

Solutions Made Real through Teamwork and Precision Delivery: Inflammation Case Study

A major pharmaceutical company engaged Covance to manage a large, global chronic obstructive pulmonary disease (COPD) program. The program, covering 12 protocols, included five Phase I studies, four Phase II profiling studies, one combination Phase study and two pivotal Phase III studies. The studies were conducted in nearly 30 countries across the Americas, Europe, Asia Pacific and South Africa, at more than 550 sites, and involved over 4,500 subjects.

Understanding the Challenge

- ▶ Identifying and enrolling highly qualified investigator sites and recruiting more than 4,500 patients in a timely fashion
- ▶ Navigating and coordinating regulatory policies of nearly 30 countries
- ▶ Managing a number of program vendors for the pulmonary function testing (PFT) while promoting data consistency and quality

Meeting and Exceeding Expectations

Upon project kickoff, Covance's scientific and operational team conducted a robust feasibility assessment of all potential sites, including an on-site visit that helped strengthen our relationship with the sites and investigators. While proactively mitigating any start-up issues with those sites, we also identified back-up sites to help keep the program on track. Once sites were initiated, we leveraged our information modeling capabilities to forecast patient enrollment timelines, resource needs and data flow. These inspiring actions resulted in achieving on-target enrollment for all the studies as well as a heightened focus on patient retention.

Because this was such a large multi-phased program, the ability to simultaneously handle varying aspects of the program was paramount as was the need to work with speed and quality. Working together with our client, we prepared multiple project plans to manage the key aspects of the program, including medical monitoring, safety reporting, risk management and quality management. In doing so, we demonstrated our accountability to the entire program – and to our client's success in managing this program. We also leveraged insights from our dedicated global regulatory team to facilitate coordinated responses to worldwide regulatory agencies and ethics committees, saving our client time and money. Specifically, we familiarized ourselves with the varying countries' regulatory approval timelines and addressed questions asked by ministries of health and international ethics committees, including those relating to the use of placebos.

Finally, we made solutions real with regards to the enormous amount of data needed for this program. Proactively, we documented all questions and approved responses in a central database to provide responses that were consistent and to provide responses in an expedited fashion. We also worked extensively with the investigator sites and centralized PFT vendor to help promote reliable PFT results and primary endpoint data. This included engaging a dedicated vendor management contact for each external vendor to provide timely feedback to investigators and to help facilitate the successful, on-time delivery of quality data. Moreover, while the trials used a paper-based data management system, our team's depth of experience in global clinical data management resulted in on-time database locks for all 12 studies in the program.

In the end, our collaborative approach to program management resulted in effective communication and ongoing reviews of project plans—including using predictive data to proactively make adjustments—enabling our client to complete their COPD program on time.

Large global trials can be complex and difficult to navigate. Working with a partner with depth and breadth of experience brings a unique perspective that promotes precision delivery, giving you the best chance of success.

Learn more about our drug development solutions at www.covance.com

Covance is an independently held company with headquarters in Princeton, New Jersey, USA.
Covance is the marketing name for Covance Inc. and its subsidiaries around the world.

The Americas + 1.888.COVANCE + 1.609.452.4440
Europe / Africa + 00.800.2682.2682 Asia Pacific + 800.6568.3000

© Copyright 2014 Covance Inc. CSCDS041-0914

COVANCE[®]
SOLUTIONS MADE REAL™