

ERT, Johns Hopkins University and the University of Washington Expand Study on Effects of Home-Health Monitoring on Exacerbations of Cystic Fibrosis

ERT, a global technology-driven provider of health outcomes research services to biopharmaceutical organizations, medical device companies and contract research organizations (CROs), along with pulmonary researchers at the Johns Hopkins University School of Medicine and University of Washington, today announced an expansion to the Early Intervention in Cystic Fibrosis Exacerbation (eICE) Study. An additional 12 investigative sites are now enrolling patients to the randomized study which was initiated in February 2012. The study is designed to determine the efficacy of home lung function testing and symptom diary use for early intervention in the treatment of adolescent and adult Cystic Fibrosis (CF) acute pulmonary exacerbation.

Supported by the National Institutes of Health and the Cystic Fibrosis Foundation, the study will compare standard care to an intervention arm. Patients enrolled in the early intervention arm are using ERT's AM2+ lung function monitors – an integrated, portable spirometer and electronic diary – twice weekly to measure FEV1 and to enter responses to the CF Respiratory Symptom Diary (CFRSD) questionnaire. Equipped with remote data transmission, the AM2+ transfers the data to the investigative site, which enables the physician to closely monitor the patient's entries. If spirometry values or symptoms have deteriorated substantially, treatment for a CF pulmonary exacerbation are initiated. By expanding the number of investigative sites, the researchers are aiming to enroll an additional 120 patients, which will enable them to study the effects of intervention on a broader, more diverse patient group.

ERT's comprehensive line of centralized spirometry devices and services have been used in hundreds of studies worldwide, delivering reliable, high-quality data to clinical trial sponsors as they develop new medical compounds and / or medical interventional strategies for the treatment of asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis, and many other respiratory diseases.

"We're honored to work with Johns Hopkins and the University of Washington on this novel study and to support their efforts at better understanding the value of greater patient involvement in their own care through home monitoring of symptoms," said Michael Taylor, Senior Director, Healthcare Solutions for ERT. "We hope that the use of home monitoring at these additional investigative sites will lead to earlier, more reliable recognition and treatment of CF exacerbations, which can improve the quality of life for those suffering from this disease and potentially lower overall healthcare costs by decreasing the demand for expensive medical care."

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