



# Adherium’s SmartInhaler Used for Large Scale Electronic Data Capture in Landmark Mild-Asthma Trials

**San Mateo, CA – May 18, 2018:** Adherium (ASX: ADR), a digital health company that improves medication adherence and patient outcomes, announced the extensive use of its SmartInhaler™ technology in two landmark clinical trials investigating the treatment of mild asthma, which have just been published in the New England Journal of Medicine and will be presented this weekend at the American Thoracic Society’s 2018 Congress.

The clinical trials, known as Sygma 1 and 2, were two large scale, international clinical trials investigating treatment strategies for mild asthma. Each of the trials was a 52-week, double blind, multi-center, randomized clinical trial involving mild asthma patients 12 years of age or older. Both trials were funded by AstraZeneca.

In total more than 8,000 patients were randomized across both Sygma clinical trials. Each patient had their medication adherence monitored electronically by Adherium’s SmartInhaler devices for the 52 week duration of each study. SmartInhalers were provided for all inhalers including combination, conventional, rescue, and placebo. In Sygma 1 the SmartInhaler data was automatically wirelessly uploaded to Adherium’s SmartChat App software directly after each dose of medication was actuated by each patient. In Sygma 2, the SmartInhaler stored the medication adherence data in its memory until it is uploaded by the investigators into the SmartChat Library. The SmartChat software then forwarded the data to the Study databases to enable real-time data collection and safety monitoring.

The trials were conducted by two leading groups of Investigators, including: Paul M. O’Byrne, M.B., Eric D. Bateman, M.D., J. Mark FitzGerald, M.D., Peter J. Barnes, M.D., Nanshan Zhong, Ph.D., Christina Keen, M.D., Carin Jorup, M.D., Rosa Lamarca, Ph.D., Stefan Ivanov, M.D., Ph.D., Helen K. Reddel, M.B., B.S., Ph.D., and Agnieszka Siwek-Posluszna, M.D.

Arik Anderson, CEO of Adherium said “These clinical trials are the largest in history to employ electronic data capture of medication adherence at the point of drug delivery, and therefore represent a key milestone in the adoption of this technology. Over the course of the two trials Adherium technology monitored around 70 million hours of patient inhaled medication usage, and generated hundreds of millions of data points. We are delighted with the outcomes of the studies for patients with mild-asthma, the investigators, and the sponsor”.

## About the Sygma 1 and Sygma 2 Clinical Trials

Mild asthma is important because it is the most common form of asthma, affecting approximately half of the asthma population that exhibits persistent asthma. Asthma exacerbations present a serious risk to patients regardless of whether the asthma is mild, moderate or severely persistent.



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The first trial Sygma 1, was run by Professor Paul M. O’Byrne and his colleagues. 3,849 patients with mild asthma were randomized into one of three different inhaled treatment groups: 1) as-needed rescue medication; 2) twice-daily steroid medication plus as-needed rescue medication; and 3) as-needed combination medication. Patients in the as-needed combination medication group achieved reductions in exacerbations similar to the twice-daily maintenance group, yet had only a fraction of the accumulated steroid exposure over the 52-week period.

The second trial Sygma 2 was run by Professor Batemen and his colleagues and randomized 4,215 mild asthma patients into two groups to receive either: 1) as-needed combination therapy; or 2) twice-daily steroid maintenance medication plus as-needed rescue medication. Patients in the combination therapy group had fewer exacerbations despite a 75% reduction in median daily dose of steroid than the maintenance group.

Full details of the trials are provided in the peer reviewed journal articles available at the New England Journal of Medicine website, <https://www.nejm.org/>. The articles are titled: “Inhaled Combined Budesonide–Formoterol as Needed in Mild Asthma”, “As-Needed Budesonide–Formoterol versus Maintenance Budesonide in Mild Asthma”, and are accompanied by an editorial “On-Demand versus Maintenance Inhaled Treatment in Mild Asthma”.

### **About Adherium**

Adherium is a provider of digital health solutions and a global leader in connected respiratory medical devices, with over 100,000 sensors distributed globally. The Company develops, manufactures and supplies patients, pharmaceutical companies, healthcare providers and contract research organizations with the broadest range of connected medical devices for respiratory medications. The devices and accompanying technology address sub-optimal medication use and strive to improve health outcomes in chronic disease. Adherium is headquartered in the USA, and operates globally from bases in the USA, Europe and Australasia. Learn more at [adherium.com](http://adherium.com).

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