

# Welcome!

## Cardinal

A Collaborative Leap Towards Harmonization of Clinical Reporting Standards

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# Instructors

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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 {gtsummary}, {crane}



Exercises to create TLGs

# Workshop Expectations



Please ask questions at any time!



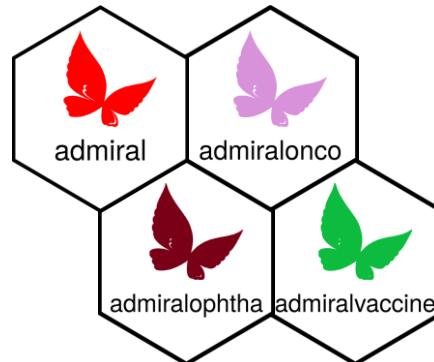
Turn your cameras on if you're comfortable! We'd love to see you 😊

## **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*



# How About TLGs?

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

**Table 1.2**  
Baseline Demographics and Characteristics  
Safety Set

Age (Years)	xx
n	xx (xx-x)
Mean (SD)	xx, x
Median	xx, xx
Min, Max	
Age Group, n (%) <>Age breakdown 1 per protocol>> <>Age breakdown 1 per protocol>>	
.....	
Sex, n (%)	
Male	xx (xx-x)
Female	xx (xx-x)
Race, n (%)	
White	xx (xx-x)
Black or African American	xx (xx-x)
Asian	xx (xx-x)
American Indian or Alaska Native	xx (xx-x)
Native Hawaiian or Other Pacific Islander	xx (xx-x)
Other	xx (xx-x)
Unknown / Not Reported	xx (xx-x)
Ethnicity, n (%)	
Hispanic or Latino	xx (xx-x)
Not Hispanic or Latino	xx (xx-x)
Unknown / Not Reported	xx (xx-x)
Weight (kg)	
n	xx
Mean (SD)	xx (xx-x)
Median	xx, x
Min, Max	xx, xx, xx-x

#### 2.1.4.2.1 Example: Demographic data

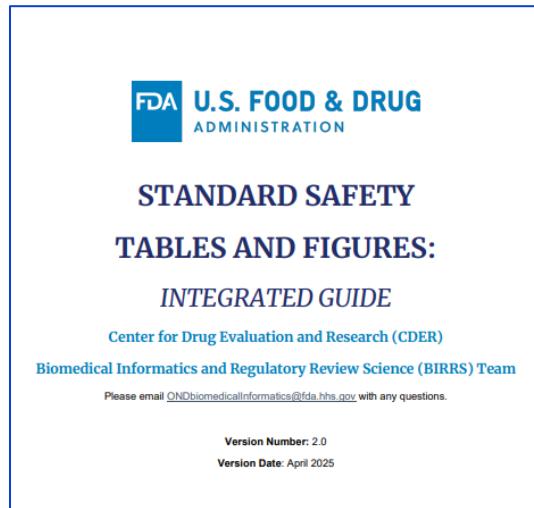
	A: Drug X (N=134)	
Age (yr)		
n	134	
Mean (SD)	33.8 (6.6)	
Median	33.0	
Min - Max		
Age Group	21.0 - 50.0	
18-40		
41-64	134	
>=65	113 (84.3%)	
ex	21 (15.7%)	
n	0	
Female		
Male	134	
Ethnicity		
White	79 (59%)	82
Black or African American	55 (41%)	52
HISPANIC OR LATINO		
Unknown	134	
Hispanic or Latino	6 (4.5%)	16
Non-Hispanic or Latino	15 (11.2%)	18
Asian	27 (20.6%)	31
American Indian or Alaskan Native	21 (15.9%)	26
Other	18 (13.6%)	21
Total	103 (76.5%)	103
Missing	9 (6.7%)	3
Asian		
Chinese	134	
Black or African American	68 (50.7%)	67
White	31 (23.1%)	28
American Indian or Alaska Native	27 (20.8%)	26
Title	8 (6%)	11
Hawaiian or Other Pacific Islander		
Native Hawaiian	0	1 (0.7%)
Other	0	1 (0.7%)
Asian	0	0
Other	0	0
Missing	0	0
Missing Level Biomarker 1		
Level	134	134
n	6.0 (3.6)	5.7 (3.1)
Mean	5.4	4.8
SD	0.4 - 17.7	0.6 - 17.7

Page

		A: Drug X (N=133)	B: Placebo (N=144)	C: Combination (N=126)	All (N=400)
Age (years)					
11 Number					
15 Mean (SD)		133	141	126	400
15 Medium		35.4 (7.5)	34.9 (7.4)	34.3 (7.4)	34.9 (7.4)
101 Q1 ; Q3		36.0	34.0	33.0	34.6
5 Min ; Max		29.0 ; 40.0	30.0 ; 39.0	29.0 ; 38.0	29.0 ; 39.0
Age group [n (%)]					
73 Number					
32 From 18 - 64 years		133	141	126	400
21 From 65 - 84 years		133 (100)	141 (100)	125 (99.2)	399 (99.8)
6 Sex [n (%)]		0	0	1 (0.8)	1 (0.2)
Number					
Male					
Female		133	141	126	400
Race [n (%)]					
5.6 Number					
Black or African American		56 (42.1)	66 (46.8)	47 (37.3)	169 (42.2)
Asian		77 (57.9)	75 (53.2)	79 (62.7)	231 (57.8)
Native Hawaiian or Other Pacific Islander					
American Indian or Alaska Native					
Multiple					
White		133	141	126	400
0.2					
Black or African American		70 (52.6)	86 (61.0)	62 (49.2)	218 (54.5)
Asian		28 (21.1)	28 (19.9)	24 (19.0)	80 (20.0)
Native Hawaiian or Other Pacific Islander		26 (19.5)	22 (15.6)	32 (25.4)	80 (20.0)
American Indian or Alaska Native		7 (5.3)	5 (3.5)	8 (6.3)	20 (5.0)
Multiple		1 (0.8)	0	0	1 (0.2)
White		1 (0.8)	0	0	1 (0.2)

# An Opportunity Arose

FDA proposed an integrated guide for standard safety tables & figures



Boehringer  
Ingelheim



## 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***

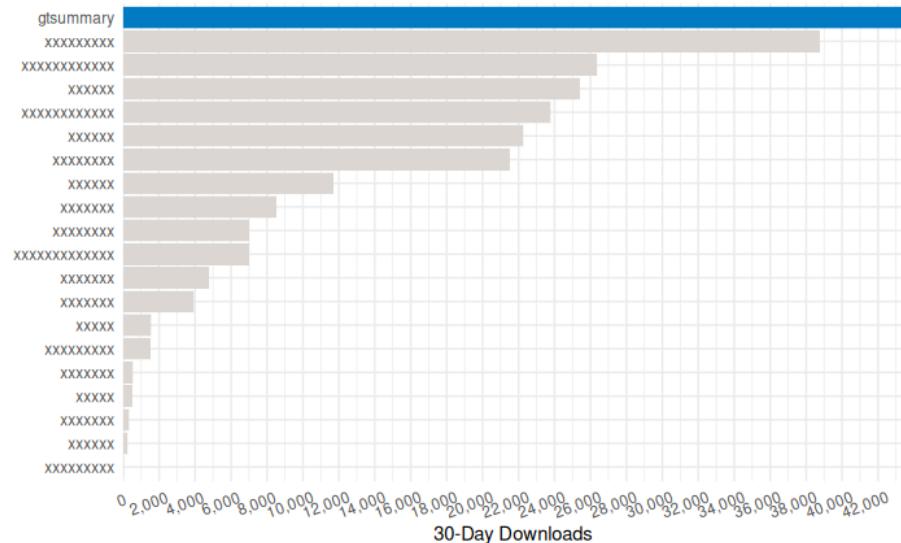
# {gtsummary}



- Widely adopted = more resources
- Consistent communication with the author
- Readable code
- Complex tables are easier to create using simpler tables
- Recently refactored to have an ARD backbone
- Compatibility with {cards} and {cardx}

## 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*

If you can guess why we chose the name “cardinal”,  
drop in the chat (for bragging rights)

# **Current Progress**

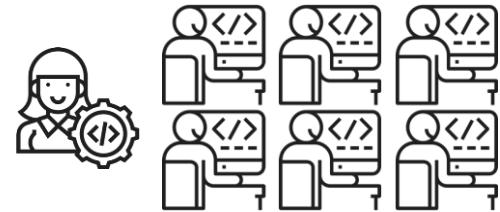
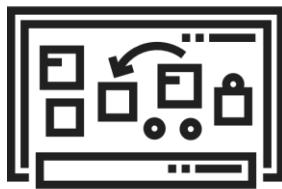
# Project Coordination

How does a cross-company team work?



## Product Owners

- Template prioritization
- Refine requirements
- Project roadmap

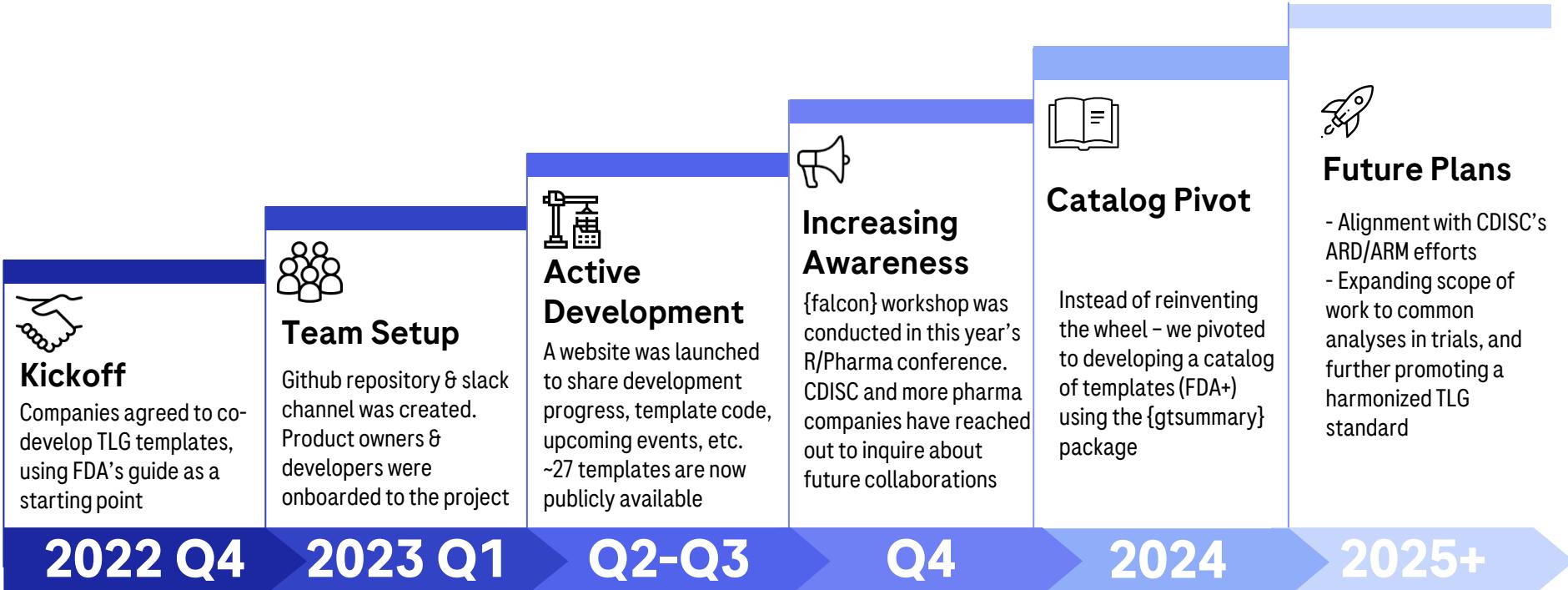


## Developers

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

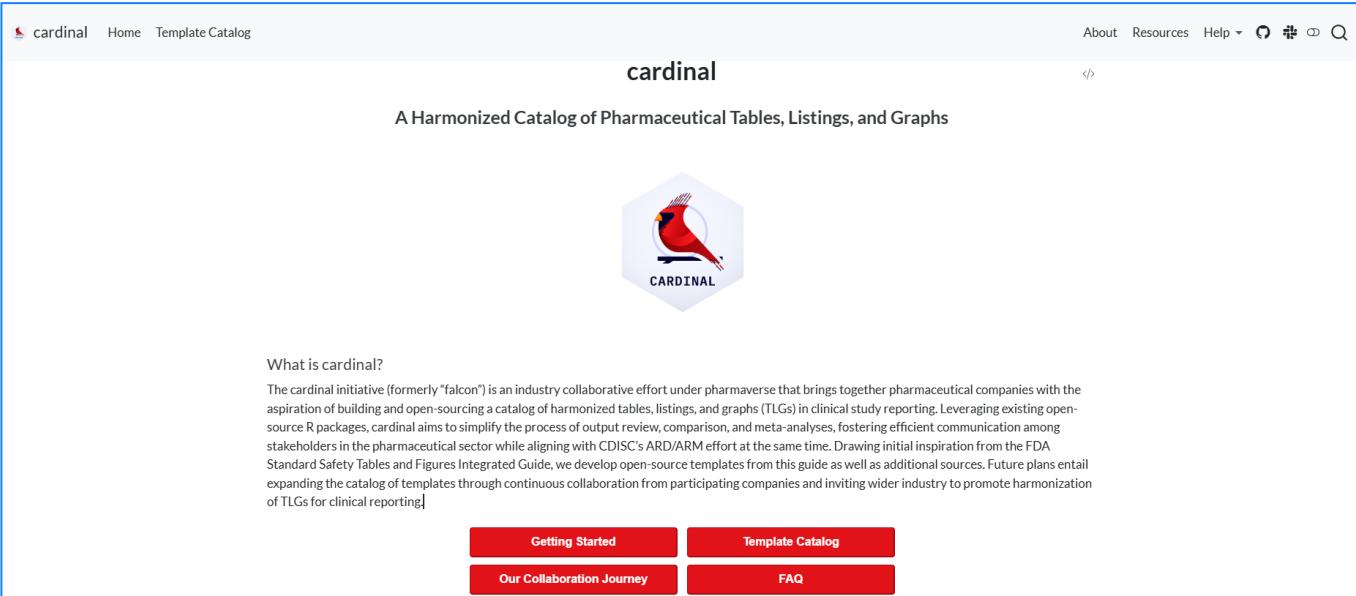
# Our Journey

What have we achieved so far?



# A Deeper Look

Explore cardinal in detail



The screenshot shows the homepage of the cardinal initiative. At the top, there is a navigation bar with links for "About", "Resources", "Help", and search icons. The main title "cardinal" is centered above a subtitle "A Harmonized Catalog of Pharmaceutical Tables, Listings, and Graphs". Below the subtitle is a logo featuring a red cardinal bird inside a hexagonal frame with the word "CARDINAL" at the bottom. A section titled "What is cardinal?" provides a detailed explanation of the initiative's purpose and goals, mentioning its industry collaboration, harmonization efforts, and alignment with CDISC's ARD/ARM effort. At the bottom, there are four red buttons labeled "Getting Started", "Template Catalog", "Our Collaboration Journey", and "FAQ".

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

# Template Catalog

**Template Catalog**

Order ByFilter

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/>

# Catalog Entry

**Demographics and Baseline Clinical Characteristics, Safety Population,  
Pooled Analysis (or Trial X)** </>

FDA Table 02

TABLE FDA SAFETY DEMOGRAPHICS

Table Preview Setup Build Table Build ARD

Characteristic	A: Drug X N = 134	B: Placebo N = 134	C: Combination N = 132	Total Population N = 400
Sex				
F	79 (59%)	82 (61%)	70 (53%)	231 (58%)
M	55 (41%)	52 (39%)	62 (47%)	169 (42%)
Age				
Mean (SD)	34 (7)	35 (8)	35 (8)	35 (7)
Median (Min, Max)	33 (21, 50)	35 (21, 62)	35 (20, 69)	34 (20, 69)
Age Group, Years				
>=17 to <65	134 (100%)	134 (100%)	131 (99%)	399 (100%)
65-74	0 (0%)	0 (0%)	1 (0.8%)	1 (0.3%)
>=75	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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

# Data Setup

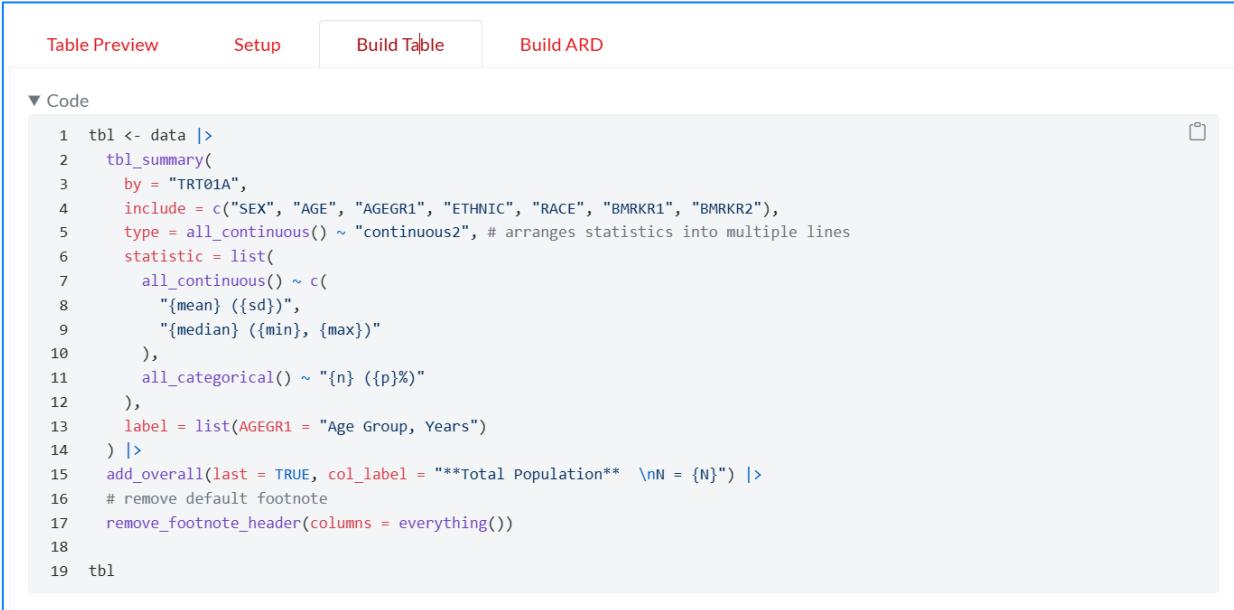


The screenshot shows a user interface for data setup. At the top, there are four tabs: "Table Preview" (red), "Setup" (white, selected), "Build Table", and "Build ARD". Below the tabs is a section titled "▼ Code" containing the following R code:

```
1 # Load libraries & data -----
2 library(dplyr)
3 library(gtsummary)
4
5 adsl <- random.cdisc.data::cadsl |>
6   mutate(
7     AGEGR1 = factor(
8       case_when(
9         AGE >= 17 & AGE < 65 ~ ">=17 to <65",
10        AGE >= 65 & AGE < 75 ~ "65-74",
11        AGE >= 75 ~ ">=75"
12      ),
13      levels = c(">=17 to <65", "65-74", ">=75")
14    )
15  )
16
17 # Pre-processing -----
18 # Filter for the safety population, x
19 data <- adsl |>
20   filter(SAFFL == "Y")
```

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

# Build Table



The screenshot shows a software interface for building a table. At the top, there are four tabs: 'Table Preview', 'Setup', 'Build Table' (which is highlighted in blue), and 'Build ARD'. Below the tabs, there is a section titled '▼ Code' containing the following R code:

```
1  tbl <- data |>
2    tbl_summary(
3      by = "TRT01A",
4      include = c("SEX", "AGE", "AGEGR1", "ETHNIC", "RACE", "BMRKR1", "BMRKR2"),
5      type = all_continuous() ~ "continuous2", # arranges statistics into multiple lines
6      statistic = list(
7        all_continuous() ~ c(
8          "{mean} ({sd})",
9          "{median} ({min}, {max})"
10        ),
11        all_categorical() ~ "{n} ({p}%)"
12      ),
13        label = list(AGEGR1 = "Age Group, Years")
14    ) |>
15    add_overall(last = TRUE, col_label = "***Total Population**\nN = {N}") |>
16    # remove default footnote
17    remove_footnote_header(columns = everything())
18
19  tbl
```

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

# Extract ARD

Table Preview      Setup      Build Table      Build ARD

▼ Code

```
1 ard <- gather_ard(tbl)
2 ard
```

\$tbl\_summary

{cards} data frame: 347 x 12

	group1	group1_level	variable	variable_level	context	stat_name	stat_label	stat	fmt_fun	warning	error	gts_column
1	TRT01A	A: Drug X	SEX		F tabulate	n	n	79	<fn>		stat_1	
2	TRT01A	A: Drug X	SEX		F tabulate	N	N	134	<fn>		stat_1	
3	TRT01A	A: Drug X	SEX		F tabulate	p	%	0.59	<fn>		stat_1	
4	TRT01A	A: Drug X	SEX		M tabulate	n	n	55	<fn>		stat_1	
5	TRT01A	A: Drug X	SEX		M tabulate	N	N	134	<fn>		stat_1	
6	TRT01A	A: Drug X	SEX		M tabulate	p	%	0.41	<fn>		stat_1	
7	TRT01A	A: Drug X	RACE		ASIAN tabulate	n	n	68	<fn>		stat_1	
8	TRT01A	A: Drug X	RACE		ASIAN tabulate	N	N	134	<fn>		stat_1	
9	TRT01A	A: Drug X	RACE		ASIAN tabulate	p	%	0.507	<fn>		stat_1	
10	TRT01A	A: Drug X	RACE	BLACK OR...	tabulate	n	n	31	<fn>		stat_1	

i 337 more rows

<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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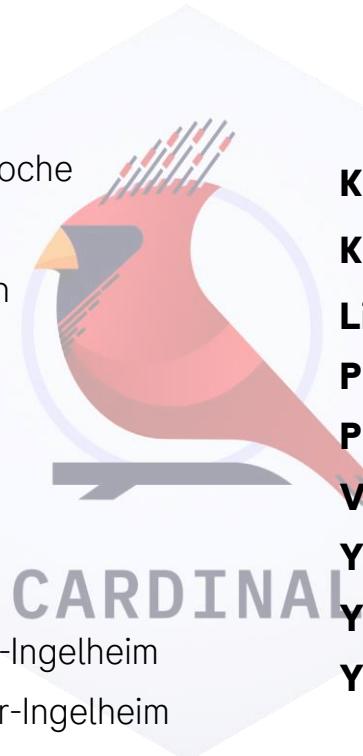
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**Juergen Boehl** - Boehringer-Ingelheim



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**Yuye Wang** - Moderna

# Technical Overview

