Grass & Birch Allergy Phase II Parallel Studies

Pharm-Olam was contracted to provide a full-service solution for two Phase II, dose escalation allergy studies that required a total of 500 patients in Europe and were ran in parallel. With two different indications required, Grass Pollen Allergy and Birch Pollen Allergy, Pharm-Olam completed a comprehensive feasibility program and presented the findings to the sponsor for analysis and approval. Once approved, Pharm-Olam committed to recruit the required patients within 4 months, while adhering to strict inclusion and exclusion criteria.

Grass Study Overview

Randomized, double-blind, placebo controlled, multicenter, 5-arm, staggered start, subjects with allergic rhinitis/rhinoconjunctivitis related to grass pollen allergy.

Therapeutic Area

Allergy

Patient Population

250 (Randomized 268)

Inclusion Criteria

Allergic rhinitis/conjunctivitis related to grass pollen, positive SPT for grass pollen, positive serum specific anti-grass IgE-test, a positive TNPT for grass pollen at screening

Sites & Locations

23 Sites (Germany & Poland)

Enrollment Period

Contracted = 4 months

Actual = 2.5 months

Study Timeline Snapshot

- Recruitment = September to December
- Treatment = December to May
- Database Lock = May to June
- Statistical Analysis - Clinical Study Report = June to October
- Total Duration = 17 months

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Allergy Case Study | Grass & Birch Allergy Phase II Parallel Studies

Birch Study Overview

Randomized, double-blind, placebo controlled, multicenter, 5-arm, staggered start, subjects with allergic rhinitis/rhinoconjunctivitis related to birch pollen allergy.

Therapeutic Area

Allergy

Patient Population

250 (Randomized 270)

Inclusion Criteria

Allergic rhinitis/rhinoconjunctivitis related to birch pollen, positive SPT for birch pollen, positive serum specific anti-birch IgE-test, positive TNPT for birch pollen at screening

Sites & Locations

21 Sites (Czech Republic, Germany & Poland)

Enrollment Period

Contracted = 4 months
Actual = 3 months

Study Timeline Snapshot

- Recruitment = July to September
- Treatment = September to March
- Database Lock = April to May
- Statistical Analysis - Clinical Study Report = May to October
- Total Duration = ~20 months

Program Challenges Seen & Overcome:

Unpredictable seasons, screen failure rates, symptom score severity, co-existing allergies, IgE levels, patient compliance and withdrawal rates.

"We highly appreciated the professional, proficient and personable management of the studies by Pharm-Olam. Communication was open and friendly. The established communication lines worked well, so that any questions or concerns that have arisen have been responded to in a timely manner. The timelines for the two studies were tight. The Pharm-Olam team showed commitment and focus in helping us to meet our corporate goals. Patient recruitment for both studies exceeded the target despite challenging recruitment timelines. The expertise of Regulatory Management ensured that the Authorities received comprehensive and adequate replies on their requests in time. Project Management was pro-active in identifying and resolving issues. We were kept well informed by the Project Managers. Both Project Managers provided excellent leadership to the study teams. The CRAs had a good working relationship with the sites and they supported the sites very well. As a result, the patient data collected from Pharm-Olam sites was of high quality. We are very pleased to have worked with Pharm-Olam and we have no hesitation in recommending them to future clients."

— SPONSOR'S MEDICAL DIRECTOR

For more information about Pharm-Olam, please visit
www.pharm-olam.com

About Pharm-Olam

Pharm-Olam is Helping Create a Healthier World as a global, midsized CRO that offers flexible, innovative and highly personalized clinical solutions to pharmaceutical, biotechnology and life science companies. Our team is well-known for producing quality results with reduced risk, costs and timelines in challenging international trials. Offering full-service solutions and deep expertise in oncology, infectious diseases and vaccines, rare and orphan diseases.