



{falcon}: Harmonizing Clinical Reporting Standards for TLGs



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Note: Content in this slide deck was built based on {falcon} v0.1.0.9043. In the future the {falcon} package will be released on CRAN under a different name due to conflict with another package.

Agenda

- 
1. Motivation
 2. Current Progress
 3. Getting Started
 4. Technical Overview
 5. Navigating the {falcon} Website
 6. Goals
 7. Call for Collaboration

Motivation



Established Data Standards Already Exist in the Pharma Industry

CDISC's SDTM and ADaM standards enable industry collaboration

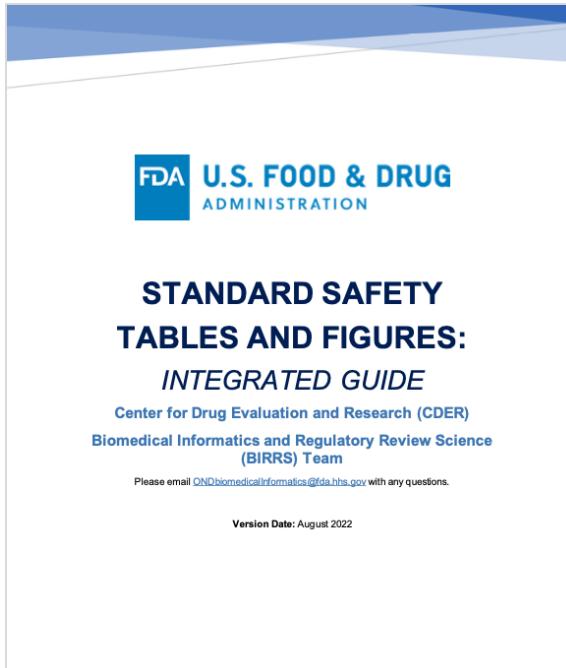


Data variable attributes (names, inputs, data types, etc.) are standardized across datasets and companies in the industry

TLGs created by different companies process data the same way but differ in layout/appearance

Can we standardize the TLGs created using this data?

The FDA Integrated Guide for Standard Safety Tables and Figures



Idea: We can implement the FDA guide together to create cohesive TLG outputs

- **A common toolkit:** Use open-source R packages already available on CRAN for TLG creation
- **Pooled Resources:** Developers from different companies collaborate to establish best practices and design standardized templates for each TLG
- **One layout:** Standardized layouts allow for easy collaboration in the future and a more efficient data review process, allowing pharma companies to deliver products quicker

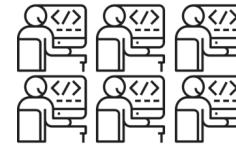


Current Progress

Our Current Team



6 Product Owners



9 Active Developers

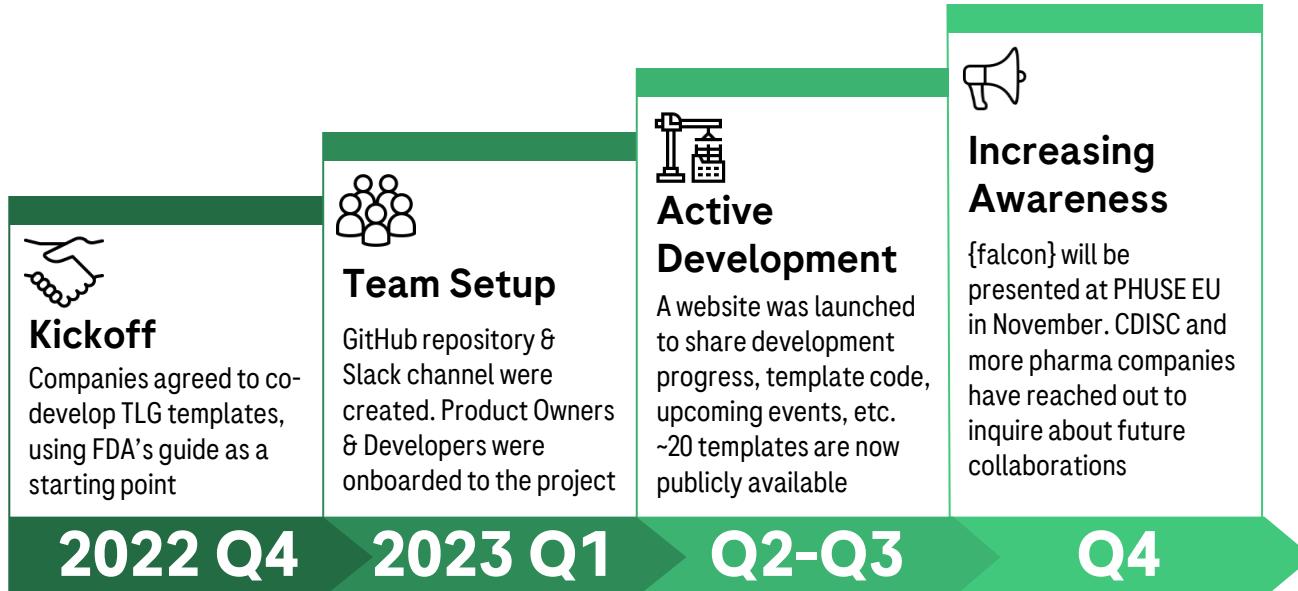


Boehringer
Ingelheim

sanofi

moderna[®]

What Have We Accomplished So Far?

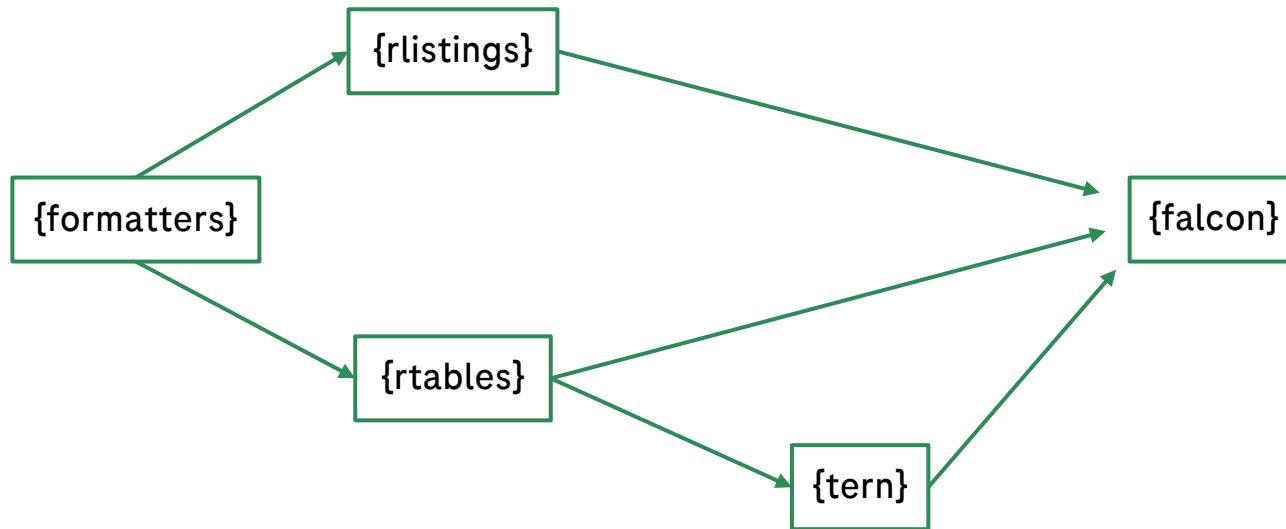


Getting Started

{falcon} is Built Using an Open-Source Toolkit

All table-generating functions are built using functions from {rtables} & {tern}

NEST-falcon Dependency Graph



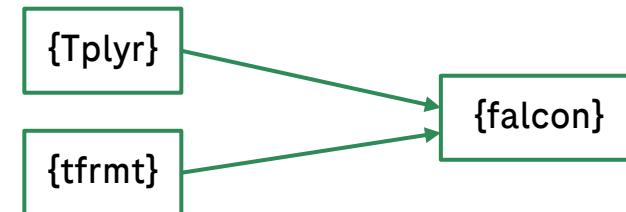
{falcon} is Built Using an Open-Source Toolkit

To gauge interest in other table engines, some table functions are also built using {Tplyr} & {gtsummary}

Alternative 1:



Alternative 2:



Package Installation

1. Ensure NEST package dependencies are installed from CRAN:

```
if (!require("formatters")) install.packages("formatters")
if (!require("rtables")) install.packages("rtables")
if (!require("rlistings")) install.packages("rlistings")
if (!require("tern")) install.packages("tern")
```

2. Install the latest development version of {falcon} from GitHub:

```
if (!require("remotes")) install.packages("remotes")
remotes::install_github("pharmaverse/falcon")
```

Technical Overview

Breaking Down a TLG-Generating Function

FDA Integrated Guide - Table 7: Deaths, Safety Population, Pooled Analyses

Table 7. Deaths, Safety Population, Pooled Analyses¹

	Drug Name Dosage X N = XXX	Drug Name Dosage Y N = XXX	Active Control N = XXX	Placebo N = XXX	Risk Difference (%) (95% CI) ²
Deaths	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Total deaths	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cause of death 1	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cause of death 2	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Treatment-emergent deaths³	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cause of death 1	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cause of death 2	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Nontreatment-emergent deaths⁴	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cause of death 1	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cause of death 2	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cause of death 3	n (%)	n (%)	n (%)	n (%)	X (Y, Z)

Source: [Include Applicant source, datasets and/or software tools used].

¹ Duration = [e.g., X week double-blind treatment period or median and a range indicating pooled trial durations].

² Difference is shown between [treatment arms] (e.g., difference is shown between Drug Name dosage X vs. placebo).

³ Treatment-emergent AE defined as [definition]. MedDRA version X.

⁴ Defined as [(e.g., deaths beyond the protocol-defined treatment-emergent adverse event period in the same trial or deaths from other trials with drug)].

Abbreviations: AE, adverse event; MedDRA, Medical Dictionary for Regulatory Activities; N, number of patients in treatment arm; n, number of patients with adverse event

Breaking Down a TLG-Generating Function

Table generated using {falcon}

Table 7. Deaths, Safety Population, Pooled Analyses

Deaths	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)	Risk Difference (%) (N=268)
Total deaths	23 (17.2%)	18 (13.4%)	19 (14.4%)	3.7 (-4.9 - 12.3)
ADVERSE EVENT	8 (34.8%)	6 (33.3%)	10 (52.6%)	1.5 (-3.8 - 6.8)
DISEASE PROGRESSION	8 (34.8%)	5 (27.8%)	6 (31.6%)	2.2 (-2.9 - 7.4)
LOST TO FOLLOW UP	2 (8.7%)	1 (5.6%)	1 (5.3%)	0.7 (-1.8 - 3.3)
MISSING	2 (8.7%)	3 (16.7%)	1 (5.3%)	-0.7 (-4.0 - 2.5)
SUICIDE	2 (8.7%)	2 (11.1%)	1 (5.3%)	0.0 (-2.9 - 2.9)
UNKNOWN	1 (4.3%)	1 (5.6%)	0	0.0 (-2.1 - 2.1)
Treatment-emergent deaths	12 (9.0%)	14 (10.4%)	15 (11.4%)	-1.5 (-8.6 - 5.6)
ADVERSE EVENT	3 (25.0%)	5 (35.7%)	9 (60.0%)	-1.5 (-5.6 - 2.6)
DISEASE PROGRESSION	3 (25.0%)	5 (35.7%)	4 (26.7%)	-1.5 (-5.6 - 2.6)
LOST TO FOLLOW UP	1 (8.3%)	0	0	0.7 (-0.7 - 2.2)
MISSING	2 (16.7%)	1 (7.1%)	1 (6.7%)	0.7 (-1.8 - 3.3)
SUICIDE	2 (16.7%)	2 (14.3%)	1 (6.7%)	0.0 (-2.9 - 2.9)
UNKNOWN	1 (8.3%)	1 (7.1%)	0	0.0 (-2.1 - 2.1)
Nontreatment-emergent deaths	11 (8.2%)	4 (3.0%)	4 (3.0%)	5.2 (-0.2 - 10.7)
ADVERSE EVENT	5 (45.5%)	1 (25.0%)	1 (25.0%)	3.0 (-0.5 - 6.5)
DISEASE PROGRESSION	5 (45.5%)	0	2 (50.0%)	3.7 (0.5 - 6.9)
LOST TO FOLLOW UP	1 (9.1%)	1 (25.0%)	1 (25.0%)	0.0 (-2.1 - 2.1)
MISSING	0	2 (50.0%)	0	-1.5 (-3.5 - 0.6)

Source: [include Applicant source, datasets and/or software tools used].

Abbreviations: AE, adverse event; MedDRA, Medical Dictionary for Regulatory Activities;
N, number of patients in treatment arm; n, number of patients with adverse event

Breaking Down a TLG-Generating Function

Function Arguments Overview

```
make_table_07 <- function(adae,  
                           alt_counts_df = NULL,  
                           show_colcounts = TRUE,  
                           arm_var = "ARM",  
                           saffl_var = "SAFFL",  
                           lbl_overall = NULL,  
                           risk_diff = NULL,  
                           prune_0 = TRUE,  
                           na_level = "MISSING",  
                           annotations = NULL) {...}
```

Breaking Down a TLG-Generating Function

Standard arguments used across most tables

```
make_table_07 <- function(adae, ←  
  alt_counts_df = NULL,  
  show_colcounts = TRUE,  
  arm_var = "ARM",  
  saffl_var = "SAFFL",  
  lbl_overall = NULL,  
  risk_diff = NULL,  
  prune_0 = TRUE,  
  na_level = "MISSING",  
  annotations = NULL) {...}
```

Which dataset is expected for this template (or `df` if no dataset-specific variables are needed), in this case ADAE.

Breaking Down a TLG-Generating Function

Standard arguments used across most tables

```
make_table_07 <- function(adae,  
                           alt_counts_df = NULL, ←  
                           show_colcounts = TRUE,  
                           arm_var = "ARM",  
                           saffl_var = "SAFFL",  
                           lbl_overall = NULL,  
                           risk_diff = NULL,  
                           prune_0 = TRUE,  
                           na_level = "MISSING",  
                           annotations = NULL) {...}
```

An optional secondary dataset used only to calculate *overall* patients counts & percentages, in most cases ADSL.

Breaking Down a TLG-Generating Function

Standard arguments used across most tables

```
make_table_07 <- function(adae,  
                           alt_counts_df = NULL,  
                           show_colcounts = TRUE, ←  
                           arm_var = "ARM",  
                           saffl_var = "SAFFL",  
                           lbl_overall = NULL,  
                           risk_diff = NULL,  
                           prune_0 = TRUE,  
                           na_level = "MISSING",  
                           annotations = NULL) {...}
```

Whether total counts
(N=XX) should be printed for
each column.

Breaking Down a TLG-Generating Function

Standard arguments used across most tables

```
make_table_07 <- function(adae,  
                           alt_counts_df = NULL,  
                           show_colcounts = TRUE,  
                           arm_var = "ARM", ←  
                           saffl_var = "SAFFL",  
                           lbl_overall = NULL,  
                           risk_diff = NULL,  
                           prune_θ = TRUE,  
                           na_level = "MISSING",  
                           annotations = NULL) {...}
```

Name of the arm variable
used to split data into
columns.

Breaking Down a TLG-Generating Function

Standard arguments used across most tables

```
make_table_07 <- function(adae,  
                           alt_counts_df = NULL,  
                           show_colcounts = TRUE,  
                           arm_var = "ARM",  
                           saffl_var = "SAFFL", ←  
                           lbl_overall = NULL,  
                           risk_diff = NULL,  
                           prune_θ = TRUE,  
                           na_level = "MISSING",  
                           annotations = NULL) {...}
```

Name of the variable that
indicates inclusion in a
safety population.

Breaking Down a TLG-Generating Function

Standard arguments used across most tables

```
make_table_07 <- function(adae,  
                           alt_counts_df = NULL,  
                           show_colcounts = TRUE,  
                           arm_var = "ARM",  
                           saffl_var = "SAFFL",  
                           lbl_overall = NULL,  
                           risk_diff = NULL,  
                           prune_0 = TRUE,  
                           na_level = "MISSING",  
                           annotations = NULL) {...}
```

A label for the “overall” population column if one should be included in the table.

Breaking Down a TLG-Generating Function

Standard arguments used across most tables

```
make_table_07 <- function(adae,  
                           alt_counts_df = NULL,  
                           show_colcounts = TRUE,  
                           arm_var = "ARM",  
                           saffl_var = "SAFFL",  
                           lbl_overall = NULL,  
                           risk_diff = NULL, ←  
                           prune_0 = TRUE,  
                           na_level = "MISSING",  
                           annotations = NULL) {...}
```

Settings for the “risk difference” column: columns to compare, label, etc., if this column is needed.

Breaking Down a TLG-Generating Function

Standard arguments used across most tables

```
make_table_07 <- function(adae,  
                           alt_counts_df = NULL,  
                           show_colcounts = TRUE,  
                           arm_var = "ARM",  
                           saffl_var = "SAFFL",  
                           lbl_overall = NULL,  
                           risk_diff = NULL,  
                           prune_0 = TRUE, ←  
                           na_level = "MISSING",  
                           annotations = NULL) {...}
```

Whether all-zero rows
should be pruned from the
table.

Breaking Down a TLG-Generating Function

Standard arguments used across most tables

```
make_table_07 <- function(adae,  
                           alt_counts_df = NULL,  
                           show_colcounts = TRUE,  
                           arm_var = "ARM",  
                           saffl_var = "SAFFL",  
                           lbl_overall = NULL,  
                           risk_diff = NULL,  
                           prune_0 = TRUE,  
                           na_level = "MISSING", ←  
                           annotations = NULL) {...}
```

A string that should be used
in the table to indicate
missing (NA) values.

Breaking Down a TLG-Generating Function

Standard arguments used across most tables

```
make_table_07 <- function(adae,  
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                           show_colcounts = TRUE,  
                           arm_var = "ARM",  
                           saffl_var = "SAFFL",  
                           lbl_overall = NULL,  
                           risk_diff = NULL,  
                           prune_0 = TRUE,  
                           na_level = "MISSING",  
                           annotations = NULL) {...}
```

Any titles and footnotes that
should be printed for the
table.

Breaking Down a TLG-Generating Function

Function Contents: Pre-Processing

```
checkmate::assert_subset(c(
  "USUBJID", "TRTEMFL", "DTHFL", "DTHCAUS", arm_var, saffl_var
), names(adae))
assert_flag_variables(adae, c(saffl_var, "TRTEMFL", "DTHFL"), na_level = na_level)
```

Variable
checks

```
adae <- adae %>%
  filter(.data[[saffl_var]] == "Y", DTHFL == "Y") %>%
  mutate(
    TRTEMFL = ifelse(TRTEMFL == "Y", "Y", "N") %>% factor(levels = c("Y", "N")),
    trtem_lab = ifelse(TRTEMFL == "Y", "Treatment-emergent deaths", "Nontreatment-emergent deaths")
  ) %>%
  df_explicit_na(na_level = na_level)

alt_counts_df <- alt_counts_df_preproc(alt_counts_df, arm_var, saffl_var)
```

Data
processing

Breaking Down a TLG-Generating Function

Function Contents: Layout Creation

```
lyt <- basic_table_annot(show_colcounts, annotations) %>%
  split_cols_by_arm(arm_var, lbl_overall, risk_diff) %>%
  split_rows_by(
    var = "TRTEMFL", labels_var = "trtem_lab",
    split_fun = add_overall_level("Total deaths")
  ) %>%
  summarize_num_patients(
    var = "USUBJID",
    riskdiff = !is.null(risk_diff),
    .stats = "unique", .labels = c(unique = NULL)
  ) %>%
  count_occurrences(
    vars = "DTHCAUS",
    denom = "n", drop = FALSE,
    riskdiff = !is.null(risk_diff)
  ) %>%
  append_topleft(c("", "Deaths"))
```

Deaths	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)
Total deaths	23 (17.2%)	18 (13.4%)	19 (14.4%)
ADVERSE EVENT	8 (34.8%)	6 (33.3%)	10 (52.6%)
DISEASE PROGRESSION	8 (34.8%)	5 (27.8%)	6 (31.6%)
LOST TO FOLLOW UP	2 (8.7%)	1 (5.6%)	1 (5.3%)
MISSING	2 (8.7%)	3 (16.7%)	1 (5.3%)
SUICIDE	2 (8.7%)	2 (11.1%)	1 (5.3%)
UNKNOWN	1 (4.3%)	1 (5.6%)	0
Treatment-emergent deaths	12 (9.0%)	14 (10.4%)	15 (11.4%)
ADVERSE EVENT	3 (25.0%)	5 (35.7%)	9 (60.0%)
DISEASE PROGRESSION	3 (25.0%)	5 (35.7%)	4 (26.7%)
LOST TO FOLLOW UP	1 (8.3%)	0	0
MISSING	2 (16.7%)	1 (7.1%)	1 (6.7%)
SUICIDE	2 (16.7%)	2 (14.3%)	1 (6.7%)
UNKNOWN	1 (8.3%)	1 (7.1%)	0
Nontreatment-emergent deaths	11 (8.2%)	4 (3.0%)	4 (3.0%)
ADVERSE EVENT	5 (45.5%)	1 (25.0%)	1 (25.0%)
DISEASE PROGRESSION	5 (45.5%)	0	2 (50.0%)
LOST TO FOLLOW UP	1 (9.1%)	1 (25.0%)	1 (25.0%)
MISSING	0	2 (50.0%)	0

Breaking Down a TLG-Generating Function

Function Contents: Layout Creation

```
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  ) %>%
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    .stats = "unique", .labels = c(unique = NULL)
  ) %>%
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    vars = "DTHCAUS",
    denom = "n", drop = FALSE,
    riskdiff = !is.null(risk_diff)
  ) %>%
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SUICIDE	2 (16.7%)	2 (14.3%)	1 (6.7%)
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Nontreatment-emergent deaths	11 (8.2%)	4 (3.0%)	4 (3.0%)
ADVERSE EVENT	5 (45.5%)	1 (25.0%)	1 (25.0%)
DISEASE PROGRESSION	5 (45.5%)	0	2 (50.0%)
LOST TO FOLLOW UP	1 (9.1%)	1 (25.0%)	1 (25.0%)
MISSING	0	2 (50.0%)	0

Breaking Down a TLG-Generating Function

Function Contents: Table Generation & Post-Processing

```
tbl <- build_table(  
  lyt,  
  df = adae,  
  alt_counts_df = alt_counts_df  
)  
  
if (prune_0) tbl <- prune_table(tbl)  
  
tbl
```

Deaths	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)
Total deaths	23 (17.2%)	18 (13.4%)	19 (14.4%)
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LOST TO FOLLOW UP	2 (8.7%)	1 (5.6%)	1 (5.3%)
MISSING	2 (8.7%)	3 (16.7%)	1 (5.3%)
Post-study reporting of death	0	0	0
SUICIDE	2 (8.7%)	2 (11.1%)	1 (5.3%)
UNKNOWN	1 (4.3%)	1 (5.6%)	0
Treatment-emergent deaths	12 (9.0%)	14 (10.4%)	15 (11.4%)
ADVERSE EVENT	3 (25.0%)	5 (35.7%)	9 (60.0%)
DISEASE PROGRESSION	3 (25.0%)	5 (35.7%)	4 (26.7%)
LOST TO FOLLOW UP	1 (8.3%)	0	0
MISSING	2 (16.7%)	1 (7.1%)	1 (6.7%)
Post-study reporting of death	0	0	0
SUICIDE	2 (16.7%)	2 (14.3%)	1 (6.7%)
UNKNOWN	1 (8.3%)	1 (7.1%)	0
Nontreatment-emergent deaths	11 (8.2%)	4 (3.0%)	4 (3.0%)
ADVERSE EVENT	5 (45.5%)	1 (25.0%)	1 (25.0%)
DISEASE PROGRESSION	5 (45.5%)	0	2 (50.0%)
LOST TO FOLLOW UP	1 (9.1%)	1 (25.0%)	1 (25.0%)
MISSING	0	2 (50.0%)	0
Post-study reporting of death	0	0	0
SUICIDE	0	0	0
UNKNOWN	0	0	0

Breaking Down a TLG-Generating Function

Function Contents: Table Generation & Post-Processing

```
tbl <- build_table(  
  lyt,  
  df = adae,  
  alt_counts_df = alt_counts_df  
)  
if (prune_0) tbl <- prune_table(tbl)  
  
tbl
```

Deaths	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)
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DISEASE PROGRESSION	8 (34.8%)	5 (27.8%)	6 (31.6%)
LOST TO FOLLOW UP	2 (8.7%)	1 (5.6%)	1 (5.3%)
MISSING	2 (8.7%)	3 (16.7%)	1 (5.3%)
<u>Post-study reporting of death</u>	<u>0</u>	<u>0</u>	<u>0</u>
SUICIDE	2 (8.7%)	2 (11.1%)	1 (5.3%)
UNKNOWN	1 (4.3%)	1 (5.6%)	0
Treatment-emergent deaths	12 (9.0%)	14 (10.4%)	15 (11.4%)
ADVERSE EVENT	3 (25.0%)	5 (35.7%)	9 (60.0%)
DISEASE PROGRESSION	3 (25.0%)	5 (35.7%)	4 (26.7%)
LOST TO FOLLOW UP	1 (8.3%)	0	0
MISSING	2 (16.7%)	1 (7.1%)	1 (6.7%)
<u>Post-study reporting of death</u>	<u>0</u>	<u>0</u>	<u>0</u>
SUICIDE	2 (16.7%)	2 (14.3%)	1 (6.7%)
UNKNOWN	1 (8.3%)	1 (7.1%)	0
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ADVERSE EVENT	5 (45.5%)	1 (25.0%)	1 (25.0%)
DISEASE PROGRESSION	5 (45.5%)	0	2 (50.0%)
LOST TO FOLLOW UP	1 (9.1%)	1 (25.0%)	1 (25.0%)
MISSING	0	2 (50.0%)	0
<u>Post-study reporting of death</u>	<u>0</u>	<u>0</u>	<u>0</u>
SUICIDE	0	0	0
UNKNOWN	0	0	0

Breaking Down a TLG-Generating Function

Output can be further customized via function parameters

Table 7. Deaths, Safety Population, Pooled Analyses

Deaths	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)	Risk Difference (%) (95% CI) (N=268)
Total deaths	23 (17.2%)	18 (13.4%)	19 (14.4%)	3.7 (-4.9 - 12.3)
ADVERSE EVENT	8 (34.8%)	6 (33.3%)	10 (52.6%)	1.5 (-3.8 - 6.8)
DISEASE PROGRESSION	8 (34.8%)	5 (27.8%)	6 (31.6%)	2.2 (-2.9 - 7.4)
LOST TO FOLLOW UP	2 (8.7%)	1 (5.6%)	1 (5.3%)	0.7 (-1.8 - 3.3)
MISSING	2 (8.7%)	3 (16.7%)	1 (5.3%)	-0.7 (-4.0 - 2.5)
SUICIDE	2 (8.7%)	2 (11.1%)	1 (5.3%)	0.0 (-2.9 - 2.9)
UNKNOWN	1 (4.3%)	1 (5.6%)	0	0.0 (-2.1 - 2.1)
Treatment-emergent deaths	12 (9.0%)	14 (10.4%)	15 (11.4%)	-1.5 (-8.6 - 5.6)
ADVERSE EVENT	3 (25.0%)	5 (35.7%)	9 (60.0%)	-1.5 (-5.6 - 2.6)
DISEASE PROGRESSION	3 (25.0%)	5 (35.7%)	4 (26.7%)	-1.5 (-5.6 - 2.6)
LOST TO FOLLOW UP	1 (8.3%)	0	0	0.7 (-0.7 - 2.2)
MISSING	2 (16.7%)	1 (7.1%)	1 (6.7%)	0.7 (-1.8 - 3.3)
SUICIDE	2 (16.7%)	2 (14.3%)	1 (6.7%)	0.0 (-2.9 - 2.9)
UNKNOWN	1 (8.3%)	1 (7.1%)	0	0.0 (-2.1 - 2.1)
Nontreatment-emergent deaths	11 (8.2%)	4 (3.0%)	4 (3.0%)	5.2 (-0.2 - 10.7)
ADVERSE EVENT	5 (45.5%)	1 (25.0%)	1 (25.0%)	3.0 (-0.5 - 6.5)
DISEASE PROGRESSION	5 (45.5%)	0	2 (50.0%)	3.7 (0.5 - 6.9)
LOST TO FOLLOW UP	1 (9.1%)	1 (25.0%)	1 (25.0%)	0.0 (-2.1 - 2.1)
MISSING	0	2 (50.0%)	0	-1.5 (-3.5 - 0.6)

Source: [include Applicant source, datasets and/or software tools used].

Abbreviations: AE, adverse event; MedDRA, Medical Dictionary for Regulatory Activities;
N, number of patients in treatment arm; n, number of patients with adverse event

Breaking Down a TLG-Generating Function

Table 7. Deaths, Safety Population, Pooled Analyses¹

	Drug Name Dosage X N = XXX n (%)	Drug Name Dosage Y N = XXX n (%)	Active Control N = XXX n (%)	Placebo N = XXX n (%)	Risk Difference (%) (95% CI) ²
Deaths					
Total deaths	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cause of death 1	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cause of death 2	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Treatment-emergent deaths³	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cause of death 1	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cause of death 2	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Nontreatment-emergent deaths⁴	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cause of death 1	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cause of death 2	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cause of death 3	n (%)	n (%)	n (%)	n (%)	X (Y, Z)

Source: [include Applicant source, datasets and/or software tools used].

¹ Duration = [e.g., X week double-blind treatment period or median and a range indicating pooled trial durations].

² Difference is shown between [treatment arms] (e.g., difference is shown between Drug Name dosage X vs. placebo).

³ Treatment-emergent AE defined as [definition]. MedDRA version X.

⁴ Defined as [(e.g., deaths beyond the protocol-defined treatment-emergent adverse event period in the same trial or deaths from other trials with drug)].

Abbreviations: AE, adverse event; MedDRA, Medical Dictionary for Regulatory Activities; N, number of patients in treatment arm; n, number of patients with adverse event

Navigating the {falcon} Website





pharmaverse.github.io/falcon

Exploring the Home Page

Introductory information, upcoming talks, & the development team

The screenshot shows the homepage of the falcon initiative. At the top, there is a navigation bar with links for "Home", "Template Library", "About", and "Help". On the right side of the header is a search bar. The main title "falcon" is centered above a subtitle "Implementation of FDA Safety Tables and Figures". Below the title is a large green hexagonal logo featuring a stylized falcon silhouette and the word "falcon". A brief description follows:

What is falcon?

The falcon initiative is an industry collaborative effort under pharmaverse that brings together pharmaceutical companies with the aspiration of building and open-sourcing a catalog of harmonized tables, listings, and graphs (TLGs) in clinical study reporting. Leveraging existing open-source R packages, falcon aims to simplify the process of output review, comparison, and meta-analyses, fostering efficient communication among stakeholders in the pharmaceutical sector while aligning with CDISC's ARD/ARM effort at the same time. Drawing inspiration from the FDA Standard Safety Tables and Figures Integrated Guide, we develop open-source templates. Future plans entail expanding the catalog of templates through continuous collaboration from participating companies and inviting wider industry to promote harmonization of TLGs for clinical reporting.

Below the description are four green buttons:

- Getting Started
- Template Library Index
- Our Collaboration Journey
- FAQ

At the bottom, there is a section titled "Upcoming Talks & Presentations" with two items:

- 20 October 2023 - [R/Pharma Online Workshop](#)
- 6 November 2023 - [PHUSE EU Connect 2023](#)

Exploring the Home Page

Additional pages reachable from the navigation bar

The screenshot shows the falcon home page with a navigation bar at the top. The navigation bar includes a logo, links for Home, Template Library, About, and Help, and a search icon.

The main content area features a sidebar on the left with a list of FDA tables from 2 to 34. A dropdown menu on the right provides links to Getting Started, Report a Bug, and FAQ. The central area displays the falcon logo and the title "Implementation of FDA Safety Tables and Figures". Below the title is a large green hexagonal icon with a falcon silhouette and the word "falcon".

The main text area discusses the collaborative effort under pharmaverse to build harmonized tables, listings, and graphs (TLGs) in clinical study reporting, leveraging open-source R packages, and fostering efficient communication among stakeholders.

Navigation Bar:

- falcon
- Home
- Template Library
- About
- Help

Sidebar (FDA Tables):

- FDA Table 2
- FDA Table 3
- FDA Table 4
- FDA Table 5
- FDA Table 6
- FDA Table 7
- FDA Table 8
- FDA Table 9
- FDA Table 10
- FDA Table 11
- FDA Table 12
- FDA Table 13
- V FDA Table 14
- TI FDA Table 20
- ar FDA Table 21
- fa FDA Table 22
- pl FDA Table 32
- Fi FDA Table 33
- fr FDA Table 34

Dropdown Menu:

- Getting Started
- Report a Bug
- FAQ

Main Content Area:

falcon

Implementation of FDA Safety Tables and Figures

A large green hexagonal icon with a falcon silhouette and the word "falcon" inside.

ry collaborative effort under pharmaverse that brings together pharmaceutical companies with the aspiration of building harmonized tables, listings, and graphs (TLGs) in clinical study reporting. Leveraging existing open-source R packages, less of output review, comparison, and meta-analyses, fostering efficient communication among stakeholders in the gning with CDISC's ARD/ARM effort at the same time. Drawing inspiration from the FDA Standard Safety Tables and evelop open-source templates. Future plans entail expanding the catalog of templates through continuous collaboration and inviting wider industry to promote harmonization of TLGs for clinical reporting.

Footer Buttons:

- Getting Started
- Template Library Index

The Template Index - Which Tables are Available?

Accessible via “Template Library Index” button on the Home Page

The screenshot shows the Falcon software interface with the following details:

- Header:** falcon Home Template Library ▾ About Help ▾ Q
- Title:** Template Library Index
- Section:** FDA Tables
- List:** A bulleted list of 22 FDA tables, each with a green link:
 - FDA Table 2 – Baseline Demographic and Clinical Characteristics, Safety Population, Pooled Analyses
 - FDA Table 3 – Patient Screening and Enrollment, Trials A and B
 - FDA Table 4 – Patient Disposition, Pooled Analyses
 - FDA Table 5 – Duration of Treatment Exposure, Safety Population, Pooled Analyses
 - FDA Table 6 – Overview of Adverse Events, Safety Population, Pooled Analyses
 - FDA Table 7 – Deaths, Safety Population, Pooled Analyses
 - FDA Table 8 – All Individual Patient Deaths, Safety Population, Pooled Analyses
 - FDA Table 9 – Patients With Serious Adverse Events by System Organ Class and Preferred Term, Safety Population, Pooled Analyses
 - FDA Table 10 – Patients With Serious Adverse Events by System Organ Class and FDA Medical Query (Narrow), Safety Population, Pooled Analyses
 - FDA Table 11 – Patients with FDA Medical Query (Narrow) Leading to Treatment Discontinuation, Safety Population, Pooled Analyses
 - FDA Table 12 – Patients With Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term, Safety Population, Pooled Analyses
 - FDA Table 13 – Patients With Common Adverse Events Occurring at >=X% Frequency, Safety Population, Pooled Analyses
 - FDA Table 14 – Patients With Adverse Events by System Organ Class and FDA Medical Query, Safety Population, Pooled Analyses
 - FDA Table 20 – Adverse Events of Special Interest Assessment, Safety Population, Pooled Analysis (or Trial X)
 - FDA Table 21 – Overview of Serious Adverse Events1 by Demographic Subgroup, Safety Population, Pooled Analysis (or Trial X)
 - FDA Table 32 – Percentage of Patients With Maximum Diastolic Blood Pressure by Category of Blood Pressure Postbaseline, Safety Population,

A Deeper Dive into Table Templates

Specification screenshot taken from the FDA Safety TLGs Integrated Guide

The screenshot shows a user interface for creating tables. At the top, there's a navigation bar with a 'falcon' logo, 'Home', 'Template Library', 'About', 'Help', and a search icon. Below the navigation is the title 'FDA Table 9' and a subtitle 'Patients With Serious Adverse Events by System Organ Class and Preferred Term, Safety Population, Pooled Analyses'. A toolbar below the title includes tabs for 'Spec. Screenshot' (selected), 'Table', 'Table Setup', and 'Function Details'. The main area contains a table template with the following structure:

System Organ Class Preferred Term	Drug Name Dosage X N = XXX n (%)	Drug Name Dosage Y N = XXX n (%)	Active Control N = XXX n (%)	Placebo N = XXX n (%)	Risk Difference (%) (95% CI) ³
Any SAE	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
SOC1	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
PT1	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
PT2	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
PT3	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
SOC2	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
PT1	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
PT2	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
PT3	n (%)	n (%)	n (%)	n (%)	X (Y, Z)

Source: [Include Applicant source, datasets and/or software tools used].
¹Defined as any untoward medical occurrence that, at any dose that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent incapacity or substantial disruption of the ability to conduct normal life functions, or is a congenital anomaly or birth defect.
²Duration = [e.g., X week double-blind treatment period or median and a range indicating pooled trial durations].
³Difference is shown between [treatment arms] (e.g., difference is shown between Drug Name dosage X vs. placebo). Abbreviations: AE, adverse event; CI, confidence interval; N, number of patients in treatment arm; n, number of patients with adverse event; PT, preferred term; SAE, serious adverse event; SOC, System Organ Class.

A Deeper Dive into Table Templates

Table created using {falcon}

falcon Home Template Library ▾ About Help ▾

FDA Table 9

</>

Patients With Serious Adverse Events by System Organ Class and Preferred Term, Safety Population, Pooled Analyses

Spec. Screenshot Table Table Setup Function Details

System Organ Class Dictionary-Derived Term	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)	Risk Difference (%) (95% CI) (N=268)
Any SAE	104 (77.6%)	101 (75.4%)	99 (75.0%)	-2.2 (-12.4 - 7.9)
c1 A	48 (35.8%)	48 (35.8%)	50 (37.9%)	0.0 (-11.5 - 11.5)
dcd A.1.1.1.2	48 (35.8%)	48 (35.8%)	50 (37.9%)	0.0 (-11.5 - 11.5)
c1 B	79 (59.0%)	78 (58.2%)	76 (57.6%)	-0.7 (-12.5 - 11.0)
dcd B.1.1.1.1	47 (35.1%)	49 (36.6%)	43 (32.6%)	1.5 (-10.0 - 13.0)
dcd B.2.2.3.1	48 (35.8%)	54 (40.3%)	51 (38.6%)	4.5 (-7.1 - 16.1)
c1 D	50 (37.3%)	42 (31.3%)	51 (38.6%)	-6.0 (-17.3 - 5.4)
dcd D.1.1.1.1	50 (37.3%)	42 (31.3%)	51 (38.6%)	-6.0 (-17.3 - 5.4)

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A Deeper Dive into Table Templates

Code used to generate the table via the make_table_09 function

The screenshot shows the Falcon interface with the title "FDA Table 9" and subtitle "Patients With Serious Adverse Events by System Organ Class and Preferred Term, Safety Population, Pooled Analyses". Below the title are tabs for "Spec. Screenshot", "Table", "Table Setup" (which is selected), and "Function Details". A code editor window displays the R code for generating the table:

```
1 # Load Libraries & Data
2 library(scda)
3 library(falcon)
4
5 adsl <- scda::synthetic_cdisc_dataset("rcd_2022_10_13", "adsl")
6 adae <- scda::synthetic_cdisc_dataset("rcd_2022_10_13", "adae")
7
8 # Select Preferred Term Variable
9 pref_var <- "AEDECOD"
10
11 # Output Table
12 risk_diff <- list(arm_x = "B: Placebo", arm_y = "A: Drug X") # optional
13 make_table_09(adae = adae, alt_counts_df = adsl, pref_var = pref_var, risk_diff = risk_diff)
```

At the bottom of the page, there is a footer note: "This website as well as code examples are licensed under the Apache License, Version 2.0." and a "Cookie Preferences" link. On the right side, there are social media sharing icons.

A Deeper Dive into Table Templates

Details on the function used to generate the table

The screenshot shows the Falcon interface with the 'Function Details' tab selected for 'FDA Table 9'. The page title is 'FDA Table 9: Patients With Serious Adverse Events by System Organ Class and Preferred Term, Safety Population, Pooled Analyses'. Below the title, there are tabs for 'Spec. Screenshot', 'Table', 'Table Setup', and 'Function Details'. The 'Function Details' tab is active, displaying the code for 'make_table_09()' and its required variables.

make_table_09()

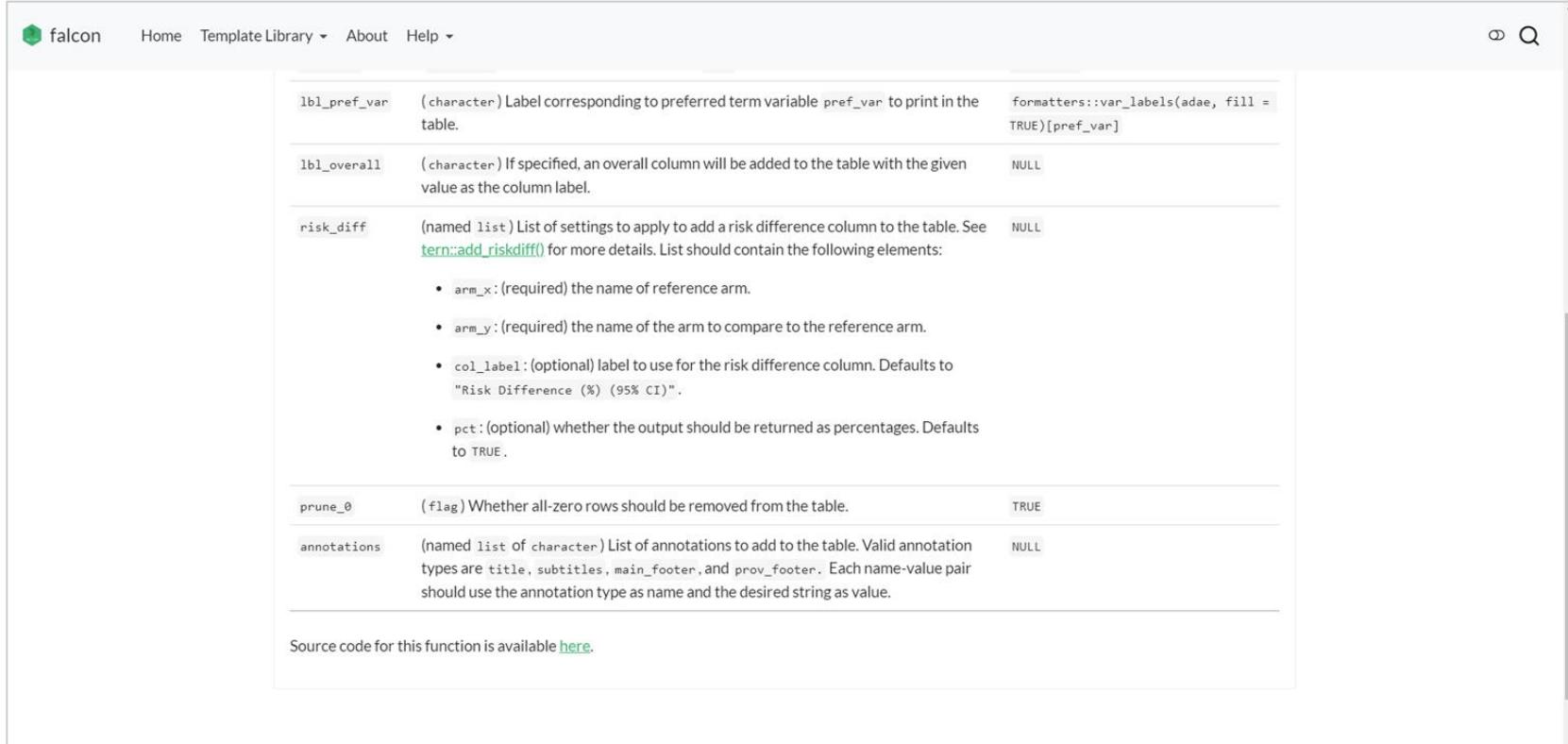
Required variables:

- `adae`: SAFFL, USUBJID, AESER, AESOC, and the variables specified by `pref_var` and `arm_var`.
- `alt_counts_df` (if specified): SAFFL, USUBJID, and the variable specified by `arm_var`.

Argument	Description	Default
<code>adae</code>	(<code>data.frame</code>) Dataset (typically ADAE) required to build table.	<code>No default</code>
<code>alt_counts_df</code>	(<code>character</code>) Alternative dataset (typically ADSL) used only to calculate column counts.	<code>NULL</code>
<code>show_colcounts</code>	(<code>flag</code>) Whether column counts should be printed.	<code>TRUE</code>
<code>arm_var</code>	(<code>character</code>) Arm variable used to split table into columns.	<code>"ARM"</code>
<code>pref_var</code>	(<code>character</code>) Preferred term variable from <code>adae</code> to include in the table.	<code>"AEDECOD"</code>
<code>lbl_pref_var</code>	(<code>character</code>) Label corresponding to preferred term variable <code>pref_var</code> to print in the table.	<code>formatters::var_labels(adae, fill = TRUE)[pref_var]</code>
<code>tbl_overall</code>	(<code>character</code>) If specified, an overall column will be added to the table with the given	<code>NULL</code>

A Deeper Dive into Table Templates

Details on the function used to generate the table



The screenshot shows a web-based documentation interface for the `falcon` R package. The top navigation bar includes links for Home, Template Library, About, Help, and a search icon. The main content area displays a table of parameters for the `table` function:

Parameter	Description	Default Value
<code>tbl_pref_var</code>	(character) Label corresponding to preferred term variable <code>pref_var</code> to print in the table.	<code>formatters::var_labels(adae, fill = TRUE)[pref_var]</code>
<code>tbl_overall</code>	(character) If specified, an overall column will be added to the table with the given value as the column label.	NULL
<code>risk_diff</code>	(named list) List of settings to apply to add a risk difference column to the table. See tern::add_riskdiff() for more details. List should contain the following elements: <ul style="list-style-type: none"><code>arm_x</code>: (required) the name of reference arm.<code>arm_y</code>: (required) the name of the arm to compare to the reference arm.<code>col_label</code>: (optional) label to use for the risk difference column. Defaults to "Risk Difference (%) (95% CI)".<code>pct</code>: (optional) whether the output should be returned as percentages. Defaults to TRUE.	NULL
<code>prune_0</code>	(flag) Whether all-zero rows should be removed from the table.	TRUE
<code>annotations</code>	(named list of character) List of annotations to add to the table. Valid annotation types are <code>title</code> , <code>subtitles</code> , <code>main_footer</code> , and <code>prev_footer</code> . Each name-value pair should use the annotation type as name and the desired string as value.	NULL

At the bottom of the table, a note states: "Source code for this function is available [here](#)".

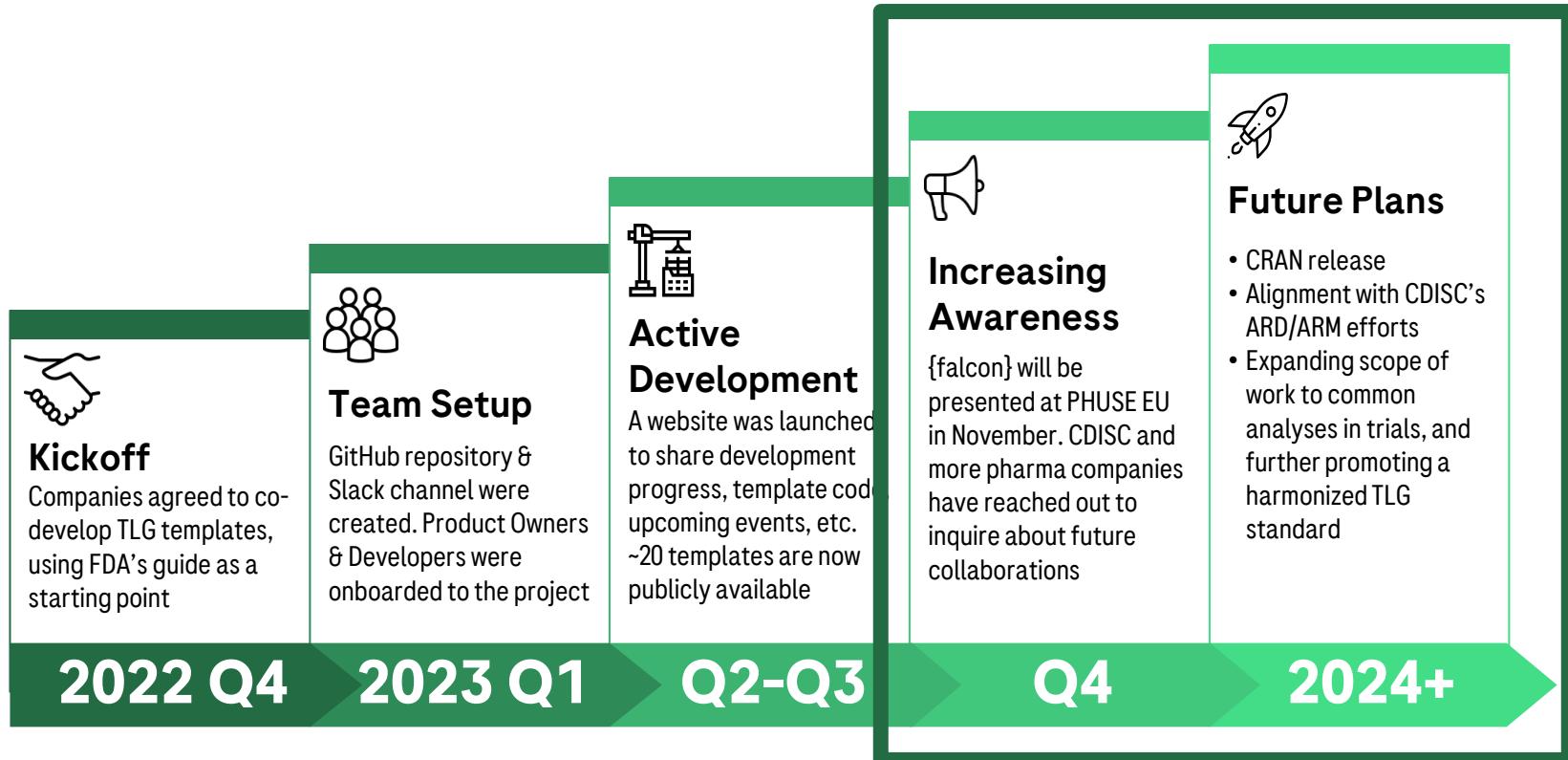
Goals



Goals



Our Roadmap



Call for Collaboration

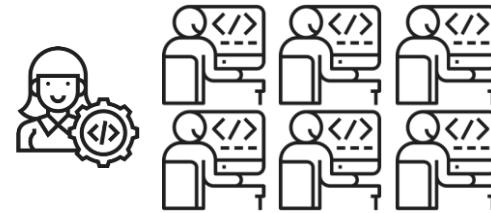
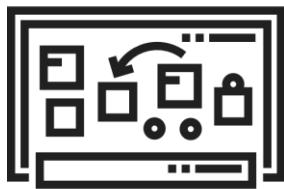
Project Coordination

How does a cross-company team work?



Product Owners

- Feature prioritization
- Refine requirements
- Project roadmap



Developers

- Agile package development
- Weekly standup meeting
- GitHub project board to track progress

Call for Collaboration

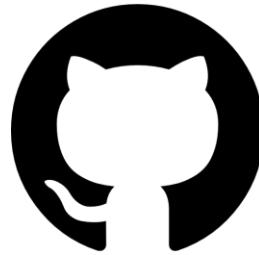
Join the {falcon} project!



pharmaverse.org



bit.ly/48KVL2R



bit.ly/45txBaq



pharmaverse.github.io/falcon

Visit the [About page](#) on our website for additional details on how you can join as a collaborator!

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Thank you!