EMPOWAIR: A real-world, multicenter, prospective cohort study using innovative remote patient monitoring technologies in adults with Severe Eosinophilic Asthma treated with Benralizumab in routine care settings in Greece

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INTRODUCTION

- Asthma is a chronic respiratory disease that encompasses a broad spectrum of phenotypes and endotypes [1].
- Approximately 5-10% of patients with asthma suffer from severe disease, which cannot be adequately controlled by conventional treatment with a high dose of inhaled corticosteroids combined with long-acting β2-agonists or oral corticosteroids (OCS), or control is lost when de-escalating treatment.
- Based on a 2021 report of the International Severe Asthma Registry, in >80% of patients with severe asthma, the disease is characterized by the presence of eosinophilia, which causes inflammation and hyperresponsiveness of the airways, and is referred to as severe eosinophilic asthma (SEA) [2,3].
- **Patients with SEA experience substantial symptom burden and frequent disease exacerbations, which contribute to disease-related morbidity and progressive loss of lung function.**
- Benralizumab is a monoclonal antibody (mAb) approved for add-on biologic treatment of SEA, in 2017 and 2018 in the USA and Europe, respectively.

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STUDY DESIGN- RESEARCH OBJECTIVES

- EMPOWAIR ("A r**E**al-world, **M**ulticenter, 48-week **P**rospective cohort study to capture clinical and patient-centered **O**utcomes in adults **W**ith severe eosinophilic **A**sthma treated w**I**th ben**R**alizumab in routine care settings in Greece", NCT05440656) is a single-country, non-interventional, multicenter, 48-week prospective cohort study which will include adult patients with SEA initiated on benralizumab in routine care settings of Greece ***(Table 1)***.
- **The study will be carried out by 20-25 sites comprising private practices and hospital clinics specializing in the management of asthma in geographically diverse locations throughout Greece**
- The overall duration of the study is expected to be approximately **126 weeks (~29 months)**, including a recruitment period of **78 weeks** and an observation period of **48 weeks** (***Figure 1***).

DATA COLLECTION

- ✓ Primary data will be collected at enrollment and study visits
- ✓ Study-specific **physical activity data** will be collected using a **WAT device (Fitbit® wristband)**.
- ✓ For the **home-based spirometric measurements**, patients will be provided **the portable hand-held Air Next spirometer.**
- ✓ Secondary data will be abstracted from patients' medical records and through patient self-report.

PRIMARY OBJECTIVE

- ✓ To assess the change from baseline in HRQoL (measured by the SGRQ) and to estimate the proportion of patients achieving a minimum clinically important improvement in respiratory health status after 16 weeks of treatment with benralizumab.

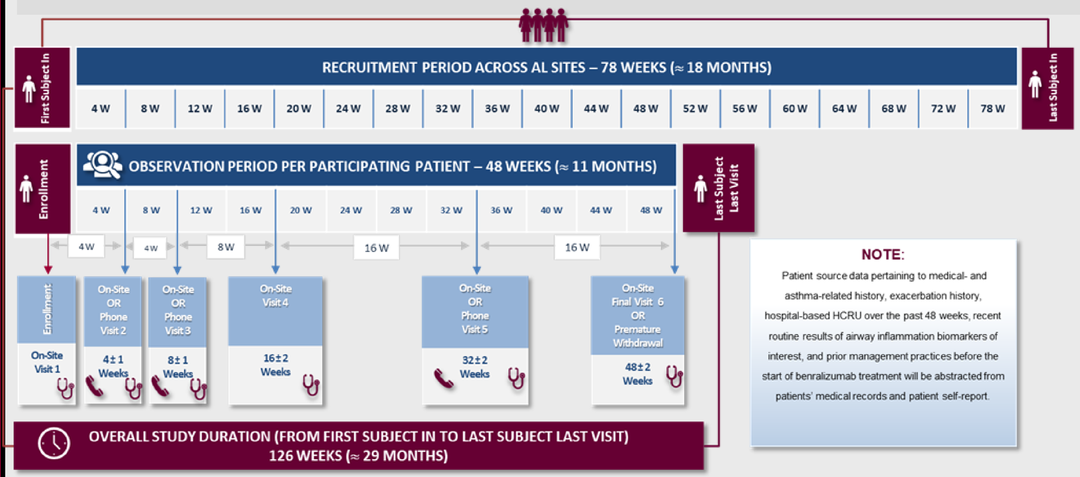

Figure 1. Overview of the study design

Table 1: Study eligibility criteria

INCLUSION CRITERIA	EXCLUSION CRITERIA
☑ Male or female outpatients, aged 18-75 years at the time of benralizumab prescription.	☒ Any of the contraindications to the administration of the benralizumab per the SmPC.
☑ Physician-diagnosed SEA inadequately controlled despite high-dose inhaled corticosteroids plus long-acting β-agonists.	☒ Concomitant treatment with any other biologic agent for any indication.
☑ Patients prescribed but not yet having initiated treatment with benralizumab according to the SmPC, prior to signed Informed Consent, and for whom the decision to prescribe this therapy is clearly separated from the physician's decision to include the patient in the study.	☒ Previous exposure to any anti-IL5/IL5R treatment.
	☒ Exposure to omalizumab in the past 6 months prior to benralizumab initiation.
	☒ Clinically important pulmonary disease or prior diagnosis with any disease, other than asthma, associated with elevated BEC.
☑ For patients not OCS-dependent: BEC ≥150 cells/μL in the 2 weeks before benralizumab initiation and a historical value of ≥300 cells/μL during the previous year.	☒ Acute respiratory infections within 8 weeks prior to informed consent.
	☒ Heavy smokers with a >20 pack-year smoking history.
	☒ Pregnancy, lactation or pregnancy intention during the study period
☑ For OCS-dependent patients: BEC ≥150 cells/μL in the 2 weeks before benralizumab initiation or a historical value of ≥300 cells/μL during the previous year.	☒ Known evidence of lack of adherence to asthma controller medications.
☑ History of ≥1 documented CSE in the 48 weeks prior to benralizumab initiation, and of ≥2 CSEs in the previous 24 months.	☒ Use of immunosuppressive medication for reasons other than asthma within 3 months prior to informed consent.
☑ Patients willing and able to read and complete the study specific questionnaires.	
☑ Patients willing and able to use the study-specific wearable/handheld devices.	☒ Current receipt of any investigational drug/device/intervention or investigational product within 30 days or 5 half-lives of the agent before benralizumab initiation.
☑ Patients must provide a written Informed Consent prior to inclusion to the study.	

DISCUSSION

EMPOWAIR employs a multifaceted approach to assess the effect of **benralizumab treatment** on clinical and patient-centered outcomes in **patients with SEA treated in routine care settings in Greece.**

- **The study will make use of portable spirometers and WATs, handled by the patients themselves, to measure and record spirometric parameters and physical activity, respectively.**
- **This is the first time that such technological devices are being used in a real-world study of asthma at a country-level in Greece.**
- **The devices are thought to empower patients in their everyday asthma self-management with no intention to interfere with clinicians' decision-making and patient treatment plan.**
- **The study outcomes will be enhanced by enrolling patients from geographically diverse locations throughout Greece, accounting for variations in medical practice paradigms.**

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