ERT®
Confidence at every turn™

CASE STUDY

GLOBAL PHARMACEUTICAL COMPANY PROVES EFFICACY OF BRONCHODILATOR FOR COPD PATIENTS

ERT Safety & Efficacy solutions integrated with Enhanced Business Intelligence helps secure new drug approval from global regulatory authorities

SITUATION

Chronic obstructive pulmonary disease (COPD) is a progressive disease that makes breathing difficult and is a leading cause of mortality worldwide. Although up to half of all COPD exacerbations are not reported by patients, exacerbations worsen COPD symptoms and lung function, lead to hospitalization or death and negatively impact a patient's quality of life.

A leading global pharmaceutical sponsor began a program of clinical trials to discover if a new bronchodilator could demonstrate superior and sustained lung function for the long-term maintenance of airflow obstruction of patients with COPD, including chronic bronchitis and emphysema. ERT provided integrated Respiratory, eCOA, Cardiac Safety and Enhanced Business Intelligence for Respiratory Trials solutions for this clinical research.

SUMMARY

- Study designed to demonstrate superiority of bronchodilator vs. existing treatment for FEV1, capture patient reported outcomes and reduce reliance on rescue medication
- ERT MasterScope™ for spirometry and ECGs integrated with ERT EXPERT® platform
- ERT AM3™ used for home monitoring and electronic patient reported outcomes (ePRO) collection

IMPACT

- Established patient baseline prior to randomization
- Detected exacerbations with patient and investigator alerts
- Identified worsening of sensitive symptoms
- Robust assessment of treatment effects

SOLUTION

The primary objective of the study was to demonstrate the superiority of the bronchodilator versus an existing treatment for the FEV1 respiratory parameter. Centralized spirometry and overread was accomplished with ERT's MasterScope™ spirometer and integrated ERT EXPERT® platform. Secondary objectives included multiple respiratory patient questionnaires and a reduction in daily rescue medication use with the treatment versus placebo.

ERT's AM3™ was used for home monitoring and ePRO collection via eDiary. The AM3 collected each patient's symptoms data daily, assisted in detecting exacerbations with patient and investigator alerts and also established patient baseline prior to randomization. This electronic, centralized solution helped patients to report on their exacerbations as they occurred, identified worsening of sensitive symptoms beyond normal day-to-day variation and provided a robust assessment of treatment effects.

ERT's Cardiac Safety solutions were also used for centralized ECG collection and analysis, while Enhanced Business Intelligence for Respiratory Trials helped proactively identify issues relating to data quality.

CENTRALIZED, ELECTRONIC SOLUTIONS INCREASE DATA QUALITY

IMPACT

Our integrated technology, data and project management, education and training, overread and logistics expertise came together to support the sponsor in proving efficacy and safety during this program. The global pharmaceutical company secured new drug approval from U.S. and European regulatory bodies.

REGULATORY APPROVAL GRANTED

Demand data quality and breathe easy in your clinical trials.
To learn more, go to ert.com or email info@ert.com.