# Using JMP® Scripting Language (JSL) To Create An Application Interface For Automated Analysis Of Lab Data In Clinical Trial

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## ABSTRACT

Laboratory data is the key element of the safety profile in drug development. Due to its complexity, it often represents a great challenge to conduct an efficient and effective review. JMP® has been proven to be a powerful interactive visualization tool in analyzing clinical data. This paper describes the development of JMP® Add-in Lab Analyzer using JSL, which takes ADaM datasets as input and allows interactive visualization and customized analysis of Laboratory data. The analysis approaches are based on the FDA reviewer guidance on lab data, including measures of central tendency, outliers or shifts from normal to abnormal, and marked outliers as well as exploratory lab data analysis such as Hy's Law. The Lab Analyzer takes advantage of the powerful visualization capability of JMP® and uses a variety of graphs such as scatter plots, box plots, and scatter matrices to enable reviewers to quickly identify outliers, to detect data patterns, and to drill down to the patient level by viewing individual profiles. Standard summary reports on measures of central tendency, shift tables in both interactive tabular and PDF format are incorporated.

Key words: JMP®, JMP® Scripting Language (JSL), ADaM, Visualization

## INTRODUCTION

Evaluation of safety profiles is an integral part of drug development. Among the safety data, laboratory data is the key element because it contains a variety of information about the effects of a drug on the human body organs and the data contains potential signals of safety issues. One of the signals that can be readily picked from lab data is the drug induced liver injury (DILI). It has been shown that greater than 3-fold elevation above upper limit of normal (ULN) in a lab result for ALT, together with a 2-fold elevation of ULN for Bilirubin and without elevation of ALP suggests that there is potential hepatoxicity (Zimmerman, 1978). DILI is believed to be the single most important adverse event that may result in the failure to get drug approval or withdrawal of a drug from market. Therefore, careful review and monitoring of lab data is critical during drug development.

Due to its complexity, laboratory data often poses a great challenge for reviewers to conduct an efficient and effective review. In 2005, the FDA published a guidance on how to review lab data findings. Basically, three standard approaches are proposed. Number one is the comparison of mean or median changes from baseline across treatments. The second approach proposed is to identify and evaluate outliers by reporting or displaying shifts from normal to abnormal on treatment and patient levels. Thirdly, large deviations from normal at baseline and across treatment need to be evaluated. The FDA reviewer guidance also suggests that exploratory analysis such as Hy's law (Zimmerman, 1978) should be conducted. Traditionally, a reviewer relies on static paper outputs produced in the format of PDF and RTF and is expected to browse through a report page by page. This inefficient process requires enormous time and effort on preparation of the programs and related outputs and demands that the reviewer go through hundreds of pages.

JMP® is a statistical software developed by SAS institute. It integrates powerful statistical capability with interactive graphics, which makes data discovery extremely easy. In addition, with powerful scripting embedded, extended JMP® functionality can be utilized to make automation of customized data analysis a reality. Furthermore, JMP® can interact with other software such as SAS, R and MATLAB. All these advantages make it powerful and unique software to summarize, analyze, and visualize clinical data much more easily.

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In this paper, I am presenting an Add-in Lab Data Analyzer tool developed in JSL language which is based on the analysis approaches described in the FDA reviewer guidance with an aim of enhancing efficiency of analyzing and visualizing lab data.

## METHOD

Datasets: ADaM dataset ADLB is used as the main input for analysis. General development of ADLB will not be discussed in this paper, however, variables included in the ADLB should be developed according to the requirements described in the FDA reviewer guidance. In addition to the ADLB, SDTM datasets DM, EX, AE, and CM are also required in order to visualize patient profiles. Note that all data presented in this paper is fictitious.

Development of Add-In: The JMP® add-in Lab Data Analyzer is developed using JMP® scripting language and is deployed as an Add-In in JMP® Clinical v 6.1 as described in the JMP® scripting guide v12. The deployed Add-In Lab Data Analyzer will appear in the menu of JMP® Clinical.

## STUDY FOLDER SELECTION

To bring out the KRI analyzer window, users need to click on Lab Analyzer in the menu of Add-in in JMP® Clinical. First the user needs to specify the location of the data as shown in Figure 1.
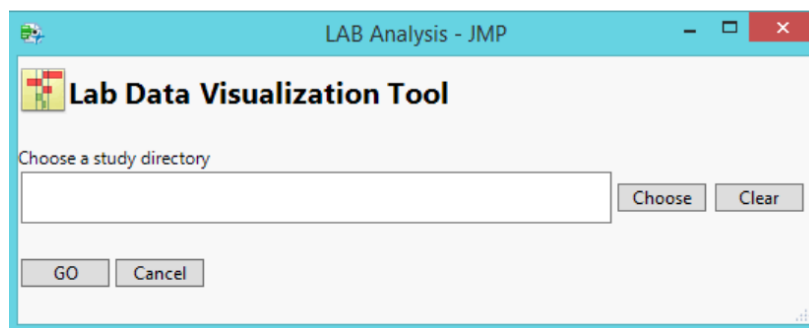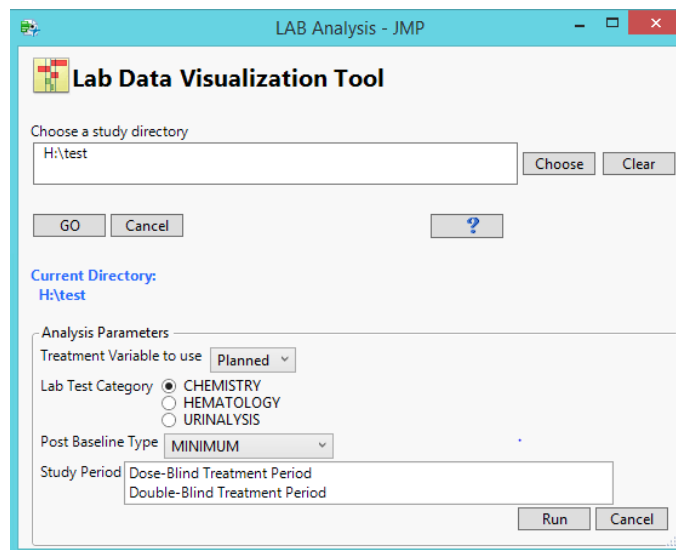


**Figure 1. Window for Selecting a Study Directory.**

The lab dataset ADLB located in the specified folder will be opened in the background and a new window will be created and appended to the window of study folder selection to allow further selections of analysis parameters. At the same time, the selected folder path is added to the bottom of the folder selection window.

## PARAMETER SELECTIONS

Complexity of lab data demands for analysis to be performed in a break-down manner. The Parameter Selection window allows users to select treatment variable, lab test category, post baseline type of lab values during the treatment period, and study period. The treatment variable will be used to compare the treatment effects on the lab data. To make it easy for the selection of parameters, the Parameter Selection window provides a drop-down menu or radio buttons. For example, Chemistry, Hematology or Urinalysis are provided as options in radio buttons as shown in Figure 2.

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**Figure 2. Window for Parameter Selection.**

The options of those parameters in the drop -down menu or radio buttons are based on the values of relevant variables in ADLB opened in the background. For example, the values of for Post Baseline Type in the drop-down menu are the extraction of the distinct values of DTYPE in the ADLB.

## ANALYSIS REPORT

Once parameters are selected, a user can click the Run button to start the analysis of lab data.  As mentioned above, this analysis tool is designed to be centered around the three standard approaches proposed by FDA.

### OUTLIERS DEVIATING FROM NORMAL RANGE

The first of the three standard analysis approaches requires that reviewers be focused on the patients whose laboratory values deviate substantially from normal range. To identify patients with such deviations, shift plots of baseline lab values versus their extreme post-baseline values for each lab test are created.

Figure 3 shows the shift plots of baseline versus maximum treatment period values for various chemistry lab parameters.  Each shift plot represents one parameter in the chemistry category with lab parameter name being shown in the outline box. Different markers and colors are used to distinguish treatment groups. The vertical reference lines are at the lower and upper limits of the normal range. With reference lines on the plots, a reviewer can easily identify the subjects whose lab values deviate from the normal range in the example presented, the upper middle area marked by the reference lines contains normal lab values at baseline but shifted to the abnormal range during treatment period. The data points in the plot are selectable and can serve as starting points for further investigation.

Although graphs are created for a full set of parameters within the selected lab category, a user can filter the data to focus on certain parameters of interest. The list box on the right containing lab tests within the lab category are selectable and once they are selected, shift plots will be updated based on the user's selections.
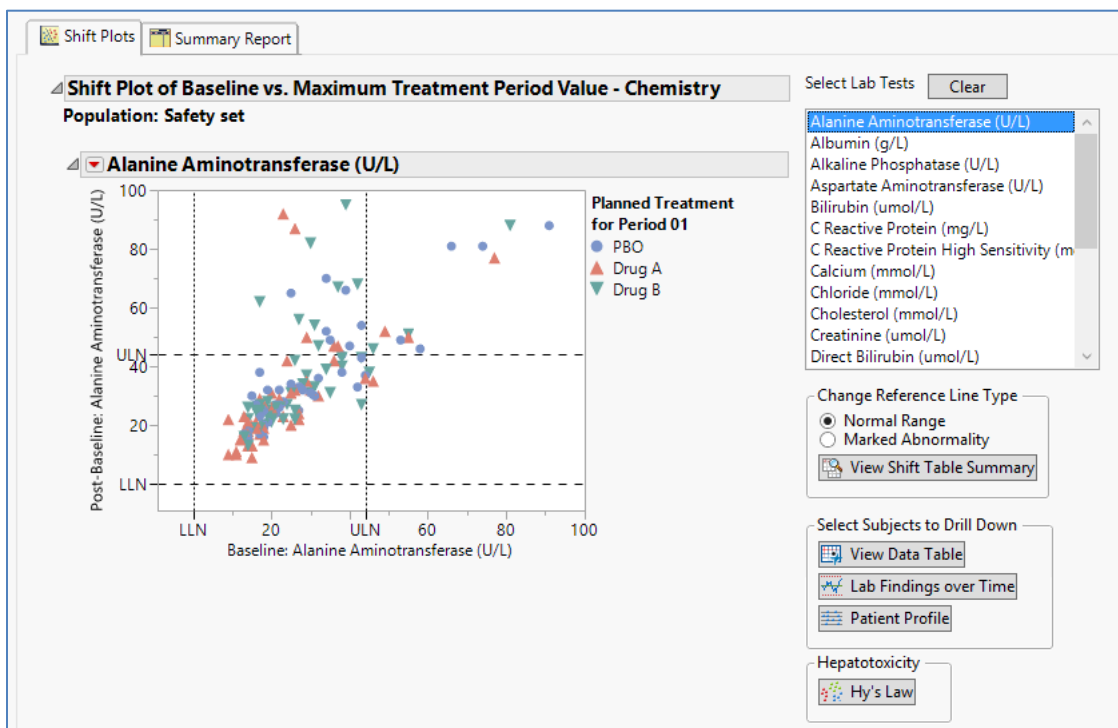
**Figure 3. Shift Plots of Baseline vs. Maximum Treatment Period Value for Chemistry Lab.**

Each marker represents an individual subject data point in the graph. In contrast to static graphs on paper in which only values of X and Y can be read out, graphs in JMP® can embed more information with data points and the hidden information is displayed by hovering the mouse over them. Lab Data Analyzer takes advantage of this capability and is designed to include some critical information for each data point. Thus, a reviewer can quickly get a glimpse of essential information about outliers by simply hovering the mouse on any data points. This information includes subject identifiers, baseline lab values, maximum values, and treatment group.
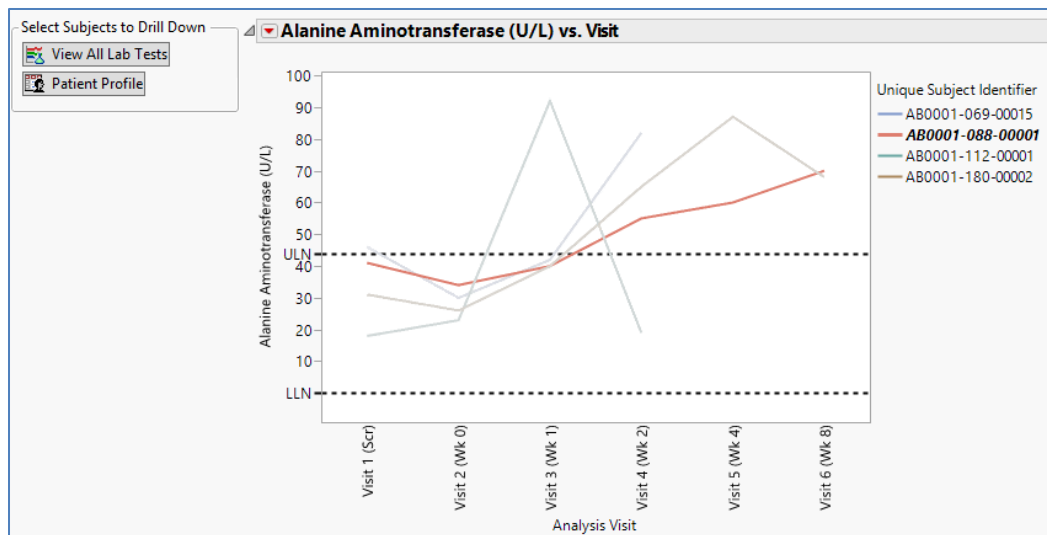


**Figure 4.  Lab Values over Time. LLN Indicates Lower Limit of Normal. ULN Represents Upper Limit of Normal.**

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The shift plots are created using a single baseline value against a single maximum value during the treatment period, so it is logical to next investigate the pattern of identified outliers in the graph throughout treatment period. To achieve this goal, line plots are created using lab values versus clinical visits. To view those plots, after highlighting data points of interest, simply clicking on the button View Lab Finding over Time (Figure 3) will lead to the line plots for selected outliers. Figure 4 shows the specified lab values of ALT across clinical study visits. In this example, the ALT values for subject AB0001-088-0001 increase steadily after drug administration in contrast to other subjects where values are elevated once above ULN. It should be noted that reference lines are displayed to help identify where the values are above ULN and how long this persists.

Once subjects of interest have been identified, a question to follow up is to see whether there is a similar trend for other lab parameters. In other words, we would like to investigate whether the subjects of interest would have a similar response to the drug treatment. To view all lab changes, the user can simply select specific subjects by either clicking on the subject identifier in the legend or highlight the lines of interest in the graph and then click the button View All Lab Tests. Figure 5 shows a line plot of ALT for subject AB0001-112-0001. A reviewer can go through line plots of each lab test to evaluate whether there is a hidden safety issue.
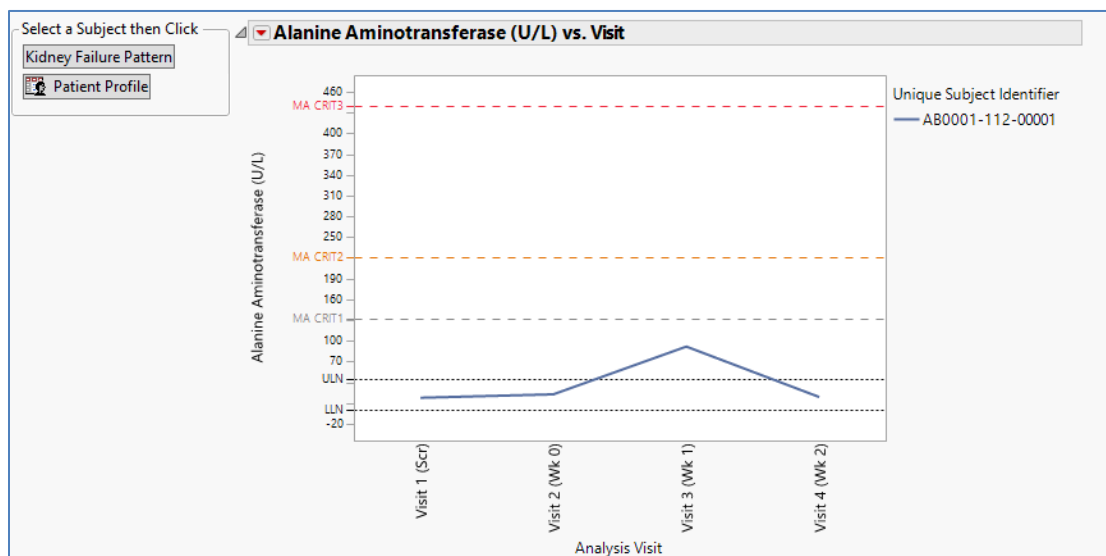


**Figure 5. Lab Values over Time Throughout Clinical Trial. MA-CRIT1, MA-CRIT2, and MA-CRIT3 Represents the Marked Abnormality Criteria 1, 2, 3 and are Defined to be >=3xULN, >=5xULN, and 10xULN respectively.**

If a subject shows consistent abnormalities among some or all the lab tests, one direction to go further is to create a patient profile for the subject of interest because it contains a broad range of information including demographics, drug exposure, vital signs, and ECG in addition to lab data. A patient profile will help reviewers to get a better picture about the patients. In this JMP® add-in, generation of a patient profile for a subject is simply initiated by clicking on the button Patient Profile. The patient profile plot includes visits conducted, drug exposure, all adverse events a subject experienced, lab values and vital signs (Figure 6). What is unique about the patient profile in JMP® is that it uses a combination of markers and colors to show the attributes associated with findings. For example, the symbol of an upward triangle is used to indicate elevation of lab values above normal range. With these easy visual aids, a reviewer can quickly identify the abnormality at any time point in the treatment regarding the subject.

Data trends, patterns, and outliers can be easily and quickly identified by graphical display. With powerful interactive functionalities embedded in JMP®, subjects of interest can be further probed and drilled down to a more granular level. However, graphical display often is less powerful in presenting summary statistics when compared to tabular format. Therefore, to complement the graphic presentation, the user

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can simply click Shift Plot Summary Table button to display a shift summary in tabular format. Figure 7 displays a shift table of baseline value versus maximum treatment value, enabling the reviewer to review the numbers across treatments. It is worth pointing out that unlike the tabular format presentation in PDF format, the tabular presentation in JMP® is also interactive.  With a filter box on the right side, a reviewer can slice the data by selecting the filter criteria and zoom in to focus on the parameters, subjects or treatment groups of interest.
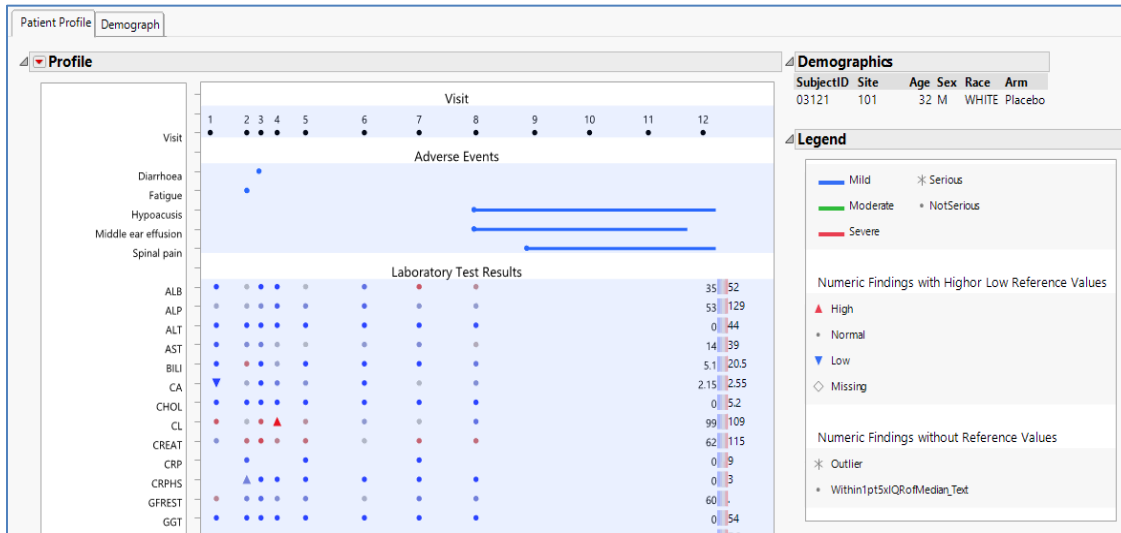


**Figure 6. Patient Profile of a Selected Subject.**
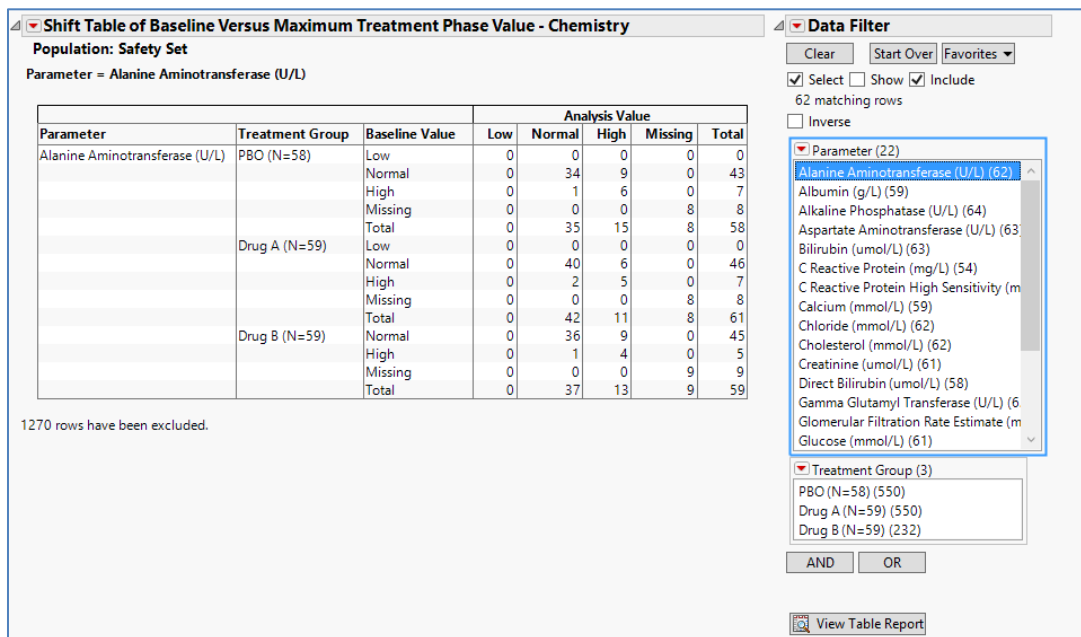


**Figure 7. Shift Table of Baseline versus Maximum Treatment Period Values for Chemistry Lab Based on the Normal Range.**

## OUTLIERS OF MARKED ABNORMALITY

The FDA reviewer guidance stresses the importance of individual analysis of patients with large changes in laboratory values. As it states, these changes are much more likely to identify significant problems than mean or median changes. In additional to enabling identification of patients with marked abnormalities,

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Lab Analyzer also provides a table to display and compare incidence rates between treatment group and placebo along with a list to identify patients with extreme changes.
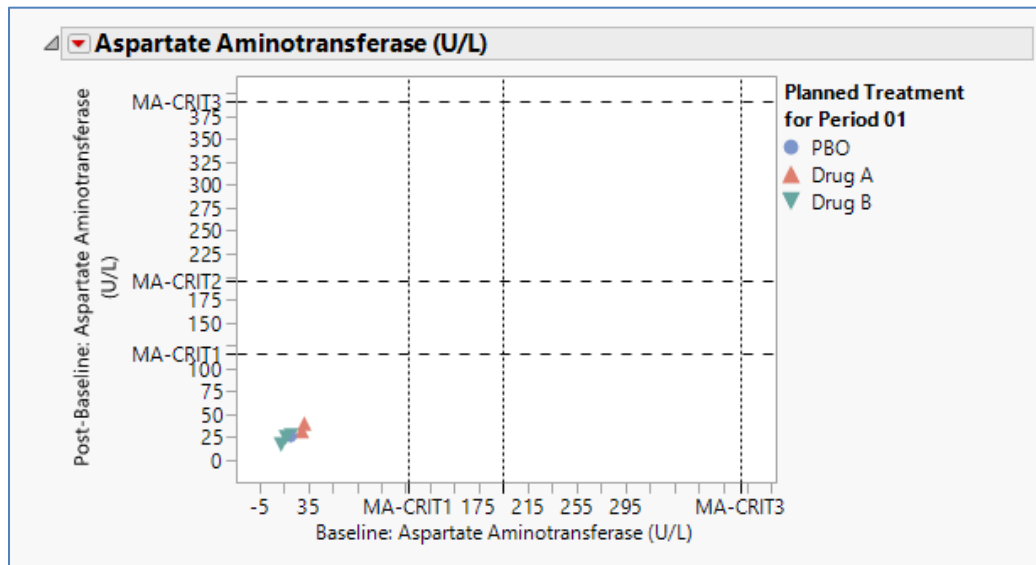


**Figure 8. Shift Plots of Baseline vs. Maximum Treatment Period Values for AST with Marked Abnormality Criteria displayed. MA-CRIT1, MA-CRIT2, and MA-CRIT3 Represent the Marked Abnormality Criteria 1, 2, 3 and Defined to be >=3xULN, >=5xULN, and 10xULN Respectively.**

Figure 8 shows shift plots from normal to marked abnormality regarding AST. A drill-down to the subject level can be performed using similar strategy as described above. It should be noted that the definitions of Marked Abnormality may vary slightly from study to study.

**Incidence of Treatment Emergent Marked Abnormalities - Chemistry**
**Population: Safety Set**

| Parameter | criteria | PBO | Drug A | Drug B | Total | seq |
|---|---|---|---|---|---|---|
| Alanine Aminotransferase (U/L) | >=3xULN | 0/50 | 0/53 | 1/49 (2.0) | 1/152 (0.7) | 1 |
| Alanine Aminotransferase (U/L) | >=5xULN | 0/50 | 0/53 | 0/49 | 0/152 | 2 |
| Alanine Aminotransferase (U/L) | >=10xULN | 0/50 | 0/53 | 0/49 | 0/152 | 3 |
| Albumin (g/L) | <26 g/L | 0/51 | 0/53 | 0/49 | 0/153 | 1 |
| Alkaline Phosphatase (U/L) | >=3xULN | 0/51 | 0/53 | 0/49 | 0/153 | 1 |
| Aspartate Aminotransferase (U/L) | >=3xULN | 0/50 | 0/53 | 0/49 | 0/152 | 1 |
| Aspartate Aminotransferase (U/L) | >=5xULN | 0/50 | 0/53 | 0/49 | 0/152 | 2 |
| Aspartate Aminotransferase (U/L) | >=10xULN | 0/50 | 0/53 | 0/49 | 0/152 | 3 |

**ChemistryTreatment Emergent Marked Abnormalities - Subject Numbers**
**Population: Safety Set**

| Treatment Group | Parameter | Marked Abnormality Criteria | Analysis Reference Range Indicator | Gender/ Age/Race | Site / Subject ID / [#] | Unique Subject Identifier |
|---|---|---|---|---|---|---|
| Drug B | Alanine Aminotransferase (U/L) | >=3xULN | 0 - 44 | M/30/White | 039 / 00002 [1] | AB0001-039-00002 |

Note: # = Number of individual Occurrences

**Figure 9.  Incidence of Treatment-Emergent Marked Abnormalities (Upper Panel) and the Subject Number with Marked Abnormalities (Lower Panel).**

Within the marked abnormality settings, clicking on the button Shift Table Summary will lead to a table showing the incidence of treatment-emergent marked abnormalities. The counts of marked abnormality and rates are displayed by lab parameters and treatment group. A reviewer can compare the incidence rates between the treatment group and placebo to evaluate the drug effects.

If you see a difference in incidence rates between treatment groups and placebo in the table, you can select the row of interest and view subject numbers that are associated with specific incidence rates (Figure 9). Based on this listing, a reviewer can continue to select subjects number and dig further into the profile to see whether there is an additional safety signal in the other domains.

## MEASURES OF CENTRAL TENDENCY

As the FDA reviewer guidance points out, although marked outliers are typically of greatest interest from a safety standpoint, at times a potentially important effect may be revealed only in analyses looking at differences in mean change from baseline. Based on this rational, the FDA proposed a central tendency analysis. Basically, this proposal requires the reviewers to compare the mean or median change from baseline across treatment groups for each lab parameter.

In the Lab Data Analyzer, a simple click the tab box Summary Report (Figure 1) will take a reviewer to a summary table presenting the number of subjects, mean, standard deviation, median, minimum, and maximum for observed results and change from baseline by lab tests and treatments (Figure 10). Unlike
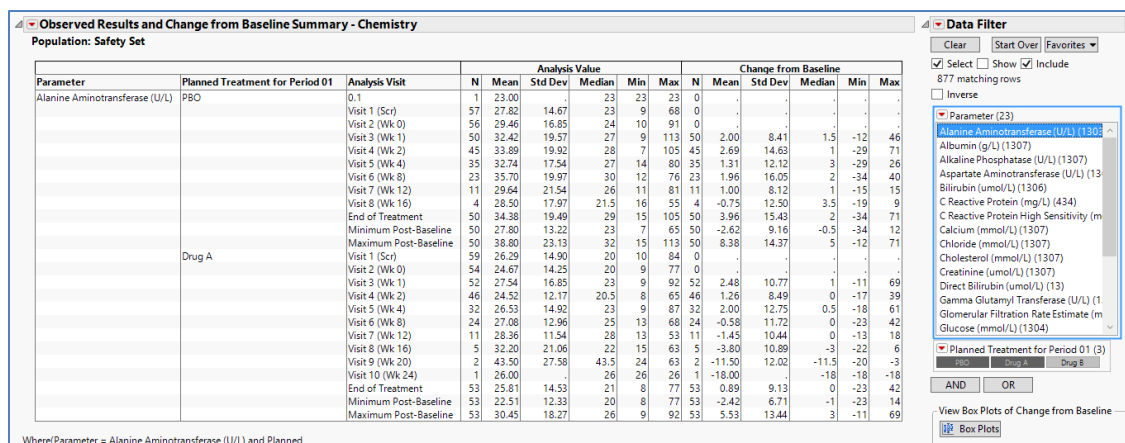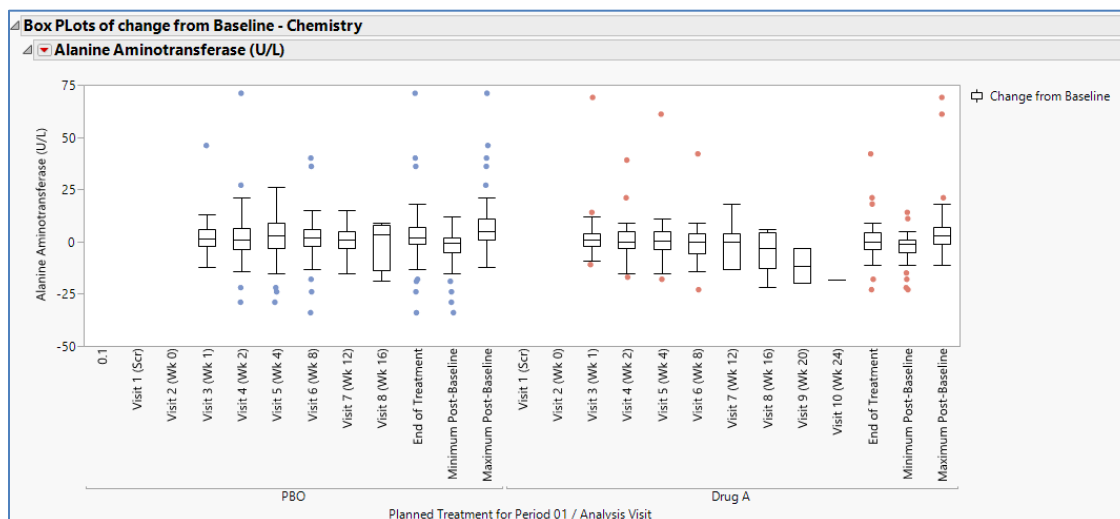
**Observed Results and Change from Baseline Summary - Chemistry**
**Population: Safety Set**

| Parameter | Planned Treatment for Period 01 | Analysis Visit | Analysis Value | | | | | | Change from Baseline | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | N | Mean | Std Dev | Median | Min | Max | N | Mean | Std Dev | Median | Min | Max |
| Alanine Aminotransferase (U/L) | PBO | 0.1 | 1 | 23.00 | | | 23 | 23 | 23 | 0 | | | | | |
| | | Visit 1 (Scr) | 57 | 27.82 | 14.67 | 23 | 9 | 68 | 0 | | | | | |
| | | Visit 2 (Wk 0) | 56 | 29.46 | 16.85 | 24 | 10 | 91 | 0 | | | | | |
| | | Visit 3 (Wk 1) | 50 | 32.42 | 19.57 | 27 | 9 | 113 | 50 | 2.00 | 8.41 | 1.5 | -12 | 46 |
| | | Visit 4 (Wk 2) | 45 | 33.89 | 19.92 | 28 | 7 | 105 | 45 | 2.69 | 14.63 | 1 | -29 | 71 |
| | | Visit 5 (Wk 4) | 35 | 32.74 | 17.54 | 27 | 14 | 80 | 35 | 1.31 | 12.12 | 3 | -29 | 26 |
| | | Visit 6 (Wk 8) | 23 | 35.70 | 19.97 | 30 | 12 | 76 | 23 | 1.96 | 16.05 | 2 | -34 | 40 |
| | | Visit 7 (Wk 12) | 11 | 29.64 | 21.54 | 26 | 11 | 81 | 11 | 1.00 | 8.12 | 1 | -15 | 15 |
| | | Visit 8 (Wk 16) | 4 | 28.50 | 17.97 | 21.5 | 16 | 55 | 4 | -0.75 | 12.50 | 3.5 | -19 | 9 |
| | | End of Treatment | 50 | 34.38 | 19.49 | 29 | 15 | 105 | 50 | 3.96 | 15.43 | 2 | -34 | 71 |
| | | Minimum Post-Baseline | 50 | 27.80 | 13.22 | 23 | 7 | 65 | 50 | -2.62 | 9.16 | -0.5 | -34 | 12 |
| | | Maximum Post-Baseline | 50 | 38.80 | 23.13 | 32 | 15 | 113 | 50 | 8.38 | 14.37 | 5 | -12 | 71 |
| | Drug A | Visit 1 (Scr) | 59 | 26.29 | 14.90 | 20 | 10 | 84 | 0 | | | | | |
| | | Visit 2 (Wk 0) | 54 | 24.67 | 14.25 | 20 | 9 | 77 | 0 | | | | | |
| | | Visit 3 (Wk 1) | 52 | 27.54 | 16.85 | 23 | 9 | 92 | 52 | 2.48 | 10.77 | 1 | -11 | 69 |
| | | Visit 4 (Wk 2) | 46 | 24.52 | 12.17 | 20.5 | 8 | 65 | 46 | 1.26 | 8.49 | 0 | -17 | 39 |
| | | Visit 5 (Wk 4) | 32 | 26.53 | 14.92 | 23 | 9 | 87 | 32 | 2.00 | 12.75 | 0.5 | -18 | 61 |
| | | Visit 6 (Wk 8) | 24 | 27.08 | 12.96 | 25 | 13 | 68 | 24 | -0.58 | 11.72 | 0 | -23 | 42 |
| | | Visit 7 (Wk 12) | 11 | 28.36 | 11.54 | 28 | 13 | 53 | 11 | -1.45 | 10.44 | 0 | -13 | 18 |
| | | Visit 8 (Wk 16) | 5 | 32.20 | 21.06 | 22 | 15 | 63 | 5 | -3.80 | 10.89 | -3 | -22 | 6 |
| | | Visit 9 (Wk 20) | 2 | 43.50 | 27.58 | 43.5 | 24 | 63 | 2 | -11.50 | 12.02 | -11.5 | -20 | -3 |
| | | Visit 10 (Wk 24) | 1 | 26.00 | | | 26 | 26 | 1 | -18.00 | | | -18 | -18 |
| | | End of Treatment | 53 | 25.81 | 14.53 | 21 | 8 | 77 | 53 | 0.89 | 9.13 | 0 | -23 | 42 |
| | | Minimum Post-Baseline | 53 | 22.51 | 12.33 | 20 | 8 | 77 | 53 | -2.42 | 6.71 | -1 | -23 | 14 |
| | | Maximum Post-Baseline | 53 | 30.45 | 18.27 | 26 | 9 | 92 | 53 | 5.53 | 13.44 | 3 | -11 | 69 |

Where(Parameter = Alanine Aminotransferase (U/L) and Planned

**Data Filter**
Clear | Start Over | Favorites
☑ Select ☐ Show ☑ Include
877 matching rows
☐ Inverse

Parameter (23)
Alanine Aminotransferase (U/L) (1303
Albumin (g/L) (1307)
Alkaline Phosphatase (U/L) (1307)
Aspartate Aminotransferase (U/L) (13
Bilirubin (umol/L) (1306)
C Reactive Protein (mg/L) (434)
C Reactive Protein High Sensitivity (m
Calcium (mmol/L) (1307)
Chloride (mmol/L) (1307)
Cholesterol (mmol/L) (1307)
Creatinine (umol/L) (1307)
Direct Bilirubin (umol/L) (13)
Gamma Glutamyl Transferase (U/L) (1
Glomerular Filtration Rate Estimate (m
Glucose (mmol/L) (1304)

Planned Treatment for Period 01 (3)
PBO | Drug A | Drug B
AND | OR

View Box Plots of Change from Baseline
Box Plots

**Figure 10. Observed Values and Change from Baseline by Treatment and Visits.**

any other report in PDF format, the summary table is interactive so that a reviewer can use a filter box to select parameters, treatment groups to only view a subset of the summary. As shown in Figure 10, a filter box contains parameters and treatment code that is added on the right side of table. The reviewer can use the filter box to select which parameters to see and which treatment group to compare. As a result, a reviewer does not need to go through every parameter all the time and can focus on the criteria of interest.

In addition to this table display, box plots of changes from baseline are also provided. A reviewer can view the box plots to compare distributions between treatment groups and placebo and therefore easily identify potential abnormality for further investigation (Figure 11).

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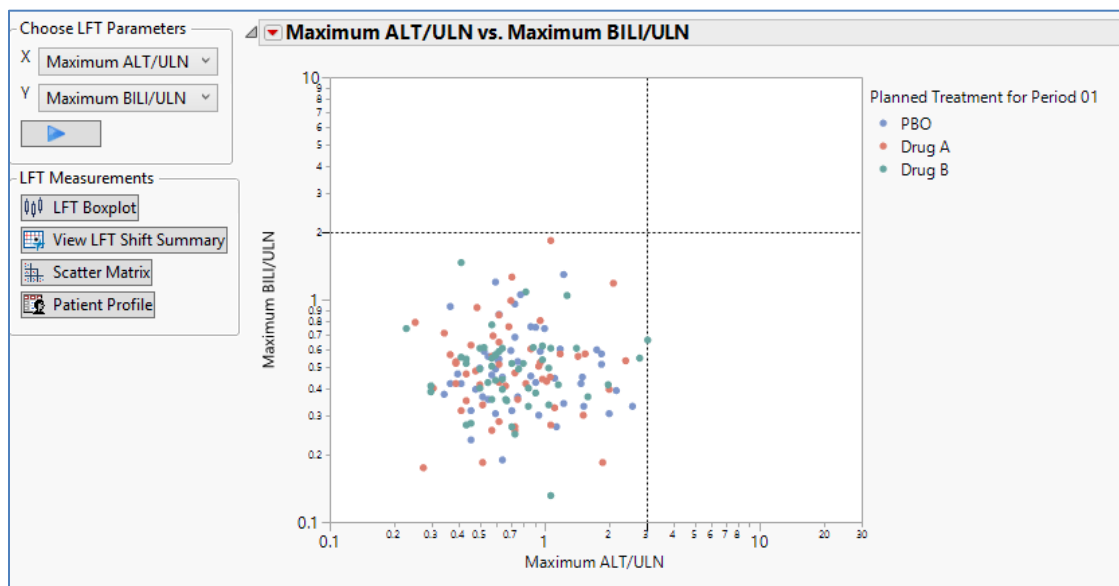**Figure 11. Boxplots of Change from Baseline Values across Visits in the Clinical Trial.**

## HY'S LAW

As mentioned above, hepatotoxicity has proven to be the single most important adverse event in the drug development and has prevented approval of numerous drugs. Thus, it deserves special attention. Lab data is a main source data to detect the signal of hepatotoxicity. Hy's law stipulates that more than 3-fold increase over ULN of ALT or AST, no significant increase of ALP and at least 2-fold increase over ULN of Bilirubin is a signal of severe hepatotoxicity (Zimmerman, 1978).

To detect hepatotoxicity signals, scatter plots of ALT/AST, Bilirubin(BILI), and ALP maximum values during treatment period are provided by simply clicking on the button Hy's Law in Figure 1. Figure 12 depicts a scatter plot of ALT maximum value against maximum BILI value. Notice that the lab values are normalized by the respective upper limit of normal and the X axis and Y axis are log-based. The reference lines are displayed based on Hy's law definition, e.g. a 3-fold increase for ALT and a 2-fold for BILI. A reviewer can focus attention on the upper right quadrant, which contains subjects whose values have reached the threshold of Hy's Law. To view scatter plots for other lab parameters, parameter can be simply selected from the drop-down menu in the X and Y drop-down box (Figure 12).

In addition to the scatter plots for identification of outliers, other visualization displays such as box plots and scatter matrices of Liver function tests are provided to make identification of hepatotoxicity signals more convenient. All those plots can be viewed by simply clicking on the relevant buttons. It is worth mentioning that a shift table showing value change from baseline to treatment maximum values in the multiple of upper lime normal are also included as a button (Data not shown). By reviewing the incidence rate in the table, a reviewer can evaluate treatment effects on the potential liver damage.

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**Figure 12. Scatter Plot of Treatment Period Maximum Values of ALT/ULN versus BILI/ULN.**

## CONCLUSION

In this paper, a JMP® add-in Lab Data Analyzer is presented with the aim of streamlining analysis of laboratory data based on the FDA review's guidance.  Basically, three standard approaches and application of Hy's law as described in the guidance are covered. For each assessment, both graphic- and table-based summaries are provided, ensuring that a reviewer has a complete picture of the lab data. This add-in takes advantage of a platform provided by JMP® and makes the review of table and graphics interactive in every aspect, so that reviewers can start with high-level summary data and drill down to the subject level as needed. In addition, this add-in is loaded with many functional and easy-to-use buttons and list boxes to ensure that the review of complex lab data may be conducted in an automatic way. Altogether, the use of Lab Data Analyzer Add-in can make laboratory data review to be conducted in an efficient and effective way.

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