Clinical Intelligence

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Elevating medical monitoring: Harnessing the power of guided analytics with Phastar's Clinical Intelligence Platform

Medical monitoring is one of the most important aspects of any clinical trial, but traditional approaches are time-consuming, leave room for error, and provide only a limited view of the data.

Guided analytics consolidates near real-time data from multiple sources into a single, filterable dashboard, providing users with step-by-step assistance in exploring, analyzing, and interpreting data to make informed decisions. This approach is transforming the medical monitoring landscape by enhancing accuracy, efficiency, and insights into study progress, ultimately improving patient safety with all necessary data at your fingertips.

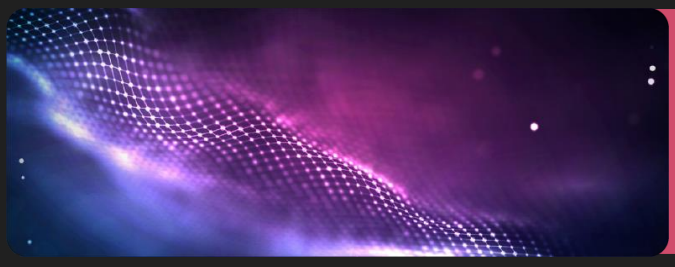
Medical monitoring: The whys and the wherefores

Medical monitoring is vital to the success of clinical trials. It is only through the ongoing monitoring of participants' health status and the timely management of any adverse events or other emerging issues that medical monitors can protect patient safety and data integrity.

It is why bodies including the International Council for Harmonization of Technical Requirements of Pharmaceuticals for Human Use (ICH), the US Food and Drug Agency (FDA), and the European Medical Agency (EMA) all mandate the process.

However, it can be challenging to achieve the aims of medical monitoring effectively using the traditional model. Site monitors have only a single-central view of the data and tend to rely on spreadsheet-based lists of information or a Patient Profile that can be hard to compare and contrast across metrics. In short, it is a highly labor-intensive process with a high margin of potential error.

In recent years, centralized monitoring, or review of the aggregated data generated across all trial sites, has emerged as a more accurate and efficient method. But it still has its difficulties. The growing complexity of clinical trials, for example, means there are multiple data sources to draw from. In addition, protocol changes, patient diversity and varying adherence to the intervention can make like for like comparisons challenging, threatening data integrity.



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Guided analytics

To overcome such obstacles and unleash centralized monitoring's ability to protect safety, ensure compliance, and guide timely decision making, the industry needs robust, consistent practices – such as guided analytics.

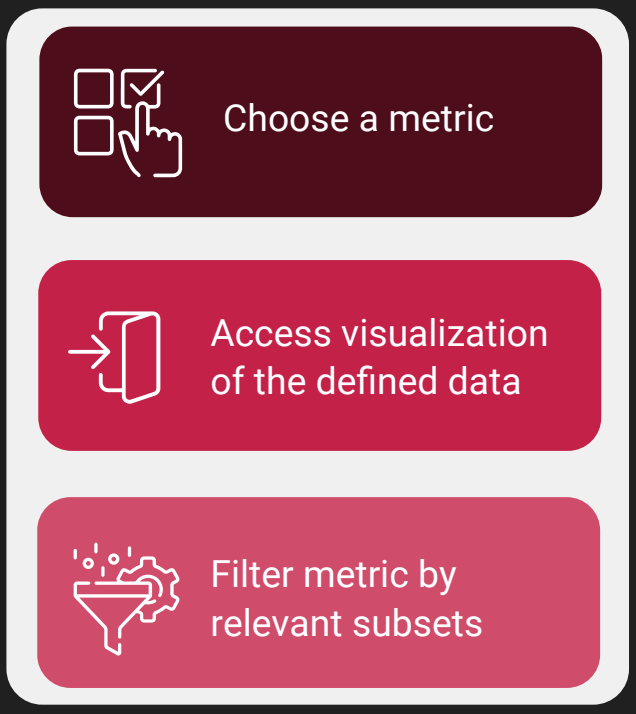
The model combines near real-time data from multiple sources, including clinical data such as EDC, CTMS, Lab, ECG, Protocol Violation Assessments, ePROs but also metadata and audit data trails, into a single dashboard of powerful visualizations. It gives researchers instant access to the metrics that matter at the click of a button, eradicating the need to manually check, compare and contrast multiple spreadsheets.

Clinical intelligence, powered by Phastar's expertise, also offers a bird's eye view of the whole-trial data set, allowing users to quickly identify trends and outliers. These can then be investigated and, if necessary, rectified before they can impact on participant safety or data integrity.

What's more, it facilitates greater quality assurance and compliance, by providing a single, searchable audit trial of queries, signals, and investigation outcomes.

Clinical Intelligence's seamless, unified approach can empower research teams and other stakeholders with swift, precise and accurate data mapping and analytics, enhancing decision making, driving efficiencies and improving patient safety.

How it works



Scientists have always known that presenting data graphically can aid rapid understanding. Bar, plot, and area graphs have long been a feature of medical journals and congress lectures. Guided analytics within Clinical Intelligence applies the same principle to near real time trial data, integrating unstructured data into user-friendly dashboards and offering rich information exploration from a single view.

Rather than search through multiple spreadsheets, a process that is not only time consuming, but prone to error, monitors can simply choose the metric they wish to focus on, and instantly access a visualization of the defined data. It allows them to quickly spot trends or outliers and delve deeper into the data, enabling any necessary, remedial action to be carried out quickly.

Metrics can be further filtered by relevant subsets, to reduce noise and provide a clear picture. Adverse events, for example, can be filtered by cohort, trial arm, or demographic, giving teams an overall understanding of where, when, and in who the events are happening. Concomitant medications can be filtered by indication or drug, or medical history by term or standard of care, illuminating possible drug-drug interactions.

Laboratory results can be displayed as a timeline, and filtered by factors such as cohort, site, or adverse events. Teams can also monitor data related to endpoints, whether that be in absolute numbers, treatment arm, or visit and gender, race or age group to track the progress of the trial in near real time.

Furthermore, they can use the dashboard, which can be deployed in weeks not months, to view queries, and group them by topics including site, subject, or duration open. This allows them to spot the signs of issues such as potential protocol deviations, site monitor over or under zealousness, or equipment malfunction and investigate accordingly.

Sponsor X used guided analytics and visualization software from Phastar to gain valuable insights into participant recruitment, predict when the last participant would receive treatment and propose strategic reallocation scenarios. The system used real-time data updates and an integrated write-back solution. This guided analytics approach allowed Sponsor X to overcome previously unidentified bottlenecks, adapt dynamically to recruitment challenges and optimize participant distribution. Reported benefits included accelerated trial completion, proactive enrolment management and data-driven decision making.

An elevated view

Guided analytics allow medical monitors to consolidate and analyze data from across all sources and sites, offering a more elevated view of data. They offer a holistic approach to medical monitoring, clinical operations, safety and risk-based quality management.

Not only does this make the process easier, faster, more efficient, and more accurate, but it will also help medical monitors to spot possible threats to patient safety or data integrity as they arise – and act before they can impair the chances of study success.

To find out more about medical monitoring with Phastar, please visit:
https://phastar.com/solutions/digital-acceleration/

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