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SAS Report Writing Interface vs R Markdown for Patient Profile Generation

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ABSTRACT

Patient profile report can explicitly display the patient's data during the whole clinical trial period. The report mainly includes treatment records, demographic characteristics, lab test results, adverse events, tests for specific therapeutic areas, etc. Depending on different end users' needs and therapeutic areas, the report can contain versatile forms of tables and graphs. In this paper, we will compare two different tools to generate the patient profile report, SAS Report Writing Interface and R Markdown. SAS Report Writing Interface promotes the flexibility and reusability for the patient profile report. R Markdown can transform the analytical data into high-quality documents, reports or presentations, even in an interactive manner. Side by side comparison, we'll comprehensively demonstrate the pros and cons of those two tools in patient profile generation and give recommendations for you.

THE PATIENT PROFILE REPORTS FOR DIFFERENT CLINICAL TRIAL STUDIES

Patient profile report for the clinical trial studies displays the collected data and information within tables or graphs, one patient profile report is generated for only one patient, and the file is usually in PDF format. According to the type or purpose of different clinical trials, the patient profile report for them is designed to show some specific contents for specific studies. For example, in the Phase I, dose escalation and research studies, the researchers will show their interests to the patients' adverse events especially the DLT (dose limited tolerate) events. For these purposes, the patient profile will be designed to display their safety status and DLT events on the top or on the first page as well as the common demographic information. What's more, it's better to include more details for the parts of safety in the report.

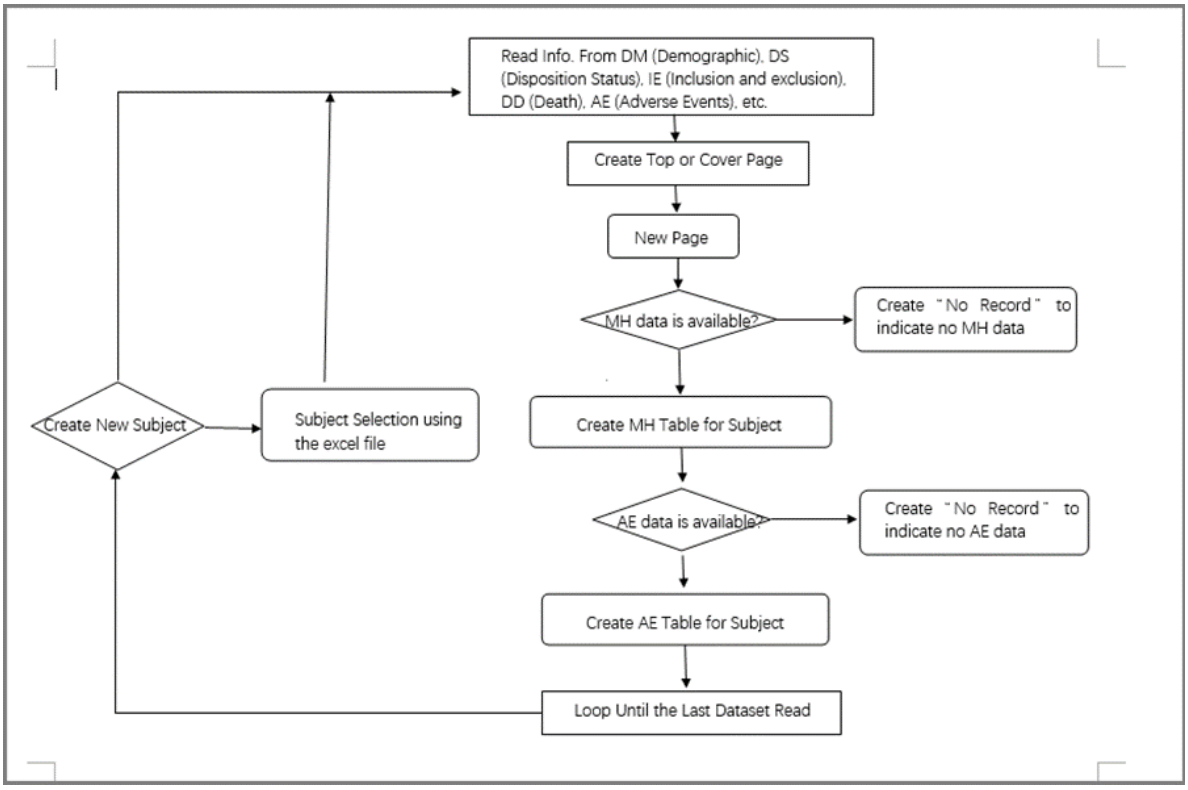
For the patient profiles for oncology studies, the PFS and OS related results and RECIST (Response Evaluation Criteria in Solid Tumors) results are expected to be collected, calculated and displayed on the top of the page as well as in the tumor assessment parts in the report.

If we want to generate patient profiles for data monitoring and data quality review, the patient profile report needs to be designed for the CRF (case report form) data, as much as collected data should be included and it's better to be sorted by visits in the reporting file.

Not only the tables but also the charts or graphs could be included in the patient profile report. The visualization of patient safety data can aid researchers in efficiently discovering potential safety and efficacy trends. Sometimes for this purpose, we can combine the concomitant drug treatment and the adverse events in the same graph, this kind of figures can directly show the relationship of the adverse event, dosage regimen, patient's vital signs, and laboratory tests.

THE MACRO PROCESS OF PATIENT PROFILE GENERATION

Process of patient profile generation figure:



Subject selection process:

After running the program at first time, an external excel file will be generated as below, modify the file and mark “Y” to the subjects selected, and then run the program again.

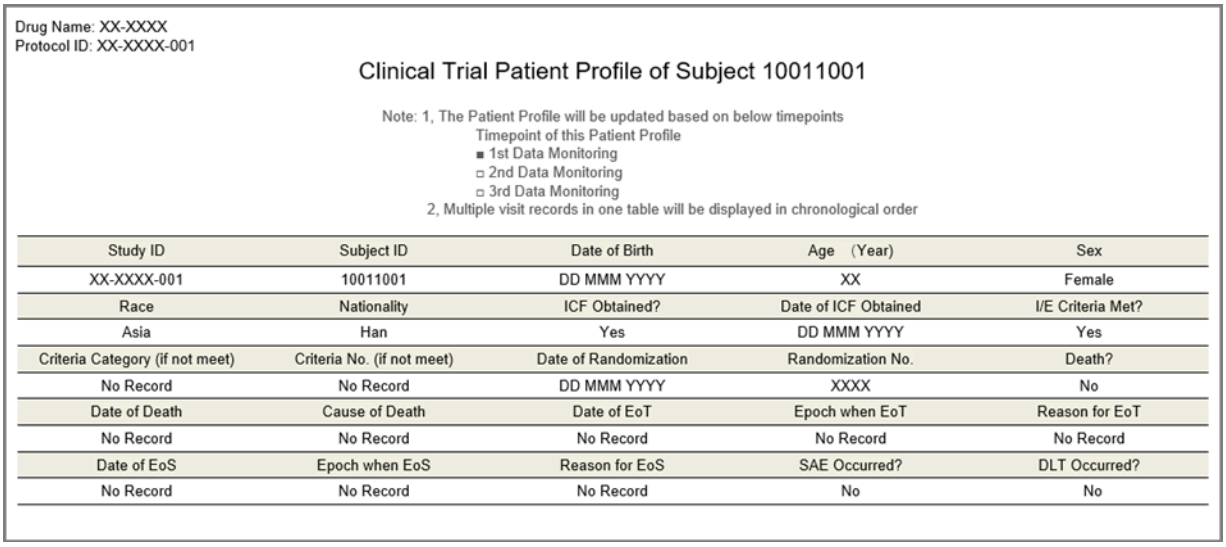


O	Subject ID	Selection (Y/N)
1	10011001	
2	10011002	
3	10011003	
4	10011004	
5	10011005	
6	10011006	
7	10011007	
8	10011008	
9	10011009	
10	10011010	

O	Subject ID	Selection (Y/N)
1	10011001	Y
2	10011002	
3	10011003	Y
4	10011004	Y
5	10011005	Y
6	10011006	
7	10011007	
8	10011008	Y
9	10011009	Y

SubjectID Selection.xlsx

The top or cover page design example:



Drug Name: XX-XXXX
Protocol ID: XX-XXXX-001

Clinical Trial Patient Profile of Subject 10011001

Note: 1, The Patient Profile will be updated based on below timepoints
Timepoint of this Patient Profile
■ 1st Data Monitoring
□ 2nd Data Monitoring
□ 3rd Data Monitoring
2, Multiple visit records in one table will be displayed in chronological order

Study ID	Subject ID	Date of Birth	Age (Year)	Sex
XX-XXXX-001	10011001	DD MMM YYYY	XX	Female
Race	Nationality	ICF Obtained?	Date of ICF Obtained	I/E Criteria Met?
Asia	Han	Yes	DD MMM YYYY	Yes
Criteria Category (if not meet)	Criteria No. (if not meet)	Date of Randomization	Randomization No.	Death?
No Record	No Record	DD MMM YYYY	XXXX	No
Date of Death	Cause of Death	Date of EoT	Epoch when EoT	Reason for EoT
No Record	No Record	No Record	No Record	No Record
Date of EoS	Epoch when EoS	Reason for EoS	SAE Occurred?	DLT Occurred?
No Record	No Record	No Record	No	No

SAS ODS REPORT WRITING INTERFACE FOR PATIENT PROFILE GENERATION

As mentioned above, some basic information and the demographic information can be generated at the top of the patient profile report, and it is suggested to use the ODS Report Writing Interface which is designed exclusively for custom report writing purposes. The ODS Report Writing Interface is intended to fully embrace ODS features including fonts, colors, images, lines, titles etc. The ODS Report Writing Interface is not only fully integrated with the capabilities of the ODS System, but also takes advantage of the rich programming features of DATA step, including conditional sentences, formatting capabilities, by-group processing, do- loops programming etc. The ODS Report Writing Interface is an object-oriented language which can provide us the flexibility, when we met the real complicated reporting requirements, we can program and organize them easily and effectively.

For the titles, the top page and the main parts in the patient profile reports, we can use the ODS Report Writing Interface, some common codes are listed as examples below:

```
filename rwiOut "D:\&location.\PatientProfile\";
ods rtf close;
ods rtf path=rwiOut file="TopPage.rtf";

title1 j=l h=16pt font=Calibri "The Top Page Example";
title2 j=c h=12pt font=Calibri "Patient Profile - Thomas";

proc format;
   value $gender
      F = "Females"
      M = "Males"
;
run;

proc sort data=sashelp.class out=class;
   by sex name;
run;

data _null_;
    set class;
    by sex name;
```

```
    where name eq "Thomas"; /* <= Subject Selection */

    if _N_ = 1 then do;
    dcl odsout obj();
    end;
    if first.sex then do;
    obj.table_start();
       obj.head_start();

          obj.row_start();
             obj.format_cell(data: "Name", row_span: 3, vjust: "B");
             obj.format_cell(data: sex, column_span: 4, format: "$gender.");
          obj.row_end();

          obj.row_start();
             obj.format_cell(data: "Age", row_span: 2, vjust: "B");
             obj.format_cell(data: "Vitals", column_span: 3);
          obj.row_end();

          obj.row_start();
                   obj.format_cell(data: "Height");
                   obj.format_cell(data: "Weight");
                   obj.format_cell(data: "BMI");
        obj.row_end();

       obj.head_end();
    end;
    bmi = ( weight / ( height * height ) ) * 703;

       obj.row_start();
          obj.format_cell(data: name);
          obj.format_cell(data: age);
          obj.format_cell(data: height);
          obj.format_cell(data: weight);
          obj.format_cell(data: bmi, format: "8.2");
       obj.row_end();

    if last.sex then do;
       obj.table_end();
    end;
run;

ods rtf close;
ods rtf;
```

Output:

The Top Page Example

Patient Profile - Thomas

Name	Males			
	Age	Vitals		
		Height	Weight	BMI
Thomas	11	57.5	85	18.07

Besides, we can also program the ODS Report Writing Interface with other SAS procedure or tool to generate the patient profile accordingly. The graph or figures are suggested to be created using the SAS GRAPH procedure called SGPLOT which is part of the ODS Statistical Graphics architecture and designed to create complex statistical graphics, and there is another recommended SAS procedure called SGRENDER, it is a utility procedure that produces graphs using the underlying Graph Template Language (GTL).

Additionally, in the oncology studies, the SAS procedure called PROC LIFETEST will automatically produce Survival Estimate Plots. It is also supported to be used in our patient profile report.

In conclusion, in the patient profile generation, ODS Report Writing Interface is suggested to be used to produce the parts of tables in the report with its both ODS features and rich programming features of DATA step. Some other SAS procedure can be co-used with ODS Report Writing Interface for the other kinds of charts or graphs including SGPLOT, GTL, LIFETEST etc.

R MARKDOWN FOR PATIENT PROFILE GENERATION

R is a statistical programming language and tool, has many useful capabilities in common with SAS. R studio is a suggested application for R and R Markdown is one of the packages from R. R Markdown is recommended to generate high quality reports that can be shared with audiences. R Markdown documents are fully reproducible and support dozens of static and dynamic output formats. R Markdown is also an authoring format that enables easy creation of dynamic documents, presentations, and reports from R. It combines the core syntax of markdown (an easy-to-write plain text format) with embedded R code chunks that are run so their output can be included in the final document.

If you have R studio already, you may need to install the rmarkdown package using the following sentence.

```
install.packages("rmarkdown")
```

There is a new definition in Rmarkdown called “code chunks”, R code chunks surrounded by ```s. When we want to open the file in the RStudio IDE, it becomes a notebook interface for R. We can run each code chunk by clicking the “ ▶ ” icon. RStudio executes the code and display the results consistent with our file. In the patient profile reports, for the main parts of the tables, which are used to display the collected data, we can use R markdown, some common usages are listed below for reference.

````
title: "Patient Profile Test"
author: "Qin"
date: "7/20/2019"
output: html_document
---

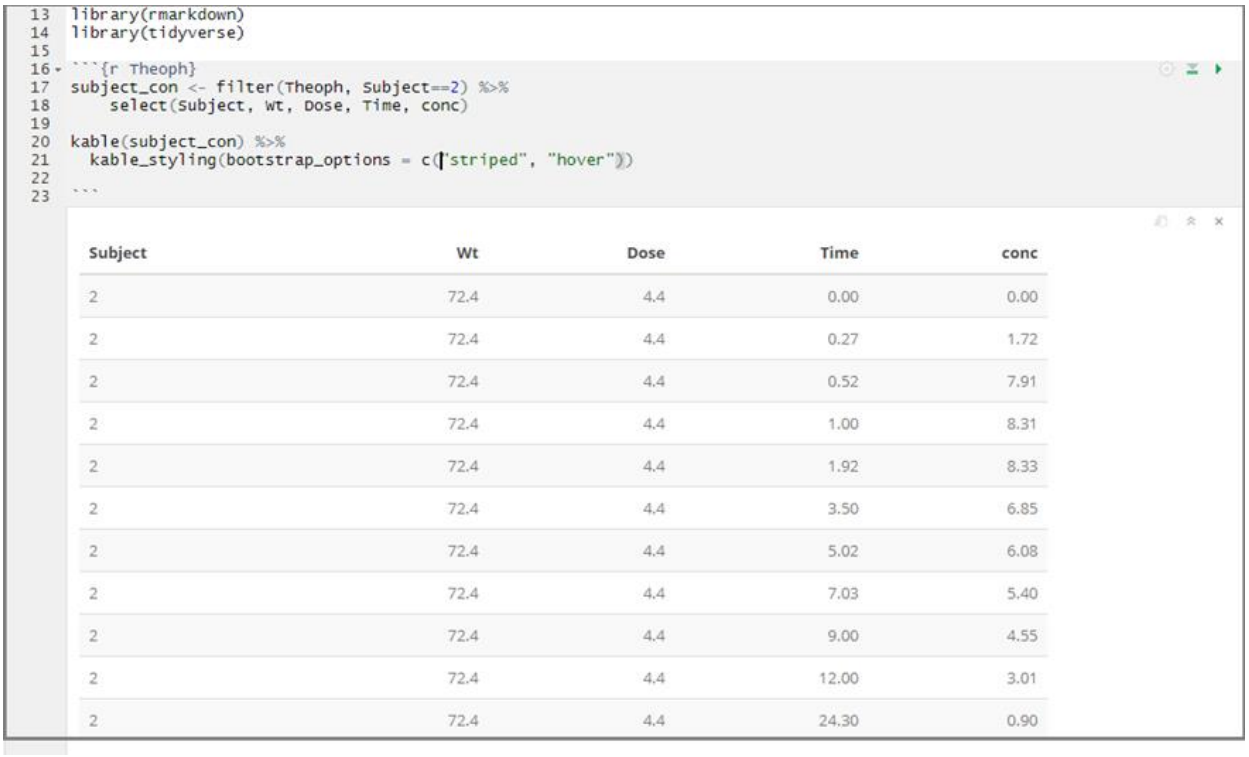
```{r setup, include=FALSE}
knitr::opts_chunk$set(echo = TRUE)
library(rmarkdown)
library(tidyverse)

```{r Theoph}
subject_con <- filter(Theoph, Subject==2) %>%
    select(Subject, Wt, Dose, Time, conc)

kable(subject_con) %>%
  kable_styling(bootstrap_options = c("striped", "hover"))

```
````
````

Please find the following screenshot, we can click the “ ▶ ” on the upper right corner, and the result would be displayed under the program clearly.



```
library(rmarkdown)
library(tidyverse)

```{r Theoph}
subject_con <- filter(Theoph, Subject==2) %>%
    select(Subject, Wt, Dose, Time, conc)

kable(subject_con) %>%
  kable_styling(bootstrap_options = c("striped", "hover"))
```
```

Subject	Wt	Dose	Time	conc
2	72.4	4.4	0.00	0.00
2	72.4	4.4	0.27	1.72
2	72.4	4.4	0.52	7.91
2	72.4	4.4	1.00	8.31
2	72.4	4.4	1.92	8.33
2	72.4	4.4	3.50	6.85
2	72.4	4.4	5.02	6.08
2	72.4	4.4	7.03	5.40
2	72.4	4.4	9.00	4.55
2	72.4	4.4	12.00	3.01
2	72.4	4.4	24.30	0.90

We can also embed plots with R markdown, for example, ggplot can be used to generate visualized and interactive graphs. When you move your pointer to the dots in the plots, the values will be shown accordingly.

Reference Code:

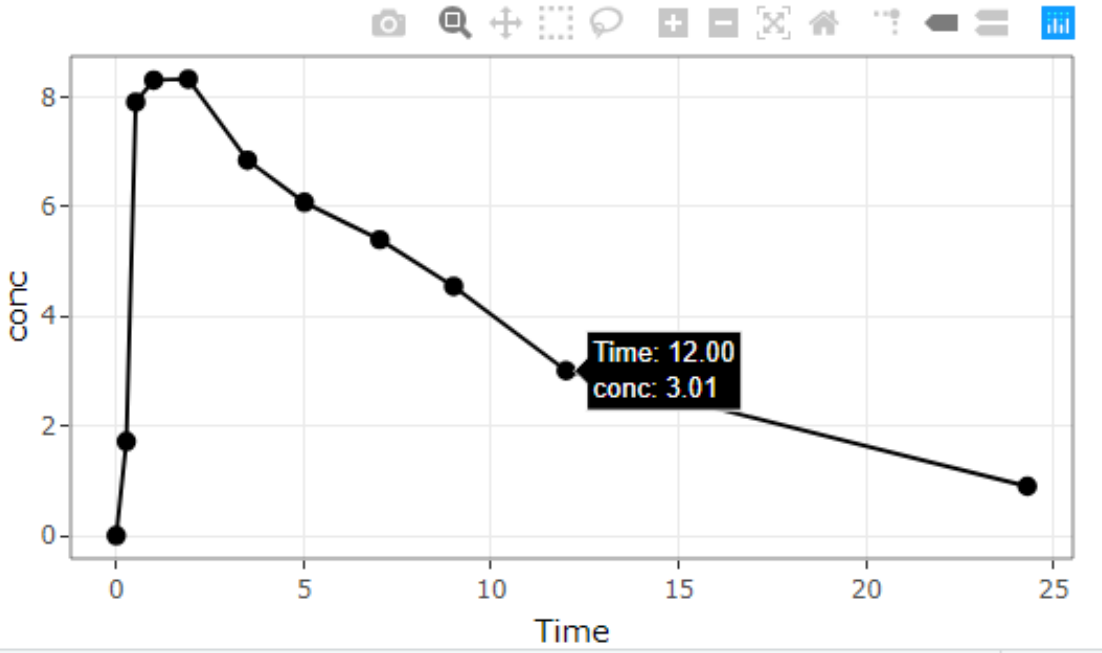
```
```{r Theoph, echo=FALSE}

subject_con <- filter(Theoph, Subject==2) %>%
    select(Time, conc)

p <- ggplot(data=subject_con,mapping=aes(x=Time,y=conc)) +
  geom_point(size=2) +
  geom_line() +
  theme_bw()
ggplotly(p)
```
```

```{r Theoph, echo=FALSE}
subject_con <- filter(Theoph, Subject==2) %>%
    select(Time, conc)

p <- ggplot(data=subject_con,mapping=aes(x=Time,y=conc)) +
  geom_point(size=2) +
  geom_line() +
  theme_bw()
ggplotly(p)
```



CONCLUSION

Comparing SAS ODS Report Writing Interface with R Markdown for patient profile, both methods have their advantages. SAS program might be more formal to run, and when you want the report in an interactive manner, Rmarkdown is a better choice. Both SAS ODS Report Writing Interface and R Markdown are suggested to be used in the process of patient profile generation, they always can meet your requirements easily and effectively.

REFERENCES

Introduction to the Report Writing Interface

https://documentation.sas.com/?docsetId=odsadvug&docsetTarget=n0w8et93ubh1enn1f34empn5948l.htm&docsetVersion=9.4&locale=en

R Markdown - Dynamic Documents for R

https://support.rstudio.com/hc/en-us/articles/205368677-R-Markdown-Dynamic-Documents-for-R