

## Different Ways to Create Patient Profiles

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### ABSTRACT

In the patient profiles, the demographics and baseline characteristics, the safety information such as adverse events, concomitant medication and laboratory results are all closely and neatly packed into a few pages. This is different from the way we create with SAS® for clinical study report the after-text tables where we display only one table on each page. The ODS LAYOUT in SAS, R shiny, and R markdown can be used to stack multiple tables on top of each other. The data \_null\_ with put statement in SAS can be used to output an HTML file for this purpose as well. In this paper we discuss these different methods for the generation of patient profiles.

### INTRODUCTION

Patient profile is really a collection of tables. These tables are crowded into a few pages. If we only display one table on each page, the reviewers of the patient profiles would have to flip through many pages.

The ODS LAYOUT is a new feature in SAS 9.4. It can be used to create patient profiles. The tables are displayed next to each other, and the contents can run into the next page if we use ODS LAYOUT GRIDDED.

R shiny is a versatile tool for visualization. It can be used to display data. R Markdown is a file format for making dynamic documents. Both R shiny and R markdown can create the patient profiles.

Another way to create the patient profile is to write out an html file with SAS. In the SAS program the number of columns and the relative column width are all specified so that the output looks quite neat.

For illustration purpose, we will look at the data for one patient. The datasets are for demographics and baseline characteristics, adverse events and concomitant medications.

### GET INTO THE DETAILS

#### ODS LAYOUT IN SAS

In the ODS LAYOUT there are absolute layout and gridded layout. In the absolute layout the user specifies the exact page location using the x and y coordinate. In the gridded layout the user arranges the layout in a grid structure. See references [1] and [2]. We use the gridded layout in the program pp1.sas.

```
* pp1.sas;
ods pdf file="C:\xxxx\pp.pdf";
ods Layout gridded width = 6in ;

ods region width = 6in;

proc report data=adsl style(report)={outputwidth=100%};
columns ("Demographics and Baseline" subjid trtsdt trtedt age sex race
heightbl weightbl);
run;

proc report data=adae style(report)={outputwidth=100%};
columns ("Adverse Events" subjid aedecod aeterm aestdct aeendtc aeser
trtemfl);
run;

proc report data=adcm style(report)={outputwidth=100%};
```

```

columns ("Concomitant Medication" subjid cmdecod cmtrtr cmstdtc cmendtc);
run;

ODS layout end;
ods pdf close;

```

The output 1 shows the output in pdf format.

Demographics and Baseline							
Subject Identifier for the Study	Date of First Exposure to Treatment	Date of Last Exposure to Treatment	Age	Sex	Race	Baseline Height (cm)	Baseline Weight (kg)
5671201	27AUG2015	17SEP2015	33	F	WHITE	165.1	63.68

Adverse Events						
Subject Identifier for the Study	Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date Time of Adverse Event	End Date Time of Adverse Event	Serious Event	Treatment Emergent Analysis Flag
5671201	Diarrhoea	DIARRHEA	2015-09-02	2015-09-08	N	Y
5671201	Nausea	NAUSEA	2015-09-02	2015-09-08	N	Y
5671201	Dehydration	DEHYDRATION	2015-09-03	2015-09-08	N	Y

Concomitant Medication				
Subject Identifier for the Study	Standardized Medication Name	Reported Name of Drug, Med, or Therapy	Start Date Time of Medication	End Date Time of Medication
5671201	HERCEPTIN+D+P	HERCEPTIN+D+P	2013-09-13	2013-12-24
5671201	HERCEPTIN	HERCEPTIN	2014-03	2015-05-21
5671201	PERTUZUMAB	PERTUZUMAB	2014-03	2014-09-25
5671201	LEVETIRACETAM	KEPPRA	2015-06	

**Output 1: The output of the program pp1.sas**

Note that you can produce the same output using ODS PDF and the option STARTPAGE=NO, without using the ODS LAYOUT statements.

**USE R SHINY**

The second way of creating the output is to use R Shiny. We can use the renderTable with the option bordered=TRUE to display the three tables. Notice that for variables TRTSDT and TRTEDT in ADSL, we use format function in R so that those variables are shown in numeric date format.

```

#pp.R

library(haven)
library(tidyverse)
library(lubridate)
library(DT)
library(shiny)
library(ggplot2)
# Read in the SAS data
adsl <- read_sas("adsl.sas7bdat")
adsl$TRTSDDT <- format(as.Date(adsl$TRTSDDT, origin='1960-01-01'),
"%Y/%m/%d")
adsl$TRTEDT <- format(as.Date(adsl$TRTEDT, origin='1960-01-01'),
"%Y/%m/%d")

adae <- read_sas("adae.sas7bdat")
adcm <- read_sas("adcm.sas7bdat")

ui <- fluidPage(

  tabPanel(
    "1 column",
    fluidRow(
      column(width = 10,
        h4("Demographics and Baseline Characteristics"),
        tableOutput("table1")),
      column(width = 10,
        h4("Adverse Events"),
        tableOutput("table2")),
      column(width = 10,
        h4("Concomitant Medication "),
        tableOutput("table3"))
    ))
)
server <- function(input, output) {

  output$table1 <- renderTable(adsl, bordered=TRUE)
  output$table2 <- renderTable(adae, bordered=TRUE)
  output$table3 <- renderTable(adcm, bordered=TRUE)

}
shinyApp(ui=ui, server=server)

```

The output 2 shows the output from the program pp.R.

## Demographics and Baseline Characteristics

SUBJID	SEX	AGE	RACE	TRTSDT	TRTEDT	HEIGHTBL	WEIGHTBL
5671201	F	33.00	WHITE	2015/08/27	2015/09/17	165.10	63.68

## Adverse Events

SUBJID	AETERM	AEDECOD	AESER	AESTDTC	AEENDTC	TRTEMFL
5671201	DIARRHEA	Diarrhoea	N	2015-09-02	2015-09-08	Y
5671201	NAUSEA	Nausea	N	2015-09-02	2015-09-08	Y
5671201	DEHYDRATION	Dehydration	N	2015-09-03	2015-09-08	Y

## Concomitant Medication

SUBJID	CMDECOD	CMTRT	CMSTDTC	CMENDTC
5671201	HERCEPTIN+D+P	HERCEPTIN+D+P	2013-09-13	2013-12-24
5671201	HERCEPTIN	HERCEPTIN	2014-03	2015-05-21
5671201	PERTUZUMAB	PERTUZUMAB	2014-03	2014-09-25
5671201	LEVETIRACETAM	KEPPRA	2015-06	

## Output 2: The output of the program pp.R

### USE R MARKDOWN

R Markdown is a file format for making dynamic documents with R. An R Markdown document is written in markdown and contains R code. See reference [3], [4] and [5] for more information regarding R markdown.

To run the program pp.Rmd, you can choose the Knit to HTML, Knit to PDF or Knit to Word command in RStudio.

```
# pp.Rmd
** Demographics and Baseline Characteristics **
```{r echo=FALSE}
library(haven)
adsl <- read_sas("adsl.sas7bdat")
library(knitr)
kable(adsl)
```

** Adverse Events **
```{r echo=FALSE}
library(knitr)
library(haven)
adae <- read_sas("adae.sas7bdat")
kable(adae)
```
```

```

** Concomitant Medication **
```{r echo=FALSE}
library(knitr)
library(haven)
adcm <- read_sas("adcm.sas7bdat")
kable(adcm)
```

```

The output 3 shows the output.

\*\* Demographics and Baseline Characteristics \*\*

| SUBJID  | SEX | AGE | RACE  | TRTSDT     | TRTEDT     | HEIGHTBL | WEIGHTBL |
|---------|-----|-----|-------|------------|------------|----------|----------|
| 5671201 | F   | 33  | WHITE | 2015-08-27 | 2015-09-17 | 165.1    | 63.68    |

\*\* Adverse Events \*\*

| SUBJID  | AETERM      | AEDECOD     | AESEER | AESTDTC    | AEENDTC    | TRTEMFL |
|---------|-------------|-------------|--------|------------|------------|---------|
| 5671201 | DIARRHEA    | Diarrhoea   | N      | 2015-09-02 | 2015-09-08 | Y       |
| 5671201 | NAUSEA      | Nausea      | N      | 2015-09-02 | 2015-09-08 | Y       |
| 5671201 | DEHYDRATION | Dehydration | N      | 2015-09-03 | 2015-09-08 | Y       |

\*\* Concomitant Medication \*\*

| SUBJID  | CMDECOD       | CMTRT         | CMSTDTC    | CMENDTC    |
|---------|---------------|---------------|------------|------------|
| 5671201 | HERCEPTIN+D+P | HERCEPTIN+D+P | 2013-09-13 | 2013-12-24 |
| 5671201 | HERCEPTIN     | HERCEPTIN     | 2014-03    | 2015-05-21 |
| 5671201 | PERTUZUMAB    | PERTUZUMAB    | 2014-03    | 2014-09-25 |
| 5671201 | LEVETIRACETAM | KEPPRA        | 2015-06    |            |

### Output 3: The Output of the Program pp.Rmd

## USE SAS TO CREATE HTML DOCUMENT

The fourth way of doing it is to use html language. The html language, just like xml, is a structured language. We can use the data \_null\_ and the put statements to write out all the starting tags and closing tags of the html language and insert the SAS variable names in appropriate places. We also specify the relative width of each column in the put statement.

```

** pp2.sas;
data adsl; set adsl; order=1;
data adae; set adae; order=2;
data adcm; set adcm; order=3;

data final;
set adsl adae adcm;
run;

proc printto file='C:\xxxx\pp.html' new;
data _null_;
file print notitles ll=ll ls=256 ps=2000 n=ps;
set final;
by subjid order;
if first.subjid then do;

```

```

put "<!DOCTYPE html>";
put "<html>";
put "<body>";
end;

if order=1 then do;
if first.order then do;
put "<table border=""2"" width=100%>";
put "<tr><th colspan=""8""><font size=2>Demographics and Baseline
Characteristics</th></tr>";
put "<tr><th align=left width=13%><font size=2>SUBJID</th>";
put " <th align=left width=13%><font size=2>TRTSDT</th>";
put " <th align=left width=13%><font size=2>TRTEDT</th>";
put " <th align=left width=13%><font size=2>AGE</th>";
put " <th align=left width=12%><font size=2>SEX</th>";
put " <th align=left width=12%><font size=2>RACE</th>";
put " <th align=left width=12%><font size=2>HEIGHTBL</th>";
put " <th align=left width=12%><font size=2>WEIGHTBL</th></tr>";
end;
put " <tr><td><font size=2>" subjid "</td>";
put " <td><font size=2>" trtsdt "</td>";
put " <td><font size=2>" trtedt "</td>";
put " <td><font size=2>" age "</td>";
put " <td><font size=2>" sex "</td>";
put " <td><font size=2>" race "</td>";
put " <td><font size=2>" heightbl "</td>";
put " <td><font size=2>" weightbl "</td></tr>";
if last.order then do;
put "</table>";
end;
end;

if order=2 then do;
if first.order then do;
put "<table border=""2"" width=100%>";
put "<tr><th colspan=""7""><font size=2>Adverse Events</th></tr>";
put "<tr><th align=left width=15%><font size=2>SUBJID</th>";
put " <th align=left width=15%><font size=2>AEDECOD</th>";
put " <th align=left width=14%><font size=2>AETERM</th>";
put " <th align=left width=14%><font size=2>AESTDTC</th>";
put " <th align=left width=14%><font size=2>AEENDTC</th>";
put " <th align=left width=14%><font size=2>AESER</th>";
put " <th align=left width=14%><font size=2>TRTEMFL</th></tr>";
end;
put " <tr><td><font size=2>" subjid "</td>";
put " <td><font size=2>" aeecod "</td>";
put " <td><font size=2>" aeterm "</td>";
put " <td><font size=2>" aestdct "</td>";
put " <td><font size=2>" aeendtc "</td>";
put " <td><font size=2>" aeser "</td>";
put " <td><font size=2>" trtemfl "</td></tr>";
if last.order then do;
put "</table>";
end;
end;

if order=3 then do;

```

```

if first.order then do;
put "<table border=""2"" width=100%";
put "<tr><th colspan=""7""><font size=2>Concomitant Medication</th></tr>";
put "<tr><th align=left width=20%><font size=2>SUBJID</th>";
put " <th align=left width=20%><font size=2>CMDECOD</th>";
put " <th align=left width=20%><font size=2>CMTRT</th>";
put " <th align=left width=20%><font size=2>CMSTDTC</th>";
put " <th align=left width=20%><font size=2>CMENDTC</th></tr>";
end;
put " <tr><td><font size=2>" subjid "</td>";
put " <td><font size=2>" cmdecod "</td>";
put " <td><font size=2>" cmtrt "</td>";
put " <td><font size=2>" cmstdtc "</td>";
put " <td><font size=2>" cmendtc "</td></tr>";
if last.order then do;
put "</table>";
end;
end;

if last.subjid then do;
put "</body>";
put "</html>";
end;
run;
proc printto;

```

The output 4 shows the sample output of the pp2.sas.

| Demographics and Baseline Characteristics |           |           |     |     |       |          |          |
|---|-----------|-----------|-----|-----|-------|----------|----------|
| SUBJID                                    | TRTSDT    | TRTEDT    | AGE | SEX | RACE  | HEIGHTBL | WEIGHTBL |
| 5671201                                   | 27AUG2015 | 17SEP2015 | 33  | F   | WHITE | 165.1    | 63.68    |

  

| Adverse Events |             |             |            |            |       |         |
|----------------|-------------|-------------|------------|------------|-------|---------|
| SUBJID         | AEDECOD     | AETERM      | AESTDTC    | AEENDTC    | AESER | TRTEMFL |
| 5671201        | Diarrhoea   | DIARRHEA    | 2015-09-02 | 2015-09-08 | N     | Y       |
| 5671201        | Nausea      | NAUSEA      | 2015-09-02 | 2015-09-08 | N     | Y       |
| 5671201        | Dehydration | DEHYDRATION | 2015-09-03 | 2015-09-08 | N     | Y       |

  

| Concomitant Medication |               |               |            |            |
|------------------------|---------------|---------------|------------|------------|
| SUBJID                 | CMDECOD       | CMTRT         | CMSTDTC    | CMENDTC    |
| 5671201                | HERCEPTIN+D+P | HERCEPTIN+D+P | 2013-09-13 | 2013-12-24 |
| 5671201                | HERCEPTIN     | HERCEPTIN     | 2014-03    | 2015-05-21 |
| 5671201                | PERTUZUMAB    | PERTUZUMAB    | 2014-03    | 2014-09-25 |
| 5671201                | LEVETIRACETAM | KEPPRA        | 2015-06    |            |

Output 4: The Output of the Program pp2.sas in html format

## CONCLUSION

There are different ways to create the patient profiles. In this paper we discussed four tools: the ODS LAYOUT in SAS, the R shiny, R markdown and data \_null\_ with put statement in SAS that creates html

output. Programmers can choose the way that meets the study's need and make the creation of patient profiles a relatively easy and enjoyable task.

## ACKNOWLEDGEMENT

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## REFERENCES

[1] SAS ODS LAYOUT tip sheet

[https://support.sas.com/rnd/base/ods/Tipsheet\\_ods\\_layout.pdf](https://support.sas.com/rnd/base/ods/Tipsheet_ods_layout.pdf)

[2] Lassman, Doug. Producing Patient Profiles Using PROC Document and ODS Layout. Paper CC24, PharmaSUG 2005.

[3] Meng, Qin. SAS Report Writing Interface vs. R Markdown for Patient Profile Generation. Paper CC-022, PharmaSUG China 2019.

[4] A short video about R markdown

<https://www.youtube.com/watch?v=tKUufzpoHDE>

[5] Introduction to R Markdown, available at

[Introduction to R Markdown \(rstudio.com\)](https://www.rstudio.com/resources/learn/r-markdown/)

## CONTACT INFORMATION

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