The Impact of an INTEGRATED EXECUTION ENVIRONMENT on Data Management in Adaptive Clinical Trials

Aptiv Solutions

Anyone who has baked a cake can tell you that the quality of the ingredients is equally as important as following the recipe. Data quality in clinical trials is much the same way. You can follow the protocol and standard operating procedures completely but neither fully control for the quality of the data.

Thankfully, that job falls to the Clinical Data Manager (CDM), the organizers and consolidators of the data. Their job is to ensure the irrational is made rationale via query and making sure data meets the quality standards required to deliver results that can be held with the highest of confidence.

Data Management and Quality Control

Most experienced CDMs will tell you that it's been a while since the days of old where they would sit with a case report form and turn the pages and let the data speak to them. In today's modern age, data management quality control has shifted to a real-time precise programmed validation check environment, where each data point is logic-checked independently against discrete standards. Yet the challenge remains at data lock to ensure that data management (DM) has not lost its perspective and is still able to clean data at a higher level and in a holistic manner. These manual reviews are generally done in batch just prior to data lock. Therein lies the challenge in the execution of adaptive design trials, which by design necessitate many fully clean interim locks to facilitate future planning. Compounding these locks is that if they are to be done correctly they should be done in such a manner that only a handful of individuals are aware that the data are being taken for analysis. It becomes difficult to batch review data for each interim analysis without generating a wave of queries to sites.

Best Practices

So how can this be done while still ensuring the timely collection and highest data quality for each interim lock? A couple of solutions are analytics, data frequency reports, and programmed listings that look for data anomalies within a given site or cohort. The key is to do these batch reviews on a daily/ weekly basis so as to keep building upon the data quality as it's collected. This requires a bridge that allows a bidirectional flow of data from the EDC or data collector into a powerful analytical environment (SAS) and a mechanism to take the output and post queries back to sites. We developed what we call the Aptiv Execution Environment (AEE) for this purpose. This is a large collaborative undertaking and requires an investment in custom-built technologies that are scaled to an organization. Tools commercially available today to do these types of analytics have traditionally been relegated to the statistics department. Aptiv Solutions recently announced a partnership with SAS Institute that is aimed at taking those analytics and making them more readily available to clinical operations and data management through an integrated execution environment.

It's important that the tools allow the DM team to quickly identify in real time data outliers and relationships previously derived through manual review of paper listings. Technology, for example, can easily detect in the execution environment safety signals, such as a slow incremental rise in blood pressure; this may fail to trigger the checks on the discrete data points but when observed holistically show a clear trend. Issues such as these can be sent to the CDM in near real time to be followed up by query to ensure quality.

Contributed by

COREY B. DUNHAM, VP Data Management and Statistics, North America

The Future

The future of successful trial execution lies in the ability to clean data as close to the source as possible. The holy grail of an integrated electronic health records (EMR) and electronic data collection (EDC) environment remains a ways off, and a robust analytical engine to work in concert with it is even further still. In the interim the job falls to data management, and development of an execution environment is critical to the successful running of adaptive clinical trials. PV

Attribution: *Aptiv Solutions is a full-service international CRO with proven expertise in supporting global clinical trials for biopharmaceutical and medical device companies. Its well-designed trials span the development lifecycle from first-in-human through regulatory approval and beyond. For more information, visit aptivsolutions.com.*

AptivSolutions

Accelerating the Possibilities

ACCELERATING THE POSSIBILITIES

That's what Aptiv Solutions is all about. We offer flexible, customized solutions that enable biopharmaceutical and medical device companies to adapt to the rapidly changing development market.v

HARNESSING THE POWER OF ADAPTIVE TRIALS

Aptiv Solutions is the only CRO to offer design, simulation and execution of adaptive clinical trials – and the only partner to make fully functional adaptive trials a reality.

THE INDUSTRY LEADER IN MEDICAL DEVICE DEVELOPMENT

Aptiv Solutions has conducted hundreds of medical device studies – and every one of the PMA applications accepted for filing was approved.

THE OPERATIONAL SUPPORT OF A GLOBAL CRO

Aptiv Solutions has more than 700 professionals providing expert services from early phase product development consulting through to regulatory approval and beyond.

Learn how Aptiv Solutions can accelerate the possibilities for you, visit us online at www.aptivsolutions.com