› CASE STUDY

VERISTAT

Data Collection Efficiency for a Sponsor Developing a Novel Anti-Infective Therapy

A Creative Database Design Approach Streamlines Data Capture from Phase II-III

Background

More than five years ago, Veristat began working with a clinical-stage biotechnology company focused on the development of novel anti-infectives. The partnership began with strategic and statistical consulting on the study design for a program of multiple antifungal products in both topical and intravenous (IV) formulations. Once the programs were ready to begin, Veristat supported two Phase II studies, providing Data Management (including design of the Electronic Data Capture [EDC] system), Biostatistics & Programming, CDISC Data Conversion, and related Project Management oversight.

Study Demographics

Phase II

200 Patients

Sites in NA and EU

THE CHALLENGE

A Complex Situation

The first Phase II study anticipated the enrollment of more than 200 extremely sick patients diagnosed with fungal infections. The full global project team included more than 25 members from the sponsor, Veristat, various clinical monitoring organizations, Central Labs, and third-party vendors. Due to the patient disease-state, the study duration for each patient was less than one month, yet the amount of data collected was much higher than a typical study. For example, most patients had more than 100 concomitant medications and more than 60 medical history reports to collect.

For the first of the Phase II studies, the sponsor requested an interim analysis where all patient data would be locked partway through the study, a recommendation from the Regulatory Agency.

SOLUTIONS

Meeting Both Regulatory and Sponsor Needs

Initially, our sponsor planned to build two databases to accommodate the Regulatory Agency's request. However, Veristat's data management team devised a more flexible approach to save time and cost. We built a single database but partitioned it into two parts, Part A and Part B. Part A would contain the patients in the interim analysis, which would be locked at the time of the analysis. Part B of the database could continue enrolling and collecting data for patients after Part A was locked. We had to customize all data management processes to accommodate this design-build in the EDC system. Our client was extremely appreciative of this as they didn't have the budget to build multiple databases to accommodate the interim analysis.

Our data management team also performed data cleaning, safety reconciliation, and lab reconciliation. We provided the clinical monitors with regular metrics, such as open queries and other data points, to help them keep up. With the short time of patient treatment and the need to lock Part A of the database for the interim analysis, the monitors and sites needed to keep current with all data entry and query resolutions. A healthy communication plan between the sponsor, Veristat, and all the third parties involved in this project was key to the success of this trial. Moreover, the interim analysis was critical for the sponsor to move forward with their Phase III trial.

Critical Success Factors

- **Flexibility to adapt processes –** The Veristat data management team modified and customized the normal processes and Standard Operating Procedures (SOPs) to accommodate the interim analysis.
- **Responsiveness –** Overcommunication and metrics sharing with the sites enabled swift responses to resolve outstanding data queries.
- **Collaboration amongst the global team –** The sponsor, our team and all the other vendors involved in this program were very collaborative.

"I have been the lead data manager on this program for the past 3+ years. This is my absolute favorite client because I truly feel like part of their project team, not just a data management vendor. Our client is extremely collaborative, honest, and fair, even in the most difficult conversations. It is a real pleasure to contribute to the success of their promising therapies."

Sonia Haroun, *MS, Clinical Data Manager II, Veristat*

IMPACT

Saving Time and Cost

The client's Phase II trial evaluating its lead antifungal candidate met its primary objectives for efficacy, safety, and tolerability in the treatment of its patient population. Our client was so pleased with our work on the Phase II study that we just completed the database build for the Phase III trial, which is even more extensive and now includes sites in North America, Europe, and Asia. Since our team built the Phase II database, we were able to leverage the existing eCase Report Forms (eCRFs) to reduce the time and cost to build the Phase III database. The Phase III trial is now enrolling patients, and our data management team is currently providing support for data cleaning, external data and safety data reconciliations for the Phase III program.

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Learn more about Veristat and how we can assist you capture and analyze your clinical trial data for single trials and entire programs in submission ready format.

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