Open-Source

Advancements and Opportunities

Michael Stackhouse | Co-lead Data Visualization and Open-Source Technology

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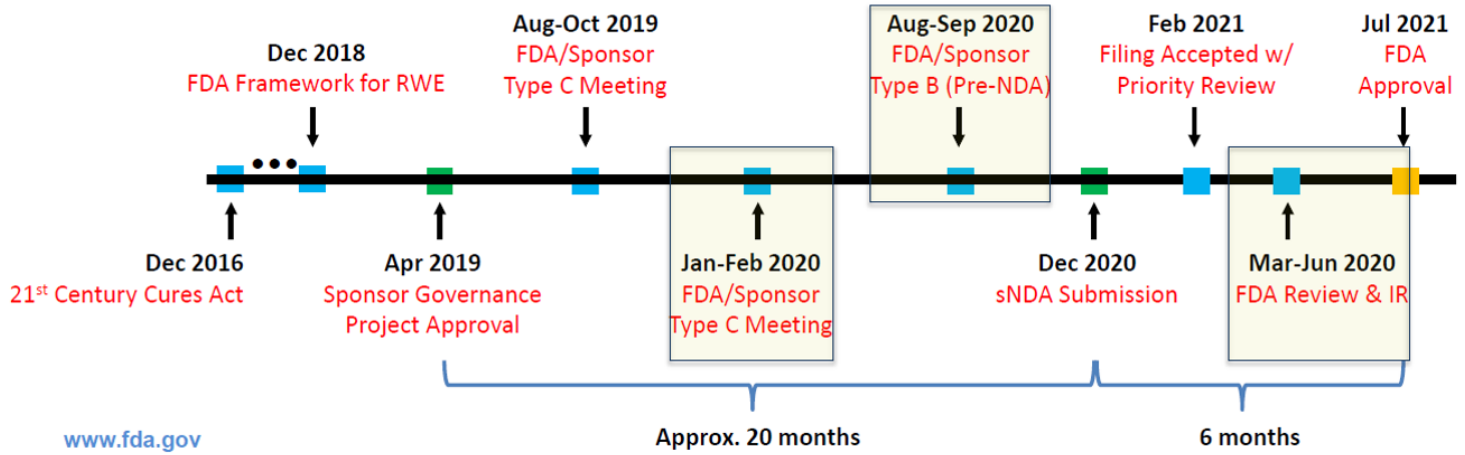
Real-World Data

New Indication for Tacrolimus (Prograf®)

CDER's **first acceptance** of an "**observational study**" as an **adequate and well-controlled study** providing the **primary support** for a finding of **substantial evidence of effectiveness**

Source: Concato, John, and Jacqueline Corrigan-Curay. "Real-World Evidence-Where Are We Now?." *The New England journal of medicine* 386.18 (2022): 1680-1682.



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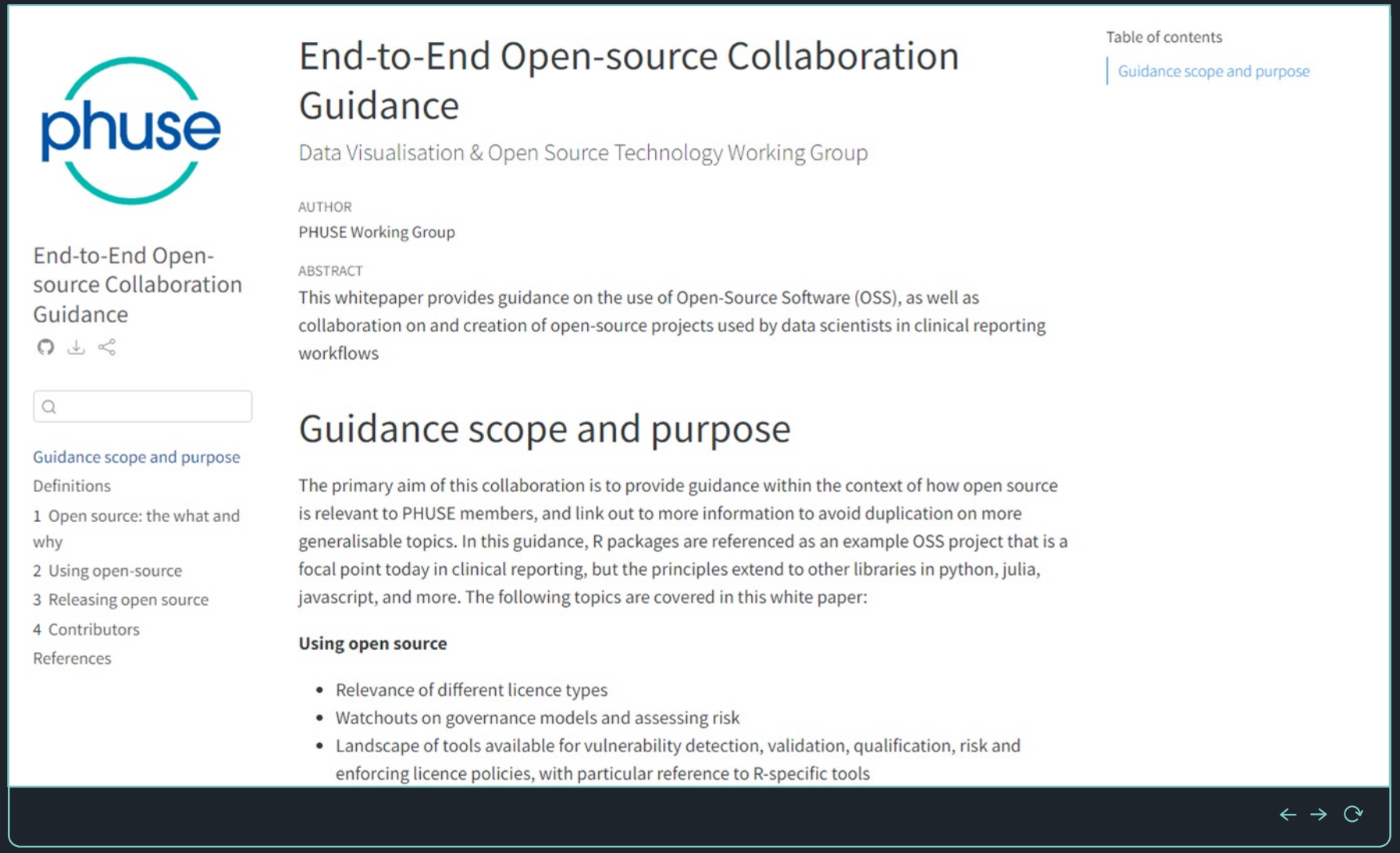
E2E Open-Source Collaboration



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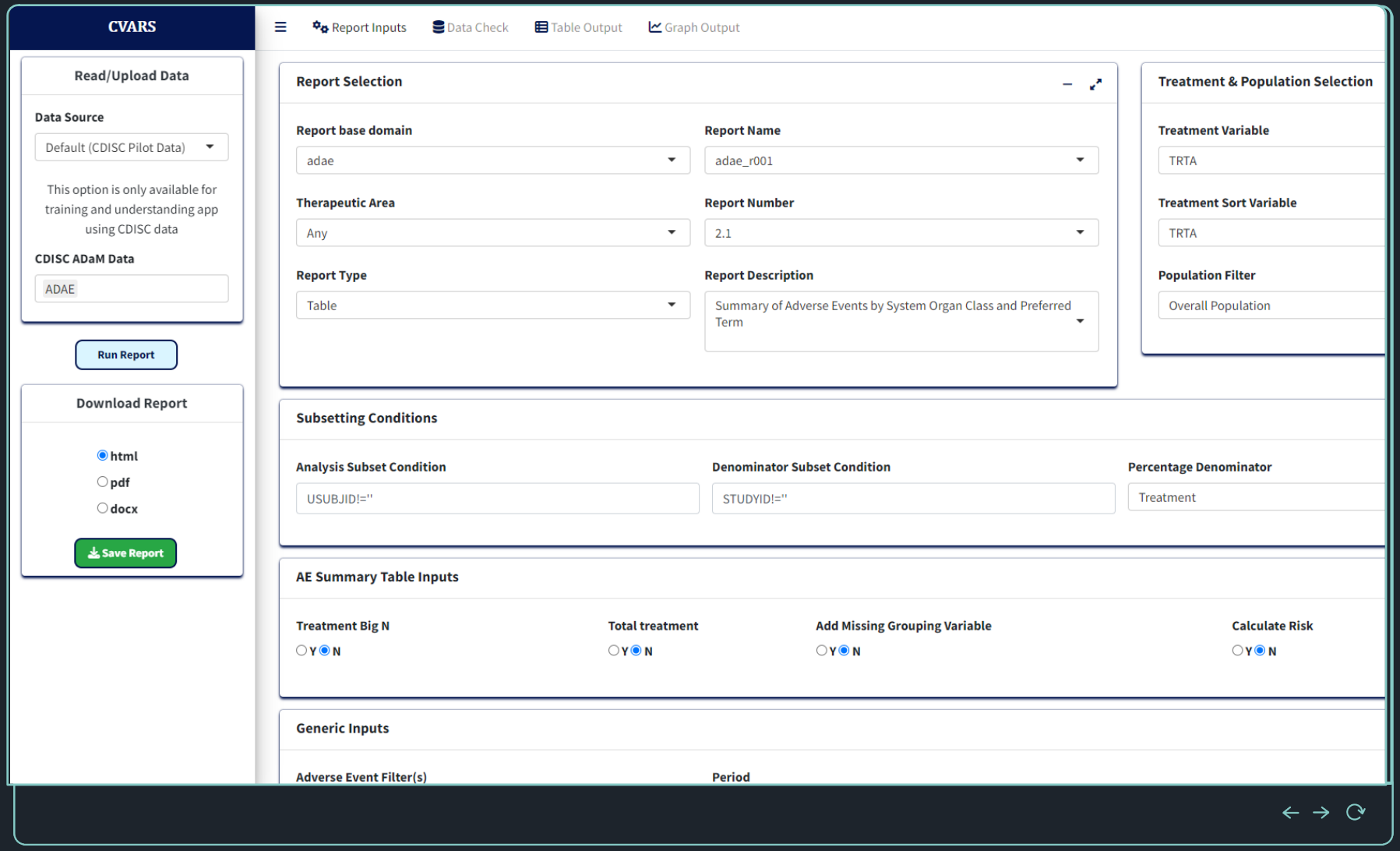
CVARS



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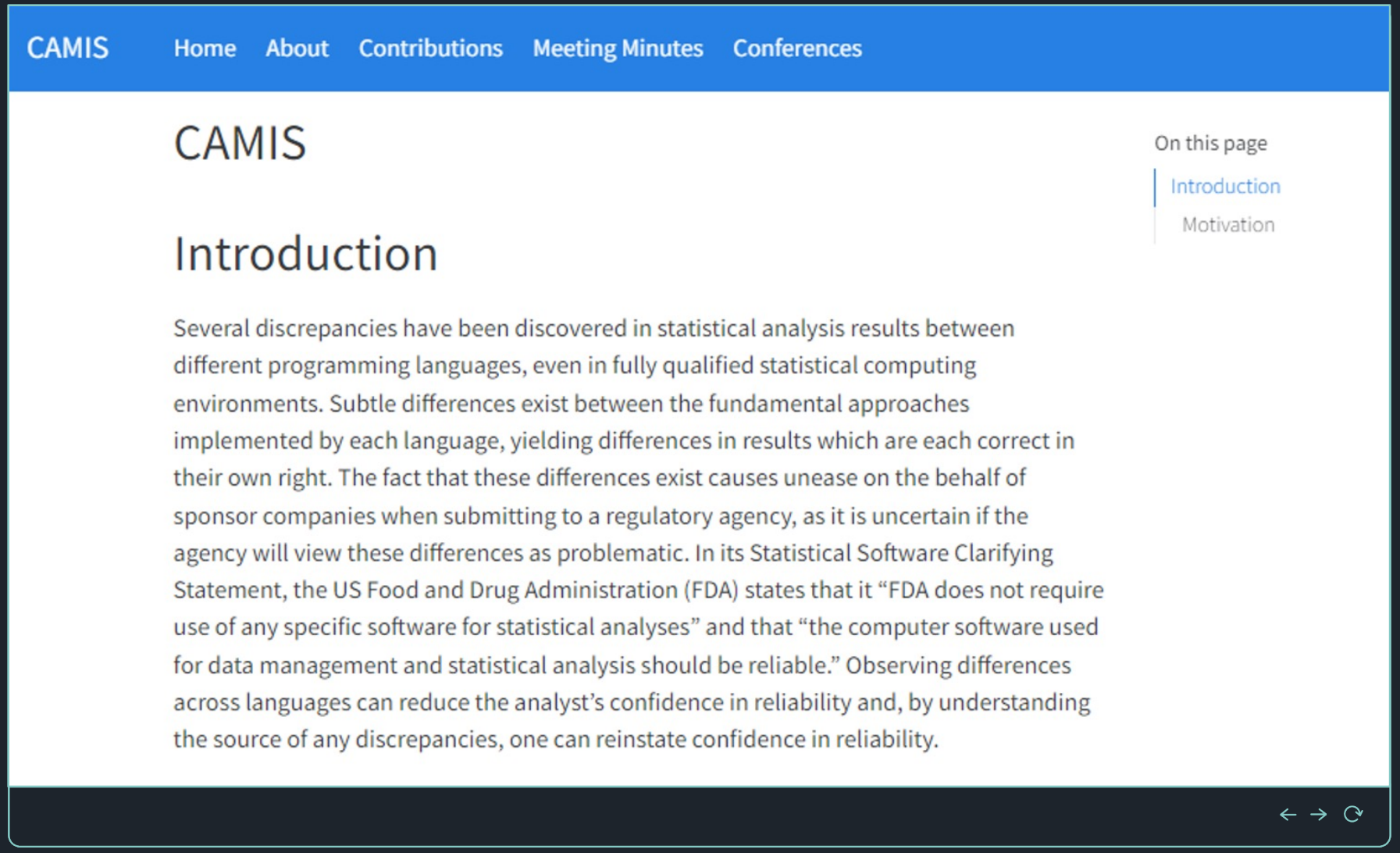
CAMIS



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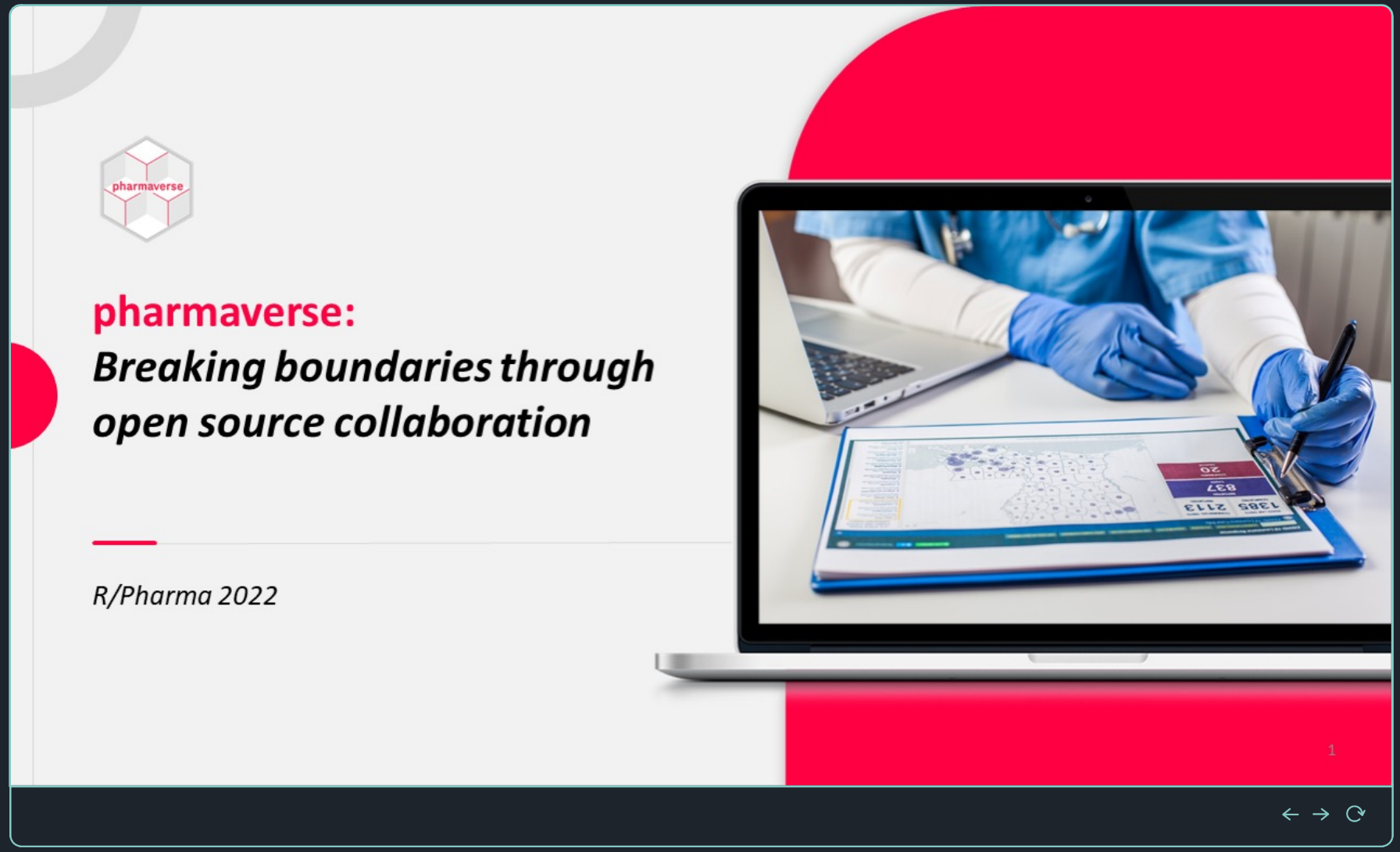
pharmaverse



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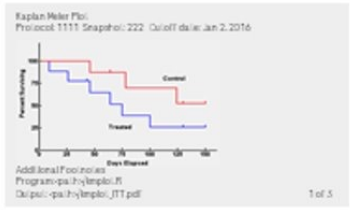
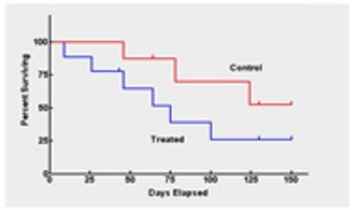
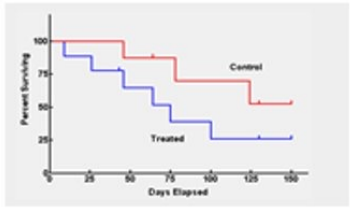
teal

Improve efficiency in the way we work

Analyzing clinical trial data requires multiple ways of presenting and interacting with our data



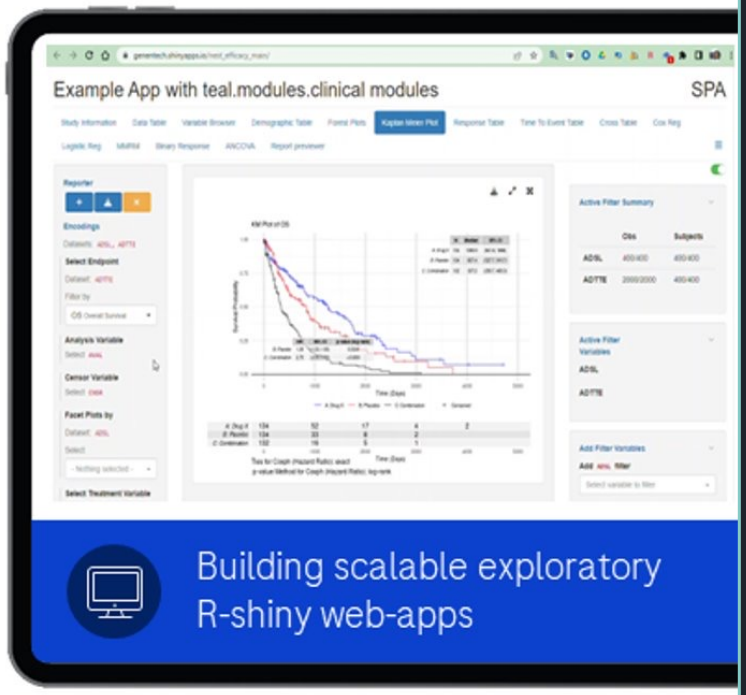




Per-SAP static output on **OS**

Ad-hoc analysis on **PFS**

Ad-hoc analysis on **PFS** in **subpopulation**



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CDISC - CORE

Why is CDISC doing CORE?

- Ensure each standard has a set of unambiguous, executable Conformance Rules
- Ensure consistency across Conformance Rule implementations
- Expedite the availability of executable Conformance Rules for new Foundational Standards
- Create executable Conformance Rules vetted by the CDISC standards development teams
- Develop an open-source engine that serves as a Reference Implementation
- Publish the Rules in the CDISC Library and the engine under the CDISC Open Source Alliance (COSA)

➡ *CORE Initiative = Rules + Engine*

https://www.cdisc.org/core

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CDISC - ARS

Shifting the Paradigm

Table 3.1.1: ADHYPO Analysis Dataset

Row	STUDYID	USUBJID	MIDS	CEDECOD	WASAEYN	ASTDTM
1	XYZ	000001	HYPO 1	Hypoglycemia	Y	07Sep2012 22:29:00
2	XYZ	000001	HYPO 2	Hypoglycemia	N	10Sep2012 09:12:00
3	XYZ	000001	HYPO 3	Hypoglycemia	N	10Sep2012 23:05:00
4	XYZ	000001	HYPO 4	Hypoglycemia	N	11Sep2012 15:24:00
5	XYZ	000001	HYPO 5	Hypoglycemia	N	18Sep2012 11:39:00
6	XYZ	000002	HYPO 1	Hypoglycemia	N	22Oct2012 13:28:00
7	XYZ	000002	HYPO 2	Hypoglycemia	N	25Oct2012 13:59:00
8	XYZ	000002	HYPO 3	Hypoglycemia	N	17Nov2012 05:01:00

ADaM Dataset

Table 4.2.2: HbA1c Longitudinal Repeated Measures Analysis Results Metadata

Metadata Field	Metadata
DISPLAY IDENTIFIER	Table 4.2.1/Figure 4.2.1
DISPLAY NAME	Mean Change from Baseline in HbA1c (Percent) Longitudinal Repeated Measures Ana Period, Intention-to-treat Population
RESULT IDENTIFIER	Treatment difference results (LSMean, confidence interval, p-value)
PARAM	HbA1c (%)
PARAMCD	HBA1C
ANALYSIS VARIABLE	CHG (Change from baseline)
ANALYSIS REASON	SPECIFIED IN SAP
ANALYSIS PURPOSE	PRIMARY OUTCOME MEASURE
ANALYSIS DATASET	ADHBA1C

ARM v1

ARM Extension Technical Specification

Automation

Reuse

Traceability

Analysis Results Dataset

Display

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