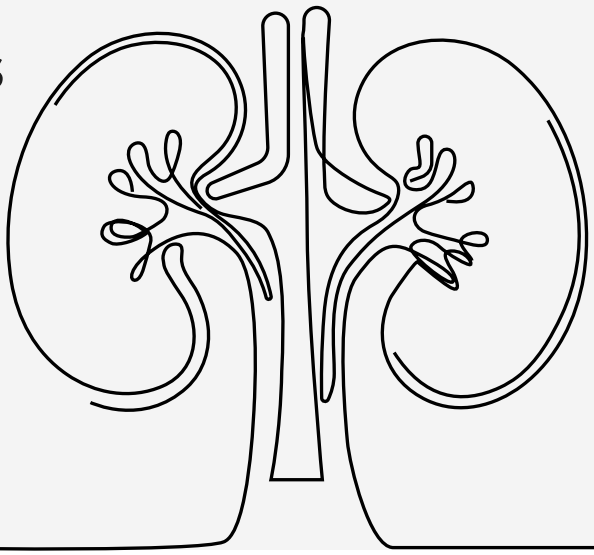
Worldwide Clinical Trials

Case Study

Case Study: Supporting Sites and Subjects in Phase III Rare Kidney Disease Study



A sponsor approached Worldwide Clinical Trials (Worldwide) with an ultra-rare indication known as C3 glomerulonephritis (C3GN), a rare kidney disease. Given the Phase III study's complex logistics and unique indication, it faced various challenges, which Worldwide promptly addressed to ensure study success.

Study Challenges

01

C3GN is an ultra-rare indication, which can often be misdiagnosed through biopsy testing.

02

The study had strict urine protein creatine ratio (UPCR) entry criteria, which impacted recruitment efforts.

03

As part of the clinical trial, participants had to endure multiple kidney biopsies, which increased the burden of participation for the patients.

Study at a Glance

19
Countries

122
Sites

124
Patients Enrolled

Screening Rate:
0.21 patients per site per month

Enrollment Rate:
0.08 patients per site per month

Worldwide's Solutions

1 Site Support

- Coordinated in-person IM meetings (data sharing, education, etc.)
- Provided pre-screening tools and chart reviews
- Utilized a collaborative sponsor/CRO approach
- Offered 24/7 medical monitor access

2 Complex Study Logistics Management

- Handled biopsies and 24-hour urine collections to support eligibility and primary efficacy endpoint
- Closely managed sample logistics

3 Focus on Patient Recruitment and Retention

- Provided home health, travel concierge, and patient navigator services to reduce patient burden
- Heavy emphasis on the physician-patient relationship
- Used patient-friendly and understandable documents
- Organized at-home pick-up services for 24-hour urine collections

Outcomes

- Study enrollment target was met **three weeks ahead** of schedule.
- Enrollment completed at **130% of target**.
- Both C3G and IC-MPGN **enrollment objectives were met**.
- **Long-term patient retention** was achieved.

Worldwide Clinical Trials

Get Worldwide's Support for Your Rare Disease Study

Given the small number of patients in rare disease clinical trials, it's essential that you partner with a CRO capable of managing the complexities and challenges that these studies often face. With decades of combined experience among our **rare disease experts**, Worldwide is here to support your rare disease study from start to finish. To learn more about our full-service capabilities, **get in touch** today.

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