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Analyzing Data on the Fly

Everything You Need to Know When You Need to Know It

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DATA ON THE FLY

Anyone who has run a clinical trial knows that having data and having actionable data are not the same. Today's trials gather increasing amounts of information from disparate sources—lab tests and mHealth devices, electronic medical records, and patient-reported data. The data contains valuable insights that might shift the trajectory of a trial. If researchers can only see them at the end of the trial, they lose much of the data's worth. Only by arming teams with the ability to analyze data on the fly can you wrest all the value it has to offer.

DATA ANALYSIS THAT IS BOTH IMMEDIATE AND IN-DEPTH

First, it's important to clarify that we are not advocating breezing through end-of-study analysis. That needs to be done in a methodical and controlled way. We are discussing the ability to swiftly examine data as they are collected. That enables researchers to identify any safety or data quality risks as they happen and correct them immediately. This ability both better protects patients and minimizes the possibility that data will be rendered invalid at the end of the trial.

This immediate insight is possible when all data come into one centralized location and are continually refreshed—hourly, daily, or weekly as trial protocols dictate. Researchers always have the most up-to-date, relevant information on which to base assessments and decisions with this centralization. Further, they can even program data management software so that those issues can trigger alerts when data reveal specific issues.

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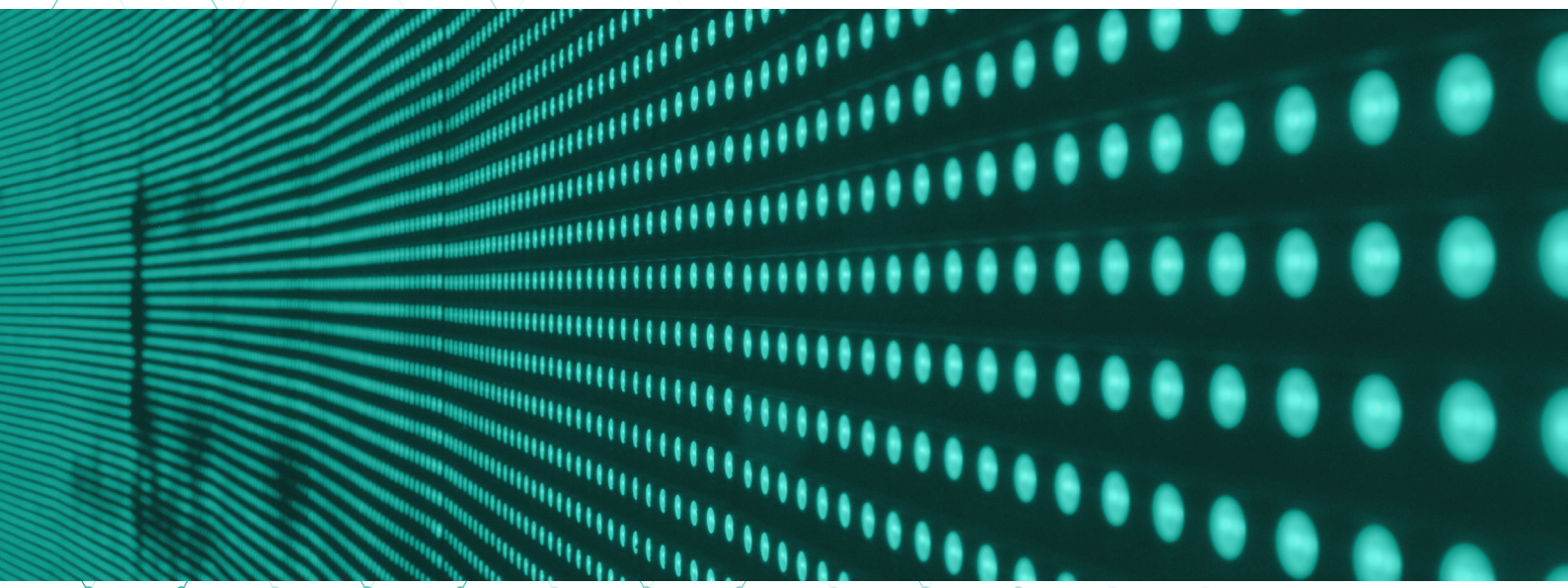
FOUR STEPS TO BECOMING A DATA-DRIVEN ORGANIZATION WHICH ENABLES THE ABILITY TO ANALYZE DATA ON THE FLY

A truly data-driven organization consistently harnesses data insights to make informed decisions. Here's how to make the transition:

- Gather all data into a single repository. Using a specialized technology platform, this can happen automatically as data are generated, so the record is always up to date. A newly emerging category of software for real-time monitoring and Management is emerging and supports these principles. Such software also facilitates analyses by formatting the data using visualizations and other tools. Bonus: automation dramatically streamlines data management activities and minimizes the potential to introduce human error.
- Offer training, so that team members are data literate—confident identifying, analyzing, and interpreting data—and technologically capable.
- Ensure consistent processes and visualizations are used across a study so that team members have a standardized way of reviewing data—remember, "on the fly" does not mean haphazardly.
- Incorporate risk-based quality management (RBQM) principles to pinpoint critical data, risk parameters, and a documented action plan ready to implement as soon as a risk appears.

Laying this foundation of technology, training, and commitment will provide stronger trials *and* save considerable time along the way.



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TRENDING: THE POWER OF REAL-TIME INSIGHTS

To understand the value of real-time data insights, consider how you currently view your clinical trial data. There is a large file folder for each patient (virtually speaking); it holds a host of subfolders with the records from every individual visit. To consider a patient's heart rate longitudinally, you have to open all the sub-folders. That is a time-consuming process—and one in which important developments may be missed.

For instance, the patient may have normal values, but those values may be trending abnormally. Examining the values one by one, you might only note that they are within a normal range. Conversely, looking at data visualization, you would notice the trend before any values dipped into an abnormal range. You could not only monitor the individual patient, but you could also query whether the trend is appearing in other patients—and whether it indicates either a site-specific or study-wide safety issue. That is essential information that enables you to minimize risk to patients proactively.

Such visualizations can also help ensure study integrity. In one study, we saw all 20 patients from one site had the same heart rate and respiratory rate at visit one. At visit two, their rates had changed, but they were still all uniform. That seemed odd. On investigation, the sponsor learned that the study team wasn't measuring the vital signs because those numbers didn't seem relevant to the study; instead, they were entering a random figure. If these odd readings had only been discovered at the study's conclusion, those patients—and all their relevant data—would have been excluded from the final analysis. Because the anomaly was identified promptly, the situation was rectified, and their data was secured.

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IT'S TIME TO UNLOCK THE REAL VALUE OF YOUR DATA

The value of clinical trial outputs lies not in individual data points but in the story they tell collectively. That story manifests through trends and outliers, paths and outcomes. The conclusion is not foregone; the plot can shift—depending on the actions you take during the trial.

Grounding those actions in fact-based insights is simple if your team can analyze the data on the fly. It's the most effective way to protect the quality of the data, the safety of your patients, and the integrity of your study.

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