



## A FLEXIBLE APPROACH TO RESPIRATORY CLINICAL TRIALS

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WHEN YOUR FOCUS IS CLINICAL TRIALS,  
QPS' global clinic network provides the  
ideal support for your Phase I - IV clinical  
trials from initiation through filing.



# BURDEN OF RESPIRATORY DISEASE

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The global burden of pulmonary diseases like asthma and comorbid allergic airway disease, COPD, pulmonary fibrosis and lung cancer appears to be increasing worldwide. In particular, individuals living in urban areas are affected. Evidence suggests that urbanization, with its westernized lifestyle and high levels of vehicle emissions are linked to the rising frequency of many of these diseases observed in most industrialized countries.

According to several sources:

- ▶ 339 million people of all ages worldwide have asthma (GINA 2018)
- ▶ 383 000 people died of asthma worldwide in 2015 (WHO 2015)
- ▶ COPD caused 3.17 million deaths in 2015, 5% of all deaths (WHO 2017)

## CURRENT CHALLENGES

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Changing environmental conditions along with increases in smoking, air pollution and urbanization has caused an increase in the prevalence of pulmonary diseases. Big data analysis and prospective clinical studies play an important role in understanding risk factors, long term effects and drawbacks of current therapies. Presently, chronic inflammatory airway diseases such as asthma and COPD cannot be cured, but recent insights into their underlying complex

and heterogeneous nature, have driven the development of several novel targeted treatments, including biologics.

In close collaboration with key opinion leaders and having experts in respiratory diseases and certified technicians onboard, QPS can pride itself with a long-standing tradition in strategic and scientific input and high-quality clinical conduct of clinical studies in specific patient populations with respiratory diseases. Our respiratory clinical studies include all developmental phases, including data intensive biomarker sampling studies and exacerbation models (e.g. inhaled allergen, virus, LPS) and our experience and data bases include several study populations including healthy volunteers, patients with asthma, COPD and interstitial lung diseases (e.g. pulmonary fibrosis (PF)). Clinical studies can be conducted in our sites and collaborating centers in Europe, USA and Asia.

## QPS FOR YOUR NEXT RESPIRATORY TRIAL

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We have the experience to take your compound from the preclinical stage into a strategic set up and planning, to subsequent clinical studies, including the collection and analysis of relevant data, to registration. Whether your candidate drug is a small molecule,

biologic, immunotherapy or other medication, QPS has the experience and resources to handle your drug development program in an efficient and effective manner, in the right study population using adequate biomarkers and validated outcome measures and help to get your product to market.

Finding the right study population is crucial for the success of your respiratory studies. QPS' staff collaborates with worldwide networks of clinical experts experienced in clinical study conduct in specific patient populations to ensure high patient enrollment rates conforming to strict selection criteria.

## QPS SPECIFIC CAPABILITIES

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QPS has conducted over 100 clinical studies in the past 10 years in asthma and COPD. We have studied a broad range of lung function measurements, including:

- ▶ Spirometry, including static and dynamic lung volume measurements, and airway resistance measurements (body plethysmography)
- ▶ Impulse oscillometry
- ▶ Diffusion tests
- ▶ Bronchoprovocation challenges
  - Methacholine
  - Histamine/Mannitol
  - AMP/Hypertonic saline
  - Inhaled and intranasal allergens
  - Virus challenge
  - LPS (inhaled or intranasal endotoxin)
  - Experimental challenges



We have extensively utilized invasive and non-invasive airway sampling methods, including:

- ▶ Bronchoscopy (biopsies, BAL, brush, wash) and Induced sputum (inflammatory cells, RNA, soluble markers, PK measurements)
- ▶ Exhaled breath analysis
  - FeNO
  - Exhaled breath condensate
  - Soluble biomarkers, PK measurements
  - Temperature
  - eNose
- ▶ Nasal samplings
  - Nasal lavage (inflammatory cells and soluble biomarkers)
  - Brushing and scraping (inflammatory cells and RNA)
  - Nasal filter papers (soluble biomarkers)



## QPS IS A GLOBAL CRO WITH LOCATIONS AROUND THE WORLD

### BENEFIT FROM THE RESOURCES OF A GLOBAL CRO



Whether your focus is small molecules, protein biotherapeutics, vaccines, gene therapy or cell therapy, QPS provides a full range of clinical trial services to support all drug development needs from discovery, through clinical development and regulatory filing.



CUSTOM-BUILT RESEARCH™

**TIME IS OF THE ESSENCE IN DRUG DEVELOPMENT.  
CONTACT THE QPS BUSINESS DEVELOPMENT  
TEAM TODAY!**

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