Case Study

Creating an Innovative EDC Build Solution for Oncology Master Protocol Designs



PROJECT BACKGROUND

With oncology research, the clock is always ticking. This is why many oncology clinical trials use master protocols and other innovative designs. These kinds of studies, such as basket and umbrella trials, look to speed therapy development by investigating as many hypotheses as possible, all at once, through multiple concurrent studies and sub-studies. This increases the complexity of the trials and requires a high degree of flexibility – to deal with the inevitable need for amendments.

COMPANY PROFILE

- Oncology-focused biopharmaceutical company
- Headquartered in United States

SERVICES UTILIZED

- Biometrics Services
- Clinical Data Acquisition

THE CHALLENGE

A leading specialty biopharma company focused on developing innovative new oncology therapies planned several early phase clinical trials using complex designs including master protocol approaches. The company's portfolio included trials with up to 12 study arms, some with over 15 patient cohorts. These study arms typically involve multiple external data sources and protocol amendments are common.

Traditional EDC build approaches for these types of designs require a new casebook for each study part, a time-consuming and labor-intensive process that creates an operationally inefficient EDC build, risks downstream complications when study arms are added or dropped, and incurs greater (up to 4x) software pass-through costs as well as overall services costs.

The company needed a flexible electronic data capture (EDC) build solution that would allow them to collect the data from multiple study arms within complex master protocols in a more streamlined manner, avoiding time delays as compared with the traditional EDC approach, without the additional software costs.

THE APPROACH

The company understood the need for a more robust and flexible EDC database design to support its complex trials. Seeking a partner experienced with these types of studies, they turned to eClinical Solutions' Biometrics Services team. With over 15 years of innovative trial experience and longstanding partnership with Medidata, the eClinical Solutions' clinical data acquisition team was well placed to create a database design tailored to the client's requirements.

eClinical Solutions' approach to database build is to assign a lead programmer end to end – this streamlines communication and ensures that client queries and issues are resolved quickly to smooth the process to database go-live. Working closely with the client team, the assigned lead clinical programmer created and proposed an adaptive database design that could address the dynamic nature of trials operating within master protocols. This highly innovative database structure effectively builds multiple studies in one and is well suited to study designs with multiple cohorts, dose escalations, and other study-specific complexities. This flexibility enables the study team to efficiently manage and implement changes, such as post-production amendments, without causing disruptions to ongoing studies.

In line with its typical processes the eClinical Solutions team implemented global library and portfolio standards for the client, ensuring consistency and reusability across different studies and study arms, and allowing for the rapid deployment of standardized elements while retaining the ability to make changes as necessary.

RESULTS

By collaborating with eClinical Solutions, the biopharma company has been able to effectively collect and manage the data for its portfolio of complex trials, achieving rapid study start-up with the ability to easily customize to meet specific study requirements. The solution delivered flexibility throughout the life of the study, not solely at study start-up and reduced the client's risk by mitigating the potential for costly delays and bottlenecks when introducing changes or amendments to study protocols.

Subsequently, the eClinical Solutions team has successfully deployed this unique build approach on several master protocol type designs for other trial sponsors.

Success Factors

- Culture of innovation across the team promotes a strategic focus and the ability to craft ingenious solutions for complex data challenges.
- Deep experience in, and commitment to the Medidata Clinical Data Cloud® for EDC implementation enables greater flexibility and customization for clients.
- Over 550 trials delivered in Medidata Rave™ and over 220 oncology studies.
- All members of the clinical programming team have clinical domain knowledge and training, with the ability to translate even complex protocols into effective data capture solutions.
- Assignment of a lead programmer throughout a project and across portfolios creates deeper connection with the client's challenges and priorities and enhances overall communication.