



CDISC India Day

A Modular, Open-Source Approach to Streamline QA of CDISC-Compliant TLFs Using TEAL

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Agenda

1. Quality Oversight and Validation Challenges
2. Teal – an open-source alternative
3. Package: teal.modules.clinical
4. Code Flow
5. Use Case: Lab Data Analysis
6. Conclusion



Speakers



Mahesh Krishna
Lead Programmer
GSK

- Lead Programmer at GSK with more than six years of experience in the clinical research and pharmaceutical industry.
- His expertise includes clinical data standards, analysis-ready datasets, and statistical programming for global studies.
- He has played a key role in the delivery of CDISC-compliant SDTM and ADaM datasets and supports regulatory submission activities.
- Passionate about operational excellence, he focuses on optimizing programming workflows, fostering collaboration, and delivering reliable, high-quality data solutions for clinical development programs.

Speakers



Saravanakumar
Lead programmer
GSK

- Lead Programmer at GSK with over nine years of experience in the clinical research and pharmaceutical industry.
- He has extensive expertise in statistical programming and CDISC standards implementation, including SDTM and ADaM.
- In his current role, he leads programming activities, drives process improvements, and contributes to the adoption of industry best practices to ensure high-quality clinical trial deliverables.



Quality Oversight and Validation Challenges



Key Challenges



1. Scalability Challenges

Frequent re-runs driven by data cuts and subgroup analyses.



2. Collaboration Barriers

Dependence on programming expertise can limit broader stakeholder engagement in result exploration and interpretation.



3. Methodology Complexity

Managing advanced statistical methods while ensuring compliance.



4. Operational Inefficiencies

High manual effort, increased risk of errors, and slower insights.



Teal – an open-source alternative

teal: Interactive Exploratory Data
Analysis with Shiny Web-
Applications



Teal

Teal is a shiny-based interactive exploration framework for analyzing data.

Data, which can be:

- **CDISC data**, commonly used for clinical trial reporting
- **Independent datasets**, for example from a data.frame
- **Related datasets**, for example a set of data.frames with key columns to enable data joins
- **MultiAssayExperiment** objects which are R data structures for representing and analyzing multi-omics experiments

Teal Modules

- **teal.modules.general**: general modules for exploring relational/independent/CDISC data
- **teal.modules.clinical**: modules specific to CDISC data and clinical trial reporting
- **teal.modules.hermes**: modules for analyzing MultiAssayExperiment objects



teal.modules.clinical



teal.modules.clinical

This package contains a set of standard teal modules to be used with CDISC data in order to generate many of the standard outputs used in clinical trials.

- **Data visualizations:**

- Forest plots (tm_g_forest_rsp()/tm_g_forest_tte())
- Line plots (tm_g_lineplot())
- Kaplan-Meier plots (tm_g_km())
- ...

- **Statistical model fits:**

- MMRM (tm_a_mmrn())
- Poisson regression (tm_t_glm_counts())
- Cox regression (tm_t_coxreg())
- Analysis of variance (tm_t_ancova())
- ...

- **Summary tables:**

- Unique patients (tm_t_summary())
- Exposure across patients (tm_t_exposure())
- Change from baseline for parameters (tm_t_summary_by())
- ...

- **Patient-level profile modules:**

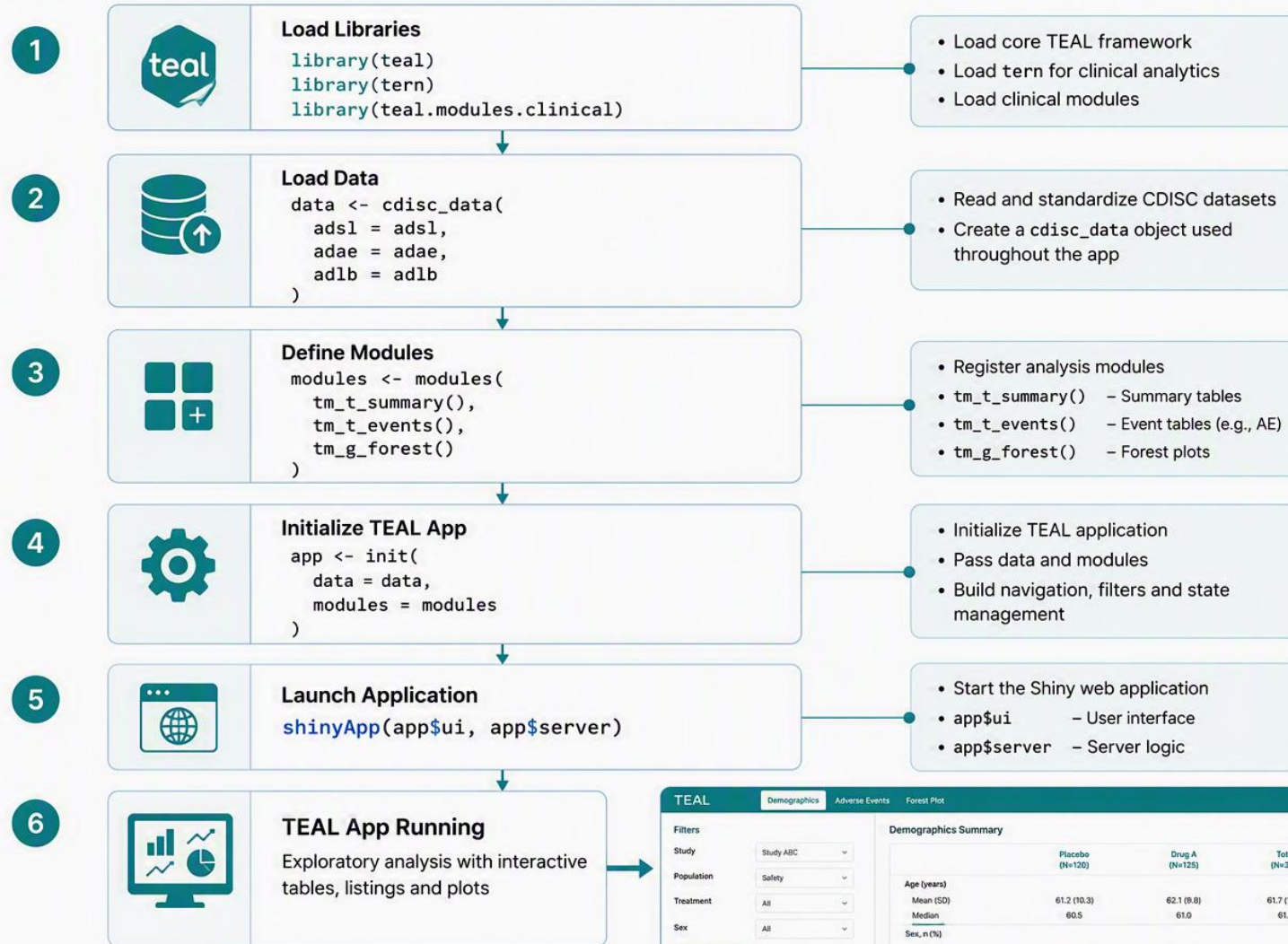
- Table of basic information about chosen patient:
(tm_t_pp_basic_info())
- Plot of patient vitals over time:
(tm_g_pp_vitals())
- General timeline for individual patients
(tm_g_pp_patient_timeline())
- ...



Code Flow



TEAL Application – Developer Code Flow



TEAL

Demographics | Adverse Events | Forest Plot

Filters

Study: Study ABC

Population: Safety

Treatment: All

Sex: All

Apply Filters

Demographics Summary

	Placebo (N=120)	Drug A (N=125)	Total (N=245)
Age (years)			
Mean (SD)	61.2 (10.3)	62.1 (9.8)	61.7 (10.1)
Median	60.5	61.0	61.0
Sex, n (%)			
Male	58 (48.3)	63 (50.4)	121 (48.4)
Female	62 (51.7)	62 (49.6)	124 (50.6)

Use Case: Lab Data Analysis

- Summary of Change from baseline for parameters using `tm_t_summary_by()`
- Line plots using `tm_g_lineplot()`



Report and Review →

+ Add to Report

Show R code

Change from baseline for parameters ← **Module**

Line Plot for parameters

Active Data Summary

Data Name	Obs	Subjects
ADSL	200/200	200/200
ADLB	1800/3000	200/200

Filter Data

ADSL 1

SAFFL Safety Population FL...

Y

ADLB 2

AVISIT Analysis Visit

WEEK 1 DAY 8, WEEK 2 DAY 15,...

Filter Data

Select Column Variable(s) Dataset: ADSL

Select

ARM Description of Planned Arm

☐ Add All Patients column

Select Endpoint Dataset: ADLB

Filter by

ALT Alanine Aminotransferase Measurement

Row By Variable Dataset: ADLB

Select

AVISIT Analysis Visit

Summarize Variables Dataset: ADLB

Select

AVAL Analysis Value, CHG Absolute Change from Base

☐ Show summarize variables in parallel

☐ Summarize number of subjects in row groups

Additional table settings

☒ Drop rows with 0 count

Display NA counts

☒ ifany

☐ no

Denominator choice

Choose the statistics to display for numeric variables

☒ n

☒ Mean (SD)

☐ Mean 95% CI

☐ Geometric Mean

☒ Median

☐ Median 95% CI

☐ 25% and 75%-ile

☒ Min - Max

Choose the statistics to display for categorical variables

☒ n

☒ Count

☐ Count (Fraction)

☐ Count (Fraction with fixed decimal places)

☐ Fraction

☐ Number of values below the limit of quantification

Summary Table for AVAL, CHG by AVISIT

	A: Drug X (N=69)	B: Placebo (N=73)	C: Combination (N=58)
Analysis Visit			
WEEK 1 DAY 8			
Analysis Value			
n	69	73	58
Mean (SD)	20.8 (4.1)	20.2 (4.1)	19.4 (3.7)
Median	20.4	20.0	19.0
Min - Max	12.8 - 34.6	12.6 - 29.0	11.6 - 30.4
Absolute Change from Baseline			
n	69	73	58
Mean (SD)	1.6 (6.1)	-0.2 (5.6)	0.2 (5.2)
Median	2.4	-0.2	0.0
Min - Max	-11.3 - 14.2	-12.8 - 10.8	-10.8 - 11.7
WEEK 2 DAY 15			
Analysis Value			
n	69	73	58
Mean (SD)	19.6 (4.4)	20.7 (4.5)	20.0 (3.6)
Median	19.7	20.5	19.9
Min - Max	10.0 - 31.4	10.4 - 31.7	9.5 - 26.6
Absolute Change from Baseline			
n	69	73	58
Mean (SD)	0.4 (6.0)	0.3 (5.8)	0.9 (5.5)
Median	0.5	-0.6	1.5
Min - Max	-12.7 - 14.7	-11.3 - 21.4	-10.2 - 10.2
WEEK 3 DAY 22			
Analysis Value			
n	69	73	58
Mean (SD)	19.6 (3.8)	19.4 (4.1)	20.3 (3.7)
Median	19.5	19.3	20.1

Summarize variables

Summary Statistics

Change from baseline for parameters

Line Plot for parameters

Module

Active Data Summary

Data Name	Obs	Subjects
ADSL	200/200	200/200
ADLB	1800/3000	200/200

Filter Data

ADSL	+
SAFFL Safety Population Fl...	+
Y	
ADLB	+
AVISIT Analysis Visit	+
WEEK 1 DAY 8, WEEK 2 DAY 15,...	

Parameters: ADSL, ADLB

Select Biomarker Dataset: ADLB

Filter by

ALT Alanine Aminotransferase Measurement x

Select Treatment Variable Dataset: ADSL

Select

ARM Description of Planned Arm x

Analysis Variable Dataset: ADLB

Select

AVAL Analysis Value x

Time Variable

Select AVISIT

Midpoint Statistic

Mean

Interval

Mean CI x

☒ Include screening visit

Additional plot settings

Level of Confidence

0.95 x

Midpoint symbol size

1 2 5

Whiskers to display

☒ Upper☒ Lower

Plot type

☒ Point and line☐ Point☐ Line

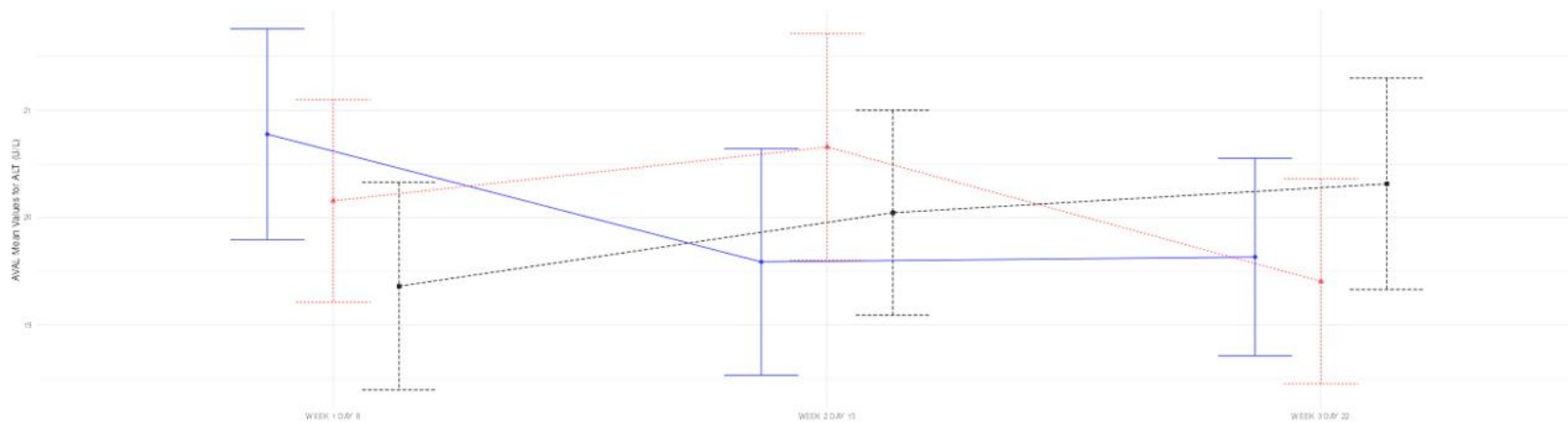
Analysis Unit Variable

Select AVALU

Parameter Code Variable

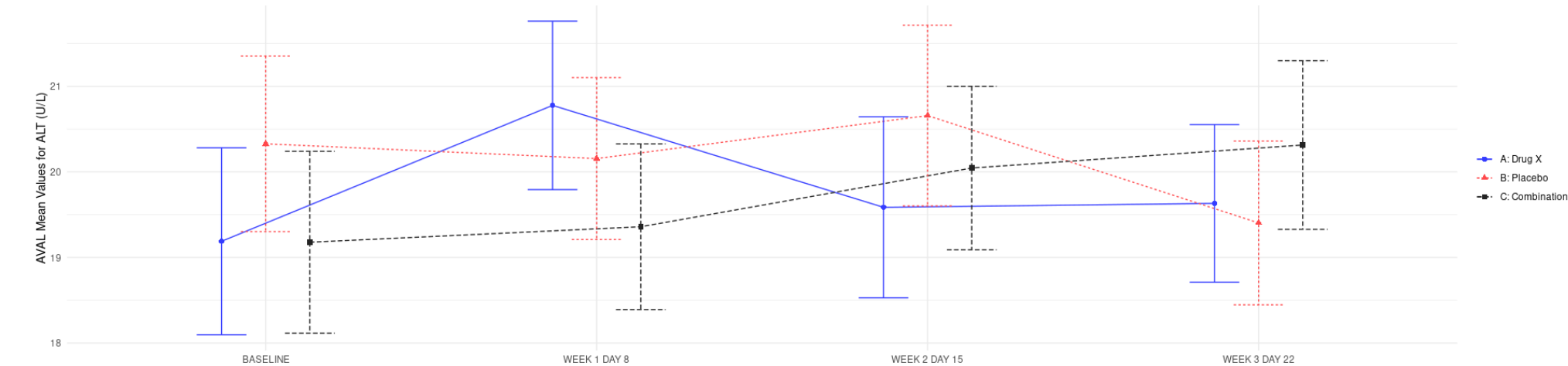
Select PARAMCO

Plot of Mean and 95% Mean Confidence Interval of AVAL by Visit



A: Drug X			
n	69	69	69
Mean (SD)	20.8 (4.1)	19.6 (4.4)	19.6 (3.8)
Median	20.4	19.7	19.5
Min - Max	12.8 - 34.6	10.0 - 31.4	12.1 - 27.3
B: Placebo			
n	73	73	73
Mean (SD)	20.2 (4.1)	20.7 (4.5)	19.4 (4.1)
Median	20.0	20.5	19.3
Min - Max	12.6 - 29.0	10.4 - 31.7	5.8 - 27.3
C: Combination			
n	58	58	58
Mean (SD)	19.4 (3.7)	20.0 (3.6)	20.3 (3.7)
Median	19.0	19.9	20.1
Min - Max	11.6 - 30.4	9.5 - 26.6	11.0 - 28.4

Plot of Mean and 95% Mean Confidence Interval of AVAL by Visit

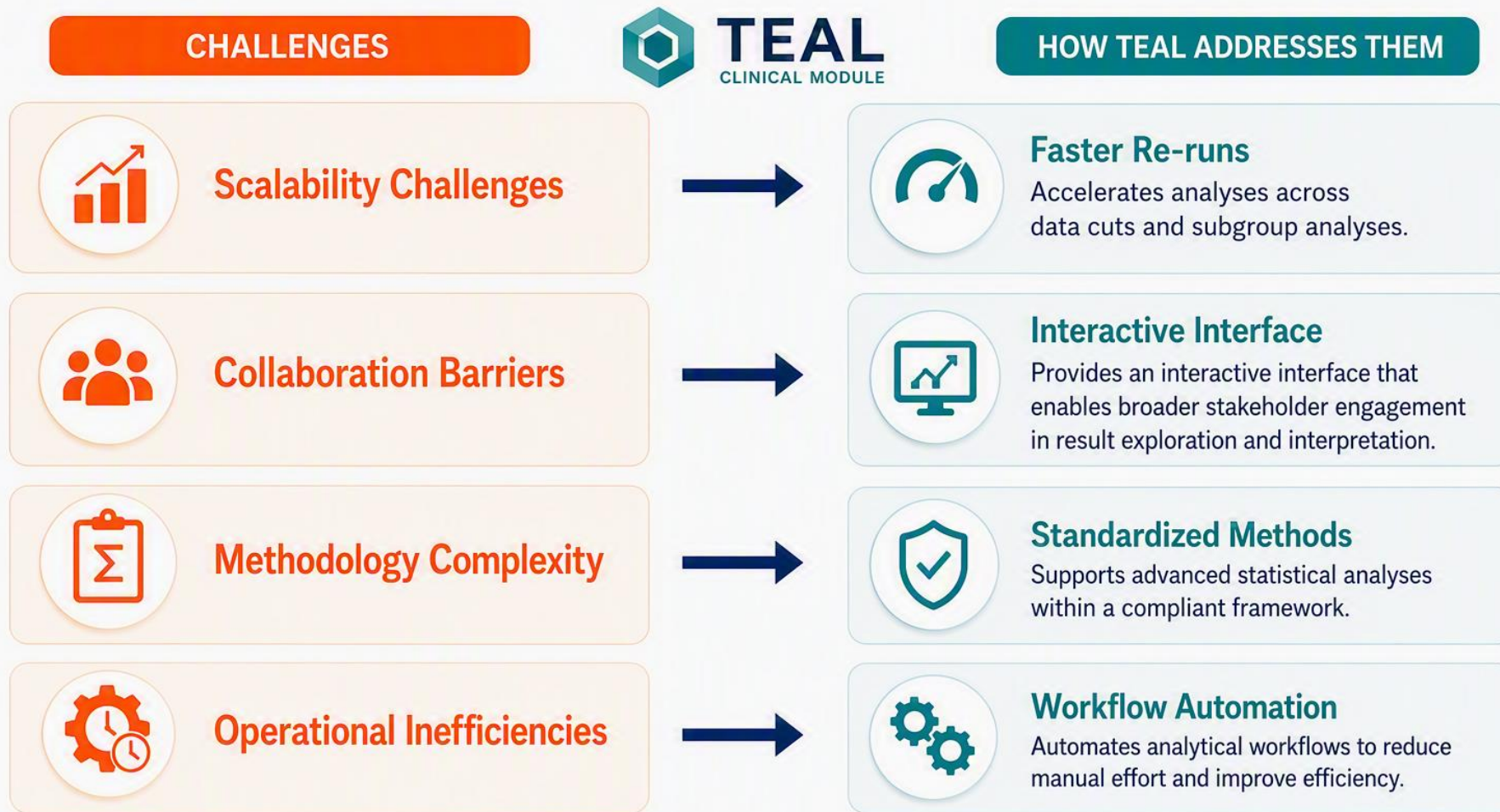


A: Drug X				
n	69	69	69	69
Mean (SD)	19.2 (4.5)	20.8 (4.1)	19.6 (4.4)	19.6 (3.8)
Median	19.0	20.4	19.7	19.5
Min - Max	8.2 - 27.9	12.8 - 34.6	10.0 - 31.4	12.1 - 27.3
B: Placebo				
n	73	73	73	73
Mean (SD)	20.3 (4.4)	20.2 (4.1)	20.7 (4.5)	19.4 (4.1)
Median	20.3	20.0	20.5	19.3
Min - Max	9.6 - 30.7	12.6 - 29.0	10.4 - 31.7	5.8 - 27.3
C: Combination				
n	58	58	58	58
Mean (SD)	19.2 (4.0)	19.4 (3.7)	20.0 (3.6)	20.3 (3.7)
Median	18.6	19.0	19.9	20.1
Min - Max	11.0 - 28.8	11.6 - 30.4	9.5 - 26.6	11.0 - 28.4

Conclusion



Addressing Quality Oversight and Validation Challenges with TEAL Clinical Module





Thank You!





Questions?

