PhUSE 2017

Paper SD04

A Targeted Approach to Medical and Safety Reviews

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ABSTRACT

Medical and safety monitoring is performed by reviewing a set of clinical parameters of interest, patient by patient. The current practice is to perform the review using paper based listings or visualization tools in support.

This software demonstration will introduce a targeted approach relying on statistical methods to effectively highlight atypical patients and clinical parameters. The paper will demonstrate how Patient Profiles can provide detailed insight into patient experiences and offer targeted approach by identifying anomalies in data and ranking patients by their relative degree of risk.

It will be shown that the solution helps to enhance overall quality management, guiding study teams to quickly and effectively characterize risk signals and enable centralized medical and safety reviews.

IMPLEMENTATION OF A TARGETED MEDICAL REVIEW

The purpose of this section is to illustrate how a targeted approach to medical review can be implemented. Medical review consists of reviewing a set of clinical endpoints and variables per patient. This activity used to be performed based on listings and tables printed on paper. Nowadays, visualization tools are becoming more widely used in support of this labour intensive activity.

It has been shown that statistical methods are useful for assessing data quality, detecting outliers and atypical patterns. The principle behind the approach is that as all centers and all patients follow the same protocol, the same data structure is expected by design. It is therefore possible to compare data the different units against each other (patients, centers, countries). The statistical assessment can be automated and performed on all relevant variables.

Figure 1 shows a summary information from the statistical assessment. This graph can be used to identify patients that exhibit data inconsistencies. The vertical axis corresponds to the DIS (Data Inconsistency Score) while the horizontal axis represents the volume of data collected for the patient. Patients with a high DIS are the most atypical from a statistical perspective and require further investigation.

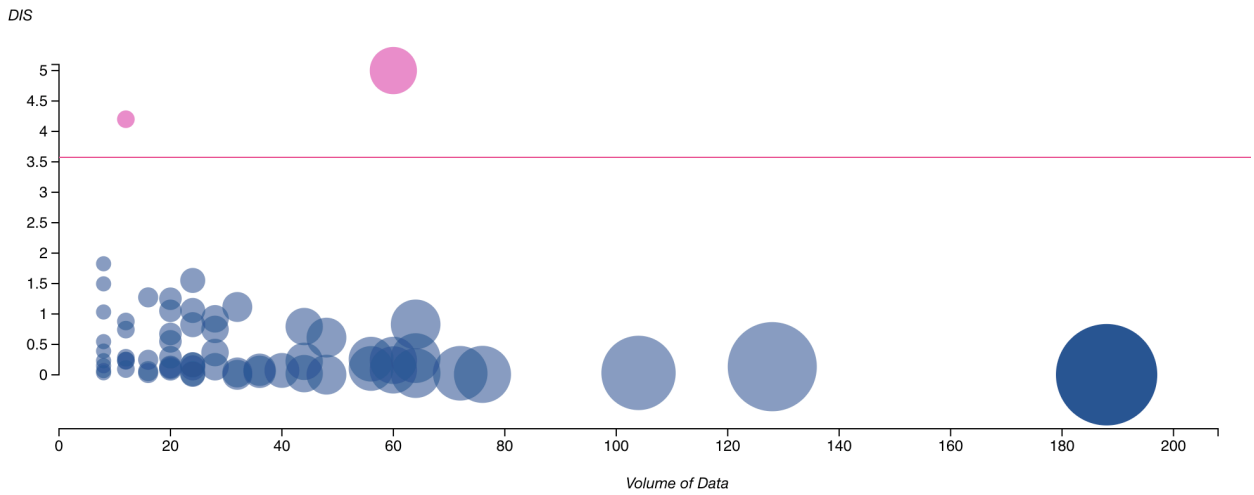

Figure 1 – Bubble Plot per Patient

Figure 1 – Bubble Plot

Medical reviewers can investigate atypical patients with different data visualizations and tables. The visualizations help medical review understand the patient experiences throughout the trial. Figure 2 provides an example of Gantt chart showing data for the Adverse Events and the Vital Signs. This graph provides a visual representation of different events and what occurred over time. Having the data from different domains and variables present on the graph allows users to quickly see events and the relationship between different events.

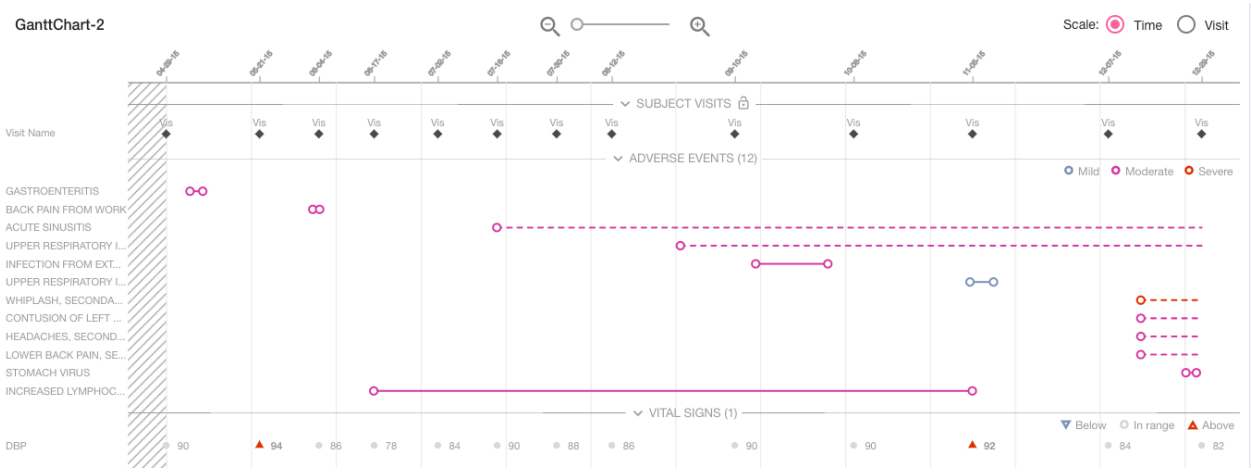

Figure 2 – Gantt Chart

Documentation of the Patient Profiles review can be performed directly within the tool and follow-up actions can be triggered where appropriate. Having all information in the same system facilitates the follow-up of issue resolution.

CONCLUSION

As demonstrated in this paper, the combination of interactive visualization and advanced statistical methods allows medical reviewers to focus effort where it matters the most. With this approach, efforts can be directed at patients that exhibit anomalies in their data.

A benefit of using a full electronic approach for Patient Profiles review is that traceability is ensured as every action and decision is recorded in the system.

CONTACT INFORMATION

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