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First Time in Human Reporting

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ABSTRACT

An important milestone in the development of a drug is the first time it is administered to a human subject. The Safety Board need to consider a large number of factors before making their critical decisions. In order to make their verdict, the board needs a tool to enable them to visualize the combined effect of all the dimensions involved in the decision to maximize the likelihood of a safe and successful trial.

The decisions made by the Safety Board have enormous significance for the drug companies and the people involved in the trial. All the information presented to the board must be validated and reproducible to enable the decisions to be examined, re-examined and supported.

To present a large amount of disparate information in a single graphical report is a challenge for any technology. Mango elected to use an interactive graphing technology to enable the presenter to override the default layout and control the level of the information that is displayed on a graph.

INTRODUCTION

This paper is intended to provide a brief overview of First Time In Human (FTIH) requirements, describe the need for tools to aid the decision making process involved, and provide a introduction and demonstration of the tool Mango Solutions has developed to meet these needs.

FIRST TIME IN HUMAN REPORTING

An important milestone in the development of a drug is the first time it is administered to a human subject. Prior to a drug's first time in human trial, the drug company's Safety Board will meet to determine the appropriate doses to be administered during the trial.

The Safety Board need to consider a large number of factors before making their critical decisions; for example, they need to consider the predicted responses, results of pre-clinical trials, drug receptor response characteristics, toxicology and target concentrations.

In order to reach their verdict, the board needs a tool to enable them to visualize the combined effect of all the dimensions involved, in order to maximize the likelihood of a safe and successful trial.

SELECTION OF SUITABLE TECHNOLOGIES

To present a large amount of disparate information in a single graphical report is a challenge for any technology.

Utilizing standard graphic technologies such as bitmaps was unlikely to be successful due to the large

amounts of data to be displayed and the flexibility in layout that is required to ensure the graph conveys all the information required in a correct manner.

Mango elected to use an interactive graphing technology to enable the presenter to override the default layout and control the level of the information that is displayed on a graph.

The interactivity has the additional benefit that mouse events can be captured, displaying additional information to the user when required.

Mango selected Scalable Vector Graphics (SVG) as the technology to display graphics to the Safety Board.

WHAT IS SVG?

SVG is an Extensible Markup Language (XML) based standard for describing graphical content in a web browser. It was initially developed by the World Wide Web Consortium (W3C).

SVG provides a tag based syntax to describe how a browser should render the graphical content of an image; it does not physically create image files.

Unlike SVG, proprietary image formats are non-interactive views of a data set. SVG supports export to proprietary image formats able to be embedded in reports and presentations.

As a standard web technology SVG can be integrated with JavaScript to provide powerful interaction and the ability to interrogate the data on display.

As SVG is text-based, the source is available at all times. A user is able to take a snapshot of the document source used to generate a specific SVG image and recreate the same graphical content at any time by viewing that file in a browser.

THE REPORTING ENVIRONMENT

Mango Solutions has developed a FTIH reporting environment to meet the needs of presentation of preclinical and clinical trial results to the Safety Board.

The Reporting Environment is a web based application, generating interactive and publication-quality graphical output from data stored in an Oracle database.

The reporting environment makes use of the technologies listed below:

Scalable Vector Graphics (SVG)

Batik (SVG DOM libraries) and Java

Struts (framework for client/server interaction)

Oracle database storage

CONCLUSION

The development of the FTIH Reporting Environment arose from the following needs –

Publication quality graphical output
Interactive output
Audit trail
Reproducible output

Ability to share information across networks
Ability to standardize and customize graphical output
Ability to export graphical output to embed in reports

The FTIH Reporting Environment fulfils all these requirements in a validated and consistent manner that provides the Safety Board with the correct information in a highly interactive and intuitive manner which enables safer and more robust decisions to be made.

CONTACT INFORMATION

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