

Package ‘TrialFlowR’

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Type Package

Title Clinical Trial Flow and Participant Disposition

Version 1.0.0

Description Summarizes participant flow and disposition in clinical trials, including CONSORT-style randomized controlled trials, parallel-group, crossover, cluster randomized, and multi-arm trials. Provides functions for screening failures, exclusions and reasons, allocation, follow-up, loss to follow-up, withdrawals, intention-to-treat and per-protocol populations, and participant-disposition summaries. The methods are based on established principles for reporting participant flow and disposition in randomized trials; see Schulz et al. (2010) [<doi:10.1136/bmj.c332>](https://doi.org/10.1136/bmj.c332).

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Depends R (>= 4.2.0)

Suggests testthat (>= 3.0.0), spelling

URL <https://github.com/vinodhpmr/TrialFlowR>

BugReports <https://github.com/vinodhpmr/TrialFlowR/issues>

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Author Vinodhkumar Obli Rajendran [aut, cre],
Keerthi Aaradhana [aut]

Maintainer Vinodhkumar Obli Rajendran <vinodhkumar.rajendran@gmail.com>

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add_flow_stage	<i>Add a participant-flow stage</i>
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Description

Adds a new participant-flow stage to an existing trial_flow object.

Usage

```
add_flow_stage(object, stage_name, ids = NULL)
```

Arguments

- object A trial_flow object.
- stage_name Name of the new stage.
- ids Optional participant IDs. If NULL, all participants are used.

Value

An updated trial_flow object.

Examples

```
dat <- data.frame(
  id = 1:4,
  stage = c("Screened", "Screened", "Randomized", "Randomized"),
  group = c("A", "B", "A", "B")
)

x <- trial_flow(
  dat,
  id = "id",
  stage = "stage",
  group = "group"
)

x2 <- add_flow_stage(
  x,
  stage_name = "Completed",
```

```

    ids = c(3, 4)
  )

  x2

```

flow_counts

Count participants by flow stage and group

Description

Counts participants represented at each flow stage, optionally separated by treatment or trial group.

Usage

```
flow_counts(object, include_group = TRUE)
```

Arguments

object A trial_flow object.

include_group Logical; include group in the result.

Value

A data frame of participant counts.

Examples

```

dat <- data.frame(
  id = 1:6,
  stage = c(
    "Screened",
    "Screened",
    "Randomized",
    "Randomized",
    "Completed",
    "Completed"
  ),
  group = c("A", "B", "A", "B", "A", "B")
)

x <- trial_flow(
  dat,
  id = "id",
  stage = "stage",
  group = "group"
)

flow_counts(x)

```

`participant_disposition`*Summarize participant disposition*

Description

Summarizes participant disposition by stage, reason, and optionally treatment or trial group.

Usage

```
participant_disposition(data, stage, reason = NULL, group = NULL)
```

Arguments

<code>data</code>	A participant-level data frame.
<code>stage</code>	Disposition-stage column.
<code>reason</code>	Optional reason column.
<code>group</code>	Optional treatment or trial-group column.

Value

A data frame of disposition counts.

Examples

```
dat <- data.frame(  
  stage = c(  
    "Screened",  
    "Excluded",  
    "Randomized",  
    "Withdrawn"  
  ),  
  reason = c(  
    NA,  
    "Ineligible",  
    NA,  
    "Adverse event"  
  ),  
  group = c(  
    NA,  
    NA,  
    "Treatment",  
    "Treatment"  
  )  
)  
  
participant_disposition(  
  dat,
```

```
stage = "stage",  
reason = "reason",  
group = "group"  
)
```

population_summary	<i>Summarize participant populations</i>
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Description

Summarizes the number of participants in the overall, intention-to-treat, and per-protocol populations.

Usage

```
population_summary(data, itt, pp)
```

Arguments

data	A participant-level data frame.
itt	ITT logical vector or column name.
pp	Per-protocol logical vector or column name.

Value

A data frame with population counts.

Examples

```
dat <- data.frame(  
  id = 1:6,  
  itt = c(TRUE, TRUE, TRUE, TRUE, TRUE, FALSE),  
  pp = c(TRUE, TRUE, TRUE, FALSE, TRUE, FALSE)  
)  
  
population_summary(  
  dat,  
  itt = "itt",  
  pp = "pp"  
)
```

trial_flow

*Create a clinical trial participant-flow object***Description**

Creates an object representing participant flow through the stages of a clinical trial.

Usage

```
trial_flow(
  data,
  id,
  stage,
  group = NULL,
  design = c("parallel", "crossover", "cluster", "multi-arm", "other"),
  ...
)
```

Arguments

data	A data frame with one row per participant.
id	Participant identifier column.
stage	Flow-stage column.
group	Optional treatment or trial-group column.
design	Trial design.
...	Additional arguments.

Value

An object of class trial_flow.

Examples

```
dat <- data.frame(
  id = 1:6,
  stage = c(
    "Screened",
    "Screened",
    "Randomized",
    "Randomized",
    "Completed",
    "Completed"
  ),
  group = c("A", "B", "A", "B", "A", "B")
)

x <- trial_flow(
```

```
    dat,  
    id = "id",  
    stage = "stage",  
    group = "group",  
    design = "parallel"  
  )  
x
```

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