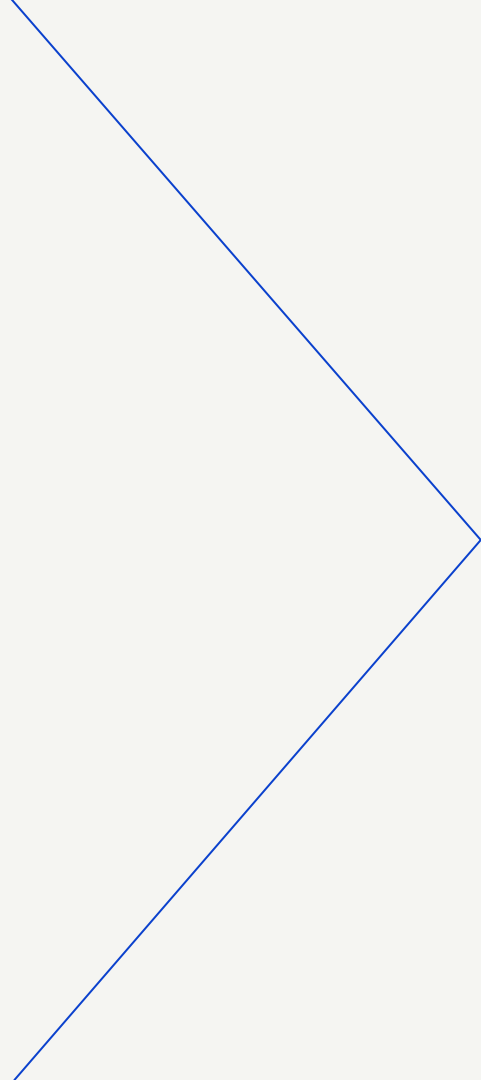


{falcon}: A Collaborative Leap Forward Towards Harmonization of Clinical Reporting Standards

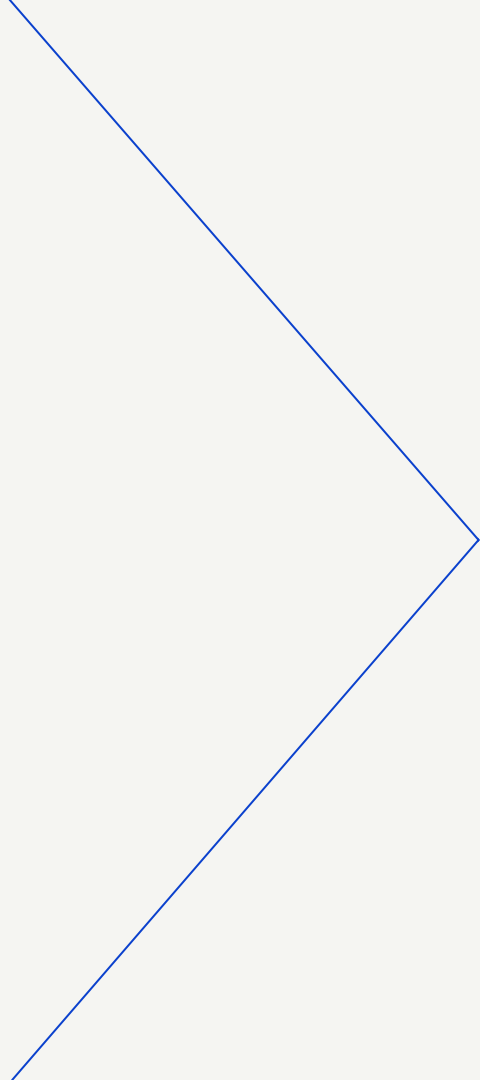
Vincent Shen, Roche
Juergen Boehl, Boehringer Ingelheim

Agenda



1. History & Motivation
2. Current Progress
3. Learnings, Outlook, & Call for Collaboration

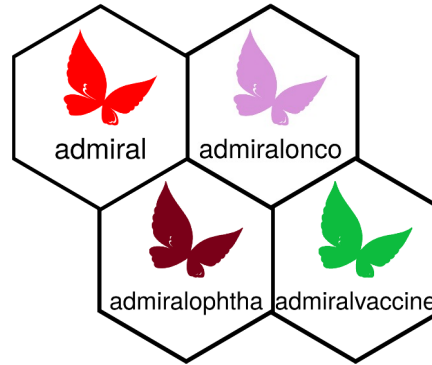
History & Motivation



Pharma Industry Has Very Well Established Data Standards

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

*Universally agreed 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

Table XX Baseline Demographics and Characteristics Safety Set			
Age (Years)			
n	XX (XX.X)		
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)		
Mean (SD)	XX.X (XX.X)		
Median	XX.X		
Min, Max	XX.X, XX.X		

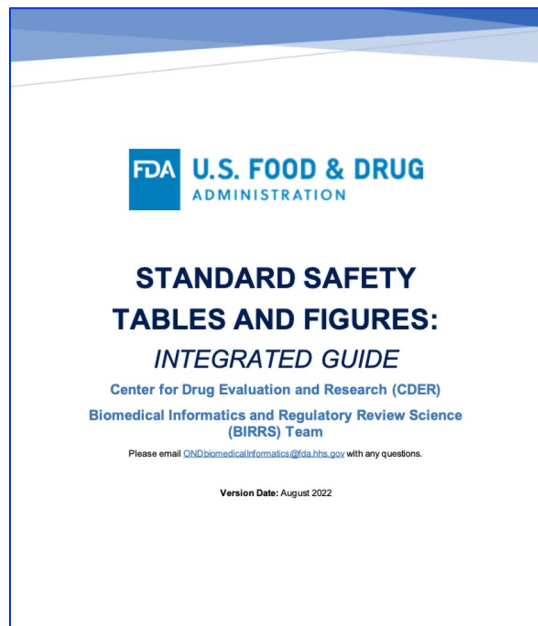
	A: Drug X (N=134)	B: Placebo (N=134)	C: Comb. (N=134)
Age (yr)			
n	134	134	132
Mean (SD)	33.8 (6.6)	35.4 (7.9)	35.4 (7.9)
Median	33.0	35.0	35.0
Min - Max	21.0 - 50.0	21.0 - 62.0	20.0 - 69.0
Age Group			
n	134	134	132
18-40	113 (84.3%)	103 (76.9%)	106 (80.3%)
41-64	21 (15.7%)	31 (23.1%)	26 (19.7%)
>=65	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%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	1 (0.7%)	0
OTHER	0	1 (0.7%)	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	
	142	100.0	219	100.0
Number of subjects (N, %)	142	100.0	219	100.0
Sex (N, %)	142	100.0	219	100.0
Male	111	78.2	173	79.0
Female	31	21.8	46	21.0
Race (N, %)	142	100.0	219	100.0
White	0	0.0	1	0.5
Black or African American	8	5.6	11	5.0
Asian	8	5.6	11	5.0
American Indian or Alaska Native	110	77.5	169	77.2
Native Hawaiian or Other Pacific Islander	24	16.9	38	17.4
Other	24	16.9	38	17.4
Unknown / Not Reported	142	100.0	219	100.0
Hispanic or Latino	110	77.5	169	77.2
Not Hispanic or Latino	31	21.8	46	21.0
Unknown / Not Reported	142	100.0	219	100.0
Weight (kg)	142	100.0	219	100.0
n	142	100.0	219	100.0
Mean (SD)	77.5	169	77.2	169
Median	5.6	12	5.5	20
Min, Max	18	17.4	62	17.2

Demographic data, data at 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	36.0	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)	126 (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)	77 (61.2)	169 (42.2)
Female	77 (57.9)	75 (53.2)	49 (38.8)	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)	26 (19.5)	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)
Native Hawaiian or Other Pacific Islander	1 (0.8)	0	0	1 (0.2)
Multiple	1 (0.8)	0	0	1 (0.2)

An Opportunity Arose

FDA proposed an integrated guide for standard safety tables & figures



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?

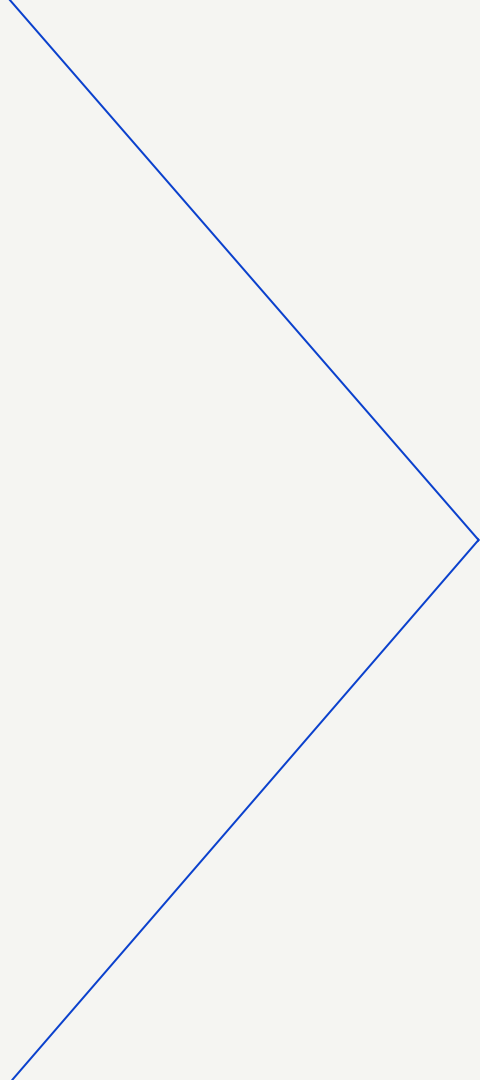
{falcon}

First industry collaborative effort for TLG creation



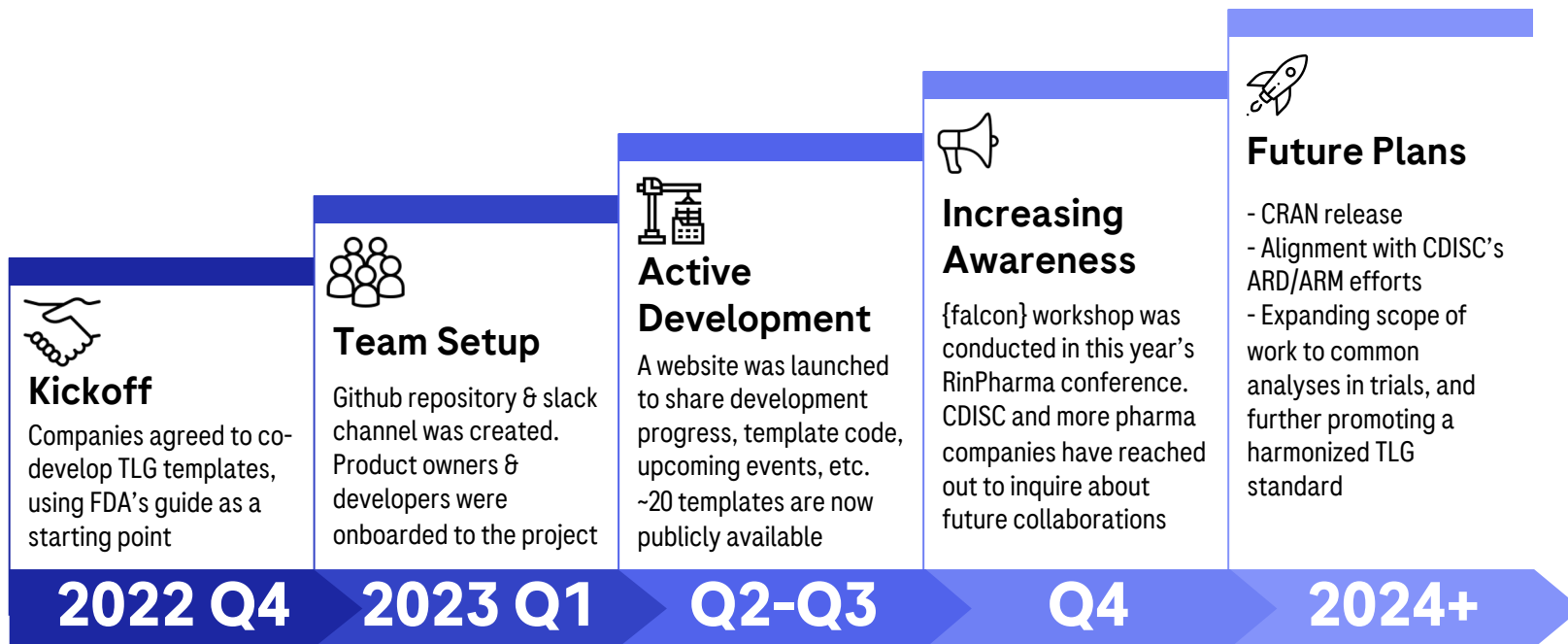
An industry collaborative effort with the aspiration of open-sourcing a catalog of harmonized TLGs for clinical study reporting and simplifying the process of output review, re-use, and meta-analyses

Current Progress



Our Journey

What have we achieved so far?



A Deeper Look

Explore {falcon} in detail

 falcon Home Template Library ▾ About Help ▾

falcon

Implementation of FDA Safety Tables and Figures



What is falcon?

The falcon initiative is an industry collaborative effort under pharmaVerse 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](#)

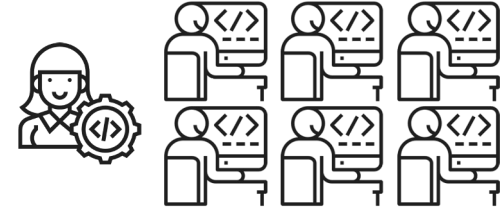
Project Coordination

How does a cross-company team work?



Product Owners

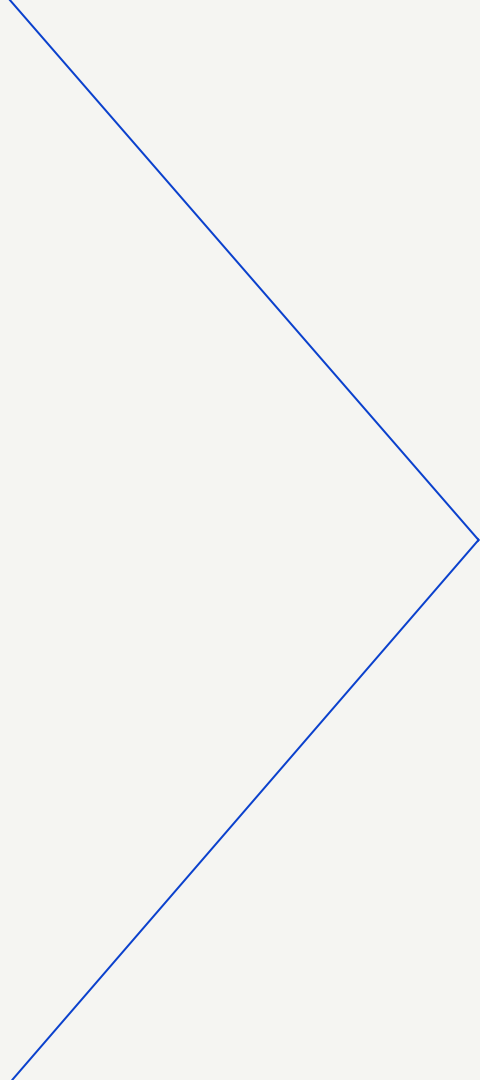
- Feature prioritization
- Refine requirements
- Project roadmap



Developers

- Agile package development
- Weekly standup meeting
- GitHub project board to track progress

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 {falcon}?



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/falcon/>

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Thank you!