ClinChoice
The Standard of Excellence

Case Study

Respiratory Program Rapid Start-Up & Complex Vendor Management

Description

A respiratory program consisting of three studies (phase II, multicenter, randomized, double-blind, placebo and active controlled dose-ranging 6-arm parallel group) to identify the optimal dose of the trial drug with respect to lung function and other clinical efficacy and safety outcomes in adult subjects with either asthma or COPD.

Study 1: A 14-week study evaluating safety and efficacy of four doses of Investigational Product (IP) compared to placebo in asthmatic subjects.

Study 2: An 8-week study evaluating safety and efficacy of three doses of alternate IP compared to placebo in asthmatic subjects.

Study 3: A 6-week study evaluating safety and efficacy of four doses of IP compared to placebo in COPD subjects.

Primary Endpoints: Study 1: To evaluate the efficacy of the IP's pMDI by comparison with placebo in terms of acutebronchodilator effect (change from baseline in FEV_1 AUC_0-12h normalized by time at Day 14).

Study 2: To evaluate the efficacy of the IP's pMDI by comparison with placebo in terms of change from baseline in pre-dose morning FEV_1 at week eight.

Study 3: To evaluate the efficacy of the IP's pMDI by comparison with placebo in terms of change from baseline in FEV_1 AUC_0-12h normalized by time at week six

Services: Full-service (including vendor management - central lab, ECG, centralized spirometry, clinical trial supply management, equipment distribution – AM3, Holter Monitor).

	Clinical Sites Total sites = 268 across all studies (10, 144 and 114 respectively) but a total of 216 unique sites as several sites participated in two of the three studies (19% overlap)
	**Patients** Study 1: 154 Screened, 67 randomized Study 2: 1940 Screened, 615 randomized Study 3: 1855 Screened, 735 randomized
	Regions United States

Study Phase: II

Indication: Study 1: Patients > 18 < 75 years old with asthma

Study 2: Patients > 18 < 75 years old with asthma

Study 3: Patients > 40 years old with COPD

Introduction

These studies were managed by ClinChoice on behalf of a mid-sized European pharmaceutical company with a strong US presence. The trials involved rapid site selection and qualification in order to achieve the client's goals for the first patients enrolled. ClinChoice conducted a feasibility on 500 sites and qualified 216 unique sites that were utilized for the study.

Primary endpoints were changed in spirometry at specific timepoints in each study. The spirometry equipment and results were managed by a third party vendor but training and adherence to proper technique was managed by ClinChoice.

Study drug management (packaging, labeling, storage, distribution and central randomization) was supported by specialized vendors as shipments contained subject training kits as well as the investigational product and strict adherence to temperature management was required.

The Challenges

The first challenge was to achieve first patient enrolled within four months of contract signature with the client.

The second challenge was managing multiple vendors that provided very different services across all the three studies of the program and ensuring that results were reported appropriately and timely.

Operational Plan

Rapid Start Up

ClinChoice created a feasibility survey that would collect relevant information for all three studies in order to determine the best suited sites as well as sites that could possibly participate in two of the three studies. A full Feasibility Plus™ analysis was conducted on a rolling basis as the data was submitted and follow up questions were posed of sites via teleconference to ensure the best sites were visited for Pre-Study Qualification visits.

A face-to-face training was scheduled with the US CRAs and the operational leaders prior to the conduct of any study visits. Training included protocol overview, study drug management, monitoring manual, communication and training from third party vendors on each of the required assessments that utilized vendor equipment.

Pre-Study Visits (PSVs) were scheduled as data was received and greater than 200 PSVs were conducted in the first month following the study contract execution in order to determine eligible sites and how many studies to engage each site on.
ClinChoice combined visits (for those sites participating in two studies) and looped visits to ensure the most efficient and cost effective plan.

ClinChoice conducted 68 SIVs within a month in order to achieve first subject enrolled within the client's required timelines. In total, 327 PSVs and 270 SIVs were conducted across all three studies.

Complex Vendor Management

Multiple vendors were utilized for these studies in order to ensure consistency and protocol adherence throughout the study. As all three studies had primary endpoints related to spirometry, a specialized vendor was utilized to provide equipment to the sites along with training manuals. Sites were responsible for the calibration of their equipment on a routine basis and this was closely monitored by ClinChoice as uncalibrated devices could provide false results.

Enrollment criteria for each study was based on a required spirometry range for a minimum of three attempts for each subject but up to eight attempts. Results received through the vendor were also reviewed and validated by ClinChoice's trained medical staff to ensure the eligibility criteria was met. This verification required careful coordination and oversight of screening visits and test result reporting in order to provide each site permission to enroll subjects that qualified for the study. Additionally, a randomization vendor, drug supply vendor, central ECG readers, Holter monitor vendor and lab vendor were essential to the conduct of this study. ClinChoice assigned a dedicated vendor manager and team to set up the vendors specifications and coordinate required supplies and re-supplies to each site as the equipment required site specific programming and was very costly.

Result

Rapid Start Up

Due to the rapid planning and subsequent development of a detailed feasibility questionnaire, ClinChoice was able to contact over 500 potential sites quickly utilizing our investigator database and other resources through our FERMI system which enabled us to have nearly paperless contact with sites while ensuring confidentiality. Rapid feedback from sites coupled with immediate action in scheduling 327 PSVs allowed ClinChoice to identify the best sites suited for participation in all three studies.

The end result was that ClinChoice was able to achieve the goal of First Patient In (FPI) for all three studies within the client's timelines despite the delays by the client during contracting process.

RESPIRATORY EXPERTISE

For over 28 years, ClinChoice has conducted trials focused on respiratory disease. We are able to advise clients on the design and implementation of the entire respiratory development plan.

ClinChoice's respiratory experience includes hundreds of studies in thousands of patients, both in adult and pediatric populations, Phase I through Registry, in a wide range of indications including, but not limited to, asthma, COPD, cystic fibrosis, lower respiratory tract infections, lung cancer, smoking cessation, upper respiratory tract infections, rhino sinusitis, and chronic bronchitis.

Complex Vendor Management

With careful coordination, continual communication and oversight, ClinChoice successfully collaborated with each vendor to ensure a smooth process from project specifications to study drug shipment/resupply to collection of primary endpoints and safety parameters. There were no instances where delays in subject randomization or subsequent visits were affected due to vendors and as such the study was conducted in accordance to the protocol with a high level of compliance from all vendors involved. Further, there were cost savings recognized with equipment and supplies due to the close management of distribution to the sites by the vendors in collaboration with ClinChoice.

With immediate action by ClinChoice and close collaboration with vendors, we achieved highly successful recruitment and enrollment and study conduct for all three studies.

About ClinChoice

ClinChoice is a global full-service CRO specializing in clinical development and functional solutions for pharmaceutical, biotechnology, medical device, and consumer health companies. We have over 28 years of proven high-quality delivery and results across all our services. With over 4,000 professionals in more than 20 countries across the Americas, Europe, and Asia-Pacific, we are positioned to fulfill our clients' business requirements locally and globally. We offer high-quality, full-service clinical development and post-marketing solutions. For our clients, it means a reliable partner and quality results.

CONTACT US

ClinChoice Inc.
1300 Virginia Drive, Suite 408
Fort Washington, PA 19034 USA
Phone: +1 215 283 6035
Fax: +1 215 283 6382
Email: info@clinchoice.com

ClinChoice

www.clinchoice.com