POPE-Study
Phenotypes of COPD
in Central and Eastern Europe Study

POPE STUDY Phenotypes of COPD in Central and Eastern Europe

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POPE study is a multinational, multicentre, prospective, observational, non-interventional registry in patients with COPD in Central and Eastern Europe. The aim of the POPE study is to assess the distribution of patients with COPD in clinical practice within the CEE region according to disease severity, disease category, and phenotypes. The study was initiated as the first cooperation in CEE region of COPD PLATFORM and 12 countries from Central and Eastern Europe have been involved in POPE study. The data collection is planned for 6 months during 2014. Data on 300 consecutive patients with positive smoking history eligible to inclusion criteria will be collected per each participating country. Consecutive non-smokers with COPD can also be enrolled above this limit and this group will be analysed separately. Five centres in Austria have taken part in the project.
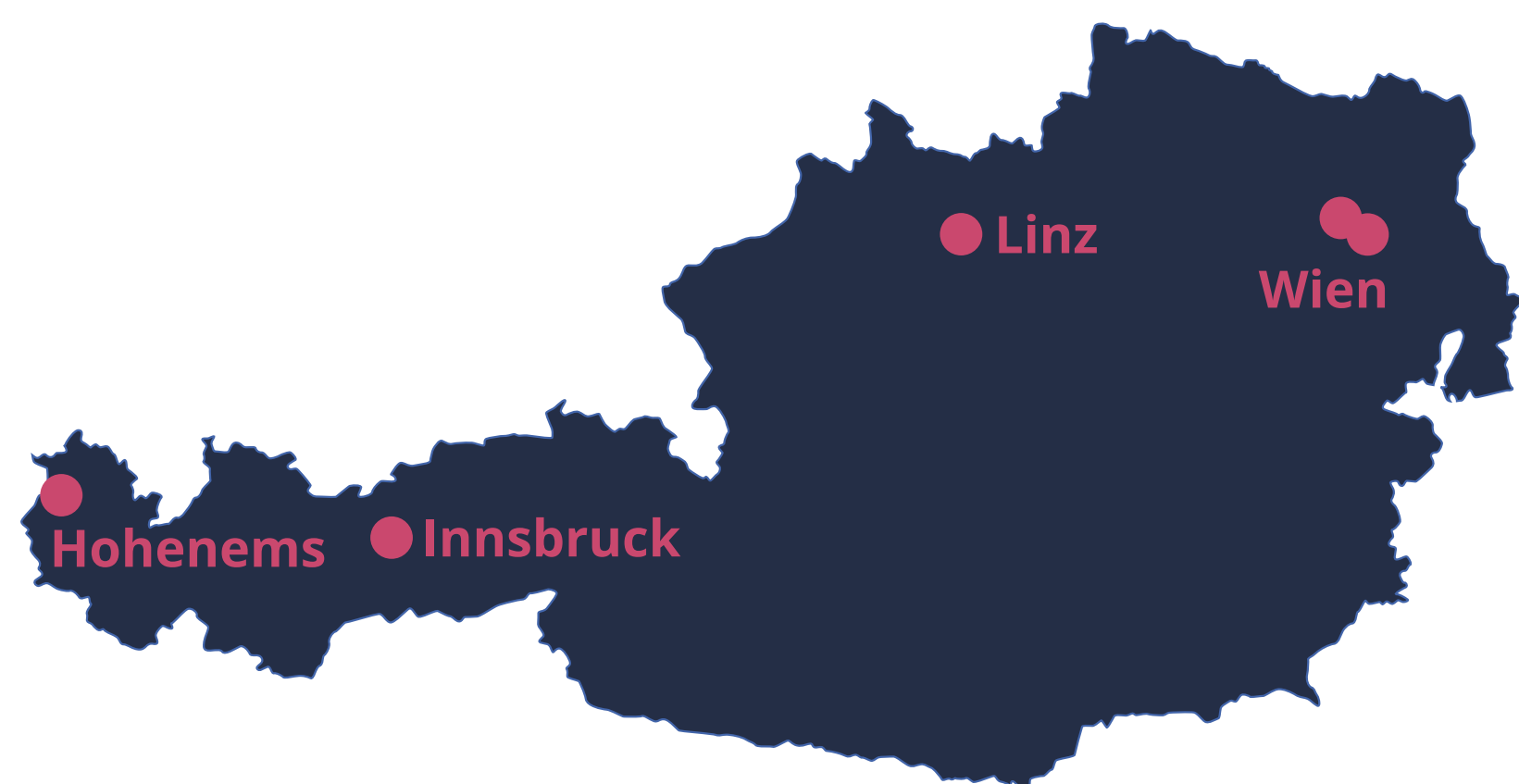
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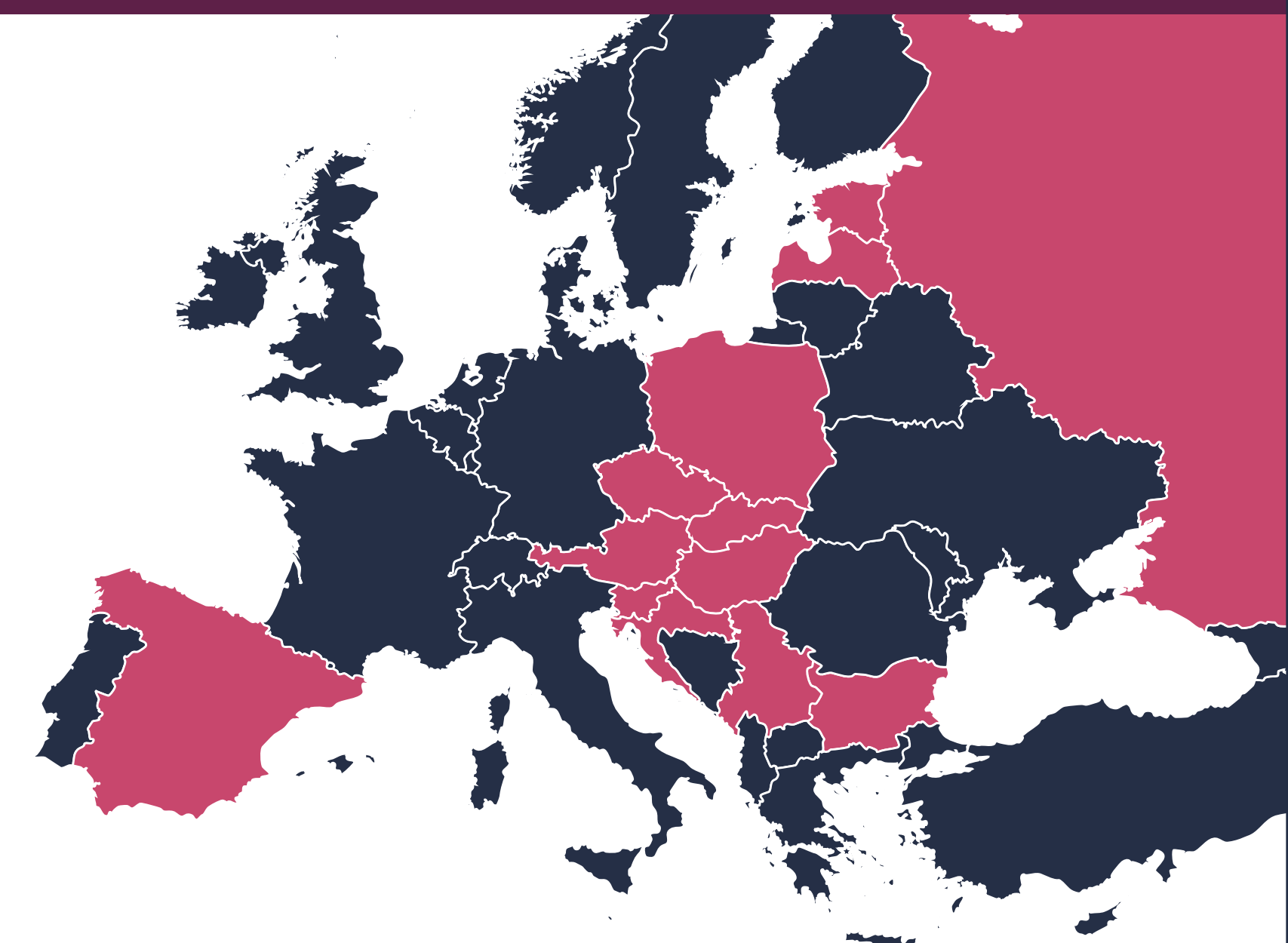|	
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(Map of Austria showing: Linz, Wien, Hohenems, Innsbruck)

INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is a significant cause of morbidity and mortality in Europe and a major consumer of resources in both primary and secondary healthcare. Both clinical features of disease severity and quality of COPD patient care may have substantial influence on disease outcomes. Traditionally, COPD has been categorized using the FEV1-based GOLD (2011) classification. Other factors independently associated with survival include age, dyspnoea, health status, lung hyperinflation, gas exchange abnormalities, exacerbation frequency, exercise capacity, pulmonary hemodynamic, and nutritional status. Together these factors explain some of the existent heterogeneity within each GOLD stage in terms of symptoms, exacerbations, quality of life and exercise capacity.

The most frequently reported phenotypes are emphysema and chronic bronchitis, along with a subset of asthma sufferers. Recently, an extended list of proposed phenotypes have been proposed (6) including: (A) infrequent exacerbators with either chronic bronchitis or emphysema; (B) overlap COPD-asthma; (C) frequent exacerbators with emphysema predominant; and (D) frequent exacerbators with chronic bronchitis predominant. While there is consensus of substantial, but not complete, overlap among these phenotypes, the distribution of these phenotypes may differ widely between different countries and healthcare systems.

The objectives of this study are to better understand the patient characteristics and treatment patterns of those diagnosed with COPD between different CEE countries. Knowledge of this information may provide insight into the variability of phenotypes between different healthcare systems and may subsequently contribute to a better understanding of the factors associated with patient outcomes and have the potential to improve the care of COPD patients.

Primary aims
- To determine the proportion of patients within the GOLD 2011 strategy disease severity (Stage 1, 2, 3, 4) and risk classification category (A, B, C, D) in an unselected group of consecutively examined patients with COPD in the CEE region

Secondary aims
- To evaluate the prevalence of disease phenotypes according to predefined criteria
- To evaluate the diagnostic approach to COPD in CEE countries
- To assess the differences in treatment habits in CEE countries

Inclusion Criteria
- Age > 40 years
- Clinical diagnosis of COPD with post-BD FEV1/FVC < 0.7
- Smoking burden ≥ 10 pack-years in smokers (group A). Evidence of exposure to at least one other typical inhaled COPD risk factor: ETS, professional exposures, etc. (group B)
- Each country will include 300 COPD subjects with positive history of smoking (at least 10 pack-years). Consecutive non-smokers with COPD can be enrolled above this limit. IBA will analyze both COPD groups (A and B) separately
- Stable disease for at least 4 weeks
- Outpatient status
- Informed Consent

Exclusion Criteria
Exclusion criteria are defined to distinguish other primary conditions that might produce symptoms similar to those of a COPD
- Exacerbation of COPD and/or instable co-morbid condition
- Patient during hospital stay for whatever reason (lung or co-morbidities)
- Patient is not able and willing to participate

METHODOLOGY

The database system has been designed as a robust base for collection of large amount of data in clinical trials and/or clinical registries, is fully customized to the structure of POPE project.

The on-line application is accessible to users via the internet browser. The security of individual records within the registry is guaranteed via de-identified data collection. Each patient's identity is replaced with a number (ID) which does not allow any backward identification of that person. The unequivocal identification of patient is only known to the attending physician or to an authorized health care professional. The quality of collected data is ensured by continuous data validation enabled y the system itself. The main advantages of the system involve centralized administration, uniform appearance of forms for data collection in all registries and easy development of new, extending functions.

POPE study is a cross-sectional survey of patients with COPD across Central and Eastern European Countries. The aim of the study is to identify clinical characteristics, phenotypes, and treatment preferences in patients with stable COPD. The design of this study is similar to recent audits in COPD. Additional analysis of lifelong non-smoking COPD patients will be prepared. The group of non-smoking COPD patients will be analysed separately and this analysis will try to identify the differences between patients with COPD caused by smoking and COPD patients with the absence of smoking history.

PROJECT SCHEDULE

Phase	2013 6	7	8	9	10	11	12	2014 1	2	3	4	5	6	7	8	9	10	11	12	2015 1	2
Phase 0																					
Kick-off																					
Protocol																					
eCRF, ICF																					
Phase I																					
Centres recruitment, EC																					
Phase II																					
Data collection																					
Phase III																					
Data validation																					
Data analysis, results publication																					

The data collection is planned for approximately 6 months and will be finished after the limit of 300 consecutive with smoking history per each participating country is reached. No limit is set for consecutive patient with non-smoking history.
The interim data analysis is planned to be presented in Vienna on 24-25 October in **COPD Platform Conference.** The POPE study will be submitted to clinicaltrials.gov. The further information can be found on www.copdplatform.com.

CONCLUSION

The POPE study has been designed to answer both primary and secondary aims and to describe the incidence of individual categories and phenotypes, including the lesser seen categories such as cachectic and bronchiectasis phenotypes, both of which occur at less than 10%. It is necessary for COPD PLATFORM to find an adequate testing strength and a high accuracy of estimation for the objective of generalization of the results on the whole of population of the region (CEE). The optimal number of patients from CEE region should be 3600. The first analysis on interim data is planned in October 2014, the final data set will be analysed at the beginning of 2015.