

# Package: trialfigs (via r-universe)

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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.

**License** MIT + file LICENSE

**Encoding** UTF-8

**Depends** R (>= 4.1.0)

**Imports** ggplot2, survival, withr

**Suggests** testthat (>= 3.0.0)

**Config/testthat/edition** 3

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|                   |                                                                  |
|-------------------|------------------------------------------------------------------|
| trialfigs-package | <i>Efficacy and safety graphics for clinical review packages</i> |
|-------------------|------------------------------------------------------------------|

---

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)

Shekhar

See Also

[plot\\_km](#), [plot\\_waterfall](#), [plot\\_edish](#)

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|        |                                                                       |
|--------|-----------------------------------------------------------------------|
| 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> |
|-----------|---------------------------------|

---

**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`*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

|                                          |                                                                          |
|------------------------------------------|--------------------------------------------------------------------------|
| <code>data</code>                        | Subject-level data.                                                      |
| <code>time, event, arm</code>            | Column names. <code>event</code> is 1 for the event and 0 for censoring. |
| <code>xlab, ylab, title, subtitle</code> | Labels.                                                                  |
| <code>conf_int</code>                    | Draw pointwise confidence limits.                                        |
| <code>risk_times</code>                  | Times for the number at risk. Default is <code>pretty()</code> .         |
| <code>palette</code>                     | Named color vector.                                                      |
| <code>population</code>                  | 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")
```

---

|                                |                                                 |
|--------------------------------|-------------------------------------------------|
| <code>simulate_oncology</code> | <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)
```

---

|                              |                                  |
|------------------------------|----------------------------------|
| <code>simulate_safety</code> | <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())
```

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