



CASE STUDY

Does Size Matter? Rescue from a Large CRO

THE CHALLENGE

Missed timelines and EDC build errors compromised the potential success of the company's phase 1 study.

THE SOLUTION

Experienced team members and robust internal reviews resulted in a timely, high-quality EDC build and data management plan.

THE OUTCOME

After the successful rescue, the partnership has expanded to include other studies.

A US-based biotechnology company contracted with a large CRO for a phase 1 study of an immune disease, with the intent of keeping the entire study under a single contract and project manager. However, very early in the study, the company realized that it was not getting the desired performance from the CRO's database build and data management teams. A key challenge was poor communication within the CRO's internal EDC build, data management, and statistics teams as well as between the CRO and the biotech company. In addition, timelines were not met, and the first database build had significant errors. Therefore, the company contacted the Veranex Clinical Data Services (CDS) team to rescue the study.

The Veranex CDS team assigned to this project consisted of EDC build engineers and data managers with years of experience across a number of therapeutic areas who use robust, standardized processes to approach all projects. After receiving

access to the company's Medidata URL, the Veranex CDS team leveraged as much existing work as they could to create the rest of the study. All work was reviewed by the internal Veranex team within the CDS data management ecosystem for the highest quality work possible. As a result, the team quickly finished the EDC build and related data management plan and completion guidelines.

The study was put into production within only 6 weeks. The company has since transitioned all data management activities to Veranex CDS. Veranex CDS has also built the EDC and data managed 7 other studies, ranging from phase 1 through phase 3, for multiple conditions. Veranex also manages the company's Medidata URL and global library.

6 weeks

to rescue and put the study into production

8 studies

built and data managed by Veranex CDS

