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Bridging the Gap between Visual Analytics and EDC Software to Accelerate Centralized Data Monitoring

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As clinical trials grow in scale and data sources proliferate, Data Managers and Medical Reviewers experience increasing pressure in meeting their safety surveillance responsibilities. The risk of missing a safety signal is ever present. Fortunately, self-service Visual Analytics tools are helping them increase their productivity and thoroughness by allowing them to quickly and easily spot trends and anomalies in the data they review. These tools extract data from multiple data repositories (such as the trial's Electronic Data Capture (EDC) system) and support high-level data views as well as detailed drill downs.

However, in most applications of Visual Analytics software, sponsors and Contract Research Organizations (CROs) have stopped short of taking a step that could make the review and resolution process even more efficient. They have failed to take advantage of a more advanced integration with the EDC system such that *queries directed to investigators can be posted directly in the EDC*. Here, we explain why that's problematic and how it can be rectified through technology.

The Standard Review Workflow

Visual Analytics solutions support companies' responsibility for patient safety and ability to generate quality data for submission to regulators. However, uptake has been gradual, and even among adopters, few companies are using visual analytics to their fullest in improving the efficiency of work processes once a data value needs to be investigated.

Currently, in order to post a query about a potential signal or to explore a discrepancy in the data, reviewers working in the Visual Analytics tool must interrupt their data review and switch systems. They must log into the EDC system, drill down to the appropriate site/patient/data field, and then post their query. Once that's been done, they only have one way of checking to see if the query has been answered or resolved; they must return to the EDC system at some later point to review the query status.

Busy Medical Reviewers often adopt a workaround that puts the onus on Data Managers to deal with posting the queries and tracking them. Medical Reviewers record their queries in a spreadsheet, which is passed to the Data Manager who must enter the query in the EDC and manually track its progress.

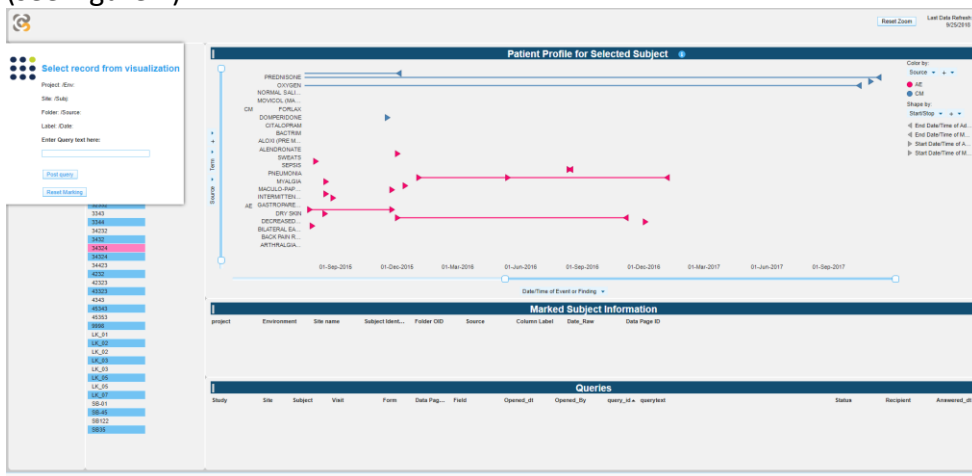
Both of these approaches have serious drawbacks that impact productivity. First, during the initial review in the Visual Analytics software, it is not possible to tell if a similar query has already been raised and addressed. Thus, there is a high potential for duplicate work. Second, the need to leave one system and enter another adds unnecessary time, and ultimately, expense to the process. Third, anytime a manual process is used, such as tracking queries on a spreadsheet, there's the potential for human error. Given that the primary purpose of medical monitoring is to reduce patient risk, any introduction of human error should be avoided.

Working within a Single System

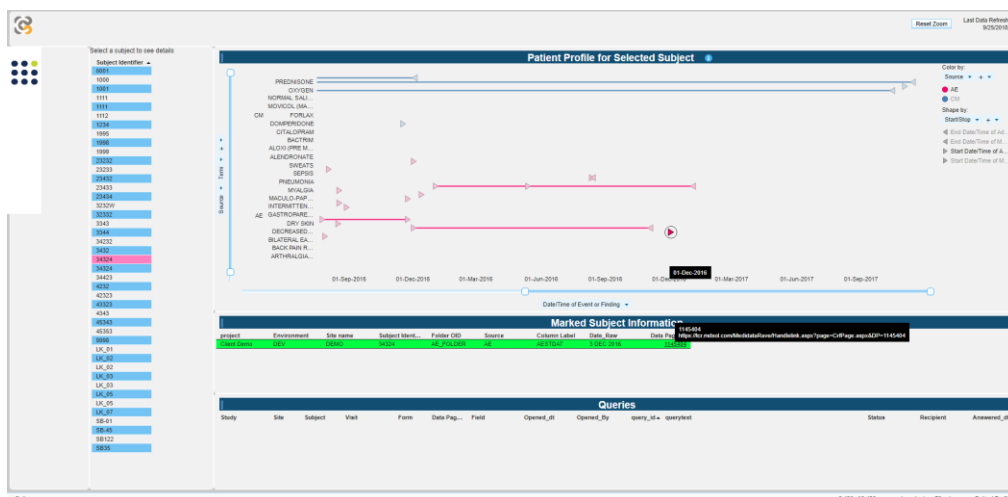
The inconvenience and risk involved in moving back and forth between systems and tracking query status manually can be avoided by leveraging the Application Programming Interfaces (APIs) that EDC vendors already provide. Following minor customization of the integration between the two systems, users can post queries for investigators directly in the EDC system while they are still working in the Visual Analytics software. Queries are thus viewed alongside the data in the Visual Analytics tool.

Such a simple integration can be accomplished without involving IT and can be performed retroactively on studies that are already up and running. The resulting linkage permits users to:

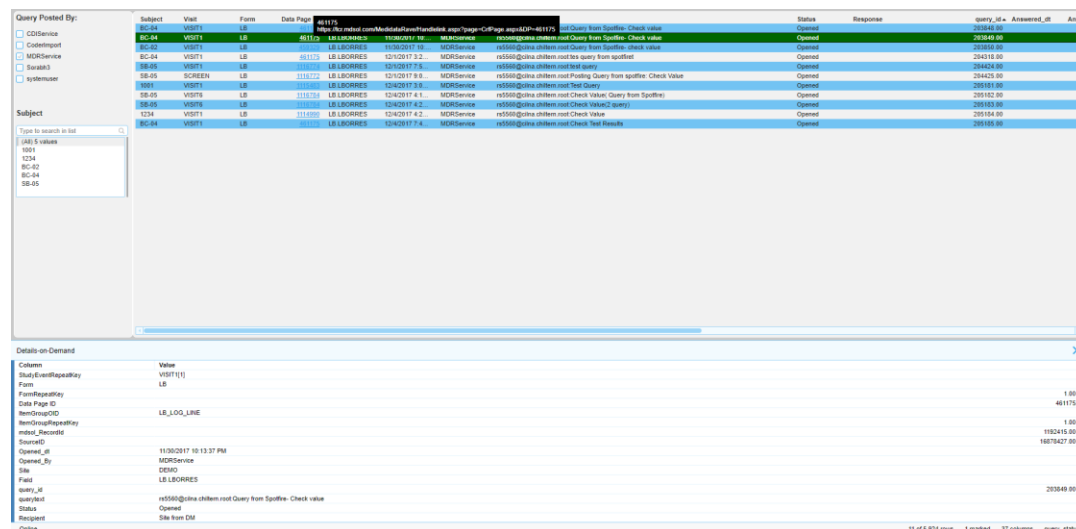
- Easily identify where to enter the necessary information to post a query. A pop-up window separates the data and guides the user in entering the correct information into the system (see Figure 1)



- Rapidly post queries to data points in question within the EDC system, eliminating the need to manually search for records in EDC (see Figure 2)



- See existing queries before posting new ones, thus avoiding duplicates (see Figure 3)



Broad Benefits from a Simple Solution

A more customized integration between Visual Analytics and EDC systems will reduce the manual workload for Data Managers and Medical Reviewers as well as increase the efficiency of their work and the quality of the outcome. This should also improve adoption rates among Medical Reviewers, as doctors are often hesitant to pick up new technology – especially if it fails to meet all of their needs.

In addition, there is less chance of an error being introduced, as visualizations and queries are presented side by side.

Conclusion

While many companies are giving a lot of attention to Artificial Intelligence (AI) and Machine Learning (ML) to improve clinical trial data management, there's also value in focusing on quick wins. The type of integration described here is one such solution that can be easily deployed to eliminate tedious and time-consuming tasks for costly resources.

Contact Information

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