



{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

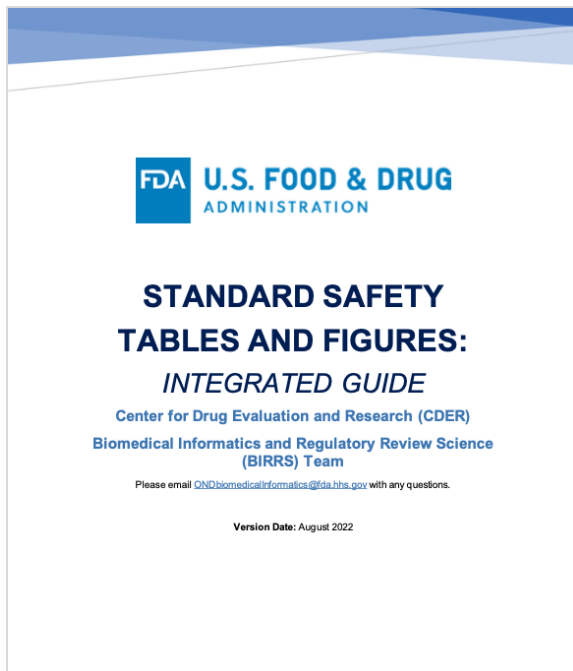


Data variable attributes (names, inputs, data types, etc.) are standardized across datasets and companies in the industry

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



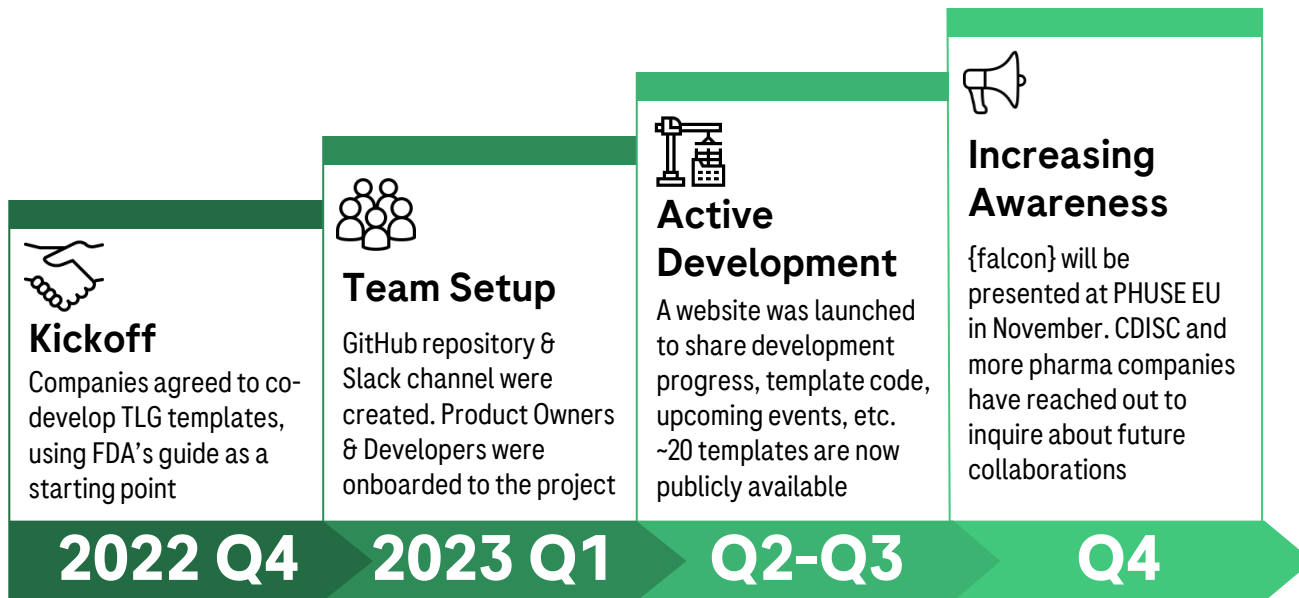
6 Product Owners



9 Active Developers



What Have We Accomplished So Far?



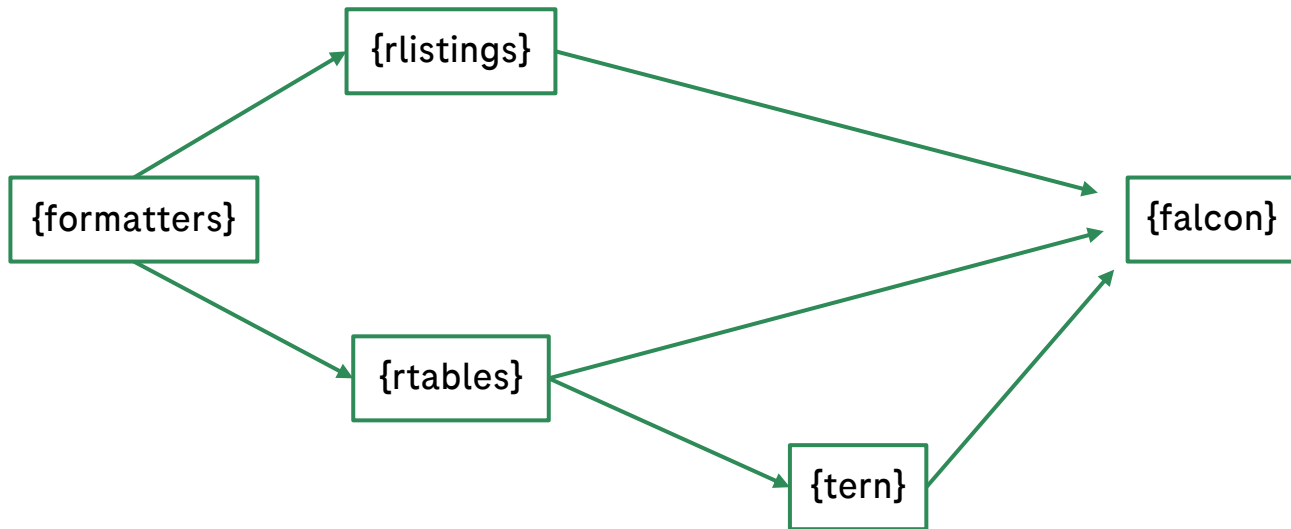
Getting Started



{falcon} is Built Using an Open-Source Toolkit

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

NEST-falcon Dependency Graph



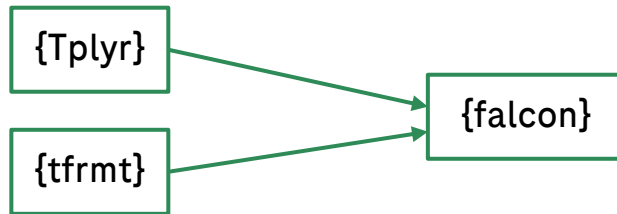
{falcon} is Built Using an Open-Source Toolkit

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 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

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 (%) (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

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_0 = 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_0 = 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,  
                           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) {...}
```

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"))
```

	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)
Deaths			
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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  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"))
```

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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%)
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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,
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LOST TO FOLLOW UP	1 (8.3%)	0	0
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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

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

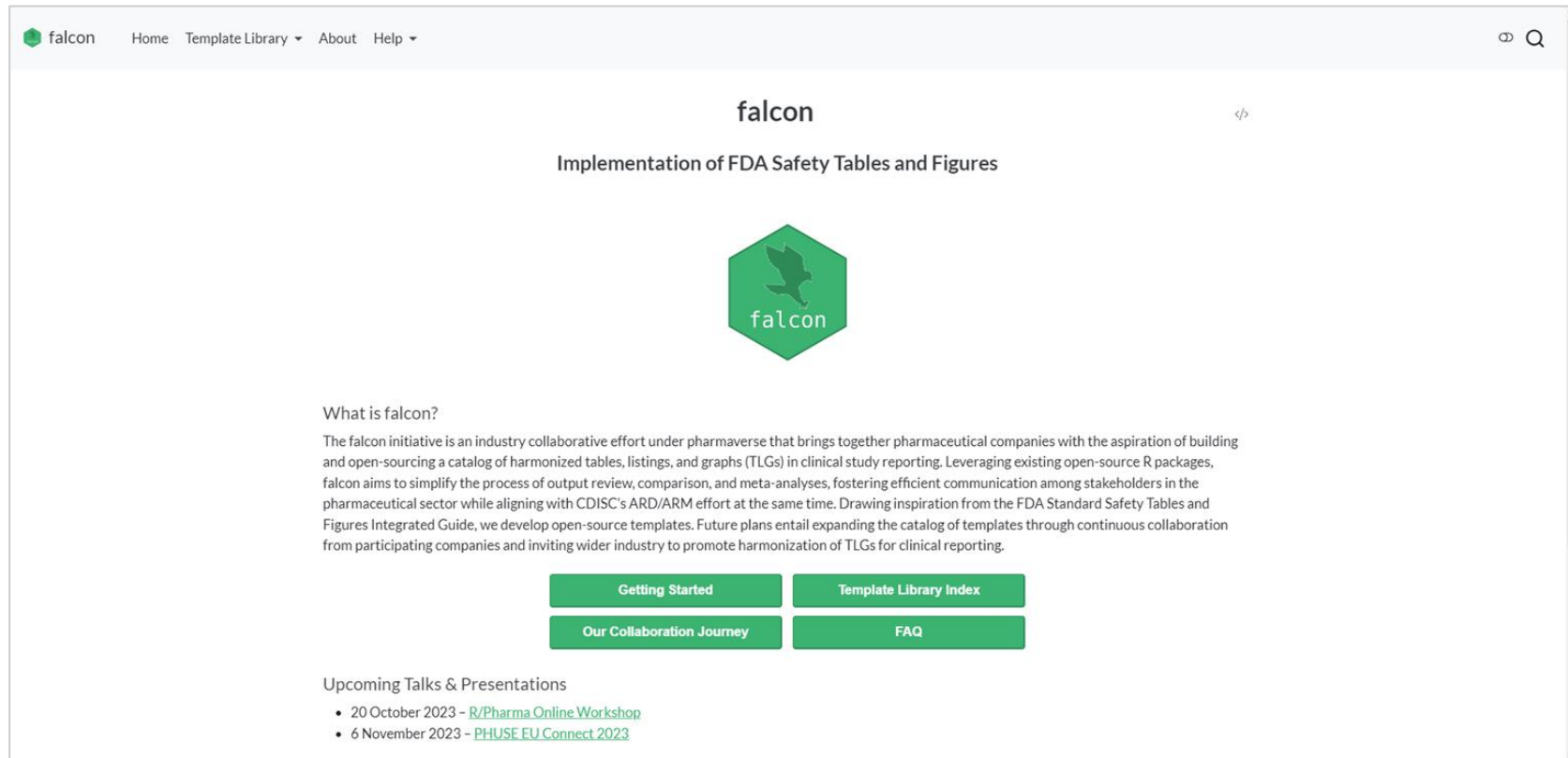




pharmaverse.github.io/falcon

Exploring the Home Page


Introductory information, upcoming talks, & the development team



The screenshot shows the Falcon project's home page. At the top is a navigation bar with the Falcon logo, 'Home', 'Template Library', 'About', and 'Help' links, along with a search icon. The main heading is 'falcon' with a subtitle 'Implementation of FDA Safety Tables and Figures'. Below this is a large green hexagonal logo featuring a falcon silhouette and the word 'falcon'. The section 'What is falcon?' contains a paragraph about the project's goals. Below the text are four green buttons: 'Getting Started', 'Template Library Index', 'Our Collaboration Journey', and 'FAQ'. The 'Upcoming Talks & Presentations' section lists two events: '20 October 2023 - R/Pharma Online Workshop' and '6 November 2023 - PHUSE EU Connect 2023'.

falcon

Implementation of FDA Safety Tables and Figures



What is falcon?

The falcon initiative is an industry collaborative effort under pharmanet 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.

Getting Started

Template Library Index

Our Collaboration Journey

FAQ

Upcoming Talks & Presentations

- 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 displays the Falcon website's home page. At the top, a navigation bar includes the Falcon logo, a search icon, and links for Home, Template Library, About, and Help. A sidebar on the left lists various FDA tables (Table 2 through Table 34) and other resources like 'Getting Started', 'Report a Bug', and 'FAQ'. The main content area features the Falcon logo, the title 'Implementation of FDA Safety Tables and Figures', and a paragraph describing the project's collaborative effort. At the bottom, there are two prominent green buttons: 'Getting Started' and 'Template Library Index'.

Navigation Bar: falcon Home Template Library About Help


Sidebar Menu:

- 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
- FDA Table 14
- FDA Table 20
- FDA Table 21
- FDA Table 32
- FDA Table 33
- FDA Table 34
- Getting Started
- Report a Bug
- FAQ

Main Content Area:

falcon

Implementation of FDA Safety Tables and Figures

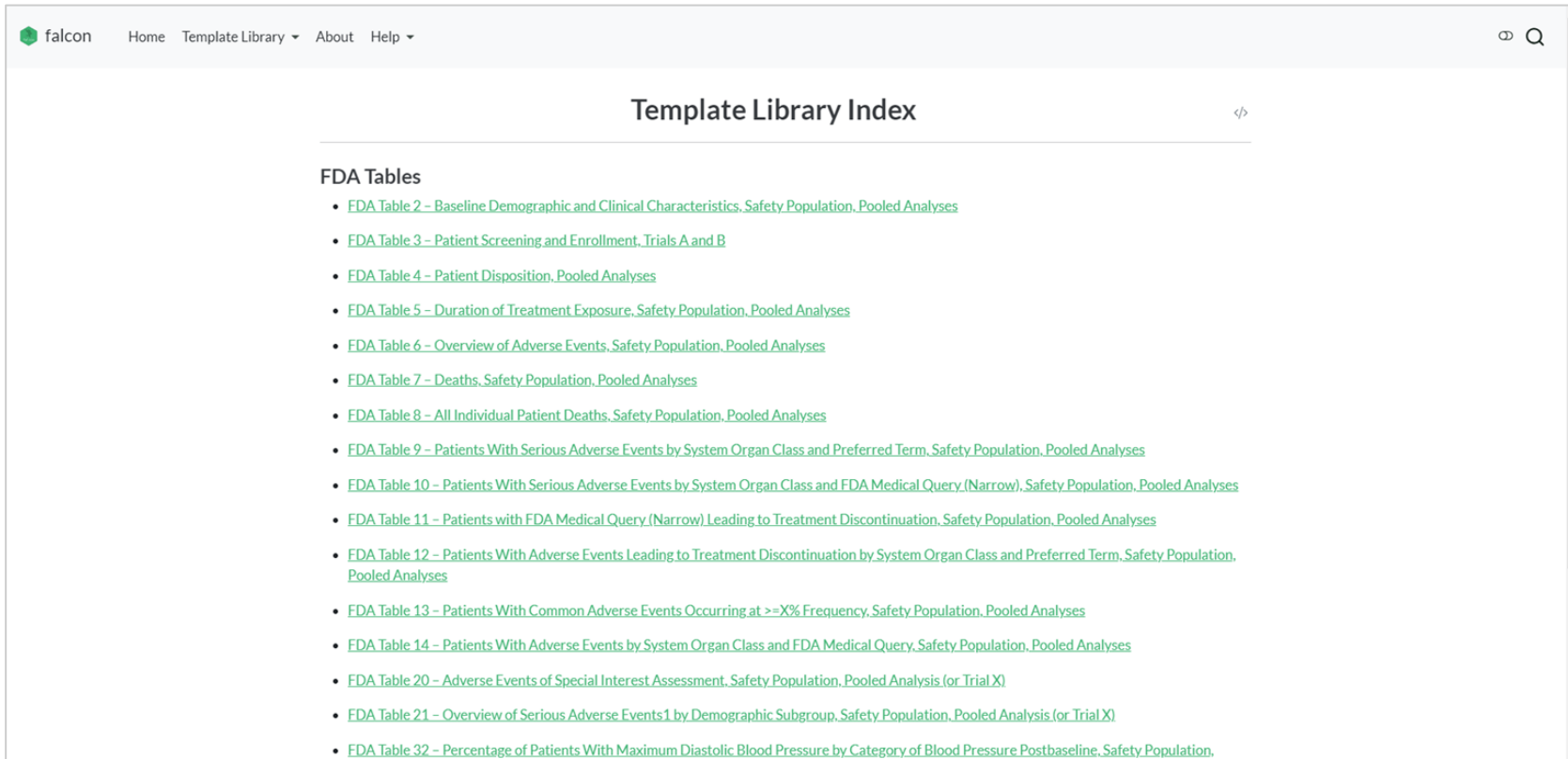


...ry collaborative effort under pharaverse that brings together pharmaceutical companies with the aspiration of building harmonized tables, listings, and graphs (TLGs) in clinical study reporting. Leveraging existing open-source R packages, ess of output review, comparison, and meta-analyses, fostering 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 develop 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.

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 Template Library Index page. The header includes the Falcon logo and navigation links: Home, Template Library (with a dropdown arrow), About, and Help (with a dropdown arrow). On the right side of the header, there are icons for a document and a search function. The main content area is titled "Template Library Index" and features a section for "FDA Tables". This section contains a list of 16 links, each representing a specific FDA table and its associated analysis type. The links are as follows:

- [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 \$\geq\$ 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



 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

Table 9. Patients With Serious Adverse Events¹ by System Organ Class and Preferred Term, Safety Population, Pooled Analyses²

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].

¹ Defined 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.


² Duration = [e.g., X week double-blind treatment period or median and a range indicating pooled trial durations].



³ Difference is shown between [treatment arms] [e.g., difference in placebo 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

 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

```
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)
```




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A Deeper Dive into Table Templates

Details on the function used to generate the table

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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](#)

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

A Deeper Dive into Table Templates

Details on the function used to generate the table

falcon	Home Template Library ▾ About Help ▾	⌕
lbl_pref_var	(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>
lbl_overall	(character) If specified, an overall column will be added to the table with the given value as the column label.	NULL
risk_diff	(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 <code>TRUE</code>.	NULL
prune_0	(flag) Whether all-zero rows should be removed from the table.	TRUE
annotations	(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>prov_footer</code> . Each name-value pair should use the annotation type as name and the desired string as value.	NULL
Source code for this function is available here .		

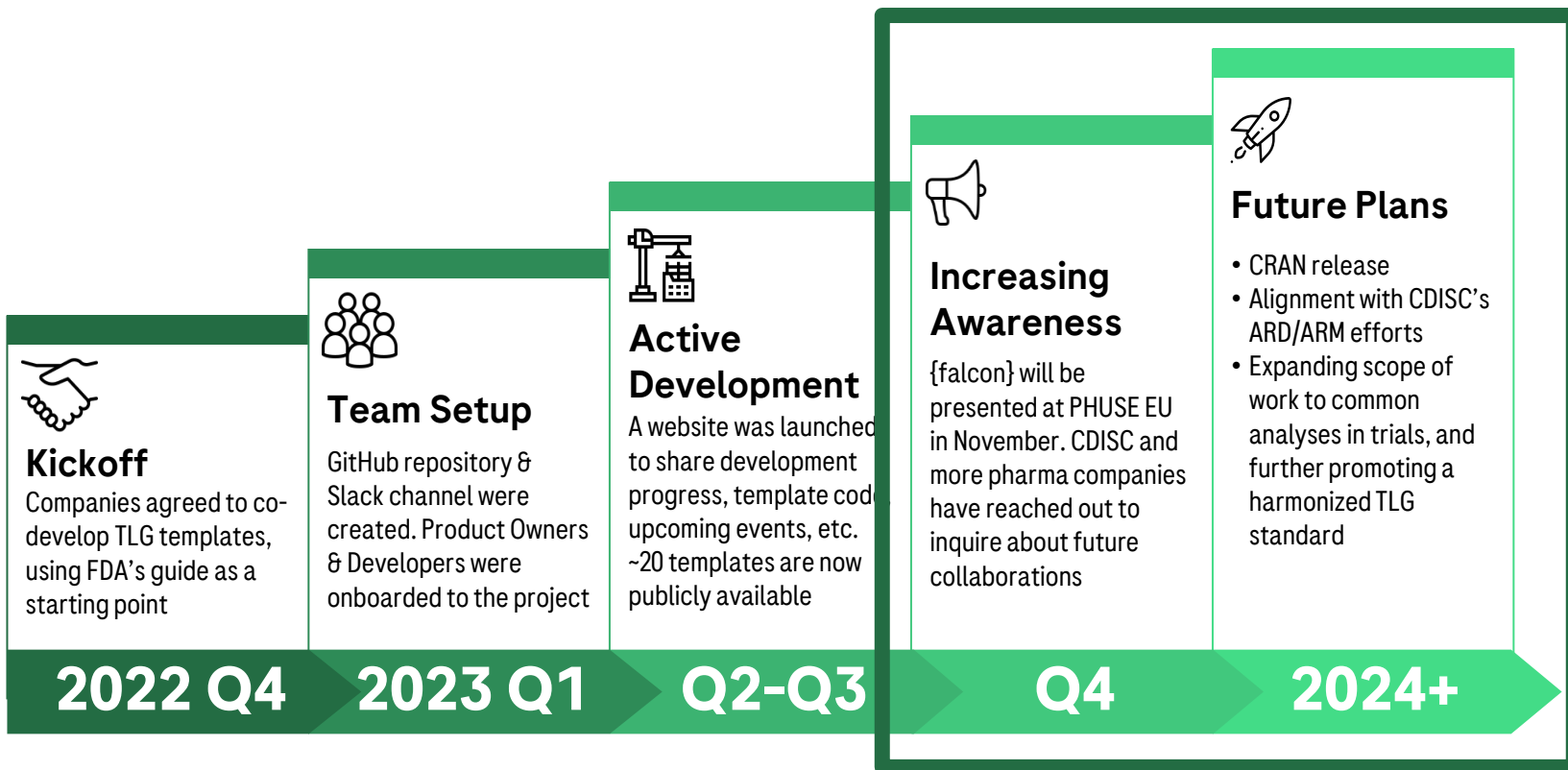
Goals



Goals



Our Roadmap



Call for Collaboration



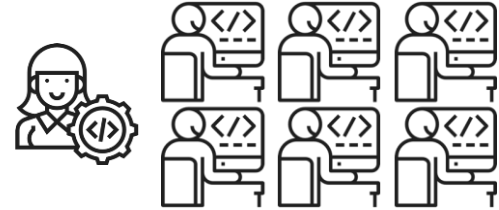
Project Coordination

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!