



COMPREHENSIVE CAPABILITIES IN RESPIRATORY STUDIES

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 paediatric trials, orphan drugs and medical devices, non-interventional studies (NIS) and post-authorization studies. With our close relationships with leading investigators and Key Opinion Leaders worldwide, we can 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 full clinical development programme.

A key quality that distinguishes SCOPE from our competitors is our ability to consistently provide this expertise and achieve enrolment goals on time and budget. SCOPE can help develop and deliver the enrolment strategy for your respiratory or allergy clinical trial.

In business since 2000, we have conducted over 220 studies with 60,000 patients worldwide. We have offices in 17 countries across Europe, Russia, Ukraine and the US with 250 permanent employees – And 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 25 studies in respiratory for various disease states, including:

- 18 trials in asthma phase II/III (mild, moderate, severe)
- 5 trials including paediatric subjects in asthma treatment
- 2 studies concentrating on COPD (Phase III, NIS)
- 1 trial in Asthma/COPD-overlapping syndrome (ACOS)
- In total more than 11,000 patients in 28 countries with global reach
- Development of dry-powder inhalator – M.A. in 2013, EU
- Large international investigator networks at hand
- Ready access to large patient pools
- Knowledge of applicable EMA, FDA, EC and CA requirements

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-IV), post-authorization, 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 development phases 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 have 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 AND 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. Here's what sets us apart:

PROJECT TEAM

- Our staff have the specific respiratory/spirometry clinical expertise required by most studies
- Our low 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 and in particular with reference to Randomization & Stratification, Non-inferiority and adaptive design. Additionally SCOPE is able to support post marketing and pharmaco-economic assessments.

STUDY POPULATION	AGE GROUP	GINA
Mid to moderate asthma	Adult/Paediatric	Step 2-3/0-1
Moderate asthma	Adult/Paediatric	Step 3/1-2
Moderate to severe asthma	Adult/Paediatric	Step 2-3/0-1
Severe asthma	Adult/Paediatric	Step 4/2

SAFETY CONSIDERATIONS

SCOPE Medical and Pharmacovigilance departments are highly experienced in the development of study safety plans, safety database set-up and reporting as well as offering a full medical monitoring service and DSMB/DMC management to assure sponsors of meeting study safety monitoring requirements.

SUMMARY

SCOPE is able to support the study design and operational delivery of a wide range of respiratory studies, with our experienced team and network of local investigators in local investigators. We would welcome the opportunity for further 'no-obligation' discussions concerning the planning of your forthcoming projects.

FOR FURTHER INFORMATION

Please contact SCOPE's Business Development Team at contact@scope-international.com.