How to Use Data Visualization to Improve Clinical Trial Efficiency and Drive Business Value

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Due to advances in science and technology, the amount of data per clinical trial has increased 183% in the past decade.[1] The volume and diversity of that data has expanded far beyond what a simple spreadsheet can manage.

As clinical trials move to decentralized models, the amount and variety of data they generate will grow even further. Importing and analyzing data from wearables, imaging platforms, apps, and central labs are primary challenges among sponsors of all sizes. At the same time, curating and presenting that data to stakeholders is becoming more difficult and time-consuming — while also becoming more important.

To keep clinical trials on schedule and maintain pricing efficiency, sponsors must analyze clinical data to make informed business decisions. Meanwhile, the study teams need to review clinical data to mitigate risk and monitor safety and effectiveness. The need for a platform that allows study teams to access all data in one place to accomplish these tasks has become a priority.

What Is Data Visualization?

In the research field, data visualization is an all-encompassing term that describes the direct transfer of biomedical data into displays of plots, graphs, and charts. In this article, data visualization describes software systems that filter, sort, and display raw clinical data such as charts, tables, graphs, heat maps, and other visuals. The goal is to enhance business intelligence and drive operational improvements.

What Is a Dashboard?

A dashboard is a data visualization tool that allows you to view relevant key performance indicators (KPIs). Data is updated in real time and viewable via a mobile app or web browser.

Data visualization tools allow study teams to pull together all clinical trial data sources into an actionable report for all stakeholders — project teams, sponsor and CRO executive teams, and CEC/DMC committees. Using an interactive dashboard, study teams can view the analytics that matter without sorting, copying, and pasting from multiple spreadsheets, and without logging in to several databases to view data. They can also compile the necessary information into an easily digestible format for other stakeholders.

What Are the Benefits of Data Visualization?

The bottom-line benefits of an intuitive visualization tool include:

- Faster analysis
- More informed business decisions
- Improved organizational efficiency
- Increased competitive advantage
- Improved customer experience

Business intelligence (BI) data visualization tools allow for better management and monitoring of clinical trials compared to other methods. They also improve outlier detection, screening and enrollment tracking, and safety review.

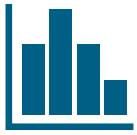
With data visualization, monitors can do more than simple review of data listings. They can review reports to look for underlying trends, such as potential or emerging risks. With access to a dashboard, monitors can filter, sort, and cross-reference data to get the information they need immediately.

5 Steps to Building a Dashboard

Using data pooling and automation, a sponsor or their CRO can build a dashboard to visualize clinical study data in real time. Building a dashboard generally involves the following five steps:

Identify Data Sources

Wearables? EDC? Imaging?



Connect Data to BI Platform

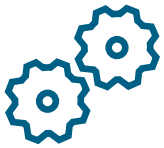
Consider programming modifications needed

Specify Target Outputs

For your report

Build Out Report Pages

With visualizations and tables configured; consider custom derivations



Automate Data Process

To get real-time data

Questions to Ask When Building a Dashboard

Many visualization platforms offer a drag-and-drop process for building your dashboard, making it easy for non-programmers to set up. Before you start customizing, understand the dashboard's primary use and the data stakeholders will need to view. From there, consider the following:

- What data is needed?
- How will we pull the data?
- What tabs should we include?
- What data sources will we need for each of the tabs?
- What visuals do we want to create?
- What filters will we need to drill down the data?
- How often will we need updates?
- Who will need access?

Why Use Automated Dashboards for Patient Safety Data Review?

Patient safety data analysis is important in all studies both to protect clinical trial participants as well as to develop safety profiles and benefit-risk assessments. Reviewing patient safety data thoroughly becomes even more critical in smaller Phase I studies. Automating that data ensures the study team can easily view and analyze all safety data to catch and address any anomalies.

Case Study: Automating Patient Safety Data

Client: The sponsor of a dose escalation and expansion study that involved three cohorts.

Challenge: The sponsor needed a better way to review and analyze patient safety data. The study team met weekly to review new EDC and central lab data. The EDC extracts were spread across multiple spreadsheets. Multiple team members spent several hours each week compiling the data. The master spreadsheet was created by cutting and pasting information from multiple CSV files, which took too much time, led to errors, and would increase risk as the trial progressed.

Solution: Avania developed a Power BI dashboard with interactive reports and visuals, customized to the protocol and key data of interest. The report allowed the sponsor to sort data by cohort or by patient and view new data added since the previous week's review. The sponsor could view all adverse event data summarized by patient, system organ class, and preferred term codes, as well as over time through several graphs and charts. The dashboard also featured outlier detection with out-of-range variables highlighted.

Weekly reports were developed by routing the EDC extract through SAS to identify newly entered key fields. The study team could quickly view new data added since the previous week's review on a Summary of Changes screen using filters and conditional formatting — no manual sorting through multiple spreadsheets required.

Result: The sponsor could easily view existing and new key safety and efficacy data. They could also filter data down to patient and cohort levels. By automating reporting, the sponsor dramatically reduced time spent generating reports and increased reporting accuracy.

What Are the Benefits of Efficient Site Management?

Delayed timelines can significantly impact the cost of a clinical trial. Low-performing sites contribute to delays as well as the cancellation of trials. While clinical trial management systems (CTMS) help sites perform their myriad duties more efficiently, it is still critical that CROs and sponsors monitor sites' performance to identify and resolve performance issues. Leveraging these reports and data from previous trials can be used to determine the optimal sites for future trials during the site selection phase.

Case Study: Efficient Site Management

Client: Sponsor of a pivotal IDE clinical trial. These studies typically involve about 300 patients and between 20 and 30 sites.

Challenge: Pivotal IDE studies focus on site selection, startup, and performance. Information from multiple feasibility databases, past study site performance data, qualification questionnaires, site startup trackers, and performance needs to be analyzed. Managing this information involves accessing several different files and databases using multiple logins. The sponsor in this case study needed a more efficient site management process.

Solution: Avania used its analytics platform to develop a Power BI dashboard that compiled all site-related information. The platform pulled de-identified patient data from the CMS database, targeting ICD-10 codes that related to the study. It combined that claims data with information from Avania's CTMS database to create a site selection heatmap and listings for feasibility. Study startup trackers provided status on timelines from site selection to site activation. Site performance tabs tracked enrollment numbers, screen failures, adverse event rates, protocol deviations, and other metrics.

The Power BI dashboards also provided the option to create and export site-specific reports into a CSV file or a worksheet. Clinical monitors, data managers, project managers, and sponsors could then review safety summaries, query metrics, and other study-specific information they needed on an ongoing basis.

Result: The study team could access all study data from one central location using one login. They accessed site information faster and easier with the Power BI dashboards compared to previous methods. They also enhanced their ability to track site performance and startup using the tool's powerful analytics.

How to Optimize Trial Visualizations and Dashboards

Implementing a visualization tool does require up-front investment in time and resources. However, the gains in efficiency throughout the clinical trial life cycle produce long-term operational benefits.

To get the most from a visualization platform, keep the following tips in mind:

Choose a platform. There are several advanced business intelligence platforms available, a few of them designed for life sciences. Naturally, look for features that serve your needs, such as integration with your EDC, features for managing wearables, and robust security features.

Microsoft Power BI, for example, is a powerful, customizable platform that provides visual interpretations similar to Tableau, but it also aligns with Office 365. Power BI features regulatory-compliant security and permissions, as well.

When used in clinical trials, Power BI can proactively identify and manage study risks in compliance with the ICH E6 GCP guidance. It simplifies the ability to make data-driven decisions, spot trends, and identify ways to improve clinical trial efficiency and effectiveness.

Experiment and get feedback. It will take some trial and error to design report pages, create tabs, and design tables. Find out what information users have readily available and customize from there. As the trial continues, solicit feedback to refine the dashboard. Because people process information differently, replacing a table with a graph may help a team member work with the data more efficiently.

Consider the audience. Typically, clinically focused study team members will need multiple pages, tabs, and filters. Executives may only need a couple tabs that provide high-level overviews. Customize dashboards and tabs based on those audiences.

Take inspiration from others. Research how other industries use data visualization to create graphics and charts. Banking, financial, insurance, and real estate businesses use these tools well.

Design with mobile in mind. Choose a visualization platform that's available for both desktop and mobile. Monitors and many stakeholders will want to access reports or review trial status when they're on the go.

Highlight key KPIs. Customize your dashboard to highlight the most relevant information without overcrowding the dashboard. Create additional tabs to space out information.

The Persuasive Power of Data Visualization

As the volume of data expands, and as decentralized trials become more commonplace, traditional processes simply don't allow for efficient use and management of that data. Visualization tools let you quickly integrate, sort, and analyze clinical data to improve operational efficiency and drive business success.

References

[1] Getz, K., Anticipating the Impact of the Patient Engagement Movement on Clinical Operations, Presentation at CROWN conference, Slide #9, January 2020.

To learn more about the efficiency benefits of data visualization, watch our webinar on the power of data visualization.

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