

Welcome!



Cardinal

A Collaborative Leap Towards Harmonization of Clinical Reporting Standards

Abi Yogasekaram, Roche
Emily de la Rua, Roche

November 3 2025

Instructors

Abinaya Yogasekaram



linkedin.com/in/ayogasek



github.com/ayogasekaram



Emily de la Rua



linkedin.com/in/emilydelarua



github.com/edularua



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

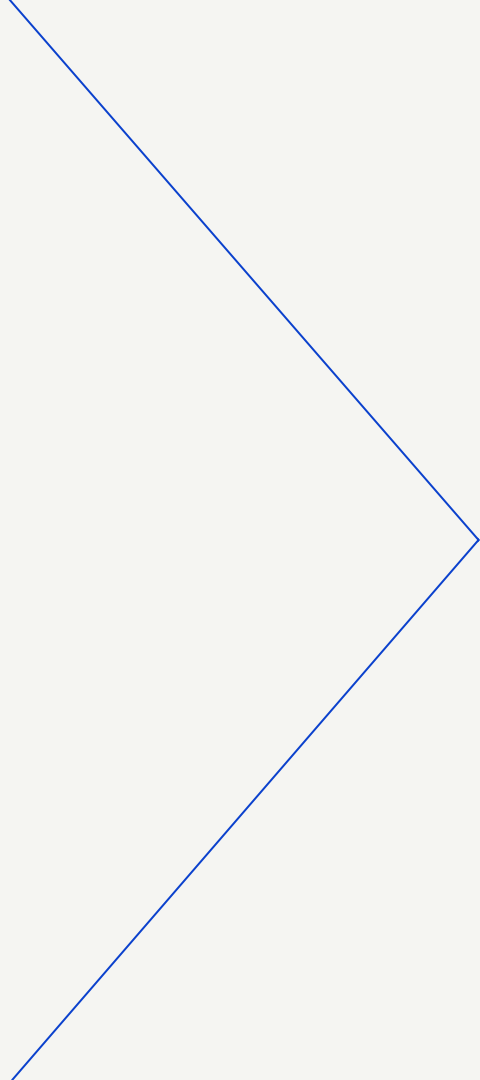


Please ask questions at any time!



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

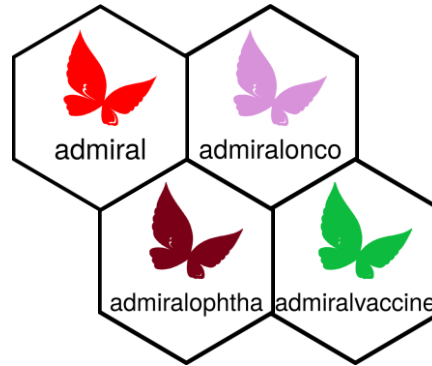
History & Motivation



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 XX Baseline Demographics and Characteristics Safety Set			
Age (Years)			
n	XX (XX.X)	XX	
Mean (SD)	XX.X		
Median	XX.X		
Min, Max	XX.X		
Age Group, n (%)			
<<Age breakdown 1 per protocol>>	XX (XX.X)		
<<Age breakdown 1 per protocol>>	XX (XX.X)		
.....	XX (XX.X)		
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.X (XX.X)	XX.X, XX.X	
Mean (SD)	XX.X		
Median	XX.X, XX.X		
Min, Max	XX.X, XX.X		

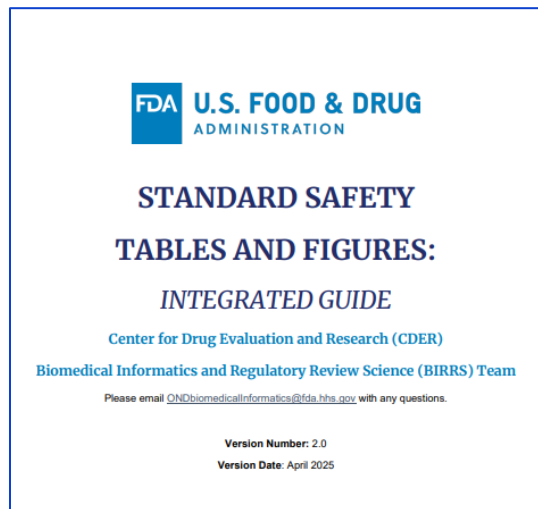
	A: Drug X (N=134)	B: Placebo (N=134)	C: Comb (N=134)
Age (yr)			
n	134	134	132
Mean (SD)	33.8 (6.6)	35.4 (7.9)	35.4 (7.9)
Median	33.0	35.0	35.0
Min - Max	21.0 - 50.0	21.0 - 62.0	20.0 - 69.0
Age Group			
n	134	134	132
18-40	113 (84.3%)	103 (76.9%)	106 (80.3%)
41-64	21 (15.7%)	31 (23.1%)	26 (19.7%)
>=65	0	0	0
Sex			
n	134	134	132
Female	79 (59%)	82 (61.2%)	76 (57.6%)
Male	55 (41%)	52 (38.8%)	56 (42.4%)
Ethnicity			
n	134	134	132
NOT REPORTED	6 (4.5%)	10 (7.5%)	11 (8.3%)
HISPANIC OR LATINO	15 (11.2%)	18 (13.4%)	15 (11.4%)
NOT HISPANIC OR LATINO	104 (77.6%)	103 (76.9%)	101 (76.3%)
UNKNOWN	9 (6.7%)	3 (2.2%)	5 (3.8%)
Race			
n	134	134	132
ASIAN	68 (50.7%)	67 (50%)	73 (55.3%)
BLACK OR AFRICAN AMERICAN	31 (23.1%)	28 (20.9%)	32 (24.3%)
WHITE	27 (20.1%)	26 (19.4%)	21 (15.9%)
AMERICAN INDIAN OR ALASKA NATIVE	8 (6%)	11 (8.2%)	6 (4.6%)
MULTIPLE	0	1 (0.7%)	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	1 (0.7%)	0
OTHER	0	0	0
UNKNOWN	0	0	0
Continuous Level Biomarker 1			
n	134	134	132
Mean (SD)	6.0 (3.6)	5.7 (3.3)	5.6 (3.0)
Median	5.4	4.8	4.8
Min - Max	0.4 - 17.7	0.6 - 14.2	0.2 - 14.2

2.1.4.2.1 Example: Demographic data				
	Drug A	Drug B	Total	
Number of subjects (N, %)	142	100.0 219	100.0 361	100.0
Sex (N, %)	142	100.0 219	100.0 361	100.0
Male	111	78.2 173	79.0 284	78.7
Female	31	21.8 46	21.0 77	21.3
Race (N, %)	142	100.0 219	100.0 361	100.0
White	0	0.0 1	0.5 1	0.3
Black or African American	8	5.6 11	5.0 19	5.3
American Indian or Alaska Native	8	77.5 169	77.2 279	77.3
Asian	24	16.9 38	17.4 62	17.2
Native Hawaiian or Other Pacific Islander	142	100.0 219	100.0 361	100.0
Other	110	77.5 169	77.2 279	77.3
Unknown / Not Reported	10	5.6 12	5.5 20	5.5
Ethnicity	142	100.0 219	100.0 361	100.0
Hispanic or Latino	110	77.5 169	77.2 279	77.3
Not Hispanic or Latino	32	16.9 38	17.4 62	17.2

Demographic data, data of baseline and medication details				
Demographics and patient characteristics at baseline - Randomized population				
	A: Drug X (N=133)	B: Placebo (N=141)	C: Combination (N=126)	All (N=400)
Age (years)				
Number	133	141	126	400
Mean (SD)	35.4 (7.5)	34.9 (7.4)	34.3 (7.4)	34.9 (7.4)
Median	34.0	34.0	33.0	34.0
Q1; Q3	29.0; 40.0	30.0; 39.0	29.0; 38.0	29.0; 39.0
Min; Max	21; 58	20; 62	23; 69	20; 69
Age group (n (%))				
Number	133	141	126	400
From 18 - 64 years	133 (100)	141 (100)	125 (99.2)	399 (99.8)
From 65 - 84 years	0	0	1 (0.8)	1 (0.2)
Sex (n (%))				
Number	133	141	126	400
Male	56 (42.1)	66 (46.8)	47 (37.3)	169 (42.2)
Female	77 (57.9)	75 (53.2)	79 (62.7)	231 (57.8)
Race (n (%))				
Number	133	141	126	400
White	70 (52.6)	86 (61.0)	62 (49.2)	218 (54.5)
Black or African American	28 (21.1)	28 (19.9)	24 (19.0)	80 (20.0)
Asian	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)
Native Hawaiian or Other Pacific Islander	1 (0.8)	0	0	1 (0.2)
Other	0	0	0	0
Unknown / Not Reported	0	0	0	0

An Opportunity Arose

FDA proposed an integrated guide for standard safety tables & figures



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***

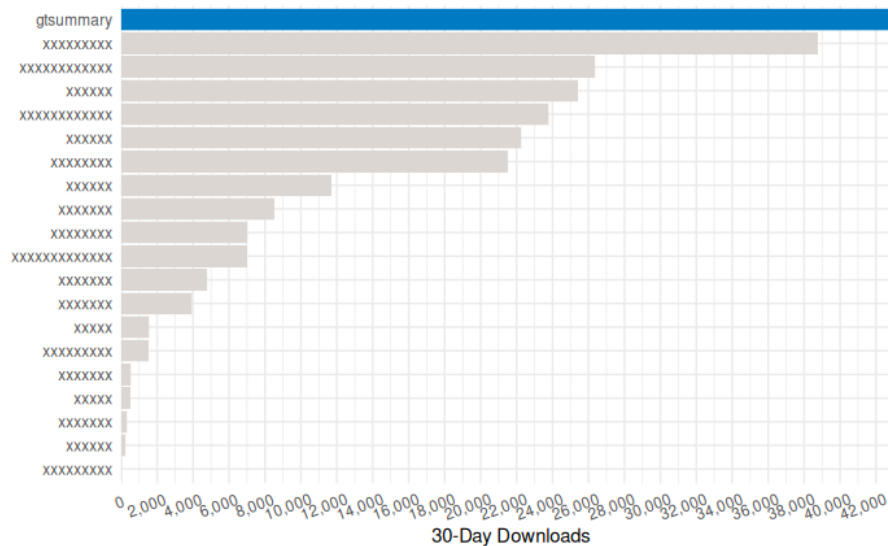
{gtsummary}



- 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

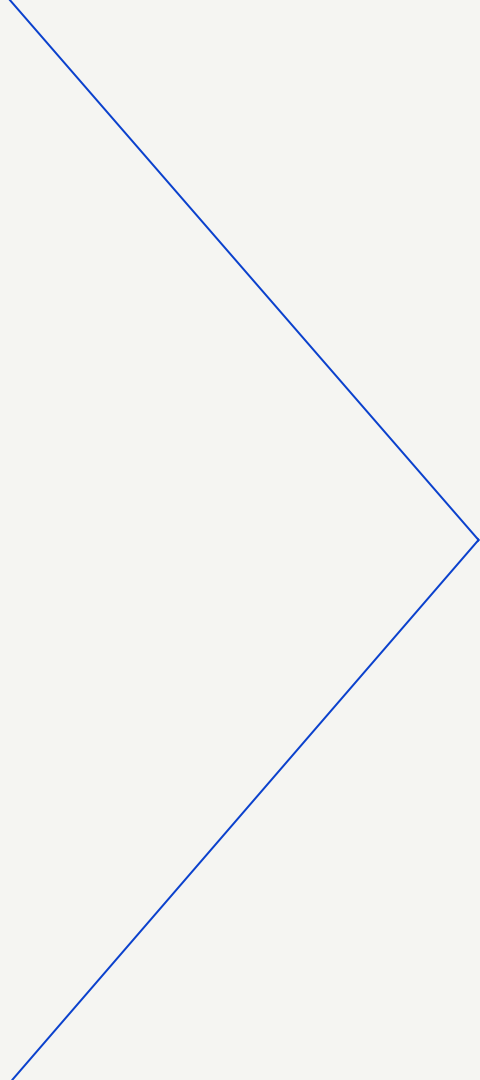
First industry collaborative effort for TLG creation



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



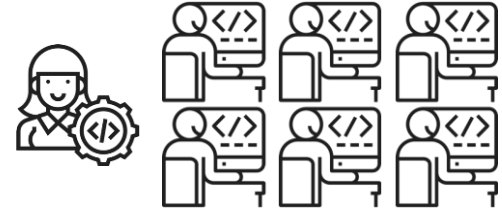
Project Coordination

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?



Kickoff

Companies agreed to co-develop TLG templates, using FDA's guide as a starting point

2022 Q4



Team Setup

Github repository & slack channel was created. Product owners & developers were onboarded to the project

2023 Q1



Active Development

A website was launched to share development progress, template code, upcoming events, etc. ~27 templates are now publicly available

Q2-Q3



Increasing Awareness

{falcon} workshop was conducted in this year's R/Pharma conference. CDISC and more pharma companies have reached out to inquire about future collaborations

Q4



Catalog Pivot

Instead of reinventing the wheel - we pivoted to developing a catalog of templates (FDA+) using the {gtsummary} package

2024



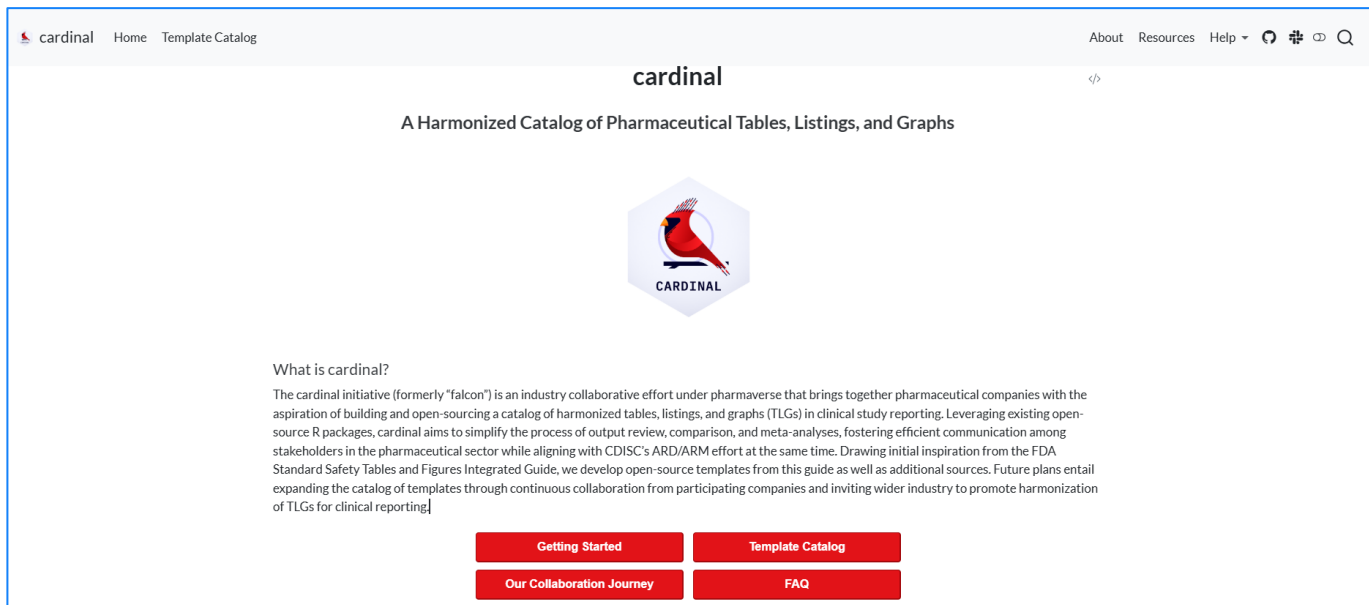
Future Plans

- Alignment with CDISC's ARD/ARM efforts
- Expanding scope of work to common analyses in trials, and further promoting a harmonized TLG standard

2025+

A Deeper Look

Explore cardinal in detail



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

Template Catalog

Template Catalog			</>
1F	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/>

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

Table Preview Setup Build Table Build ARD

▼ Code

```
1 # Load libraries & data -----
2 library(dplyr)
3 library(gtsummary)
4
5 adsl <- random.cdisc.data::cads1 |>
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

Table Preview Setup **Build Table** Build ARD

▼ 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

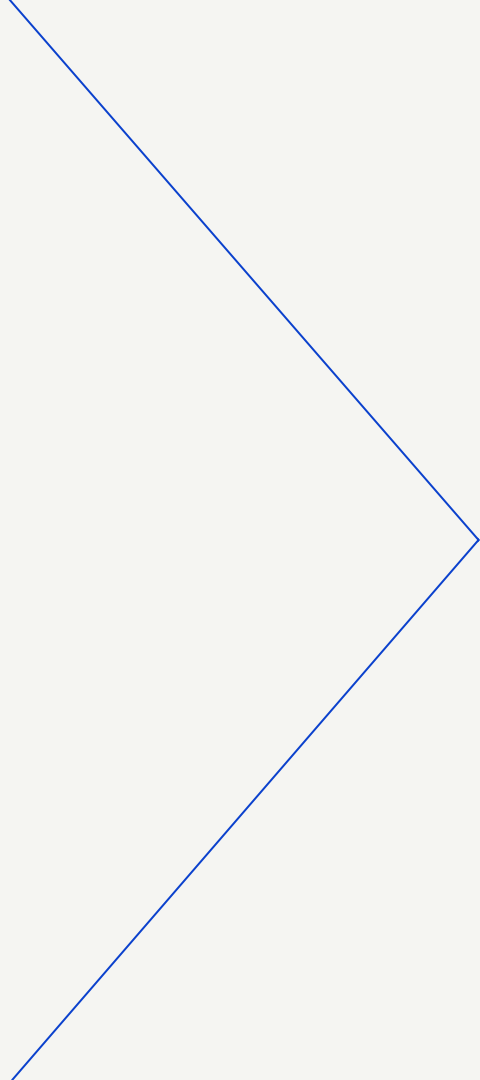
{cards} data frame: 347 x 12

	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

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

Abinaya Yogasekaram - Roche

Alex Assuied - Sanofi

Daniel Sjoberg - Genentech

Emily de la Rua - Roche

Freeman Wang - Sanofi

Harsha Kalikivayi - Sanofi

Huan Lu - Sanofi

Jaime Pires - Roche

Jessica Knizia - Boehringer-Ingelheim

Juergen Boehl - Boehringer-Ingelheim



Kavitha Allala - Boehringer-Ingelheim

Korbinian Matthias - Boehringer-Ingelheim

Lian Lin - Moderna

Padmaja Chiruvolu - Amgen

Pawel Rucki - Roche

Vincent Shen - Roche

Yichen Wang - Moderna

Yoshito Koujin - Boehringer-Ingelheim

Yuye Wang - Moderna

Technical Overview

