

Graph Display of Patient Profile Using SAS®

Yanwei Han, Seqirus USA Inc., Cambridge, MA

Hongyu Liu, Seqirus USA Inc., Cambridge, MA

ABSTRACT

We usually create patient profile listings to present clinical study subject individual information. If we present most the information in one graph using SAS®, it would be easier for reviewers to read them visually.

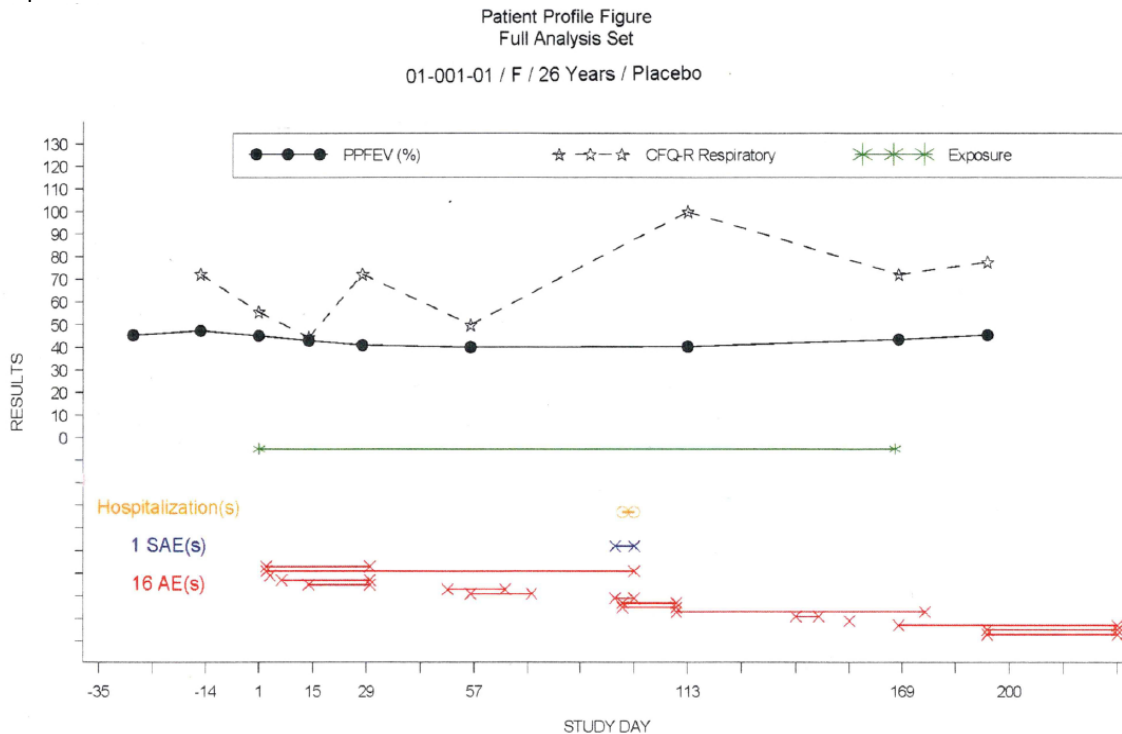
INTRODUCTION

This paper will discuss

- 1) what information will be presented in one graph? Each graph displays an individual subject with four categories of information, including demographic, study treatment administration, safety analysis part (e.g., adverse events, concomitant medication, pulmonary exacerbation, hospitalization etc.), and efficacy analysis part (e.g., BMI Z-scores, Questionnaire etc.).
- 2) How to present the information? Study days or visits will be set as horizontal axes. Subject ID, Gender, Age, Treatment and other demographic data can be listed in the graph title. Study exposure will be indicated in the middle of the display by a horizontal line. Efficacy clinical response is plotted above the study exposure line based on study schedule visits. Each safety analysis event, for example adverse events, concomitant medication, hospitalization, will be displayed as one line under the study exposure line in the graph.

EXAMPLE OF PATIENT PROFILE GRAPH

Graph 1



<Graph Display of patient Profile Using SAS>, continued

In this example, each subject is presented in one graph. Horizontal axes is study day. It is 24 weeks (169 days) of treatment and a follow-up visit 4 weeks (± 7 days) after the last dose of study drug. For ongoing or missing end date events, the end day is imputed to 228 days based on internal rules.

Demographic information including Subject ID, Gender, Age, Gene Mutations and Treatment, is listed in the graph title.

Study drug exposure information is indicated in the middle of the display by a horizontal green line.

Percent predicted FEV₁ (the ratio of FEV₁ (L) to the predicted FEV₁ (L)) and Questionnaire CRQ-R respiratory score as efficacy clinical responses are plotted above the exposure line based on study days.

Each adverse events(AE), serious adverse events (SAE), pulmonary exacerbation, hospitalizations are displayed from start date to end date as one line under the dose exposure line. The numbers of AE(s) and SAE(s) are also indicated in the graph.

DISPLAY DATA AS AGRAPH USING SAS PROC GPLOT

```
proc gplot data=xxx gout=gout ;
  plot aval*days = type /haxis=axis2 vaxis=axis1 noframe lvref=3
                                legend=legend1 annotate=annos;
run;
```

PREPARE DATA FOR PATIENT PROFILE GRAPH

Demographic

Subject demographic information can be read from CDISC SDTM DM or ADaM ADSL. In this example the subjects are in full analysis set, we call ADaM ADSL datasets to prepare data.

```
data dm;
  set adam.adsl;
  by subjid;
  where fasfl='Y'; /* Full Analysis Set */

  length info $45;
  info=strip(subjid)||' / '||strip(sex)||' / '||strip(put(age,best.))||
  '\ / '|| strip(genoa) ||'/ '|| strip(trt01p) ;
  i=_n_;

  /*each subject number */;
  call symput('sub' || strip(put(i,best.)),strip(subjid));

  /*each subject demographic information*/;
  call symput('infor' || strip(put(i,best.)),strip(info));

  /* total subject numbers*/;
  if last.subjid then call symput('total', strip(put(i,best.)));
run;
```

We call macro variable &&infor&n in the title to present demographic information.

<Graph Display of patient Profile Using SAS>, continued

Exposure

Study exposure information is indicated in the middle of the display by a horizontal line. The line starts at each subject Study Day of Start of Treatment, it is set as day 1 or visit 1 (we will focus on Study day as horizontal axes in this paper, each subject exposure starts from day1) and ends at each subject Study Day of End of Treatment. Its value is equal to End date of treatment - Start Date of Treatment + 1. If subject has missing doses between start date of treatment to end date of treatment, blank space will be used.

The example used here is a double-blind study comparing Treatment1 (two 250-mg tablets once daily) vs Placebo. Subject 01-001-01 took 2 placebo tablets from 2015-01-14 to 2015-07-01 (see Graph 1). Subject 01-002-01 took 2 Treatment1 tablets within the same timeframe, but missed dosing 4 days (see Graph 2).

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFR	EXROUTE
1	01	EX	01-001-01	1	PLACEBO	0	mg	TABLET	ORAL
2	01	EX	01-002-01	1	TREATMENT1	500	mg	TABLET	ORAL
3	01	EX	01-002-01	2	TREATMENT1	500	mg	TABLET	ORAL

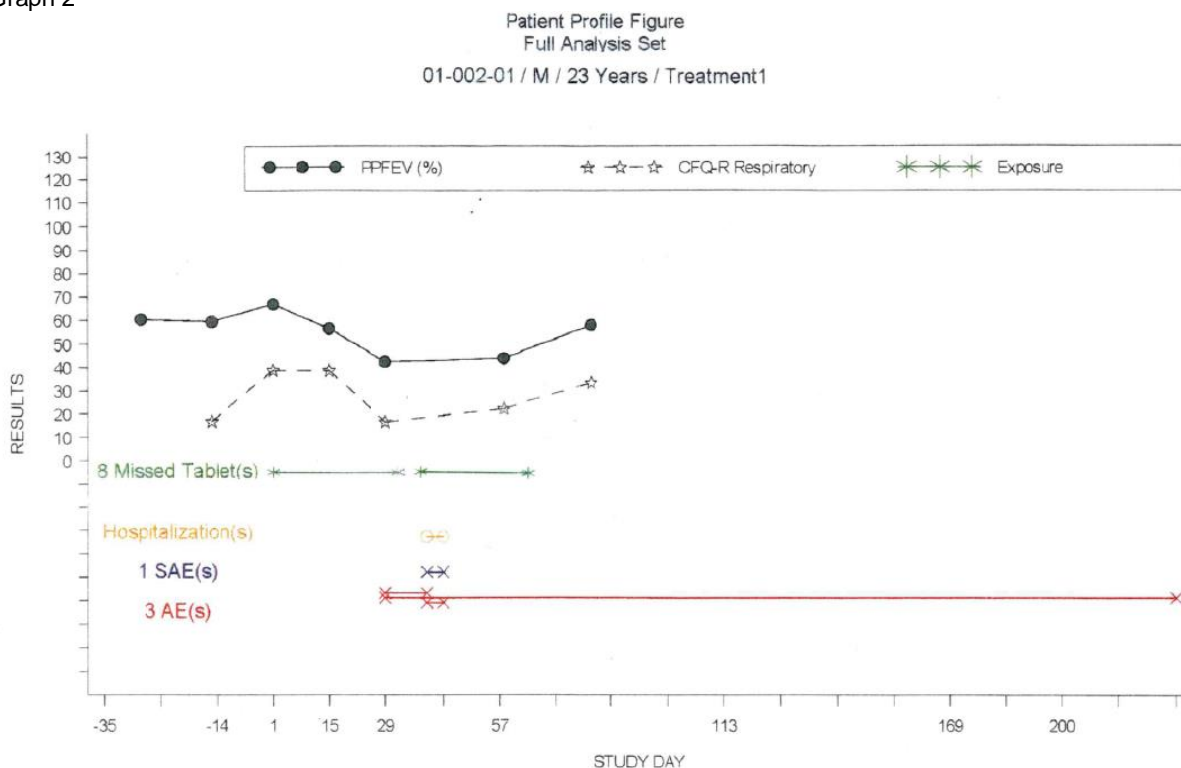
Row	EPOCH	EXSTDTC	EXENDTC	EXSTD	EXENDY
1	TREATMENT	2015-01-14	2015-07-01	1	169
2	TREATMENT	2015-01-14	2015-02-15	1	33
3	TREATMENT	2015-02-20	2015-03-17	38	63

Subject 01-001-01 will have one exposure line. It starts from day 1 and stops at day 169;
 Subject 01-002-01 will have one exposure line, too. It starts from day 1 and stops at day 33, restarts from day 38 and stops at day 63.

Variable AVAL is assigned to “-5” instead of “0” to leave space for efficacy response values that may close to “0”.
 Variable TYPE is assigned to “3DOSE”.

We also can annotate missed doses based on DA domain – Drug Accountability details (amount dispensed, amount returned), or EC domain - Exposure as Collected according to SDTM Version 3.2.

Graph 2



Safety Analysis Events

In this paper, three safety events are displayed in the graph. They are “Hospitalizations”, “Serious Adverse Events (SAE)” and “Adverse Events(AE)”. Adverse Events(AE) is used here as a detailed example. Other safety events are the same as AE.

AEs are Treatment Emergent AEs, including serious adverse events (SAE) in this paper. SAE(s) is presented above AE(s) already.

```

data ae0;
  set adam.adae;

  /* TRTEMFL = Treatment Emergent Analysis Flag */;
  where TRTEMFL='Y' and subjid="&&sub&i..";

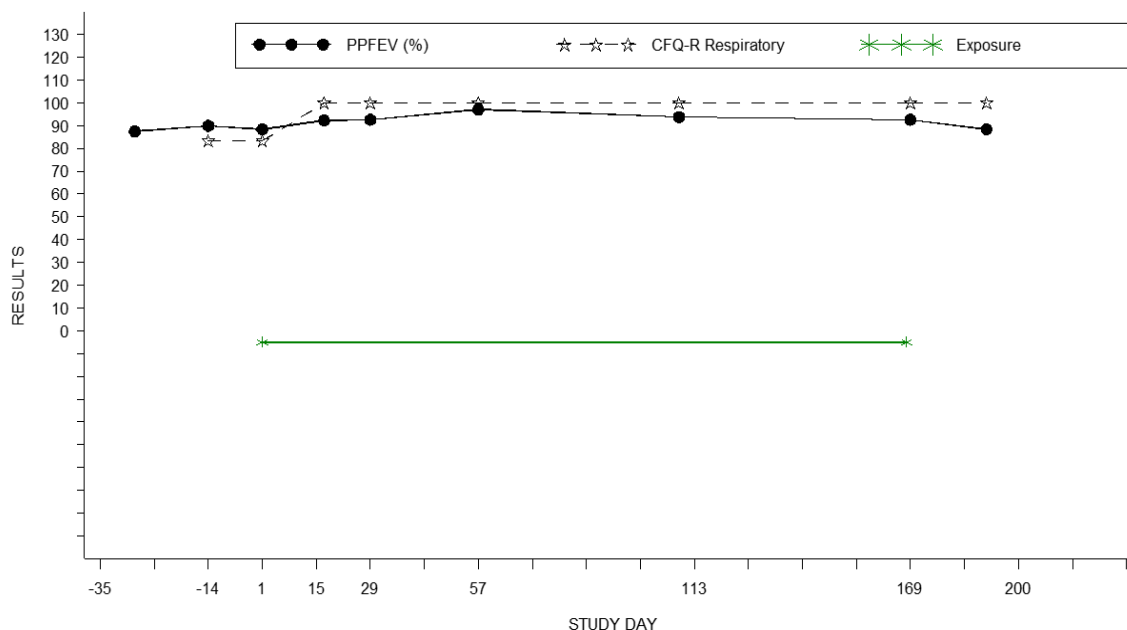
  /* For ongoing or missing end date events, the end day is imputed to
     228 per meeting minutes recorded in internal rules*/
  if aeendy=. then aeendy=228;
run;

/* check how many AE records of the subject*/
proc contents data=ae0 out=checkae noprint;
run;
proc sql noprint;
  select distinct NOBS into: aeno
  from checkae;
quit;
%put aeno=&aeno;

```

AE area can be blank if the subject does not have AE records.
For example, the subject does not have any event in Graph 3

Graph 3



Each AE record will have a serial number by code n=_n_;

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```
%if &aeno^=0 %then %do;
data ae;
  set ae0;
  by subjid astdy aeendy aeseq;
  length type $15 stat $10;
  stat='AE';
  n=_n_;
  type="7"||strip(put(n,best.))||subjid;

  if last.subjid then call symput('aenum', strip(put(n,best.)));

  /* the subject 10-044-03 has 28 AEs, reduce each AE records space for this
     Special subject*/
  if subjid='10-044-03' then aval=-55-1.5*n ;
  else aval=-55-2*n;

  keep AEENDY ASTDY subjid type stat aval aeser;
run;

proc sort data=ae;
  by subjid type stat aval;
run;

proc transpose data=ae out=ael(rename=(coll=days));
  by subjid type stat aval;
  var astdy aeendy;
run;
  %let tickaes=%eval(&ticksae+1);
  %let tickae=%eval(&ticksae+&aenum);

%put &aenum &tickae;

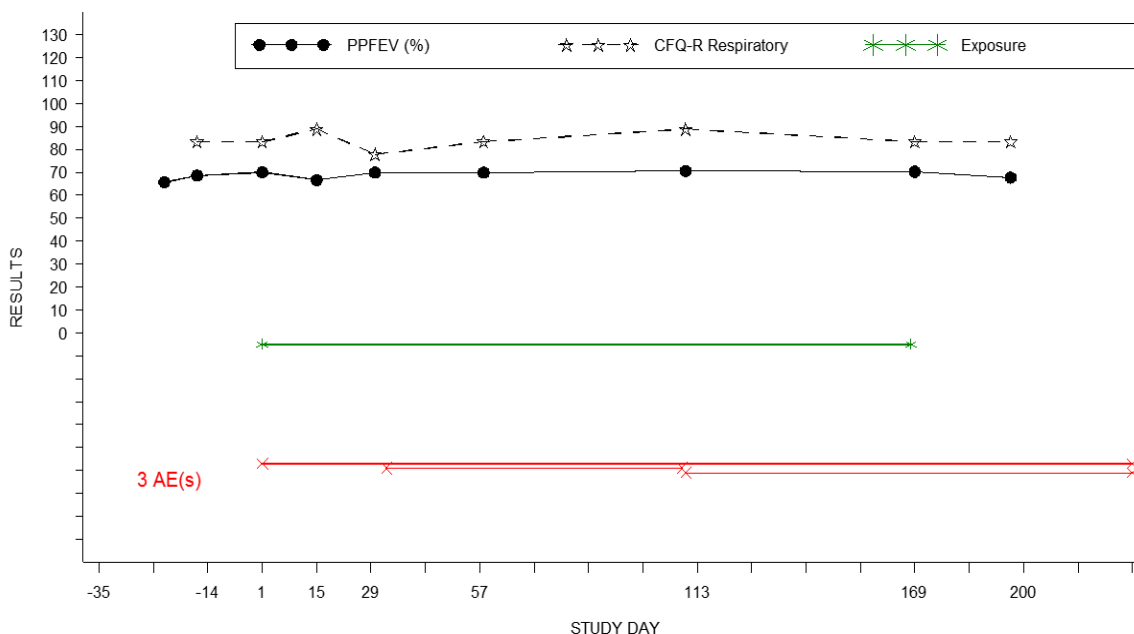
  /* add AE dataset into all dataset */;
data all;
  set all ael;
  drop usubjid nn _name_ _label_;
run;

proc sort data=all;
  by subjid;
run;
%end;

  /* present each AE records in the graph*/;
%if &aeno^=0 %then %do;
  %do j=&tickaes %to &tickae %by 1;
    symbol&j interpol=hiloj width=2 line=1 value=x c=red;
  %end;
%end;

  /* annotate how many AE(s) for the subject*/;
%if &aeno^=0 %then %do;
  function='LABEL'; color='red'; x=15; y=15; text="&aenum AE(s)";
  size=1.8; output;
%end;
```

Graph 4



Efficacy Clinical Response

The examples in this paper draw “Spaghetti plot” that contains one plot line per efficacy response over all study day. For example, Percent predicted FEV₁ values at each scheduled visit (study day) are connected by dots.

Variable AVAL is the value in each efficacy response scheduled visit (study day); Variable DAYS is equal to scheduled date – first treatment date +1.

SYMBOL statements are generated dynamically based on the value of the clinical response for each line. Percent predicted FEV₁ (the ratio of FEV₁ (L) to the predicted FEV₁ (L)) symbol statement is `symbol1 interpol=hiloj width=2 line=1 value=dot c=black;` type is assigned to "1SP"; and Questionnaire CRQ-R respiratory score symbol statement is `symbol2 interpol=hiloj width=2 line=20 value== c=black;` type is assigned to "2QS";

Efficacy clinical response plot lines can be displayed with multiple axis scales and label plot points, or displayed with the left and right axes, and a single combined legend based on your data values. More information can be find in https://support.sas.com/sassamples/graphgallery/PROC_GPLOT.html.

CONCLUSION

This paper proposes a method how to present clinical study subject individual information in one-page graph.

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<Graph Display of patient Profile Using SAS>, continued

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Name: Yanwei Han
Enterprise: Seqirus USA Inc.
Phone: 617-909-5548
E-mail: yanwei.han@seqirus.com

Name: Hongyu Liu
Enterprise: Seqirus USA Inc.
Phone: 617-702-6753
E-mail: Hongyu.liu@seqirus.com

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