

Clinical Graphs using ODS Graphics Garage Malarga, SAS Institute, Cary, NC

ABSTRACT

Safety data for clinical trials is often collected in tabular form. The process of interpretation and analysis that we create using software for the design of graphical display of this data along with the associated statistics. Examples such as Least Squares Trend Plots and ANOVA, Standard Plots, Patient Plots, Adverse Event Plots, Life Table Plots for Event Occurrence and Mortality are commonly used in the Health and Life Sciences domain. Many of these graphs are easy to do using one of the many tools available in the ODS Graphics tool set. This paper will describe in detail how to create these standard graphs for the Health and Life Sciences industry using ODS Graphics.

INTRODUCTION

High quality graphs are essential for analysis of data in the Health and Life Sciences domain. Large volumes of such data are generated in the duration of a clinical trial, and visualizing the data along with the derived statistics is essential for the analysis of such data. Some of the key features of the graphs include:

- Summary of the raw data and the statistics in the same display.
- Inclusion of other indicators such as identifiable events, adverse events, etc.
- Comparison of the results for a drug with the corresponding results for other drugs or placebo.
- Classification of the results by multiple variables.
- Display of the results over time.

The goal of this paper is to show how to create graphs commonly used in the Health and Life Sciences domain using ODS Graphics. In this paper, we will take various graphs commonly used for analysis of safety data for Clinical Trials, Patient Plots graphs, graphs for testing laboratory tests, etc., and show the code needed to build such graphs in detail. These graphs have been developed by professionals in the field who have the necessary domain expertise to design the right graphs. It is not the intent of this paper to substitute the effectiveness of such graphs. So, the design of the graphs used is beyond the scope of this paper. In this paper, we will cover various techniques that can be used to build such graphs that providing the information you need to customize them to your needs.

GRAPHS FOR HEALTH AND LIFE SCIENCES

We will review and build some common graphs that have been frequently used in the Health and Life Sciences domain. We will start with some graphs discussed in the paper "Graphical Approaches to the Analysis of Safety Data from Clinical Trials" (John Kirk, et. al., Pharmaceutical Statistics, SAS). Additionally, we will cover other popular graphs in the field. These are:

1. Empirical distribution function for maximum change in QTc.
2. Box Plot of change from baseline in QTc by time and treatment.
3. Mean change from baseline in QTc by time and treatment.
4. Distribution of AARF by time and treatment.
5. Distribution of maximum LFT values by treatment.
6. Plot of LFT with from baseline to maximum by treatment.
7. Mean change of maximum LFT values.
8. LFT Patient profiles.
9. Mean frequency on therapy adverse events sorted by relative risk.
10. Cumulative distribution (with 95% CI) of time to first AE of special interest.
11. Kaplan-Meier curves for AEs of special interest (with 95% CI).
12. Adverse event profiles.
13. Least Squares Over Time.
14. Mortality Profile by Treatment.

Let us review each graph along with the code needed to create the graphs using the Statistical Graphics (SG) Procedures or the Graph Template Language (GTL):

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