Package: trialfigs (via r-universe)

October 15, 2026

Title Efficacy and Safety Graphics for Clinical Review Packages

Version 0.1.0

Description Builds submission-style efficacy and safety figures used in clinical review packages, with one simulator for each therapeutic area. Oncology figures include Kaplan-Meier curves, RECIST waterfalls, swimmer plots and spider plots. Cardiovascular, endocrine, immunology, infectious disease and neuroscience figures include time-to-event curves, mean change from baseline and responder rates. Shared safety figures include an adverse-event dot plot, an eDISH liver plot, a laboratory shift plot and an exposure plot. Reference lines follow RECIST 1.1 and the FDA drug-induced liver injury guidance. This is not an FDA product and does not guarantee regulatory acceptance.

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Encoding UTF-8

Depends R (>= 4.1.0)

Imports ggplot2, survival, withr

Suggests testthat (>= 3.0.0)

Config/testthat/edition 3

Language en-US

URL https://github.com/shekharchalwadigrepo-hub/trialfigs

BugReports https://github.com/shekharchalwadigrepo-hub/trialfigs/issues

RoxygenNote 7.3.2

NeedsCompilation no

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Repository https://cran.r-universe.dev

Date/Publication 2026-10-15 15:50:02 UTC

RemoteUrl https://github.com/cran/trialfigs

RemoteRef HEAD

RemoteSha ca42fa2e7a7fe1c2f1d6e4ff1f117541ea88cd1b

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`trialfigs-package` *Efficacy and safety graphics for clinical review packages*

Description

Simulated-data utilities and submission-style figures commonly used in clinical review packages. Not an FDA product. See `ta_plot_catalog` for the therapeutic-area map.

Author(s)

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See Also

`plot_km`, `plot_waterfall`, `plot_edish`

cox_hr — *Cox hazard ratio with the investigational arm in the numerator*

Description

The reference level is the other arm, so a ratio below 1 favours the investigational arm. One row is returned, for binding into a forest.

Usage

```
cox_hr(data, time, event, arm, investigational = "Investigational",
  subgroup = "Overall")
```

Arguments

`data`	Subject-level data.
`time`, `event`, `arm`	Column names.
`investigational`	Level of `arm` treated as the experimental arm.
`subgroup`	Label stored in the result.

Value

A one-row data frame with subgroup, estimate, limits and n.

Examples

```
onc <- simulate_oncology(n_per_arm = 20)
cox_hr(onc$adsl, "os_months", "os_event", "arm")
```

fda_palette — *Color palette for review figures*

Description

Named colors for treatment arms and RECIST responses.

Usage

```
fda_palette()
```

Value

A named character vector of colors.

Examples

```
fda_palette()
```

fda_theme — *Theme for review figures*

Description

Classic theme with a left-aligned caption for population notes.

Usage

```
fda_theme(base_size = 11)
```

Arguments

base_size	Base font size in points.

Value

A ggplot2 theme object.

Examples

```
fda_theme()
```

plot_ae — *Adverse-event incidence dot plot*

Description

Percent of subjects with each term and a Wilson interval, ordered by the risk difference versus the reference arm.

Usage

```
plot_ae(data, term = "term", arm = "arm", denom = NULL, id = "usubjid",
  reference = "Placebo", title = "Subjects with an adverse event")
```

Arguments

data	One row per subject per event.
term, arm, id	Column names.
denom	Subject-level denominator. Required for a correct percent.
reference	Arm used when ordering by risk difference.
title	Plot title.

Value

A ggplot object.

Examples

```
saf <- simulate_safety(n_per_arm = 25)
plot_ae(saf$adae, denom = saf$adsl, reference = "Placebo")
```

---

plot_change *Mean change from baseline with a confidence interval*

Description

The band is the normal approximation to the standard error of the mean. Replace it with the model named in the statistical analysis plan for a primary contrast.

Usage

```
plot_change(data, visit = "week", change = "chg", arm = "arm",
  title = "Mean change from baseline", xlab = "Week",
  ylab = "Mean change (95% CI)")
```

Arguments

`data`	Longitudinal data.
`visit`, `change`, `arm`	Column names.
`title`, `xlab`, `ylab`	Labels.

Value

A ggplot object.

Examples

```
endo <- simulate_endocrinology(n_per_arm = 15)
plot_change(endo$adlb, title = "HbA1c")
```

plot_edish — *eDISH plot of peak ALT versus peak bilirubin*

Description

Log-scale multiples of the upper limit of normal. Reference lines are ALT 3x ULN and total bilirubin 2x ULN. A point in that quadrant needs narrative review; it is not by itself a Hy's law case.

Usage

```
plot_edish(data, alt = "alt_xuln", bili = "bili_xuln", arm = "arm",
  id = "usubjid", title = "eDISH: peak ALT vs peak total bilirubin")
```

Arguments

`data`	One row per subject, peak values.
`alt`, `bili`, `arm`	Column names, values in multiples of ULN.
`id`	Optional subject id, labelled for quadrant cases.
`title`	Plot title.

Value

A ggplot object.

Examples

```
saf <- simulate_safety(n_per_arm = 25)
plot_edish(saf$adlb)
```

plot_exposure — *Treatment duration by arm*

Description

Box plot of exposure with the median in the caption.

Usage

```
plot_exposure(data, duration = "trtdur_days", arm = "arm",
  xlab = "Treatment duration (days)", title = "Exposure")
```

Arguments

`data`	Subject-level data.
`duration`, `arm`	Column names.
`xlab`, `title`	Labels.

Value

A ggplot object.

Examples

```
saf <- simulate_safety(n_per_arm = 20)
plot_exposure(saf$adsl)
```

---

plot_forest *Forest plot of a ratio or a difference*

Description

Use `null = 1` for hazard ratios and `null = 0` for mean differences. Intervals that cross the null are drawn in grey.

Usage

```
plot_forest(data, label = "subgroup", estimate = "estimate", lcl = "lcl",
  ucl = "ucl", n = NULL, null = 1, xlab = "Hazard ratio (95% CI)",
  title = "Subgroup forest plot", subtitle = NULL,
  favour_left = "Favours investigational",
  favour_right = "Favours control")
```

Arguments

`data`	One row per subgroup or endpoint.
`label`, `estimate`, `lcl`, `ucl`	Column names.
`n`	Optional sample-size column.
`null`	Null value drawn as a vertical line.
`xlab`, `title`, `subtitle`, `favour_left`, `favour_right`	Labels.

Value

A ggplot object.

Examples

```
onc <- simulate_oncology(n_per_arm = 20)
forest <- cox_hr(onc$adsl, "os_months", "os_event", "arm")
plot_forest(forest)
```

plot_km — *Kaplan-Meier curve with number at risk*

Description

Event-free curve with censoring ticks, dashed confidence limits, a log-rank p-value and the number at risk. Competing risks are not modelled.

Usage

```
plot_km(data, time, event, arm, xlab = "Time (months)",
  ylab = "Event-free probability", title = "Kaplan-Meier estimate",
  subtitle = NULL, conf_int = TRUE, risk_times = NULL, palette = NULL,
  population = "Intent-to-treat population")
```

Arguments

`data`	Subject-level data.
`time`, `event`, `arm`	Column names. `event` is 1 for the event and 0 for censoring.
`xlab`, `ylab`, `title`, `subtitle`	Labels.
`conf_int`	Draw pointwise confidence limits.
`risk_times`	Times for the number at risk. Default is `pretty()`.
`palette`	Named color vector.
`population`	Analysis-population note printed in the caption.

Value

A ggplot object.

Examples

```
onc <- simulate_oncology(n_per_arm = 15)
plot_km(onc$adsl, time = "os_months", event = "os_event", arm = "arm")
```

plot_lab_shift *Baseline versus post-baseline maximum*

Description

Points above the identity line rose after baseline.

Usage

```
plot_lab_shift(data, baseline = "alt_base", post = "alt_max", arm = "arm",
  uln = NULL, title = "Baseline vs post-baseline maximum",
  xlab = "Baseline", ylab = "Post-baseline maximum")
```

Arguments

`data`	One row per subject.
`baseline`, `post`, `arm`	Column names.
`uln`	Upper limit of normal, drawn if not NULL.
`title`, `xlab`, `ylab`	Labels.

Value

A ggplot object.

Examples

```
saf <- simulate_safety(n_per_arm = 20)
plot_lab_shift(saf$adlb, uln = 1)
```

plot_responder *Binary responder rate with a Wilson interval*

Description

Percent of responders by arm, with a Wilson score interval.

Usage

```
plot_responder(data, responder, arm, title = "Responder rate",
  ylab = "Responders, percent (Wilson 95% CI)")
```

Arguments

`data`	Subject-level data.
`responder`	Logical or 0/1 column name.
`arm`	Arm column name.
`title`, `ylab`	Labels.

Value

A ggplot object.

Examples

```
onc <- simulate_oncology(n_per_arm = 15)
onc$adsl$responder <- onc$adsl$bor %in% c("CR", "PR")
plot_responder(onc$adsl, responder = "responder", arm = "arm")
```

`plot_spider` *Spider plot of percent change over time*

Description

Individual tumor trajectories with the arm mean overlaid.

Usage

```
plot_spider(data, id = "usubjid", time = "week", pct = "pct_change",
  arm = "arm", title = "Percent change in sum of diameters")
```

Arguments

`data`	Longitudinal data, one row per subject per visit.
`id`, `time`, `pct`, `arm`	Column names.
`title`	Plot title.

Value

A ggplot object.

Examples

```
onc <- simulate_oncology(n_per_arm = 8)
plot_spider(onc$adtr)
```

plot_swimmer *Swimmer plot of time on treatment*

Description

One bar per subject, with points for objective response and progression. Limited to the longest durations so the figure stays readable.

Usage

```
plot_swimmer(data, id = "usubjid", arm = "arm",
  duration = "trtdur_months", response_time = "resp_months",
  progression_time = "pd_months", max_n = 30, xlab = "Months",
  title = "Time on treatment")
```

Arguments

`data`	Subject-level data.
`id`, `arm`, `duration`	Column names.
`response_time`, `progression_time`	Optional column names.
`max_n`	Maximum subjects, taken as the longest durations.
`xlab`, `title`	Labels.

Value

A ggplot object.

Examples

```
onc <- simulate_oncology(n_per_arm = 12)
plot_swimmer(onc$adsl, max_n = 10)
```

plot_waterfall *RECIST waterfall of best percent change*

Description

Bars of best percent change in the sum of diameters. Reference lines at -30 and +20 follow RECIST 1.1. Subjects with no post-baseline value are omitted.

Usage

```
plot_waterfall(data, pct = "pct_change", response = "bor", arm = "arm",
  id = "usubjid", title = "Best percent change in sum of diameters",
  subtitle = "RECIST 1.1 reference lines at -30% and +20%",
  palette = NULL)
```

Arguments

`data`	Subject-level data.
`pct`, `response`, `arm`, `id`	Column names.
`title`, `subtitle`	Labels.
`palette`	Named colors for response categories.

Value

A ggplot object.

Examples

```
onc <- simulate_oncology(n_per_arm = 15)
plot_waterfall(onc$adsl)
```

`simulate_cardiovascular` *Simulate a cardiovascular outcomes set*

Description

Time to first MACE and systolic blood pressure. Synthetic data.

Usage

```
simulate_cardiovascular(n_per_arm = 220, seed = 20260316)
```

Arguments

`n_per_arm`	Subjects per arm.
`seed`	Random seed, restored after the call.

Value

A list with `adsl` and `advs`.

Examples

```
cv <- simulate_cardiovascular(n_per_arm = 20)
plot_km(cv$adsl, time = "mace_months", event = "mace_event", arm = "arm")
```

simulate_endocrinology *Simulate a type 2 diabetes HbA1c set*

Description

Longitudinal HbA1c. Synthetic data.

Usage

```
simulate_endocrinology(n_per_arm = 150, seed = 20260317)
```

Arguments

n_per_arm	Subjects per arm.
seed	Random seed, restored after the call.

Value

A list with adsl and adlb.

Examples

```
endo <- simulate_endocrinology(n_per_arm = 15)
plot_change(endo$adlb)
```

simulate_immunology *Simulate a rheumatoid-arthritis DAS28 set*

Description

Longitudinal DAS28. Synthetic data.

Usage

```
simulate_immunology(n_per_arm = 120, seed = 20260318)
```

Arguments

n_per_arm	Subjects per arm.
seed	Random seed, restored after the call.

Value

A list with adsl and adeff.

Examples

```
imm <- simulate_immunology(n_per_arm = 15)
plot_change(imm$adeff, title = "DAS28")
```

---

simulate_infectious *Simulate an antiviral viral-load set*

Description

Log10 viral load and time to clearance. Synthetic data.

Usage

```
simulate_infectious(n_per_arm = 100, seed = 20260319)
```

Arguments

n_per_arm	Subjects per arm.
seed	Random seed, restored after the call.

Value

A list with adsl and adlb.

Examples

```
id <- simulate_infectious(n_per_arm = 15)
plot_change(id$adlb, visit = "day", xlab = "Day")
```

---

simulate_neuroscience *Simulate a depression MADRS set*

Description

Longitudinal MADRS. Synthetic data.

Usage

```
simulate_neuroscience(n_per_arm = 140, seed = 20260320)
```

Arguments

n_per_arm	Subjects per arm.
seed	Random seed, restored after the call.

Value

A list with `adsl` and `adeff`.

Examples

```
cns <- simulate_neuroscience(n_per_arm = 15)
plot_change(cns$adeff, title = "MADRS")
```

`simulate_oncology` *Simulate a two-arm oncology efficacy set*

Description

Subject-level survival, RECIST response, and longitudinal tumor measurements. Data are synthetic. The random-number stream is restored on exit.

Usage

```
simulate_oncology(n_per_arm = 80, seed = 20260315)
```

Arguments

`n_per_arm`	Subjects per arm.
`seed`	Random seed, restored after the call.

Value

A list with `adsl` and `adtr`.

Examples

```
onc <- simulate_oncology(n_per_arm = 10)
plot_waterfall(onc$adsl)
```

`simulate_safety` *Simulate core safety data*

Description

Adverse events and peak liver tests in multiples of the upper limit of normal. Synthetic data.

Usage

```
simulate_safety(n_per_arm = 160, seed = 20260321)
```

Arguments

`n_per_arm`	Subjects per arm.
`seed`	Random seed, restored after the call.

Value

A list with `adsl`, `adae` and `adlb`.

Examples

```
saf <- simulate_safety(n_per_arm = 20)
plot_edish(saf$adlb)
```

`ta_plot_catalog` *Recommended displays by therapeutic area*

Description

Working catalog of figures commonly discussed in a clinical review. Not a regulatory requirement.

Usage

```
ta_plot_catalog()
```

Value

A data frame with therapeutic area, display, function name and anchor.

Examples

```
head(ta_plot_catalog())
```

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