

Package ‘trialfigs’

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

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

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Contents

trialfigs-package	2
cox_hr	3
fda_palette	3
fda_theme	4
plot_ae	4
plot_change	5
plot_edish	6
plot_exposure	6
plot_forest	7
plot_km	8
plot_lab_shift	9
plot_responder	9
plot_spider	10
plot_swimmer	11
plot_waterfall	11
simulate_cardiovascular	12
simulate_endocrinology	13
simulate_immunology	13
simulate_infectious	14
simulate_neuroscience	14
simulate_oncology	15
simulate_safety	15
ta_plot_catalog	16
Index	17

trialfigs-package	<i>Efficacy and safety graphics for clinical review packages</i>
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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	<i>Cox hazard ratio with the investigational arm in the numerator</i>
--------	---

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	<i>Color palette for review figures</i>
-------------	---

Description

Named colors for treatment arms and RECIST responses.

Usage

```
fda_palette()
```

Value

A named character vector of colors.

Examples

```
fda_palette()
```

fda_theme	<i>Theme for review figures</i>
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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	<i>Adverse-event incidence dot plot</i>
---------	---

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	<i>Mean change from baseline with a confidence interval</i>
-------------	---

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	<i>eDISH plot of peak ALT versus peak bilirubin</i>
------------	---

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	<i>Treatment duration by arm</i>
---------------	----------------------------------

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	<i>Kaplan-Meier curve with number at risk</i>
---------	---

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	<i>Baseline versus post-baseline maximum</i>
----------------	--

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	<i>Binary responder rate with a Wilson interval</i>
----------------	---

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	<i>Spider plot of percent change over time</i>
-------------	--

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	<i>Swimmer plot of time on treatment</i>
--------------	--

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	<i>RECIST waterfall of best percent change</i>
----------------	--

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

<code>n_per_arm</code>	Subjects per arm.
<code>seed</code>	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

<code>n_per_arm</code>	Subjects per arm.
<code>seed</code>	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	<i>Simulate an antiviral viral-load set</i>
---------------------	---

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	<i>Simulate a depression MADRS set</i>
-----------------------	--

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	<i>Simulate a two-arm oncology efficacy set</i>
-------------------	---

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

<code>n_per_arm</code>	Subjects per arm.
<code>seed</code>	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	<i>Simulate core safety data</i>
-----------------	----------------------------------

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	<i>Recommended displays by therapeutic area</i>
-----------------	---

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())
```

Index

- * **package**
 - trialfigs-package, 2
- cox_hr, 3
- fda_palette, 3
- fda_theme, 4
- plot_ae, 4
- plot_change, 5
- plot_edish, 2, 6
- plot_exposure, 6
- plot_forest, 7
- plot_km, 2, 8
- plot_lab_shift, 9
- plot_responder, 9
- plot_spider, 10
- plot_swimmer, 11
- plot_waterfall, 2, 11
- simulate_cardiovascular, 12
- simulate_endocrinology, 13
- simulate_immunology, 13
- simulate_infectious, 14
- simulate_neuroscience, 14
- simulate_oncology, 15
- simulate_safety, 15
- ta_plot_catalog, 2, 16
- trialfigs (trialfigs-package), 2
- trialfigs-package, 2