



NEW YORK (GBI Research), 20 June 2012 - We all know that smoking and some allergies take a toll on our lungs, but now science is standardizing the way that we **measure respiratory health**, helping to judge the **effectiveness** of **drug treatments** better than ever, according to a new report by healthcare experts GBI Research.

The new report\* shows that asthma and chronic obstructive pulmonary disorder (COPD), common conditions causing breathing difficulties, are now being studied using a set of common clinical endpoints, which help to standardize test results and draw conclusions regarding the effectiveness of new drugs.

COPD is cited as the fourth most common cause of death in the US by the National Institute of Health, representing a collection of progressive lung diseases including emphysema and chronic bronchitis, often caused by smoking, and is proving a heavy economic burden for state healthcare. Therefore, it has been imperative for health authorities to further improve on their endpoint measurements in order to compare the available treatment options for these disorders.

Clinical trial endpoints are used to measure the outcomes of medical testing, assessing the effects of new treatments. Endpoints in respiratory disease clinical trials should be accurate, precise, easily measurable and reliable, and range from techniques such as daily symptoms scoring, use of rescue medication and the quality of life score, to more specific vital signs such as measuring pulmonary function, respiratory rate and pulse.

The endpoints used in respiratory clinical trials are often chosen depending on the developmental stage of the molecule being studied, as agencies require Phase III trials to study direct clinical endpoints in order to grant drug approvals.

Physicians confirm diagnoses of asthma using pulmonary function tests (PFT), and classify the condition based on Peak Expiratory Flow (PEF) rate, frequency of symptoms and Forced Expiratory Volume (FEV). It is therefore not surprising that FEV was used in 29.9% of completed Phase III clinical trials for asthma products as a primary endpoint during 2000-2010, while another 29.3% of these trials used multiple PFT as a secondary endpoint.

Similarly, 49.2% of phase III COPD clinical trials during 2000-010 used FEV as a primary endpoint, while 20.3% used multiple PFTs as endpoints. PFTs were employed as a primary endpoint in 64 completed clinical trials for asthma and COPD.