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BUSINESS BRIEF

Optimizing Data Quality: A Critical Factor in Minimizing Clinical Trial Risk

It's a well-known fact that poor data quality increases the risk in clinical trials. So, when designing/ conducting a clinical trial, it's important to ask questions relating to the gathering, management, and evaluation of the data. What is being measured? Are data sources validated? How many sites are involved? Are they all measuring the same things? How accurate is the data? On what was it measured? How often was it measured?

Today, collecting and sharing clinical trial data is easier than ever with the aid of cloud-based technologies. Still, there is no guarantee that the resulting data metrics from all systems can identify any risk in a given trial or help researchers make decisions about protocol, such as making changes or requiring monitoring of a conditional event.

In order to mitigate this risk, a recent *Applied Clinical Trials* article contends, there needs to be cross-industry, standardized, metrics tools — like those offered by TransCelerate Biopharma — that track data quality performance and identify risk factors.

Over 15 years ago, the Tufts Center for the Study of Drug Development (CSDD) first emphasized the importance of using standardized performance metrics for clinical data quality (and therefore risk). In 2015, the Metrics Champion Consortium (MCC) defined some of the benefits that can be derived from these kinds of tools:

- Establishing clear, consistent performance expectations for internal and external operations
- Facilitating adoption of best practices across sponsors and services providers
- Ensuring consistent measures [which] reduces the "garbage in-garbage out" problem

SRINIVAS KARRI
DIRECTOR, PRODUCT STRATEGY
ORACLE HEALTH SCIENCES

Srinivas Karri leads Oracle Health Sciences' Data Management capabilities, and brings years of experience consulting on and managing large data volumes in complex clinical trials

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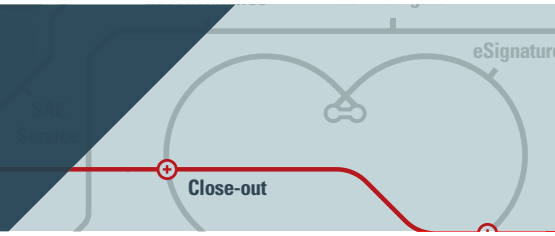
Oracle Health Sciences breaks down barriers and opens new pathways to unify people and processes, helping to bring new drugs to market faster.



- Avoiding the cost of custom programming
- Supporting comparison of performance across all studies within an organization, including across multiple vendors
- Decreasing time spent trying to understand what is being measured and focusing on achieving meaningful process improvement

The MCC also created standard definitions for common data elements from site activation to database lock. Additionally, specific to its risk-based monitoring initiative, TransCelerate has defined standardized tools for assessing and monitoring risks.

Standardization of data and reporting capabilities will become even more critical as more clinical trials are implemented with a risk management approach. Ensuring there are standard processes and data reporting capabilities will allow companies to assess their risk-based monitoring approaches and take action to ensure effectiveness.

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*TransCelerate Biopharma Inc. is a nonprofit organization with a mission to collaborate across the biopharmaceutical research and development community to identify, prioritize, design and facilitate the implementation of solutions to drive efficient, effective and high-quality delivery.

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