

PP03 Risk Management Plan (RMP) Tables using R

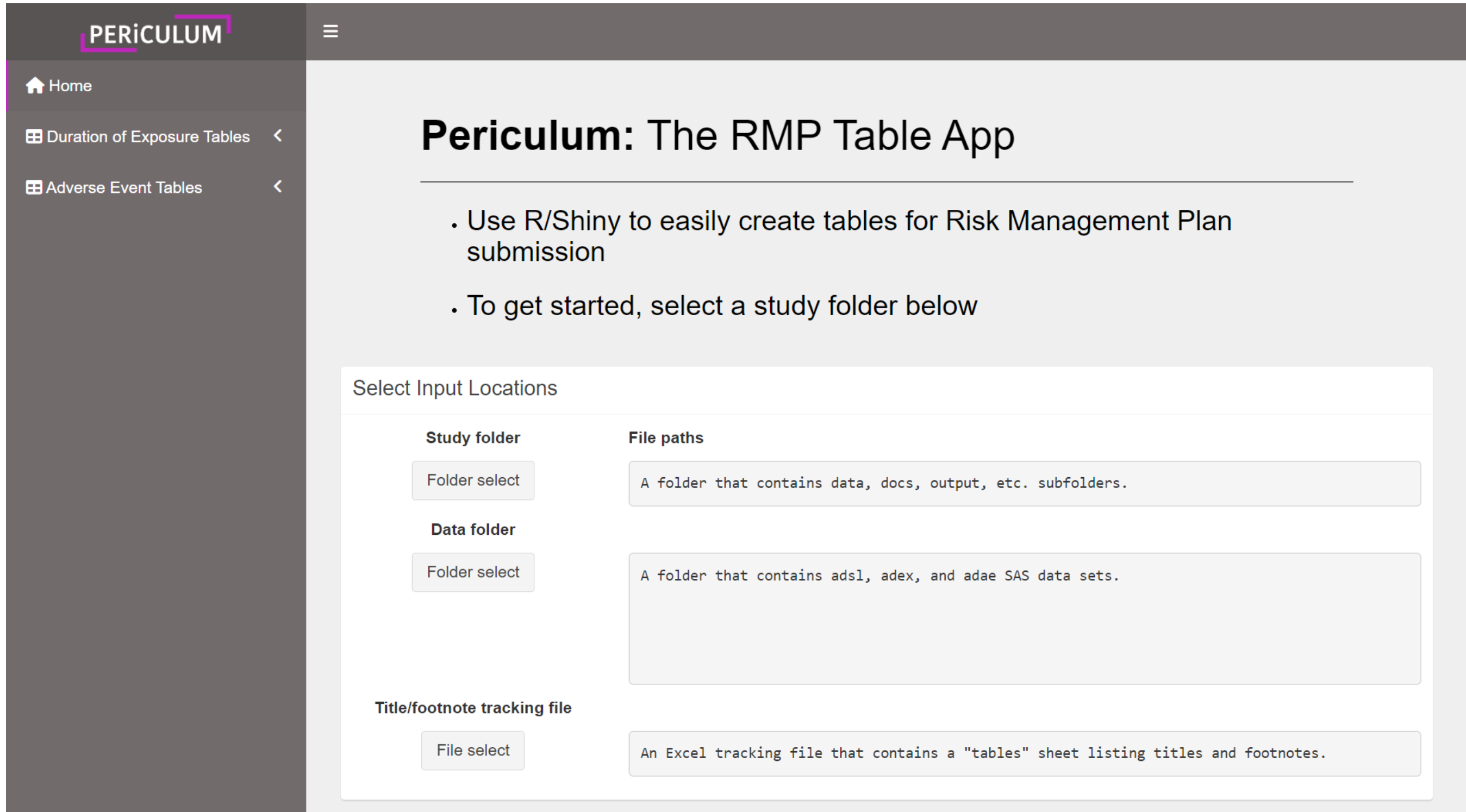
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Background

- The EMA requires a Risk Management Plan (RMP) submission when applying for marketing authorization
- Traditionally, SAS has been used to develop the tables
- We created a user-friendly application to generate these tables using R Shiny and other R packages

Packages for Reading in Data

- `haven::read_sas()` for .sas7bdat ADaM data sets
- `readxl::read_excel()` for Excel file (with titles/footnotes)
- `shinyFiles` to allow users to select folder and file locations



Flexibility

- Variables are not hard coded, instead use `shiny::selectInput()` to allow for user control, with list of possible values coming directly from the uploaded data sets
- This allows for more flexibility within the app, in case the variables are different from expected, or if the user wishes to create non-standard tables

Variables from Datasets

ADSL

Subject ID	Study ID	Treatment	Treatment (N)	Flag	Flag Value
SUBJID	STUDYID	TRT01A	TRT01AN	SAFFL	Y

ADEX

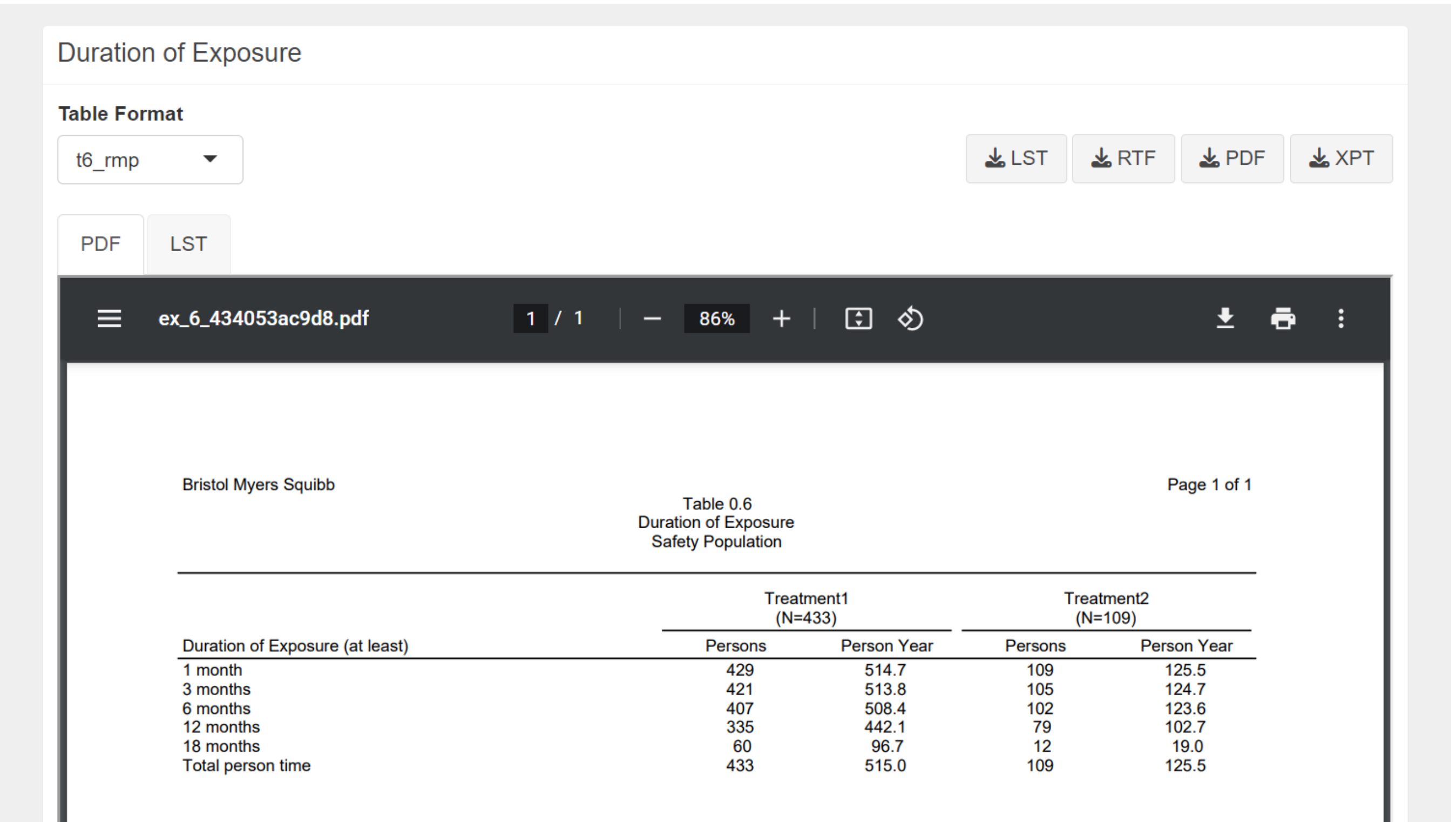
Parameter	Value	Treatment Duration	Duration Unit
PARAMCD	AVAL	TRTDUR	Days

ADAE

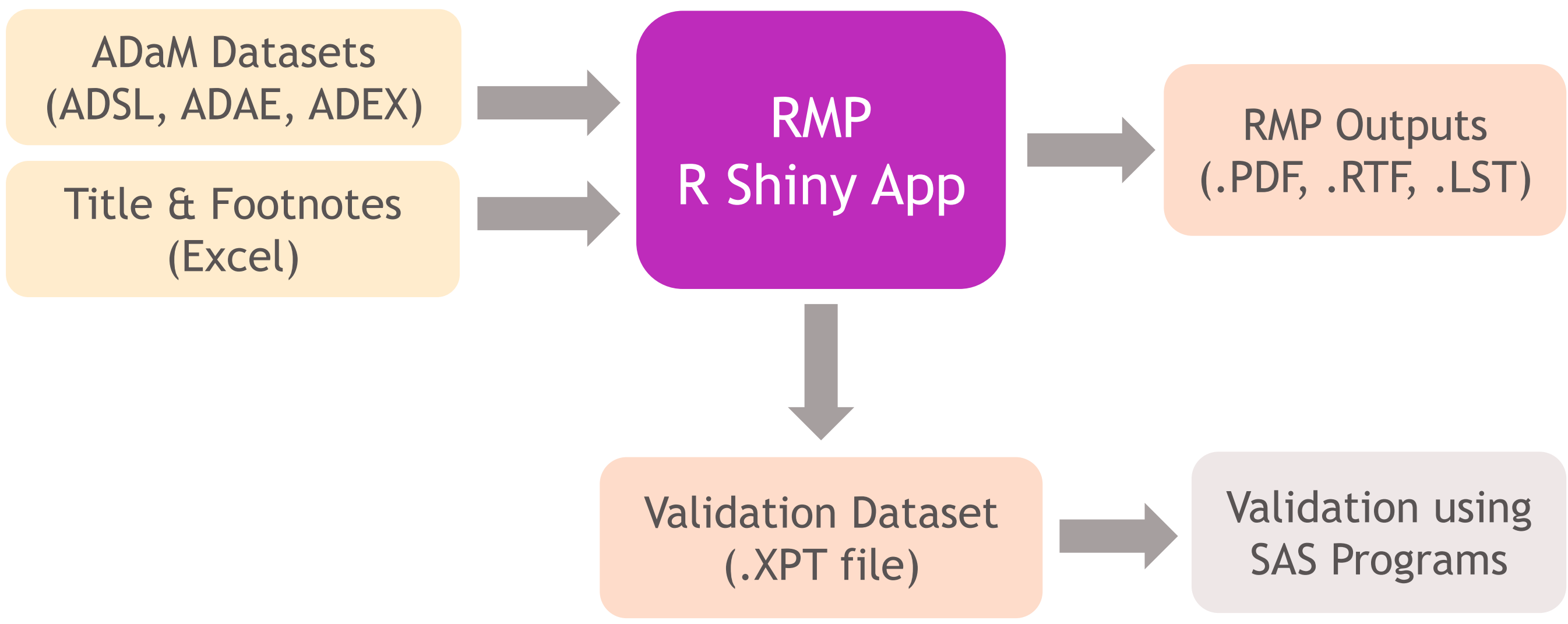
Variables of Special Interest	Preferred Term	Treatment-Emergent Flag	Flag Value	Category Label
AESIPM, AESIM, AESITP	AEDECOD	TRTEMFL	Y	AESI

Table Download

- `reporter` to create final RMP outputs
- Buttons to download table in PDF, RTF, and LST formats for submission
- Additional XPT option to save as SAS transport format for later validation



Overview



Data Preview

- `DT` to display previews of uploaded files
- No need for user to leave app to check uploaded data sets and tracking file

adsl

adex

adae

tracking

Show

5

entries

Search:

STUDYID

SITEID

COUNTRY

COUNGR1

COUNGR1N

RANDNO

TRT01P

TRT01PN

TRT01A

All

All

All

All

All

A

All

A

1

XXXX

001

UNITED STATES

NORTH AMERICA & EUROPE

1

9000001

Treatment1

1

Treatment1

2

XXXX

001

UNITED STATES

NORTH AMERICA & EUROPE

1

9000002

Treatment1

1

Treatment1

3

XXXX

001

UNITED STATES

NORTH AMERICA & EUROPE

1

9000003

Treatment2

2

Treatment2

Sample Table

- Duration of Exposure
- Shows Persons and Persons Years for each treatment

```
df <- ex %>%
  filter(PARAMCD == "TRTDUR") %>%
  mutate(months = AVAL/30.4375,
         years = AVAL/365.25)
dur_breaks <- c(0, 1, 3, 6, 12, 18, 24)
dur_labels <- c("Total person time",
               "1 month", "3 months",
               "6 months", "12 months",
               "18 months", "24 months")
dur_max <- findInterval(max(df$months), dur_breaks)
df %>%
  mutate(group = cut(months,
                    c(dur_breaks[1:dur_max], Inf),
                    dur_labels[1:dur_max],
                    right = FALSE)) %>%
  select(TRT01A, group, years) %>%
  drop_na() %>%
  group_by(TRT01A, group) %>%
  summarize(Persons = n(),
            Person_Year = sum(years))
```

	group	Persons_Treatment1	Person_Year_Treatment1	Persons_Treatment2	Person_Year_Treatment2
1	1 month	429	514.7	109	125.5
2	3 months	421	513.8	105	124.7
3	6 months	407	508.4	102	123.6
4	12 months	335	442.1	79	102.7
5	18 months	60	96.7	12	19.0
6	Total person time	433	515.0	109	125.5

Summary

- This app streamlines the process of creating RMP tables for EMA submission
- R has the capability to create all necessary tables
- With Shiny, no prior R knowledge is required of users