

SAS/Graph to help data Dose/Concentration consistency review

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ABSTRACT

SAS 9.2 introduces a family of new procedures that make data analysis and review more simples. This paper will present some figures created using some of the new procedures that are useful in performing dataset review.

INTRODUCTION

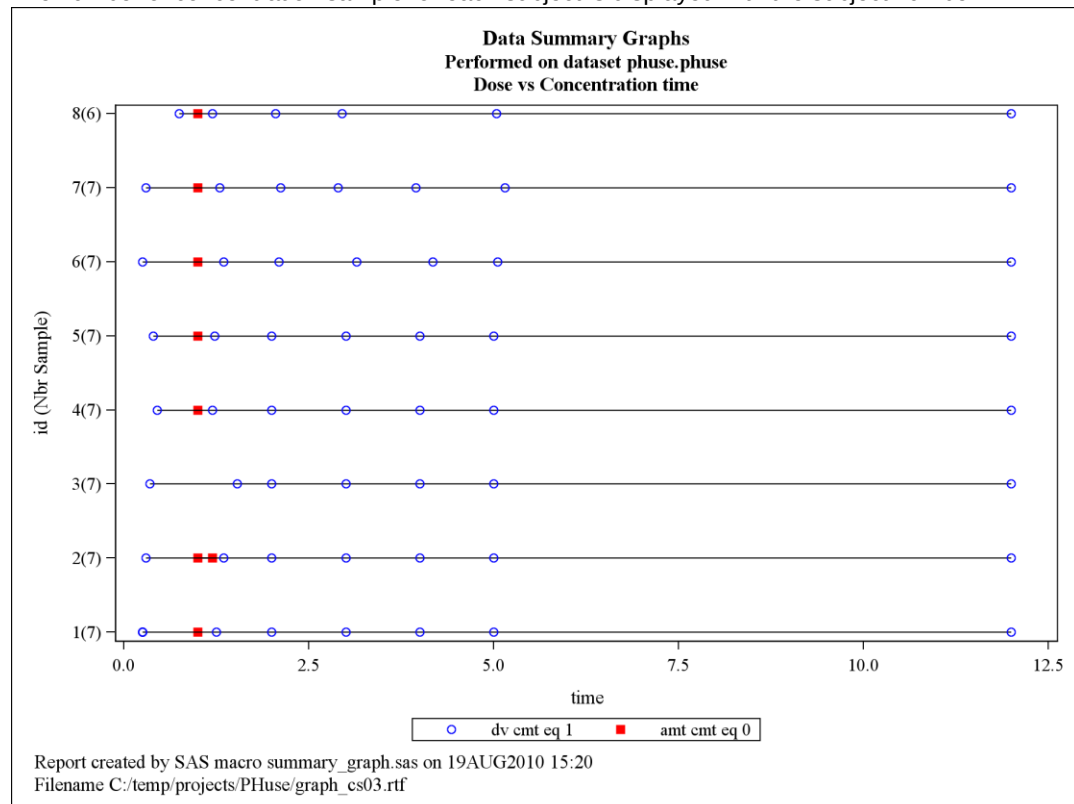
Review and validation of datasets used for modelisation can be a difficult and time consuming task. Proper review does reduce the need to for executing many times model due to data issues.

To ease this process a set of SAS utilities macro were develop in Novartis Modeling and Simulation programming group. One of them creates a rtf file with up to four SAS/Graph figures. They consist of a dose vs concentration time, overall concentration, log of the overall concentration and subjects profiles. Each of those figures will be explained in this paper

GRAPH DOSE VS CONCENTRATION TIME

Ensuring dosing and concentration date and time are follow what is defined the protocol is important for the model to performs correctly. This figure allows easy review the dose vs concentration time. It also make easy to see cases of missing dose for instance.

The number of concentration sample for each subject is displayed with the subject number.



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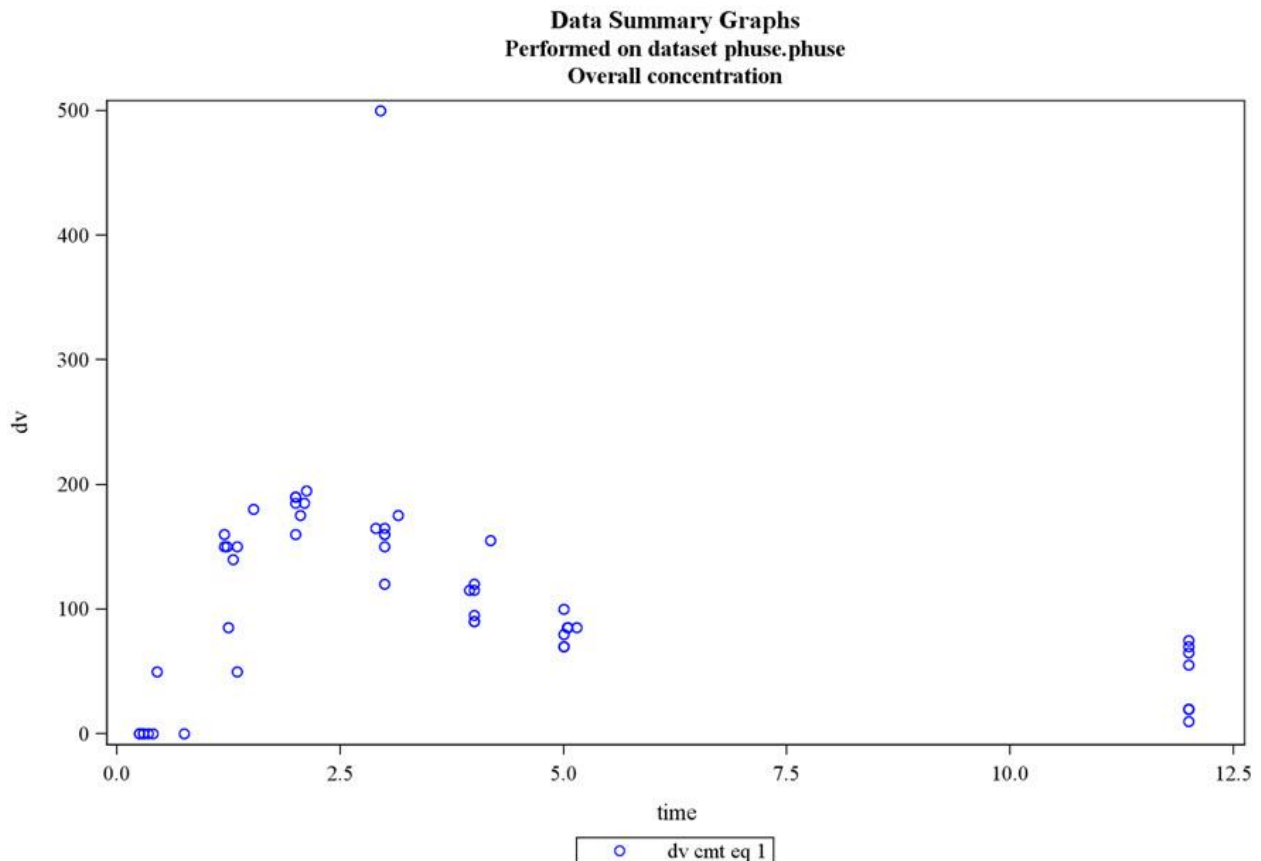
In the above example, some issues can be seen:
subject 2 have two dosing observations
subject 3 do not have any dosing observation
subject 8 have one less concentration that the other subjects

The code to create this figure is the following:

```
proc sgplot data=work._dsPlotg1 ;  
  by _msbreak ;  
  format _yaxisDose1 _yaxisPk1 _msgrph. ;  
  
  series x=_timeDose1 y=_yaxisDose1 /  
    group=_yaxisDose1 lineattrs=(pattern=solid color=black) markers  
    markerattrs=(symbol=squareFilled color=red) name ="GX1" ;  
  series x=_timePk1 y=_yaxisPk1 / group=_yaxisPk1  
    lineattrs=(pattern=solid color=black)  
    markers markerattrs=(symbol=circle color=blue) name ="GY1" ;  
  yaxis type=discrete label="id (Nbr Sample)" ;  
  xaxis label="time" ;  
run ;
```

OVERALL CONCENTRATION

Out layer can have major impact in a model and identifying allow for quicker reviews. While some will be real out layer a more detail review often show it is a data issue that can be solve before the model is executed.



In the above example a out layer can be easily seen.

The simplify code to create this figure is the following:

```
proc sgplot data=work._dsPlotg2 ;
```

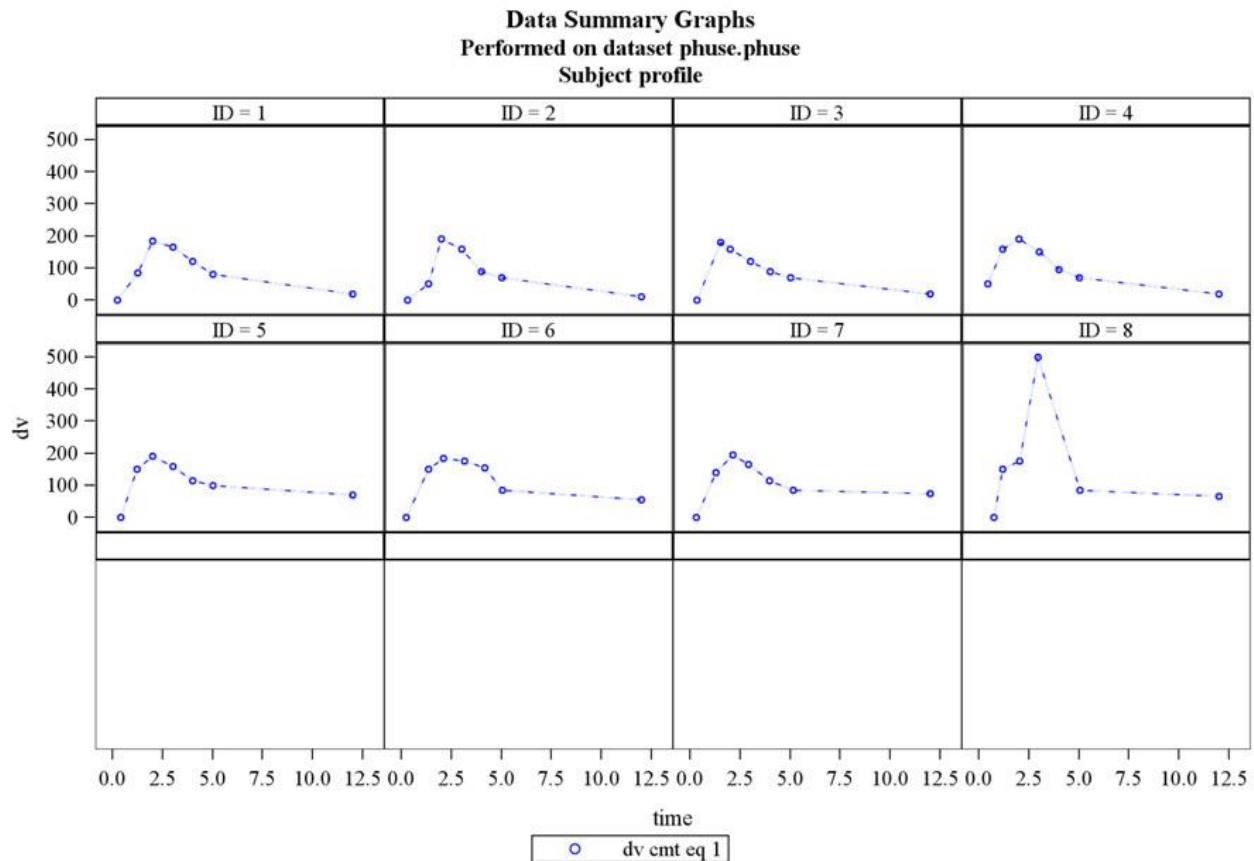
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```
series x=_plot2xaxis_pk1 y=_plot2yaxis_pk1 /
  lineattrs =(color=white) markers
  markerattrs=(symbol=circle color=blue) ;
run ;
```

In addition to the above graph, the same graph can also be created using log scale of the selected column.

SUBJECT PROFILE

This figure allow for a review of each subject profiles. It can be used prior to model execution to have a ensure the concentration follow a normal trend and it can also be helpful after model execution in case issue have been encountered during the model execution.



In the above example a out layer can be easily seen.

While creating this figure type of figure before 9.2 was complicated, with the new SG procedure SGPPANEL this is very simple as can be seen below:

```
proc sgpanel data=work._dsPlotg3 ;
  panelby id / columns=4 rows=3 ;
  series x=_plot3xaxis_pk1 y=_plot3yaxis_pk1 /
    lineattrs=(pattern=solid color=blue)
    markers markerattrs=(symbol=circle color=blue) ;
run ;
```

MORE OPTIONS

In addition to supporting multiple type of figures, the summary graph macro does allow for multiples dosing regiment and multiple concentration type, each one being separated by ' / ' in the appropriate parameter when calling the macro.

Since treatment regimen can have very different profiles, each figures can also be created using a by statements.

CONCLUSION

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The new SAS/Graph SG procedures provide new tools for displaying results from clinical trials. The syntax for the procedures is straightforward and easy to use. They can be used as basis for SAS macros to allow more easy data review.

ACKNOWLEDGMENTS (HEADER 1)

The author would like to thank Georges Ette, programmer in M&S programming group for his thoughtful comments, continual support and encouragement in the development of this macro.

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RECOMMENDED READING (HEADER 1)

SAS/Graph 9.2: Statistical Graphics Procedure Guide.

Frank Ivis, *Guidelines on Writing SAS Macros for Public Use* Paper presented at the SAS Users Group International 29.

Daniel O'Connor, *SAS Graphics on ODS 9.2 Performance-Enhancing Steroids* Paper presented at the SAS Global Forum 2008.

Susan Schwartz, *Clinical Trial Reporting Using SAS/Graph SG Procedures* Paper presented at the SAS Global Forum 2009.

CONTACT INFORMATION (HEADER 1)

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