

LiveTFL -- A Centralized Clinical Analysis Platform Based on the Teal Framework and Enhanced by AI

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ABSTRACT

This paper introduces a web app called **LiveTFL**, which is developed based on the **R-based teal framework**. The app allows users to select different clinical trial studies and snapshot dates through UI to generate ADaM data for subsequent TFL analysis. The app consists of two parts: **data processing** and **TFL platform**. The data processing part is responsible for data preprocessing according to the user's selection, and the TFL platform part is responsible for reading the processed data to perform interactive TFL analysis. This paper mainly introduces the extensions that the app has compared to the teal framework and enhanced by AI automation.

Extensions

LiveTFL app has the following extensions compared to the teal framework:

- Extension: The app extends the interactivity of the teal framework data preprocessing by splitting it into two parts, allowing users to generate different ADaM data according to their own choices.
- Improvement: The app enhances the display function of listing and figure by transforming the existing module, and adds the function of selecting the population analysis set of TFL.
- Customization: The app builds a configuration file database for different studies and combines it with UI, allowing users to dynamically modify the configuration file and feedback to the server side to generate interactive TFL, improving the customization level of TFL.
- Quality: The app ensures the quality of TFL while maintaining its flexibility by using leader programmer to perform unified authority management.
- Convenience: One-click custom download and archiving of all TFL, code, and logs for future reproducibility and submission.

AI & Automation

- Config Automation: Auto-generates config files from ADaM standards
- Data Insight:
 - AI translates to pandas code, displays results in UI, and saves data.
 - The user inputs natural language and the AI directly generates the TFL
- Copilot: Guides users, updates configs, and changes settings via AI-linked commands.

INTRODUCTION

In the contemporary landscape of medical research, the analysis of clinical trial data is a pivotal aspect of drug development and research. Accurate and efficient data analysis not only expedites the journey of new drugs to market but also enhances the safety and efficacy of treatment options for patients. However, traditional methods for the analysis of clinical trial data are often complex and time-consuming, necessitating the involvement of specialized statisticians for meticulous data processing and analysis, which in turn imposes limitations on the efficiency and quality of data analysis.

To address this challenge, we have introduced LiveTFL, a web-based application developed on the R language teal framework. The primary objective of LiveTFL is to streamline the process of clinical trial analysis, enabling researchers to effortlessly generate and analyze ADaM (Analysis Data Model) data, as well as perform TFL (Table, Figure, and Listing) analyses. With a user-friendly interface, LiveTFL allows users to select different clinical trial studies and snapshot dates according to their needs, automating the generation of the required ADaM datasets and subsequent TFL analyses.

LiveTFL is a web-based, real-time interactive platform that provides clinical outcome TFLs (Tables, Figures, and Listings). The platform aims to develop a tool that is rapid, automated, and user-friendly to support the generation and review of clinical outcomes. Through LiveTFL, we can achieve online and real-time data review, enhancing the efficiency and quality of data analysis.

This paper will delve into the main functionalities of LiveTFL, including data preprocessing, the TFL platform, and extended features such as interactivity, improved display functions, customizable configurations, and quality control. Additionally, we will explore how LiveTFL leverages AI and automation technologies to enhance the efficiency of configuration file generation, strengthen data insights, and guide users through more in-depth analyses with AI-driven Copilot features.

By combining the robust capabilities of the teal framework with AI automation, LiveTFL offers a more efficient, convenient, and intelligent solution for clinical trial analysis. We believe that the application of LiveTFL will significantly advance the field of clinical trial data analysis and bring revolutionary changes to medical research.

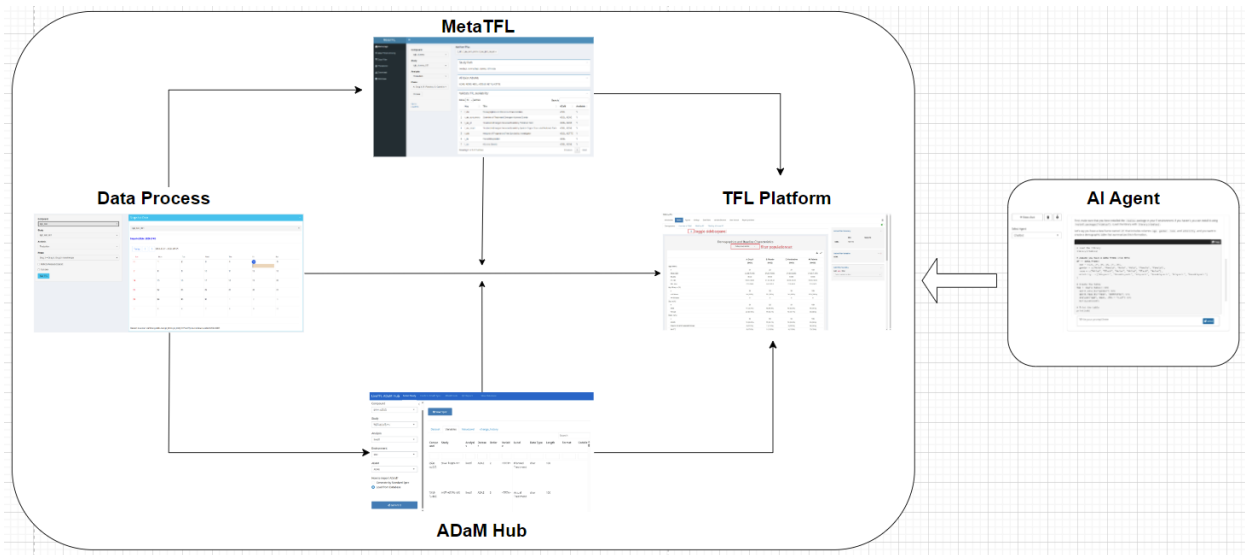
LIVETFL

LiveTFL is a web app developed based on the R teal framework (interactive Exploratory Data Analysis with Shiny Web-Applications), which can provide real-time and interactive clinical trial data analysis results (TFL) display to support data-driven decision making.

LIVETFL VERSE

LiveTFL is currently made up of five apps:

- The Data Process App is responsible for data processing.
- TFL Platform App is responsible for displaying TFL;
- MetaTFL is responsible for centrally and dynamically managing the configuration file information behind TFL;
- ADaM Hub App is responsible for the centralized dynamic management of ADaM Spec and generation of ADaM.
- AI Agent App permeates the interaction link of each app, and enhances the function and service of the App through artificial intelligence technology



TEAL FRAMEWORK

The teal framework is a tool for building TFL interactive analysis web applications, which includes the following components:

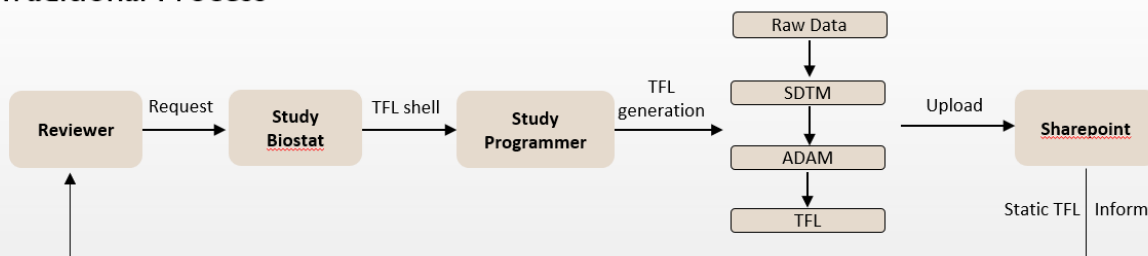
- **teal:** A Exploratory Web Apps package for Analyzing Clinical Trials Data
- **teal.data:** A package for defining data models and loading data sources
- **teal.transform:** Functions for extracting and merging data
- **teal.code:** A class for storing and executing code
- **teal.widgets:** A package for creating shiny widgets
- **teal.logger:** A package for setting up logging
- **teal.reporter:** A tool for generating reports
- **teal.modules.general:** A package for adding general modules to teal applications
- **teal.modules.clinical:** A package for adding standard clinical output modules to teal applications

ADVANTAGES

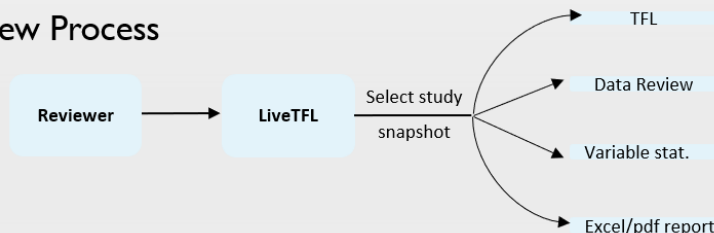
Compared to traditional TFL, LiveTFL has the following advantages:

- **Centralization:** All data and code are stored on the server side, no need to install or update software locally
- **Real-time:** All outputs are generated based on the latest EDC data, no need to wait or refresh
- **Interactivity:** Users can adjust the output results dynamically by selecting different parameters through the UI, such as study, phase, snapshot date, group, filter, etc.
- **Exploratory:** Users can view the distribution of each variable through the variable browser, view different levels of statistical results through tables, listings, figures, and combine and download selected outputs through the report previewer
- **Possibility:** Users can customize the output content and format through the configuration file database and permission management system, increasing flexibility and quality control

Traditional Process



New Process



FLOW CHART

LiveTFL consists of three parts: data processing, configuration files and TFL platform.

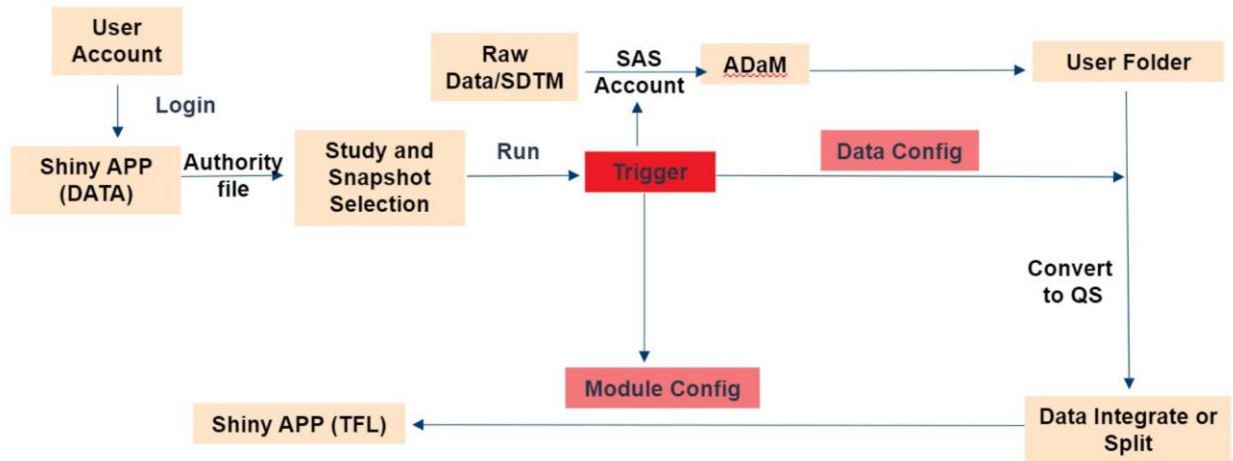
- **Data Process:** Users first select different clinical trial study, phase and snapshot date through the data processing app to generate ADAM data for subsequent TFL analysis.
- **Configuration Files:** Data preprocessing and subsequent TFL platforms were dynamically updated through the configuration files of different studies.
- **TFL Platform:** Using the TFL platform app to read the processed data from the previous app to perform TFL interactive analysis.

The shiny app is divided into two parts, the first part is data preprocessing and the second part is the TFL platform.

When a user logs in, the shiny app updates the Study and Snapshot date Selection based on user permissions via the Authority file.

When the App is running, the final data required by TFL is generated through three Trigger processes:

1. shiny calls the SAS server to generate ADaM Data from Raw Data/SDTM into the user folder
2. Use the data config file to Integrate or Split Data and convert the SAS file to the qs file.
3. Use the Module Config file to generate a user-specific TFL platform



The Trigger controls the user's input from the Study Information File and the final TFL output from the ADaM Information File.

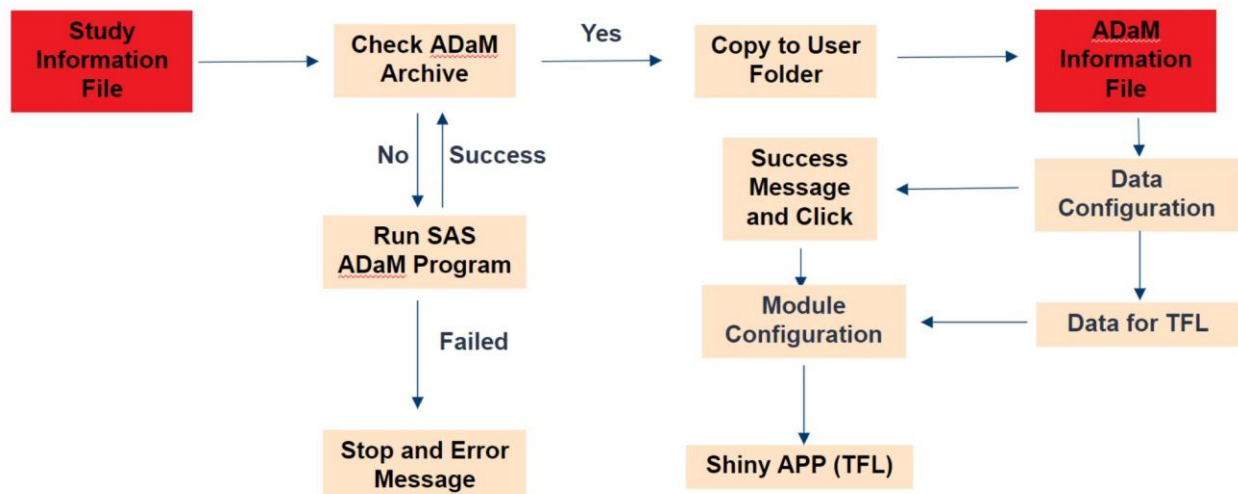
The Shiny app first checks whether data exists in the ADaM Archive according to the Information in the Study Information File. If Yes, it copies to the User Folder, if No, it runs SAS ADaM Program.

If SAS ADaM Program fails to run, stop the App and report an Error Message.

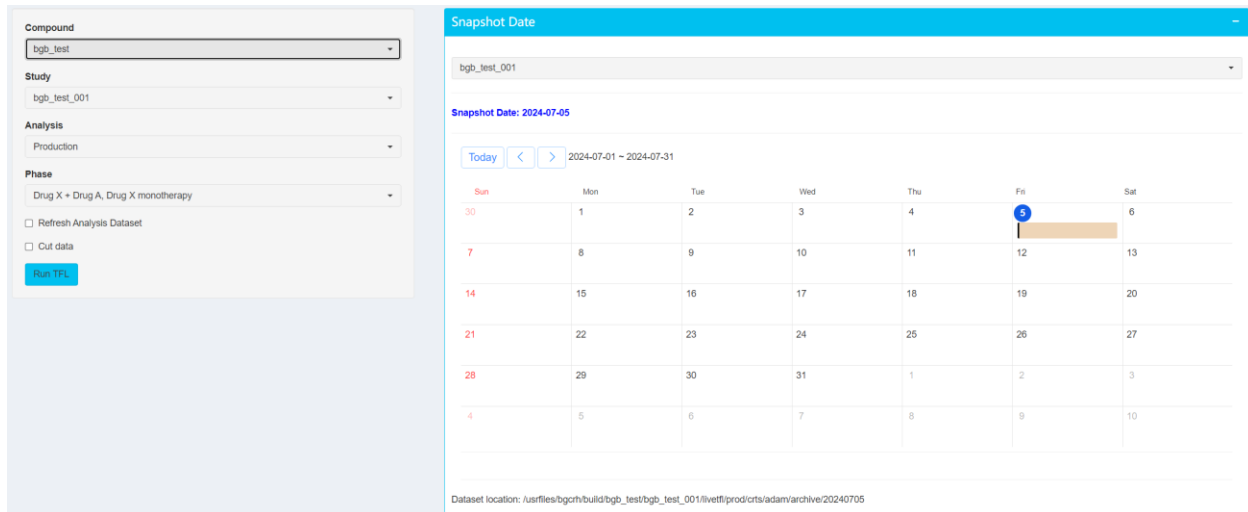
If it runs successfully, back up the ADaM data and Copy to the User Folder.

The Shiny app then makes a Data Configuration based on the Information from the ADaM Information File. This will produce Data for TFL And a Success Message is reported.

When the user clicks, the Shiny app Module Configuration produces a user-specific TFL platform interface.



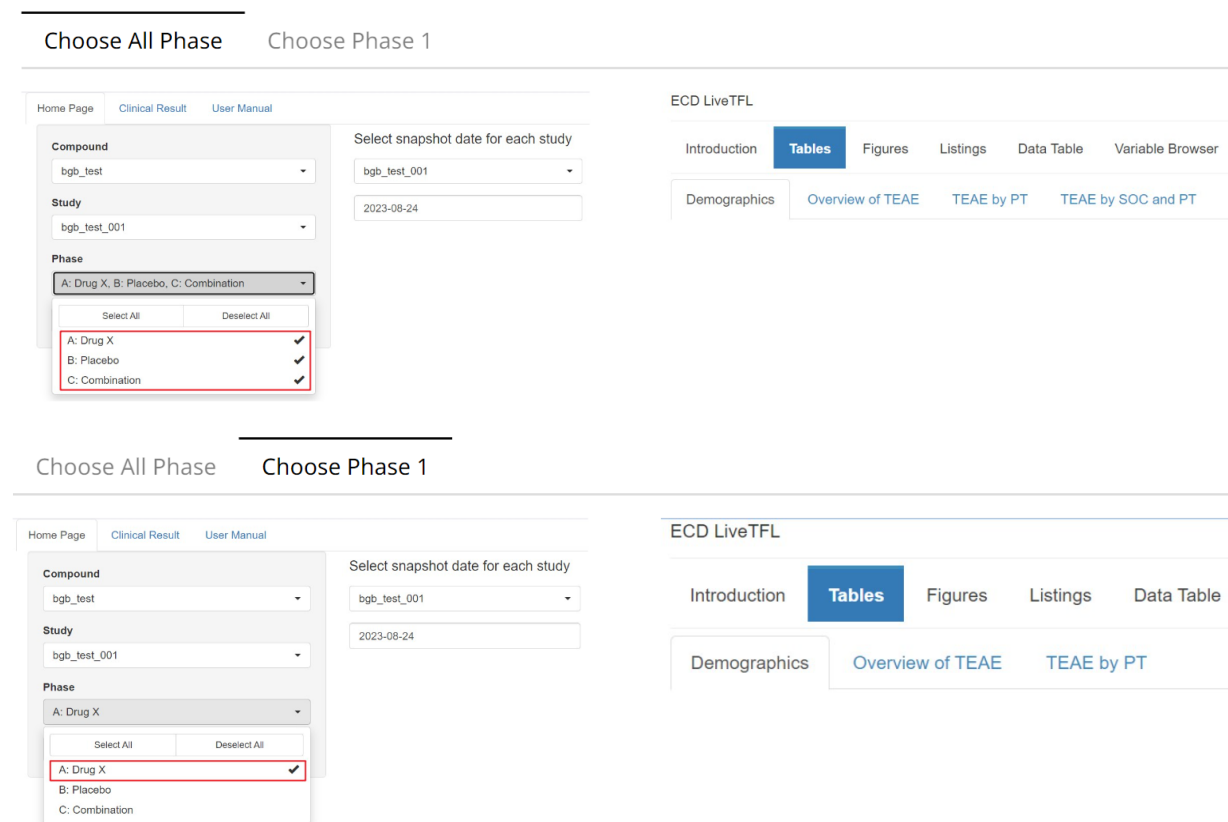
DATA PROCESS



CONFIGURATION FILES

- **Update TFL layout dynamically**

Different studies and phases have different configuration files, and you can dynamically get different TFL layouts by switching phase on the configuration files.



- **Data Configure**

The Shiny app reads the study's configuration file based on user input to Prepare Data for TFLs. For example, when we need to pre-process the data of DM table, we filter the variables to be

processed according to Key, Phase and Order, assign the Label of the Variable according to the value of label column, and generate Variable according to the condition logic.

Prepare Data for TFLs

Choose TFLs

t_dm, t_ae_sum_mono, t_ae_pt, t_ae_soc

Data Derive for ADaMs		Data Merge for Listings		Data Derive for Listings	
Key	AnalysisData	Variable	Label	Condition	
1	t_dm	ADSL	AGE	Age (Years)	AGE1
2	t_dm	ADSL	AGEGR	Age Group, n (%)	factor(if_else(AGE < 60, "<60", ">=60"), levels = c("<60", ">=60"), labels = c("< 60 Years", ">= 60 Years"))
3	t_dm	ADSL	SEX1	Sex, n (%)	factor(SEX, levels = c("M", "F"), labels = c("Male", "Female"))
4	t_dm	ADSL	RACE1	Race, n (%)	RACE
5	t_dm	ADSL	WGTBL	Weight (kg)	list(data = "ADSUB", var = "AVAL", filter = "PARAMCD == "BWGHTSI")
6	t_ae_sum_mono	ADAE	MONO_TEAE_1	Patients With Any TEAE	TRTEMFL == "Y"
7	t_ae_sum_mono	ADAE	MONO_TRTEAE_2	Treatment-Related	TRTEMFL == "Y" & AEREL == "Y"
8	t_ae_sum_mono	ADAE	MONO_TOXGR3_1	>= Grade 3	AETOXGR %in% c("3", "4", "5")
9	t_ae_sum_mono	ADAE	MONO_TRTOXGR3_2	Treatment-Related >= Grade 3	AETOXGR %in% c("3", "4", "5") & AEREL == "Y"
10	t_ae_sum_mono	ADAE	MONO_SAE_1	Serious	AESER == "Y"
11	t_ae_sum_mono	ADAE	MONO_TRSAE_2	Treatment-Related Serious	AESER == "Y" & AEREL == "Y"
12	t_ae_sum_mono	ADAE	MONO_TOXGR5_1	Leading to Death	AETOXGR == "5" AESDTH == "Y" AEOUT == "FATAL"
13	t_ae_sum_mono	ADAE	MONO_TRTOXGR5_2	Treatment-Related Leading to Death	(AETOXGR == "5" AESDTH == "Y" AEOUT == "FATAL") & AEREL == "Y"

Module Configure

The Shiny app reads the study's configuration file based on user input to set default parameter values for the TFL module. For example, when we need to generate a DM table, we filter the parameters required by the table module according to Key, Phase and modulename, and obtain the parameter name and parameter value required by the table module according to the parameter and value columns. Finally, the interactive page of the DM table is generated.

Default Setting

Choose a TFL

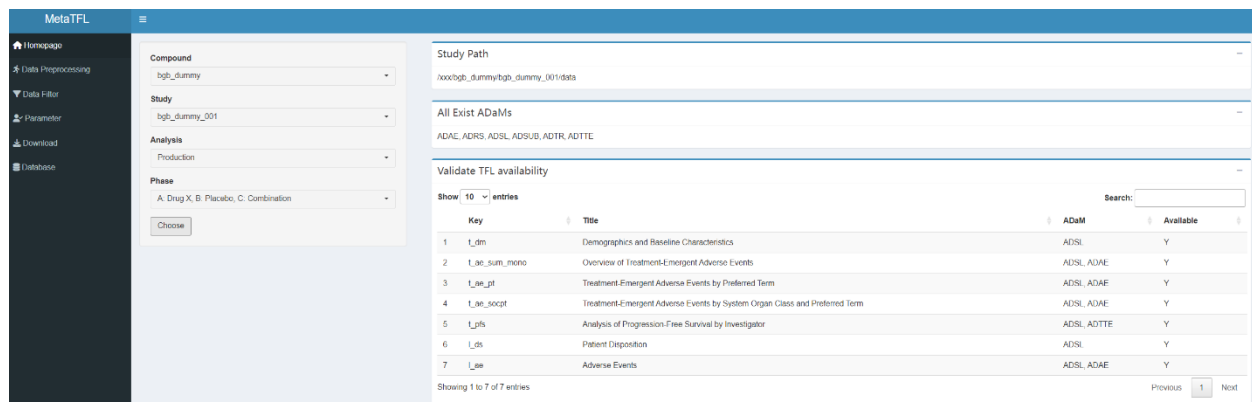
t_dm

Edit Module Parameter

Key	Module/Function	Parameter	Value	Update
t_dm	bgdm_t_summary	TabSetName	Demographics	↻
t_dm	bgdm_t_summary	Title	Demographics and Baseline Characteristics	↻
t_dm	bgdm_t_summary	Population	Safety Analysis Set	↻
t_dm	bgdm_t_summary	GroupVariable	1 TRT01A, BMRKR2, TRT01P, ARM, ARMCD	↻
t_dm	bgdm_t_summary	AddTotal	Y	↻
t_dm	bgdm_t_summary	AddSubtotal	N	↻
t_dm	bgdm_t_summary	AnalysisData	ADSL	↻
t_dm	bgdm_t_summary	PopulationData	ADSL	↻
t_dm	bgdm_t_summary	AnalysisVariable	AGE, AGEGR, SEX1, RACE1, WGTBL	↻
t_dm	bgdm_t_summary	Footnote		↻

Configuration Automation

Create Configuration File Automatically Based on ADaM and Standard



TFL PLATFORM

The TFL Platform app has 9 tabs, which are:

- **Introduction:** Introduction of Study information

Introduction
Tables
Listings
Download All
User Manual
Report previewer

Welcome to ECD LiveTFL!

Study Information

Item	Contents
Study	BGB-DUMMY-001
Snapshot Date	20240725
Phase	A: Drug X;B: Placebo;C: Combination
User	
Data Path	/teal/config_demo/data

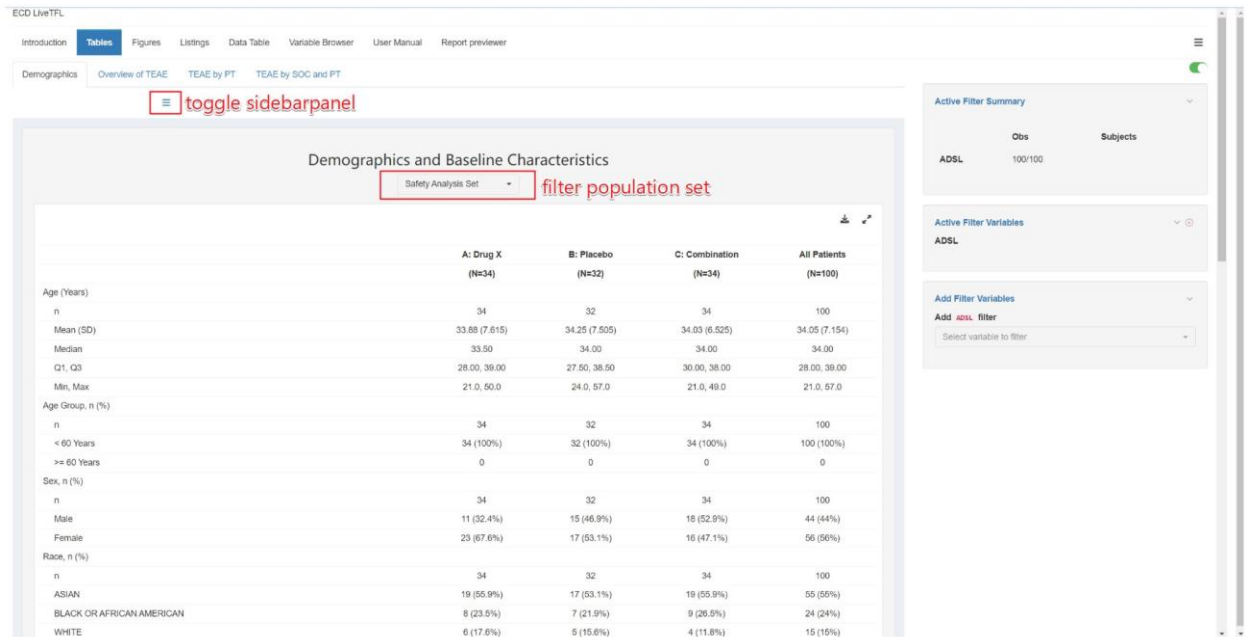
Developer

This is provided by Statistical Programming Team with Statistician Team.

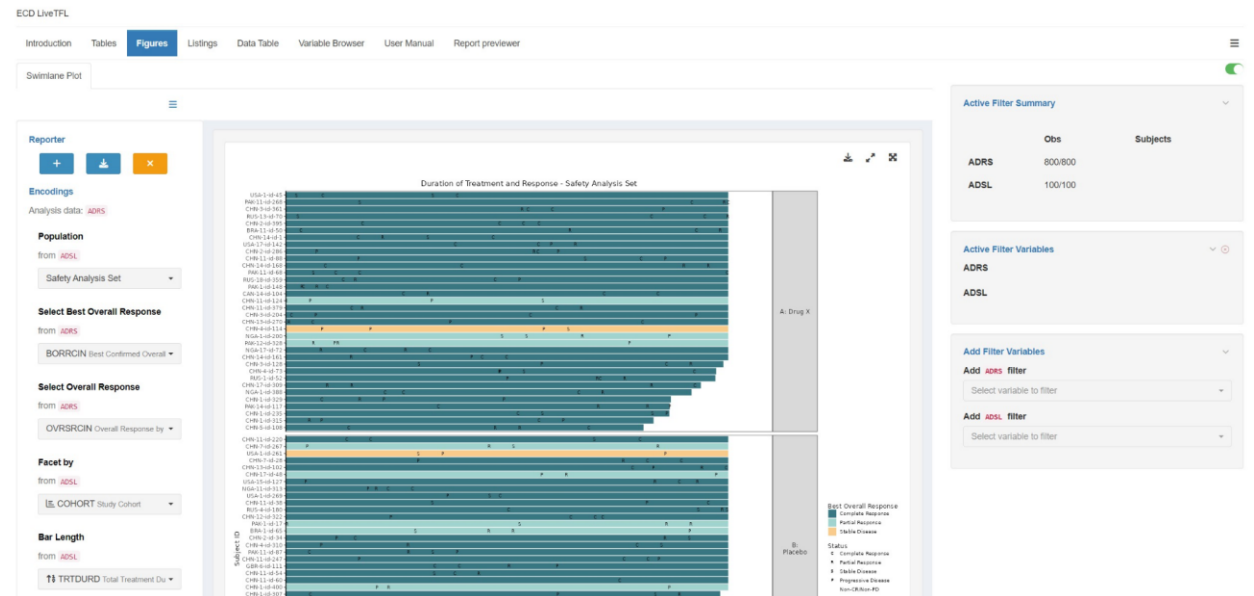
Declaration

All output generated by the platform instantly is based on real-time EDC data. They are draft versions for ongoing monitoring of clinical results. For official use in any clinical decision-making, publication/manuscript or communication, please contact study Biostatistician and Lead Statistical Programmer for formal validation.

- **Tables:** Displays summary tables, allowing you to select different table types and parameters, as well as filter by grouping variables and filtering conditions



- **Figures:** Displays dynamic graphs, allowing you to select different graph types and parameters, as well as filter by grouping variables and filtering conditions



- **Listings:** Displays data listings, allowing you to select different listing types and parameters, as well as sort and filter by sorting variables and filtering conditions

ECD LiveTFL

Introduction Tables Figures Listings Data Table Variable Browser User Manual Report previewer

Patient Disposition Adverse Events

Reporter
+ - ×
Encodings

reporter button

Patient Disposition
Safety Analysis Set

Select variables:
SUBJID: Subject Identifier for the Study, TRT01A: Actual Treatment for Period 01, AGE: Age (Years), SEX: Sex, RACE: Race, TRTSDTM: Datetime of First Exposure to Trei

Show 30 entries

download button

	Subject Identifier for the Study	Actual Treatment for Period 01	Age (Years)	Sex	Race	Datetime of First Exposure to Treatment
1	id-1	A: Drug X	27	F	ASIAN	2019-05-07T11:59:24Z
2	id-104	A: Drug X	39	F	BLACK OR AFRICAN AMERICAN	2019-06-28T02:51:57Z
3	id-108	A: Drug X	28	F	BLACK OR AFRICAN AMERICAN	2019-09-11T06:10:06Z
4	id-114	A: Drug X	23	F	ASIAN	2019-08-18T22:39:14Z
5	id-117	A: Drug X	25	F	ASIAN	2019-07-15T04:23:49Z
6	id-142	A: Drug X	31	F	WHITE	2019-05-14T12:56:10Z
7	id-161	A: Drug X	33	F	ASIAN	2019-09-12T02:39:34Z
8	id-200	A: Drug X	25	F	ASIAN	2019-09-01T00:38:52Z
9	id-268	A: Drug X	28	F	BLACK OR AFRICAN AMERICAN	2019-03-21T23:53:53Z

Active Filter Summary

GLOBAL Obs 56/100
L_DS 100/100

Active Filter Variables

GLOBAL

SEX
F (56)
M (44)

L_DS

Add Filter Variables

Add GLOBAL filter
Select variable to filter

Add L_DS filter
Select variable to filter

- **Data Tables:** Displays tables of all source data (ADaM) in the current session, allowing you to view the structure and content of each table

☐ Show only distinct rows:

ADAE ADRS ADSL ADSUB ADTR ADTTE

Select variables:
STUDYID: Study Identifier, USUBJID: Unique Subject Identifier, SUBJID: Subject Identifier for the Study, SITEID: Study Site Identifier, AGE: Age, AGEU

Show 30 entries

	STUDYID	USUBJID	SUBJID	SITEID	AGE	AGEU
1	AB12345	AB12345-BRA-1-id-134	id-134	BRA-1	47	YEARS
2	AB12345	AB12345-BRA-1-id-134	id-134	BRA-1	47	YEARS
3	AB12345	AB12345-BRA-1-id-134	id-134	BRA-1	47	YEARS
4	AB12345	AB12345-BRA-1-id-134	id-134	BRA-1	47	YEARS
5	AB12345	AB12345-BRA-1-id-141	id-141	BRA-1	35	YEARS
6	AB12345	AB12345-BRA-1-id-141	id-141	BRA-1	35	YEARS
7	AB12345	AB12345-BRA-1-id-141	id-141	BRA-1	35	YEARS
8	AB12345	AB12345-BRA-1-id-141	id-141	BRA-1	35	YEARS
9	AB12345	AB12345-BRA-1-id-141	id-141	BRA-1	35	YEARS
10	AB12345	AB12345-BRA-1-id-141	id-141	BRA-1	35	YEARS
11	AB12345	AB12345-BRA-1-id-238	id-238	BRA-1	33	YEARS

Active Filter Summary

Obs Subjects

ADAE 1934/1934

ADRS 3200/3200

ADSL 231/400

ADSUB 2000/2000

ADTR 2800/2800

ADTTE 2000/2000

Active Filter Variables

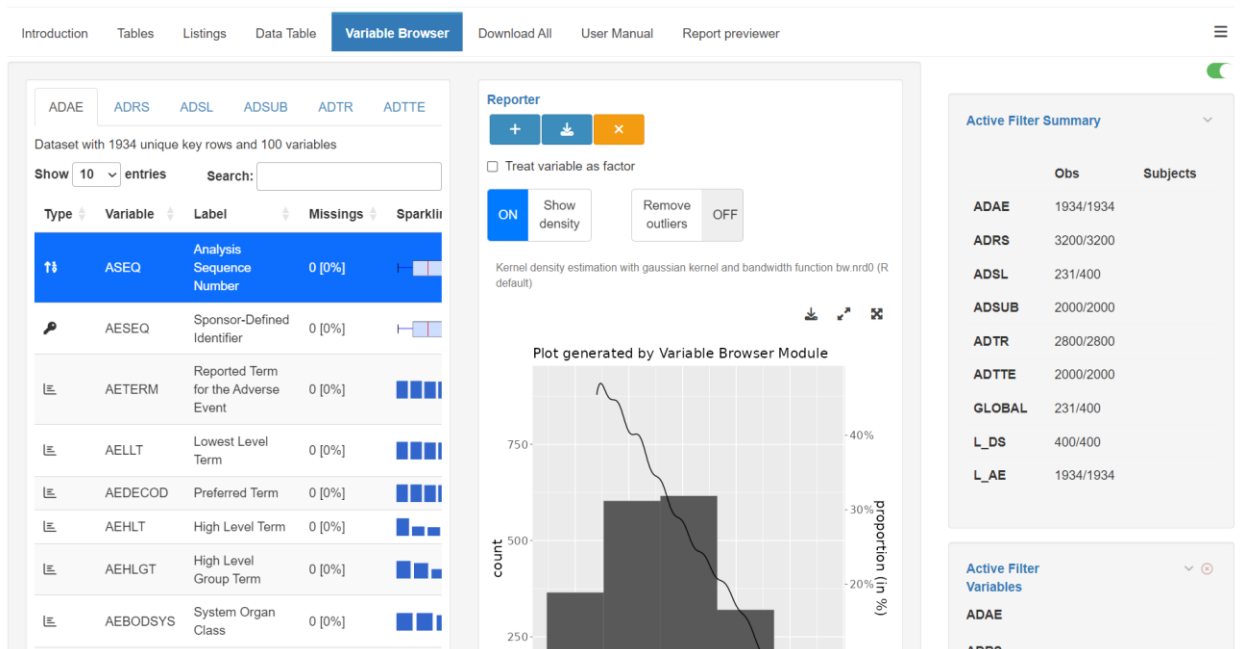
ADAE

ADRS

ADSL

SEX

- **Variable Browser:** Displays the distribution of each variable, allowing you to select different variable types and statistical methods, as well as whether to stratify by grouping variables



- **Download All:** Download all the TFLs, which are set by default in the configuration file.

The TFL Download interface shows a list of TFLs with columns for Key, Title, and Population. The 'Download TFL' button is highlighted. The 'TFL archive' section shows 'Coming Soon!'. The interface also includes a sidebar with options for 'Archive or not?', 'Table type', 'Listing type', 'Figure type', and 'File Name'.

Key	Title	Population
t_ds	Patient Disposition and Reasons for Discontinuation	Safety Analysis Set
t_dm	Demographics and Baseline Characteristics	Safety Analysis Set
t_ae_sum_mono	Overview of Treatment-Emergent Adverse Events	Safety Analysis Set
t_ae_socpt	Treatment-Emergent Adverse Events by System Organ Class and Preferred Term	Safety Analysis Set
t_ae_socpt_rel1	Related 24714 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term	Safety Analysis Set
t_ae_socpt_ge3	Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term	Safety Analysis Set

- **User Manual:** User Manual of LiveTFL

Contents

- 1 Introduction and Overview
- 2 App login, compound/study selection and analysis data creation
- 3 Creating the TFL and browsing the data
- 4 Trouble shooting
- 5 Frequent Ask Questions
- 6 Contacts and Support

Scope: Support LiveTFL

Document date: 10JUL2023

Version: 0.01

Contents

1 Introduction and Overview

1.1 Overview

LiveTFL is an interactive TFL platform. It is a web app which can provide real-time and interactive analysis result (TFL) display to enable data-driven decision making. You can instantly generate TFL and ADAM by selecting the study and any data snapshot.

This app has the following six major functionalities/TABs. The pre-defined TFL for a study will be included and displayed. The user has the flexibilities to interact with app and generate the TFL report(s) with various data subset/filters.

- Tables
- Listings
- Figures
- Data Table

- **Report previewer:** Displays the report preview interface, allowing you to combine and select outputs from the previous tabs and download them in PDF or PPT format.

Download the Report

Author:

NEST

Title:

Report

Date:

2024-07-31

Choose a document type:

html

☐ Include Table of Contents

☐ Include R Code

Download Report

Reset Report

Card 1: Summary Table

Summary Table

Filter State

Filters for dataset: ADSL
 Filtering on: SEX
 Selected values: F
 Include missing values: FALSE
 Filters for dataset: GLOBAL
 Filtering on: SEX
 Selected values: F
 Include missing values: FALSE

Demographics and Baseline Characteristics Safety Analysis Set

	A: Drug X (N=79)	B: Placebo (N=82)	C: Combination (N=70)	Total (N=231)
Age (Years)				
n	79	82	70	231
Mean (SD)	32.76 (6.087)	34.24 (6.988)	35.20 (7.373)	34.03 (6.860)
Median	32.00	32.00	35.00	34.00
Q1, Q3	28.00, 37.00	29.00, 38.00	31.00, 38.00	29.00, 38.00
Min, Max	21.0, 47.0	23.0, 58.0	21.0, 64.0	21.0, 64.0
Age Group, n (%)				
n	79	82	70	231
< 60 Years	79 (100%)	82 (100%)	69 (98.6%)	230 (99.6%)

LIVETFL ADAM HUB

LiveTFL ADaM Hub is a centralized ADaM management platform. Its main features are:

- Automated ADaM Spec generation

LiveTFL ADaM Hub [Select Study](#) [Confirm ADaM Spec](#) [ADaM Code](#) [QC Report](#) [View Database](#)

Compound:

Study:

Analysis:

Environment:

ADaM:

How to import ADaM?
☐ Generate by Standard Spec
☒ Load from Database

[Generate](#)

[Save Spec](#)

[Dataset](#) [Variables](#) [ValueLevel](#) [change_history](#)

Search

Compound	Study	Analysis	Dataset	Order	Variable	Label	Data Type	Length	Format	Codelist
ADA-1000	Study 123	livetfl	ADAE	2	<TRTP>	Planned Treatment	char	100		
ADA-1000	Study 123	livetfl	ADAE	3	<TRTA>	Actual Treatment	char	100		

- Centralized management of ADaM Spec

LiveTFL ADaM Hub [Select Study](#) [Confirm ADaM Spec](#) [ADaM Code](#) [QC Report](#) [View Database](#)

[Download Spec](#) [How to Generate Code?](#) [Refresh Code!](#) [Generate Full Code!](#)

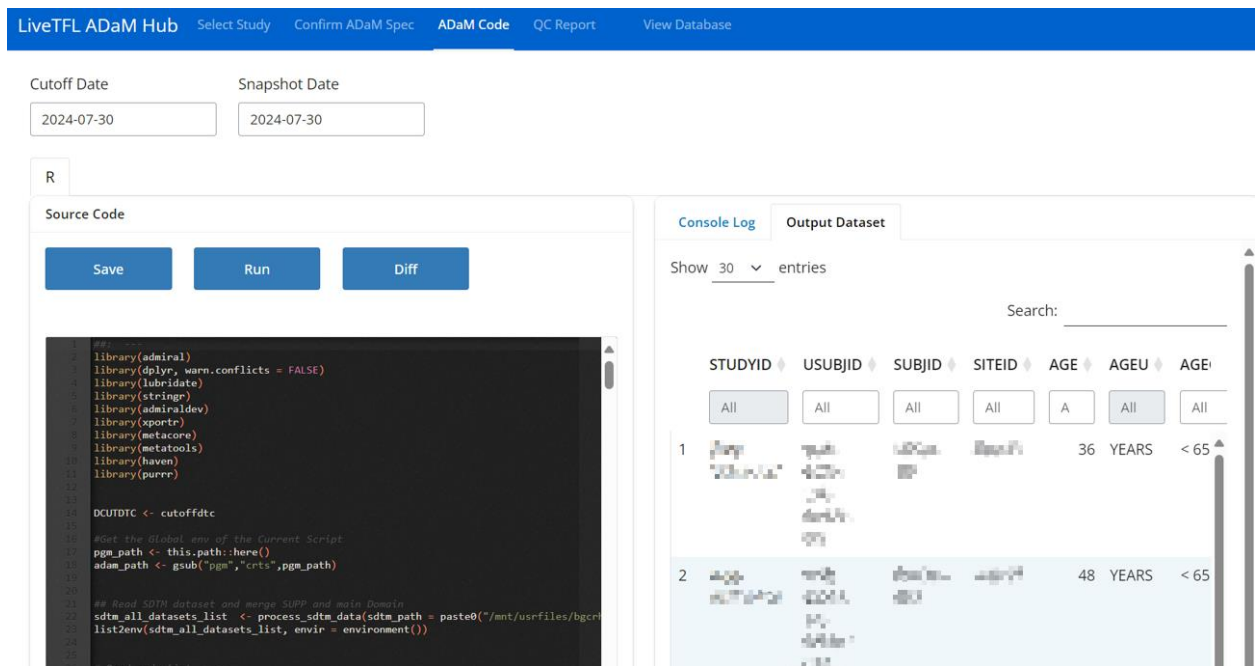
[Dataset](#) [Variables](#) [ValueLevel](#) [change_history](#)

[edit](#) [save](#)

Search

Compound	Study	Analysis	Dataset	Order	Variable	Label	Data Type	Length	Format	Codelist	Origin	Comment
ADA-1000	Study 123	livetfl	ADAE	2	<TRTP>	Planned Treatment	char	100			Derived	
ADA-1000	Study 123	livetfl	ADAE	3	<TRTA>	Actual Treatment	char	100			Derived	

- Automatically generate and execute ADaM Code



EXTENSIONS

ENHANCED INTERACTIVITY FOR DATA PREPROCESSING:

- **Dynamic Configuration Management:**

LiveTFL enables users to dynamically manage data preprocessing workflows through configuration files. Users can select data sources, define transformation rules, and make adjustments based on their needs without modifying the code, achieving flexible data preprocessing.

- **Phased Application Design:**

The application is divided into two parts: Data Processing and TFL Platform. Users select and preprocess data in the Data Processing section, and the TFL Platform section then reads and displays the processed data in real-time. Users can directly perform interactive analysis without waiting for data processing to complete before launching the application.

USER EXPERIENCE OPTIMIZATION:

- **Access Management:**

Permissions are centrally managed by a leader programmer, ensuring that different users can only access data and analysis results within their authorized scope. This guarantees the accuracy and consistency of analysis results.

- **Module Modification:**

Modifications are made to existing modules, including:

- **Enhanced Listing Display Functionality:** Utilizing the DT package, listing display, filtering, searching, and downloading functionalities are enhanced. For example, pagination, sorting, and filtering controls are added to facilitate users in quickly finding the required data.
- **Adding Population Analysis Set Selection Function:** Users are allowed to select different population analysis sets for TFL analysis, such as full analysis sets and safety sets, to meet different analysis needs.

- **Data Association:** Using the teal.slice module, the functionality to uniformly filter all listings is realized. Users only need to perform filtering operations on any listing, and all related listings will automatically update the filtering results, facilitating data exploration.

CUSTOMIZATION AND EXTENSIBILITY:

- **Configuration File Database:**

A configuration file database for different studies is built, and a UI interface is used to allow users to dynamically modify configuration files. Users can select different data sources, define different transformation rules, and more. After the configuration file is updated, the server-side will automatically apply the new configuration for data preprocessing without the need to restart the application.

- **Statistical Function Extension:**

Custom statistical functions and result labels are extended using the tern package, such as:

- **Displaying Counts for Numerical Variables Only:** For numerical variables, users can choose to display only their count results, without displaying the count results of categorical variables, making the results clearer.
- **Modifying Quantile Label Formats:** Users can customize the format of quantile labels, for example, using different languages or units.
- **Modifying Statistical Result Formats:** Users can customize the format of statistical results, for example, not displaying percentages or currency symbols.

- **Layout Framework Extension:**

More layout frameworks are added to the teal package, such as shinydashboard, and drop-down tab functionality to enhance the interface's simplicity and usability, such as:

- **Shinydashboard:** Provides richer layout options, such as sidebars and navigation bars, making it convenient for users to build complex interfaces.
- **Drop-Down Tabs:** When there are too many tables, listings, and figures to display, drop-down tabs can save page space and make it easier for users to switch between different analysis results.

- **Report Rendering Optimization:**

Enhances the rendering effects of PDF and docx reports, such as:

- **Resolving Data Truncation and Typesetting Issues:** Ensures that data is displayed in the report in its entirety and typeset beautifully.
- **Providing More Customizable Styling Functionality:** Gradually allows users to customize the font, color, background, and other styles of the report, making it more personalized.

- **Report Download Functionality:**

Develops a Download All module to support the function of downloading all TFL content with default configuration of the config file, facilitating users to integrate reports, such as:

- **One-Click Download of All TFL Content:** Users do not need to click the download button one by one and can download all TFL content with one click, saving time on reporting.
- **Supporting Multiple Download Formats:** Supports downloading in various formats, such as csv, svg, html, PDF, docx, etc., making it convenient for users to use.

Demographics and Baseline Characteristics				
Safety Analysis Set				
	A: Drug X (N=34)	B: Placebo (N=32)	C: Combination (N=34)	All Patients (N=100)
Age (Years)				
n	34	32	34	100
Mean (SD)	33.88 (7.615)	34.25 (7.505)	34.03 (6.525)	34.05 (7.154)
Median	33.50	34.00	34.00	34.00
Q1, Q3	28.00, 39.00	27.50, 38.50	30.00, 38.00	28.00, 39.00
Min, Max	21.0, 50.0	24.0, 57.0	21.0, 49.0	21.0, 57.0
Age Group, n (%)				
n	34	32	34	100
< 60 Years	34 (100%)	32 (100%)	34 (100%)	100 (100%)
>= 60 Years	0	0	0	0
Sex, n (%)				
n	34	32	34	100
Male	11 (32.4%)	15 (46.9%)	18 (52.9%)	44 (44%)
Female	23 (67.6%)	17 (53.1%)	16 (47.1%)	56 (56%)

Data cutoff: 24AUG2023. Data extraction: 24AUG2023BMI: body mass indexPatients with multiple races checked were included only in "Multiple" category.

Patient Disposition													
Safety Analysis Set													
Subject Identifier for the Study	Actual Treatment for Period 01	Age (Years)	Sex	Race	Datetime of First Exposure to Treatment	Datetime of Last Exposure to Treatment	End of Study Date	End of Study Relative Day	Date of Death	Relative Day of Death	Reason for Discontinuation from Study	Cause of Death	
id-1	A: Drug X	27	F	ASIAN	2019-05-07 11:59:24	2022-05-07 05:59:24	2022-05-07	1,096					
id-104	A: Drug X	39	F	BLACK OR AFRICAN AMERICAN	2019-06-28 02:51:57	2022-06-27 20:51:57	2022-06-27	1,096					
id-108	A: Drug X	28	F	BLACK OR AFRICAN AMERICAN	2019-09-11 06:10:06	2022-02-13 05:36:22	2022-02-13	886	2022-04-04	935	DEATH	MISSING	
id-114	A: Drug X	23	F	ASIAN	2019-08-18 22:39:14	2022-08-18 16:39:14	2022-08-18	1,096					
id-117	A: Drug X	25	F	ASIAN	2019-07-15 04:23:49	2022-02-20 01:27:23	2022-02-20	951			PROTOCOL VIOLATION		
id-124	A: Drug X	41	M	ASIAN	2019-07-14 08:51:46	2022-07-14 02:51:46	2022-07-14	1,096					
id-102	B: Placebo	37	M	ASIAN	2019-03-23 06:06:17	2022-03-23 00:06:17	2022-03-23	1,096					
id-111	B: Placebo	30	F	ASIAN	2019-07-29 00:29:19	2022-07-28 18:29:19	2022-07-28	1,096					
id-126	B: Placebo	27	M	WHITE	2019-05-02 14:23:21	2022-02-20 00:30:20	2022-02-20	1,025	2022-04-03	1,066	DEATH	ADVERSE EVENT	
id-115	C: Combination	38	M	ASIAN	2019-03-28 09:33:43	2022-03-28 03:33:43	2022-03-28	1,096					

Data cutoff: 24AUG2023. Data extraction: 24AUG2023a Study follow-up time is defined as the time from first dose date to the death date or end-of-study date (whichever occurs first) for patients discontinued from the study, or the data cutoff date for patients continuing in the study.

AI & AUTOMATION

AUTOMATED DATA IMPORT AND CLEANING

- **Data Source Connection:** LiveTFL can automatically connect to various data sources, such as databases, Electronic Data Capture (EDC) systems, etc., eliminating the need for manual data import.
- **Data Cleaning Rules:** Users can define data cleaning rules, such as handling missing values, detecting outliers, and converting data types. LiveTFL will automatically execute these rules to ensure data quality.
- **Scheduled Tasks:** Users can set scheduled tasks to regularly import and clean data, ensuring data timeliness.

INTERACTIVE DATA EXPLORATION

- **Visual Analysis:** LiveTFL offers a rich set of visualization tools, such as charts, tables, maps, etc., to help users intuitively explore data. Users can easily perform data filtering, sorting, grouping, and other operations for interactive analysis.
- **Data Association Analysis:** LiveTFL supports data association analysis to help users discover hidden patterns in the data.

AUTOMATED REPORT GENERATION

- **Template-Based Reports:** LiveTFL supports template-based reports, allowing users to customize the format and content of reports. LiveTFL will automatically generate reports based on templates, saving users time and effort.
- **Automated Report Updates:** Users can set scheduled tasks to regularly update reports, ensuring report timeliness.
- **Multiple Report Formats:** LiveTFL supports various report formats, such as PDF, Word, etc., making it convenient for users to share and present analysis results.

SECURITY AND RELIABILITY

- **Data Security:** LiveTFL employs various security measures, such as user access management and data encryption, to ensure data security.
- **System Stability:** LiveTFL boasts high availability and scalability, ensuring stable system operation.

CONTINUOUS ITERATION AND IMPROVEMENT

- **User Feedback:** LiveTFL values user feedback and iterates and improves the product based on user needs.
- **Technological Updates:** LiveTFL keeps abreast of the latest AI and automation technologies and integrates them into the product to continuously enhance functionality and services.

AI AGENT EXAMPLE

- **LiveTFL AI:** LiveTFL AI allows users to get TFL through natural language interaction and show R code to see the code given by the AI.

Live TFL AI

prompt

Next I'll ask you for the R code that generates the clinical table.

The complete code consists of two parts

- Data Setup
- Standard Table

You need to use the scda package to generate dummy data.

If you are using a custom function, please describe how the complete custom function is created.

The final result must be stored in the result object.

Show R code

query

Generate demographic table.

send

	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)	All Patients (N=400)
Age (yr)				
n	134	134	132	400
Mean (SD)	33.8 (6.6)	35.4 (7.9)	35.4 (7.7)	34.9 (7.4)
Median	33.0	35.0	35.0	34.0
Min - Max	21.0 - 50.0	21.0 - 62.0	20.0 - 69.0	20.0 - 69.0
Age group				
n	134	134	132	400
18-40	113 (84.3%)	103 (76.9%)	106 (80.3%)	322 (80.5%)
41-64	21 (15.7%)	31 (23.1%)	25 (18.9%)	77 (19.2%)
>=65	0	0	1 (0.8%)	1 (0.2%)
Sex				
n	134	134	132	400
Female	79 (59%)	82 (61.2%)	70 (53%)	231 (57.8%)
Male	55 (41%)	52 (38.8%)	62 (47%)	169 (42.2%)
Race				

- **Chatbot Agent:** The Chatbot Agent can allow the user to ask any question about LiveTFL, such as how to create a demographic table with the `ratbles` package.

+ New chat

Select Agent

Chatbot

Hello and welcome to LiveTFL AI! I'm your virtual assistant, and I'm here to help you use LiveTFL with ease.

Type anything to start our conversation.

Chatbot settings

AI prompt

You are LiveTFL assistant

how to use R package `ratbles` to generate clinical table: Demographic table?

The `ratbles` package in R is a powerful tool for creating and manipulating complex tabular displays. Here is a basic example of how to generate a demographic table using `ratbles`.

Write your prompt here

send

- **DataFrame Agent:** DataFrame agents allow non-programming users to ask any questions about ADaM data sets, such as descriptive statistics, distribution of variables, and so on.

+ New chat

Select Agent

Dataframe Agent

Dataframe Agent settings

Select ADaM dataframe

ADSL

Descriptive statistical analysis was performed on the data and give me the results were returned as markdown tables

Here are the descriptive statistics for the dataframe:

	count	unique	top	freq	mean	min	25%	50%
STUDYID	200	1	AB12345	200	nan	nan	nan	nan
COUNTRY	200	9	CHN	100	nan	nan	nan	nan
SITEID	200	66	CHN-1	33	nan	nan	nan	nan
SUBJID	200	200	id-1	1	nan	nan	nan	nan
AGE	200	nan	nan	nan	35.34140994889407	22.358149652126215	29.65212602727681	34.78979458982317
SEX	200	2	F	110	nan	nan	nan	nan
ARMCD	200	3	ARM B	73	nan	nan	nan	nan
ARM	200	3	B: Placebo	73	nan	nan	nan	nan

Write your prompt here

send

- **Config Agent:** Config Agent can answer any questions about the configuration file raised by the leader programmer and the configuration file developer, such as how to fill in the parameters of the module that creates `t-dm`.

+ New chat



Select Agent

Config Agent



How to fill t_dm parameters?



Sure, here is how you can fill in the parameters for t_dm:

1. **TabSetName:** The `TabSetName` parameter is used to identify the set of tables. For this parameter, you need to provide a string that best describes the set of tables. In this case, the Value given for `TabSetName` is "Demographics".
2. **Title:** The `Title` parameter is used to provide a title to the table. This should be a string that briefly explains what the data in the table represents. For this dataframe, the Value for `Title` is "Demographics and Baseline Characteristics".
3. **Population:** The `Population` parameter is used to specify the population that the data in the table pertains to. In this case, the Value for `Population` is "Safety Analysis Set".
4. **GroupVariable:** The `GroupVariable` parameter is used to specify the variable used to group the data. Here, it appears to be a string containing a list of variables - "1 | TRT01A, COHORT, TRT01P".
5. **AddTotal:** The `AddTotal` parameter is a flag indicating whether or not to add a total row at the end of the table. The Value for this parameter should be either "Y" for Yes or "N" for No. In this case, the Value for `AddTotal` is "Y".
6. **AddSubtotal:** This parameter is similar to `AddTotal`, but it adds a subtotal row after each group of data in the table. You would also use "Y" for Yes or "N" for No.
7. **AnalysisData:** The `AnalysisData` parameter is used to specify the data used for analysis in the table. This would typically be a string naming the dataset or a list of variables used in the analysis.
8. **PopulationData:** The `PopulationData` parameter is used to specify the data related to the population that the table pertains to. Similar to `AnalysisData`, this would be a string naming the dataset or a list of variables.
9. **AnalysisVariable:** The `AnalysisVariable` parameter is used to specify the variable(s) used in the analysis. This could be a single variable or a list of variables.

Write your prompt here

send

+ New chat



Select Agent

Config Agent

Remember, each parameter corresponds to a row in your dataframe and the value should be filled in the "Value" column. You have to repeat this process for each parameter you want to fill in for t_dm.

	Study	Type	Key	Analysis	Phase	ModuleFunction	Parameter	Value
33	BGB-TEST-001	Table	t_dm	Development; Production; SMC	Drug X monotherapy; Drug X + Drug A	bgtm_t_summary	TabSetName	Demcs
34	BGB-TEST-001	Table	t_dm	Development; Production; SMC	Drug X monotherapy; Drug X + Drug A	bgtm_t_summary	Title	Demcs ar Base Charics
35	BGB-TEST-001	Table	t_dm	Development; Production; SMC	Drug X monotherapy; Drug X + Drug A	bgtm_t_summary	Population	Safe: Anal
36	BGB-TEST-001	Table	t_dm	Development; Production; SMC	Drug X monotherapy; Drug X + Drug A	bgtm_t_summary	GroupVariable	1 TRT01A, COHORT, TRT01P

Write your prompt here

send

CONCLUSION

The introduction and development of LiveTFL represent a significant advancement in the field of clinical trial data analysis. By integrating the R language teal framework with AI automation technologies, LiveTFL not only enhances the efficiency and quality of data analysis but also provides researchers with a more flexible and user-friendly analytical tool.

The main features of LiveTFL, such as data preprocessing, the TFL platform, and extended functionalities like interactivity, improved display functions, customizable configurations, and quality control, have significantly simplified the process of clinical trial analysis. Furthermore, the application of AI and automation technologies, such as automated configuration file generation, enhanced data insights, and the AI-driven Copilot feature, further enhances the efficiency and practicality of LiveTFL.

Through LiveTFL, researchers can generate and analyze clinical trial data more quickly and accurately, accelerating the journey of new drugs to market and offering patients safer and more effective treatment options. Moreover, the user-friendliness and flexibility of LiveTFL allow researchers to better customize and adjust the analysis process to meet their specific research needs.

In summary, LiveTFL is an efficient, convenient, and intelligent tool for clinical trial data analysis, which will greatly advance the development of the field of clinical trial data analysis and bring revolutionary changes to medical research. With continuous technological progress and expanding applications, LiveTFL is expected to become an important tool in the field of clinical trial data analysis, providing researchers with better support and services.

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