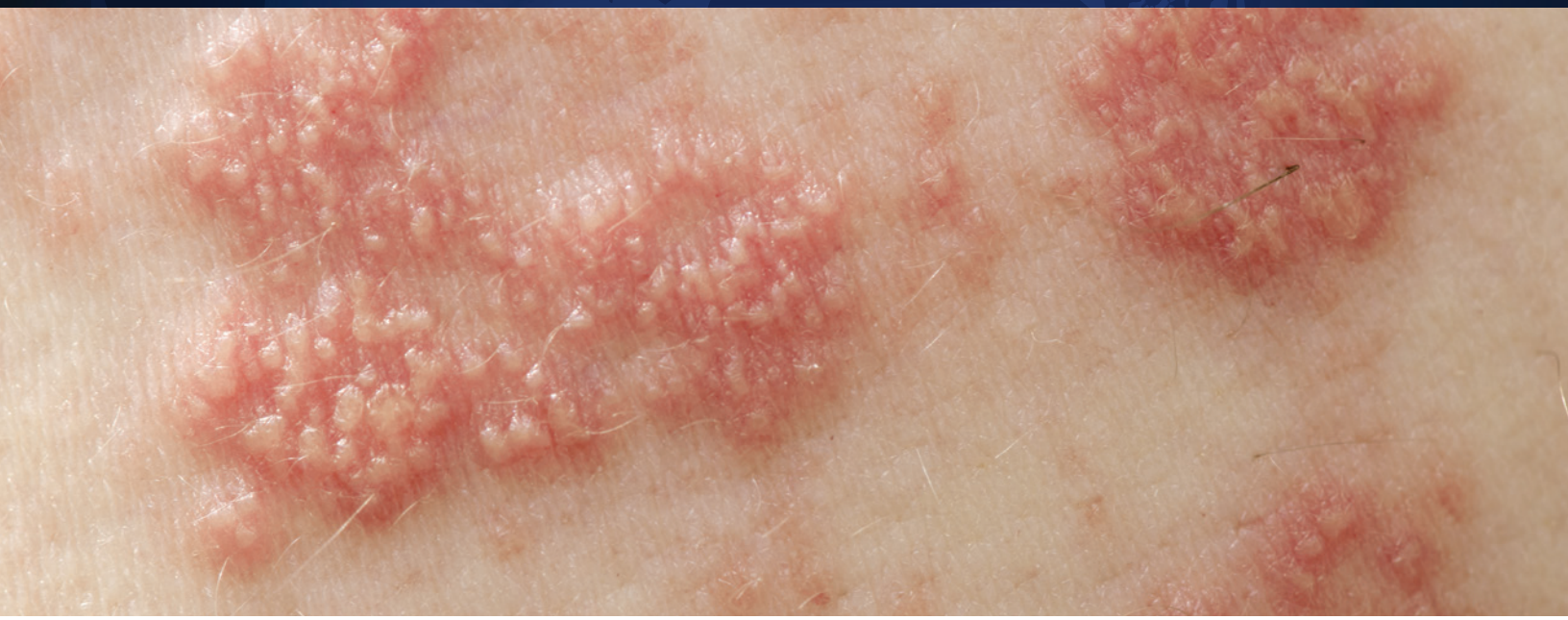
Pharm-Olam
Helping Create A Healthier World

CASE STUDY



# Post Herpetic Neuralgia Study

To successfully complete a Phase II Post Herpetic Neuralgia (PHN) study, Pharm-Olam was contracted to provide a full-service solution to support 103 patients from 27 sites in four countries. In the past, study sponsors have had difficulty recruiting patients in Post Herpetic Neuralgia studies, but due to prior experience with these studies and a proactive approach, Pharm-Olam recruited the required number of patients seven weeks prior to the sponsors' deadline.

### Study Overview:

- Phase: II
- Patients: 103
- Sites: 27 in 4 countries - South Africa, Bulgaria, Georgia, and Ukraine
- Services Provided: Regulatory, Monitoring, Project Management, Medical Writing, Data Management, Statistics, Pharmacovigilance, Medical Monitoring, DSMB Management

### Study Challenges:

### Patient Recruitment

### Challenge:

Recruiting qualified patients for Post Herpetic Neuralgia studies can be a challenge. Typically, patients are currently quite well treated following herpes rush healing and, if they do experience PHN, they are dispersed among different types of clinics (pain clinics, neurology, dermatology, infectious diseases, GP).

### Solution:

Pharm-Olam was able to use their experiences from previous PHN studies to appropriately select the countries and the sites, where patients are more readily available. Taking advantage of previously created site and investigator relationships, Pharm-Olam was able to reduce the time needed to set up the sites and complete patient recruitment seven weeks ahead of time. Pharm-Olam also worked closely with the study sponsor to identify regions and patients where the novel and expensive treatments were limited or not available. This enabled Pharm-Olam to find a higher percentage of treatment naïve patients, which is very valuable in this indication. Significantly, the study sponsor reported that this was the first time they had seen a Post Herpetic Neuralgia study trial finish ahead of time.

By relying on Pharm-Olam's established relationships, we were able to minimize the screen failure rate through active pre-screening and through searches of the investigators database of chronic patients. This required direct communication and constant support to the investigational team, with ongoing training being provided by Pharm-Olam's CRAs, Project Managers and Medical Monitors. These activities ensured that eligible patients were recruited and managed throughout the trial, which is another reason why the trial finished ahead of schedule.

### Monitoring

**Challenge:**

Ensuring data consistency across various countries.

**Solution:**

To ensure an efficient monitoring program, Pharm-Olam and the sponsor budgeted for co-monitoring visits. Pharm-Olam's lead study Project Manager and each CRA visited each site (five visits in total), which allowed for consistency between the countries and sites. This hands-on program increased data quality and allowed for an expedited data management process at the conclusion of the study.

### Data Quality / Integrity Used in Study Design

**Challenge:**

To ensure that clear, actionable, and expedited results were delivered in this study, Pharm-Olam relied on clinic referrals, over advertisements.

**Solution:**

To achieve this, Pharm-Olam recognized the need for highly targeted patient enrolment and implemented a patient profile in which increased requirements for greater baseline pain severity (≥4/10), updating the requirements for longer duration of pain (i.e., ≥3 months), while exclusion of patients with short episode durations, and screening for patients who were lacking a history of multiple treatment failures was implemented. Pharm-Olam also relied on clinic referrals, over advertisements, as the clinic referrals were a more reliable source of viable patients, since the advertisements would often attract patients with a low pain threshold that was not suitable for study inclusion.

Pharm-Olam also found a need to minimize the number of concomitant PHN treatments. We found that the majority of the patients suffering from PHN receive continuing treatments and it is very difficult to remove this treatment from the patients to sustain their daily activities. To accommodate this, Pharm-Olam allowed a single drug that was regularly used in the past was acceptable and did not alter the study results. Taking these steps required that Pharm-Olam identify a rescue medication for breakthrough pain, so that the patients would be as comfortable as possible. Pharm-Olam also excluded patients from the study if there was documented failure to maximal doses of novel treatments, which ensured that proper patients were included in the study.

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