# OBSERVATIONAL STUDY REPORT SYNOPSIS

**A cross-sectional study to determine the proportion and clinical characteristics of COPD patients with asthma symptoms in Asia (ACOS) and describe current practices in diagnosis and management**.
**Cross sectional, open label Non-Investigational study**

**Milestones:**                     Study Completed

**Phase of development:**           Not Applicable – Observational study

**Sponsor:**                        AstraZeneca Viet Nam and Taiwan

This study was performed in compliance with Good Clinical Practice and Good Pharmacoepidemiology Practice, including the archiving of essential documents.

**Background/Rationale:** The Global Initiative for Asthma (GINA) and Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines have given joint recommendations on the identification, diagnosis and treatment of these patients (6). These recommendations have been adapted for use in the Asia Area countries. Nonetheless, the application to clinical practice has not been well established and there are no prevalence data available on the COPD with asthma symptoms population based on the recommended features for identification.

## Objectives:

*Primary Objective:*

To determine the proportion and clinical characteristics of patients with ACOS as defined by the joint GINA and GOLD recommendation amongst diagnosed COPD patients seen at the out-patient clinics.

*Secondary objectives:*

- To evaluate the gap between guideline recommendations and real-world clinical practice in identifying COPD patients with asthma
- To review the medications given to COPD patients with asthma compared to guideline recommendations
- To review the current practices of symptom control assessment

## Study design:

This study was planned to conduct as an open label observational cross-sectional survey in patients with COPD seen and treated by physicians in the study sites. Patients enrolled in an unbiased manner (by consecutive sampling).

## Data source:

Data were collected by checking patients' previous records and asking questions to patients. All the data were collected and recorded in CRF which will be further used for statistical analysis.

**Study population:**

This study was planned to conduct as an open label observational cross-sectional survey in 640 outpatients (340 subjects in Taiwan and 300 subjects in Vietnam) with COPD seen and treated by physicians in the study sites. Patients enrolled in an unbiased manner (by consecutive sampling).

**Inclusion Criteria:**

The subject population that observed in the NIS, fulfilled all of the following criteria:

- All patients with confirmed diagnosis of COPD (post-bronchodilator FEV1/FVC<0.7 based on the medical records)
- Aged >40 years old at time of diagnosis
- Seen at out-patient clinic
- Signed written informed consent to participate in the study

**Exclusion criteria:**

The subject population that observed in the NIS, did not have any one of the following:

- Patients currently with acute exacerbation of COPD by GOLD definition (any worsening of a patient's respiratory symptoms that is beyond normal day-to-day variations and requires a change in medication)
- Patients with respiratory diseases that can show similar symptoms to chronic airway diseases such as bronchiectasis, tuberculosis (TB)-destroyed lung parenchyma, endobronchial TB, and lung cancer, or those who have history of these diseases based on physician's judgment
- Patients currently diagnosed with pneumonia and acute bronchitis
- Patients currently randomized in other clinical studies

**Statistical methods:**

All included patients were included in the analysis set. Additionally, data was analyzed according to the group with ACOS and those without ACOS.

With regard to the primary objective, the proportion of patients in overlapping COPD and asthma is calculated with descriptive statistics. A comprehensive statistical analysis plan was created by the data base lock points.

**Results:**

In this NIS study based on the statistical analysis it is observed that 185/640 patients were ACOS cases which is around 28.9% of the cases. All these 72.9% of the cases were diagnosed as per GINA/GOLD guidelines. Mean age of patients was 68.51 year. Of the 640 patients, 93.2%( 596/640) were male and remaining were female.

**Conclusion:**

- **28.9%** of the cases had prevalence of ACOS among COPD.

**Publications:**

None at the time of reporting writing.