Veranex
Transforming Your MedTech Innovation

CASE STUDY

VERANEX HELPS TOP 10 GENERICS SPONSOR FILE FIRST

Veranex Overcomes Trial Obstacles to Help Move Taro to the Front of the Line

The Challenge:
Enrollment and Monitoring Delays Threaten First-to-File Submission

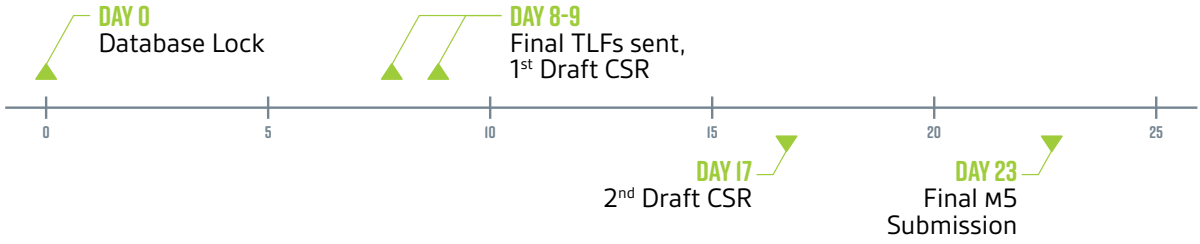
Taro Pharmaceuticals is one of the world's top 10 generics sponsors, with a portfolio spanning dozens of prescription and OTC medications and a strong foundation in dermatology topicals. Taro faced a tight timeline for a clinical program testing a generic dermatological treatment and knew they needed a strong clinical data partner to secure first-to-file status. Taro needed a provider large enough to provide the breadth of services needed, yet small and nimble enough to adapt and meet tight timelines. They called on Veranex to provide the clinical data management, statistical programming, and medical documentation needed to clear their aggressive deadline. Once the partnership was underway, two unforeseen circumstances threw a wrench into the program. The first was a delay in enrollment, which threatened the timelines of everything that followed. Monitoring issues also pushed back the database lock, further straining the client's likelihood of being first to file.

The Solution:
Round-the-Clock Data Management and a Process Tuned for Speed

Refusing to lose ground to Taro's competitors in the generics space, Veranex ensured that resources were available during the holidays to complete database lock and medical writing. To minimize delay, Veranex worked closely with Taro to plan their monitoring visits and developed backend monitoring reports to provide the CRO with CRA performance metrics. As the study progressed, Veranex provided round-the-clock coverage to clean data and lock the database on the earliest possible date. The medical writing team also finalized the clinical study report (CSR) shell early, reducing the time it would take to complete the documentation when the final tables, listings, and figures (TLFs) were released. Veranex submitted the first draft of the CSR less than 24 hours after receiving the final TLFs. By planning and frontloading as much work as possible, Veranex made every effort to help Taro complete the study quickly enough to lap their competitors filing similar generic submissions — all while providing compliant, high-quality data.

The Outcome:
First-to-File Submission

Veranex worked hard throughout the holidays, including Christmas and New Year's, and it paid off in a big way, enabling the team to meet the CSR submission date on schedule — in spite of the tightened timeline. The partnership also paid off for Taro, enabling the CRO to secure the coveted first-to-file status on their generic IP.



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, Ximedica, 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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