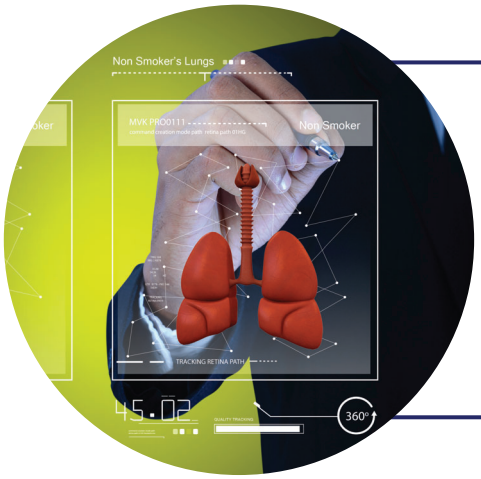
Objective Airway Challenge Testing in Clinical Research

The need to properly identify specific study populations has increased in recent years with the influx of specialized pharmacologic treatments for respiratory conditions. Direct and/or indirect airway challenge testing can offer insight into investigational drugs as objective measures to aid in phenotyping patient populations, assess response to therapies and evaluate bioequivalence.

Utilization of airway challenge testing in respiratory research is applicable beyond asthma studies. Additional disease states such as Allergic Rhinitis, Chronic Cough, and Idiopathic Pulmonary Fibrosis may potentially benefit from objective assessment of airway hyperresponsiveness and inflammation.[1-4,14]



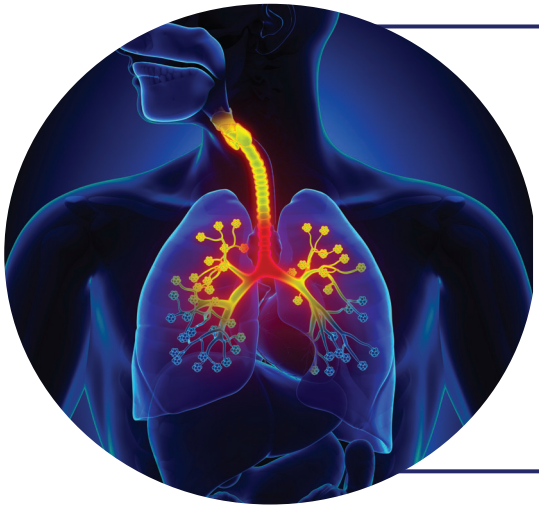
Inclusion / Exclusion Study Criteria

Correctly identifying patient populations in all phases of clinical trials is paramount to achieving successful study endpoints as well as reducing study costs associated with erroneous data. As established in the 2007 Expert Panel Report (EPR)[5], airway hyperresponsiveness and inflammation are two of the key characteristics of clinical asthma.

Since 1986 Methacholine Challenge Testing (MCT) has been utilized to directly assess airway hyperresponsiveness in clinical research studies to identify the target patient population. Indirect challenges additionally inform on both the pathogenesis of asthma and the role of anti-inflammatory agents in its treatment.[16]

Study of Pharmacodynamics / Bioequivalence

MCT has been an established marker for the assessment of study medications in compliance with FDA approval criteria. Current FDA draft guidance for generic albuterol products lists MCT as one of the methods to prove bioequivalence as a marker for the relative amount of beta agonist delivered to the airways.[8,9,13] Clinical pharmacologic dose-ranging studies can be assessed with MCT prior to and then following the test drug for bronchoprotective properties.[10, 11,12]



Development of Respiratory Treatments

In recent years, significant research has been realized in the identification of valid biomarkers for asthma.[6]

The term “precision medicine” has been proposed to define treatments targeted to the needs of individual patients on the basis of genetic, biomarker, phenotypic, or psychosocial characteristics that distinguish a given patient from other patients with similar clinical presentations. Inherent in this definition is the goal of improving clinical outcomes for individual patients and minimizing unnecessary side effects for those less likely to have a response to a particular treatment.[7,15]

Airway challenge tests allow monitoring of disease activity and effectiveness of treatments and can provide a robust disease model in early phase clinical trials.[17-20]

We invite you to contact us at:

Tel: 1-800-287-7686
E-mail: clinicalservices@methapharm.com

methapharm Respiratory