



Body Weight Gain Analysis Based on the BW Domain Using an R-Shiny Application

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Abstract

The FDA has recently required that nonclinical toxicology study data from new studies be submitted electronically in CDISC-SEND format. One of the current limitations of the CDISC-SEND data standard is that the BG domain, which encodes changes in animal body weight gains, only includes analysis of changes in body weight over precalculated time intervals. Through the PhUSE consortium, an open source software solution to this limitation has been collaboratively developed by participants from the pharmaceutical industry, software vendors, and government regulators. The R package, Shiny, facilitates the development of user-friendly, web-based “apps”, providing a platform for the analysis and visualization of SEND datasets. An R Shiny app has been developed to allow end users with little-to-no programming experience to evaluate changes in body weight gains from any SEND-encoded study across flexible user-defined time intervals. The source code is publicly available on the PhUSE GitHub website: <https://github.com/phuse-org>.

Objective:

The Body Weight Gain (BG) Domain of the SEND dataset submission contains calculated gains to support the study analysis report. However, there exists a need on the part of internal and regulatory reviewers to compute and visualize gains using different filters and different intervals than may be present in the BG domain.

Analysis:

The Body Weight (BW) domain has the data necessary to perform the additionally desired filtering and analysis, especially when joined with the demographic and grouping information found in the other domains of the dataset.

Method:

In order to allow a low cost and shareable mechanism for collaborative work, an open source tool was selected for the analysis.

“R” is a freely available language and has an integrated development environment (R-Studio). It has core and extended libraries for reading and handling SEND “xpt” formatted data. Its native vector manipulation facilitates grouping and filtering. It also has a robust and active community of contributors in the sciences.

Additionally two “R” add-ons were used. R-Shiny, which allows for generation of a web-based GUI, and “Plotly” the “R” library that allows for interactive graphics.

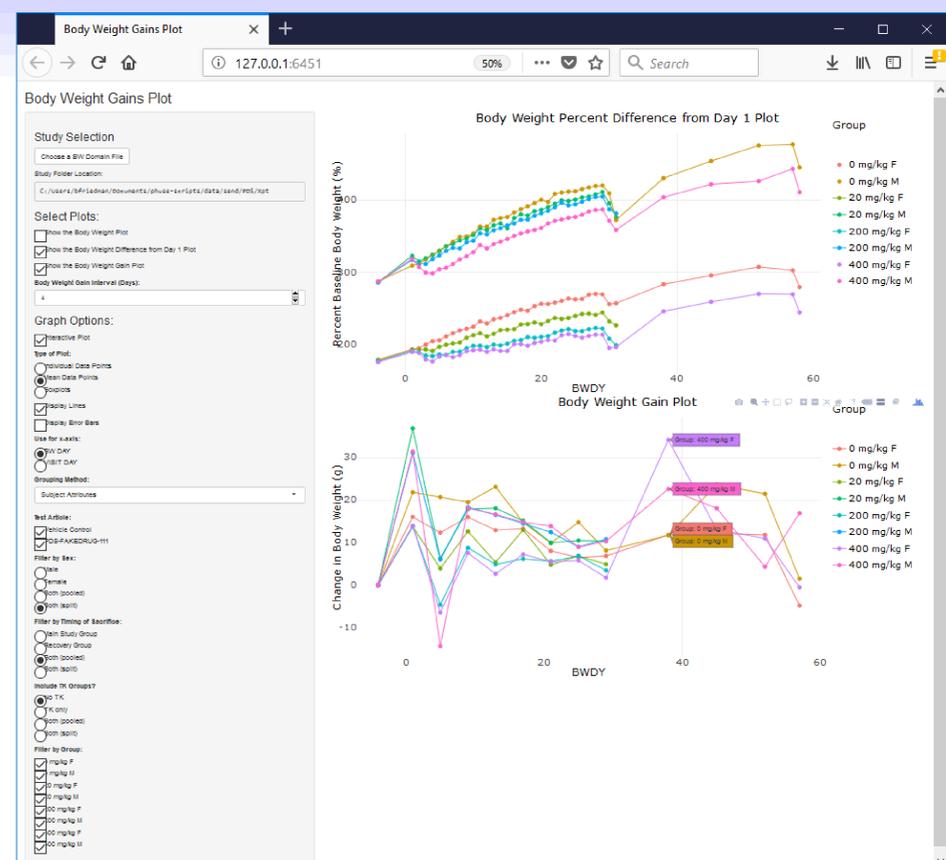
Design and development were undertaken using an agile approach, and sharing code using Github.



Figure 2: QR Code to access the Nonclinical Script Assessment Project PhUSE Wiki page



Figure 3: QR Code to access the Nonclinical Script Assessment Project Github Repository



Design:

Analysis preferences are all available from selections on the GUI and the output is dynamically altered by the following criteria:

- Selection of the dataset from contributed or local data sources.
- Gain calculation from baseline or flexible period intervals.
- Individual or mean data points, line, scatter or box plots.
- Filtering and grouping by Sex, TK groups, main versus recovery groups, test articles and vehicles.

Conclusion:

The script developed by the group can be used as is or taken as a starting point to update for individual needs.

The methods and script example can be broadened to other domains needing such analysis, such as the Laboratory Results (LB) domain.

Prior to the SEND dataset standard, developing tools for such analysis would be very specific to each laboratory data system. The availability of this data standard creates the opportunity for community collaboration to share such analysis methods, scripts and resulting visualizations.

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Note: The opinions expressed in this poster are those of the authors and do not necessarily represent the opinions of their respective organizations.