Clinical

Efficient Data Management: One Way to Expedite the Clinical Development Process

In any clinical trial, the ultimate goal is simple: Deliver effective therapies to patients as quickly as possible in order to impact and save lives.

The catch? Using past conventional trial designs, it could take 15 to 20 years for a single drug to advance from discovery to the final stages of approval—and with lives on the line, there has been a push in recent years to expedite the clinical development process.

The focus now: How can we get an earlier read on how a drug is working and the patients it's benefiting so we can move toward drug approval or disapproval faster?

This shift in mindset paved the way for adaptive trials, which utilize a change-as-you-go strategy that evolves as new data emerge.

The Push for Efficiency

Adaptive trials bring a host of benefits: By designing a single clinical trial with multiple simultaneous cohorts, we can explore a wide range of different hypotheses at once—saving a significant amount of time, costs and resources compared to multiple sequential trials.

On the flip side: Compared to conventional trial design, adaptive trials are much more complex to design, write, set up and run. Essentially, you're managing multiple studies within the scope of one protocol.

That's where the importance of your data management comes into play.

Each adaptive trial is dependent upon the reliability of the data and the flexibility of the data management—factors that might be overlooked when evaluating how to expedite the clinical development process.

5 Tips to Help Streamline Your Data Management

Consider data the foundation of any successful adaptive trial—it's the most important deliverable, after all. How you manage that data makes all the difference, and these tips can help you increase efficiency and decrease costs.

1.

Build various paths into your database from the get-go.

Suppose an adaptive trial is designed to explore varying aspects of a drug—the treatment cycles, length of treatment and combination with other drugs. The key is to take these varying scenarios and build them into the database infrastructure before the study begins.

These different scenarios will dictate the dynamic triggers that are also built in from the onset. For example, responding "yes" in one database field will cause subsequent database forms to appear or disappear, making each patient's casebook adaptable. A good rule of thumb: Limit your study to five major arms. Beyond that, it'll likely be too complex to execute properly on both the clinical and data management side, resulting in data that is difficult to manage.

2.

Practice smart data capture.

Collecting every data point possible is burdensome and time-consuming, and it also increases the chance of human error. Instead, focus on the data that will be needed for analysis at the end of the study—not every detail of what's happening in the clinic is necessary to capture in the database and report in the trial statistics.

Exhibit A: A physical exam is needed to determine eligibility for a study. Rather than entering irrelevant details—such as body weight and height—that will never be used in the end, why not capture only the fact that a physical exam was completed? Those extra details, which will likely be measured again at the start of the trial, are still available in the clinical site documentation if you ever need them, but this way you can focus more energy on the science of the study versus entering extraneous data.

3.

Consider allowing the CRO to be involved in the protocol writing.

Often, the insights brought by various members of a CRO team—data managers, database programmers, project managers and statisticians, for example—can add new perspectives on how an adaptive trial may evolve. The advantage? You can ensure the protocol is then designed in a way that facilitates smart data capture.

4.

Maintain a global library of standard database forms.

Standard safety, physical exams, vital signs, medical history, prior medications, tumor assessment—these are just a sampling of the types of standard electronic forms you should have pre-designed within the database library to ensure your trial runs as efficiently as possible. That way, you can save valuable time by merely tweaking the standard forms as needed and focusing valuable database programming time on building the more complex adaptive design forms.

Other types of global library forms can also be added to the mix, such as oncology-specific forms, which take into account the many complexities found in oncology trials.

5.

Perform continual data review.

A common frustration among trial sponsors is that the data is not reviewed on an ongoing basis. The result? You may get to a critical decision point in a trial and need data to make a decision—only the data hasn't been reviewed or cleaned yet, causing a bottleneck.

A better alternative is to perform continual data review rather than waiting to review at the end of the clinical conduct. This includes developing great relationships with the research site to ensure proactive entry of data, reviewing the EDC data throughout the trial once it is entered, as well as reconciling ancillary data and SAEs. This will enable you to resolve issues early in the study—which means the data entry is cleaner going forward. Without continual data review, there's an increased risk of uncovering a major data issue at the end of the study that can cause delays for final CSR deliverables.

Ready to Get Started?

If you're seeking a partner who can help increase the efficiency of your adaptive trial from the get-go, we can help. We specialize in oncology—it's all we do—and our expert team aims to save you time, money and resources. We can build your adaptive design protocol and produce your ICF, file your IND, efficiently and robustly build an adaptive database, and provide expert oncology project management, clinical monitoring, medical monitoring, safety and statistics.

Contact us to get started today