

RHEUMATOID ARTHRITIS

Foresight and global experience reduce the enrollment timeline for a phase II study by two months in spite of challenges due to H1N1.

ResearchPoint SERVICES:

- ▶ Global Project Management
- ▶ Clinical Monitoring
- ▶ Medical Monitoring
- ▶ Medical Writing

This phase II, placebo-controlled study involves 264 subjects across 37 sites in nine countries and evaluates the study drug as adjunct therapy in subjects currently receiving Methotrexate. A secondary study objective is to assess the drug's safety and efficacy.

CHALLENGES: The study began during the onset of the H1N1 epidemic directly impacting the start of enrollment in Argentina and Mexico. Additionally, working globally in any industry has the potential for challenges. Collaborating among a variety of geographic locations with differing regulatory environments, varying time zones, language barriers, and cultural differences all can present problems. For this study specifically, ResearchPoint Global (RPG) also experienced unexpected delays, along with significant regulatory changes from country to country, and changing timelines in each region, further intensifying issues.



37 SITES ACROSS 9 COUNTRIES

ACTION: We proactively began enrollment in Germany, ahead of H1N1 arriving in Europe, to offset the delay in Latin America. Our foresight to anticipate enrollment issues allowed us to complete enrollment **two months ahead of the projected timeline.**

As an established organization with 22 regional offices and coverage in 65 countries, ResearchPoint Global had the infrastructure in place to successfully conduct this study. Each RPG office provides local expertise of the regulatory, importation requirements and research environment and operates from RPG's common set of global Standard Operating Procedures (SOPs), thus standardizing processes and procedures across regions and organizations.

RPG appointed an experienced Global Project Manager who understood the nuances and idiosyncrasies of international studies to serve as the study's single point of contact and accountability. The Global Project Manager has ensured consistent and successful performance throughout the study and has effectively managed the global diversity providing cultural and logistical expertise. Additionally, the Project Manager has acted with insight and acumen to manage ever-changing deadlines and regulations, ensuring that all critical information has been received on or before the established project timeframes.

RESULTS: RPG has provided the Sponsor with a successful global study experience. We worked productively to facilitate an on-schedule start-up of all global sites with enrollment ending two months ahead of schedule. In response to quicker enrollment in the study, we were able to ramp up our monitoring activity, thus conducting more frequent visits than expected in a shorter timeframe, keeping the study ahead of schedule.

“The global project manager is well seasoned for complex international studies. Her sound understanding of global clinical research processes and her marvelous communication skills make her an ideal point of contact for bigger teams and clients. She is a fantastic team lead who can be counted on when issues arise and need to be resolved swiftly and decisively.”

—European Regional Project Lead