MEDPACE

CASE STUDY

Phase III, Biosimilar Global Clinical Trial Finished Ahead of Schedule

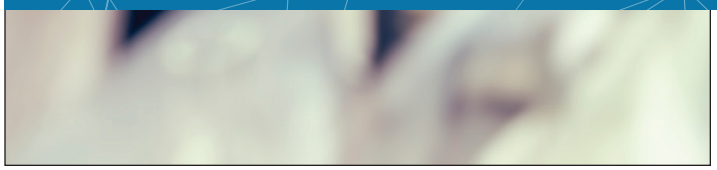
Overview

A drug manufacturer with a Phase III clinical trial for a biosimilar to treat rheumatoid arthritis (RA) required a CRO partner with global experience, therapeutic expertise and strong site and KOL relationships. Study objectives required the evaluation of the long-term safety and response to patients with RA. Patients needed to complete a 48-week evaluation that included passing numerous exclusion criterion to enroll. Once the patients were enrolled, they were given a self-administration drug. Finally, patients were required to be monitored and evaluated at monthly increments for safety and durability of response.

Challenge

- **Global Study:** The Phase III clinical trial was a global study which required hundreds of patients in multiple countries. To consistently meet and exceed timelines while treating the unique needs of patients with RA required a seamless global communication strategy between Medpace and the Sponsor.
- **Specialized Expertise:** The trial needed key global therapeutic experts in RA as well as experienced clinical teams with expertise in conducting global multi-site trials.
- **Extensive Enrollment Process:** Patients needed testing for an array of conditions before being accepted into the study. This process required an extensive enrollment phase which relied heavily on critical testing and accurate lab results.
- **Patient Monitoring:** Monitoring patients with RA required consistent manual assessments across all patients and sites.
- **Specialized Equipment:** The study required patients to receive unique drug administration with at-home self-administration procedures.

Medpace was tasked with conducting a global Phase III study with 600 plus patients across more than 100 sites in multiple countries to study an injectable biosimilar.



Solution

- **Streamlined Communication and Collaboration:** Medpace worked in tandem with the Sponsor to ensure protocols, timelines, and deliverables were completed not only on time but ahead of schedule. Streamlined communication and collaboration were critical in a global trial of this size and complexity.
- **Expedited Site Selection:** We successfully guided the Sponsor through the recruitment phase with an overwhelming response from patients. Our extensive experience in executing global clinical trials - combined with our global investigator relationships and ready patient access - played a key role in expediting site selection.
- **Consistent Patient Monitoring:** Our Principal Investigator worked closely with the Sponsor on training designed for manual assessment to ensure consistency and accuracy when monitoring patients.
- **Provided Specialized Equipment:** To accommodate the unique needs of the at-home self-administration of the drug, Medpace provided refrigerated biologics to patients in convenient portable packs.
- **Medpace Central Labs:** Our central labs played a vital role in the success of the trial by stepping in after testing issues with a previous lab to ensure agile and accurate deliverables.

Results

- **Early Completion: The Phase III clinical trial was completed two weeks ahead of schedule. The key to the successful completion was facilitated by our trusted expertise, thorough communication, site selection, accelerated patient recruitment, solid feasibility, and integrated central lab.**
- **Well-Profiled Site Networks: Our relationships with site networks around the world enabled us to recruit hundreds of patients worldwide.**
- **Consistent Care: Project team members with direct experience worked seamlessly with the Sponsor to provide consistent care and monitoring of patients.**
- **Exceeded Key Milestones: Our integrated model, which includes our global central laboratories, allowed us to address the testing issues from another vendor. With the CRO and the central laboratories working collaboratively together, the study got back on track and exceeded key milestones.**

Move Faster with a Global, Full-Service CRO

Medpace is a global full-service clinical research organization providing Phase I-IV core development services for drug, biologic, and device programs. With medical and regulatory expertise in multiple therapeutic specialties including infectious disease, Medpace has assembled experienced and therapeutically focused teams to execute at every level of the company's operations, providing complete and seamless drug development services.

MEDPACE
Therapeutically Specialized Clinical Development