

Rho Combines CTTI Resources to Operate with Optimal Efficiency and Data Quality

Rho Applies CTTI's Decentralized Clinical Trials and Quality by Design Recommendations

SUMMARY

Full-service contract research organization (CRO) Rho used a suite of CTTI resources to optimize a large observational study of risk factors for chronic lung allograft dysfunction, or CLAD. Using key resources from CTTI's Decentralized Clinical Trials (DCT) and Quality by Design (QbD) recommendations, Rho was able to build alignment to support a continual assessment of data quality throughout the study, leading to faster database lock and less pressure on sites.

GOAL(S)

The study needed to analyze 746 participants across five centers in North America through a broad spectrum of clinical information, including clinical findings, bronchoscopy, microbiology, radiographic information and more. Although they needed a wide range of data to support their endpoints, the study team did not want a protocol that placed undue burden on study coordinators and sites. To that end, the protocol allowed for data to come from multiple sources simultaneously. Traditional input from study coordinators would be complemented by electronic patient reported outcomes, or ePRO, electronic health record (EHR) data, specialized lab data, and data from a national registry.

CHALLENGES

While the multi-data-source solution eased site burden, it presented other challenges. Namely, several members of the study team had never worked with ePRO and eSOURCE data that could not be easily queried. The team needed a defined process for managing the flow of data efficiently and keeping data managers focused on the right data to appropriately meet the study endpoints.

SOLUTION(S)

To ensure they executed the study optimally, Rho, the principal investigator and the sponsor leveraged CTTI's recommendations and resources. Two stood out to address the challenges they faced: CTTI's DCT recommendations, which help trialists design trials that sit on a wide spectrum, from completely virtual, partially decentralized or those similar to traditional "brick and mortar" trials; and CTTI's QbD recommendations, which help trialists plan upfront in a way that focuses the team on the important components that are critical to the study's success.

TAKING ACTION

The first action the study team took was to ensure alignment of 1) where the data was coming from; 2) the frequency with which it was expected; and 3) the transfer routes it would take. To make this clear and understandable by the entire team and supporting sites, Rho created a data flow diagram similar to CTTI's [template for a data flow diagram](#), which outlines the typical passages of data from its collection by a mobile technology through to the composite analysis dataset. Creating a data flow diagram can support sponsors as they consider strategies associated with data integrity, access and security, as well as preparing audit trails and for FDA inspection. For Rho, this activity was critical to help them plan for how to handle data challenges. For example, once the data flow diagram was built, it was clear that the eSOURCE data would have a different patient identifier than the study. This led to the investigator site implementing a proactive solution to have sites merge data and map them to a single study identifier.

The study team also needed a strategy to ensure they were not getting overwhelmed and unfocused with all the incoming data from multiple sources. To establish alignment across all stakeholders, Rho used CTTI's QbD recommendations and resources. Specifically, the [Critical-to-Quality \(CTQ\) Factors Principles](#) document was a useful resource. The CTQ Principles document is intended to support proactive, cross-functional discussions and decision making at the time of trial development about 1) what aspects of a trial are critical to generating reliable data and providing appropriate protection of research participants and 2) what strategies and actions will effectively and efficiently support quality in these critical areas.

Using the CTQ Principles, Rho worked cross-functionally to align on the critical variables for the study. They established collaborative, central monitoring to determine what data to look at when, and regular meetings across diverse stakeholders allowed the team to assess the data continually, and cross-functionally. With a clear understanding of what elements of the study were meaningful to its success, study monitors better focused their efforts and data managers avoided wasted time on non-critical activities. For example, at several points during data collection, some surprising outliers were noted in the data. Rather than clean and understand every incoming data point, the study team used its identified CTQs to only address those surprising data that were directly aligned with the study endpoints, saving valuable time and effort. The approach also allowed the team to more quickly catch issues that were critical. At one point, missing data was identified from the national registry the study team was using, and the enhanced focus on the CTQ elements of the study allowed the issue to be captured and corrected rapidly.

IMPACT

Rho feels strongly that following CTTI's DCT and QbD resources supports higher data quality at the end of the study. By continually reviewing the data and addressing CTQ issues proactively, there was less pressure to get the database locked quickly by cleaning all the data at once. As a result, the study was not only streamlined, but also conducted with less site burden thanks to upfront thought and planning.

ADVICE


Rho stresses that having a statistician involved in the design and conduct of your study is crucial when dealing with multiple data sources. The time spent upfront to establish clarity around your data flow will allow you to reap benefits

down the road in terms of timelines. When working with ePRO, keep a close eye on data coming direct from the patient. By looking at it in real time, trialists can quickly spot issues, such as a patient not reporting at the correct frequency, and correct it before it is too late. Too often, study teams leave the data assessment until the end, only then realizing gaps and missed opportunities to support stronger data. CTTI's recommendations and resources can easily be used in complementary ways, as Rho did, to optimize multiple aspects of trial conduct.

ORGANIZATION

Rho

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ORGANIZATION TYPE

Industry

IMPLEMENTATION DATE

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TOPIC

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