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Paper #####

ARROW STATISTICAL GRAPHIC SYSTEM

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ABSTRACT

The ARROW Statistical Graphic System is an in house system used for the creation of graphical displays of clinical study data. The strength of the system is that through these graphs the results can be communicated in a clear and efficient way while the system itself is very flexible and user-friendly.

Depending on users input, the system can produce different types of displays, including mean plots, vertical/horizontal bar charts, box plots, line plots and dot plots. Statistical descriptive like means and standard deviation are derived directly from SAS procedures and then implemented for the graphic display.

There are keyword parameters available as user interface for controlling titles, head notes, footnotes, layout, colours and axes layouts. At the same time, the output can be produced in 5 different file formats allowing the graphs to be created in the most appropriate format for different applications (printing, incorporation in Word document).

All this makes the ARROW Statistical Graphic System so often used and highly appreciated.

Comment: Page: 1
Survival curves described here
with no further module details.

INTRODUCTION

This paper is mainly intended for statistical programmers and statisticians working in the pharmaceutical industry and reporting clinical study results. But also for anyone who is involved or interested in displaying SAS data graphically. Following the data preparation section, this paper will show a few of the most common ways to display clinical trial information graphically within BCI department at J&JPRD.

This graphical system is part of ARROW Statistical Analysis system, a J&JPRD in-house system, which is implemented and validated to support analysis data generation, statistical analysis, and trial reporting, in compliance with e-Submission requirements.

1. DATA PREPARATION

Data preparation consists of the following user interface:

- Read in a specific analysis data for the plot
- Read in optional demographic data
- Define population selection
- Optionally manipulate the input data set by a user defined condition
- Keep extra variables for downstream process
- Keep the selected analysis variables with internal format processed
- Output data as input for the graphic display followed
- Delete all temporary working data sets per request

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2. GRAPHICAL MODULES – EXAMPLES

The output dataset coming from the preparation module is used as the input interface for these six graphical modules: **grmean**, **grvbar**, **grbox**, **grline**, **grdot**, **grhbar**.

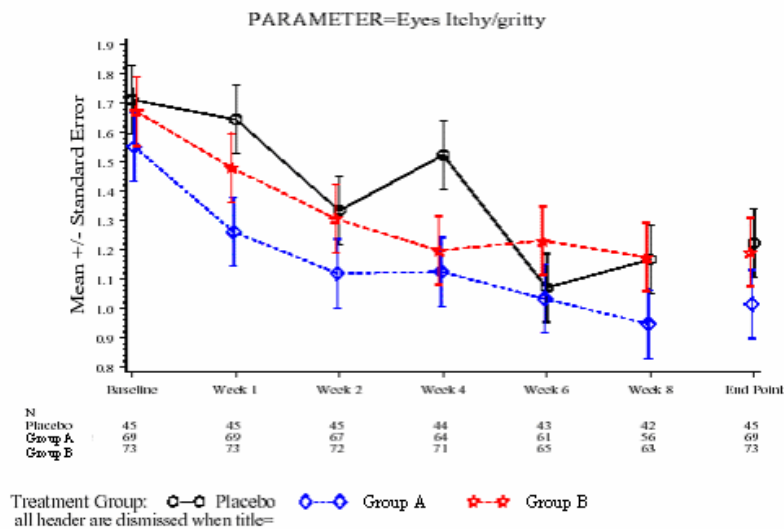
- **2.1 grmean** – module for generating mean SD/SE plots
- **2.2 grvbar** – module for generating vertical bar plots
- **2.3 grhbar** – module for generating horizontal bar plots
- **2.4 grbox** – module for generating box plots
- **2.5 grline** – module for generating y-x curves
- **2.6 grdot** – module for generating dot-type plots, including scatter, regression, needle plots

Each graphical module provides various options on the axes layout, the titles, head notes, footnotes, legend, colors, statistics below the x-axis, labels, number of graphs per page, format of the output file, etc..

It is important to know that the results shown are based on test and dummy data. This is for not revealing any company information.

2.1 GRMEAN

The module for generating mean plots provides the user, besides the standard presentation of the mean, the possibility to also display confidence intervals, SD's or standard errors.

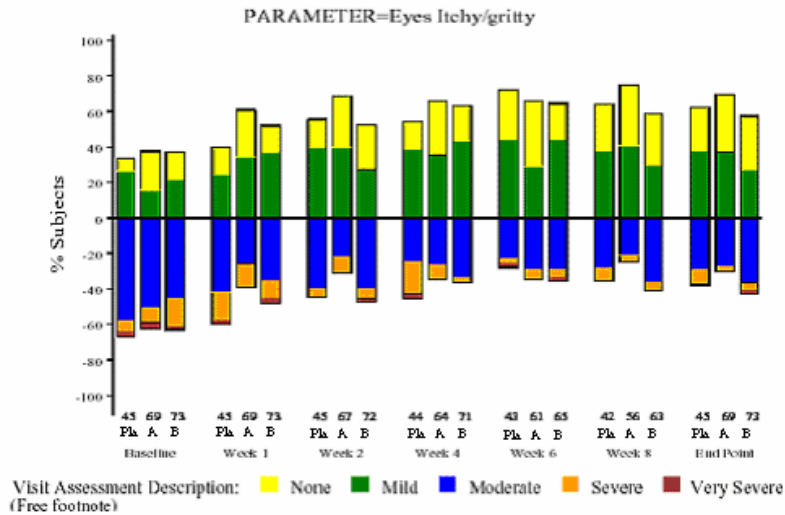


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2.2 GRVBAR

The vertical bar plots module allows the presentation of user-defined number of categories above the x-axis; in general positive results are shown above the axis. The other categories will be displayed below the x-axis.

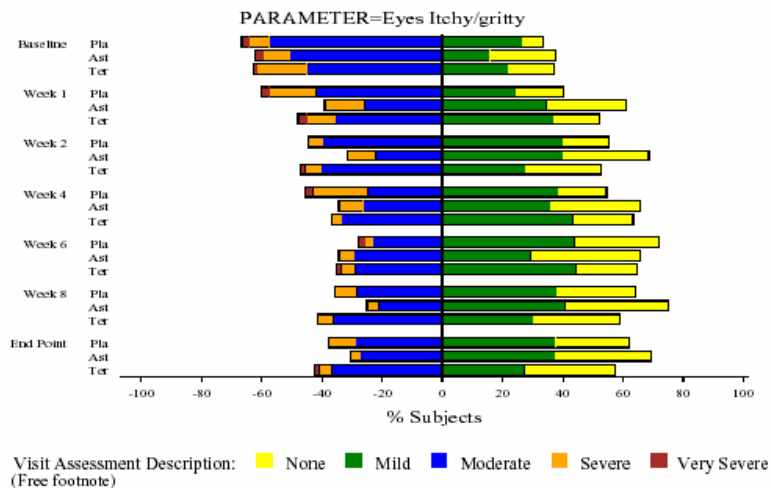
Figure B06: Distribution of Subjects Experiencing and Severity Over Time
(Study ABC-DEF-XX: Intent-to-treat Analysis Set)
(Free Headnote)



2.3 GRHBAR

Likewise, in the horizontal bar module, it is possible to choose a number of categories to be displayed to the right of the y-axis. Categories presented to the right of the y-axis indicate positive response. The other categories will be displayed to the left of the y-axis.

Figure G06: Distribution of Subjects Experiencing and Severity Over Time
(Study AST-USA-XX: Intent-to-treat Analysis Set)
(Free Headnote)

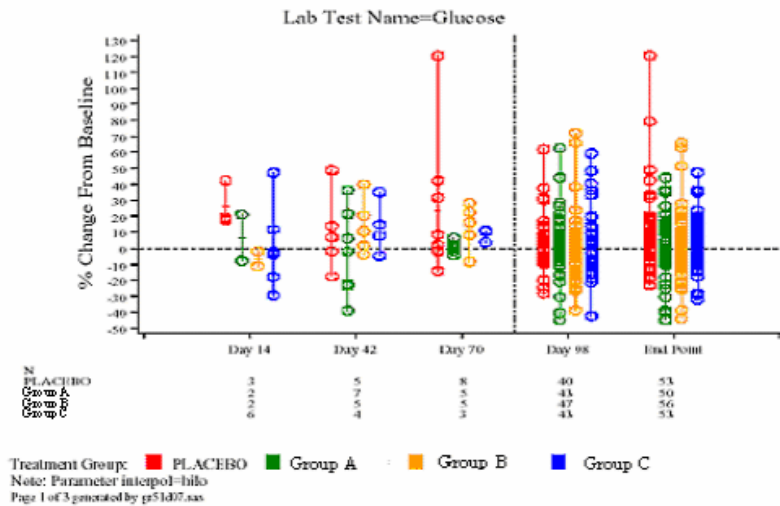


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2.4 GRBOX

The module for generating box plots gives, among others, the possibility to choose the interpolation method.

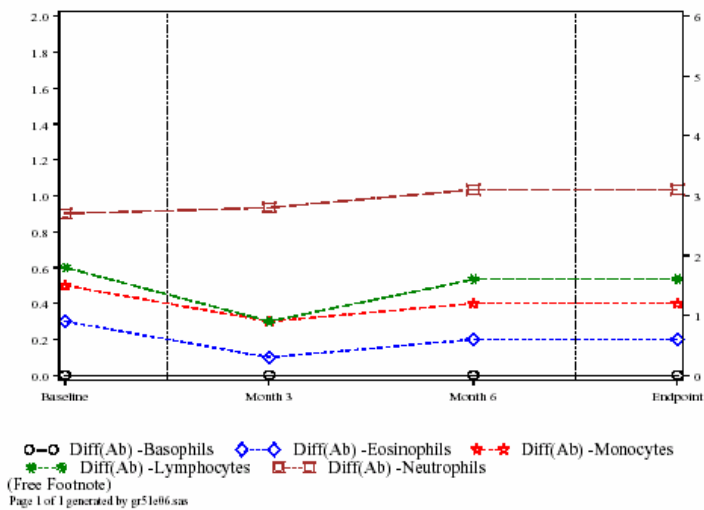
Figure FD07: Percent Change in Lipid Profile and Fast Blood Glucose
(Study Arrow-Graphic-Dxx: Safety Analysis Set)
By Laboratory Test



2.5 GRLINE

Choosing a second y-axis and reference lines are some of the numerous options of the module for generating y-x curves.

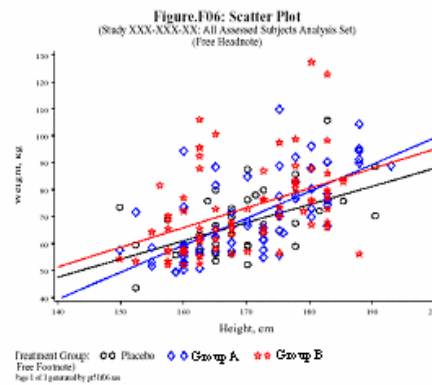
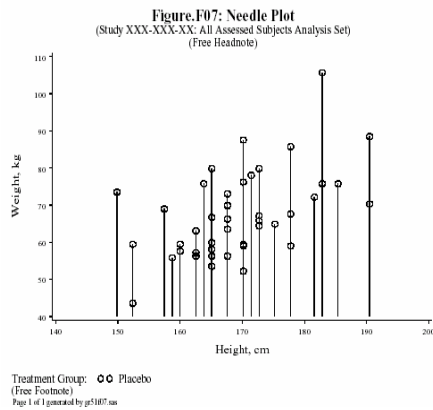
Figure.E06: Curves with Two Y-Axes
(Study XXX-XXX-XX: All Assessed Subjects Analysis Set)
(Subjid=1101)



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2.6 GRDOT

The dot-type plots module is used to display scatter plots with the option to add needles or regression lines.



CONCLUSION

Large volumes of data are common in clinical studies. Such large amounts of data can be very difficult to interpret. Data visualization tools can play an important role in the presentation of such data to regulatory health authorities. A good graphical display of data is able to communicate results with clarity, precision, and efficiency. As shown above by the examples, the ARROW Statistical Graphic System provides users the ability to create graphical displays of data that are easy to understand.

REFERENCES

SAS/GRAPH[®] SOFTWARE information:

http://www.sas.com/technologies/bi/query_reporting/graph/index.html

SAS GRAPH books:

<http://www.sas.com/apps/pubscat/booklist.jsp?attr=product&val=SAS%2FGRAPH>

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CONTACT INFORMATION

Your comments and questions are valued and encouraged.

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