Welcome!

Cardinal

A Collaborative Leap Towards Harmonization of Clinical Reporting Standards

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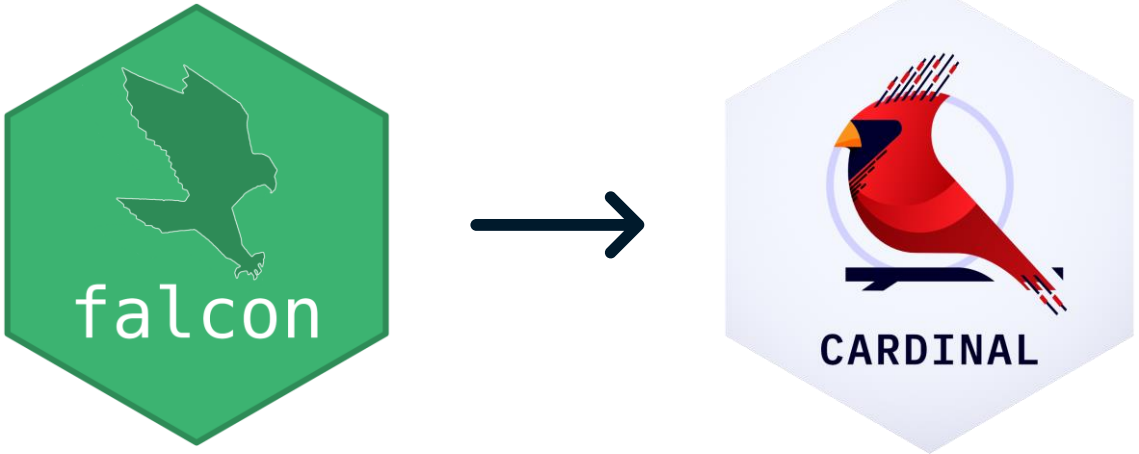
Workshop Outline

1. What is Cardinal?
    1. History & Motivation
    2. Our Journey
    3. Navigating the Cardinal website
2. Learnings, Outlook, & Call for Collaboration
3. Technical Overview
    1. {gtsummary}
    2. {crane}
    3. ARDs
4. Workshop Exercises

Cardinal

Formerly {falcon}



Workshop Scope

Understand and navigate the Cardinal template catalog

Brief technical overview of the {gtsummary} and {crane} R packages

Exercises to create TLGs

Workshop Expectations

Please ask questions at any time!

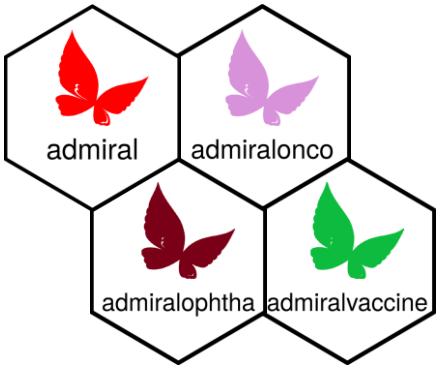
Turn your cameras on if you're comfortable! We'd love to see you ☺

History & Motivation

Pharma Industry Has Very Well Established Data Standards

SDTM & ADaM have brought great benefits to clinical trial conduct & analyses

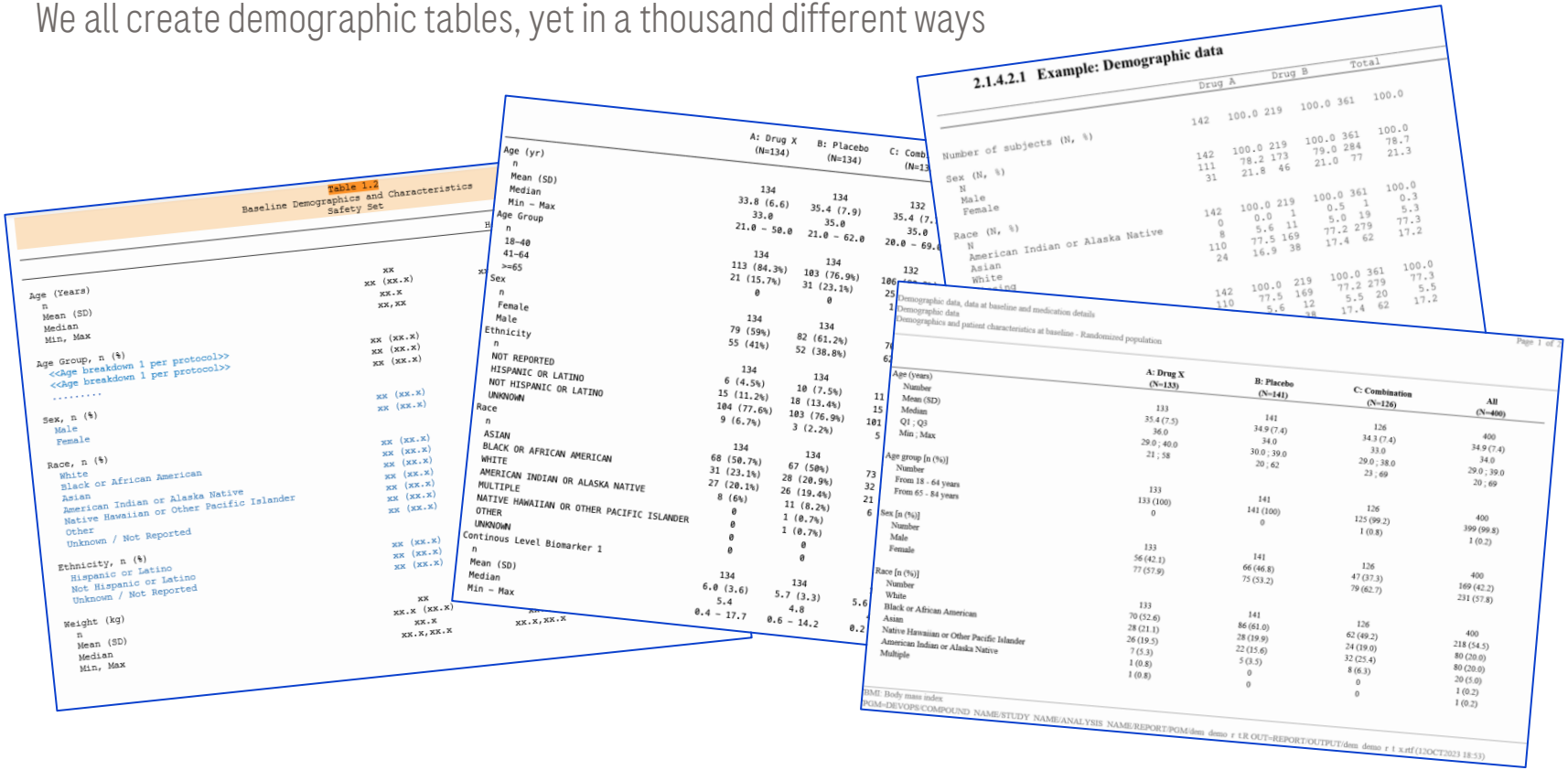
Universally agreed upon standards not only enable easier data sharing & re-use, but also foster industry collaboration



cdisc

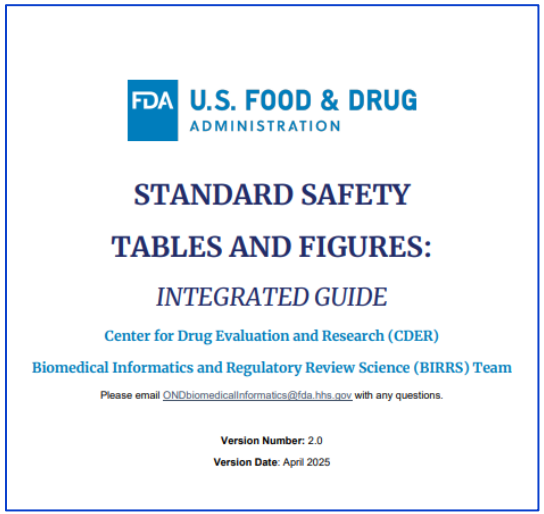
How About TLGs?

We all create demographic tables, yet in a thousand different ways



An Opportunity Arose

FDA proposed an integrated guide for standard safety tables & figures



Roche · Boehringer Ingelheim · sanofi · moderna

Common Toolkit:
Open-source R packages for TLG creation are available

Shared Resource:
Developers come from different companies

One Layout:
A much easier entry point for collaboration

Instead of potentially implementing this guide individually, why don't we do it together?

Pivot from {falcon} to Cardinal

Early 2024

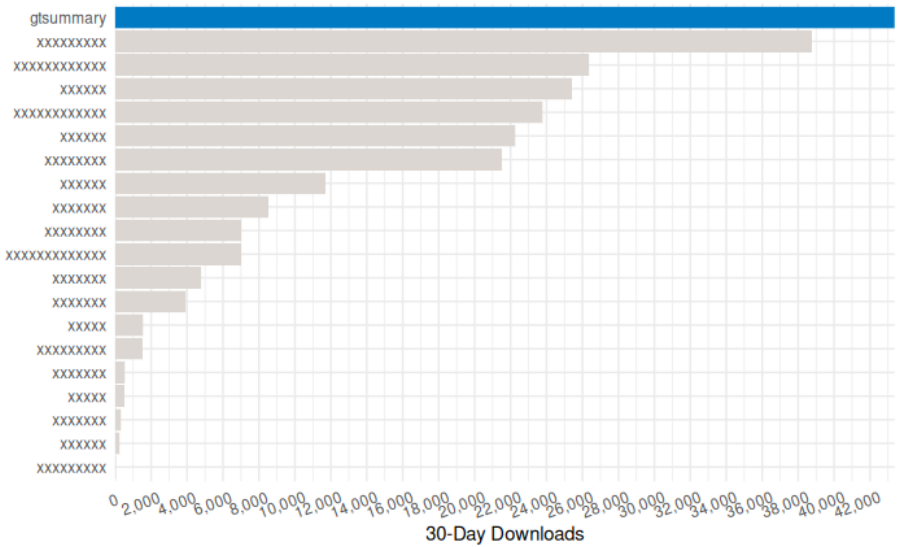
- CDISC publishes Analysis Results Datasets (ARDs)
    - Structured way to store analytic results
- Limited benefit from accommodating 3 different table engines

*Rather than developing {falcon} to accommodate different table engines – use a **single package***

{gtsummary}

- Recently refactored to have an ARD backbone
- Widely adopted = more resources available
- Channel of communication with the author
- Readable code
- Complex tables were easier to create using simpler tables

- The stats
- 1,600,000 installations from CRAN
- 1,100 GitHub stars
- 1,000 citations in peer-reviewed articles
- 350 contributors
- 50 code contributors
- Won the 2021 American Statistical Association (ASA) Innovation in Programming Award
- Won the 2024 Posit Pharma Table Contest



Cardinal

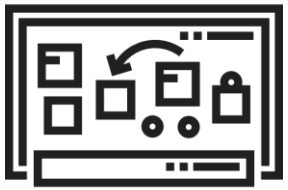
First industry collaborative effort for TLG creation

An industry collaborative effort with the aspiration of open-sourcing a catalog of harmonized TLGs for clinical study reporting and simplifying the process of output review, re-use, and meta-analyses

Current Progress

Project Coordination

How does a cross-company team work?



Product Owners

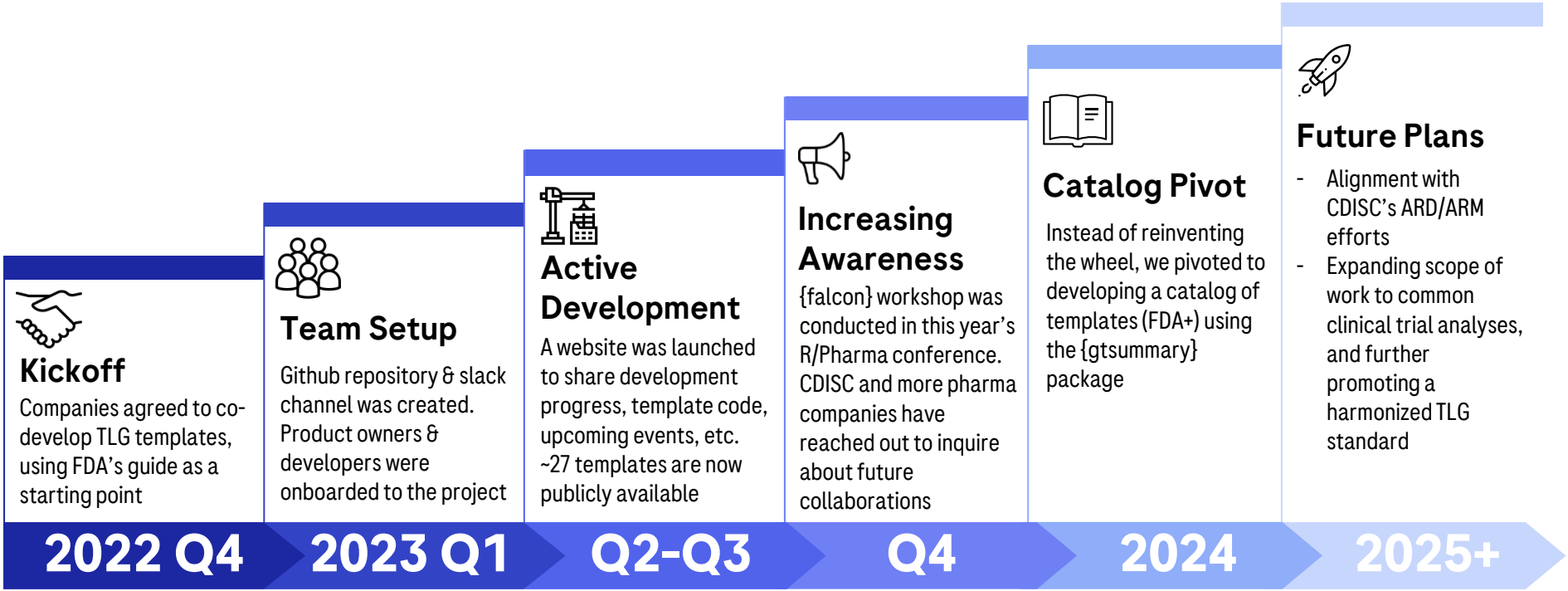
- Template prioritization
- Refine requirements
- Project roadmap

Developers

- Agile development
- Bi-weekly standup meeting
- GitHub project board to track progress

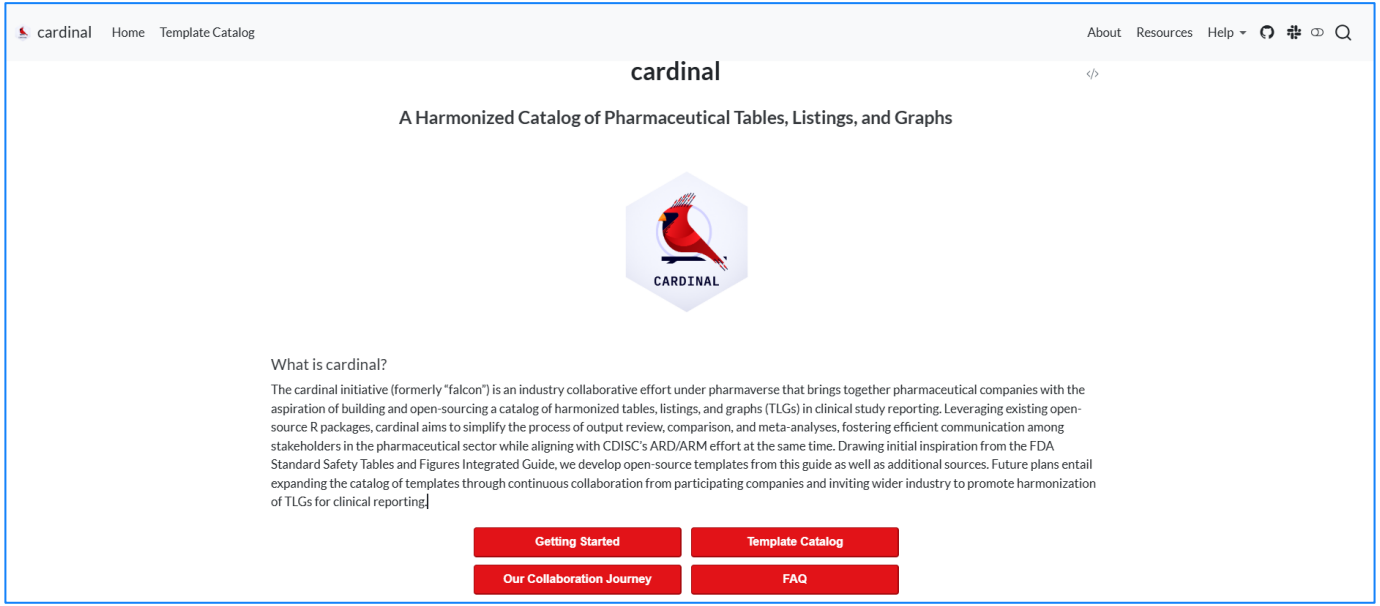
Our Journey

What have we achieved so far?



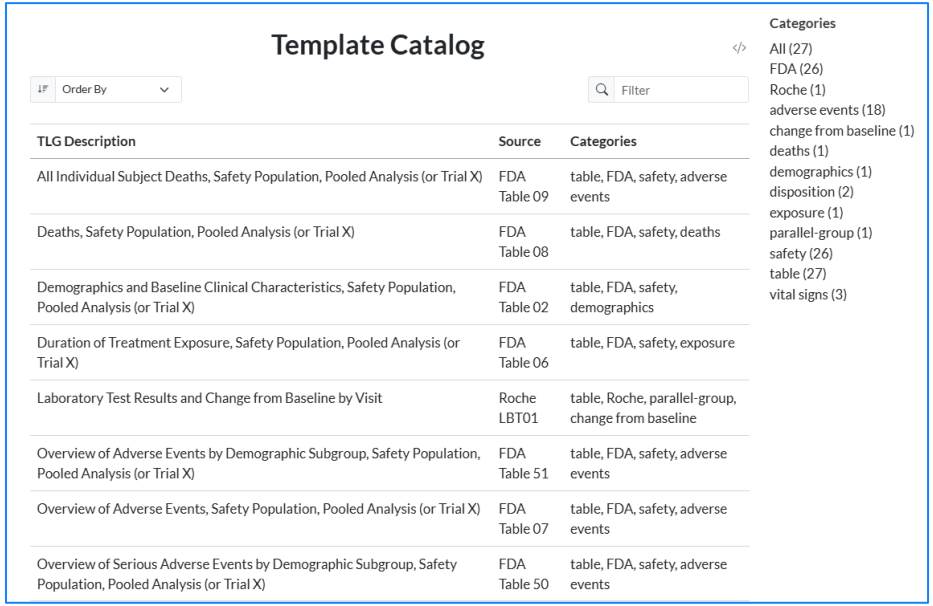
A Deeper Look

Explore Cardinal in detail



https://pharmaverse.github.io/cardinal/

Template Catalog



Template Catalog

Order By

Filter

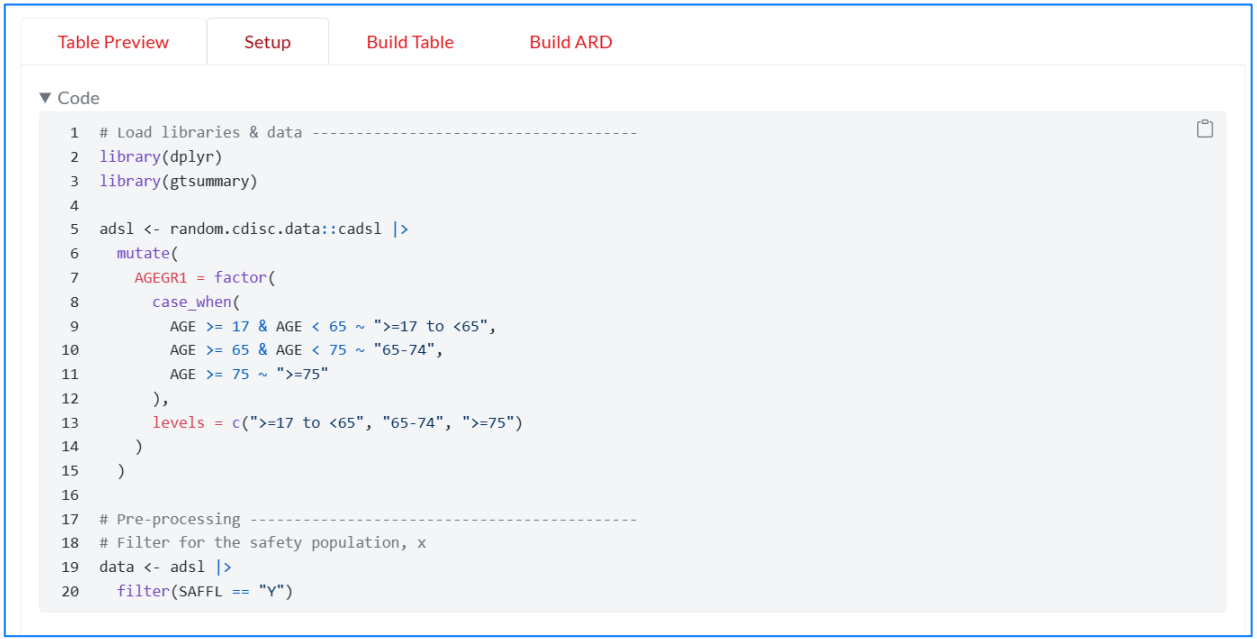
TLG Description	Source	Categories
All Individual Subject Deaths, Safety Population, Pooled Analysis (or Trial X)	FDA Table 09	table, FDA, safety, adverse events
Deaths, Safety Population, Pooled Analysis (or Trial X)	FDA Table 08	table, FDA, safety, deaths
Demographics and Baseline Clinical Characteristics, Safety Population, Pooled Analysis (or Trial X)	FDA Table 02	table, FDA, safety, demographics
Duration of Treatment Exposure, Safety Population, Pooled Analysis (or Trial X)	FDA Table 06	table, FDA, safety, exposure
Laboratory Test Results and Change from Baseline by Visit	Roche LBT01	table, Roche, parallel-group, change from baseline
Overview of Adverse Events by Demographic Subgroup, Safety Population, Pooled Analysis (or Trial X)	FDA Table 51	table, FDA, safety, adverse events
Overview of Adverse Events, Safety Population, Pooled Analysis (or Trial X)	FDA Table 07	table, FDA, safety, adverse events
Overview of Serious Adverse Events by Demographic Subgroup, Safety Population, Pooled Analysis (or Trial X)	FDA Table 50	table, FDA, safety, adverse events

Categories

All (27)
FDA (26)
Roche (1)
adverse events (18)
change from baseline (1)
deaths (1)
demographics (1)
disposition (2)
exposure (1)
parallel-group (1)
safety (26)
table (27)
vital signs (3)

https://pharmaverse.github.io/cardinal/

Data Setup

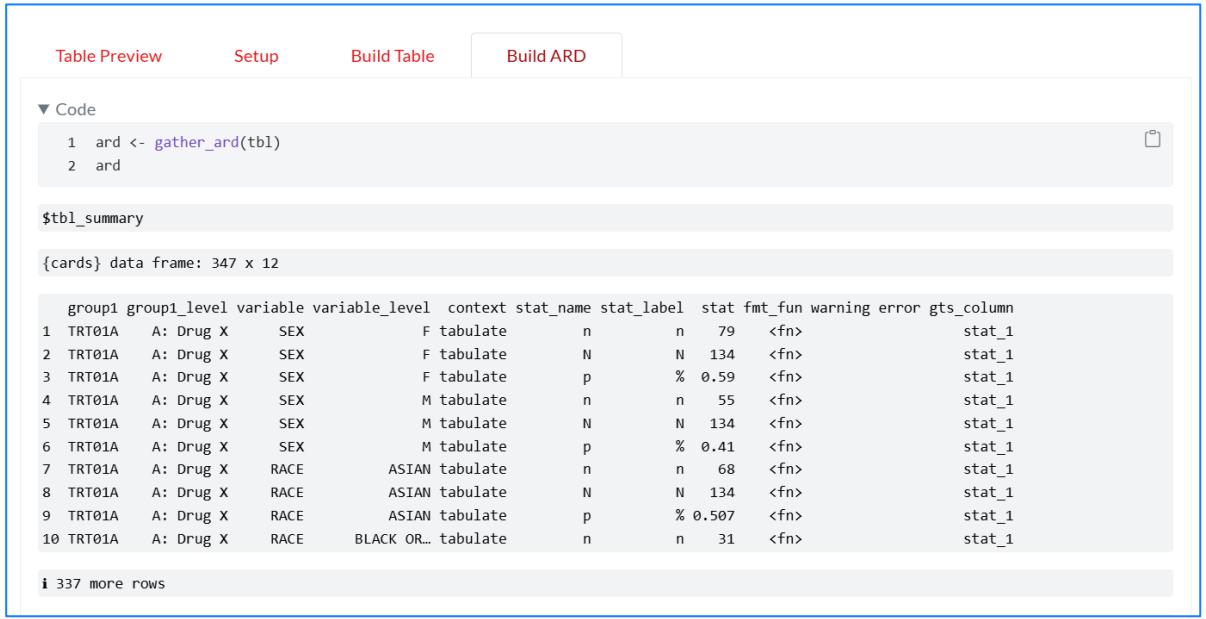


https://pharmaverse.github.io/cardinal/

Build Table

https://pharmaverse.github.io/cardinal/

Extract ARD



https://pharmaverse.github.io/cardinal/

Learnings, Outlook, & Call for Collaboration

Key Learnings

Reflections on our collaboration so far

Collaboration entry point is significantly lower when an industry-wide standard is established

Developers are motivated to work on open-source project, which opens new career opportunities

Building open-source solutions together across pharma companies is less resource intensive and more efficient

Future Outlook

How to fully realize the potential of Cardinal?

Engage more companies and collaborate closely with CDISC & health authorities

An industry harmonized TLG standard for clinical reporting would replace all internal standards, and the implementation is freely accessible for all

Call for Collaboration

The best time to join the journey was a year ago. The second best time is now.

https://pharmaverse.org/

https://bit.ly/48KVL2R

https://pharmaverse.github.io/cardinal/

Acknowledgements

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Juergen Boehl - Boehringer-Ingelheim
Kavitha Allala - Boehringer-Ingelheim
Korbinian Matthias - Boehringer-Ingelheim
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Pawel Rucki - Roche
Vincent Shen - Roche
Yichen Wang - Moderna
Yoshito Koujin - Boehringer-Ingelheim
Yuye Wang - Moderna

Technical Overview

tbl_summary()

{pharmaverseadam} Data for Examples

Reduced sizes of `adsl` and `adae`.

```
library(tidyverse)

adsl <- pharmaverseadam::adsl |>
  filter(SAFFL == "Y") |>
  mutate(ARM2 = word(ARM), FEMALE = SEX == "F") |>
  labelled::set_variable_labels(FEMALE = "Female")

adae <- pharmaverseadam::adae |>
  filter(
    USUBJID %in% adsl$USUBJID,
    AESOC %in% c("CARDIAC DISORDERS", "EYE DISORDERS"),
    AEDECOD %in% c("ATRIAL FLUTTER", "MYOCARDIAL INFARCTION", "EYE ALLERGY", "EYE SWELLING")
  ) |>
  mutate(ARM2 = word(ARM))
```

Basic tbl_summary()

```
library(gtsummary)

adsl |>
  tbl_summary(
    include = c(AGE, ETHNIC, FEMALE)
  )
```

Characteristic	N = 254[1]
Age	77 (70, 81)
Ethnicity	
HISPANIC OR LATINO	12 (4.7%)
NOT HISPANIC OR LATINO	242 (95%)
Female	143 (56%)

[1] Median (Q1, Q3); n (%)

- Four types of summaries: `continuous`, `continuous2`, `categorical`, and `dichotomous`
- Statistics are `median (IQR)` for continuous, `n (%)` for categorical/dichotomous
- Variables coded `0/1`, `TRUE/FALSE`, `Yes/No` treated as dichotomous by default
- Label attributes are printed automatically

Customize tbl_summary() output

```
adsl |>
  tbl_summary(
    include = c(AGE, ETHNIC, FEMALE),
    by = ARM2,
  )
```

Characteristic	Placebo N = 86[1]	Xanomeline N = 168[1]
Age	76 (69, 82)	77 (71, 81)
Ethnicity		
HISPANIC OR LATINO	3 (3.5%)	9 (5.4%)
NOT HISPANIC OR LATINO	83 (97%)	159 (95%)
Female	53 (62%)	90 (54%)

[1] Median (Q1, Q3); n (%)

- `by`: specify a column variable for cross-tabulation

Customize tbl_summary() output

```
adsl |>
  tbl_summary(
    include = c(AGE, ETHNIC, FEMALE),
    by = ARM2,
    type = AGE ~ "continuous2",
  )
```

Characteristic	**Placebo** N = 86[1]	**Xanomeline** N = 168[1]
Age		
Median (Q1, Q3)	76 (69, 82)	77 (71, 81)
Ethnicity		
HISPANIC OR LATINO	3 (3.5%)	9 (5.4%)
NOT HISPANIC OR LATINO	83 (97%)	159 (95%)
Female	53 (62%)	90 (54%)

[1] n (%)

- `by`: specify a column variable for cross-tabulation
- `type`: specify the summary type

Customize tbl_summary() output

```
adsl |>
  tbl_summary(
    include = c(AGE, ETHNIC, FEMALE),
    by = ARM2,
    type = AGE ~ "continuous2",
    statistic =
      list(
        AGE ~ c("{mean} ({sd})",
                "{min}, {max}"),
        FEMALE ~ "{n} / {N} ({p}%)"
      ),
  )
```

Characteristic	**Placebo** N = 86[1]	**Xanomeline** N = 168[1]
Age		
Mean (SD)	75 (9)	75 (8)
Min, Max	52, 89	51, 88
Ethnicity		
HISPANIC OR LATINO	3 (3.5%)	9 (5.4%)
NOT HISPANIC OR LATINO	83 (97%)	159 (95%)
Female	53 / 86 (62%)	90 / 168 (54%)

[1] n (%); n / N (%)

- `by`: specify a column variable for cross-tabulation
- `type`: specify the summary type
- `statistic`: customize the reported statistics

Customize tbl_summary() output

```
adsl |>
  tbl_summary(
    include = c(AGE, ETHNIC, FEMALE),
    by = ARM2,
    type = AGE ~ "continuous2",
    statistic =
      list(
        AGE ~ c("{mean} ({sd})",
                "{min}, {max}"),
        FEMALE ~ "{n} / {N} ({p}%)"
      ),
    label =
      AGE ~ "Age, years",
  )
```

Characteristic	Placebo N = 86[1]	Xanomeline N = 168[1]
Age, years		
Mean (SD)	75 (9)	75 (8)
Min, Max	52, 89	51, 88
Ethnicity		
HISPANIC OR LATINO	3 (3.5%)	9 (5.4%)
NOT HISPANIC OR LATINO	83 (97%)	159 (95%)
Female	53 / 86 (62%)	90 / 168 (54%)

[1] n (%); n / N (%)

- `by`: specify a column variable for cross-tabulation
- `type`: specify the summary type
- `statistic`: customize the reported statistics
- `label`: change or customize variable labels

Customize tbl_summary() output

```
adsl |>
  tbl_summary(
    include = c(AGE, ETHNIC, FEMALE),
    by = ARM2,
    type = AGE ~ "continuous2",
    statistic =
      list(
        AGE ~ c("{mean} ({sd})",
                "{min}, {max}"),
        FEMALE ~ "{n} / {N} ({p}%)"
      ),
    label =
      AGE ~ "Age, years",
    digits = AGE ~ list(sd = 1) # report SD(age
  )
```

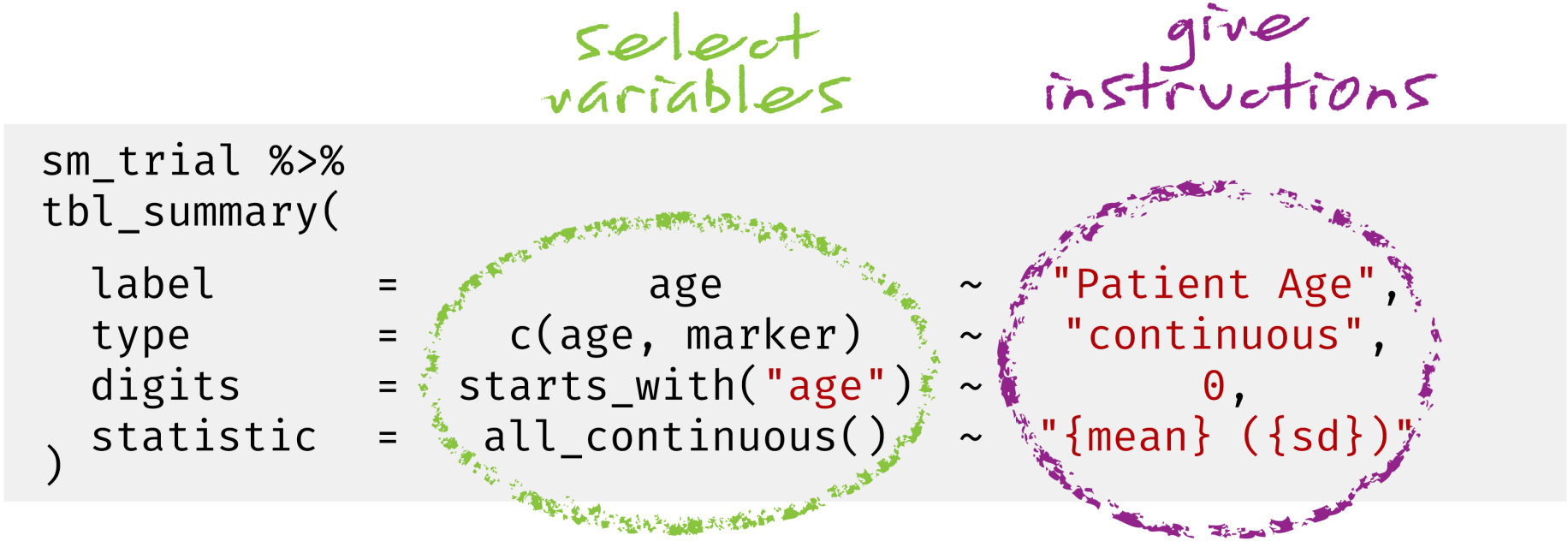
Characteristic	Placebo N = 86[1]	Xanomeline N = 168[1]
Age, years		
Mean (SD)	75 (8.6)	75 (8.1)
Min, Max	52, 89	51, 88
Ethnicity		
HISPANIC OR LATINO	3 (3.5%)	9 (5.4%)
NOT HISPANIC OR LATINO	83 (97%)	159 (95%)
Female	53 / 86 (62%)	90 / 168 (54%)

[1] n (%); n / N (%)

- `by`: specify a column variable for cross-tabulation
- `type`: specify the summary type
- `statistic`: customize the reported statistics
- `label`: change or customize variable labels
- `digits`: specify the number of decimal places for rounding

{gtsummary} + formulas

This syntax is also used in {cards}, {cardx}, {crane}, and {gt}.



Use `lists` to pass ≥2 sets of instruction:

```
label = list(age ~ "Patient Age", marker ~ "Marker Level")
```

Named list are OK too! `label = list(age = "Patient Age")`

{gtsummary} selectors

- Use the following helpers to **select groups of variables**: `all_continuous()`, `all_categorical()`
- Use `all_stat_cols()` to select the **summary statistic columns**

Add-on functions in {gtsummary}

`tbl_summary()` objects can also be updated using related functions.

- `add_*()` add **additional column** of statistics or information, e.g. p-values, q-values, overall statistics, treatment differences, N obs., and more
- `modify_*()` **modify** table headers, spanning headers, footnotes, and more

Update tbl_summary() with add_*()

```
adsl |>
  tbl_summary(
    by = ARM2,
    include = c(AGE, ETHNIC, FEMALE)
  ) |>
  add_overall(last = TRUE)
```

Characteristic	Placebo N = 86[1]	Xanomeline N = 168[1]	Overall N = 254[1]
Age	76 (69, 82)	77 (71, 81)	77 (70, 81)
Ethnicity			
HISPANIC OR LATINO	3 (3.5%)	9 (5.4%)	12 (4.7%)
NOT HISPANIC OR LATINO	83 (97%)	159 (95%)	242 (95%)
Female	53 (62%)	90 (54%)	143 (56%)

[1] Median (Q1, Q3); n (%)

- `add_overall()`: adds a column of overall statistics

Update tbl_summary() with add_*()

- `add_n()`: adds a column non-missing counts
- `add_p()`: adds a column of p-values
- `add_difference()`: mean and rate differences between two groups. Can also be adjusted differences

Update tbl_summary() with modify_*()

```
tbl <-
  adsl |>
  tbl_summary(by = ARM2, include = c("AGE",
  modify_header(
    stat_1 ~ "**Group A**",
    stat_2 ~ "**Group B**"
  ) |>
  modify_spanning_header(
    all_stat_cols() ~ "**Drug**") |>
  modify_footnote(
    all_stat_cols() ~
      paste("median (IQR) for continuous;",
            "n (%) for categorical")
  )
tbl
```

Characteristic	Drug	
	Group A[1]	Group B[1]
Age	76 (69, 82)	77 (71, 81)
Ethnicity		
HISPANIC OR LATINO	3 (3.5%)	9 (5.4%)
NOT HISPANIC OR LATINO	83 (97%)	159 (95%)
Female	53 (62%)	90 (54%)

[1] median (IQR) for continuous; n (%) for categorical

- Use `show_header_names()` to see the internal header names available for use in `modify_header()`

Column names

```
show_header_names(tbl)
```

Column Name	Header	level*	N*	n*	p*
label	"**Characteristic**"		254 <int>		
stat_1	"**Group A**"	Placebo <chr>	254 <int>	86 <int>	0.339 <dbl>
stat_2	"**Group B**"	Xanomeline <chr>	254 <int>	168 <int>	0.661 <dbl>

* These values may be dynamically placed into headers (and other locations).
i Review the `modify_header()` help for examples.

`all_stat_cols()` selects columns `"stat_1"` and `"stat_2"`

Update tbl_summary() with add_*()

```r
adsl |>
  tbl_summary(
    by = ARM2,
    include = c(AGE, ETHNIC, FEMALE)
  ) |>
  add_stat(...)
```

- Customize statistics presented with `add_stat()`
- Added statistics can be placed on the label or the level rows
- Added statistics may be a single column or multiple

Add-on functions in {gtsummary}

And many more!

See the documentation at
http://www.danieldsjoberg.com/gtsummary/reference/index.html

And a detailed `tbl_summary()` vignette at
http://www.danieldsjoberg.com/gtsummary/articles/tbl_summary.html

tbl_hierarchical()

Adverse Event Reporting (and friends)

Use `tbl_hierarchical()` and `tbl_hierarchical_count()` for reporting of AEs, Con Meds, and more.

```
tbl_ae <- adae |>
  tbl_hierarchical(
    by = "ARM2",
    variables = c("AESOC", "AEDECOD"),
    id = "USUBJID",
    denominator = adsl
  )
```

Primary System Organ Class **Dictionary-Derived Term**	**Placebo** N = 86[1]	**Xanomeline** N = 168[1]
CARDIAC DISORDERS	4 (4.7%)	8 (4.8%)
ATRIAL FLUTTER	0 (0%)	2 (1.2%)
MYOCARDIAL INFARCTION	4 (4.7%)	6 (3.6%)
EYE DISORDERS	1 (1.2%)	0 (0%)
EYE ALLERGY	1 (1.2%)	0 (0%)
EYE SWELLING	1 (1.2%)	0 (0%)

[1] n (%)

tbl_merge()/tbl_stack()

tbl_merge() for side-by-side tables

```r
tbl_n <-
  tbl_summary(adsl, include = ETHNIC, statistic = ETHNIC ~ "{n}") |>
  modify_header(all_stat_cols() ~ "**N**") |> # update column header
  remove_footnote_header() # remove footnote
tbl_age <-
  tbl_continuous(adsl, include = ETHNIC, variable = AGE, by = ARM2) |>
  modify_header(all_stat_cols() ~ "**{level}**") # update header

# combine the tables side by side
list(tbl_n, tbl_age) |>
  tbl_merge(tab_spanner = FALSE) # suppress default header
```

Characteristic	**N**	**Placebo**[1]	**Xanomeline**[1]
Ethnicity			
HISPANIC OR LATINO	12	64 (63, 86)	63 (56, 78)
NOT HISPANIC OR LATINO	242	76 (70, 82)	77 (71, 81)

[1] Age: Median (Q1, Q3)

tbl_stack() to combine vertically

```
tbl_drug_a <- filter(adsl, ARM2 == "Placebo") |>
  tbl_summary(include = ETHNIC)
tbl_drug_b <- filter(adsl, ARM2 == "Xanomeline") |>
  tbl_summary(include = ETHNIC)

# stack the two tables
list(tbl_drug_a, tbl_drug_b) |>
  tbl_stack(group_header = c("Placebo", "Xanomeline"), quiet = TRUE) |> # optionally include hea
  modify_header(all_stat_cols() ~ "**Summary Statistics**")
```

Characteristic	Summary Statistics[1]
Placebo	
Ethnicity	
HISPANIC OR LATINO	3 (3.5%)
NOT HISPANIC OR LATINO	83 (97%)
Xanomeline	
Ethnicity	
HISPANIC OR LATINO	9 (5.4%)
NOT HISPANIC OR LATINO	159 (95%)

[1] n (%)

Cobbling Tables Together

- Many tables we create in the pharma space come from a catalog of standard tables.
- The {gtsummary} package makes it simple to break complex tables into their simple parts and cobble them together in the end.
- Moreover, the internal structure of a gtsummary table is **super simple**:
  - A data frame
  - Instructions to print that data frame to make it cute.

	Control		Case				
Characteristi	**Not Exposed**	**Exposed**	**Not Exposed**	**Exposed**	**Odds Ratio**	**CMH Odds Ratio**	**p-value**
T Stage							
Crude	46	42	52	60	1.26 (0.72, 2.21)	1.23 (0.69, 2.18)	0.6
T1	16	13	12	12	1.23 (0.42, 3.64)		
T2	14	13	11	16	1.57 (0.53, 4.60)		
T3	9	12	13	9	0.52 (0.15, 1.74)		
T4	7	4	16	23	2.52 (0.63, 10.0)		
Grade							
Crude	46	42	52	60	1.26 (0.72, 2.21)	1.26 (0.71, 2.22)	0.5
I	19	16	16	17	1.26 (0.49, 3.27)		
II	16	16	16	20	1.25 (0.48, 3.25)		
III	11	10	20	23	1.27 (0.44, 3.60)		

tbl_merge()

tbl_cross()

tbl_stack()

add_stat()

Where are the ARDs?

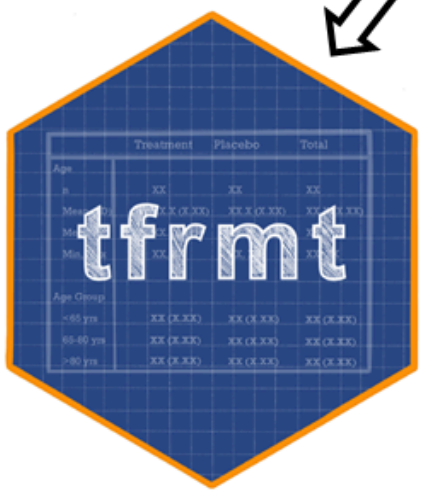
- ARDs are the backbone for all calculations in gtsummary
- Every gtsummary table saves the ARDs from each calculation

```
tbl <- tbl_summary(adsl, by = "ARM", include = "AGE")
gather_ard(tbl)
```

```
$tbl_summary
{cards} data frame: 38 x 12
   group1 group1_level variable variable_level stat_name stat_label stat
1     ARM      Placebo      AGE                   median     Median   76
2     ARM      Placebo      AGE                      p25         Q1   69
3     ARM      Placebo      AGE                      p75         Q3   82
4     ARM    Xanomeli…      AGE                   median     Median   76
5     ARM    Xanomeli…      AGE                      p25         Q1 70.5
6     ARM    Xanomeli…      AGE                      p75         Q3   80
7     ARM    Xanomeli…      AGE                   median     Median 77.5
8     ARM    Xanomeli…      AGE                      p25         Q1   71
9     ARM    Xanomeli…      AGE                      p75         Q3   82
10   <NA>                   AGE                    label  Variable…  Age
i 28 more rows
i Use `print(n = ...)` to see more rows
i 5 more variables: context, fmt_fun, warning, error, gts_column
```

ARDs

Tables



ARD + QC

ARDs are **wonderful** for QCing {gtsummary} tables. 😻

- ARDs include the formatted and un-formatted numbers that appear in the table.
- Extract the ARD from the {gtsummary} table.
- Build fresh ARD from source data, and compare it to the ARD from the table.

ARD + QC: Build and Compare ARDs

```r
ard_demog <- adsl |>
  cards::ard_stack(
    cards::ard_summary(
      variables = "AGE",
      statistic =
        AGE ~ cards::continuous_summary_fns(c("median", "p25", "p75"))
    ),
    .by = "ARM2",
  )
```

The next step is to simply compare the two ARDs to confirm results. As this is done programmatically, it is quick to repeat as data continues to accrue.

ARD-first tables

ARD-first Tables

Similar to functions that accept a data frame, the package exports functions with nearly identical APIs that accept an ARD.

```
tbl_summary()

tbl_hierarchical()

tbl_continuous()

tbl_wide_summary()
```

```
tbl_ard_summary()

tbl_ard_hierarchical()

tbl_ard_continuous()

tbl_ard_wide_summary()
```

ARD-first Tables

We can use the skills we learned earlier today to create ARDs for gtsummary tables.

```
library(cards)

ard <- ard_stack(
  data = adsl,
  ard_summary(variables = AGE),
  ard_tabulate(variables = ETHNIC),
  ard_tabulate_value(variables = FEMALE),
  # add these for best-looking tables
  .attributes = TRUE,
  .missing = TRUE
)
ard
```

```
{cards} data frame: 38 x 9
   variable variable_level  context stat_name stat_label   stat
1       AGE                summary         N          N    254
2       AGE                summary      mean       Mean 75.087
3       AGE                summary        sd         SD  8.246
4       AGE                summary    median     Median     77
5       AGE                summary       p25         Q1     70
6       AGE                summary       p75         Q3     81
7       AGE                summary       min        Min     51
8       AGE                summary       max        Max     89
9    ETHNIC      HISPANIC… tabulate         n          n     12
10   ETHNIC      HISPANIC… tabulate         N          N    254
i 28 more rows
i Use `print(n = ...)` to see more rows
i 3 more variables: fmt_fun, warning, error
```

The `.attributes=TRUE` call adds column attributes, like labels, to the ARD table, which leads to better defaults by displaying the column

ARD-first Tables

We can simply use the ARD from the previous slide, and pass it to `tbl_ard_summary()` for a summary table.

```
tbl_ard_summary(ard)
```

Characteristic	Overall[1]
Age	77.0 (70.0, 81.0)
Ethnicity	
HISPANIC OR LATINO	12 (4.7%)
NOT HISPANIC OR LATINO	242 (95.3%)
Female	143 (56.3%)

[1] Median (Q1, Q3); n (%)

{crane}

At Roche, we've created a companion R package to {gtsummary}.

- Functions are thin wrappers for {gtsummary} functions
- Built to tailor defaults to Roche "aesthetics" in tables
- Produces Standard, Hierarchical, Survival Analysis tables and Listings

Notable Functions

- **tbl_baseline_chg()**: Compute Analysis Values and Change from Baseline at each visit
- **tbl_hierarchical_rate_and_count()** : Hierarchical Rates and Counts
- **tbl_hierarchical_rate_by_grade()** : AE Rates by Highest Toxicity Grade
- **tbl_listings()** : Creates a listing from a data frame

The `tbl_roche_summary()` function is a simple wrapper for `tbl_summary()`, but with Roche defaults

Table 1

```
library(crane)

adsl |>
  dplyr::mutate(ETHNIC = forcats::fct_expand(ETHNIC, "REFUSED")) |>
  tbl_roche_summary(by = ARM, include = c(AGE, ETHNIC), nonmissing = "always")
```

	Placebo (N = 86)	Xanomeline High Dose (N = 84)	Xanomeline Low Dose (N = 84)
Age			
n	86	84	84
Mean (SD)	75 (9)	74 (8)	76 (8)
Median	76	76	78
Min - Max	52 - 89	56 - 88	51 - 88
ETHNIC			
n	86	84	84
HISPANIC OR LATINO	3 (3.5%)	3 (3.6%)	6 (7.1%)
NOT HISPANIC OR LATINO	83 (97%)	81 (96%)	78 (93%)
REFUSED	0	0	0

What else is in {crane}?

Lab values are summarized by visit and include the change from baseline.

This is a simple table that is just a `tbl_merge()` of the `AVAL` summary and the `CHG` summary.

But the general structure appears enough times in our catalog, we make it simple for our programmers to create.

```
pharmaverseadam::adlb |>
  filter(
    SAFFL == "Y", # filter for safety population
    AVISITN < 9000, # filter out invalid visits
    AVISIT %in% c("Baseline", "Week 4", "Week 8"), # keep only visits "Baseline", "Week 4", and
    PARAM %in% "Albumin (g/L)" # keep only 1 parameter
  )
```

What else is in {crane}?

	Placebo (N = 86)		Xanomeline High Dose (N = 84)		Xanomeline Low Dose (N = 84)	
Visit	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Baseline						
n	86		84		82	
Mean (SD)	39.84 (2.81)		40.29 (2.84)		39.77 (2.56)	
Median	40.00		40.00		40.00	
Min - Max	32.00 - 46.00		32.00 - 49.00		32.00 - 46.00	
Week 12						
n	67	67	50	50	51	51
Mean (SD)	39.48 (3.49)	-0.34 (2.39)	39.80 (2.45)	-0.70 (2.73)	38.86 (2.18)	-0.88 (2.12)
Median	40.00	0.00	39.50	-1.00	39.00	-1.00
Min - Max	28.00 - 47.00	-6.00 - 6.00	35.00 - 44.00	-7.00 - 6.00	31.00 - 44.00	-7.00 - 4.00
Week 24						
n	57	57	30	30	26	26
Mean (SD)	39.67 (3.34)	-0.04 (2.90)	40.53 (2.10)	-0.57 (2.65)	40.38 (2.52)	0.54 (2.39)
Median	40.00	0.00	41.00	-1.00	40.50	1.00
Min - Max	29.00 - 46.00	-10.00 - 6.00	35.00 - 44.00	-5.00 - 8.00	32.00 - 45.00	-5.00 - 4.00

What else is in {crane}?

`tbl_summary(include=AVAL)`

	Placebo (N = 86)		Xanomeline High Dose (N = 84)		Xanomeline Low Dose (N = 84)	
Visit	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Baseline						
n	86		84		82	
Mean (SD)	39.84 (2.81)		40.29 (2.84)		39.77 (2.56)	
Median	40.00		40.00		40.00	
Min - Max	32.00 - 46.00		32.00 - 49.00		32.00 - 46.00	
Week 12						
n	67	67	50	50	51	51
Mean (SD)	39.48 (3.49)	-0.34 (2.39)	39.80 (2.45)	-0.70 (2.73)	38.86 (2.18)	-0.88 (2.12)
Median	40.00	0.00	39.50	-1.00	39.00	-1.00
Min - Max	28.00 - 47.00	-6.00 - 6.00	35.00 - 44.00	-7.00 - 6.00	31.00 - 44.00	-7.00 - 4.00
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Median	40.00	0.00	41.00	-1.00	40.50	1.00
Min - Max	29.00 - 46.00	-10.00 - 6.00	35.00 - 44.00	-5.00 - 8.00	32.00 - 45.00	-5.00 - 4.00

What else is in {crane}?

`tbl_summary(include=CHG)`

	Placebo (N = 86)		Xanomeline High Dose (N = 84)		Xanomeline Low Dose (N = 84)	
Visit	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Baseline						
n	86		84		82	
Mean (SD)	39.84 (2.81)		40.29 (2.84)		39.77 (2.56)	
Median	40.00		40.00		40.00	
Min - Max	32.00 - 46.00		32.00 - 49.00		32.00 - 46.00	
Week 12						
n	67	67	50	50	51	51
Mean (SD)	39.48 (3.49)	-0.34 (2.39)	39.80 (2.45)	-0.70 (2.73)	38.86 (2.18)	-0.88 (2.12)
Median	40.00	0.00	39.50	-1.00	39.00	-1.00
Min - Max	28.00 - 47.00	-6.00 - 6.00	35.00 - 44.00	-7.00 - 6.00	31.00 - 44.00	-7.00 - 4.00
Week 24						
n	57	57	30	30	26	26
Mean (SD)	39.67 (3.34)	-0.04 (2.90)	40.53 (2.10)	-0.57 (2.65)	40.38 (2.52)	0.54 (2.39)
Median	40.00	0.00	41.00	-1.00	40.50	1.00
Min - Max	29.00 - 46.00	-10.00 - 6.00	35.00 - 44.00	-5.00 - 8.00	32.00 - 45.00	-5.00 - 4.00

What else is in {crane}?

`tbl_merge()`

	Placebo (N = 86)		Xanomeline High Dose (N = 84)		Xanomeline Low Dose (N = 84)	
Visit	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Baseline						
n	86		84		82	
Mean (SD)	39.84 (2.71)		40.29 (2.84)		39.77 (2.56)	
Median	40.00		40.00		40.00	
Min - Max	32.00 - 48.00		32.00 - 49.00		32.00 - 46.00	
Week 12						
n	67	67	50	50	51	51
Mean (SD)	39.48 (3.49)	-0.34 (2.39)	39.80 (2.45)	-0.70 (2.73)	38.86 (2.78)	-0.88 (2.12)
Median	40.00	0.00	39.50	-1.00	39.00	-1.00
Min - Max	28.00 - 47.00	-7.00 - 6.00	35.00 - 44.00	-7.00 - 6.00	32.00 - 44.00	-7.00 - 4.00
Week 24						
n	57	57	30	30	26	26
Mean (SD)	39.67 (3.34)	-0.04 (2.90)	40.53 (2.10)	-0.53 (2.65)	40.38 (2.52)	0.54 (2.39)
Median	40.00	0.00	40.00	-1.00	40.50	1.00
Min - Max	29.00 - 46.00	-10.00 - 6.00	35.00 - 44.00	-5.00 - 8.00	32.00 - 45.00	-5.00 - 4.00

Let’s get our hands dirty!

Working environment

- For consistency, we will be working in Posit Cloud
- Everything has been installed and set up for you

Thank you!

pharmaverse.github.io/cardinal