

A Cost-Effective Data Visualisation System using BASE SAS

Data visualisation of clinical trial data is important, especially to inspect for potential safety signals. Many companies have moved to using specific data visualisation software such as Spotfire or SAS Visual Analytics, but we present a cost-effective data visualisation solution using BASE SAS to generate an easy-to-use web-based visualisation solution, enabling a high level overview of the clinical data with drill-down capabilities. The system is suitable for clinical reviewers to use.

BASE SAS and SAS/GRAPH were used to generate a hierarchy of outputs: summary level outputs, detailed outputs and patient profiles. Hyperlinks were added to enable drill-down functionality. For example, an adverse event summary table is produced, where the text description for each event contains a hyperlink, which, when clicked, takes the user to an output detailing the subject IDs who experienced each event. Each subject ID can be clicked to take the user to that subject's patient profile.

Continuous data, such as lab, vital signs and ECG parameters, were visualised using a variety of plots:

- A baseline vs on-treatment plot, with a 45 degree annotated line
- Line plots of result vs study day
- Box plots of result by visit

When the user hovers the mouse over a value, the subject number appears, and the user can click to drill through to the individual subject's patient profile, where clinically significant values are highlighted. Specific plots to help identify potential Hy's Law cases where the subject may have liver damage caused by their treatments are included in the visualisation system.

Graphics have been developed with good design principles in mind. Elements of graphs that are not necessary for clinical interpretation (e.g. tick marks) have been removed to increase the data to ink ratio.

By default, when creating ODS HTML output, SAS can create a web page containing three frames: the output, a contents list and a page contents menu. However, given that a large number of outputs are generated, a menu in the form of a list is not practical. We have incorporated a JavaScript collapsible menu to allow users to expand or collapse sections of interest on the menu. Custom code was necessary to generate the call to the Javascript menu as SAS does not have the functionality to allow collapsible menus.

The generated HTML, along with necessary Javascript code and images used in the menu system are loaded to our web server which allows easy but secure access with individual user login and password details.

Since the system uses BASE SAS programming, the code is familiar to most clinical trial programmers, which makes it easy to add customised visualisations, for example to inspect efficacy data, to the system. Care is taken to ensure that any review of blinded clinical trials does not risk unblinding the study.