Pharm-Olam™
Helping Create A Healthier World

CASE STUDY

Recruitment of Patients in a Phase III Systemic Lupus Erythematosus Study

Study Overview:

During the planning of a Phase III Systemic Lupus Erythematosus (SLE) anti-B cell therapy, the Sponsor company called on Pharm-Olam to assist in the identification and enrollment of patients.

The purpose of the study was to determine the viability of a biological agent in treating SLE patients whose disease state was severe, aggressively advancing and poorly controlled. SLE is a notoriously difficult-to-diagnose autoimmune disorder with no known cure.

A detailed feasibility study, conducted by Pharm-Olam, identified new geographies with patient populations and disease profiles suitable to meeting the trial's urgent enrollment goals. Furthermore, Pharm-Olam recognized that Site-CRA relationships would be instrumental in meeting patient enrollment goals. The assignment of CRAs with extensive and relevant experience set the stage for good working relationships to evolve with the sites. In addition, Pharm-Olam implemented a robust site retention program, which proved effective in thwarting competition from several other ongoing competitive global SLE trials.

Study Details:

- Phase III
- **Indication:** Systemic Lupus Erythematosus (SLE)
- **Patients:** 209
- **Sites:** 32
- **Countries:** Belarus, Georgia, Guatemala, Mexico, Russia, Sri Lanka
- **Study Design:** Randomized, double-blind, placebo-controlled in subjects with active SLE
- **Inclusion Criteria:** SELENA-SLEDAI score ≥12 with current stable corticosteroid therapy
- **Exclusion Criteria:** Severe active vasculitis, active central nervous system Lupus, active LN, uncontrolled hypertension or poorly controlled diabetes, anemia, neutropenia
- **Services Provided:** Regulatory, Monitoring, Project Management

Study Challenges & Solutions:

Challenge # 1: Identification and Enrollment of Patients

The ideal patient profile included an SLE diagnosis, aggressive SLE symptoms and a poorly controlled disease state. To enroll the necessary patients, Pharm-Olam designed a pre-screening program and deployed it to geographies where treatment-naïve patients were available. These geographies included Russia, Belarus and Georgia. Pharm-Olam's site selections, combined with the results of a detailed feasibility study, led to enrollment requirements being met two months ahead of the Sponsor's schedule. Due to the rapid response in Eastern Europe, the Sponsor asked Pharm-Olam for additional patient recruitment support. Pharm-Olam deployed the pre-screening program to viable sites in Guatemala, Mexico and Sri Lanka, ultimately contributing 209 patients to the trial. Despite the highly competitive patient environment, the enrollment approach and implemented plan allowed the Sponsor to meet their final enrolment target.

Challenge # 2: Training on SLE Assessment Tools

During site activation, it was discovered that approximately 50% of sites had no previous experience on SLE assessment tools (BILAG, SELENA-SLEDAI, CLASI, SLE Flare Index, PGA). To overcome this knowledge gap, Pharm-Olam created an intensive training program for investigators pre-SIV. Once the assessment tools were in place, a regular database review was initiated to define the typical queries/mistakes on SLE assessment tools. Deficient or underperforming sites were re-trained whenever deviations occurred. Pharm-Olam also initiated an ongoing quarterly CRA training program with detailed reviews of patient assessment cases, so that CRAs could assist sites in an expedited manner.

Conclusion

Finding qualified patients in a resource-sensitive and timeline-intensive environment is a challenge that most study Sponsors face repeatedly in their development programs. Pharm-Olam's knowledge and on-the-ground teams in unique country locations helped keep patient recruitment numbers high and start-up timelines rapid. Three separate audits—both Sponsor- and Pharm-Olam-initiated—revealed no critical or major findings to report. Pharm-Olam and the study Sponsor have a history of working together, representing a total of five ongoing and completed studies.

> *"We relied heavily on Pharm-Olam's expertise and advice to lead us through the regulatory process, as well as on their experience to allow for a quick study start-up in projects countries. The study team at Pharm-Olam did a fantastic job in keeping up with the dynamic and aggressive recruitment plan and the team drove towards our recruitment goal as if it was their own. Their passion and dedication towards meeting our internal recruitment goals were evident. The Project Manager for this study worked effortlessly with multiple vendors across multiple time zones."*
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> — SENIOR DIRECTOR, CLINICAL OPERATIONS

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