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

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Agenda

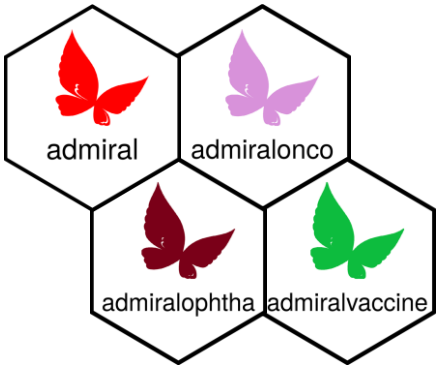
1. History & Motivation
2. Current Progress
3. Learnings, Outlook, & Call for Collaboration

History & Motivation

Pharma Industry Has Very Well Established Data Standards

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

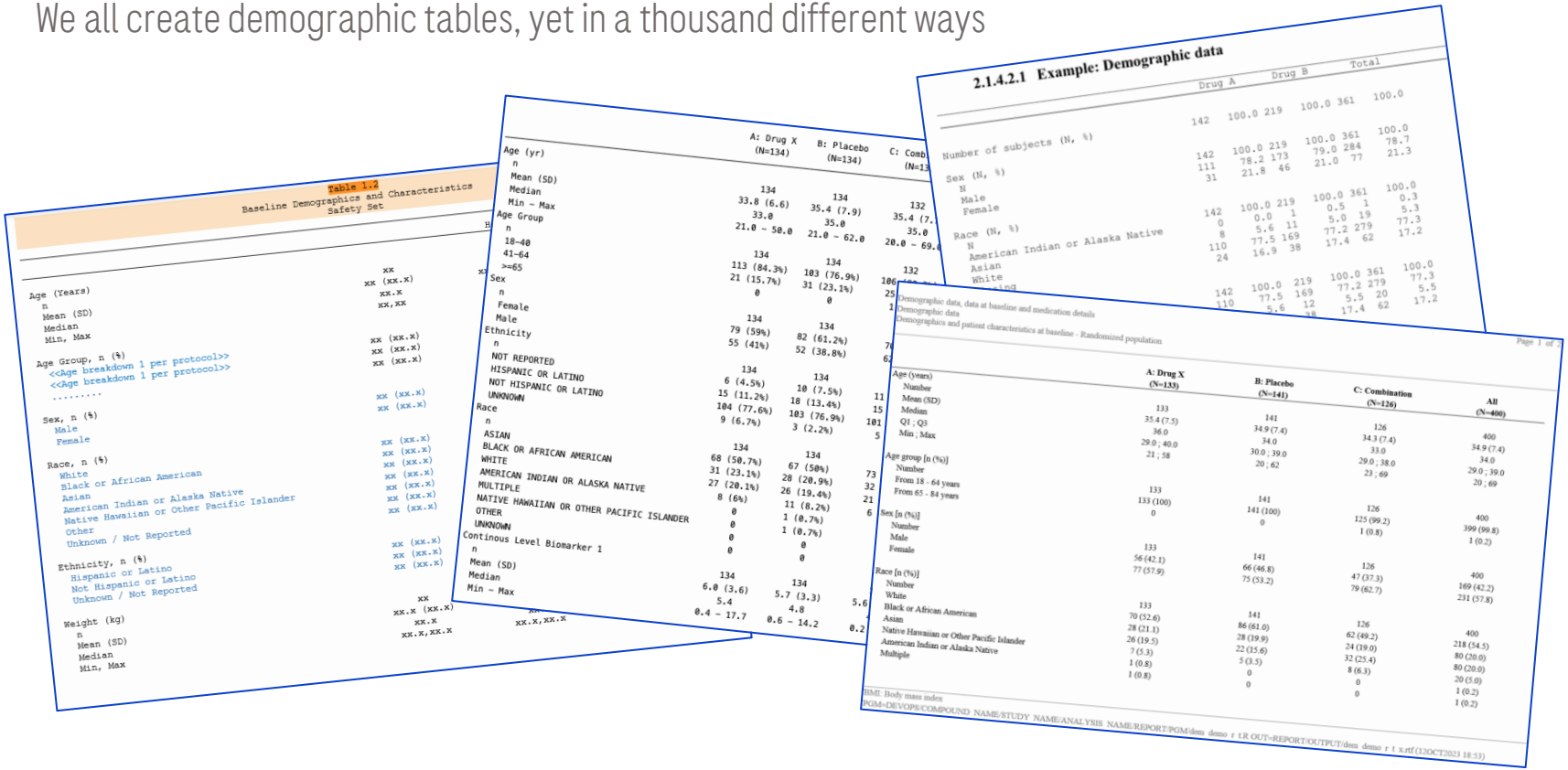
Universally agreed standards not only enable easier data sharing & re-use, but also foster industry collaboration



cdisc

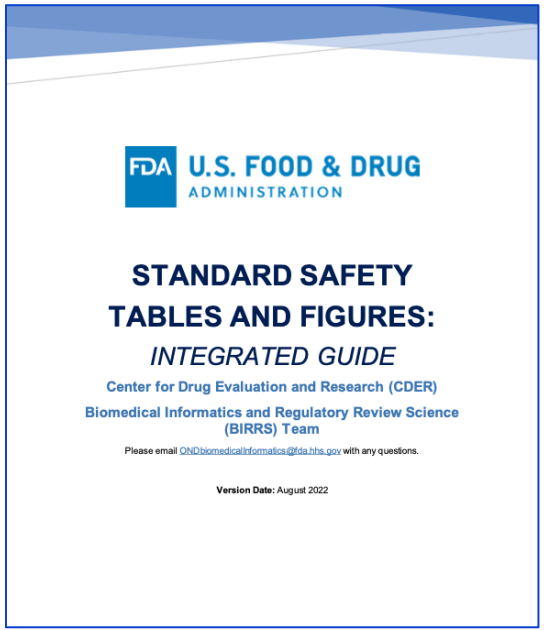
How About TLGs?

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



An Opportunity Arose

FDA proposed an integrated guide for standard safety tables & figures



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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}

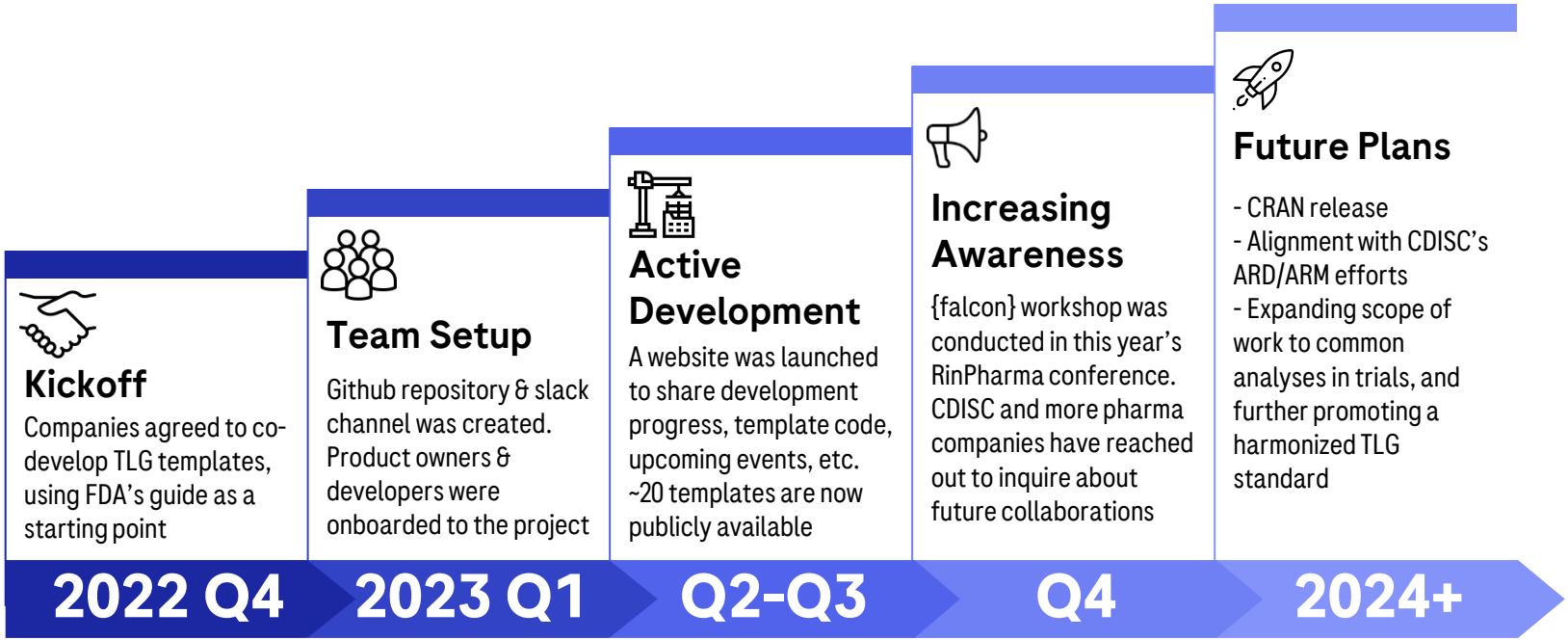
First industry collaborative effort for TLG creation

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

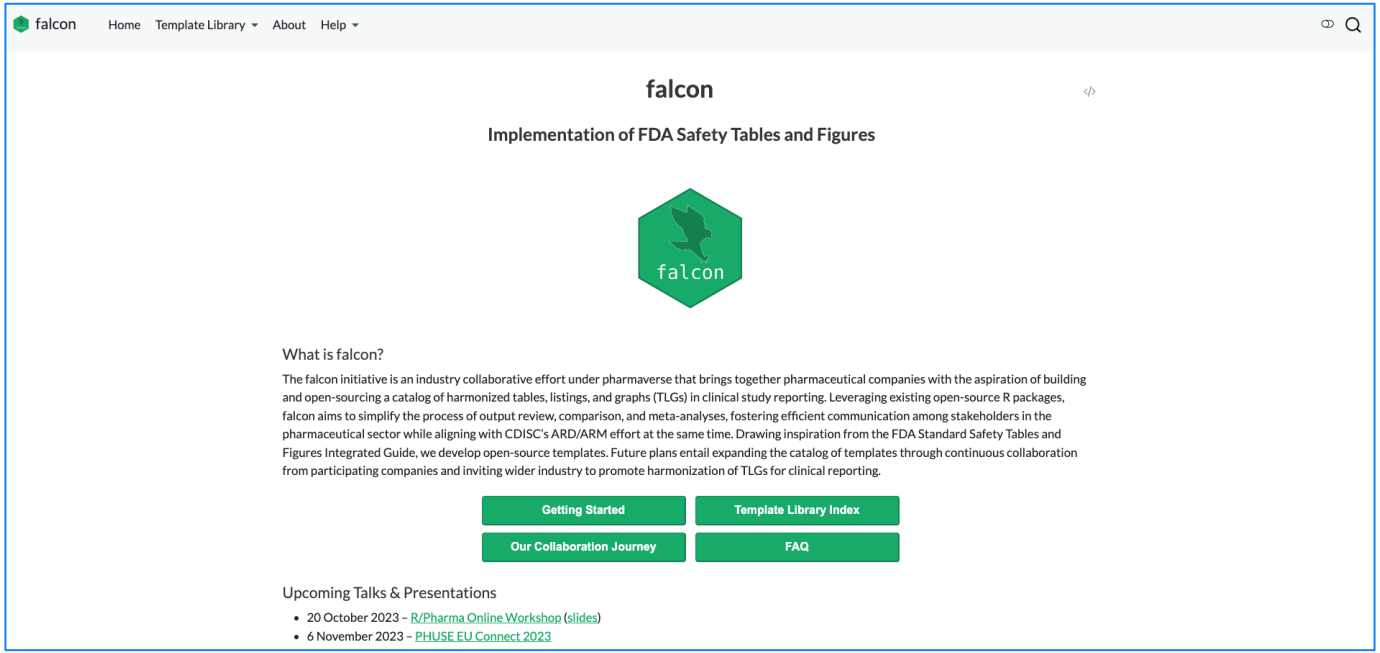
Our Journey

What have we achieved so far?



A Deeper Look

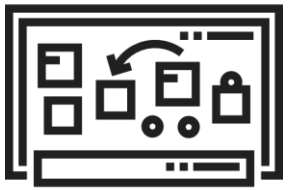
Explore {falcon} in detail



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

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