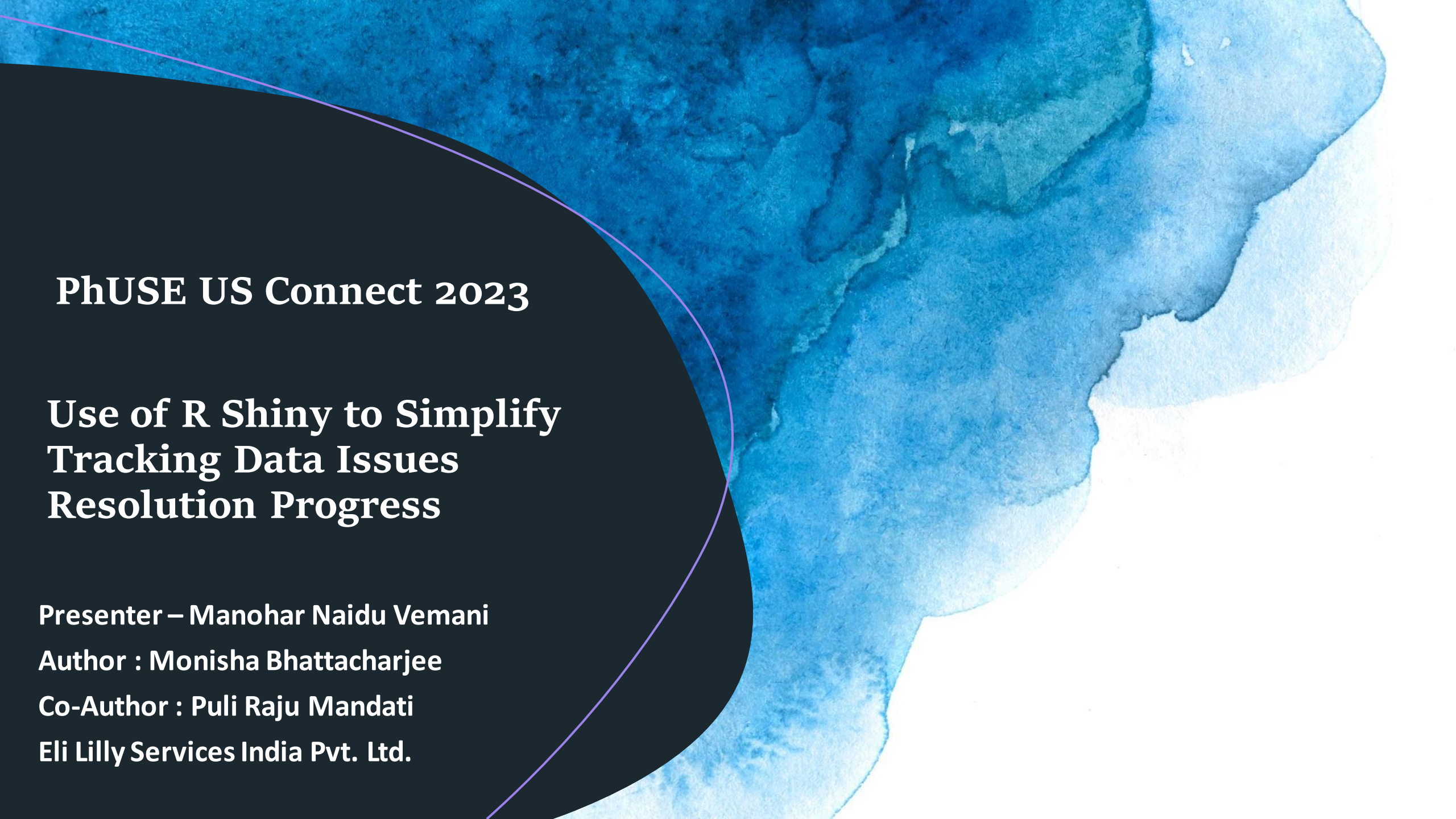




**PhUSE US Connect 2023**

**Use of R Shiny to Simplify  
Tracking Data Issues  
Resolution Progress**

**Presenter – Manohar Naidu Vemani**

**Author : Monisha Bhattacharjee**

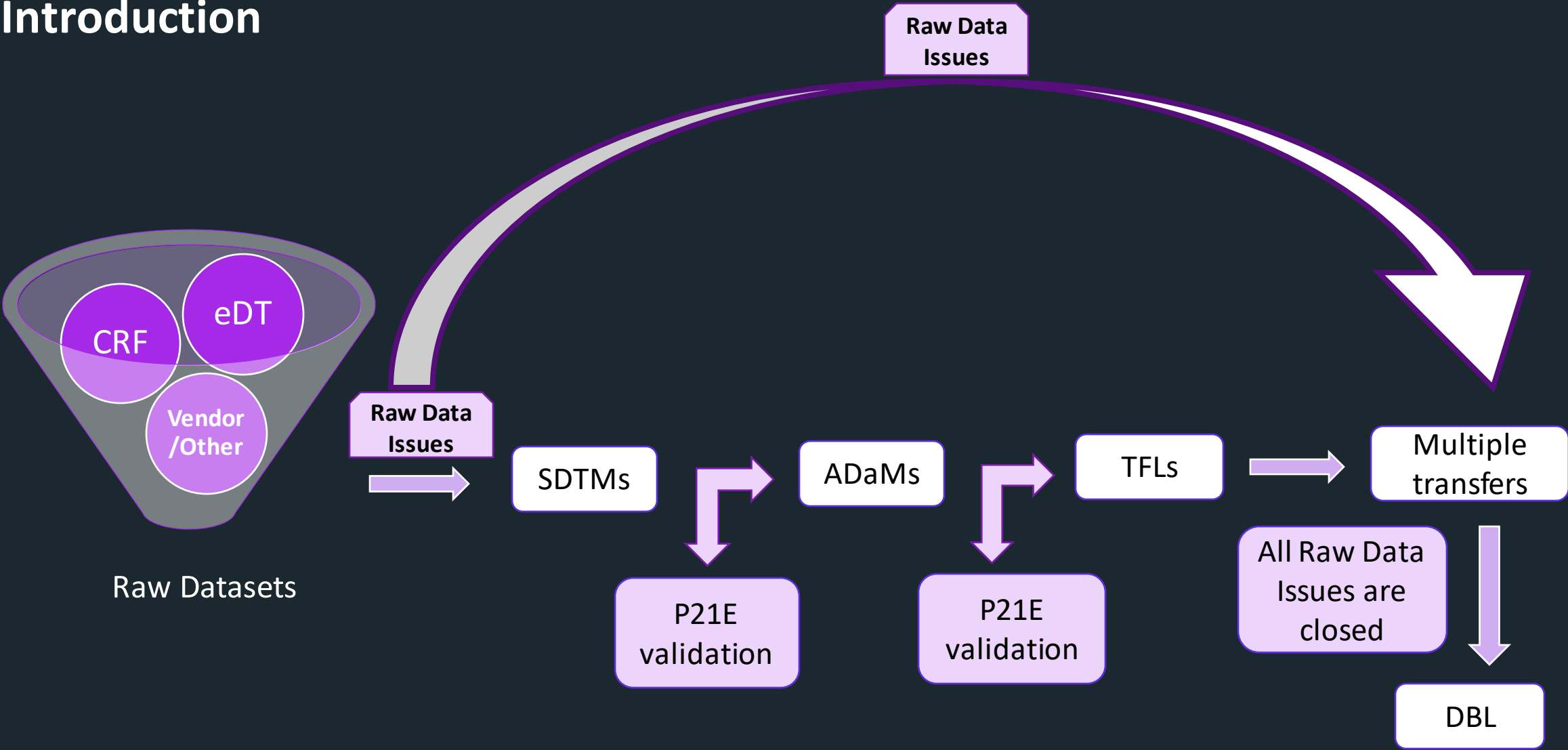
**Co-Author : Puli Raju Mandati**

**Eli Lilly Services India Pvt. Ltd.**

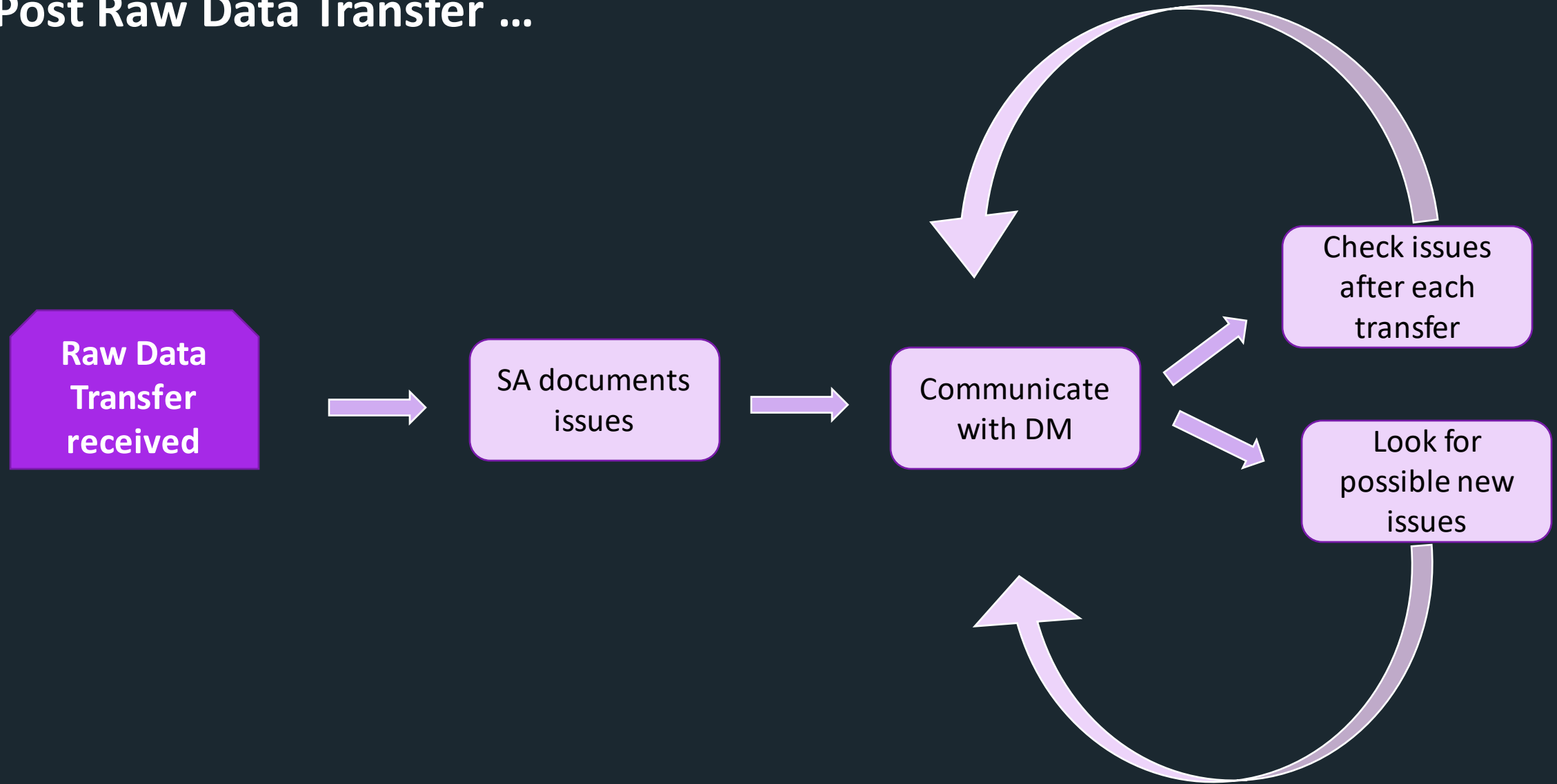
# AGENDA

- Introduction
- Statistical Programmer Challenges – Tracking Data Issues
- Bridging the gap with R Shiny
- Logical flow of R Shiny app
- Future Scope

# Introduction



## Post Raw Data Transfer ...



# Statistical Programmer Challenges – Tracking Data Issues and Impact

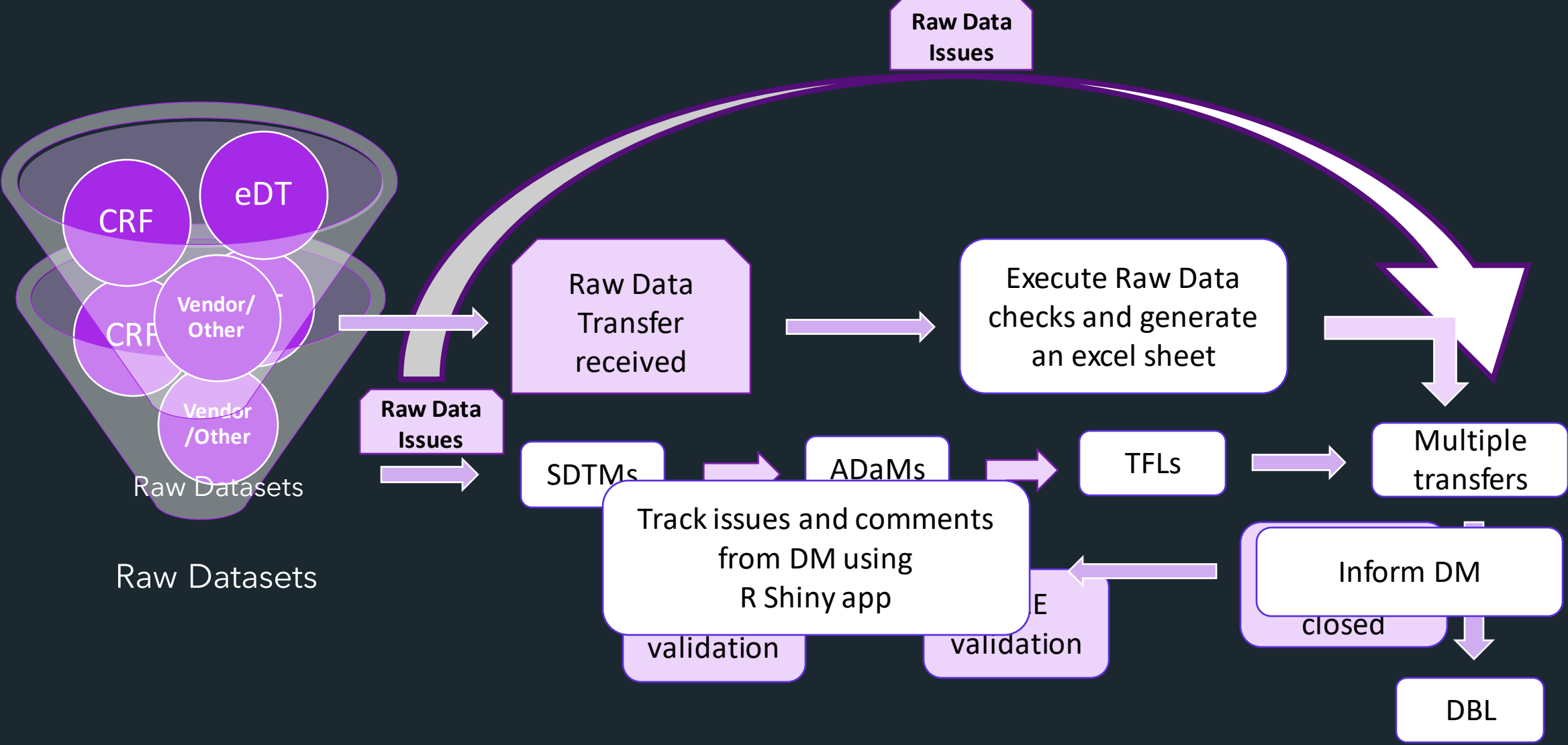
## Challenges

- Time consuming
- Manual efforts involved in tracking large number of issues
- Delay in identifying the issues
- Keep track with DM to resolve issues

## Impact

- Impact on SDTM and beyond.
- Invest resource and time for checking P21E issues (separating raw data issues from conformance issues and programming errors)
- Re-work and, or Milestone/DBL delay

# Bridging the gap between DM and SA



## Brief on R Shiny

- Shiny is a package in R
- Build interactive web applications, dashboards.
- Execute R code in the backend
- Can be combined with HTML widgets, CSS themes, JavaScript
- No web development skills are required
- Easy to write

# Continued..

- Raw data checks executed in SAS

| DM COMMENTS                                                                                                                                                                                                                                                   | CMSC | CMCA   | SUBJ1 | CMYA | CMST | CMST | CMST | CMOP | CMEN | CMEN | CMEN | CMDOSE | CMDC | CMCLAS          | ISSUE                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|--------|-------|------|------|------|------|------|------|------|------|--------|------|-----------------|-------------------------------------------------|
| Q LDR 30Aug2022: STATS: If Fluticasone furoate is a corticosteroid, confirm this record requires update to the category of Systemic non-topical Corticosteroids where route and dosage can be recorded separately or clarify. Category is incorrect; query to |      | CONCOM | 1044  |      | 02   | 07   | 2022 | N    | 29   | 07   | 2022 |        |      | CORTICOSTEROIDS | Conmed corticosteroid records with dose missing |
| LDR 30Aug2022: Subject locked. 2022-0816: Category is incorrect; query to site to change to corticosteroid category LM20220531: Corticosteroid not captured for systemic use but instead as General Concomitant medication which does not                     |      | CONCOM | 1009  |      | 10   | 04   | 2018 | Y    |      |      |      |        |      | GLUCOCORTICIDS  | Conmed corticosteroid records with dose missing |

ucsd1002\_dup

pucr1001\_dup

pucal1001\_dup

lab\_visit

pr1001\_robarts\_dt

robarts\_mss1001\_visitnum

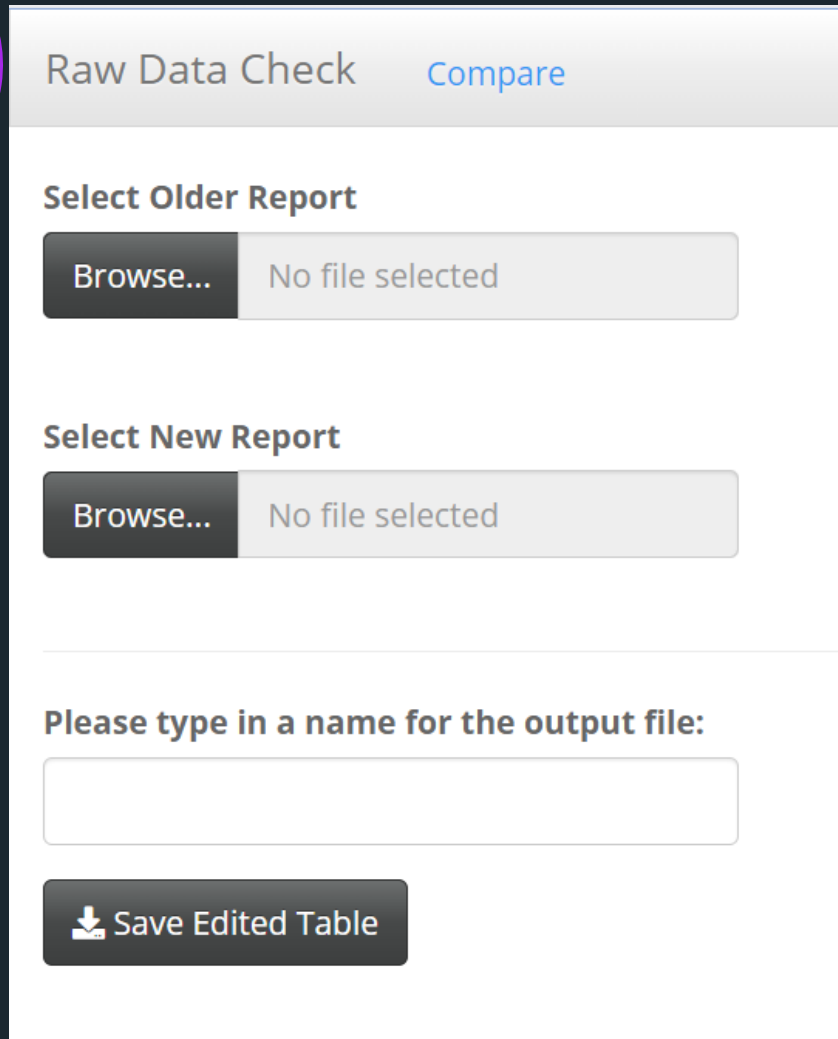
con\_med2

ex1001

endo\_score

- Other Examples : Dosed but without treatment assignment, Patient had a visit but no IC, AE caused D/C due to death but neither serious detail nor outcome was fatal
- DM\_Comments column is blank initially when the Issue file is generated
- Shared with Data Management Team
- DM Team provides comments and shares with the SA team.

# Application



The screenshot displays a web application interface with a light gray header bar. On the left of the header is a button labeled 'Raw Data Check', and on the right is a blue link labeled 'Compare'. Below the header, the interface is divided into two main sections. The first section is titled 'Select Older Report' and contains a dark gray button labeled 'Browse...' followed by a light gray box with the text 'No file selected'. The second section is titled 'Select New Report' and also contains a dark gray button labeled 'Browse...' followed by a light gray box with the text 'No file selected'. Below these sections, there is a text prompt 'Please type in a name for the output file:' followed by a white text input field with a light gray border. At the bottom of the interface is a dark gray button with a white download icon and the text 'Save Edited Table'.

## User End Interface

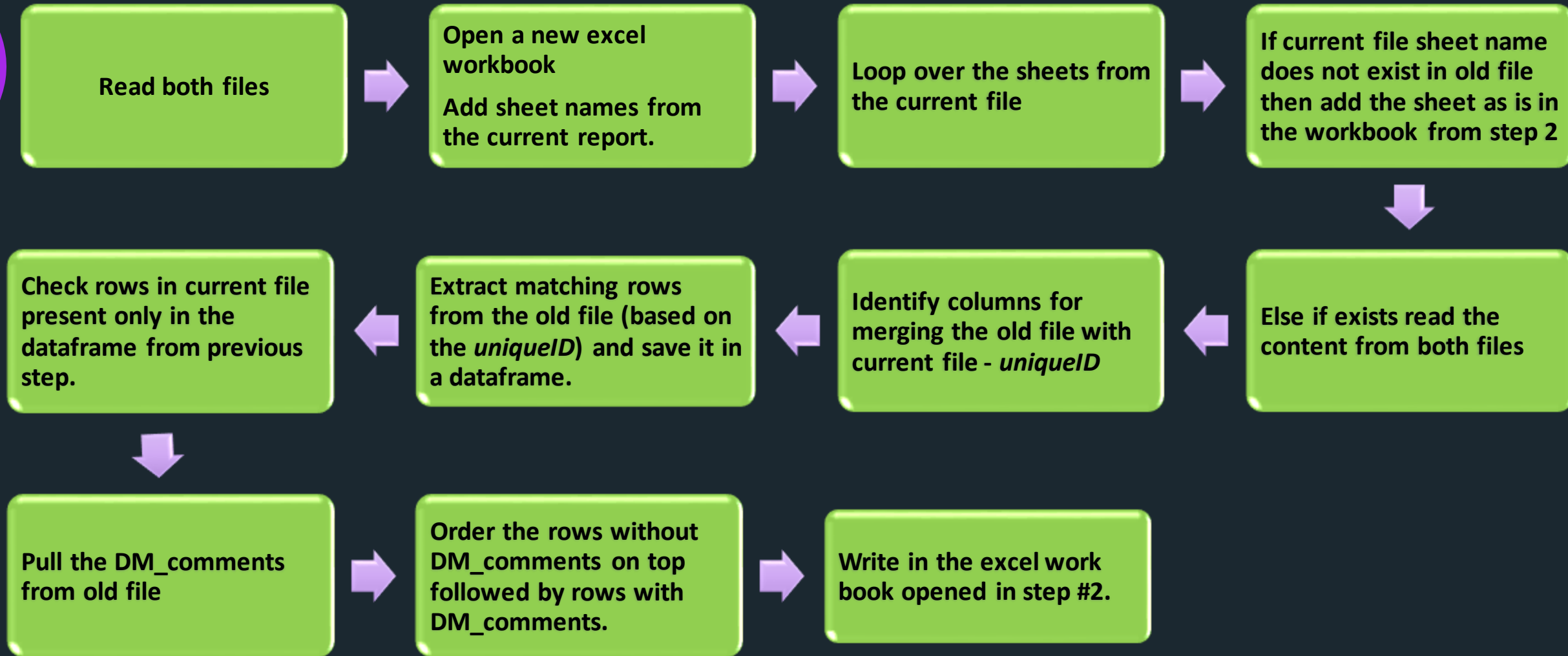
### Prerequisites :-

- Excel file containing Issues and DM comments
- New Excel file containing Issues and blank DM comments column

### How to Use :-

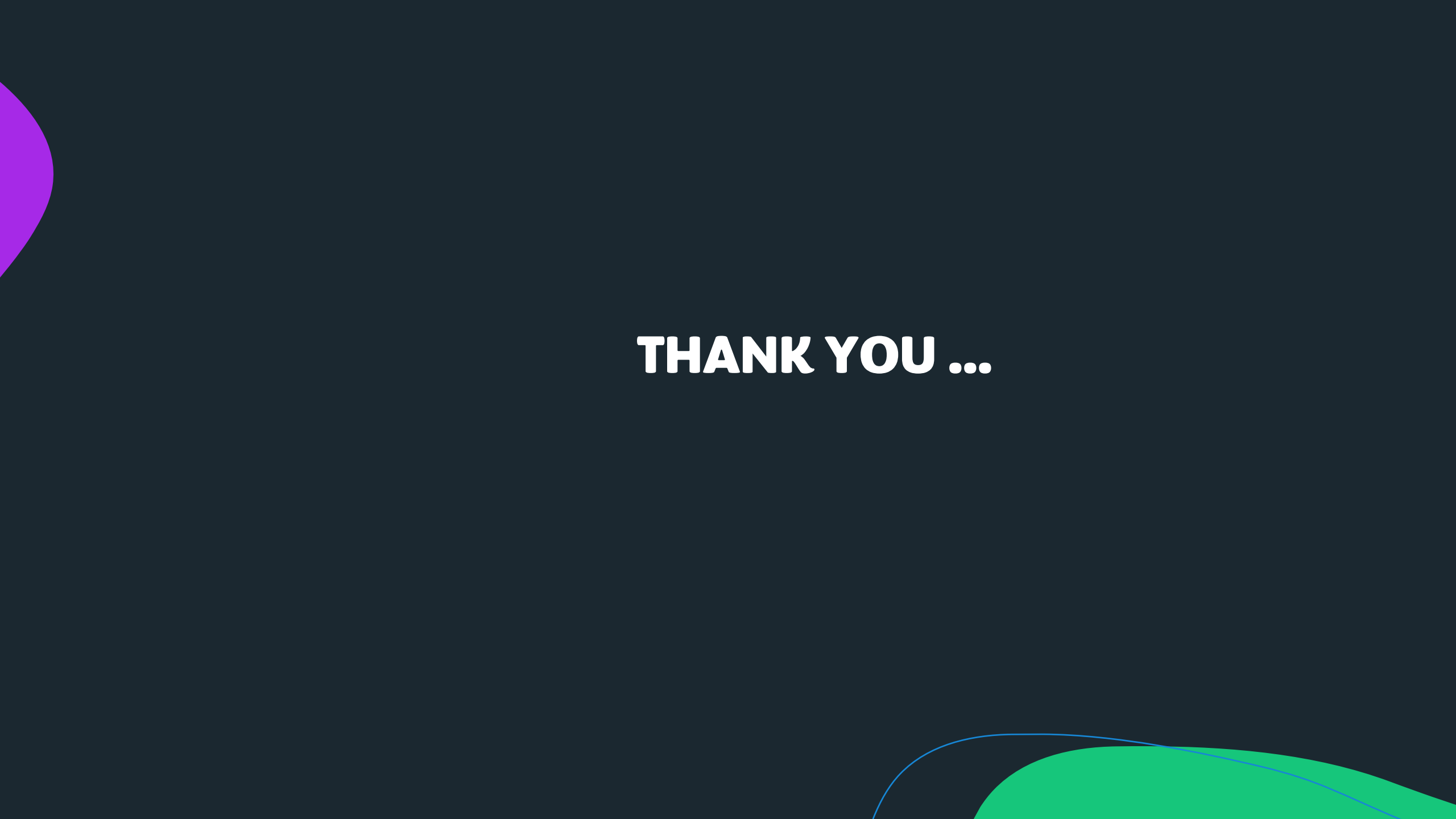
- Add old file in “*Select Older Report*” field and new file in “*Select New Report*” field
- Add a file name for Output file
- Click on ‘Save Edited Table’ to download

# Logical flow of R Shiny app



## Future Scope

- Issue tracker with comments can be used as a document
- Resolved issues for final documentation
- Combined with other line functions such as STATs/Medical Team



**THANK YOU ...**