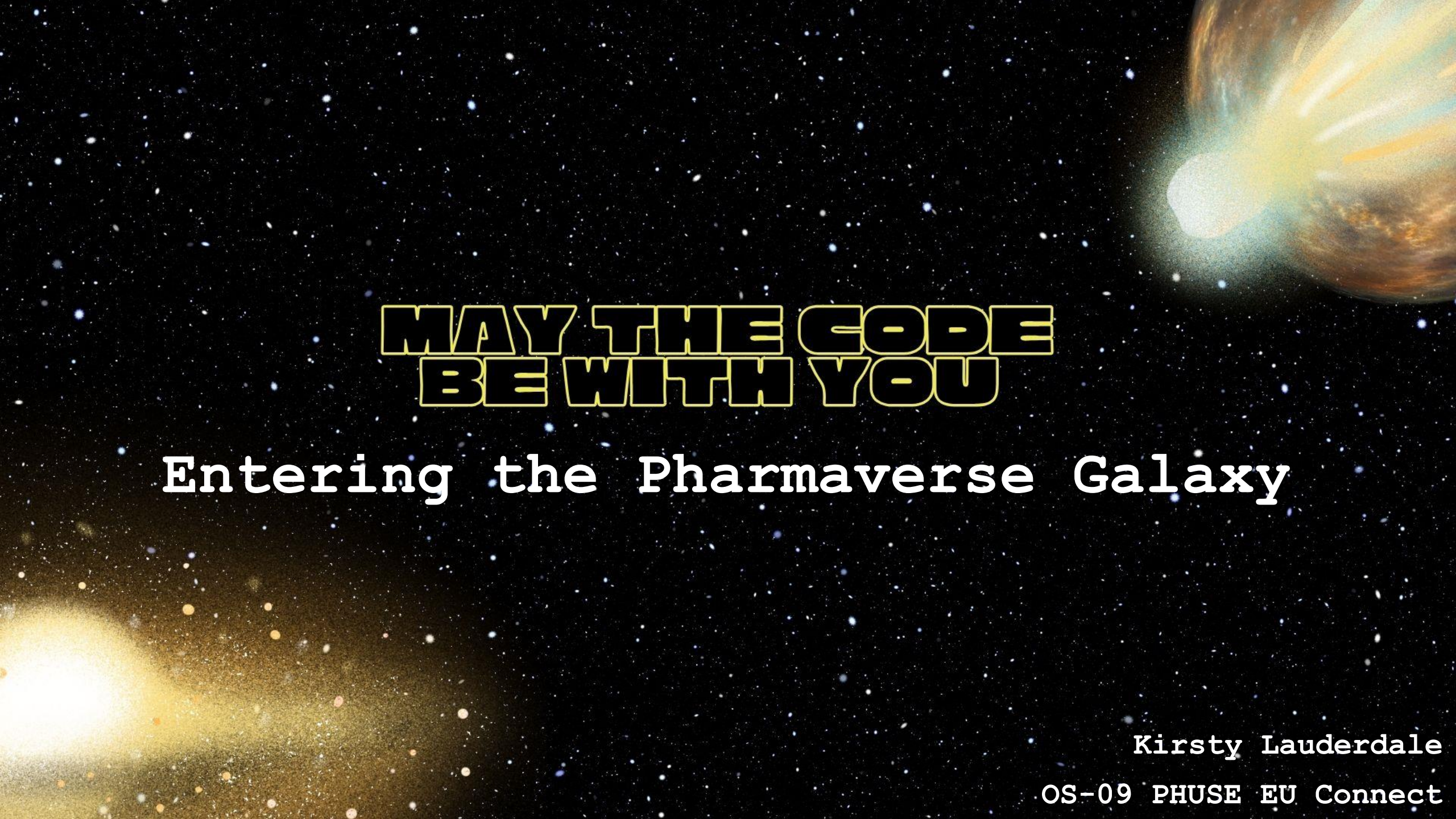


The background is a deep space scene with a black sky filled with numerous small, distant stars. In the upper right corner, a large, glowing celestial body, possibly a planet or a nebula, is partially visible, showing orange and yellow hues. In the lower left corner, there is a bright, diffuse yellow and orange light source, resembling a nebula or a distant star cluster.

**MAY THE CODE
BE WITH YOU**

Entering the Pharmaverse Galaxy

Kirsty Lauderdale

OS-09 PHUSE EU Connect

The Challenge: Legacy Systems

Clinical trial programming today is built on proprietary systems which prioritizes compliance, but limits **flexibility**, **interoperability**, and **innovation**

A New Hope: Open Source

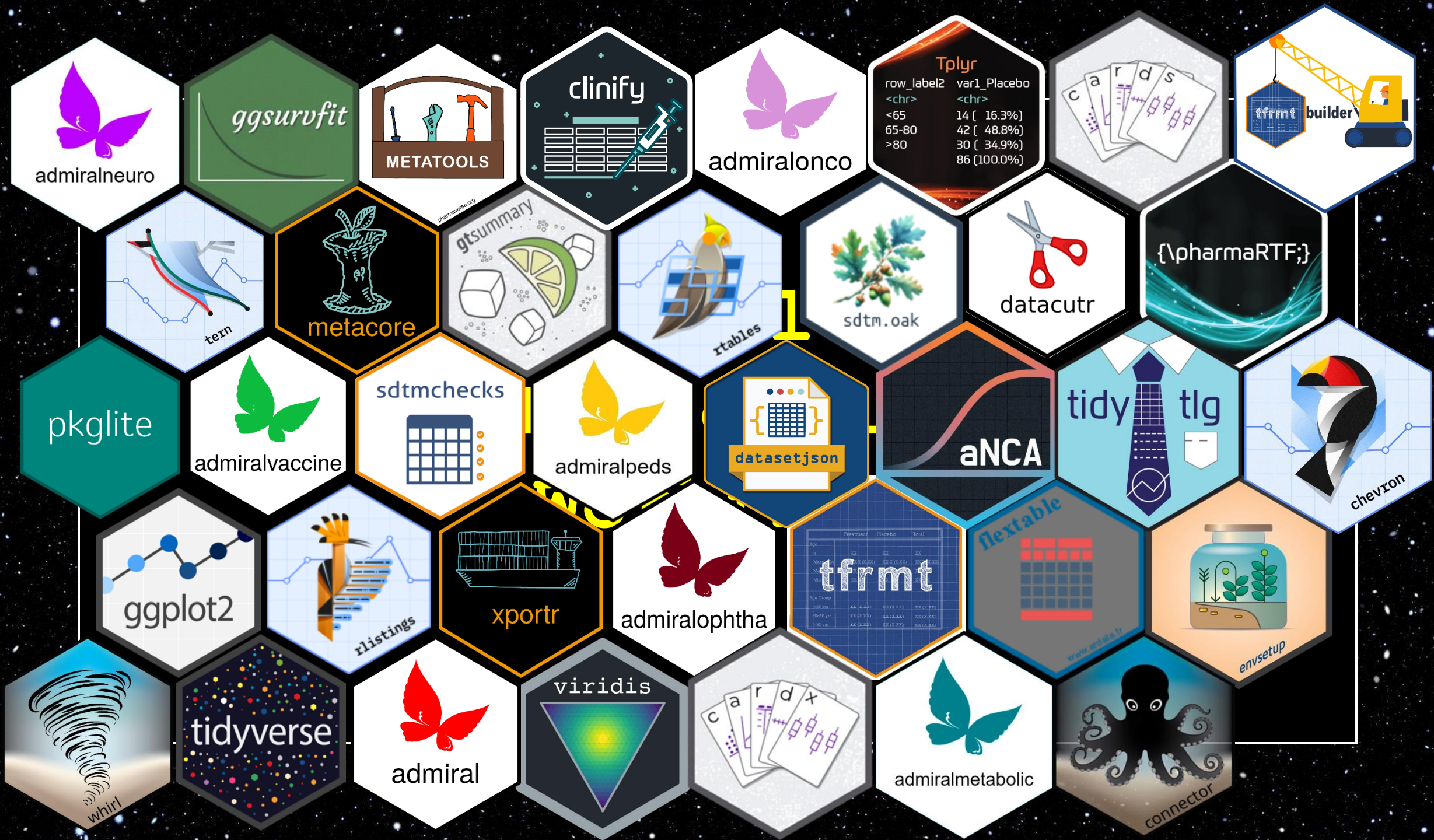
*A shift toward openness and collaboration,
shared innovation is replacing isolated development,
Transparent, reproducible tools are becoming the standard...*



What is the pharmaverse?

An **ecosystem** of R* packages developed for the entire
clinical trial lifecycle built on the
tidyverse foundation

Principles: **Transparency Validation Governance Collaboration**

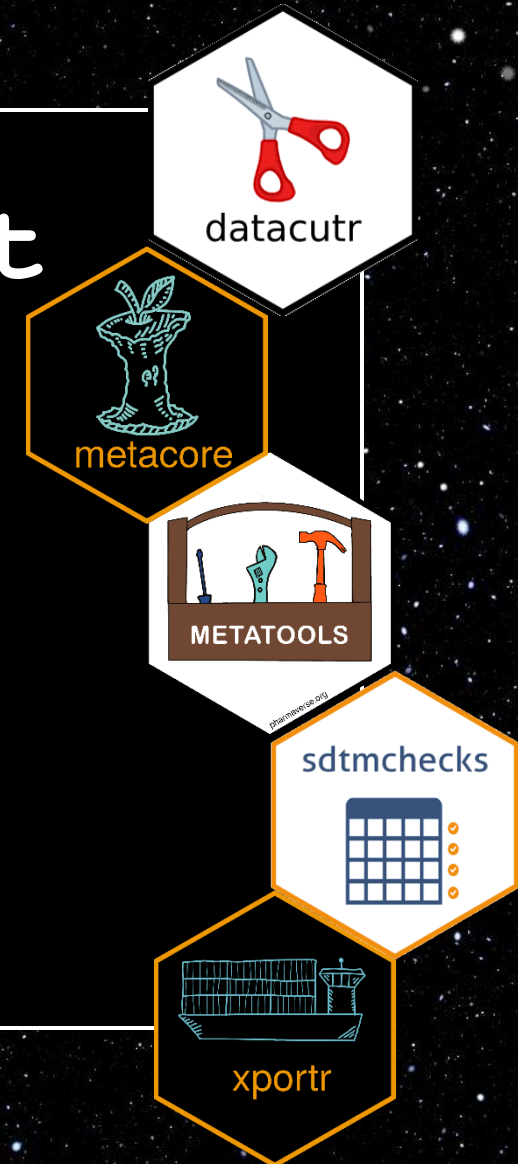


SDTM: The Blueprint

Aligns datasets with CDISC standards

Anchors traceability & interoperability

Enables automation and reproducibility

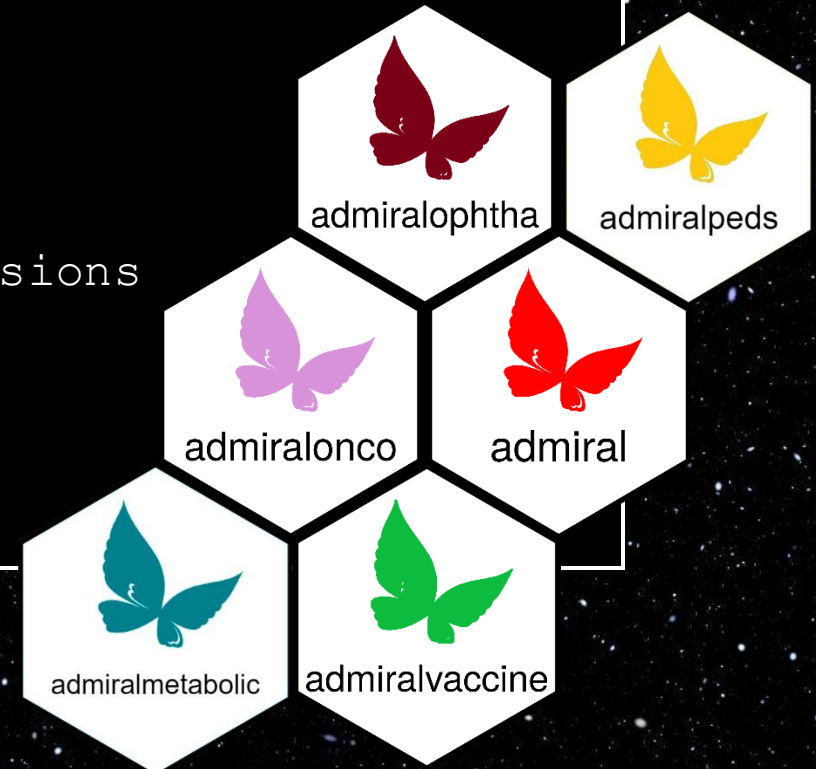


ADaM: The Analytical Base

Modular, metadata-driven derivations

Traceability from raw → SDTM → ADaM

Framework: {admiral} + therapeutic extensions



TLFs: Illuminating Insights

Tplyr

row_label2	var1_Placebo
<chr>	<chr>
<65	14 (16.3%)
65-80	42 (48.8%)
>80	30 (34.9%)
	86 (100.0%)

gtsummary



ggplot2



rtables

Automated generation of tables, figures, and listings

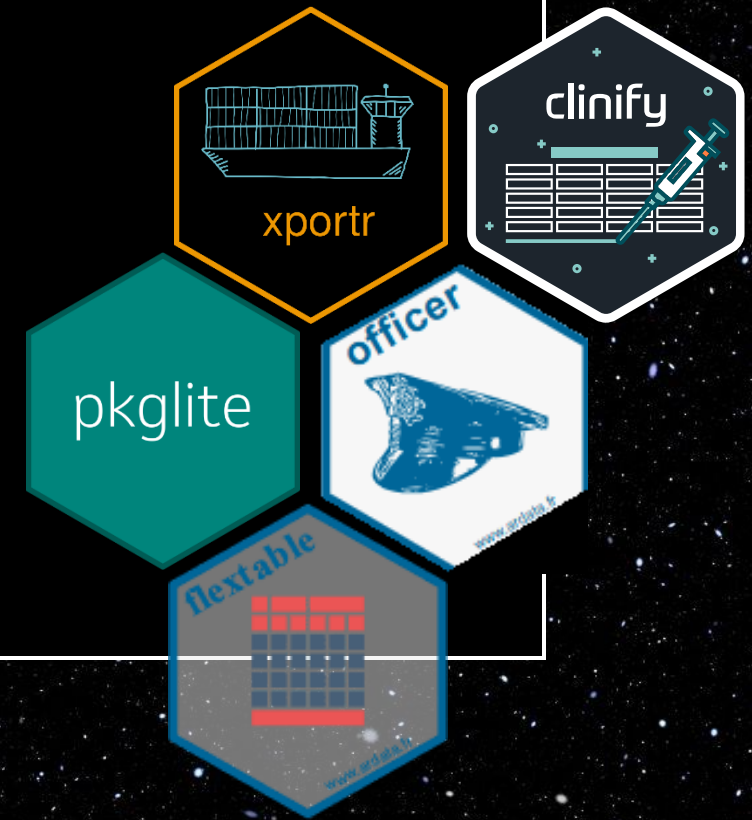
Publication-ready visualizations and tables

Integrates seamlessly with Markdown or Quarto

Submissions: The Final Trial

Automate define.xml, validation,
and outputs

Fully traceable & auditable
pipelines



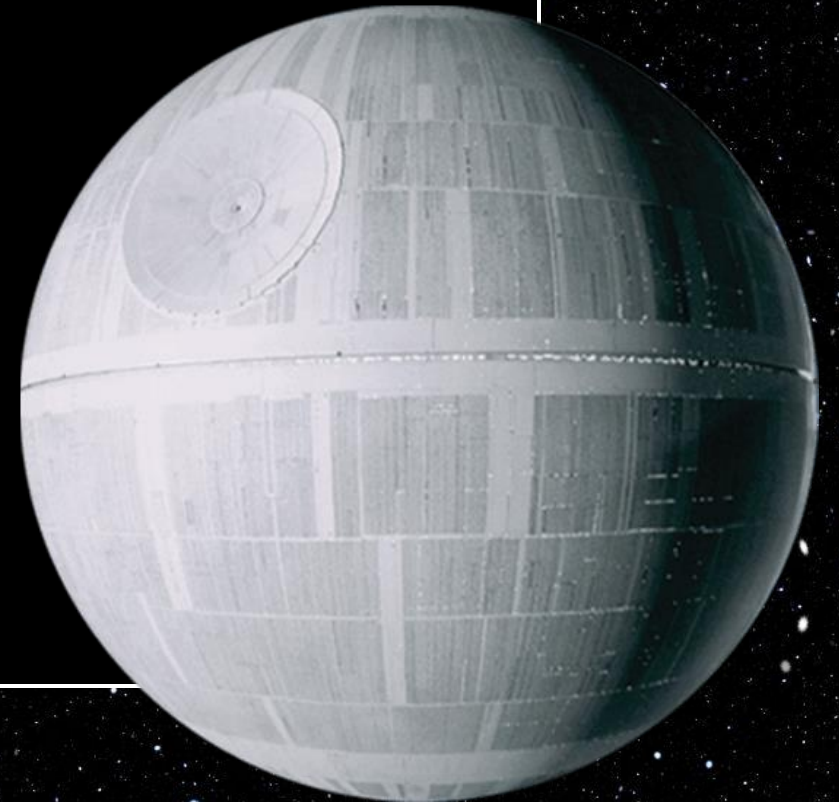
Challenges: The Dark Side

Barriers to adoption

- Cultural resistance
- Validation and compliance concerns
- Skill gaps & infrastructure needs

Counter with:

- Governance frameworks
- Validation practices (R Validation Hub)
- Continuous learning and collaboration



Team Empowerment

Reduced duplication of effort

Improved traceability & auditability

Skills growth and cross-team collaboration

Reuse, reproducibility, and rapid innovation

Framework Adoption

The logo for Johnson & Johnson, featuring the company name in a red, sans-serif font.

Open Source
Journey in R



Enterprise-level
pipelines

Submissions



End-to-end R
submission



FDA
submission

**Johnson
& Johnson**

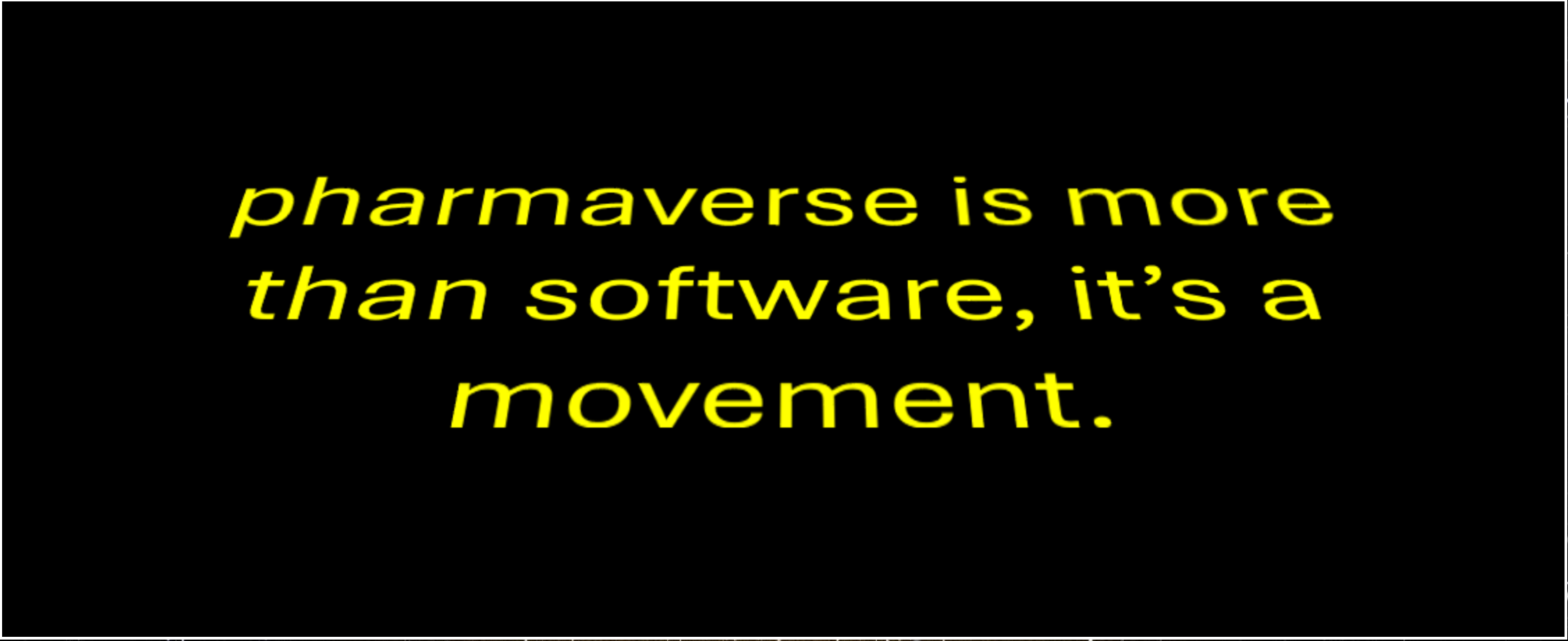
A Hybrid SAS/R
Submission Story

The Future: Return of the Developers

AI-assisted validation & mapping

AI-generated documentation and coding

Cross-language collaboration (R ↔ Python ↔ SAS)



*pharmaverse is more
than software, it's a
movement.*



Questions?

THANK YOU!

Kirsty.Lauderdale@AtorusResearch.com

GET INVOLVED

pharmaverse.org

Pharmaverse Examples

CDISC Standards

R submissions case studies