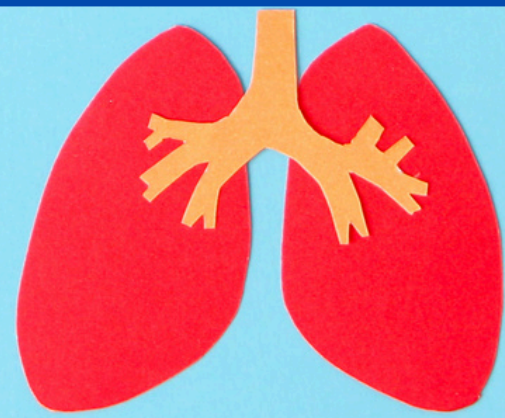


## Capability Case Study

# Exacerbations in COPD and Role of Tobacco Smoking, Clinical Indicators, and Medication Management



## What is COPD?

Chronic Obstructive Pulmonary Disease (COPD) is a progressive lung condition characterized by obstructed airflow, making it difficult to breathe. Typically caused by long-term exposure to irritants such as cigarette smoke, air pollution, or occupational dust, COPD encompasses various lung diseases like emphysema and chronic bronchitis. Symptoms include shortness of breath, chronic cough, wheezing, and chest tightness, often worsening over time and significantly impacting daily life. Early diagnosis and management, including smoking cessation and medication, are crucial in alleviating symptoms and improving quality of life for those affected by COPD.

## Objective of the Study?

- Assessment of COPD by understanding the burden of severe exacerbations of COPD.
- Assess the prevalence and impact of tobacco smoking on COPD exacerbations
- Evaluate the relationship between key clinical indicators (blood eosinophil measurement, COPD Gold Grade, mMRC dyspnea scale, and %FEV1 change) and severe COPD exacerbations, identifying potential predictors for exacerbation risk.
- Evaluating impact of Respiratory maintenance and reliever treatment medication exposure on exacerbations of COPD.

### 1 - Patient's lifestyle in terms of tobacco smoking within the COPD population.

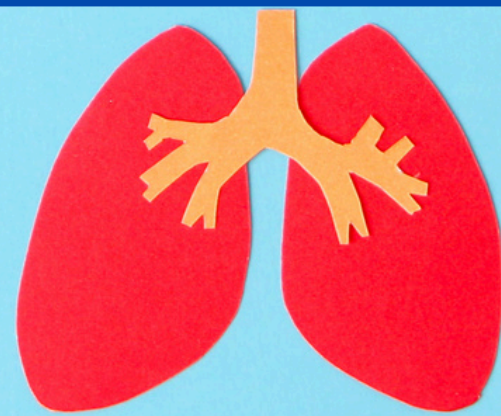
It includes the total number of patients (N) within the COPD population, as well as the breakdown of patients based on their smoking status: non-smokers, ex-smokers, and current smokers. The data is further categorized by country, providing insights into smoking prevalence across different regions. -Frequency counts give the number of patients in each smoking category, while percentages show how smoking status is distributed within the COPD population and across countries. This information can help identify patterns of tobacco use and inform public health interventions aimed at reducing smoking prevalence among COPD patients.

### 2 - Patients' dyspnea severity based on the Modified Medical Research Council (mMRC) Dyspnea Scale within the COPD population.

It presents the total number of patients (N) within the COPD population and the distribution of patients across different dyspnea grades. - The frequency counts provide a detailed breakdown of the number of patients experiencing each dyspnea grade, ranging from Grade 0 (only experiencing breathlessness with strenuous exercise) to Grade 4 (too breathless to leave the house). This comprehensive categorization enables a clear understanding of the distribution of dyspnea severity within the COPD population, delineating the spectrum of symptom severity. Additionally, percentages offer insights into the proportion of patients experiencing each level of dyspnea severity, both overall and within each country. This information can aid in identifying the prevalence of dyspnea and its impact on COPD patients' quality of life across various regions.

## Capability Case Study

# Exacerbations in COPD and Role of Tobacco Smoking, Clinical Indicators, and Medication Management



## COPD Data Analysis?

- Change in Forced Expiratory Volume was analyzed as compared to Baseline for Statistical Significance.
- COPD data was summarized as per COPD Gold Grade.
- Summary reports generated to evaluate the relationship between key clinical indicators and severe COPD exacerbations.
- Patients' data was summarized as per patients' Lifestyles to get a summary of Tobacco Smoking.

### 3 - Patient's blood eosinophil measurements within the COPD population.

It includes both overall statistics and country-specific data, offering insights into the distribution of blood eosinophil counts (BEC) across different regions. - The frequency counts provide valuable insights into the distribution of blood eosinophil levels within the COPD population, categorizing patients into different categories such as  $BEC < 100$  cells/uL,  $100 \text{ cells/uL} \leq BEC \leq 300$  cells/uL, and  $BEC > 300$  cells/uL. Additionally, percentages offer further understanding by indicating the proportion of patients within each blood eosinophil level category, both overall and within each country. This information can aid in identifying patterns of eosinophilic inflammation and its potential implications for COPD management across various regions.

### 4 - Patient's COPD GOLD grade classification based on airflow limitation within the COPD population.

Frequency: The frequency counts provide the number of patients falling within each COPD GOLD grade such as, GOLD FEV1% predicted  $\geq 80\%$ , GOLD 2: FEV1 % predicted 50-79% , GOLD 3: FEV1% predicted 30-49% ,GOLD 4: FEV1 % predicted

### 5 - Analysis of the change in %FEV1 (forced expiratory volume in one second as a percentage of predicted) from baseline to post-baseline within the COPD population.

Baseline refers to the initial measurement or assessment taken at the beginning of a study or intervention.

Here baseline %FEV1 measurement represents the lung function level at the start of the study or intervention. Postbaseline refers to measurements or assessments taken after a certain period following the baseline assessment. Here, post-baseline measurements are typically taken at specific time points after the initiation of treatment or intervention.

P-value: - The p-value is calculated using statistical tests such as the paired t-test or Wilcoxon signed-rank test to determine the significance of the observed change in %FEV1 from baseline to post-baseline.

- A low p-value ( $<0.05$ ) indicates that the observed change is statistically significant, suggesting that there is a real difference in %FEV1 measurements between baseline and post-baseline assessments.