Welcome!

Cardinal

A Collaborative Leap Towards Harmonization of Clinical Reporting Standards

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November 3 2025

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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

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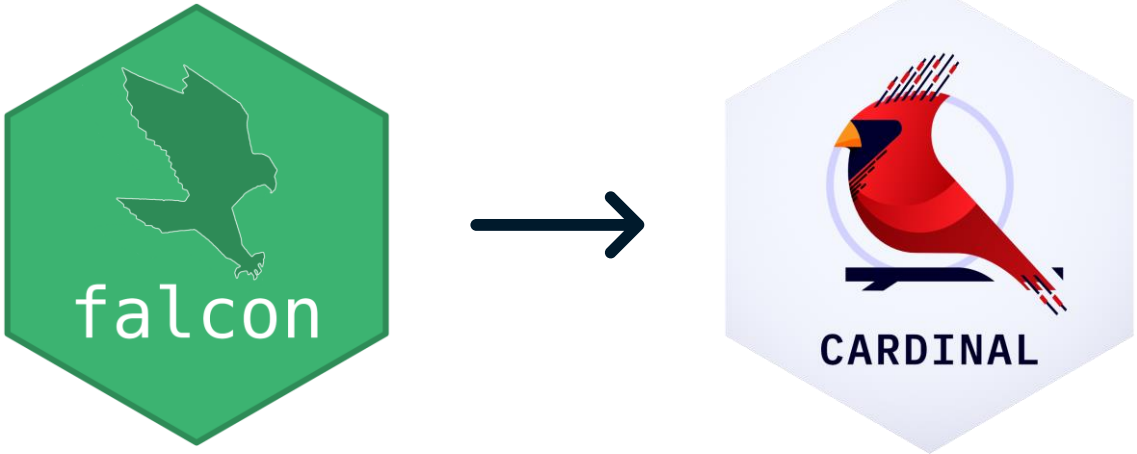
Formerly {falcon}



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!

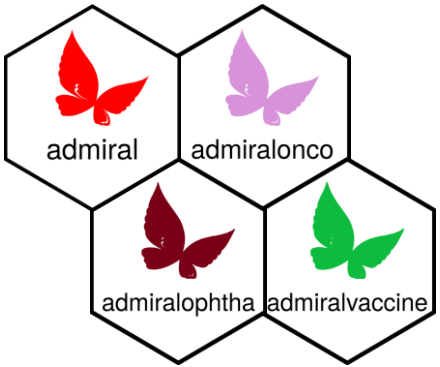
Turn your cameras on if you're comfortable! We'd love to see you ☺

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



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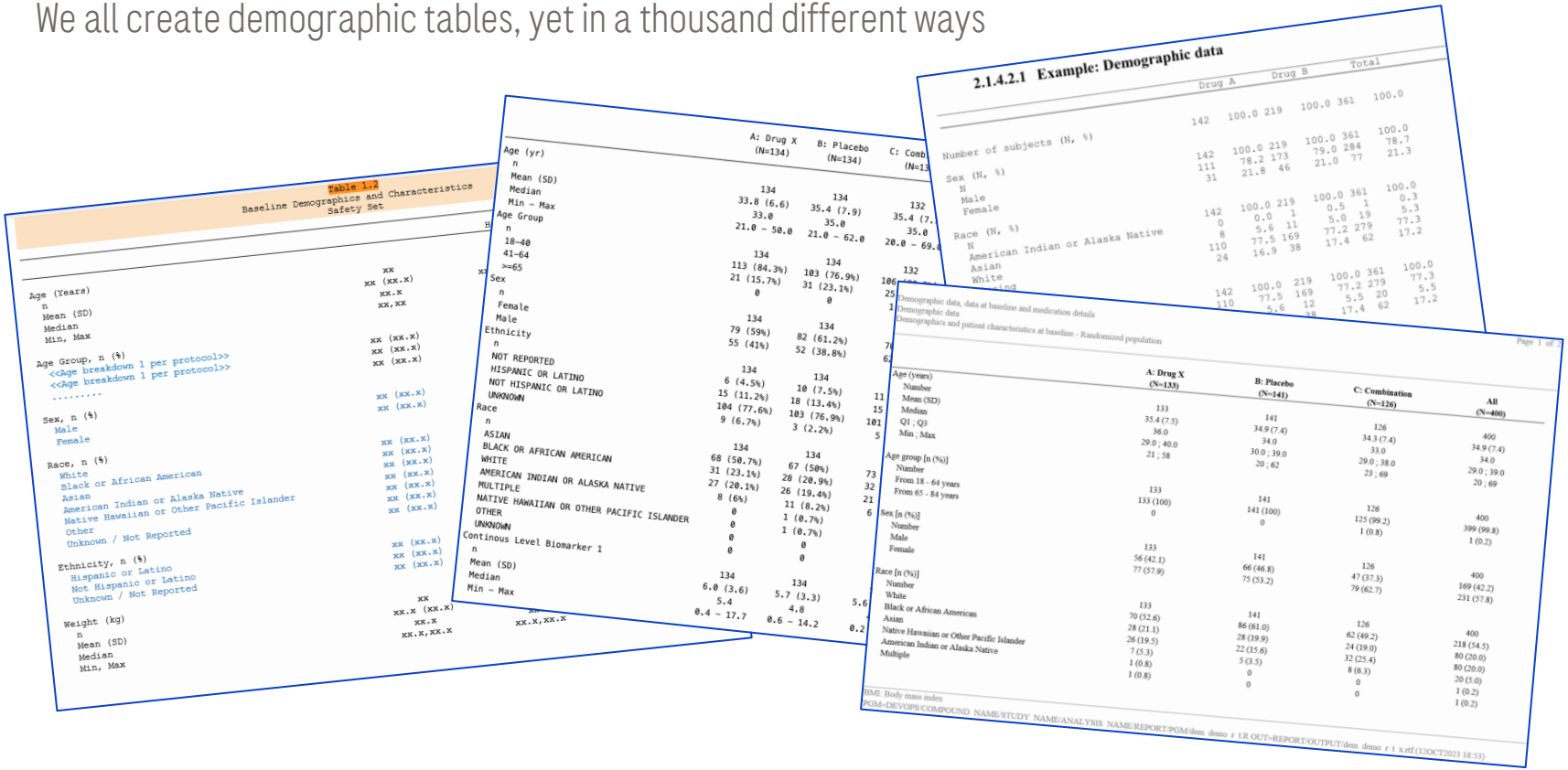
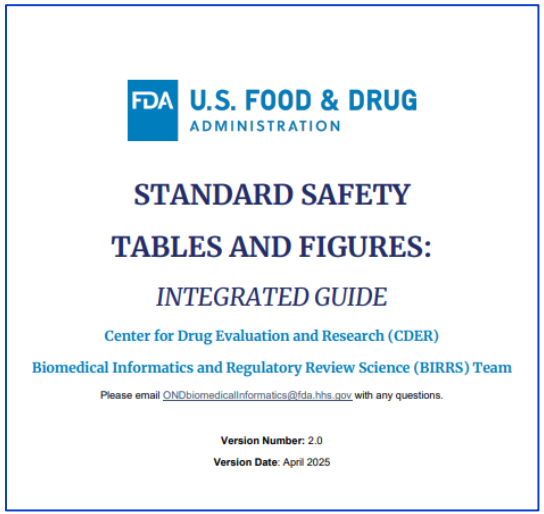
How About TLGs?

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

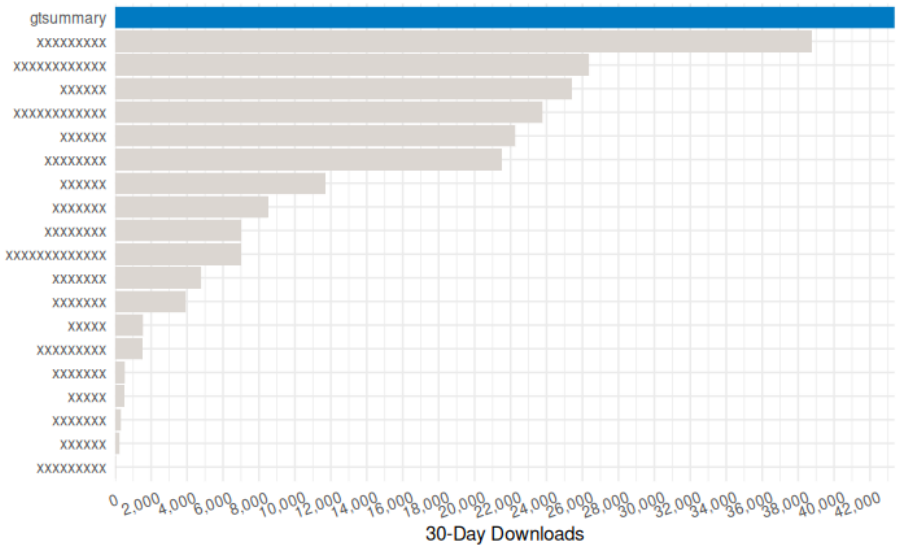
Rather than developing {falcon} to accommodate different table engines – use a ***single package***

{gtsummary}

- 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



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First industry collaborative effort for TLG creation

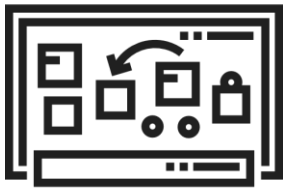
An industry collaborative effort with the aspiration of open-sourcing a catalog of harmonized TLGs for clinical study reporting and simplifying the process of output review, re-use, and meta-analyses

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

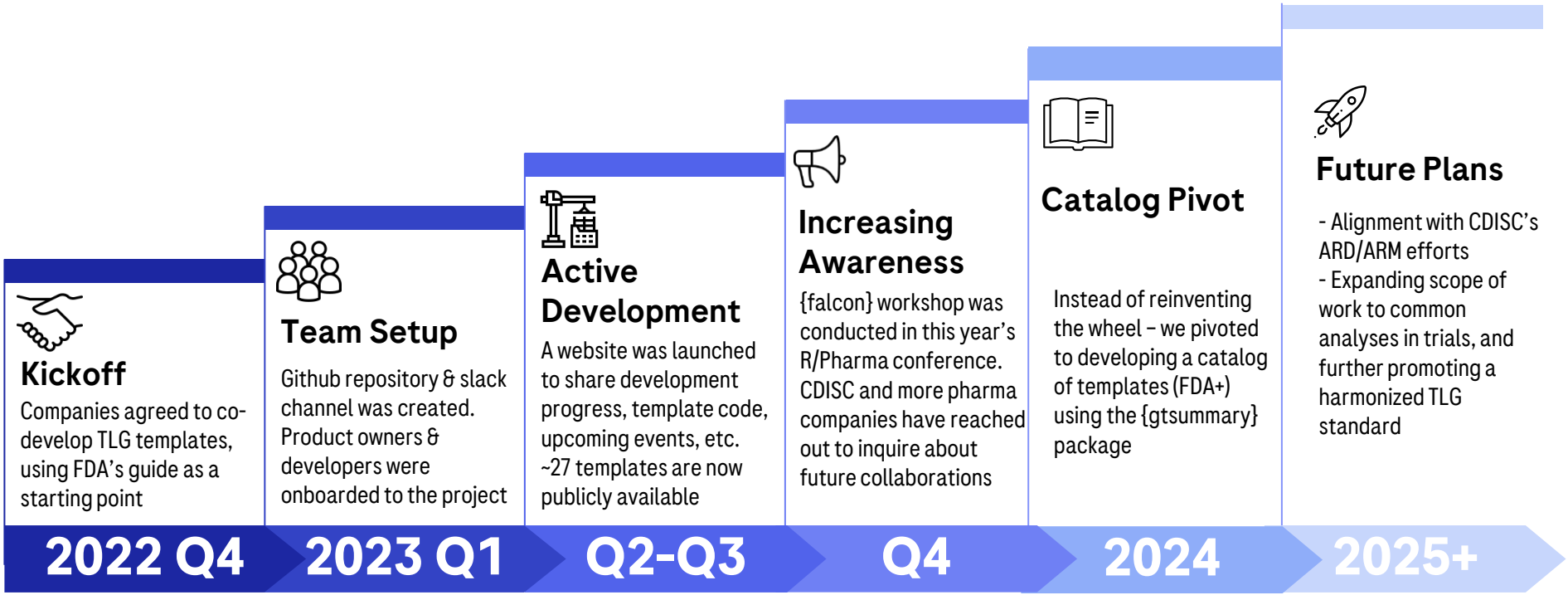
- Template prioritization
- Refine requirements
- Project roadmap

Developers

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

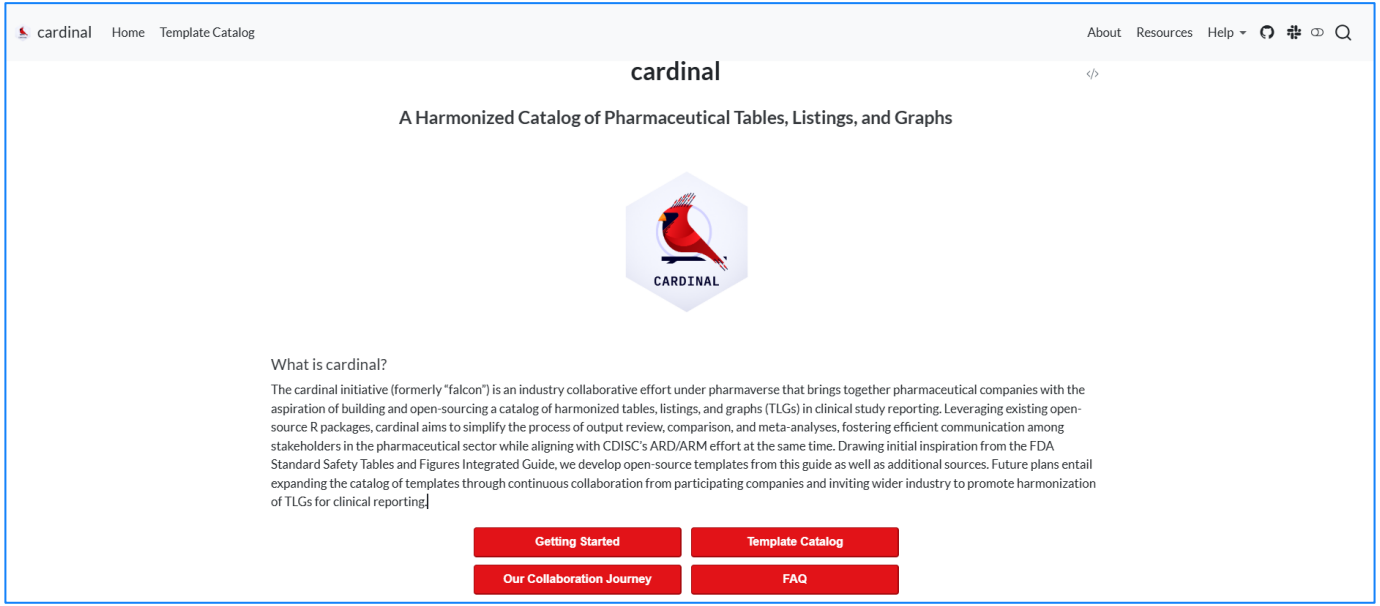
Our Journey

What have we achieved so far?



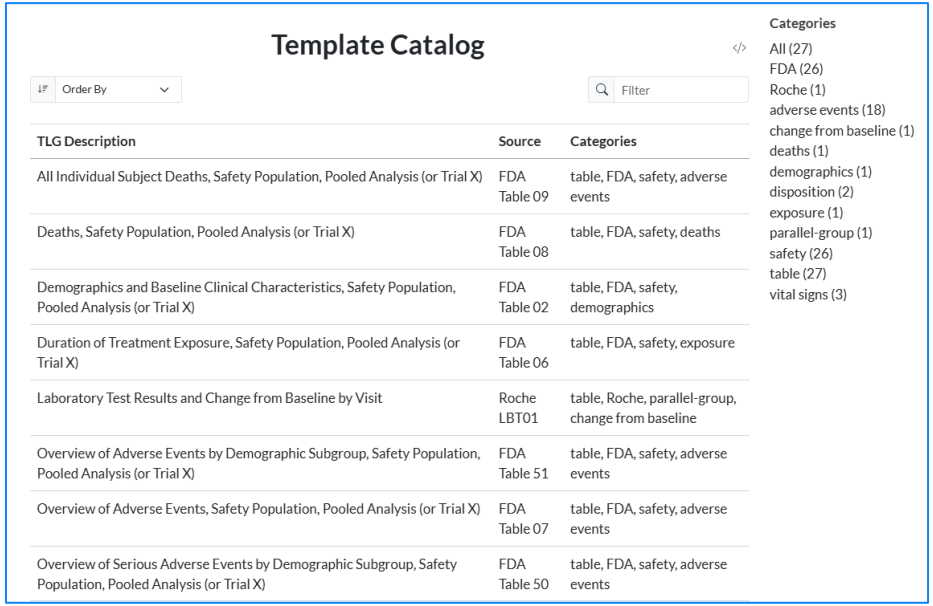
A Deeper Look

Explore cardinal in detail



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)

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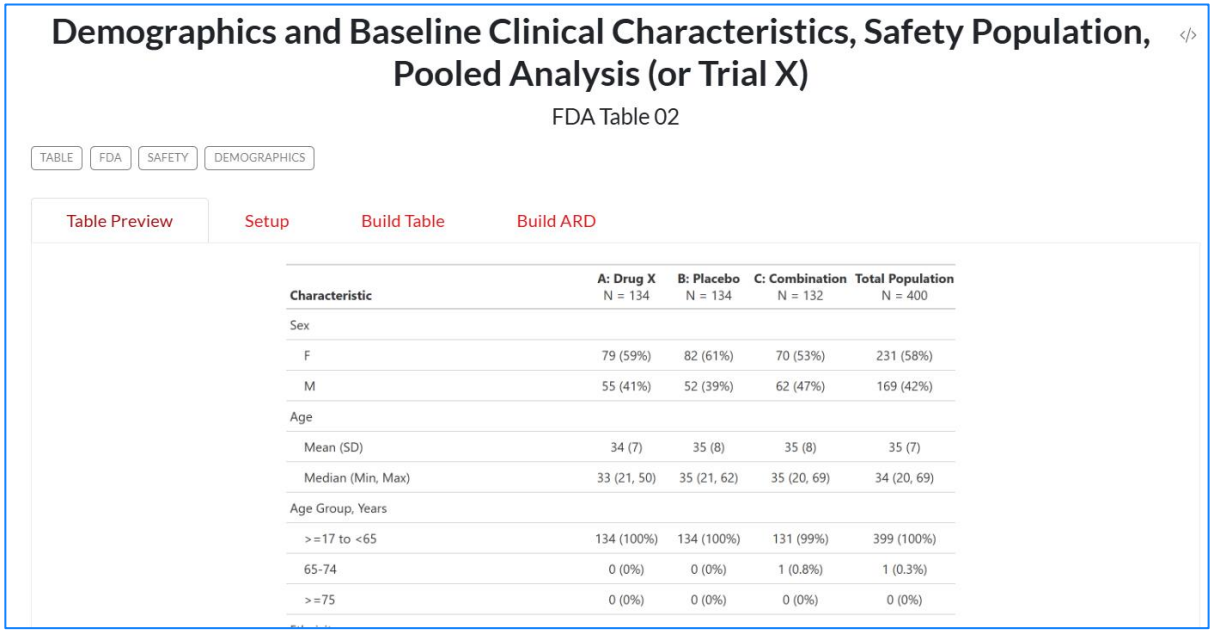
Catalog Entry



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%)

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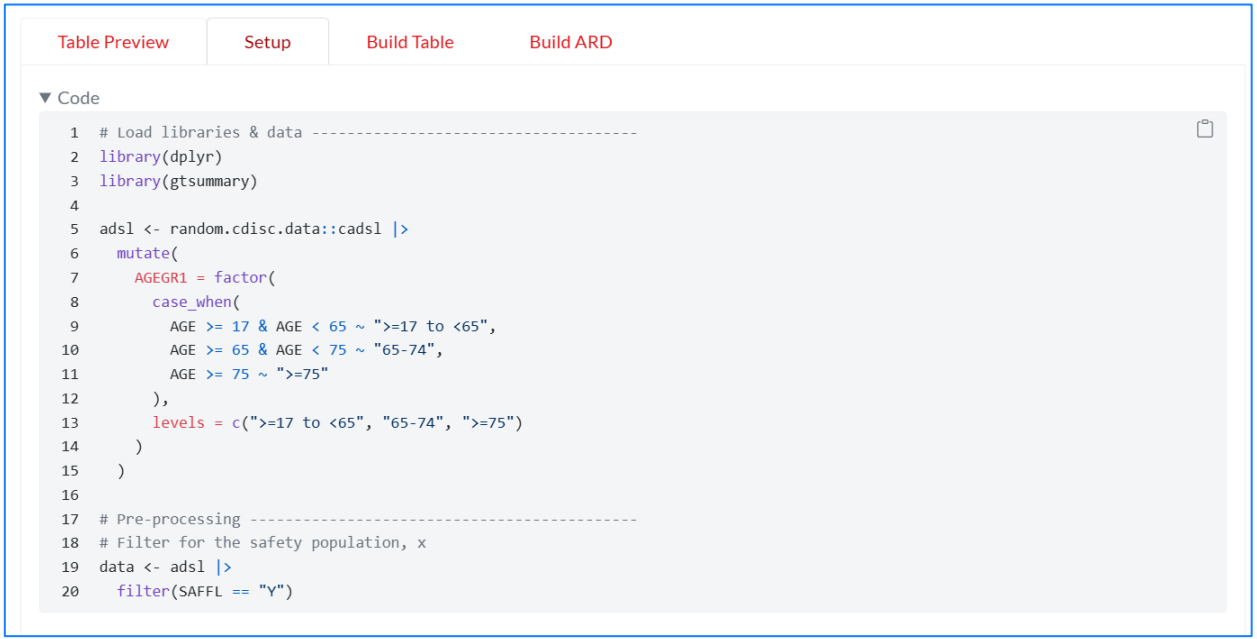
Data Setup

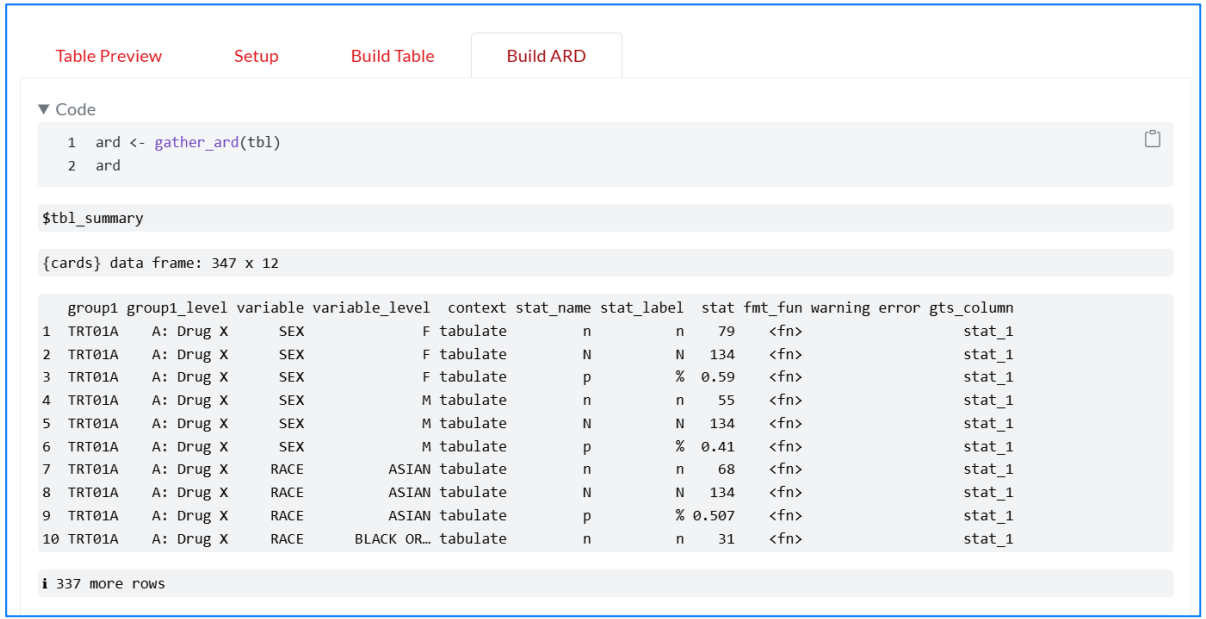


https://pharmaverse.github.io/cardinal/

Build Table

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

Extract ARD



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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