Dear Potential Investigator,

Despite the availability of many current data sources, as well as many stand-alone respiratory studies and cohorts, there is a need for new prospective, observational data on patients with obstructive lung disease (i.e.: asthma and COPD). To overcome limitations of previous studies (narrow eligibility criteria, limited detailed information on patient reported outcomes [PROs], functional measurements and healthcare resource use, etc.), this observational study will recruit patients with a diagnosis or suspected diagnosis of asthma and/or COPD, and will collect data currently lacking, to describe patient characteristics, treatment patterns and the burden of illness to identify phenotypes and endotypes, based on biomarkers and/or clinical parameters that are associated with differential outcomes for symptom burden, clinical evolution and healthcare resource utilization. In addition, it is expected that this better characterization of phenotypes and endotypes will support future development of personalized treatment strategies for patients suffering from obstructive lung disease.

Asthma and COPD have traditionally been viewed as distinct clinical entities. Recently, however, attention has also been focused on patients with overlapping features of both asthma and COPD. The concept of the asthma and COPD overlap focuses attention on the need to accelerate beyond the information available at present on populations with physician diagnoses of asthma and COPD.

In terms of representability, many previous studies have been performed in patients identified by conventional diagnostic labels, or who satisfy stringent enrolment criteria for clinical trials; the latter patients may only represent around 4-5% of patients with asthma or COPD in the general community, and those with asthma-COPD overlap are almost invariably excluded.

In summary, there is a need for new broad and consistent prospective, observational data on patients with obstructive lung disease, despite the availability of many current data sources, as well as many stand-alone respiratory studies and cohorts.

PAREXEL has been asked by AstraZeneca to identify and pre-qualify sites for this multinational observational study. The NOVELTY study will collect a comprehensive set of data pertaining to the asthma and/or COPD patient journey in current clinical practice. This study will enroll approximately 14,800 subjects between June 2016 through March 2018. Patients will be followed up for a total duration of 3 years.

If you are interested in participating in this study please contact Caitlin.Shapiro@parexel.com before March 24th 2017.

Sincerely,

PAREXEL Non-interventional Research Study Team