Data Management: Taking the Right Turn at the Clinical Trial Crossroads

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The success of a new drug depends on much more than its efficacy and safety or the ingenuity of its developers. Each clinical trial has multiple decision points, and taking the wrong turn at any of these can put the entire project at risk. Data management, fully integrated into the clinical study, is a cornerstone for informed decision-making.

Data management is an integral part of any clinical trial, enabling biotech companies to stay on top of the vast amount of data generated for a drug candidate. If performed correctly and with expert knowledge, it promotes the success of a new drug each step of the way. A thorough clinical trial design lays out the groundwork for data quality.

At this stage, the data management team should review the protocol and ensure that the data to be collected matches the chosen clinical endpoints while considering the particular medical indication and input from clinical practitioners. Data management experts should be involved in the study design phase to ensure that all data needed for the next steps in clinical development are captured.

Checking data quality in real time

Christopher Komujuni, Associate Director of Electronic Data Capture and Data Management at LINK Medical, clinical trials, data management Christopher Komujuni, Associate Director of Electronic Data Capture and Data Management at LINK Medical Throughout a clinical trial, data management experts guide the study teams and study sites to generate a smooth information flow, with all relevant data collected at the time points determined by the study design. Data entry inconsistencies should be detected and fixed as soon as possible.

“Manual reviewing, jumping between different parameters or having to go back to individual sites increases the risk for mistakes. We recommend using software solutions that provide logical checks and continuous data monitoring to identify collection and entry errors or data inconsistencies in real time,” said Christopher Komujuni, Associate Director of Electronic Data Capture and Data Management at LINK Medical, a Swedish contract research organization (CRO).

Pandemic effects on clinical trial data collection

Gunnar Danielsson, Senior Regulatory Advisor at LINK Medical, data management, clinical trials
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The need for automated data monitoring through software solutions has been reinforced during the Covid-19 pandemic. Since travel restrictions have stopped monitoring experts from visiting study sites, they cannot verify source data in person.

As a result, regulatory authorities have shifted their focus from on-site evaluations to central monitoring of the company running the trial, called the sponsor. Even if the concept of central monitoring is not new, it has become a more vital part of the quality control in the pandemic situation, making internal data review and strict adherence to regulatory requirements even more important.

“The international regulation for conducting clinical trials has recently been updated by the FDA and the EMA with specific requirements for central monitoring,” Gunnar Danielsson, Senior Regulatory Advisor at LINK Medical, explained. “So it is very likely that this trend is going to stay.”

Generating meaningful clinical trial reports

At the end of the clinical trial, data management experts prepare the collected data for statistical analysis to generate comprehensive, reproducible and verified reports compliant with current standards and regulatory requirements.

They specify the trial status, inform statisticians on how to proceed with the collected information, and give recommendations on handling data that are missing or have not been verified and officially signed.

“For every unique study, we develop a structure to organize and harmonize the data collected and generate a summary of data status throughout the study,” Komujuni explained. “We analyze trends, identify graph outliers, and make sure the official guidelines are met.”

Reliable data for a fruitful business

Clinical study reports are not only an exercise required by the authorities. They highlight the benefits and possible shortcomings of a new drug candidate. A thorough review of the reports can facilitate decisions on how to proceed – to the next clinical phase, to market authorization, or not at all – and is essential for decisions promoting the biotech’s financial success.

Besides, clinical study reports are closely evaluated by companies interested in licensing and buying a drug candidate. Poor data management has the potential to severely affect business.

“Pharma companies won’t buy a drug unless they are convinced that they can trust the data. They will look at every nitty-gritty detail to be sure that the biotech knows what they are doing,” Danielsson stated.

A team approach to successful data management

Overall, high-quality data management involves a huge effort, and most biotech companies do not have the capacity to do it on their own. Working with an experienced partner can be an ideal and cost-effective solution.

“At LINK Medical, the management of data is always a team approach between data management, statisticians, clinical operations, medical, and regulatory experts. Our sponsors are an integral part of that team,” Danielsson said.

“Our sponsors are fully aware that while you can outsource your data management, you cannot outsource the responsibility for your data. That’s where we come in to make sure that they are aligned with regulatory requirements and know what they need to do at every step of the clinical trial.”

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