

CASE STUDY

DATA EXPERTISE RESCUES STUDY BY A TOP 3 GENERICS CRO

How a Veranex FSP Partnership Helped a Leading CRO Save the Day

▶ **The Challenge:** Enrollment and Database Challenges Threaten Study Outcome

A top three generics CRO needed an FSP partner to assist with data management, statistical programming, and medical writing for a generics study. Unforeseen circumstances began to unfold, casting uncertainty over the IP's future — and, eventually, turning the project into a rescue operation. Enrollment delays tightened the study's timeline by two months, introducing the first challenge to the CRO's program. Compounding the problem were database reconciliation issues. The study leveraged three database systems — RAPIDS, ERT, and Medrio — and entries weren't consistent across all three. The CRO's RAPIDS IRT system and ERT's spirometry database contained subjects that were not present in the Medrio database, leading to the premature closure of study sites. It was beginning to look dire when the study failed to meet the equivalence criterion in both co-primary endpoints, despite meeting its superiority endpoint. Enter Veranex.

▶ **The Solution:** Data Sleuthing and Fast Action to Solve for Success

Straight away, the Veranex data management team noticed database queries were aging and failing to resolve. Veranex brought it to the CRO's attention then took the lead in identifying the root causes. Veranex collaborated with the CRO's team of clinical research associates to identify low-enrolling sites and determine whether they were at risk of closure. Then, Veranex targeted those sites for source data verification and monitoring activities to ensure data were cleaned before closure, providing round-the-clock resources from then until the final database lock. Meanwhile, the Veranex medical writing team finalized the clinical study report (CSR) shell as early as possible. This would minimize the time spent completing documentation and M5 submission once the final tables, lists, and figures (TLFs) were released. Finally, Veranex statisticians recommended a reanalysis of the study. Though the first analysis concluded that the study failed to reach its equivalence criterion endpoints as outlined in the protocol, Veranex suspected that by rooting out the source of the database resolution error, then troubleshooting the issue, they'd yield a more accurate outcome — even favorable.





The Outcome: Partnership Rises Above the Odds, and the Study Passes

Through a series of investigations, Veranex was able to determine the reason for the discrepancies in the databases: both the ERT and RAPIDS databases contained false subject entries that didn't correspond to actual study participants. Veranex worked with the CRO's CRAs to resolve the issue, eventually reconciling Medrio to RAPIDS, and provided the necessary knowledge sharing to avoid similar database issues in future studies. After a reanalysis of the resolved data, both the equivalence and superiority endpoints were met, and the study passed — adding yet another success to the CRO's already impressive generics portfolio. To round out the triumphant final lap of the study, the Veranex medical writing team finalized the M5 documentation quickly enough to shave a month from the extended timeline, minimizing delays caused by enrollment issues. It came down to the wire, but the strength of both the CRO's IP and Veranex data expertise rose above the challenges to ensure a successful outcome — all while proving the power of partnership.

ABOUT VERANEX

Veranex is a global medical product developer that brings expertise in design and engineering, human factors, regulatory affairs, quality systems, preclinical studies, clinical trial strategy/execution, data management and analytics, reimbursement, and market access together with integrated support for your entire product life cycle. By uniting these industry-leading service organizations — IMMR, Experien Group, Ximedita, Worrell, Boston Healthcare Associates, and Quartesian — Veranex delivers expert guidance that accelerates your speed to market, controls development costs, mitigates development risk, and accelerates market viability assessment. From concept-to-commercialization, Veranex customers realize efficiencies in cost and time through integrated and comprehensive solutions that unify your entire development process.



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