Allucent Case Study

Allergy

Grass & Birch Allergy Phase II Parallel Studies

Overview

Allucent was contracted to provide a full-service solution for two Phase II, dose escalation allergy studies to be ran in parallel and requiring a total of 500 patients in Europe. With two different indications required, grass pollen allergy and birch pollen allergy, Allucent completed a comprehensive feasibility program and presented the findings to the sponsor for analysis and approval. Once approved, Allucent committed to recruiting the required patients within four months, while adhering to strict inclusion and exclusion criteria.

Grass Study

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

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.

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

SITES & LOCATION

23 sites

(Germany & Poland)

PATIENT POPULATION

250

(randomized 268)

ENROLLMENT PERIOD

2.5 months

(Contracted 4 months)

Birch Study

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

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.

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, coexisting allergies, IgE levels, patient compliance and withdrawal rates.

SITES & LOCATION

21 sites

(Czech Republic, Germany, & Poland)

PATIENT POPULATION

250

(randomized 720)

ENROLLMENT PERIOD

3 months

(Contracted 4 months)

"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 PharmOlam 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