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Statistical Graphics for Clinical Research Using ODS Graphics Designer

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ABSTRACT

Statistical graphics play an important role across various stages in clinical research. They help investigators to explore and understand raw data in the early stage of statistical analysis, as well as present final analysis result in the formal publications. The graphs need to be specifically designed and carefully drawn to best represent data and analysis. While this can be done by SAS® programming using traditional SAS DATA steps and SAS/GRAPH procedures, the process is time consuming and time is spent to find the right options or annotation syntax.

Since SAS 9.2M3, ODS Graphics Designer (Designer) becomes production software. This is an interactive "point and click" application that can be used to design and create custom graphs. This new application greatly enhances the ability to effectively generate statistical graphs for clinical research.

In this paper, I will show you the application interface and walk you through creating some commonly used statistical graphs for clinical research. The intended audience doesn't need to know SAS/GRAPH syntax, but wants to create high-quality statistical graphs for clinical trials. Examples will use scrambled data from real world in CDISC format.

INTRODUCTION

ODS Statistical Graphics is a new data visualization functionality available in SAS 9 to assist clinical research. It provides the ability to create statistical graphs from many analytical SAS procedures, SAS/GRAPH Statistical Graphics (SG) procedures, and SAS/GRAPH Graph Template Language (GTL). They are all based on SAS programming syntax; the program can be simple and straight-forward few-line of code, or can be hundreds-line of code with a pretty complex SAS syntax. This prevents statistician, analysts, and managers, who usually are not familiar with the SAS syntax, from graphically exploring data or presenting their analysis results easily.

The new ODS Graphics Designer application (or "the Designer" for short) provides an interactive manual process to generate statistical graphs without much knowledge of SAS/GRAPH software or the GTL. It makes it much easier to design and create simple or complicated statistical graphs from early phase of clinical trials to late stage of regulatory submissions.

EXPLORING THE USER INTERFACE

Figure 1 shows the Designer application interface that is started after selecting Tools->ODS Graphics Designer from the main menus of the SAS session, or by submitting the following macro call from the program editor window:

```
%sgdesign; <submit>
```

On the left side is "**Elements**" pane which is two stacked panels, "**Plot Layers**" and "**Insets**". On the right side is the workspace with the "**Graph Gallery**". The main menus are shown at the top such as "File", "Edit", "View", etc. A toolbar is shown below the menus.

GRAPH GALLERY

This gallery provides some predefined, commonly used plots. There are six groups of graphs, represented as six tabs in the gallery:

1. Basic: Scatter plots, histograms, and other basic plots.
2. Grouped: Plots that have been grouped by a variable.
3. Analytical: Commonly used analytical graphs.
4. Custom: Graphs that require unique custom data.
5. Matrix: Various scatter plot matrices for visualizing variable associations.
6. Panels: Various types of classification panel graphs for comparison.

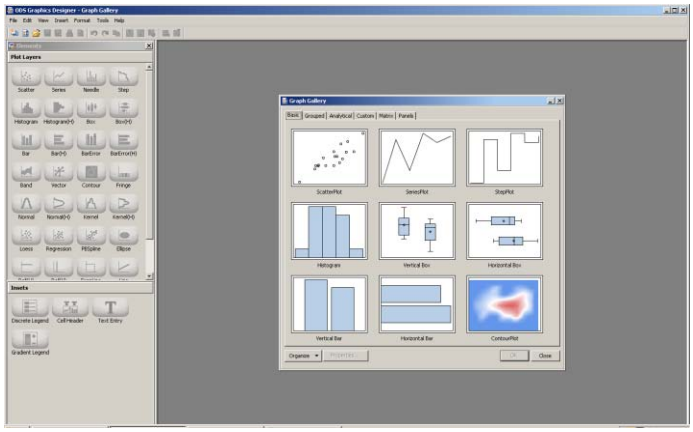

Figure 1 The Designer User Interface

ELEMENTS PANE

Elements pane is inactive initially. It will become active once the process of creating a graph is started. The **Elements** pane contains plots and insets that you can insert into the graph.

1. The **Plot Layers** panel contains plots that you can click and drag to a graph cell.
2. The **Insets** panel contains graphics elements such as legend, headers that you can click and drag to a graph cell.

CREATE A BAR CHART OF GENDER FREQUENCY

A new graph can be created from a blank graph, or from a graph in the **Graph Gallery**. In this exercise, we'll create a graph from the gallery. Let's start from one of the Basic graphs. We want to create a graph to plot the frequency of gender for a clinical trial study.

If the Graph Gallery is not visible, select View->Graph Gallery.

Select the Basic tab from the Graph Gallery. Click the Vertical Bar. Click OK. (Or just double click the Vertical Bar)

A graph will appear showing a vertical bar chart, as shown in Figure 2A.

The Assign Data dialog is displayed with the default data settings for the bar chart. (Figure 2B).

We need to provide the LIBRARY, DATASET and VARIABLE for our graph. Click on the Library drop down arrow, and select "MYLIB". Click on the Data Set drop down arrow, and select ADSL. Click on the Category drop down arrow and select "SEX". (Figure 2C).

At this stage we have a graph with a bar chart showing the frequency of the gender for all the subjects in the study. We have a place holder title at the top, a place holder footnote at the bottom, and a bar chart of gender frequency. (Figure 2).

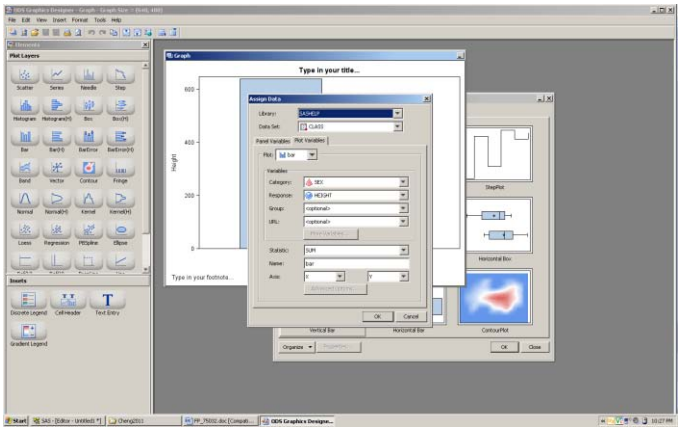

Figure 2A Selecting Vertical Bar Chart from Graph Gallery

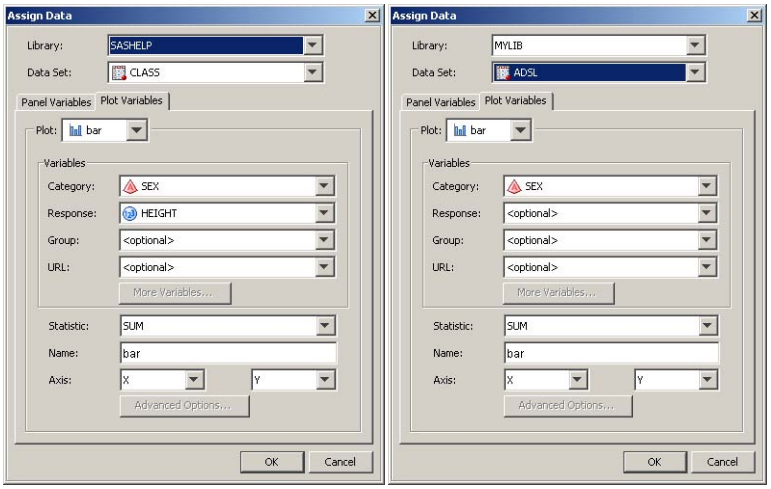

Figure 2B **Figure 2C**

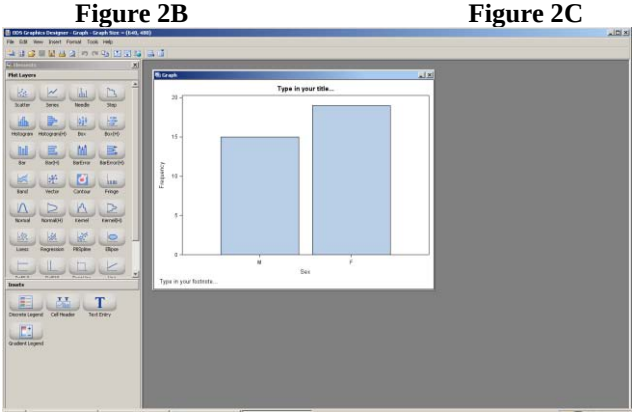

Figure 2 Vertical Bar Chart of Gender Frequency

CREATE A BAR CHART OF GENDER FREQUENCY BY TREATMENT ARM

Right click on the plot; you will see the standard graph pop-up menu as shown in Figure 3A. Select “Assign Data”, a pop-up window (Figure 3B) will allow you reassign the variable or do other settings for this plot. Click on the Group drop down arrow and select “ARM”, and then click OK.

A stacked bar chart of gender frequency is shown in Figure 3. If you move the mouse over on the bar, there is a pop-up tooltip window showing the statistics of the bar (Figure 3C).

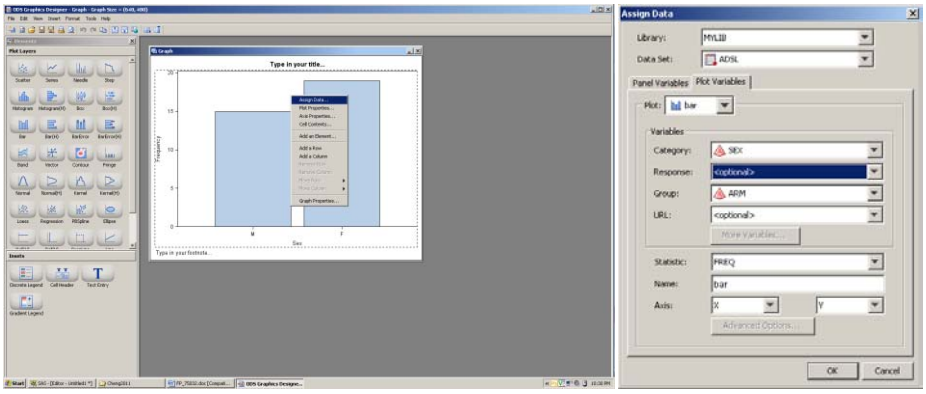

Figure 3A **Figure 3B**

Figure 3 Vertical Bar Chart of Gender Frequency by Treatment Arm

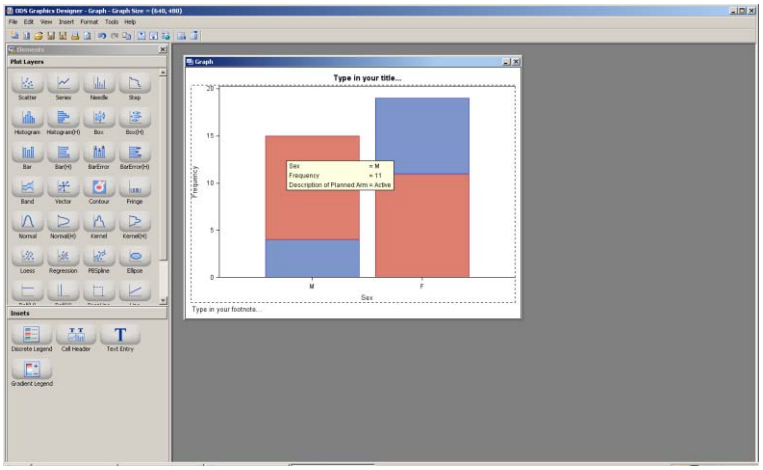

Figure 3C

SIDE BY SIDE BAR CHART

If you like to have a side-by-side bar chart instead of a stacked bar chart, you can go to the “Assign Data” window, select “Panel Variables” tab, click on the Column drop down arrow and select “ARM”. (Figure 4A) Then click OK. Figure 4 is shown the plots that you like.

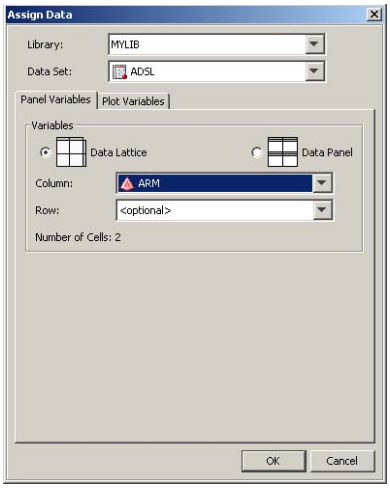

Figure 4A

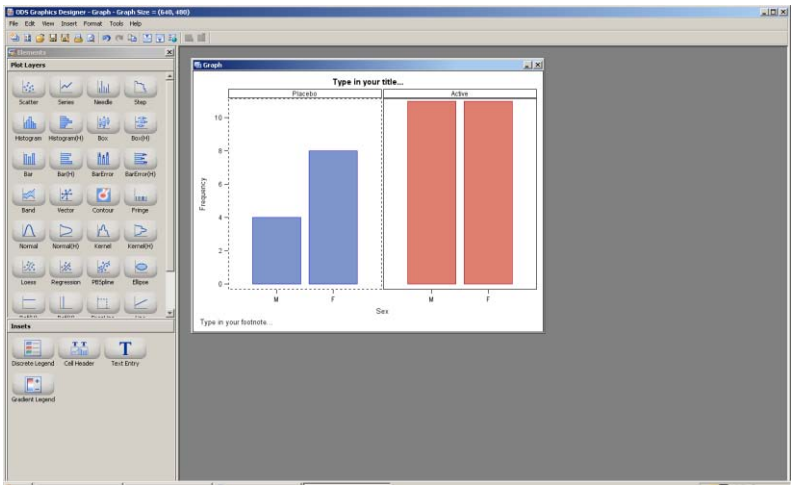

Figure 4 Side by Side Vertical Bar Chart of Gender Frequency by Treatment Arm

MEAN MEASUREMENTS OVER TIME

A graph of mean measurement over time is one of the most commonly used statistical graphs for data exploration and presentation in clinical research. I'll show you how to create the graph step by step using the Designer.

Select the Analytical tab from the Graph Gallery (Figure 5A).

Click the Means. Click OK. A graph will appear showing mean values with horizontal error bars and the Assign Data dialog (Figure 5B).

Notice this graph is merely a place holder to indicate the type of plot being customized. It uses the CARMEAN data set from WORK library (Figure 5C).

For our graph, we need to provide the LIBRARY, DATASET and VARIABLES (X, Y, and GROUP) according to Figure 5D.

Click on "More Variables…" to assign variables for the error bars (Figure 5E).

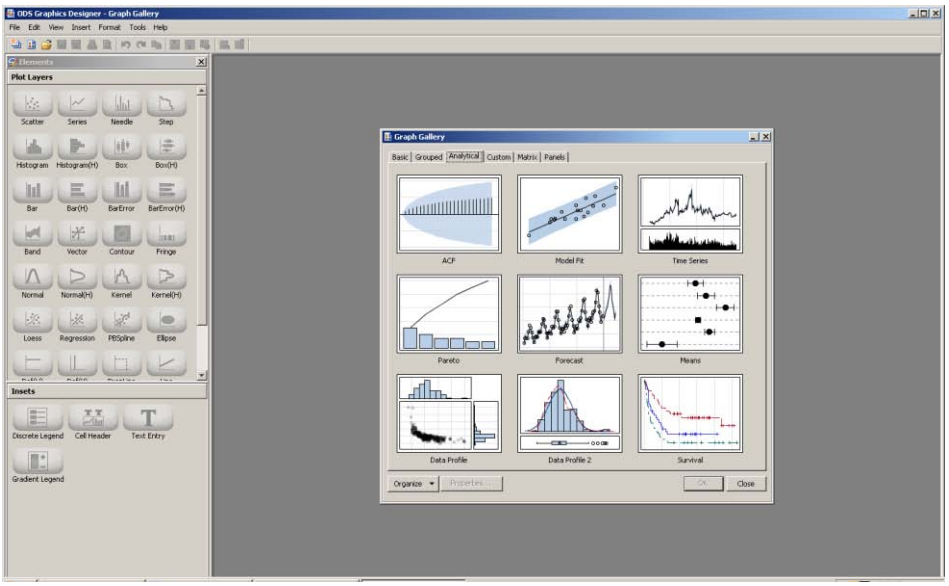

Figure 5A

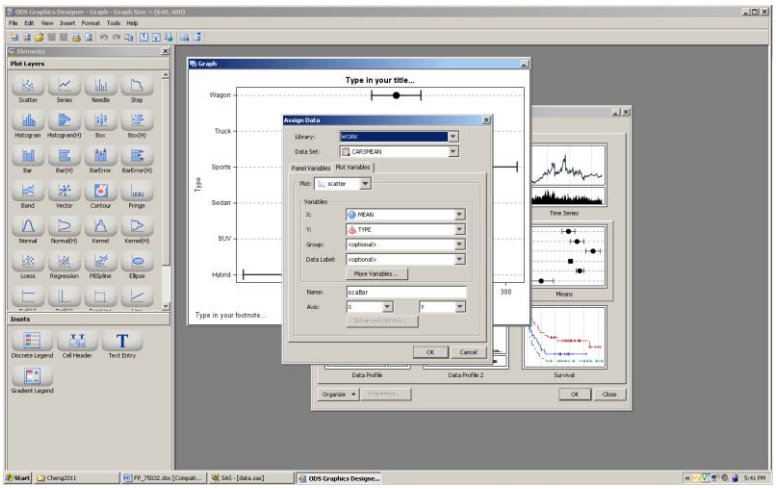

Figure 5B

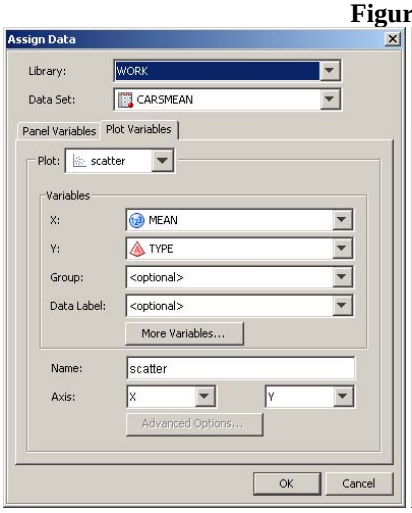

Figure 5C

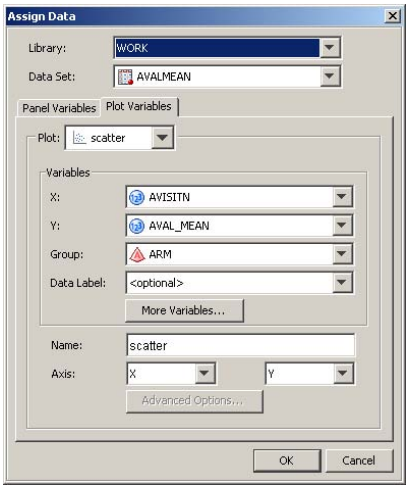

Figure 5D

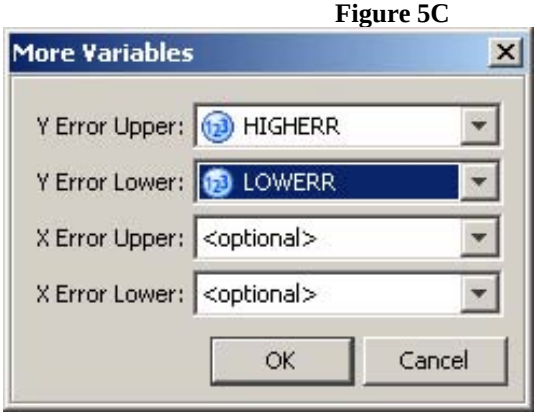

Figure 5E

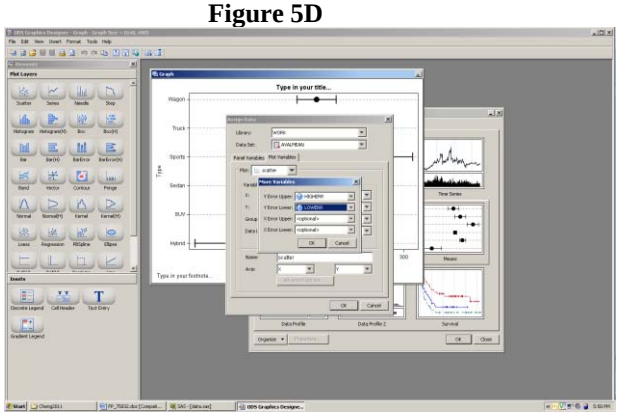

Figure 5F

After we assigned variables following the steps above (Figure 5F), a graph of mean values with error bars over time is showing in Figure 5.

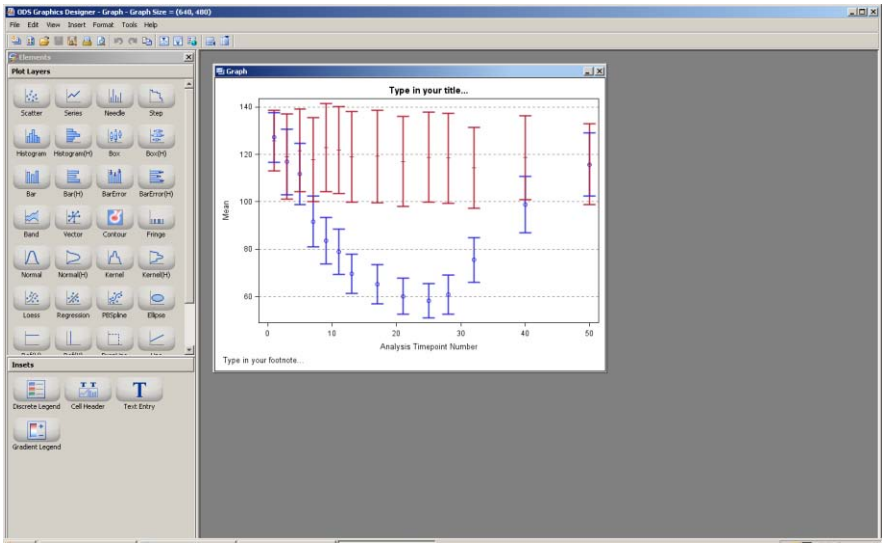

Figure 5 Mean Values with Error Bars over Time

ADD SERIES LINES

To link the mean values with connected lines, click and hold the mouse button on the icon for "Series" from **Plot Layers**, drag and drop it on top of the plots in previous exercise (Figure 6A). A "Assign Data" dialog for the series plot will be displayed as shown in Figure 6B. Assign the proper variables as shown in Figure 6C. Click OK, a graph of mean measurements over time with error bars by treatment arm is shown in Figure 6.

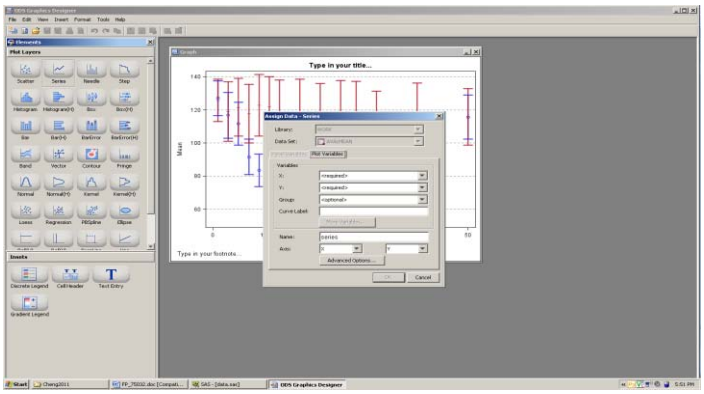

Figure 6A

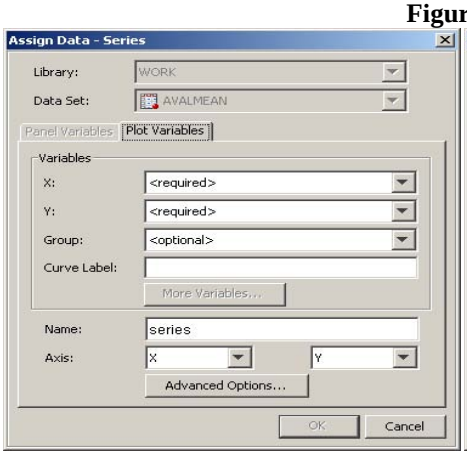

Figure 6B

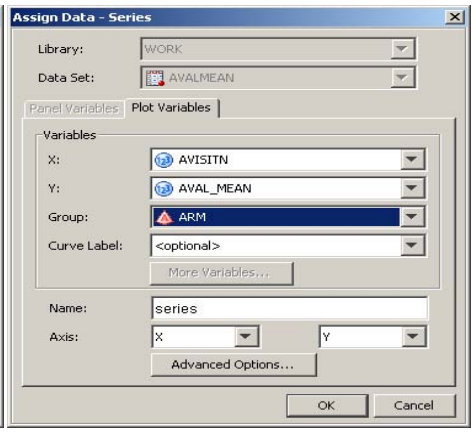

Figure 6C

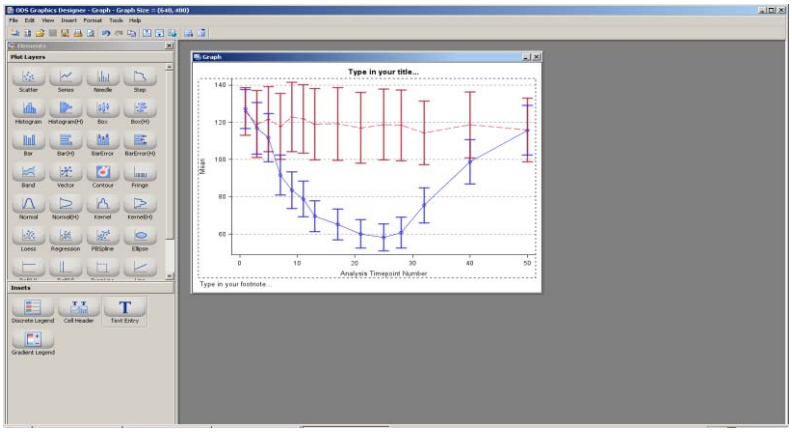

Figure 6 Mean Measurements with Error Bars over Time

ADD A CELL LEGEND

To add a discrete legend to the graph, click and drag the Discrete Legend icon from the **Insets** panel to the graph cell. You can also right-click inside the graph and choose "Add an Element". Then click the legend icon from the **Elements** pop-up window. The legend is placed near the location where the icon is dropped.

Right click the legend, and then select Legend Properties (Figure 7A).

The Legend Properties dialog opens. Select "Bottom Right" for the Position (Figure 7B). Click OK.

A legend with 4 rows (two for scatter plot and two for series plot) has been added to the graph as shown in Figure 7C.

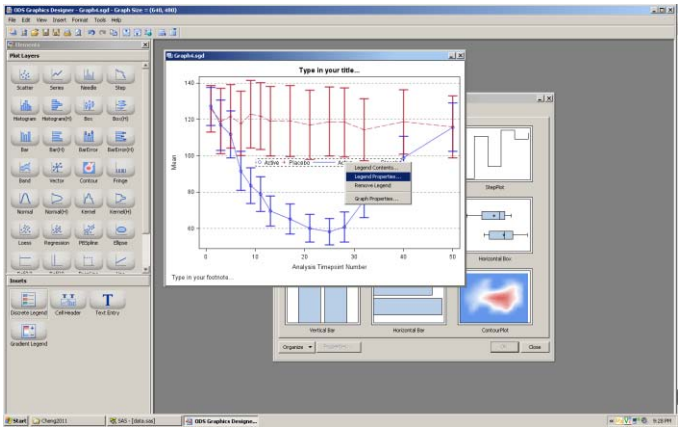

Figure 7A

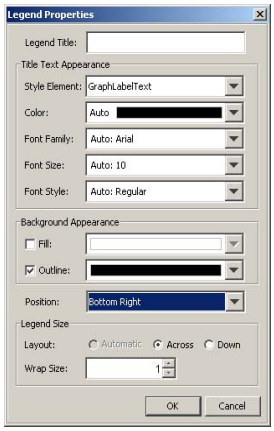

Figure 7B

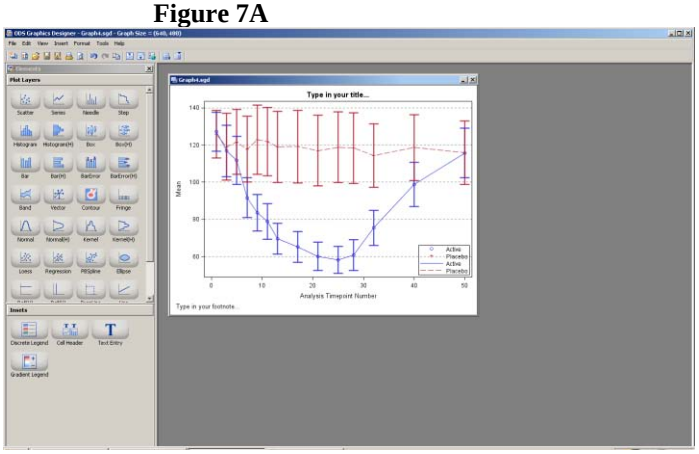

Figure 7C

If you feel the legend for series is good enough, you can right click the legend, and then select Legend Contents. The Legend Contents dialog opens, you can de-select scatter. (Figure 7D)

The final graph with legend been added to the data area is shown in Figure 7.

Figure 7D

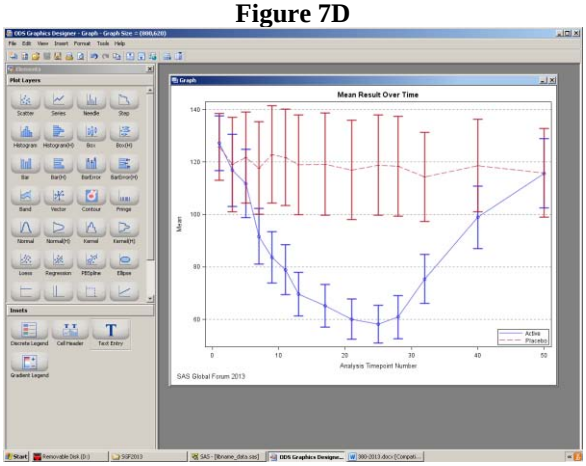

Figure 7 Legend been Added Inside the Data Area

HIGHLIGHT THE TREATMENT PERIOD

We can add a block plot to the graph to highlight the treatment period. Click and drag the Block icon from the **Plot Layers** panel to the graph. Set the variable BLOCKV as the Block variable and AVISTN as the X variable (Figure 8A).

In the Cell Properties window, you can check Value to show the variable value on the graph (Figure 8B). You can specify the location of the value too; in this case, we want the value “Treatment Period” to show at center of the bottom (Figure 8C).

The graph shows treatment period in different colors as in Figure 8.

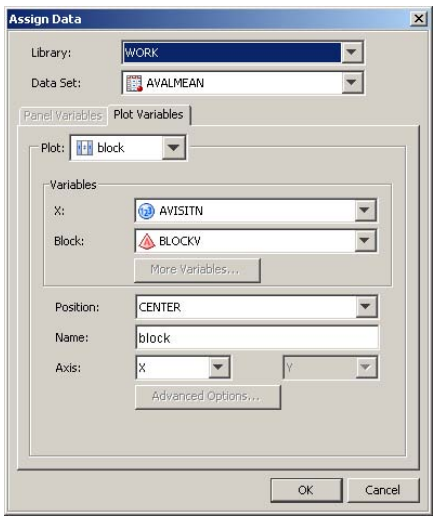

Figure 8A

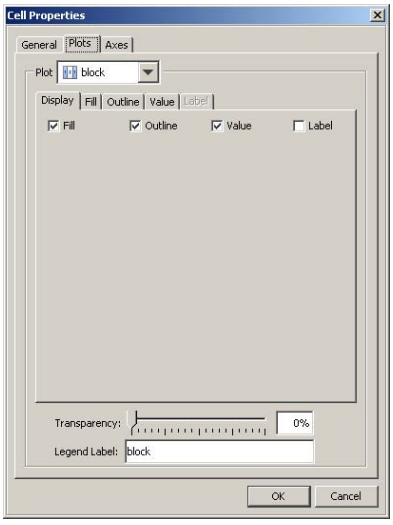

Figure 8B

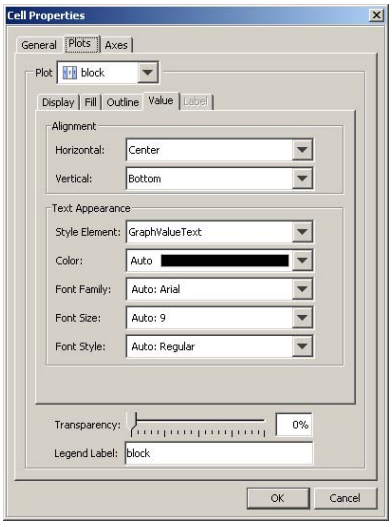

Figure 8C

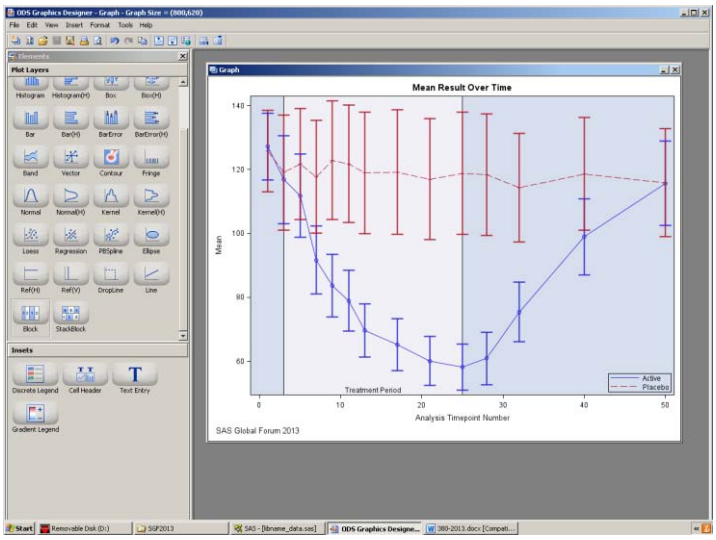

Figure 8 Treatment Period is Shown in Different Colors

MULTI-CELL GRAPH

So far, we have been working with a single cell graph, which has one graph area but may have multiple plots overlaid in the common data area. The data area, along with the axes is called a “Cell”. A graph can contain multiple cells, and each cell can have one or more plots. The cells are in a regular grid of rows and columns. We’ll add a stacked vertical bar chart below the plots in previous exercise to add the information of number of subjects at each visit to the graph.

Right click the plots, and select “Add a Row” from the graph pop-up menu as shown in Figure 9A.

The graph region is split horizontally with a new row been added to the graph. Now the graph has two rows of cells, and only one column as shown in Figure 9B. The previous graph is reformatted to fit the upper cell, and the new empty cell has a hint “drop a plot here”.

Click on the Bar icon in the **Plot Layers** panel, drag and drop it in the empty cell area. The familiar Assign Data dialog is displayed as shown in Figure 9C.

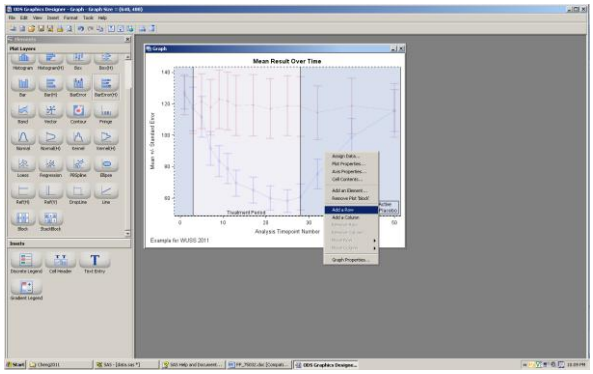

Figure 9A

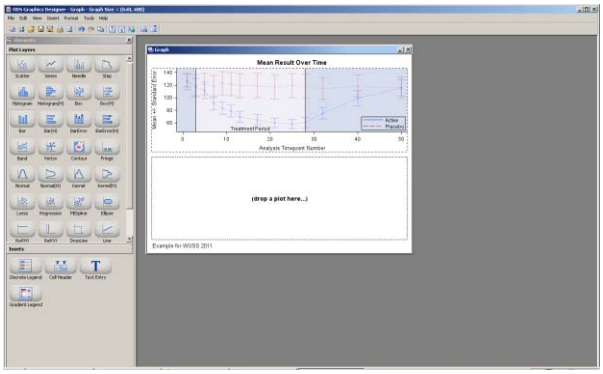

Figure 9B

Set AVISITN as Category variable, AVAL_N as Response variable, and ARM as Group variable. Click OK.

The vertical bar chart is added to the lower cell, alone with its own axis as shown in Figure 9. You can adjust the heights of the graph cells to make them looks better.

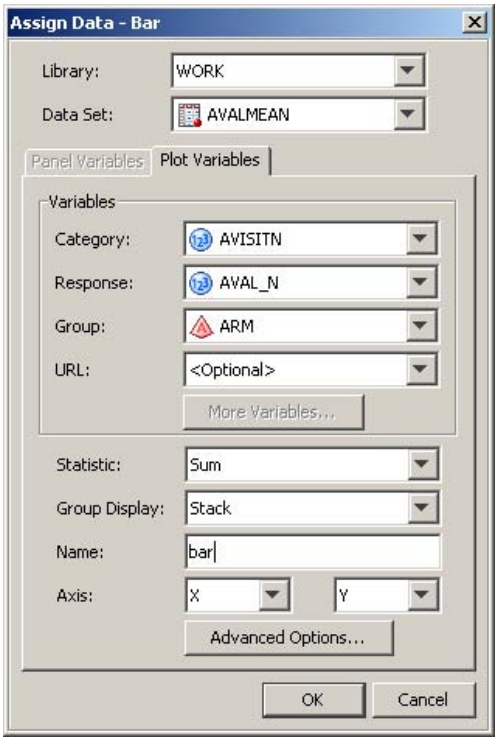

Figure 9C

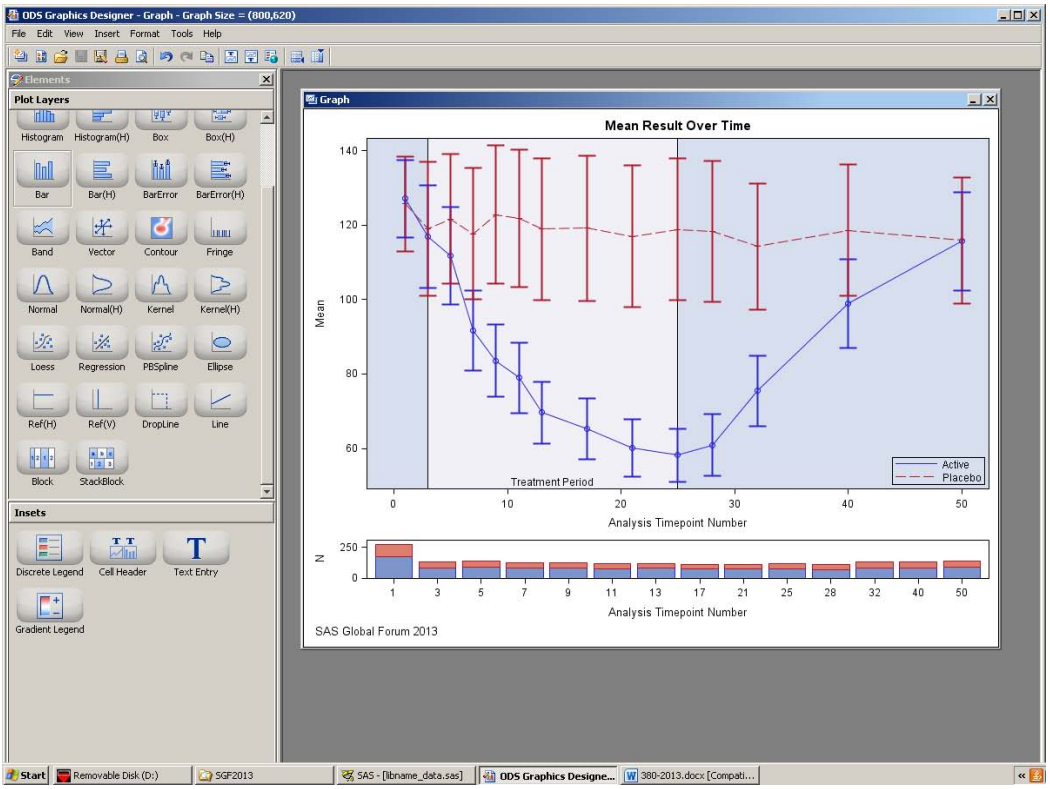

Figure 9 Multi-Cell Graph with Numbers of Subject Shown In the Bottom

CONCLUSION

ODS Graphics Designer is a very useful tool to assist statisticians and clinicians to explore the clinical data and interpret the results of the clinical studies easily and quickly. It can also help programmers to learn the GTL. There are other nice features of the Designer which are not covered in this paper due to the limit of length, such as manage and create your own Graph Gallery, shared variable graphs, Style Editor, run graphs in batch mode. Please refer to the Designer User's Guide for how to use them.

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