Data Literacy :

The Foundation for Modern Trial Execution

AUTHOR: Kristin Mauri

In 2016, the International Council for Harmonisation (ICH) updated their "Guidelines for Good Clinical Practice." One key shift was a mandate to implement a risk-based quality management system throughout all stages of a clinical trial, and to take a systematic, prioritized, risk-based approach to clinical trial monitoring—on-site monitoring, remote monitoring, or any combination thereof.

In theory, this new guidance freed researchers to take advantage of powerful new technologies that simplify remote monitoring and enable such monitoring to deliver study-wide insights that can speed answers and enhance patient safety. Yet in practice, clinical trial monitoring has remained grounded in on-site source data verification, a costly, time-consuming process that does not address risk or site performance data. It's time for that to change. Data literacy is the change agent.

It's time for that to change.
Data literacy is the change agent.

Ongoing education is necessary to keep pace with technological transformation

This issue is not unique to the clinical trial industry; it has been a challenge everywhere data are being used to enhance decision making. Yet other industries have outstripped ours in training their workforces, enhancing both employees' skills and their job satisfaction.

So why not the clinical trial industry? Yes, change is hard. People are comfortable with existing, proven frameworks. Further, with no clear roadmap for the implementation of risk-based quality management, it is easier to throw up concerns. Two standbys:

"Our sponsors may not be comfortable with the change."

"The new processes may not satisfy regulatory requirements."

Mostly, these are mere smokescreens. Sponsors will be comfortable when they are educated on the advantages of data literacy. Further, ICH regulations require at least considering the use of a risk-based approach—and, in its absence, a solid, documented rationale why it was not used. Certainly, technology systems are built with these regulatory requirements in mind; some platforms even streamline regulatory reporting with system-automated audit trails.

The real issue is more personal; technology has outpaced the data literacy of study team members, so they shy away from more advanced data-driven risk-based approaches.

Consider the pace of technological innovation and the exponential growth of data sources used in trials. If clinical trial personnel have an average tenure of 10 years, but have not been developing new data-centric skill sets in that time, they are woefully behind.

It is time to reskill the workforce.

Data literacy must become the new norm

Data literacy is a simple concept. Looking at data related to your area of specialty, you can deduce insights, ask appropriate questions, and make clear data-based decisions. Within the clinical trial ecosphere, each role requires a different degree of skill both vis-à-vis data in general and the trial data specifically. For instance, clinical research associates only require basic knowledge. They must understand elementary mathematic principles, such as mean, median, and mode; recognize the genesis of their clinical trial data, and be able to interpret simple data visualizations such as graphs and charts.

Central Monitors need a more advanced understanding of mathematical principals and an ability to recognize both the correct interpretation of data and when data are being misinterpreted. Further, they need story-telling skills to communicate data-driven insights to those who are not themselves data literate.

Data Scientists require the most advanced skills. They need an understanding of mathematical concepts such as linear algebra and probabilities and distributions, fluency in statistics, proficiency in standard and end-user configurable visualizations, programming capabilities, and a working knowledge of machine learning algorithms.

At every level, data literacy enables people to make data-based decisions rather than experience - or intuition-based decisions.

That is a key competency for risk-based quality management.

True risk-based quality management stems from data analytics

A risk-based quality management strategy sorts risks into categories of high, medium, or low. Technology then allows researchers to quickly surface and carefully monitor those risks that could actually endanger the patients or derail the study—whether or not the risks are initially anticipated.

The Central Monitor is the air traffic controller. Viewing all aggregated data at the study level, site level, and patient level, they are able to identify missing or inconsistent data, data outliers, and data variability. They can spot protocol deviations, systematic errors, and data-integrity issues. They can analyze site characteristics and performance metrics. With this analysis, central monitors can determine the need for further remote or on-site monitoring, carefully targeting investigations to data that signal possible risk. This approach exponentially increases the likelihood of identifying and correcting issues early, when action can have a real impact on both patient safety and trial outcomes. It also eliminates unnecessary (and resource-intensive) cleaning of every piece of data, keeping the focus only on the data that are most relevant.

Data Scientists take this analysis one step further, using machine learning and predictive analytics to track trends in comparison to other sites and patients, both similar and dissimilar. This broader analysis pinpoints specific sites that bear closer examination, again, targeting areas of suspected risk—and again, maximizing risk-based quality management.

To modernize trials, data alone are not enough

Today, clinical researchers are drowning in data. Yet, without data literacy, the numbers mean nothing; it is impossible to determine either the quality or the implications of the data.

Data literacy allows researchers to understand both—an understanding that is crucial to risk-based quality management. Researchers must have a facility with numbers, charts, and graphs. They must have a clear grasp of the data's origin, how the data were collected, cleaned, and analyzed. Crucially, they must be able to identify the most valuable data and to ascertain their true meaning.

Without that ability, clinical trials cannot innovate, iterate, or modernize.

It is really that simple.