

Automation of ADaM Dataset & TFL Visualization Through an R Package – GenAdam2

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Agenda

Introduction

R in Clinical Research

Overview of the GenAdam2

GenAdam2

Examples of GenAdam Output

Introduction

Problem Statement

- R is a widely used and powerful software in the pharmaceutical industry, specifically for the analysis of complex datasets.
- One of the biggest challenges faced by biostatisticians is the handling of complex datasets, specifically in generating ADaM datasets.
- Generating ADaM datasets manually is a time-consuming and error-prone process.
- It requires a deep understanding of the ADaM guidelines and a lot of manual work to ensure compliance.
- To simplify the process and reduce the risk of errors, a package is needed that automates the generation of ADaM datasets.

R in Clinical Research



Open Source



Integration



Wide Library
Support



Statistical Computing
and Libraries



Data Visualization



Interactive Apps
(Shiny)



Great Community
Support

Adoption of R for ADaM Datasets

Commonly R is utilized for exploratory analysis, routine data reading, and interpretation tasks but not for creating TFL or CDISC datasets. With the extensive library support, we can quickly do the data wrangling with minimal code. We have the following benefits and challenges while creating datasets using R.



Benefits

- Free and open-source
- Reproducible research
- Extremely easy data wrangling
- Can be easily extended
- Less code
- Community support



Challenges

- Validation
- Packages do not follow a typical SDLC
- Legacy data
- R support

GenAdam

R package

Effective alternative in creating ADaM datasets

Single function call

Visualizing dataset

Download .sas7bdat

5 Main Functions of GenAdam

sdtm_data

The sdtm_data function displays the dataset in R shiny. We will be able to filter, search and explore the data in the interactive visualization feature of R shiny and datatable (DT).

`sdtm_data(folder_path,file_name)`

adsl

The adsl() function creates the ADSL dataset with the standard variables. This function will work only with single-period simple to moderate studies, which is a package limitation.

The function call for ADSL dataset creation:: ***adsl(folder_path, varlist, metadata)***

adv

The advs() function creates the ADVS dataset with the standard variables and predecessor variables from ADSL. Here we develop a list of standard variables associated with the ADVS dataset.

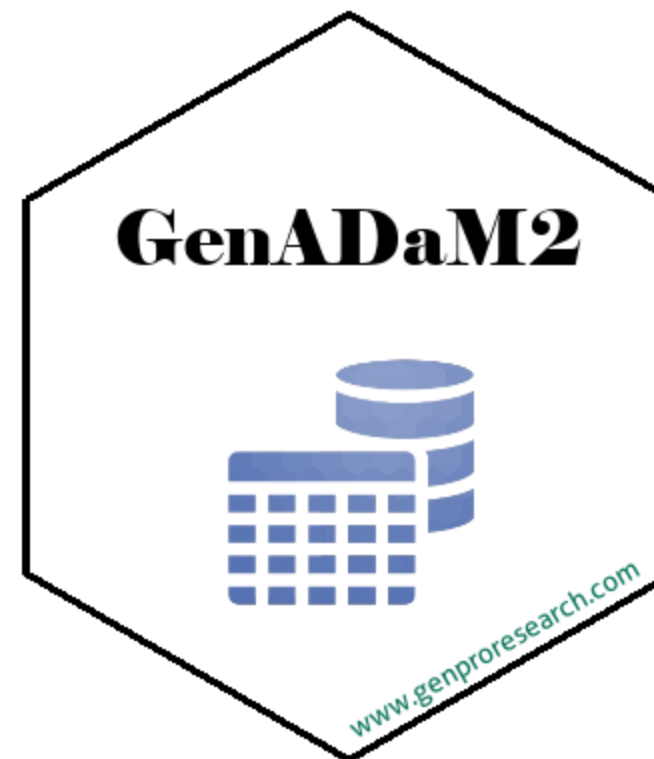
adlb

The adlb() function creates the ADLB dataset with the standard variables and predecessor variables from ADSL. Here we develop a list of standard variables associated with the ADLB dataset.

adqs

The adqs() function creates the ADQS dataset with the standard variables and predecessor variables from ADSL. Here we develop a list of standard variables associated with the ADQS dataset.

GenAdam2



Overview of the GenAdam2

The GenAdam2 package is an R package specifically designed to automate the generation of ADaM datasets.

With a single function, the GenAdam2 package generates an entire ADaM dataset.

It also provides an easy-to-use interface to visualize TFLs and apply filters to the data.

The data can be saved in several formats, such as .docx, .rtf, .html, .pdf, etc.

GenAdam2 Dependencies And Compatibility



Version :

0.2.0



Developed R Version:

R 4.2



Depends :

R (≥ 3.5)



Dependant Packages:

data.table
shiny
shinythemes
shinyjs
tidyverse
ggplot2
Plot.ly
haven
shinyWidgets
DT
reshape2
openxlsx
tidyr



License:

Apache License (≥2)

GenAdam2 - Functions

`gen_adam()`

Function to generate
ADaM dataset

gen_adam(adam,spec)

`tfl_viz()`

Function to generate
TFLs using R shiny

tfl_viz()

Demo

TFL Dashboard

Upload...

adidas70det

adidas70det

Download Data

Select variables

Drag from here

Subject Number

Age Gender

Informed Consent Date

Protocol Version

Re-Consent Date

Subject Re-Consented

Screen Failed

Screen Failure

Primary Reason for Screen Failure

Data View Listing Figure

Show 50 entries

Search

	Subject Number	Age Gender	Informed Consent Date	Protocol Version	Re-Consent Date	Subject Re-Consented	Screen Failed	Screen Failure	Primary Reason for Screen Failure
1	801-010	50/M	2020-09-02	NW-2509-006 V1 AMENDMENT 2.02 MARCH 2020			Yes	2020-09-15	1. DID NOT MEET ENTRY CRITERIA HBA3C IS MORE THAN 7.0N; MET THE EXCLUSION CRITERIA NO. 12 (A)
2	801-019	27/M	2020-09-15	NW-2509-006 V1 AMENDMENT 2.02 MARCH 2020					
3	801-020	44/F	2020-08-31	NW-2509-006 V1 AMENDMENT 2.02 MARCH 2020			Yes	2020-08-31	DID NOT MEET ENTRY CRITERIA
4	801-021	45/M	2020-09-24	NW-2509-006 V1 AMENDMENT 2.02 MARCH 2020			Yes	2020-10-14	4. WITHDRAWAL OF CONSENT WITHDREW ICF

Showing 1 to 4 of 4 entries

Previous

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Next

Demo

File Home Insert Design Layout References Mailings Review View Help Tell me what you want to do

Paste Cut Copy Format Painter

Courier New 9 A A Aa

B I U abc x₂ x² A a

Clipboard Font Paragraph Styles Editing

Find Replace Select

Training Project
Protocol : TRID - 002

Confidential

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Listing 16.2.1.1
Subject Enrollment
All Subjects Screened

Subject Number	Age/ Gender	Informed Consent Date	Protocol Version	Re-Consent Date	Protocol Version Subject Re-Consented	Screen Failed	Date of Screen Failure	Primary Reason for Screen Failure
801-010	50/M	2020-09-03	NW-3509/008/I 1/AMENDMENT 3, 03 MARCH 2020			Yes	2020-09-15	1. DID NOT MEET ENTRY CRITERIA. HBA1C IS MORE THAN 7.0% ; MET THE EXCLUSION CRITERIA NO.- 13 (A)
801-019	37/M	2020-09-18	NW-3509/008/I 1/AMENDMENT 3, 03 MARCH 2020					
801-020	44/F	2020-08-31	NW-3509/008/I 1/AMENDMENT 3, 03 MARCH 2020			Yes	2020-08-31	DID NOT MEET ENTRY CRITERIA
801-021	48/M	2020-09-24	NW-3509/008/I 1/AMENDMENT			Yes	2020-10-14	4.WITHDRAWAL OF CONSENT WITHDREW ICF

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THANK YOU

Any Questions ?