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Interactive Forest Plot for DMC Safety Monitoring in Clinical Trials

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Introduction

Today, we will introduce a R package `forestly()` to generate interactive forest plot to enhance Data Monitoring Committee (DMC) review process.

- Interactive features;
- High-level usage of this package;
- Future development plan.

Highlighted Interactive Features

- Labels can be revealed by hovering the mouse over a point.
- Subject level details can be drilled down by clicking ▼.
- Search bars embedded for users to quickly find adverse events of interest.
- Filters can be applied, i.e., filter the
  - discontinued due to an adverse event
  - with drug-related adverse events
  - with serious adverse events
  - with toxicity grade 3-5 adverse events
  - …
- AE tables can be downloaded as `.rtf` files.

R Package Implementation

To implement the `forestly`, please follow the steps below.

- Step 0: Get standardize `adsl` and `adae` tables.
- Step 1: Define analysis data using `tidy_ae_table()`, i.e.,

```
db <- tidy_ae_table(population_from  = ..., observation_from = ...,
                    population_where = ..., observation_where = ...,
                    treatment_var = ..., treatment_order = ...,
                    ae_var = ..., ae_interested = ..., listing_interested = ...)
```

- Step 2: Generate the interactive forest plot.

```
forestly(db,
         fig_prop_color = ..., fig_prop_label = ...,
         fig_diff_color = ..., fig_diff_label = ...,
         small_sample = ...)
```

- Step 3: Prepare TLFs to be downloaded (if needed).

```
temp_dir <- tempdir()
ae_summary <- tlf_ae_summary()
ae_spec <- tlf_ae_specific()
```

Future Development Plan

In the near future, we will do

- package validation;
- improvement of interactive features:
  - download the R code and necessary metadata for compliance;
  - forest plot for multiple arms (≥ 3);
  - ...

Thank you

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