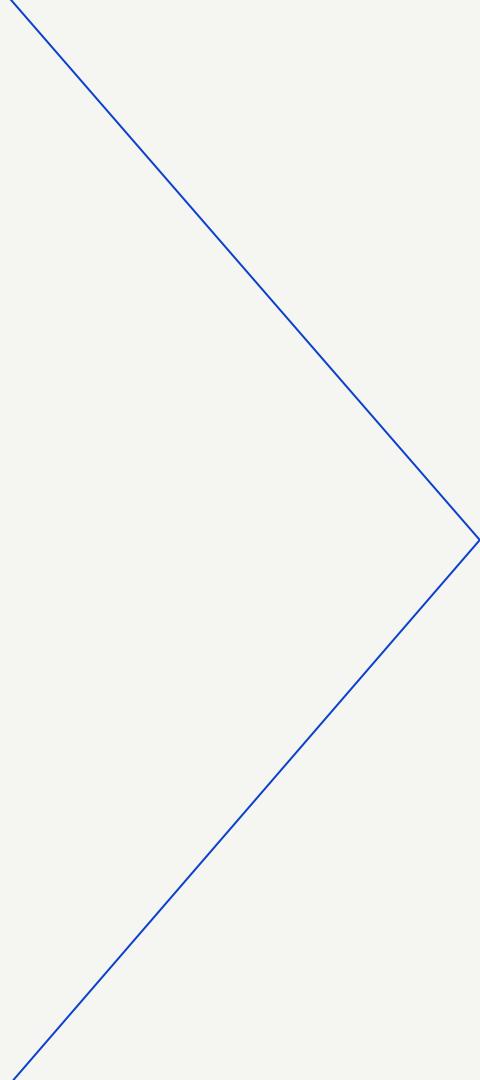


{falcon}: A Collaborative Leap Forward Towards Harmonization of Clinical Reporting Standards

Vincent Shen, Roche
Juergen Boehl, Boehringer Ingelheim

Agenda

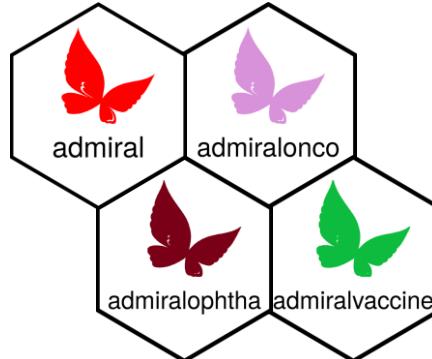
- 
1. History & Motivation
 2. Current Progress
 3. Learnings, Outlook, & Call for Collaboration

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 1.2 Baseline Demographics and Characteristics Safety Set		
Age (Years)	xx (xx,x)	
n	xx,x	
Mean (SD)	xx,xx	
Median		
Min, Max		
Age Group, n (%)	xx (xx,x)	
<<Age breakdown 1 per protocol>>	xx (xx,x)	
<<Age breakdown 1 per protocol>>	xx (xx,x)	
Sex, n (%)	xx (xx,x)	
Male	xx (xx,x)	
Female	xx (xx,x)	
Race, n (%)	xx (xx,x)	
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 (%)	xx (xx,x)	
Hispanic or Latino	xx (xx,x)	
Not Hispanic or Latino	xx (xx,x)	
Unknown / Not Reported	xx (xx,x)	
Weight (kg)	xx,x (xx,x)	
n	xx,x	
Mean (SD)	xx,xx,xx	
Median		
Min, Max		

	A: Drug X (N=134)	B: Placebo (N=134)	C: Comb. (N=132)
Age (yr)			
n			
Mean (SD)	33.8 (6.6)	35.4 (7.9)	35.4 (7.9)
Median	33.8	35.0	35.0
Min - Max	21.0 - 50.0	21.0 - 62.0	20.0 - 69.0
Age Group			
n			
18-40	134	134	132
41-64	113 (84.3%)	103 (76.9%)	106 (79.2%)
>=65	21 (15.7%)	31 (23.1%)	25 (20.8%)
Sex			
n			
Female	0	0	0
Male	134	134	132
Ethnicity			
n			
NOT REPORTED	79 (59%)	82 (61.2%)	82 (61.2%)
HISPANIC OR LATINO	55 (41%)	52 (38.8%)	52 (38.8%)
NOT HISPANIC OR LATINO			
UNKNOWN	104 (77.6%)	103 (76.9%)	101 (76.6%)
Race			
n			
ASIAN	6 (4.5%)	10 (7.5%)	11 (8.3%)
BLACK OR AFRICAN AMERICAN	31 (23.1%)	18 (13.4%)	27 (20.1%)
WHITE	68 (50.7%)	67 (50%)	73 (56.2%)
AMERICAN INDIAN OR ALASKA NATIVE	27 (20.1%)	28 (20.9%)	32 (24.2%)
MULTIPLE	8 (6%)	26 (19.4%)	21 (16.1%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	11 (8.2%)	0
OTHER	0	1 (0.7%)	1 (0.7%)
UNKNOWN	0	1 (0.7%)	0
Continuous Level Biomarker 1			
n			
Mean (SD)	6.0 (3.6)	5.7 (3.3)	5.6 (3.7)
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)
N	142 (100.0)	219 (100.0)	361 (100.0)
Male	0 (0.0)	1 (0.5)	1 (0.3)
Female	142 (100.0)	219 (100.0)	361 (100.0)
Race (N, %)	142 (100.0)	219 (100.0)	361 (100.0)
Asian	0 (0.0)	11 (5.0)	11 (3.1)
American Indian or Alaska Native	8 (5.6)	169 (77.2)	177 (49.1)
White	110 (77.5)	52 (23.7)	162 (44.4)
Black or African American	24 (16.9)	38 (17.4)	62 (17.2)

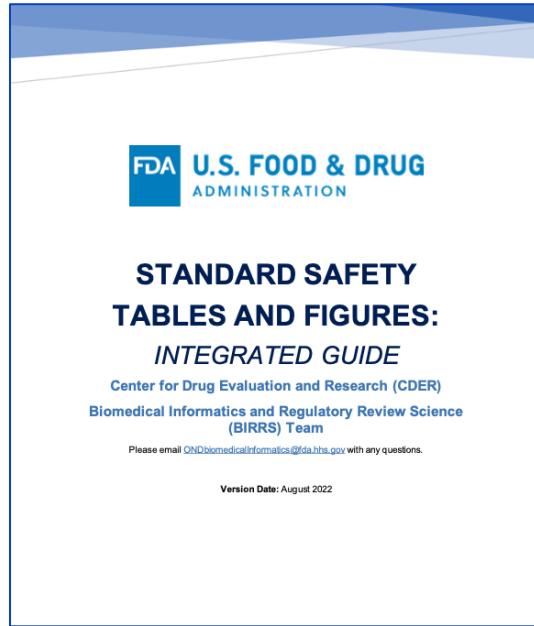
Demographic data, data at baseline and medication details
Demographic and patient characteristics at baseline - Randomized population

	A: Drug X (N=133)	B: Placebo (N=144)	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 (100)	141 (100)	126 (99.2)	400 (100)
From 18 - 64 years	0	0	1 (0.8)	399 (99.8)
From 65 - 84 years	133 (100)	141 (100)	126 (99.2)	400 (100)
Sex [n (%)]				
Number	133	141	126	400
Male	0	0	1 (0.8)	1 (0.2)
Female	133	141	126	399 (99.8)
Race [n (%)]				
Number	56 (42.1)	66 (46.8)	47 (37.3)	169 (42.2)
White	77 (57.8)	75 (53.2)	79 (62.7)	231 (57.8)
Black or African American	28 (21.1)	28 (19.9)	62 (49.2)	400 (100)
Asian	26 (19.5)	5 (3.5)	24 (18.9)	218 (54.5)
American Indian or Alaska Native	7 (5.3)	22 (15.6)	32 (25.4)	80 (20.0)
Native Hawaiian or Other Pacific Islander	1 (0.8)	5 (0.5)	8 (6.3)	80 (20.0)
Multiple	1 (0.8)	0	0	20 (5.0)
		0	0	1 (0.2)
		0	0	1 (0.2)

BMI: Body mass index
PGM=DEVS/COMPOUND NAME/STUDY NAME/ANALYSIS NAME/REPORT/PGM/dem demo r t R OUT-REPORT/OUTPUT/dem demo r t x.tif (13/05/2023 18:53)

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

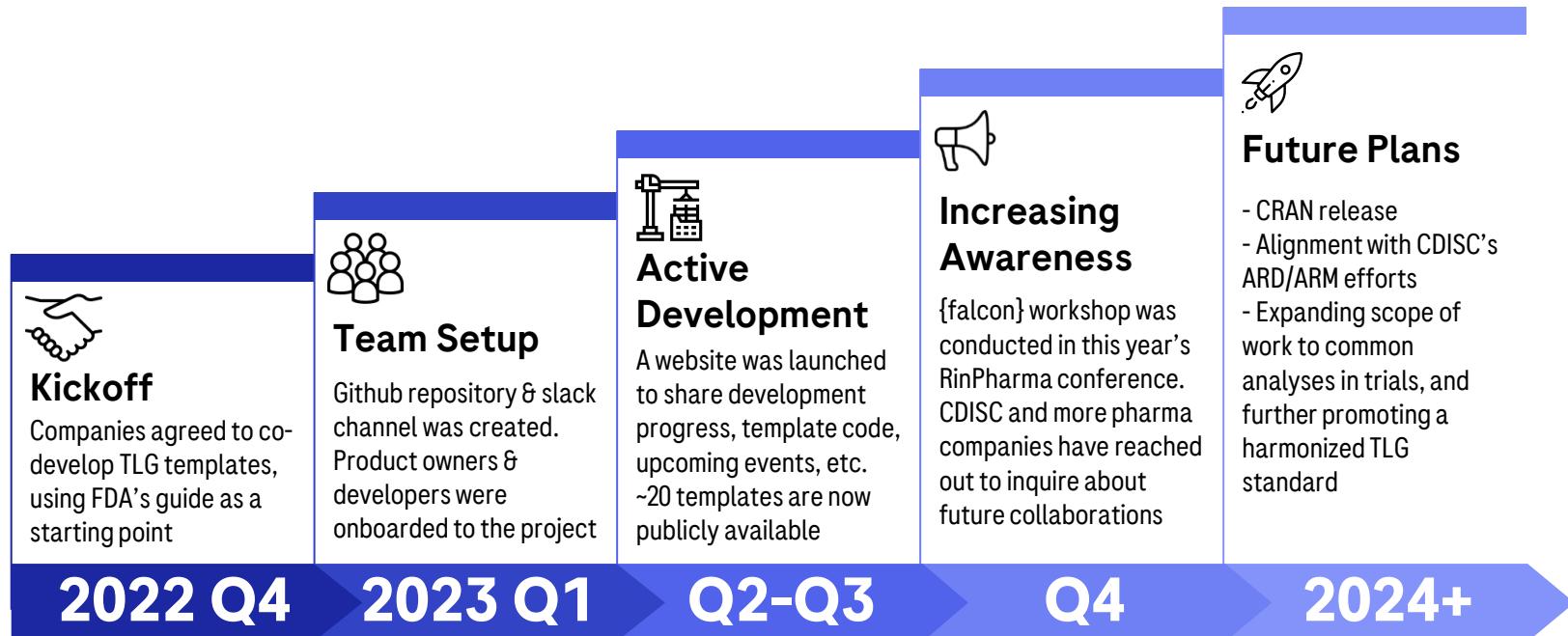


An industry collaborative effort with the aspiration of open-sourcing a catalog of harmonized TLGs for clinical study reporting and simplifying the process of output review, re-use, and meta-analyses

Current Progress

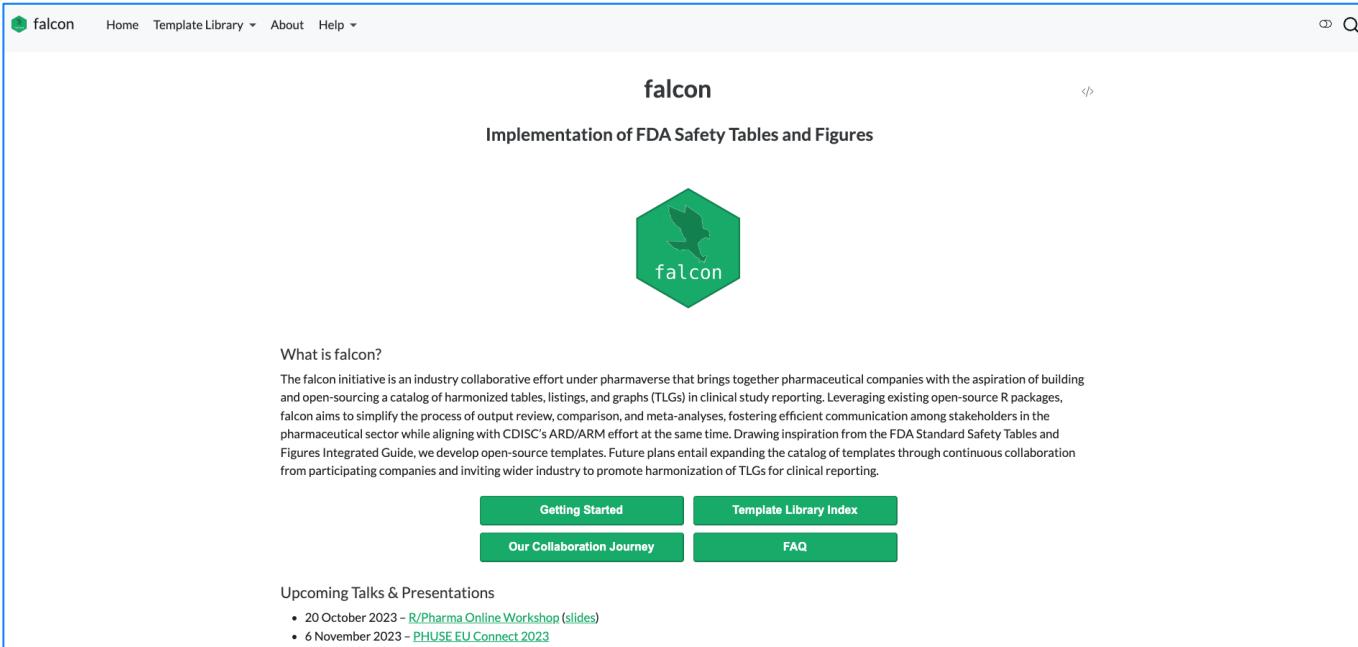
Our Journey

What have we achieved so far?



A Deeper Look

Explore {falcon} in detail



The screenshot shows the homepage of the falcon initiative. At the top, there is a navigation bar with links for Home, Template Library, About, and Help. To the right of the navigation bar is a search icon. The main title "falcon" is centered above the subtitle "Implementation of FDA Safety Tables and Figures". Below the subtitle is a green hexagonal logo featuring a stylized falcon in flight. A brief description follows: "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." Below this text are four green buttons: "Getting Started", "Template Library Index", "Our Collaboration Journey", and "FAQ". At the bottom, there is a section titled "Upcoming Talks & Presentations" with two items: "20 October 2023 – [R/Pharma Online Workshop \(slides\)](#)" and "6 November 2023 – [PHUSE EU Connect 2023](#)".

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

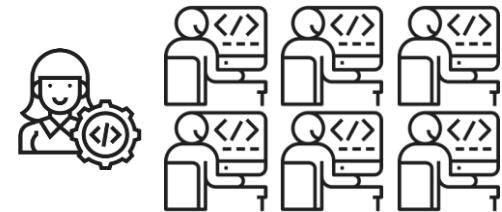
Project Coordination

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/>

Acknowledgements

Abinaya Yogasekaram - Roche

Alex Assued - Sanofi

Emily de la Rua - Roche

Freeman Wang - 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

Thank you!