

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

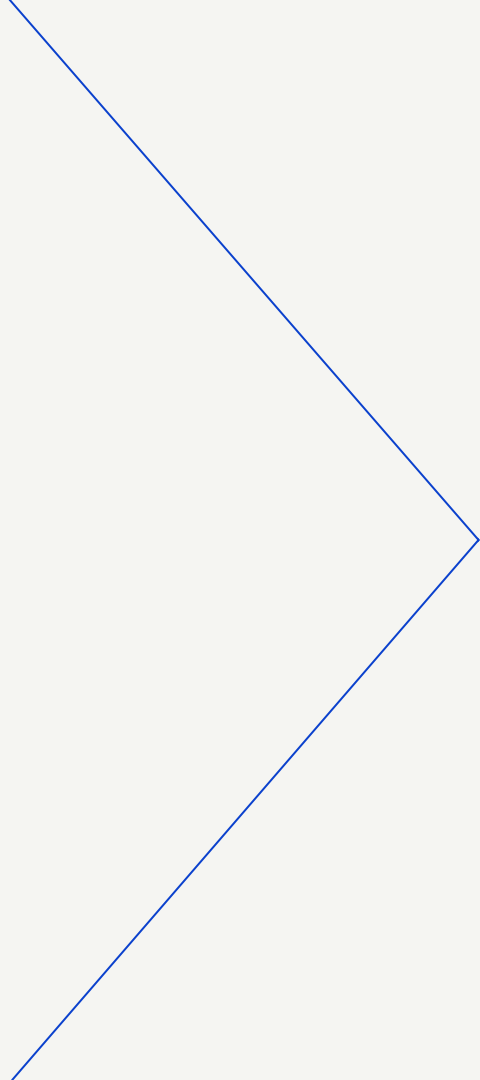
Vincent Shen, Roche  
Juergen Boehl, Boehringer Ingelheim

# Agenda



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

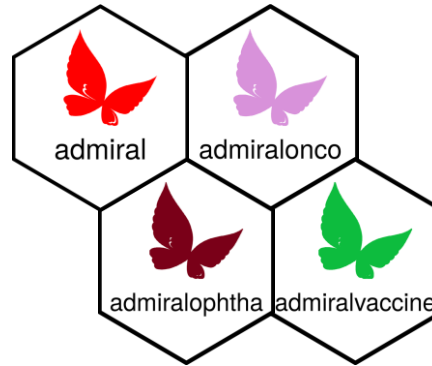
# History & Motivation



# 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***



# How About TLGs?

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

Table X-1 Baseline Demographics and Characteristics Safety Set			
Age (Years)			
n	XX (XX.X)	XX	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	XX.X, XX.X
Mean (SD)	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%)
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 (3.2)
Median	5.4	4.8	4.8
Min - Max	0.4 - 17.7	0.6 - 14.2	0.2 - 14.2

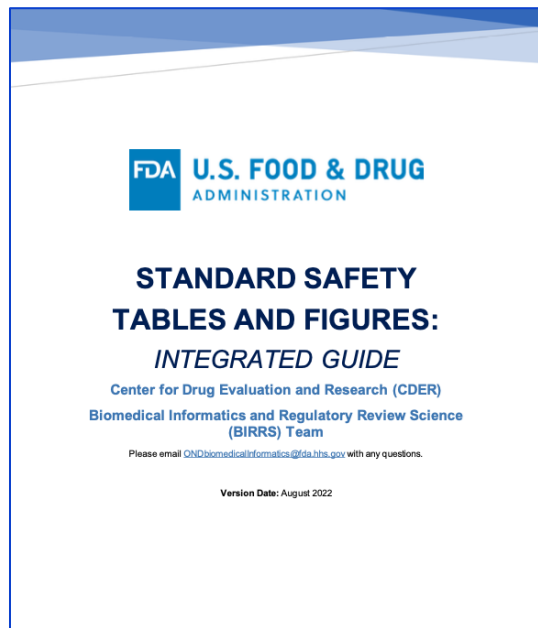
2.1.4.2.1 Example: Demographic data				
	Drug A		Drug B	
	142	100.0	219	100.0
Number of subjects (N, %)	142	100.0	219	100.0
Sex (N, %)	142	100.0	219	100.0
Male	111	78.2	173	79.0
Female	31	21.8	46	21.0
Race (N, %)	142	100.0	219	100.0
White	0	0.0	1	0.5
Black or African American	8	5.6	11	5.0
Asian	8	5.6	169	77.2
American Indian or Alaska Native	24	16.9	38	17.4
Native Hawaiian or Other Pacific Islander	142	100.0	219	100.0
Other	110	77.5	169	77.2
Unknown	110	77.5	169	77.2

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	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 (100)	399 (99.8)
From 65 - 84 years	0	0	0	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)
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



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?**

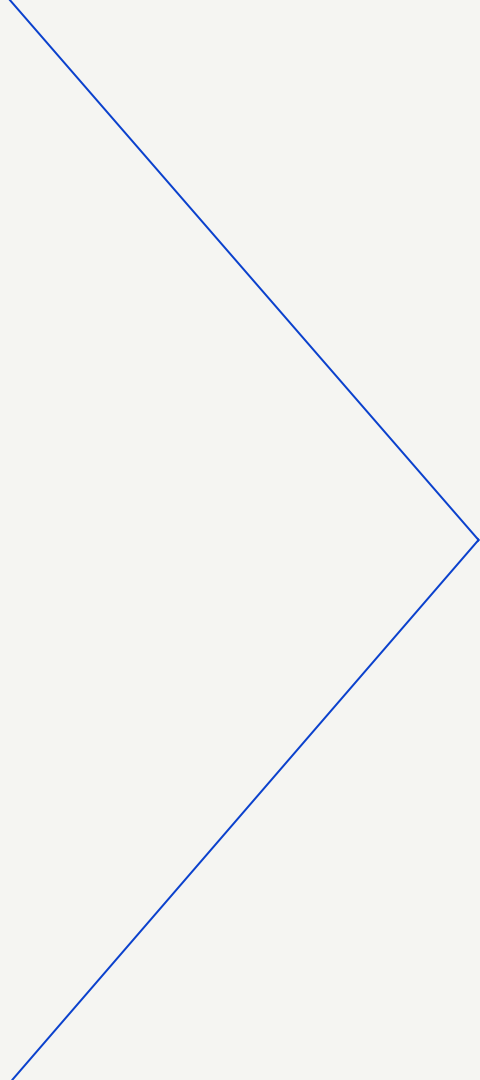
# {falcon}

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*

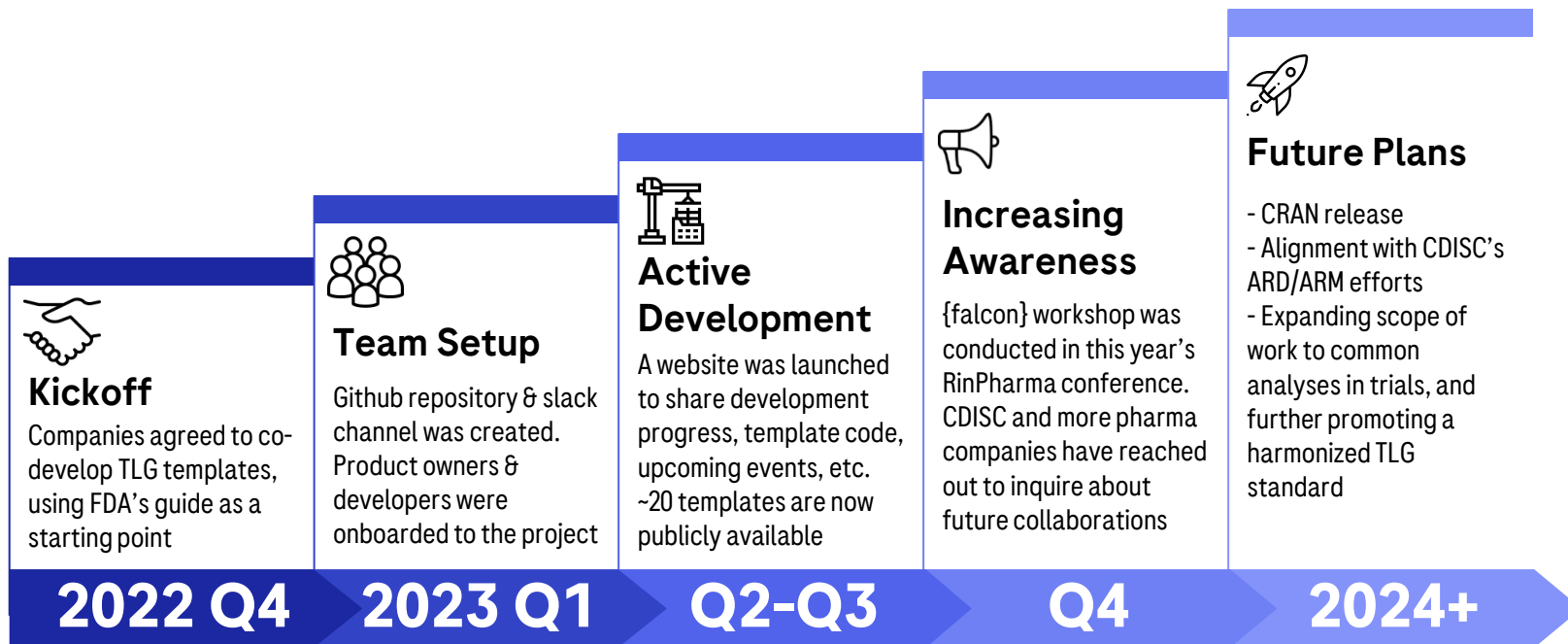
**Current Progress**





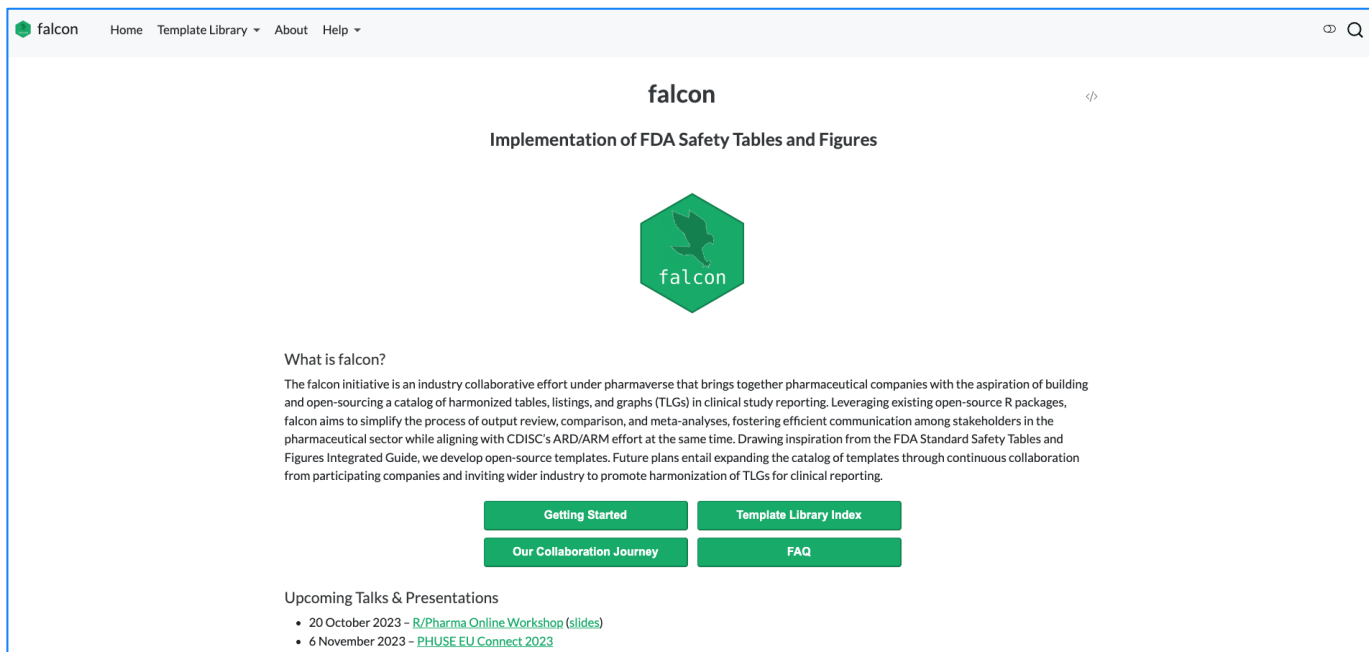
# Our Journey

What have we achieved so far?



# A Deeper Look

Explore {falcon} in detail



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

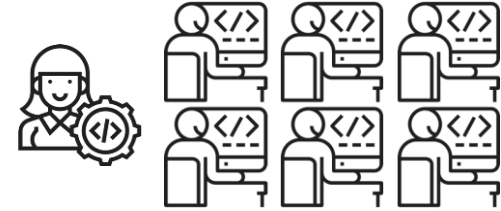
# Project Coordination

How does a cross-company team work?



## Product Owners

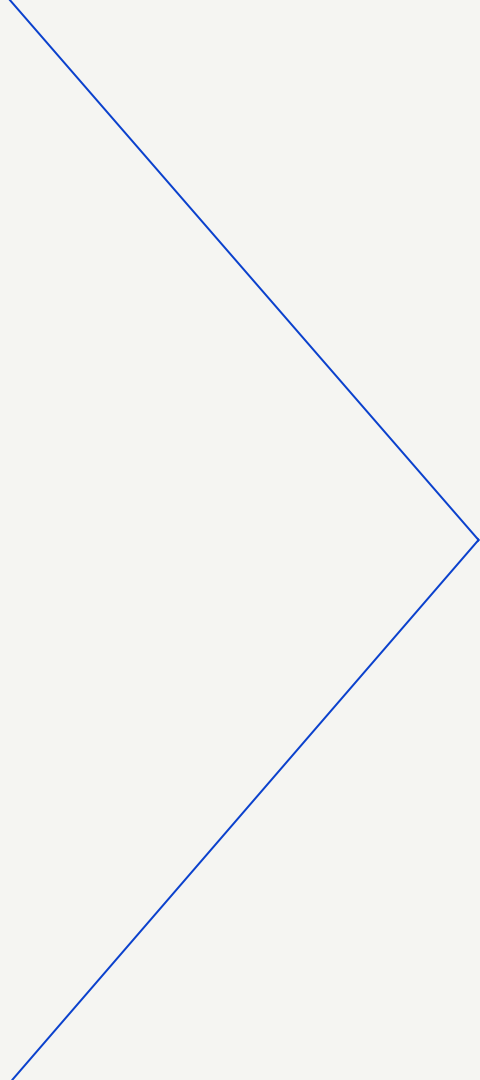
- Feature prioritization
- Refine requirements
- Project roadmap



## 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

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