Worldwide Clinical Trials

Case Study

First FDA-Approved Oral Therapy for Adult Lupus Nephritis

Pivotal Phase III data delivered on the timeline our sponsor needed to win first-to-market approval in a competitive class.

Background

Our sponsor was developing a breakthrough oral therapy for adult lupus nephritis in a class where another agent was approaching FDA approval at the same time. The Phase III pivotal trial had to deliver clean data on schedule despite natural disasters at sites, unpredictable patient flares, and the complexity of recruiting in an episodic disease. Slippage on the trial timeline would have delayed both the FDA submission and the first-to-market positioning.

27
Countries

270
Sites

358
Patients met primary endpoint

Delivering On-Time Enrollment in a Rare, Episodic Disease

Challenge

Narrow enrollment windows

Patients often feel well between flares, and sites risked missing short windows to administer treatment.

Complex eligibility & diagnostic pathways

Lupus nephritis diagnosis depends on renal biopsy and tightly defined serological criteria, adding risk to screening accuracy.

Unpredictable external events

Natural disasters and unexpected medical events disrupted site activities across multiple regions during the study.

Data quality under time pressure

The sponsor's regulatory timeline required a database lock on schedule without compromising data integrity for a pivotal endpoint.

Solutions

Strategic site deployment

We selected sites with strong lupus referral networks and aligned them with high-prevalence regions, thereby maximizing access to eligible patients during active periods.

Tailored therapeutic area expertise

Worldwide nephrology and autoimmune medical experts supported clinicians in interpreting eligibility criteria, reviewing histology, and conducting protocol-specific assessments throughout enrollment.

Trust-based site relationships

Established relationships with investigators and patient advocacy groups enabled us to quickly move enrollment to unaffected sites and keep the overall timeline on track.

High-quality patient education & data oversight

Educational materials supported consistent patient-reported outcomes, and real-time central monitoring kept query resolution up to date, ensuring the data package was submission-ready at lock.

Results

Enrollment

The study enrolled ahead of schedule, even after natural disasters affected some sites.

Delivery

We delivered the database lock on time, with data quality strong enough to support a pivotal regulatory submission.

First to Market

Our sponsor became the first FDA-approved oral therapy for adult lupus nephritis, supported by the trial data we delivered on schedule.

Worldwide Nephrology Franchise Experience

Proven delivery in lupus nephritis, C3G, IgA nephropathy, primary hyperoxaluria, and other rare renal indications. Global access to ultra-rare patient populations. Diagnostic accuracy through central pathology review. Creative enrollment tactics including early flare detection.

> Lupus nephritis patients often don't feel immediately unwell between flares. If we miss that window, we miss the chance to treat them.

Ingrid van Rompaey, PhD

Executive Director, Project Management, Rare Disease, Worldwide Clinical Trials

Worldwide Clinical Trials

About Worldwide Clinical Trials

Worldwide Clinical Trials (Worldwide) is a global CRO serving development-driven biopharmaceutical companies, with more than 4,400 professionals operating across more than 70 countries. The company delivers therapeutically dedicated expertise in neuroscience, oncology, rare disease, and internal medicine, with comprehensive support across every development phase – from early-stage and first-in-human studies through Phase III registration trials.

The company's flexible service model – spanning full-service trial management to functional service partnerships through Worldwide Flex – is powered by a people-first, partnership-driven outsourcing approach that strengthens collaboration, enhances data transparency, and supports more informed decision-making. This provides sponsors with tailored, adaptable solutions that keep pace with the evolving demands of clinical research.

Learn more at www.worldwide.com.