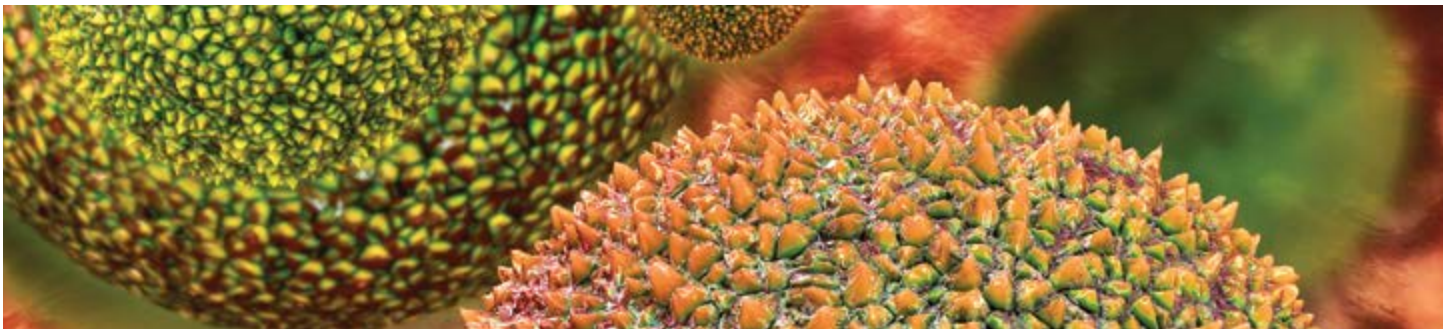
Pharm-Olam
Helping Create A Healthier World

CASE STUDY

Pharm-Olam Completes Birch and Grass Pollen Allergy Studies

2 x Phase II, Full Service, Europe, Dose Escalation



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. 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.

Study Challenges:

These studies presented several processing challenges which should be considered when running similar trials. These challenges included unpredictable seasons, screen failure rates, symptom score severity, co-existing allergies, positive skin prick test, IgE levels, and poor patient compliance / high withdrawal rates.

Tips for Future Study Success:

Pharm-Olam recommends implementing contingency plans, ensuring a good protocol design, accurate site feasibility, critically assess site feedback, implement intensive training programs, employ a clear PIS/IC, include an easy to use ediary, and allow for study drop-outs to ensure proper amounts of study participation.

Pharm-Olam's team of skilled professionals is available to assist you with your allergy study programs. To learn more about our past experience, contact us at info@pharm-olam.com to setup an appointment.

I. Grass Pollen Allergy

Protocol Overview: Randomised, double-blind, placebo-controlled, multicentre, 5-arm, staggered start Subjects with allergic rhinitis/rhinoconjunctivitis related to grass pollen

Summary of Inclusion/Exclusion Criteria:

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

Exclusion Criteria: Clinically relevant symptoms due to concomitant sensitisation to allergens other than grass pollen, patients sensitized to pets, prior successful immunotherapy thin past 5 years, prior unsuccessful immunotherapy

Study Participation: 266 patients enrolled at 23 sites in Germany and Poland in 2.5 months

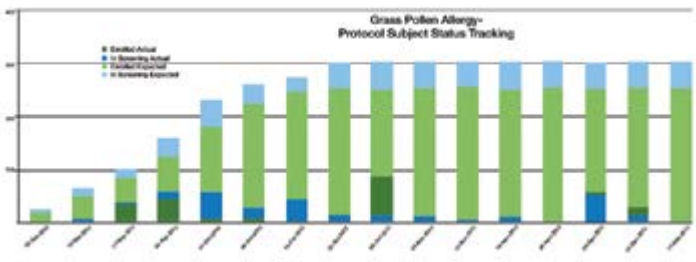
Study Timelines:

Recruitment: September 11, 2012 to December 5, 2012

Treatment: December 6, 2012 to May 9, 2013

Database Lock: May 10, 2013 to June 24, 2013

Study Close Out - Statistical Analysis: June 25, 2013 to October 15, 2013



II. Birch Pollen Allergy

Protocol Overview: Randomised, double-blind, placebo-controlled, multicentre, 5-arm, staggered start, Subjects suffering from birch pollen-induced allergic rhinitis/ rhinoconjunctivitis

Summary of Inclusion/Exclusion Criteria:

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

Exclusion Criteria: Patients with (expected) clinically relevant symptoms during the course of the trial due to concomitant sensitization to allergens other than birch pollen, patients sensitized to pets, completed immunotherapy with birch pollen allergens within the past 5 years, prior unsuccessful specific immunotherapy

Study Participation: 270 patients randomized at 21 sites in Czech Republic, Poland and Germany in under 3 months

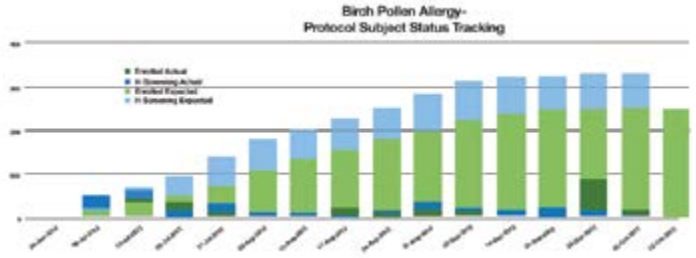
Study Timelines:

Recruitment: July 2, 2012 to September 12, 2013 (Poland and Czech Republic), November 5, 2013 (Germany)

Treatment: September 29, 2012 to March 2013

Database Lock: March 18, 2013 to May 30, 2013

Study Close-Out – Statistical Analysis: May 30, 2013 to October 1, 2013



Customer Testimonial:

"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 Manager. 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."

— Medical Director

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