



**CIMS GLOBAL & PHUSE US Connect 2025**  
**OS09**

# The Implementation of {teal} Shiny Apps in DMC Activity

# Presenter Biography



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- Clinical Data Scientist at CIMS Global
- M.S. in Biostatistics, Yale University School of Public Health
- Experience of open-source development, including R packages, R Shiny, Git, unit testing, and validation.
- Currently working on providing interactive solutions for clinical studies and DMC activities.



Peng Zhang  
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- Associate Director - Innovative Data Sciences
- Lead internal development and production of R package, R Shiny apps and software development.
- Unblinded independent statistician for 30+ DMC meetings and 10+ ongoing clinical trials from phase 2 to phase 3 for different therapeutical areas.

# Introduction

- The integration of R Shiny applications into **regulatory submission** processes has gained attention through recent pilot studies.
- While R Shiny applications have primarily been used for internal reviews, there is growing interest in leveraging these tools for Data Monitoring Committee (DMC) activities.
- **Interactive dashboards** built with R using {teal}<sup>1</sup>, {rtables}<sup>2</sup>, and {tern}<sup>3</sup> enable study-specific analyses, endpoint evaluations, and downloadable files.
- This presentation focuses on the practical aspects and advantages of **deploying R Shiny applications in DMC activities**.

# DMC

- A Data Monitoring Committee (DMC) is an independent group of experts established to oversee the progress of a clinical trial.
- The DMC evaluates the **safety & efficacy** of the treatment and make recommendations.

# DMC Meeting

- DMC meetings are formal gatherings during the interim analysis, designed to **review ongoing trial data**.
- A DMC meeting consists of two sessions: an open session and a closed session.
- **Open session** (30 min to 1 h ): Sponsor and DMC members discuss study updates using blinded data report.
- **Closed session** (30 min to 2 h): DMC analyze unblinded executive summary report and slides provided by independent statistician
- After the closed session, DMC provides **recommendations** to the sponsor regarding the trial's continuation or protocol modifications.

# Current Challenges

- **Multiple Parties:** multi-step collaboration process
- **Large Volume of DMC Report:** 1000 - 10000 pages typically
- **Inefficient Static Output:** manual search through static DMC reports
- **Insufficient Information:** reports lack critical trial information
- **Time-Consuming Follow-Up:** request for additional data causes delays

# Open-Source Solution



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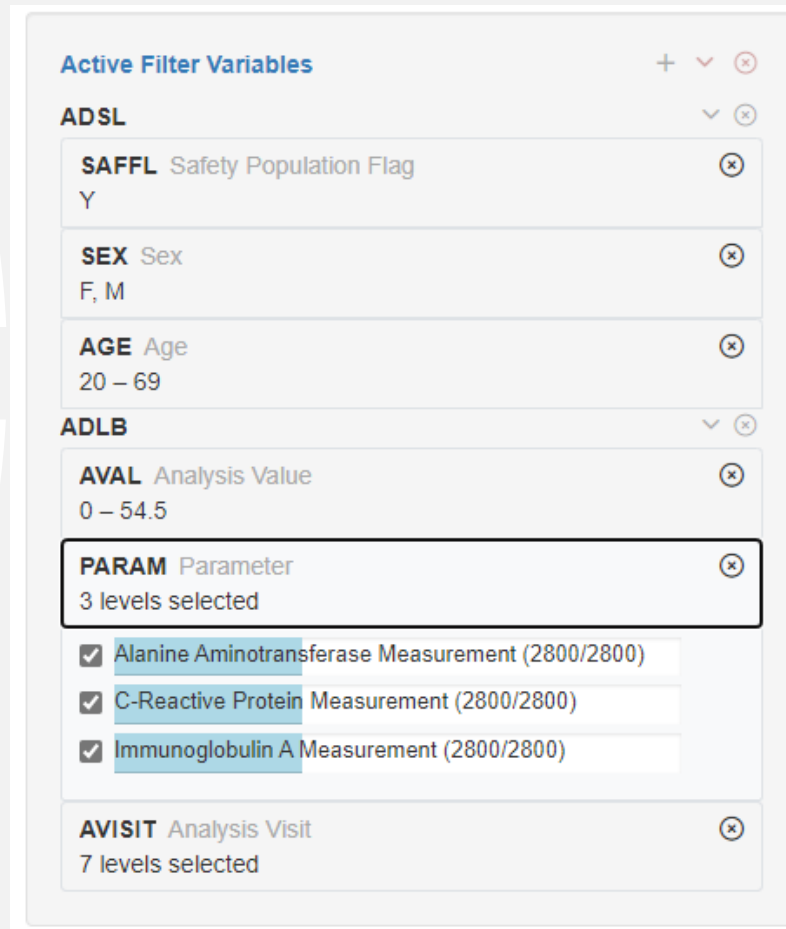
# Understanding the Components of the {teal} Series

- {teal.data}<sup>4</sup>: Facilitates ADaM data loading and merging.

```
> teal.data::default_cdisc_join_keys
A join_keys object containing foreign keys between 19 datasets:
ADSL: [STUDYID, USUBJID]
<-- ADAE: [STUDYID, USUBJID]
<-- ADEG: [STUDYID, USUBJID]
<-- ADTTE: [STUDYID, USUBJID]
<-- ADAETTE: [STUDYID, USUBJID]
<-- ADCM: [STUDYID, USUBJID]
<-- ADEX: [STUDYID, USUBJID]
<-- ADLB: [STUDYID, USUBJID]
<-- ADMH: [STUDYID, USUBJID]
<-- ADQS: [STUDYID, USUBJID]
<-- ADRS: [STUDYID, USUBJID]
<-- ADSAFTTE: [STUDYID, USUBJID]
<-- ADVS: [STUDYID, USUBJID]
<-- ADDV: [STUDYID, USUBJID]
<-- ADSUB: [STUDYID, USUBJID]
<-- ADHY: [STUDYID, USUBJID]
<-- ADQLQC: [STUDYID, USUBJID]
<-- ADCSSRS: [STUDYID, USUBJID]
<-- ADEQ5D5L: [STUDYID, USUBJID]
ADAE: [STUDYID, USUBJID, ASTDTM, AETERM, AESEQ]
--> ADSL: [STUDYID, USUBJID]
```

# Understanding the Components of the {teal} Series

- {teal.slice}<sup>5</sup>: Provides a filtering panel for data subset exploration.



The screenshot displays the 'Active Filter Variables' panel in teal.slice. It is organized into two main sections: ADSL and ADLB. The ADSL section includes filters for SAFFL (Safety Population Flag, Y), SEX (Sex, F, M), and AGE (Age, 20 - 69). The ADLB section includes filters for AVAL (Analysis Value, 0 - 54.5), PARAM (Parameter, 3 levels selected), and AVISIT (Analysis Visit, 7 levels selected). The PARAM filter is highlighted with a black border and contains a list of three checked items: Alanine Aminotransferase Measurement (2800/2800), C-Reactive Protein Measurement (2800/2800), and Immunoglobulin A Measurement (2800/2800). Each filter entry has a plus icon, a dropdown arrow, and a close icon (X).

Section	Variable	Value
ADSL	SAFFL Safety Population Flag	Y
	SEX Sex	F, M
	AGE Age	20 - 69
ADLB	AVAL Analysis Value	0 - 54.5
	PARAM Parameter	3 levels selected
	AVISIT Analysis Visit	7 levels selected

# Understanding the Components of the {teal} Series

- {teal.reporter}<sup>6</sup>: Supports the generation of reports from {teal} applications.

**Download the Report**

**Author:**

**Title:**

**Date:**

**Choose a document type:**

Include Table of Contents

Include R Code

[Download Report](#) [Reset Report](#)

Card 1: Adverse Event ▼

Card 2: Summarize Variables by Row Groups Table ▼

# Identifying Available {teal} Modules

- `{teal.modules.general}`<sup>7</sup>: general modules for exploring relational/independent/CDISC data.
- `{teal.modules.clinical}`<sup>8</sup>: modules specific to CDISC data and clinical trial reporting.

# Identifying Available {teal} Modules

- `tm_t_summary()`: Summarizes variables and generates tables.
- `tm_t_events()`: Displays events by term and generate tables.
- `tm_t_summary_by()`: Summarizes variables by row groups.
- `tm_t_tte()`: Generates time-to-event tables.
- `tm_g_km()`: Produces ggplot-style Kaplan-Meier plots.
- `tm_t_pp_xx()` and `tm_g_pp_xx()`: Provide subject-level data modules.
- `tm_data_table()`: Enables interactive dataset review.

# Categorizing Modules for the DMC Context

- **Baseline Information Module:** Disposition Table, Demographic Table, Major Protocol Deviation Table, Medical History Table, Concomitant Medication Table.
- **Safety Information Module:** Adverse Event Table, Lab Test Results Table, Vital Signs Table.
- **Efficacy Review Module:** Time to Event Table, Kaplan-Meier (KM) Plot.
- **Patient Profile Listing Module:** Basic Patient Information, Patient Vitals, Patient Lab Values, Patient Timeline.

# Connecting to External Data

- {teal} is developed for study-specific level - an app for a study.
- When it comes to the external review, we need to host **one server for each study**.

## Interactive Stats

### Upload a zip data of SAS datasets

Browse...

No file selected

### Upload the configuration file

Browse...

No file selected

Submit

Use sample data

# Compatibility of Data Connection

- To ensure a single Shiny server can support multiple studies, a **configuration file** should be uploaded to enable accurate data integration with {teal} modules.
- The configuration file contains information such as the arm variable, analysis variable, required modules for the study, and more.

Description	Variable	Value
Baseline Module	check_mod_baseline	Y
Baseline Analysis: Planned Treatment Variable	base_trt	TRT01P
Baseline Analysis: Planned Treatment Variable choices	base_trt_option	TRT01P TRT01A
Disposition	check_disp	Y
Disposition: Reason of Study Discontinuation	disp_anal_var	DSTRREAS
Demographic	check_dm	Y
Demographic: Variables	dm_anal_var	AGE SEX COUNTRY RACE
Protocol Deviation	check_pd	Y
Protocol Deviation: Primary protocol deviation variable	pd_anal_var	DVDECOD
Medical History	check_mh	Y
Medical History: Level 1 variable options	mh_anal_var_option_1	MHBODSYS MHCAT
Medical History: Level 1 variable	mh_anal_var_1	MHBODSYS
Medical History: Level 2 variable options	mh_anal_var_option_2	MHTERM MHDECOD
Medical History: Level 2 variable	mh_anal_var_2	MHDECOD

# Dashboard Layout and Interactive Features

Baseline/Study Information | Safety Information | Efficacy Review | Patient Profile Listing | Data Table | Report previewer

Disposition Table | Demographic Table | Major Protocol Deviations Table | Medical History Table | Concomitant Medication Table

**Reporter**

+ | Download | X

**Encodings**

Dataset: ADSL

**Select Column Variable(s)**

Select

ARM

Add All Patients column

**Summarize Variables**

Select

EOSSTT End of Study Status, EOT

> Additional table settings

	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)
<b>End of Study Status</b>			
n	134	134	132
COMPLETED	68 (50.7%)	66 (49.3%)	73 (55.3%)
DISCONTINUED	42 (31.3%)	40 (29.9%)	38 (28.8%)
ONGOING	24 (17.9%)	28 (20.9%)	21 (15.9%)
<b>End Of Treatment Status</b>			
n	134	134	132
COMPLETED	50 (37.3%)	47 (35.1%)	42 (31.8%)
DISCONTINUED	46 (34.3%)	42 (31.3%)	39 (29.5%)
ONGOING	38 (28.4%)	45 (33.6%)	51 (38.6%)

n represents the number of unique subject IDs such that the variable has non-NA values.

**Active Filter Summary**

Data Name	Obs	Subjects
ADSL	400/400	400/400

**Active Filter Variables**

ADSL

SAFFL Safety Population Flag Y

SEX Sex F, M

AGE Age 20 – 69

**Add Filter Variables**

Add ADSL filter

Select variable to filter

Show Warnings | Show R code

# Discussion

- {teal} is primarily designed for study-specific use, meaning it is most effective when configured with multiple server addresses
- Vendors require a **single server solution** to efficiently manage data across multiple studies simultaneously.
- Open-source initiatives like {pharmaverse} drive innovation and collaboration in clinical trial data management. **CIMS's PharmaSUG 2024 Paper<sup>9</sup>** explores how open-source solutions are reshaping data analysis in clinical trials.

# Conclusion

- A wide range of open-source tools is available for clinical data analysis, with {teal} standing out as the most **robust and reliable** option.
- Our {interactive.stats} Shiny app leverages {teal} to provide an **interactive dashboard with a user-friendly interface** tailored specifically for DMC members.
- The application enables users to focus on **specific parameters, visits, or subjects** through direct interaction with visual components.
- The application also allows users to handle various populations for **subgroup analysis** effectively.
- Additionally, the application facilitates the **download of TFLs** for documentation purposes, streamlining communications, and maintaining thorough records.

# Q&A Session



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