ASTHMA: AN XCELLERATE® – CLINICAL TRIAL OPTIMIZATION® CASE STUDY

Situation

A top-10 pharmaceutical company was planning a megatrial for the treatment of moderate to severe asthma, using an inhaled medication. The global trial would require a patient accrual period of several years as well as regulatory agency endorsement of the trial design.

Challenges

To conduct this trial efficiently, it was critical to accurately profile the pool of accessible, eligible investigators and patients, segment patient types and identify potential differences in behavior versus the protocol. This was complicated by the requirement to include a limited, difficult-to-access, pediatric sub-population as well as by the fact this new megatrial would effectively triple global demand for asthma patients and necessitate the use of primary care, non-specialist sites. Detailed, proactive planning would be crucial to optimize the likelihood of meeting the enrollment targets and to help ensure quality data. At the same time, it would be necessary to build and present a clear, concise and convincing case to win regulatory endorsement for the recommended study model and clinical trial feasibility.

Actions

Covance set out to meet the challenges set forth using its proprietary Xcellerate methodology, world-class expertise in clinical trial optimization and superior project management. Accordingly, Covance:

- Combined a top-down epidemiology analysis of the patient pool with a bottom-up analysis of accessible, eligible investigators to optimize the quality and accuracy of the study model and feasibility
- Clearly defined the global site distribution and forecast the typical proportion of enrollment by country per month
- Identified several hundred investigators worldwide, including ICH-GCP-qualified investigators who had access to asthma patients, and sent a survey to the investigators to help verify the initial enrollment and feasibility assumptions generated through Xcellerate
- Combined flexible, customized and rapid predictive modeling with investigator survey feedback and study strategy discussions with the sponsor to further refine the proposed study model and help increase the likelihood of achieving study performance and quality objectives
- Tested the revised enrollment forecasts by conducting a second round of investigator interviews across nearly a dozen countries, representing a broad cross-section of investigator types
- Proactively assessed a range of protocol logistics and analyzed the results for potential challenges to timely enrollment and quality data capture

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Results

By using Xcellerate methodology and combining it with in-depth investigator reviews and strategy discussions, Covance was able to provide the sponsor with an optimized, transparent study model and clinical trial feasibility analysis. Specifically, Covance was able to generate credible and accurate expectations and forecasts for investigator and patient enrollment across a broad and varied range of geographies, investigator types and patient populations. As a result, the regulatory agency endorsed a recommended lowering of the enrollment target as well as a significant extension of the time needed to enroll the stipulated number of patients.

Furthermore, sponsor satisfaction led to the award of the megatrial to Covance. Based on the extensive trial optimization work already carried out in close collaboration with the sponsor, Covance was able to proceed directly into trial kick-off mode, saving the sponsor valuable time.

Find out how Covance can Xcellerate your clinical trial!

- Contact your Covance account executive today to schedule a consultation and learn more about our proprietary Xcellerate approach to help deliver a stronger return on your clinical investment
- You can also contact Covance by telephone using the numbers listed below, or visit www.covance.com/Xcellerate

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

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