



# An Automation Proof of Concept of Periodic Reporting via R Shiny

Melinda, *Tree of Life*  
Melinda's artwork reflects her journey living with HIV.

Nicholas Masel (Analytics Innovation Technical Lead)  
Steven Haesendonckx (Senior Programmer Analyst - Statistical Programming, IDAR)  
Alexandra Papadopoulou (Programmer Analyst - Statistical Programming, IDAR)

September, 2019

# Disclaimer

Some of the opinions are personal and might not reflect the company's view on things.



# Agenda

- 1 R & Shiny
- 2 PSUR/DSUR as PoC
- 3 Shiny : Behind the scenes
- 4 PSUR/DSUR : The ins and outs
- 5 PSUR/DSUR : Flexibility
- 6 PSUR/DSUR: Demonstration
- 7 Fade out with Q&A

# R in Pharma

- SAS: golden standard
- R: alternative to SAS
- Ongoing efforts from industry  
<http://rinpharma.com/>  
<https://www.pharmar.org/>



# Why R and shiny?

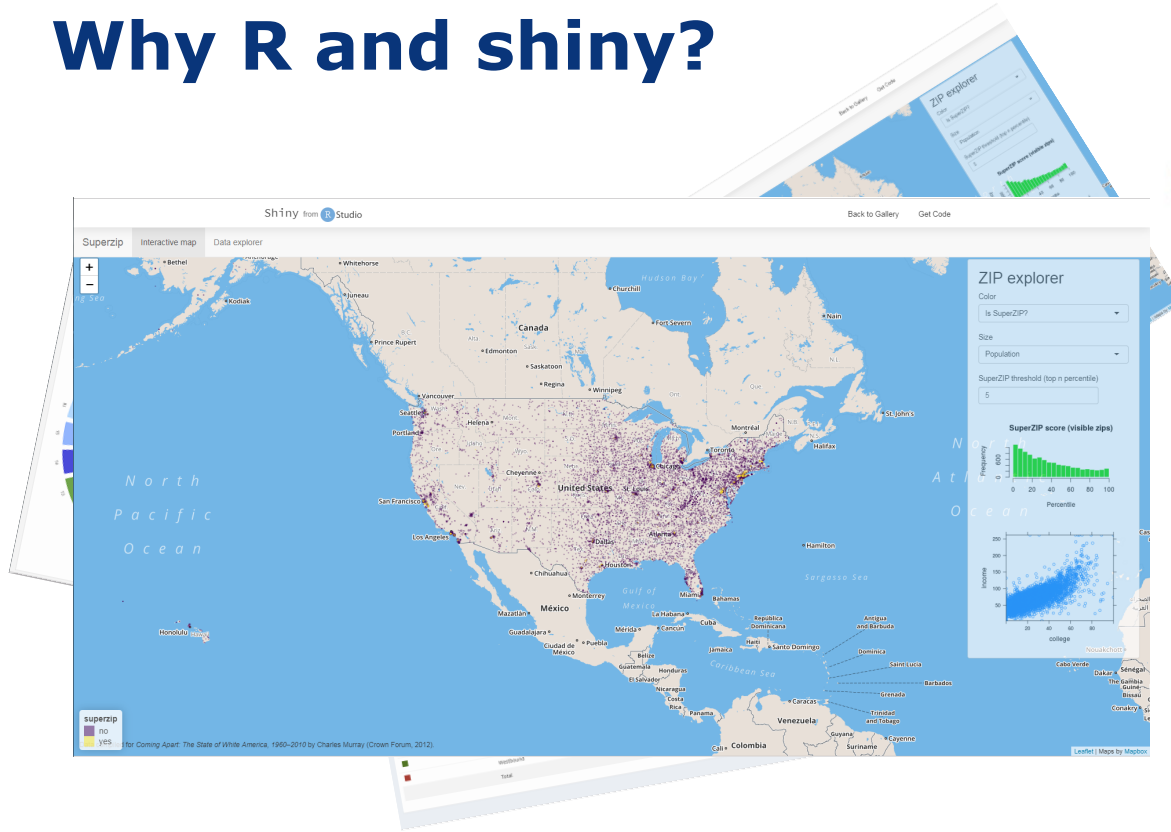


Large user base  
Active community  
Cutting edge statistical analysis  
Extensive graphical tool box  
Easy to learn



R Package  
Build interactive websites  
No knowledge of JS, HTML, ....required  
Ideal for interactive analysis and reporting

# Why R and shiny?



# PSUR/DSUR as a PoC

## PSUR/DSUR

- Periodic Safety Update Report – Development Safety Update Report
- Provided to authorities periodically
- Relatively simple safety report
- Pre-specified tables and listings generated



Automatization

# Shiny: Behind the scenes



# Shiny: Behind the scenes

 Source file in R which defines:

- User Interface (UI)
- Server function

 UI:

- Relevant code for layout
- Embedded widgets

 Server function:

- Translation of input to output

# Shiny: Behind the scenes

```
library(shiny)
```

```
# Define UI for the application
ui <- fluidPage(
  headerPanel("Hello Shiny!")
```

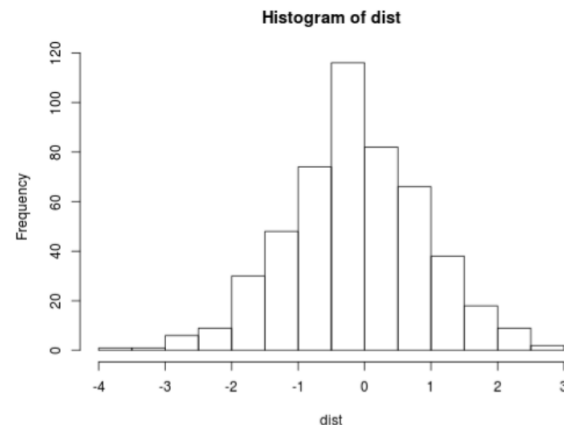
```
# Define the server logic
server <- function(input, output) {
}
```

```
# Run the application
shinyApp(ui = ui, server = server)
```

Hello Shiny!



input



output

# PSUR/DSUR: The ins and outs

PSUR/DSUR Demo
Setup
Table of Contents
TSF
LSF

Upload the ADSL and ADAE datasets:

Browse...

Deactivated

Select the study variable:

Study Identifier

Select studies:

Select population:

Safety Population Flag

Select treatment variable:

Actual Treatment for Period 01

Select investigational agent:

Placebo

Select exposure start date variable:

Date of First Exposure to Treatment

Select exposure end date variable:

Date of Last Exposure to Treatment

Reporting Period End:

06Aug2019

Reporting Period start (optional):

07Aug2018

☐ Include Start Date for Cutoff

PSUR/DSUR Demo
Setup
Table of Contents
TSF
LSF

Loaded ADSL data (5 records per study)

|   | STUDYID                | STATUS    | USUBJID     | SUBJID | SITEID | TRT01P     | TRT01PN | TRT01A     |
|---|------------------------|-----------|-------------|--------|--------|------------|---------|------------|
| 1 | CDISCPILOT01_Completed | Completed | 01-701-1015 | 1015   | 701    | Placebo    | 0       | Placebo    |
| 2 | CDISCPILOT01_Completed | Completed | 01-701-1023 | 1023   | 701    | Placebo    | 0       | Placebo    |
| 3 | CDISCPILOT01_Completed | Completed | 01-701-1028 | 1028   | 701    | Xanomeline | 1       | Xanomeline |
| 4 | CDISCPILOT01_Completed | Completed | 01-701-1033 | 1033   | 701    | Xanomeline | 1       | Xanomeline |
| 5 | CDISCPILOT01_Completed | Completed | 01-701-1034 | 1034   | 701    | Xanomeline | 1       | Xanomeline |
| 6 | SECOND_STUDY_Ongoing   | Ongoing   | 01-701-1023 | 1023   | 701    | Placebo    | 0       | Placebo    |

|   | STATUS    | AEACN            | STUDYID                | USUBJID     | TRTA    | TRTAN | SAFFL |
|---|-----------|------------------|------------------------|-------------|---------|-------|-------|
| 1 | Completed | DRUG WITHDRAWN   | CDISCPILOT01_Completed | 01-701-1015 | Placebo | 0     | Y     |
| 2 | Completed | DOSE NOT CHANGED | CDISCPILOT01_Completed | 01-701-1015 | Placebo | 0     | Y     |
| 3 | Completed | NOT APPLICABLE   | CDISCPILOT01_Completed | 01-701-1015 | Placebo | 0     | Y     |
| 4 | Completed | DOSE INCREASED   | CDISCPILOT01_Completed | 01-701-1023 | Placebo | 0     | Y     |
| 5 | Completed | NOT APPLICABLE   | CDISCPILOT01_Completed | 01-701-1023 | Placebo | 0     | Y     |
| 6 | Ongoing   | DOSE INCREASED   | SECOND_STUDY_Ongoing   | 01-701-1023 | Placebo | 0     | Y     |

# PSUR/DSUR: The ins and outs

PSUR/DSUR Demo

Setup

Table of Contents

TSF ▾

LSF ▾

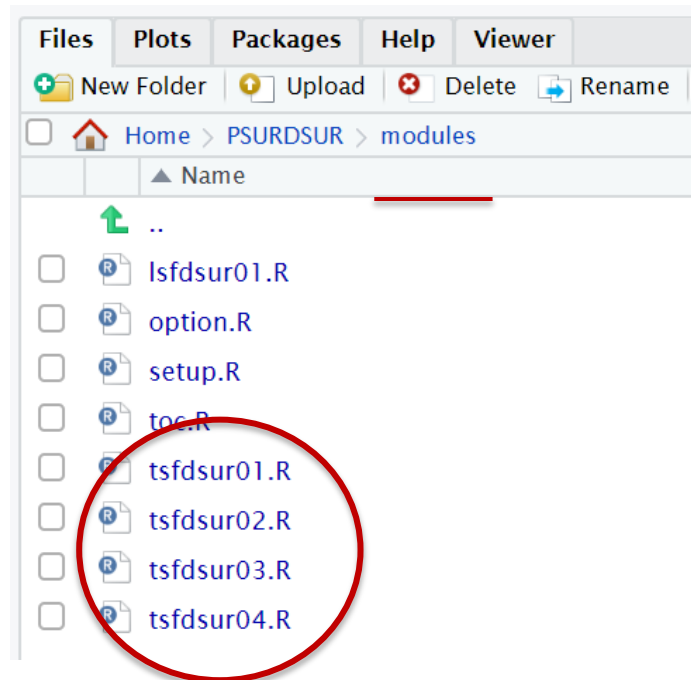
TSFDSUR01

TSFDSUR02

TSFDSUR03

TSFDSUR04

- Decreased complexity
- Better readability of source code



# PSUR/DSUR: The ins and outs

PSUR/DSUR Demo

Setup

Table of Contents

TSF

LSF

Upload the ADSL and ADAE datasets:

Browse...

Deactivated

Select the study variable:

Study Identifier

Select studies:

Select population:

Safety Population Flag

Select treatment variable:

Actual Treatment for Period 01

Select investigational agent:

Placebo

Select exposure start date variable:

Date of First Exposure to Treatment

Select exposure end date variable:

Date of Last Exposure to Treatment

Reporting Period End:

06Aug2019

Reporting Period start (optional):

07Aug2018

☐ Include Start Date for Cutoff

Loaded ADSL data (5 records per study)

|   | STUDYID                 | STATUS    | USUBJID     | SUBJID | SITEID | TRT01P     | TRT01PN | TRT01A     |
|---|-------------------------|-----------|-------------|--------|--------|------------|---------|------------|
| 1 | CDISCPILLOT01_Completed | Completed | 01-701-1015 | 1015   | 701    | Placebo    | 0       | Placebo    |
| 2 | CDISCPILLOT01_Completed | Completed | 01-701-1023 | 1023   | 701    | Placebo    | 0       | Placebo    |
| 3 | CDISCPILLOT01_Completed | Completed | 01-701-1028 | 1028   | 701    | Xanomeline | 1       | Xanomeline |
| 4 | CDISCPILLOT01_Completed | Completed | 01-701-1033 | 1033   | 701    | Xanomeline | 1       | Xanomeline |
| 5 | CDISCPILLOT01_Completed | Completed | 01-701-1034 | 1034   | 701    | Xanomeline | 1       | Xanomeline |
| 6 | SECOND_STUDY_Ongoing    | Ongoing   | 01-701-1023 | 1023   | 701    | Placebo    | 0       | Placebo    |

Loaded ADAE data (5 records per study)

|   | STATUS    | AEACN            | STUDYID                 | USUBJID     | TRTA    | TRTAN | SAFFL |
|---|-----------|------------------|-------------------------|-------------|---------|-------|-------|
| 1 | Completed | DRUG WITHDRAWN   | CDISCPILLOT01_Completed | 01-701-1015 | Placebo | 0     | Y     |
| 2 | Completed | DOSE NOT CHANGED | CDISCPILLOT01_Completed | 01-701-1015 | Placebo | 0     | Y     |
| 3 | Completed | NOT APPLICABLE   | CDISCPILLOT01_Completed | 01-701-1015 | Placebo | 0     | Y     |
| 4 | Completed | DOSE INCREASED   | CDISCPILLOT01_Completed | 01-701-1023 | Placebo | 0     | Y     |
| 5 | Completed | NOT APPLICABLE   | CDISCPILLOT01_Completed | 01-701-1023 | Placebo | 0     | Y     |
| 6 | Ongoing   | DOSE INCREASED   | SECOND_STUDY_Ongoing    | 01-701-1023 | Placebo | 0     | Y     |

# PSUR/DSUR: Flexibility

PSUR/DSUR Demo

Setup

Table of Contents

TSF ▾

LSF ▾

Other treatment(s):

Xanomeline

Additional by group variables:

Sex

RTF

TSFDSUR01: Cumulative Subject Exposure to Placebo During the Reporting Period [data through 06Aug2019]; Safety Population (Study 01)

|                             | Number of Subjects |
|-----------------------------|--------------------|
| Analysis set: Safety Popula | 211                |
| Placebo                     | 70                 |
| Xanomeline                  | 141                |
| Placebo : F                 | 44                 |
| Placebo : M                 | 26                 |
| Xanomeline : F              | 70                 |
| Xanomeline : M              | 71                 |

[TSFDSUR01][./outputs/TSFDSUR01] 06AUG19, 12:34

# PSUR/DSUR: Flexibility

PSUR/DSUR Demo

Setup

Table of Contents

TSF ▾

LSF ▾

Other treatment(s):

Xanomeline

Additional by group variables:

Sex



TSFDSUR01: Cumulative Subject Exposure to Placebo During the Reporting Period [data through 06Aug2019]; Safety Population (Study 01)

|                                 | Number of Subjects |
|---------------------------------|--------------------|
| Analysis set: Safety Population | 211                |
| Placebo                         | 70                 |
| Xanomeline                      | 141                |
| Placebo : F                     | 44                 |
| Placebo : M                     | 26                 |
| Xanomeline : F                  | 70                 |
| Xanomeline : M                  | 71                 |

[TSFDSUR01][./outputs/TSFDSUR01] 06AUG19, 12:34

# PSUR/DSUR: Flexibility

PSUR/DSUR Demo   Setup   Table of Contents   TSF ▾   LSF ▾

Other treatment(s):

Additional by group variables:

Options

- Update title/footnotes
- Save current selections
- Load previous selections

RTI

period [data through 06Aug2019]; Safety

of Subjects

11

70

41

44

26

70

71

[TSFDSUR01][./outputs/TSFDSUR01] 06AUG19, 12:34

A red rectangular box with a red border contains the word 'Options' at the top and three green text items: 'Update title/footnotes', 'Save current selections', and 'Load previous selections'. A red line extends from the right side of this box, forming a large arrow shape that points towards a circular icon containing three green horizontal bars with arrows, representing a settings or menu function. This icon is also circled in red. In the top right corner of the interface, there is another circular icon with a green download arrow and the text 'RTI', also circled in red.

# PSUR/DSUR: Demonstration



# Packages

## Tidyverse

- Data wrangling

## Shiny

- Interactive web pages
- Visualization of results

## Huxtable

- HTML output for shiny UI
- RTF output for download

# Future Enhancements

- Improve on the UI/UX
- Develop summary functions for complex outputs
- Include interactive display mode of outputs
- Include graphs
- Validation
  - Accuracy, reproducibility, traceability
  - SOP of process, package selection, justification, unit testing
  - Docker containers and R Studio Package Manager for reproducibility



# Conclusion

- ④ R: easier to learn and cost-effective
- ④ R and Shiny: potential for interactive analysis and reporting
- ④ More key features are required for other reporting efforts
- ④ PSUR/DSUR PoC is a solid starting point for expansion





# Thank you!

Melinda, *Tree of Life*  
Melinda's artwork reflects her  
journey living with HIV.

# janssen

PHARMACEUTICAL COMPANIES OF

*Johnson & Johnson*

