

Clinical Graphs using ODS Graphics

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ABSTRACT

Safety data for clinical trials is often collected in tabular form. The process of interpretation and analysis can be made more effective by the usage of graphical display of this data along with the generated statistics. Displays such as Liver Function Test Panels and Matrices, Hazard Function Plots, Patient Profiles, Adverse Event Plots, Lab Tests for Blood Chemistry and Hematology 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 itself, along with the derived statistics is essential for the analysis of such data. Some of the key features of the graphs include:

- Inclusion of the raw data and the statistics in the same display.
- Inclusion of other indicators such as desirable levels, 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 sample graphs commonly used for analysis of safety data for Clinical Trials, Patient Profile Graphs, graphs for viewing laboratory tests, etc., and show the code needed to build each graph in detail. These graphs have been designed by professionals in the field, who have the necessary domain expertise to design the right graph. It is not the intent of this paper to evaluate the effectiveness of such graphs. So, the design of the graph itself is beyond the scope of this paper. In this paper, we will cover various techniques that can be used to build such graphs thus 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" Ohad Amit, et. al., Pharmaceutical Statistics, 2008. Additionally, we will cover other popular graphs in this 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 ASAT by time and treatment.
5. Distribution of maximum LFT values by treatment.
6. Panel of LFT shift from baseline to maximum by treatment.
7. Matrix display of Maximum LFT values.
8. LFT Patient profiles.
9. Most frequent on-therapy adverse events sorted by relative risk.
10. Cumulative distribution (with SEs) of time to first AE of special interest.
11. Hazard functions for AEs of special interest (with SEs).
12. Adverse event timeline.
13. Lipid Profile Over Time.
14. Immunology 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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