoint. Plotting func-
tions are provided for graphical display of results.

License GPL-2

URL https://github.com/mjuraska/futility

Encoding UTF-8

RoxygenNote 7.3.2

Imports graphics, stats, utils

Suggests knitr, rmarkdown

VignetteBuilder knitr

NeedsCompilation no

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Contents

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completeTrial.byArm	*Treatment Arm-Specific Simulation-Based Completion of a Randomized Efficacy Trial with a Time-to-Event Endpoint and Fixed Follow-up Using an Interim Data-set*

Description

Considers MITT data collected through an interim timepoint and generates independent time-to-event data-sets, by treatment arm, to assess the distribution of the number of treatment arm-specific endpoints at the end of the follow-up period. A Bayesian model for treatment arm-specific endpoint rates is used for generating future data (see the vignette).

Usage

```
completeTrial.byArm(
  interimData,
  nTrials,
  trtNames,
  N,
  enrollRate = NULL,
  enrollRatePeriod,
  eventPriorWeight,
  eventPriorRate,
  fixedDropOutRate = NULL,
  ppAnalysis = FALSE,
  missVaccProb = NULL,
  ppAtRiskTimePoint = NULL,
  fuTime,
  visitSchedule,
  visitSchedule2 = NULL,
```

```
    saveFile = NULL,
    saveDir = NULL,
    randomSeed = NULL
)
```

Arguments

interimData
: a data frame capturing observed MITT data at an interim timepoint that contains one row per enrolled participant in the MITT cohort and the following variables: arm (treatment arm), schedule2 (an indicator that a participant follows the visitSchedule2 schedule, e.g., participants who discontinue study product administration may remain in primary follow-up on a different schedule), entry (number of weeks since the reference date until the enrollment date), exit (number of weeks since the reference date until the trial exit date defined as the date of either infection diagnosis, dropout, or primary follow-up completion, whichever occurs first; NA for participants still in primary follow-up), last_visit_dt (number of weeks since the reference date until the last visit date), event (event indicator), dropout (dropout indicator), complete (indicator of completed follow-up), followup (indicator of being in primary follow-up). The reference date is defined as the enrollment date of the first participant. The variables entry, exit, and last_visit_dt use week as the unit of time. Month is defined as 52/12 weeks.

nTrials
: the number of trials to be simulated

trtNames
: a character vector of treatment labels as specified in interimData$arm determining the order of treatment arms in other input arguments

N
: a numeric vector specifying the target number of enrolled participants in each treatment arm, with the arms in the same order as in trtNames

enrollRate
: a treatment arm-pooled weekly enrollment rate used for completing enrollment if interimData's enrollment is incomplete. If NULL (default), the rate is calculated as the average over the last enrollRatePeriod weeks of enrollment in interimData. If equal to a numeric value, then enrollRatePeriod is ignored.

enrollRatePeriod
: the length (in weeks) of the time period preceding the time of the last enrolled participant in interimData that the average weekly enrollment rate will be based on and used for completing enrollment. If NULL (default), then enrollRate must be specified.

eventPriorWeight
: a numeric value in $[0, 1]$ representing a weight assigned to the prior gamma distribution of the treatment arm-specific event rates at the time when 50% of the estimated person-time at risk in each arm has been accumulated (see the vignette)

eventPriorRate
: a numeric vector of treatment arm-specific prior mean incidence rates for the endpoint, expressed as numbers of events per person-year at risk, with the arms in the same order as in trtNames

fixedDropOutRate
: the pre-trial assumed annual treatment arm-pooled dropout rate. If NULL (default), then the observed treatment arm-pooled dropout rate is used.

ppAnalysis   a logical value (`FALSE` by default) indicating whether an indicator of member-
                    ship in the per-protocol cohort shall be generated based on complete MITT data.
                    If `TRUE`, then `interimData` must include two additional variables: `missVacc`
                    (an indicator of a missed vaccination) and pp (an indicator of membership in the
                    per-protocol cohort; `NA` for participants with an indeterminate status).

missVaccProb   a probability that a participant misses at least one vaccination. If `NULL` (default)
                    and `ppAnalysis=TRUE`, then `missVaccProb` is calculated as the sample propor-
                    tion of MITT participants in `interimData` with a missed vaccination using the
                    `missVacc` variable. If `ppAnalysis=TRUE`, then the indicator of a missed vaccina-
                    tion for participants in `interimData` with pp=NA and future enrolled participants
                    is sampled from the Bernoulli distribution with probability `missVaccProb`.

ppAtRiskTimePoint
                    a minimal follow-up time (in weeks) for a participant to qualify for inclusion in
                    the per-protocol cohort (`NULL` by default)

fuTime   a follow-up time (in weeks) of each participant

visitSchedule   a numeric vector of visit weeks at which testing for the endpoint is conducted

visitSchedule2   a numeric vector of visit weeks at which testing for the endpoint is conducted in
                    a subset of participants (e.g., those who discontinue administration of the study
                    product but remain in follow-up). If `NULL` (default), everyone is assumed to
                    follow `visitSchedule`.

saveFile   a character string specifying an `.RData` file storing the output list. If `NULL` and
                    `saveDir` is specified, the file name will be generated. If, in turn, `saveFile` is
                    specified but `saveDir` equals `NULL`, then `saveFile` is ignored, and the output
                    list will be returned.

saveDir   a character string specifying a path for the output directory. If supplied, the
                    output is saved as an `.RData` file in the directory; otherwise the output is returned
                    as a list.

randomSeed   seed of the random number generator for simulation reproducibility

Value

If `saveDir` is specified, the output list (named `trialObj`) is saved as an `.RData` file; otherwise it is
returned. The output object is a list with the following components:

- `trialData`: a list with `nTrials` components each of which is a `data.frame` with the variables
  `arm`, `entry`, `exit`, `event`, and `dropout` storing the treatment assignments, enrollment times,
  study exit times, event indicators, and dropout indicators, respectively. The observed follow-
  up times can be recovered as `exit - entry`. If `ppAnalysis=TRUE`, then the indicators of
  belonging to the per-protocol cohort (named pp) are included.

- `nTrials`: the number of simulated trials

- `N`: the total number of enrolled trial participants

- `rates`: a list with three components:

  - `enrollRate`: the treatment arm-pooled *weekly* enrollment rate
  - `dropRate`: `fixedDropOutRate`, or, if `NULL`, the *annual* treatment arm-pooled dropout
    rate in `interimData`

- **eventPostRate**: a list with `length(trtNames)` components (labeled by the levels of the `arm` variable in `interimData`) each of which is a numeric vector of length `nTrials` of the sampled treatment arm-specific posterior *annual* event rates

- `BetaOverBetaPlusTk`: a list with `length(trtNames)` components (labeled by the levels of the `arm` variable in `interimData`) each of which is the arm-specific weight placed on the prior mean event rate

- `TkOverTstar`: a list with `length(trtNames)` components (labeled by the levels of the `arm` variable in `interimData`) each of which is the ratio of the observed arm-specific person-time at risk to the estimated total arm-specific person-time at risk, with the arm-specific event rates set equal to the components of `eventPriorRate` in the estimator for the total arm-specific person-time at risk

- `randomSeed`: seed of the random number generator for simulation reproducibility

See Also

[completeTrial.pooledArms](#)

Examples

```
arm <- rep(c("C3","T1","T2"), each=250)
schedule <- rbinom(length(arm), 1, 0.01)
entry <- rpois(length(arm), lambda=60)
entry <- entry - min(entry)
last_visit_dt <- entry + runif(length(arm), min=0, max=80)
event <- rbinom(length(arm), 1, 0.01)
dropout <- rbinom(length(arm), 1, 0.02)
dropout[event==1] <- 0
exit <- rep(NA, length(arm))
exit[event==1] <- last_visit_dt[event==1] + 5
exit[dropout==1] <- last_visit_dt[dropout==1] + 5
followup <- ifelse(event==1 | dropout==1, 0, 1)
interimData <- data.frame(arm=arm, schedule2=schedule, entry=entry, exit=exit,
last_visit_dt=last_visit_dt, event=event, dropout=dropout, complete=0, followup=followup)

completeData <- completeTrial.byArm(interimData=interimData, nTrials=5,
trtNames=c("C3","T1","T2"), N=c(500,500,500), enrollRatePeriod=24, eventPriorWeight=0.5,
eventPriorRate=c(0.001,0.0004,0.0004), fuTime=80, visitSchedule=seq(0, 80, by=4),
visitSchedule2=c(0,seq(from=8,to=80,by=12)), randomSeed=9)
### alternatively, to save the .RData output file (no '<-' needed):
tmpdir <- tempfile('futility_example_'); dir.create(tmpdir)
completeTrial.byArm(interimData=interimData, nTrials=5, trtNames=c("C3","T1","T2"),
N=c(500,500,500), enrollRatePeriod=24, eventPriorWeight=0.5,
eventPriorRate=c(0.001,0.0004,0.0004), fuTime=80, visitSchedule=seq(0, 80, by=4),
visitSchedule2=c(0,seq(from=8,to=80,by=12)), saveDir=tmpdir, randomSeed=9)
```

---

completeTrial.pooledArms

> *Treatment Arm-Pooled Simulation-Based Completion of a Random-*
> *ized Efficacy Trial with a Time-to-Event Endpoint and Fixed Follow-*
> *up Using an Interim Data-set*

Description

Considers MITT data collected through an interim timepoint and generates independent time-to-
event data-sets, ignoring treatment assignments, to assess the distribution of the number of treatment
arm-pooled endpoints at the end of the follow-up period. A Bayesian model for the treatment arm-
pooled endpoint rate, offering the option to specify a robust mixture prior distribution, is used for
generating future data (see the vignette).

Usage

```
completeTrial.pooledArms(
  interimData,
  nTrials,
  N,
  enrollRate = NULL,
  enrollRatePeriod = NULL,
  eventPriorWeight,
  eventPriorRate = NULL,
  fixedDropOutRate = NULL,
  ppAnalysis = FALSE,
  missVaccProb = NULL,
  ppAtRiskTimePoint = NULL,
  expectedDose2timePoint = NULL,
  fuTime,
  targetNevents = NULL,
  mixture = FALSE,
  mix.weights = NULL,
  eventPriorWeightRobust = NULL,
  visitSchedule,
  visitSchedule2 = NULL,
  saveFile = NULL,
  saveDir = NULL,
  saveDataChars = FALSE,
  randomSeed = NULL
)
```

Arguments

interimData   a data frame capturing observed MITT data at an interim timepoint that contains
                 one row per enrolled participant in the MITT cohort and the following vari-
                 ables: `arm` (treatment arm), `schedule2` (an indicator that a participant follows

the visitSchedule2 schedule, e.g., participants who discontinue study product administration may remain in primary follow-up on a different schedule), entry (number of weeks since the reference date until the enrollment date), exit (number of weeks since the reference date until the trial exit date defined as the date of either infection diagnosis, dropout, or primary follow-up completion, whichever occurs first; NA for participants still in primary follow-up), last_visit_dt (number of weeks since the reference date until the last visit date), event (event indicator), dropout (dropout indicator), complete (indicator of completed follow-up), followup (indicator of being in primary follow-up). The reference date is defined as the enrollment date of the first participant. The variables entry, exit, and last_visit_dt use week as the unit of time. Month is defined as 52/12 weeks.

nTrials   the number of trials to be simulated

N   the total target number of enrolled participants

enrollRate   a treatment arm-pooled weekly enrollment rate used for completing enrollment if fewer than N participants were enrolled in interimData. If NULL (default), the rate is calculated as the average over the last enrollRatePeriod weeks of enrollment in interimData. If equal to a numerical value, then enrollRatePeriod is ignored.

enrollRatePeriod

the length (in weeks) of the time period preceding the time of the last enrolled participant in interimData that the average weekly enrollment rate will be based on and used for completing enrollment. If NULL (default), then enrollRate must be specified.

eventPriorWeight

a numeric value in $[0, 1]$ representing a weight assigned to the prior gamma distribution of the treatment arm-pooled event rate at the time when 50% of the estimated total person-time at risk has been accumulated (see the vignette)

eventPriorRate   a numeric value of a treatment arm-pooled prior mean incidence rate for the endpoint, expressed as the number of events per person-year at risk. If NULL (default), then use the observed rate in interimData.

fixedDropOutRate

the pre-trial assumed annual dropout rate. If NULL (default), then the observed treatment arm-pooled dropout rate is used.

ppAnalysis   a logical value (FALSE by default) indicating whether an indicator of membership in the per-protocol cohort shall be generated based on complete MITT data. If TRUE, then interimData must include two additional variables: missVacc (an indicator of a missed vaccination) and pp (an indicator of membership in the per-protocol cohort; NA for participants with an indeterminate status).

missVaccProb   a probability that a participant misses at least one vaccination. If NULL (default) and ppAnalysis=TRUE, then missVaccProb is calculated as the sample proportion of MITT participants in interimData who were expected for the second vaccination and missed it, using the missVacc variable. If ppAnalysis=TRUE, then the indicator of a missed vaccination for participants in interimData with pp=NA and future enrolled participants is sampled from the Bernoulli distribution with probability missVaccProb.

ppAtRiskTimePoint

a minimal follow-up time (in weeks) for a participant to qualify for inclusion in the per-protocol cohort (NULL by default)

expectedDose2timePoint

a numeric value specifying the follow-up time (in weeks) at which a participant is considered expected for the second dose, i.e., when the visit window of the second vaccination visit has closed (NULL by default). It must be provided if ppAnalysis=TRUE.

fuTime   a follow-up time (in weeks) of each participant

targetNevents   an integer value specifying the target number of events in an event-driven design, the accrual of which triggers the primary analysis. The value is used exclusively for estimating the total person-time at risk accumulated for the primary analysis, which in turn is used for setting the values of the hyperparameters of the prior distribution.

mixture   a logical value indicating whether to use the robust mixture approach (see the vignette). If equal to FALSE (default), then mix.weights and eventPriorWeightRobust are ignored.

mix.weights   a numeric vector of length 2 representing prior weights (values in $[0,1]$) of the informative and the weakly informative component, respectively, of the prior gamma-mixture distribution of the treatment arm-pooled event rate. The two weights must sum up to 1. If NULL (default) and mixture=TRUE, then c(0.8,0.2) is used.

eventPriorWeightRobust

a numeric value representing the weight w used to calculate the β parameter of the weakly informative gamma distribution in the mixture prior. If NULL (default) and mixture=TRUE, then $1/200$ is used.

visitSchedule   a numeric vector of visit weeks at which testing for the endpoint is conducted

visitSchedule2 a numeric vector of visit weeks at which testing for the endpoint is conducted in a subset of participants (e.g., those who discontinue administration of the study product but remain in follow-up). If NULL (default), everyone is assumed to follow visitSchedule.

saveFile   a character string specifying an .RData file storing the output list. If NULL and saveDir is specified, the file name will be generated. If, in turn, saveFile is specified but saveDir equals NULL, then saveFile is ignored, and the output list will be returned.

saveDir   a character string specifying a path for the output directory. If supplied, the output is saved as an .RData file in the directory; otherwise the output is returned as a list.

saveDataChars   a logical value (FALSE by default) for whether a file named dataChars.RData shall be generated with metrics characterizing the interim data for inclusion in the output report. If TRUE, the file is saved in saveDir.

randomSeed   seed of the random number generator for simulation reproducibility

Value

If saveDir is specified, the output list (named trialObj) is saved as an .RData file; otherwise it is returned. The output object is a list with the following components:

- trialData: a list with nTrials components each of which is a data.frame with the variables arm, entry, exit, event, and dropout storing the treatment assignments, enrollment times, study exit times, event indicators, and dropout indicators respectively. The observed follow-up times can be recovered as exit - entry. If ppAnalysis=TRUE, then the indicators of belonging to the per-protocol cohort (named pp) are included.

- nTrials: the number of simulated trials

- N: the total number of enrolled trial participants

- rates: a list with three components:

  - enrollRate: the treatment arm-pooled *weekly* enrollment rate
  - dropRate: fixedDropOutRate, or, if NULL, the *annual* treatment arm-pooled dropout rate in interimData
  - eventPostRate: a numeric vector of length nTrials of the treatment arm-pooled *annual* event rates sampled from the posterior distribution

- BetaOverBetaPlusTk: the weight placed on the prior mean event rate

- TkOverTstar: the ratio of the observed person-time at risk to the estimated total person-time at risk, with the event rate set equal to eventPriorRate in the estimator for the total person-time at risk

- randomSeed: seed of the random number generator for simulation reproducibility

- w.post: the weights, summing up to 1, of the gamma components of the posterior mixture distribution of the treatment arm-pooled event rate. If mixture=FALSE, then w.post=NA.

See Also

completeTrial.byArm

Examples

```
arm <- rep(c("C3","T1","T2"), each=250)
schedule <- rbinom(length(arm), 1, 0.01)
entry <- rpois(length(arm), lambda=60)
entry <- entry - min(entry)
last_visit_dt <- entry + runif(length(arm), min=0, max=80)
event <- rbinom(length(arm), 1, 0.01)
dropout <- rbinom(length(arm), 1, 0.02)
dropout[event==1] <- 0
exit <- rep(NA, length(arm))
exit[event==1] <- last_visit_dt[event==1] + 5
exit[dropout==1] <- last_visit_dt[dropout==1] + 5
followup <- ifelse(event==1 | dropout==1, 0, 1)
interimData <- data.frame(arm=arm, schedule2=schedule, entry=entry, exit=exit,
last_visit_dt=last_visit_dt, event=event, dropout=dropout, complete=0,
followup=followup)

completeData <- completeTrial.pooledArms(interimData=interimData, nTrials=5, N=1500,
enrollRatePeriod=24, eventPriorWeight=0.5, eventPriorRate=0.001, fuTime=80,
visitSchedule=seq(0, 80, by=4),
visitSchedule2=c(0,seq(from=8,to=80,by=12)), randomSeed=9)
### alternatively, to save the .RData output file (no '<-' needed):
```

```
tmpdir <- tempfile('futility_example_'); dir.create(tmpdir)
completeTrial.pooledArms(interimData=interimData, nTrials=5, N=1500,
enrollRatePeriod=24, eventPriorWeight=0.5, eventPriorRate=0.001, fuTime=80,
visitSchedule=seq(0, 80, by=4),
visitSchedule2=c(0,seq(from=8,to=80,by=12)), saveDir=tmpdir, randomSeed=9)
```

---

plotRCDF.byArm   *Plot Characteristics of the Estimated Distribution of the Treatment*
                                   Arm-Specific Number of Endpoints

---

Description

Takes the output from the `completeTrial.byArm` function and generates a plot describing characteristics of the estimated distribution of the treatment arm-specific number of endpoints.

Usage

```
plotRCDF.byArm(
  armLabel,
  trtNames,
  eventTimeFrame = NULL,
  eventPPcohort = FALSE,
  eventPriorRate,
  eventPriorWeight,
  xlim = NULL,
  xlab = NULL,
  ylab = NULL,
  fileDir
)
```

Arguments

armLabel	a character string matching a treatment label in the `arm` variable in `interimData` that indicates the treatment arm for which the plot will be generated
trtNames	a character vector of all treatment labels listed in the same order as in `trtNames` in `completeTrial.byArm`
eventTimeFrame	a time frame within which endpoints are counted, specified in weeks as `c(start, end)`. If `NULL` (default), then all endpoints are counted.
eventPPcohort	a logical value. If `TRUE`, only endpoints in the per-protocol cohort are counted. The default value is `FALSE`.
eventPriorRate	a numeric vector of treatment arm-specific prior mean incidence rates for the endpoint, expressed as numbers of events per person-year at risk, matching the order of treatment arms in `trtNames`

eventPriorWeight

    a numeric vector in which each value represents a weight (i.e., a separate scenario) assigned to the prior gamma distribution of the treatment arm-specific event rate at the time when 50% of the estimated person-time at risk in the given arm has been accumulated

xlim   a numeric vector of the form c(xmin, xmax) for the user-specified x-axis limits. If NULL (default), then the computed range of x-axis values will be used.

xlab   a character string for the user-specified x-axis label. If NULL (default), then the label "Number of Infections in Group armLabel (n)" will be used.

ylab   a character string for the user-specified y-axis label. If NULL (default), then the label "P(Number of Infections in Group armLabel >= n) x 100" will be used.

fileDir   a character string specifying a path for the input directory

Value

None. The function is called solely for plot generation.

See Also

[completeTrial.byArm](#) and [plotRCDF.pooledArms](#)

Examples

```
arm <- rep(c("C3","T1","T2"), each=250)
schedule <- rbinom(length(arm), 1, 0.01)
entry <- rpois(length(arm), lambda=60)
entry <- entry - min(entry)
last_visit_dt <- entry + runif(length(arm), min=0, max=80)
event <- rbinom(length(arm), 1, 0.01)
dropout <- rbinom(length(arm), 1, 0.02)
dropout[event==1] <- 0
exit <- rep(NA, length(arm))
exit[event==1] <- last_visit_dt[event==1] + 5
exit[dropout==1] <- last_visit_dt[dropout==1] + 5
followup <- ifelse(event==1 | dropout==1, 0, 1)
interimData <- data.frame(arm=arm, schedule2=schedule, entry=entry, exit=exit,
last_visit_dt=last_visit_dt, event=event, dropout=dropout, complete=0, followup=followup)

weights <- c(0.2, 0.4, 0.6)
tmpdir <- tempfile('futility_example_'); dir.create(tmpdir)
for (j in 1:length(weights)){
  completeTrial.byArm(interimData=interimData, nTrials=50,
  trtNames=c("C3","T1","T2"),N=c(500,500,500),
  enrollRatePeriod=24, eventPriorWeight=weights[j], eventPriorRate=c(0.06,0.03,0.03),
  fuTime=80, visitSchedule=seq(0, 80, by=4), visitSchedule2=c(0,seq(from=8,to=80,by=12)),
  saveDir=tmpdir, randomSeed=9)
}

pdf_file <- file.path(
  tmpdir,
```

```
   paste0('rcdf_byArm_arm=T1_',
          'eventPriorRateC3=0.06_eventPriorRateT1=0.03_eventPriorRateT2=0.03.pdf')
)
pdf(file=pdf_file, width=6, height=5)
plotRCDF.byArm(armLabel="T1", trtNames=c("C3","T1","T2"), eventPriorRate=c(0.06,0.03,0.03),
eventPriorWeight=weights, fileDir=tmpdir)
dev.off()
```

---

plotRCDF.pooledArms   *Plot Characteristics of the Estimated Distribution of the Treatment*
                           Arm-Pooled Number of Endpoints

Description

Takes the output from the [completeTrial.pooledArms](#) function and generates a plot describing
characteristics of the estimated distribution of the treatment arm-pooled number of endpoints.

Usage

```
plotRCDF.pooledArms(
  eventTimeFrame = NULL,
  eventPPcohort = FALSE,
  target,
  plotTarget = TRUE,
  power.axis = TRUE,
  null.TE = 0,
  power.TE = NULL,
  pRandTx = NULL,
  outDate = NULL,
  eventPriorRate,
  eventPriorWeight,
  xlim = NULL,
  xlab = NULL,
  ylab = NULL,
  power.lab = NULL,
  xPosLegend = 0.67,
  fileDir
)
```

Arguments

eventTimeFrame	a time frame within which endpoints are counted, specified in weeks as c(start, end). If NULL (default), then all endpoints are counted.
eventPPcohort	a logical value. If TRUE, only endpoints in the per-protocol cohort are counted. The default value is FALSE.
target	a vector of target numbers of endpoints for reporting of the estimated probability that the total number of endpoints will be $\geq$ target, with a 95% credible interval

plotTarget	a logical value. If TRUE (default), target lines are added to the plot; if FALSE, they are omitted.
power.axis	a logical value. If TRUE (default), then a top axis is added to the plot, showing power to reject H_0: TE $\leq$ null.TE using a 1-sided 0.025-level Wald test if TE = power.TE throughout the trial.
null.TE	a numeric value of treatment efficacy (zero by default) specifying the null hypothesis if power.axis is TRUE
power.TE	a numeric vector of treatment efficacy levels for which power is shown on the top axis. If power.axis is FALSE, then power.TE is ignored.
pRandTx	a numeric value specifying the probability of being randomized into the treatment group. If power.axis is FALSE, then pRandTx is ignored.
outDate	an optional character string used to match legacy output filenames created by older versions of the package (e.g., files starting with censorTrial_). If NULL (default), a default key is used for storing projection summaries.
eventPriorRate	a numeric value of the treatment arm-pooled prior mean incidence rate for the endpoint, expressed as the number of events per person-year at risk
eventPriorWeight	
	a numeric vector in which each value represents a weight (i.e., a separate scenario) assigned to the prior gamma distribution of the treatment arm-pooled event rate at the time when 50% of the estimated total person-time at risk has been accumulated
xlim	a numeric vector of the form c(xmin, xmax) for the user-specified x-axis limits. If NULL (default), then the computed range of x-axis values will be used.
xlab	a character string for the user-specified x-axis label. If NULL (default), then the label "Total Number of Infections (n)" will be used.
ylab	a character string for the user-specified y-axis label. If NULL (default), then the label "P(Total Number of Infections >= n) x 100" will be used.
power.lab	a character string for the user-specified power-axis label. If NULL (default), then the label "Power for TE = power.TE (x 100)" will be used.
xPosLegend	a numeric value in $[0, 1]$ (0.67 by default) specifying the x-coordinate for the position of the legend
fileDir	a character string specifying a path for the input directory

Value

None. The function is called solely for plot generation.

See Also

[completeTrial.pooledArms](#) and [plotRCDF.byArm](#)

Examples

```
arm <- rep(c("C3","T1","T2"), each=250)
schedule <- rbinom(length(arm), 1, 0.01)
```

```
entry <- rpois(length(arm), lambda=60)
entry <- entry - min(entry)
last_visit_dt <- entry + runif(length(arm), min=0, max=80)
event <- rbinom(length(arm), 1, 0.01)
dropout <- rbinom(length(arm), 1, 0.02)
dropout[event==1] <- 0
exit <- rep(NA, length(arm))
exit[event==1] <- last_visit_dt[event==1] + 5
exit[dropout==1] <- last_visit_dt[dropout==1] + 5
followup <- ifelse(event==1 | dropout==1, 0, 1)
interimData <- data.frame(arm=arm, schedule2=schedule, entry=entry, exit=exit,
last_visit_dt=last_visit_dt, event=event, dropout=dropout, complete=0,
followup=followup)

weights <- c(0.2, 0.4, 0.6)
tmpdir <- tempfile('futility_example_'); dir.create(tmpdir)
for (j in 1:length(weights)){
 completeTrial.pooledArms(interimData=interimData, nTrials=50, N=1500, enrollRatePeriod=24,
 eventPriorWeight=weights[j], eventPriorRate=0.06, fuTime=80, visitSchedule=seq(0, 80, by=4),
  visitSchedule2=c(0,seq(from=8,to=80,by=12)), saveDir=tmpdir, randomSeed=9)
}

pdf_file <- file.path(tmpdir, paste0('rcdf_pooled_eventPriorRate=', 0.06, '.pdf'))
pdf(file=pdf_file, width=6, height=5)
plotRCDF.pooledArms(target=c(60,30), power.axis=FALSE, eventPriorRate=0.06,
eventPriorWeight=weights, fileDir=tmpdir)
dev.off()
```

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