

PhUSE US Connect 2018

Paper DV16

How automatic visualization of summary results can Speed up review of tables

Shafi Chowdhury, Shafi Consultancy Limited, London, U.K.
Rajwanur Rahman, Shafi Consultancy Bangladesh, Sylhet, Bangladesh

ABSTRACT

How can we review hundreds of summary tables produced for each clinical trial report in an efficient and effective manner? There are different statistics to look at in each table, and with so many parameters to review, it can be both overwhelming and time consuming to complete the task. Visualization is a great way to quickly review the results and identify potential data or programming issues. However, to program these is also time consuming and they also need validation, so is this a dead end?

If graphical representations of tables can be automatically generated by a validated system without further programming, then these can be used to review the results in a quick and efficient manner. We have to produce summary tables for trial reports, so why not calculate the results and on one side view these as tables and on another side view them as graphics. This paper looks at how the automatic generation of graphical representation of results produced for summary tables is a great way forward both to review and to present results.

INTRODUCTION

Every time a summary table is produced, it needs to be reviewed, reviewed not only for its accuracy, but also for its context. Do the numbers in the summary table make sense? Is the minimum, maximum and mean value as expected? Are there unusual values in the summary table? How do these numbers compare to the numbers in other tables? If we are producing a hundred tables on treated set then currently we might calculate the number of patients in the treated set a hundred times and use them each table, if we are to produce any figures, then we may derive the numbers again in addition and use them in the figure too. However, this is not the most efficient process.

Producing the results just once, validating the numbers just once, and then viewing the results in a tabular or graphical form would be a great way to improve efficiency, consistency and quality. The tables will be consistent as each summary result will only be calculated once and then used as required, and the reviewing them graphically means many different results can be quickly reviewed. This paper will look at the different types of graphs that can be used to quickly review the different results produced when summarizing clinical trial data.

SUMMARY RESULTS

In order to review results in a graphical manner, it is important that the results are available for use. How they are produced will vary between organizations, but to maximize efficiency it would be best if the results are validated prior to being used to generate the graphics. This is important as the application used to generate the graphics can then be validated to ensure that it displays the values correctly.

If the results are produced as part of generating the normal clinical trial report (CTR) summary tables, then as these must be validated anyway, no extra work will be required to validate the numbers. The key then is to export the results prior to the last part of the program that produces the table, so that it can be used by the application for graphics. This means that any tables produced for the CTR can be used to generate the graphics.

As the results are now available for use to generate the charts, the next part is the automatic visualization of the data. There are many applications that can convert data into graphics, and once they are connected to the results database this process can then become automatic. It is often possible to configure applications to present the data in a limited range of graphs and charts, so as soon as the data is there, so the charts are also available. This is key, there should be no further programming required for converting the results to graphs and charts.

VISUALIZATION

There are so many ways to display summary results that it would be too time consuming and require too much effort if decisions have to be made for each table. It is therefore easier to identify different types of data and then agree how to best present them. Additional graphics can be used for special results, but for general data some standard graphs and charts can be pre-defined.

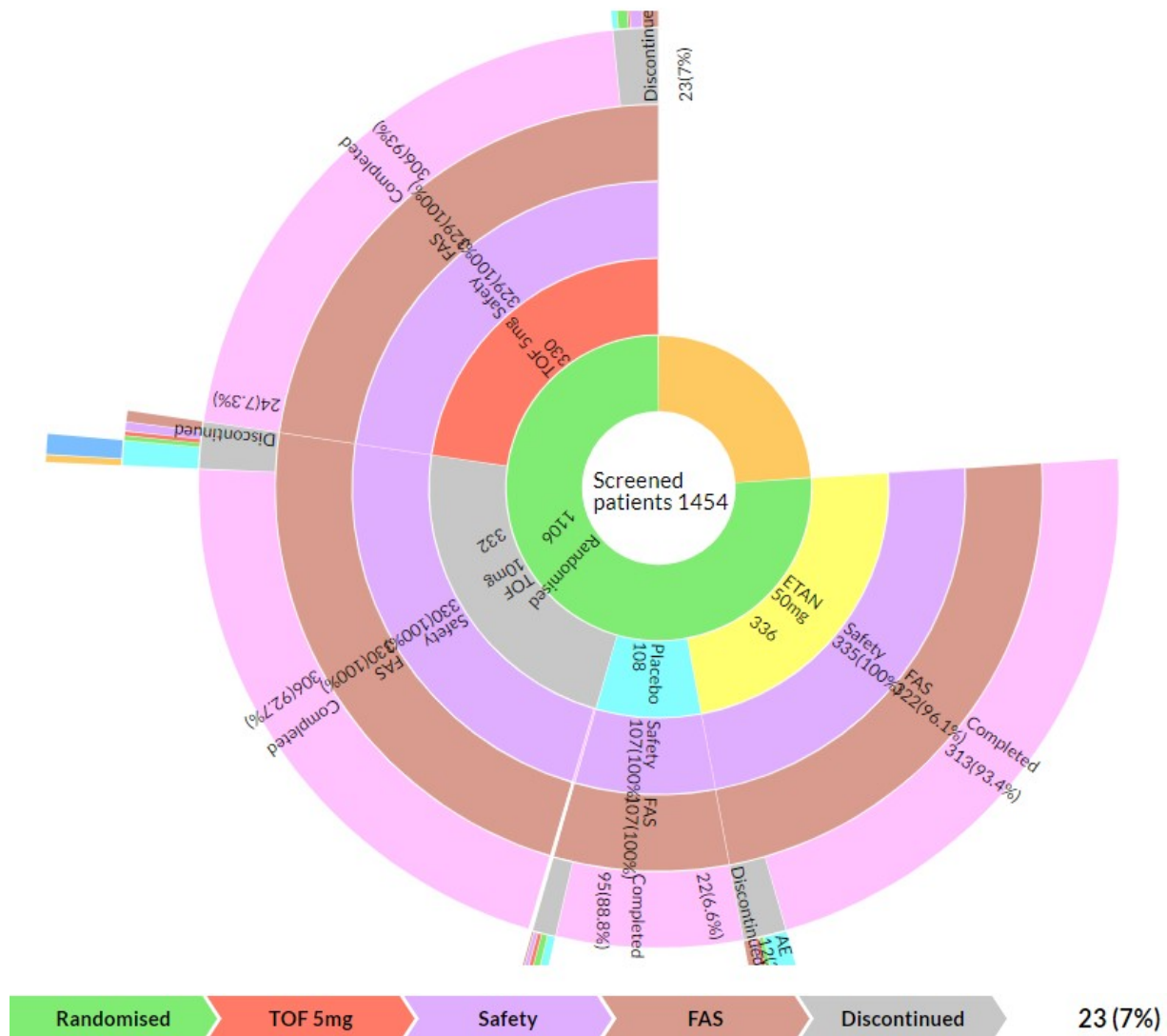
PhUSE US Connect 2018

The aim of the graphics is to make it easier to review the data, and there is so much information in summary tables, if we try to show everything in normal charts it would require many different charts to review one summary table. This would not be helpful either. However, if multi-dimensional interactive graphics is used then it would be possible to review different aspects of the data by interacting with each chart, hence removing the need to produce many different separate graphs or charts. It is important though that the graphics are appropriate and do not over complicate the simple aims or the message that should be extracted from the graph or chart.

As it should be easy to display the key tables in a graphical format, a random trial from clinicaltrialsregister.eu has been used for the summary results, and different graphics will be displayed to both reflect the table in a more informative manner, and to help review the summary results.

DISPOSITION

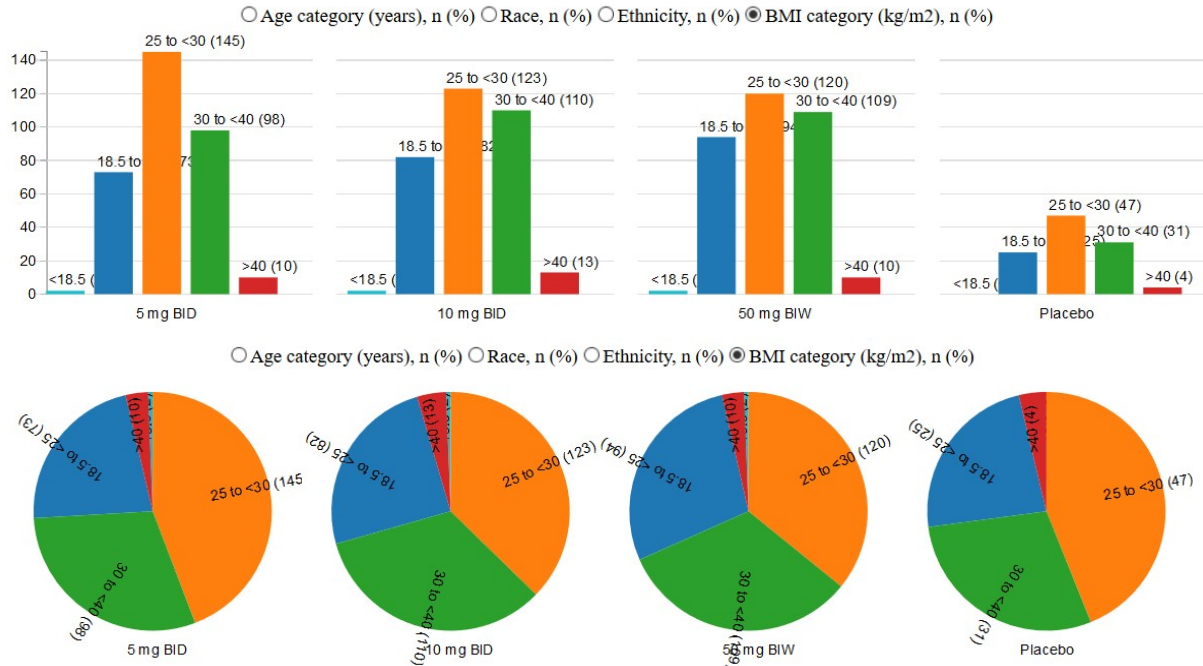
Disposition is a complex table with many different information, some related to treatment and others not. So how can this be displayed in an easy to understand manner? Sunburst is a good option where all the numbers can be easily seen, including the proportion of patients in each segment. One can click on a segment and then easily see how that is further dissected. It is also possible to have a summary row that not only shows the position, but also the value, to make it easier to read. Showing the values of a segment when hovering over it would also add to making the display more user friendly.



PhUSE US Connect 2018

DEMOGRAPHY AND BASELINE CHARACTERISTICS

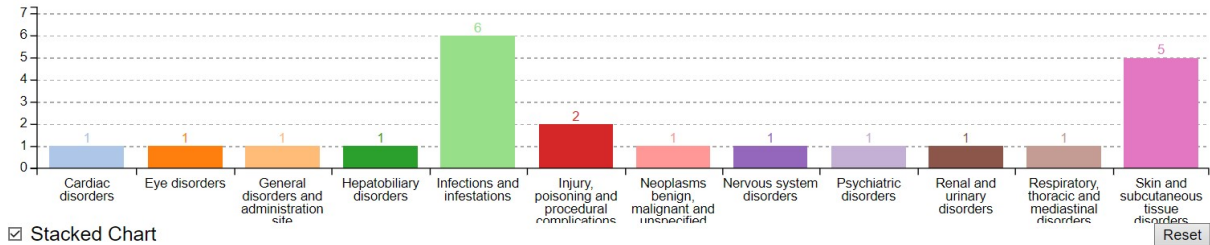
Demography table is a key table when it comes to reporting. It not only shows the patients who are in the study, but it contains many different types of data, and so requires different types of graphics. Once again, allowing interactivity means that multidimensional figures can be reviewed to look at results from different perspectives. Mean and whisker plots can be used to show the mean and standard deviations or range for quantitative results, while qualitative data can be presented in either bar or pie charts. Whereas bar charts allow easy comparison between groups, pie charts can often provide a better distribution within each group or treatment. Here is an example:



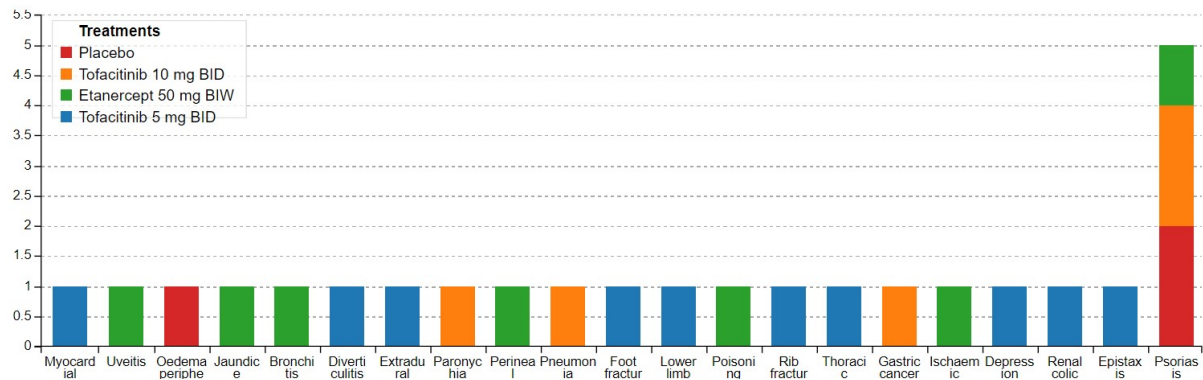
PhUSE US Connect 2018

SERIOUS ADVERSE EVENTS

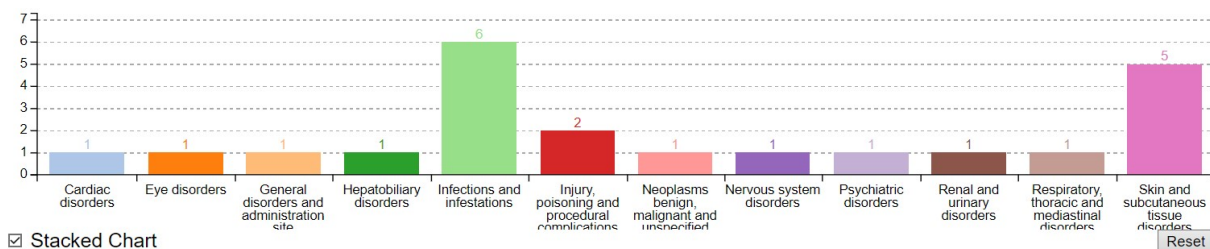
Adverse events are usually summarized by System Organ Class (SOC) and Preferred Terms (PT). However, going through a log table makes it difficult so what is there, which might be prominent and which is appearing in many different treatment groups or only in one. However, having both SOC and PT in the same figure and being able to select individual SOC's which then refreshes the PT's makes it easier and quicker.



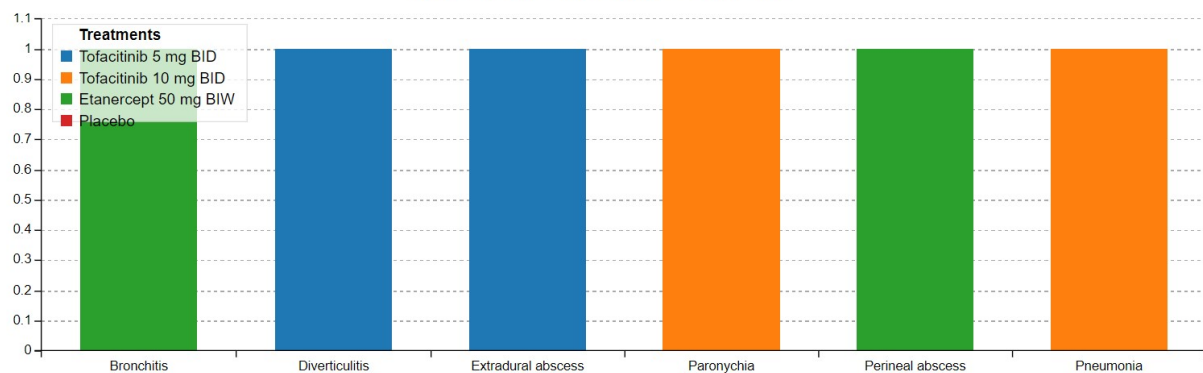
Preferred Terms from all System Organ Class



Click on an individual SOC in order to see the preferred terms associated with that SOC.



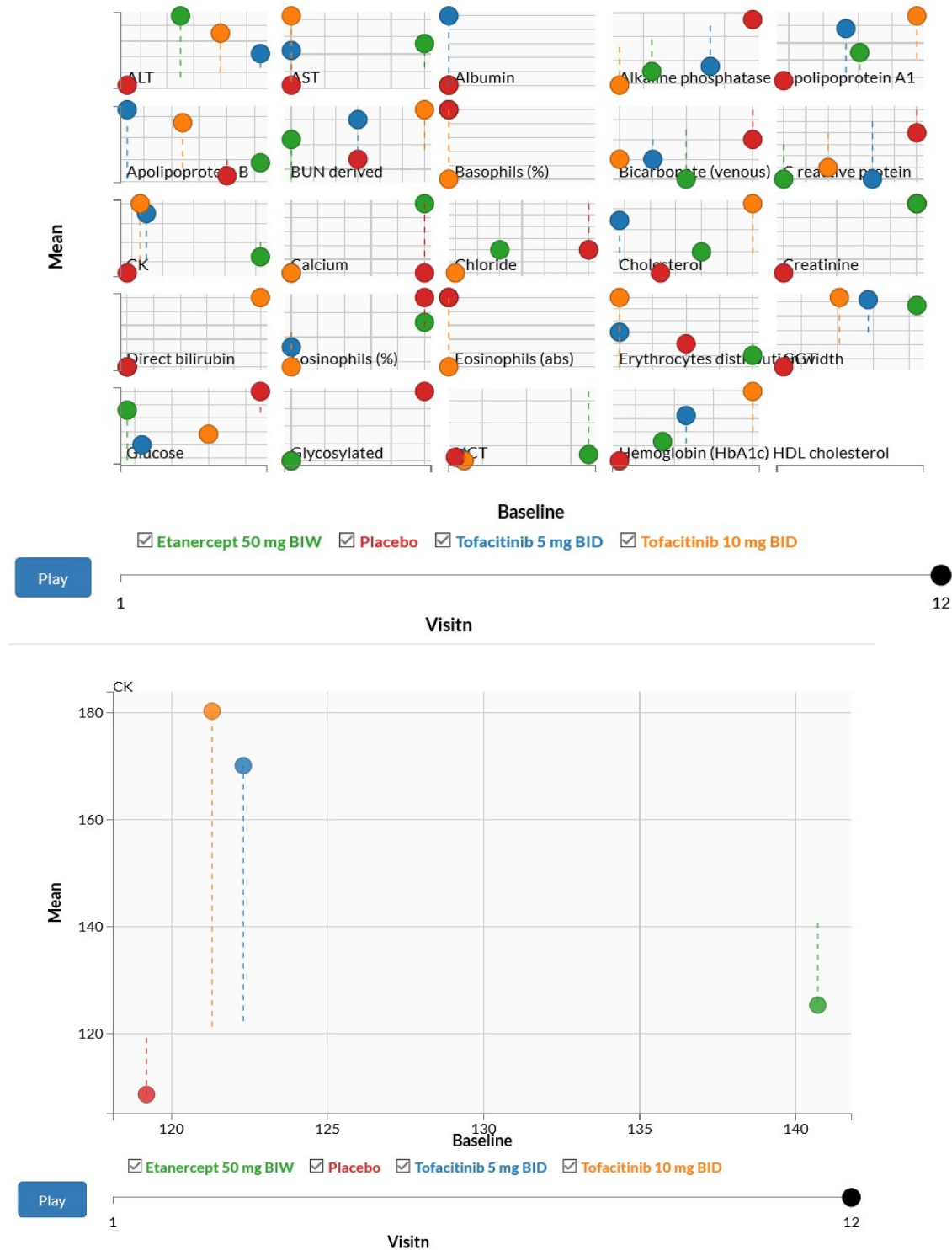
Infections and infestations



PhUSE US Connect 2018

LABORATORY DATA

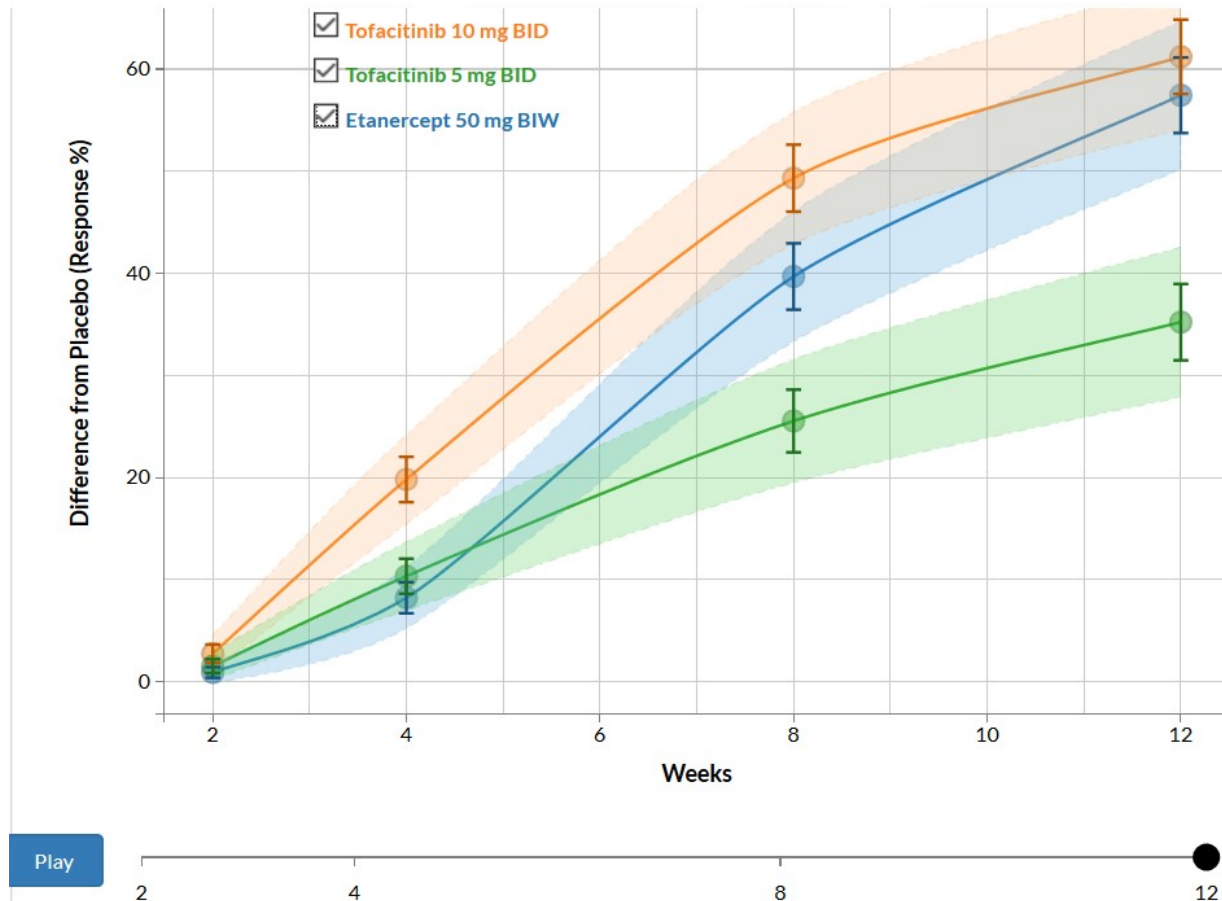
Laboratory data is one that often produces the most number of tables and is the most difficult to review. How are the values changing over time? Which parameters have significant change? Data must be reviewed for HY's law as well as compare against reference ranges and previous values. Here is one method to review all parameters per lab type, and perhaps make single parameters bigger for a better view if they are of interest.



PhUSE US Connect 2018

EFFICACY RESULTS

For continuous data it is perhaps easiest to just view the results using a mean and whisker plot, and for statistical analysis where confidence intervals are also calculated, showing them would be the best way to review the data. This is a great way to review the data as any data issues can be very easily seen, and the analysis programs can be reviewed.



CONCLUSION

Reviewing the output is a very time consuming process, and although there are many ways to see if there are any data issues, or perhaps problems with calculations, being able to see them in a graphical manner can often make issues very easy to spot. Once an issue is identified, then of course the reviewer can dig deeper, but the initial hard work can be minimized by the use of a graphical tool.

Many available applications can be configured to display results in various formats, and ideally on the same screen as the summary table. As these are software, they are fully validated, and no further validation is necessary from the reviewer's side to confirm that the graph on display is accurately reflecting the summary table. This then means that users can visualize the results straight away without any further programming.

Reviewing multidimensional data in an interactive manner where the size of circles can reflect the number of patients, colour can separate treatment, shading can show the confidence interval and whiskers can mark the standard error, shows how we can review and take in much more information visually than we can in tabular form. Using applications or platforms which makes this easy is indeed the way forward to speeding up review and analysis of clinical trial results.

PhUSE US Connect 2018

REFERENCES

Title: A Phase 3, multi-site, open-label study of the long term safety and tolerability of 2 oral doses of CP-690,550 in subjects with moderate to severe chronic plaque psoriasis

Protocol Number:A3921061

EudraCT Number: 2010-020002-15

Web: <https://www.clinicaltrialsregister.eu/ctr-search/search>

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Shafi Chowdhury

Shafi Consultancy Limited

7 Blossom Way, Uxbridge UB10 9LL

United Kingdom

Email: shafi@shaficonsultancy.com

Md. Rajwanur Rahman

Shafi Consultancy Bangladesh

Sylhet, Bangladesh

Email: rajwan@shaficonsultancy.com

Brand and product names are trademarks of their respective companies.