

Getting the Most Out of Your Oncology Clinical Trial: A Conversation with Ashok Bhat



Overview

Oncology is one of the fastest-growing therapeutic areas for clinical research and is predicted to be the major revenue contributor to the top 12 pharmaceutical companies by 2012. The conduct of oncology clinical trials, however, is uniquely challenging, and requires a holistic approach to technology to obtain maximum efficiencies.

Ashok Bhat understands the specific challenges facing oncology trials. As Oracle Health Sciences vice president of EDC Global Service Practice, he is responsible for the design, development and project management of an integrated clinical research suite: Oracle Health Sciences InForm GTM and Oracle Health Sciences OutcomeLogix On Demand. In addition, he has assisted worldwide enterprise adoption customers who have installed and utilize Oracle Health Sciences InForm GTM and related technologies. Previously, Bhat held senior roles at GSK, Cell Tech, and Covance. He holds an MSc in mathematical statistics and a postgraduate certificate in health economics. He is a chartered statistician and Fellow of the Royal Statistical Society. Here, Bhat discusses the challenges facing clinical oncology trials.

Frequently Asked Questions

Why is the conduct of oncology trials so challenging?

The very nature of the diseases targeted in these studies is the source of the complexities encountered by sites and sponsors. Cancers often involve complex and toxic therapies, a high incidence of treatment- and disease-related adverse events, and co-morbidities. To account for these challenges, many oncology studies have novel study designs, detailed inclusion and exclusion criteria defining eligibility, complex randomization schemas, carefully defined treatment regimens, and detailed requirements for treatment and management of emergent events.

Given the complexities of these studies, what is a sound technology strategy for sponsors conducting oncology trials?

To fully assess the safety and efficacy of an oncology investigational compound, study sponsors should utilize a broad spectrum of integrated clinical technology. These trials require a lot of flexibility, as study protocols can change midtrial and from patient to patient. Having easy access to all the necessary technology at the start of a study allows sites to quickly apply the correct solution when a technology gap materializes.

Ideally, sponsors should also look to leverage preexisting technology integrations and employ a central data repository where data can be aggregated and tracked and discrepancies can be reconciled. These capabilities will help sponsors better ensure that data analysis is current and accurate.

When selecting technology for oncology research, where should sponsors start?

Central to any well-designed oncology study is the need to accommodate the complex study designs, cycles, branching, and the huge number of rules and edit checks inherent to the therapeutic area through an industrial-strength electronic data capture [EDC] system. Because midstudy protocol changes exacerbate all of these challenges, the EDC system should also be flexible and capable of handling the rigors of high data volumes and long trial durations.

What other key areas benefit from technology?

Automating and centralizing the overall supply chain for randomizing subjects and dispensing medication kits helps organizations better manage their supply inventories and eases trial overhead by reducing drug waste, which can be particularly costly in oncology studies involving extremely expensive pharmaceuticals and biopharmaceuticals. Interactive response technology [IRT] solutions or interactive voice/Web

response systems [IVR/IWR] are typically employed to manage this activity.

Cancer patients, however, often take a powerful combination of therapies—for example, chemotherapy or radiation in addition to drugs and inhibitors. The combination and toxicity of therapies can produce different reactions in patients, which complicates developing and executing a dosing regimen. The more-advanced IRT systems offer the most benefits to trial sponsors by allowing study personnel to change study parameters midstream to accommodate the irregular needs of cancer patients and to intelligently forecast clinical supply.

How does medical imaging fit into the technology puzzle?

Oncology trials typically rely heavily on medical imaging to evaluate the performance of new drug candidates. Such imaging can be effectively used to make drug development “go/no-go decisions” regarding the potential efficacy of a drug, so as to end or continue projects before they become too costly. Positron emission tomography [PET] scans, for example, are used to detect whether a cancer has spread, which can help determine the effectiveness of a therapy or drug.

When imaging technology is integrated with a robust EDC system, sponsors have the ability to fully synchronize the trial’s clinical and imaging data. This combination gives the sponsor insight into when images are shipped, tracked, and received, improving the reconciliation process and leading to quicker database lock.

What is the importance of the central data repository?

With the enormous amount of data generated in oncology trials from multiple sources—including EDC, IRT, electronic patient reported outcome [ePRO], imaging, laboratories, safety tracking, and reporting—sponsors need a central repository to aggregate, transform, and store all the data and metadata.

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Hardware and Software, Engineered to Work Together

Controlling all this information from multiple collaborators and partners is highly complex, and maintaining traceability between the flow of new information and the analysis of results is difficult. Consolidating overall data integrations can help sponsors meet regulatory requirements more effectively.

When the repository is coupled with a statistical control environment, all the upstream data in the repository can be linked to the downstream analysis, reporting, and submission processes. Understanding all the upstream and downstream dependencies can help sponsors make better decisions and manage the full lifecycle of data and results. This can bring new levels of efficiency to oncology trials and help accelerate the time to database lock, as well as drive down costs.

How can this holistic technology strategy be best achieved?

Harnessing a full suite of clinical development technology that can automate the management of the entire clinical development process through a single environment (from study setup through regulatory submission) can reduce total cost of technology ownership and ease much of the complexity inherent in oncology trials. There are many opportunities today for trial sponsors to invest in technologies that will automate much of the clinical development space. Yet maximum efficiencies can be gained only with a full suite of clinical and safety technology from one provider with existing integrations. With a single point of delivery and accountability, sponsors can reduce development costs and the difficulty of managing unique environments and custom integrations. Sponsors can then focus on delivering quality results, rather than managing a ballooning stable of technology vendors.