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SCOPE International is an international and independent contract research organization (CRO) with a proven track record in managing all major respiratory indications in clinical phases I – IV, including pediatric trials, orphan drugs and medical devices, non-interventional studies (NIS) and post-authorization studies. Our close relationships with leading investigators and key opinion leaders worldwide enable us to deliver the highest quality solutions.



With the **increasing incidence of respiratory diseases** and **allergies worldwide**, the need for clinical trial expertise in these areas is **essential to running a clinical study or a full clinical development program**. A key quality that distinguishes SCOPE from our competitors is **our ability to consistently provide this expertise and achieve enrollment goals on time and budget**. SCOPE can help develop and **deliver the enrollment strategy** for your respiratory or allergy clinical trial.

In business since 2000, we have conducted **over 250 studies with 65,000 subjects worldwide**. We have **offices in 17 countries across Europe, Russia, Ukraine** and the **USA** with **250 permanent employees**. With our partner network, we are operational across all continents and markets wherever clinical trial services are required. SCOPE has **significant experience in conducting phase II-IV respiratory clinical trials**, ranging from a single protocol to full development programs. In recent years, we conducted **more than 36 studies in the respiratory area** for various disease states.

Our patient recruitment, site management and extensive support strategies are uniquely adapted to the specific therapeutic areas and clinical development stages of your product. With our expertise and experience, we can make sure your trial runs as efficiently as possible, meeting all regulatory standards while ensuring consistent quality.

Whether it's a **clinical developmental trial** (phase I-III), **post-authorization** (phase IV), **rescue, adaptive design study** or **even a complex device or diagnostic combination design**, we have the expertise, know-how and resources to guide you smoothly through all phases of development while meeting your objectives in a timely and cost-efficient manner.

## HERE'S WHAT SETS US APART

Our team of clinical project managers, clinical research associates (CRAs), data managers, experienced biostatisticians and medical staff are well-versed in managing and monitoring the procedures associated with objectives and end points used in many respiratory protocols. We value strong relationships with clinical investigators and key opinion leaders, and our expertise enables us to provide rapid feasibility and consulting services on a wide variety of respiratory protocol concepts and designs. As a result, our pharmaceutical and biotech clients can make decisions quickly and move their development programs forward at a rapid pace.

## KEY SUCCESS FACTORS IN RESPIRATORY STUDY DESIGN & MANAGEMENT

Our expertise in respiratory development enables us to accomplish recruitment of clinical research projects using the experience of each member of our project team to ensure the successful outcome of your important projects. SCOPE provides a well-established approach for successful respiratory trials.

SCOPE'S ADVANTAGE:

### Project Team

- **Our staff have the specific respiratory / pulmonology clinical expertise required by most studies**
- **Our low employee turnover rate allows consistency and continuity in your respiratory research projects**

### Device Experience

SCOPE International's team has also managed device clinical trials for

- **Asthma**
- **Chronic Obstructive Pulmonary Disease (COPD)**
- **Acute Respiratory Distress Syndrome (ARDS)**
- **Acute Hypercapnic Respiratory Failure**
- **Respiratory Viral Infections (RSV) in children**

## STUDY DESIGN, RANDOMIZATION & STRATIFICATION

Our team of Biostatisticians are able to provide advice about study design with reference to randomization & stratification, non-inferiority and adaptive design. Additionally, SCOPE is able to support post-marketing and pharmacoeconomic assessments.

**Asthma  
(mild, moderate,  
severe, pediatrics)**

**COPD**

**Asthma / COPD-Overlapping  
Syndrome (ACOS)**

**More than 18,000 patients  
in 28 countries globally**

**Development of a  
dry-powder inhaler**

**Large international  
investigator networks**

**Direct access to  
large patient pools**

—  
EXPERIENCE IN RESPIRATORY



STRATEGIC  
DEVELOPMENT



MEDICAL  
WRITING



BIOSTATISTICS AND  
SAS® PROGRAMMING



QUALITY  
MANAGEMENT



CLINICAL  
OPERATIONS



CLINICAL DATA  
MANAGEMENT



SAFETY  
MANAGEMENT



REGULATORY  
AFFAIRS

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CONTACT