**ASTRO-LAB — Result In Brief**

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**Assessing bronchodilator safety**

*Evidence suggests that asthma patients do not always adhere to treatment routines prescribed by their doctors. EU-funded researchers are linking actual pharmaceutical usage to outcomes to better understand drug safety and efficacy.*

Long-acting beta-2 adrenergic agonists (LABAs) are bronchodilators given to treat asthma. They are prescribed in Europe in the case of persistent asthma, to be used with inhaled corticosteroids (ICs) or on their own. Although effective, LABA safety is an issue, particularly in children – a factor that must be addressed in order to assess the benefits and risks.

EU-funded researchers working on the project ASTRO-LAB (Assessment of the safety of LABAs in asthma in routine care by combining health-care databases and direct patient follow-up) are investigating these issues in detail to link usage data with asthma outcomes. The study includes adult patients as well as children. It takes into account how patients use LABA and IC inhalers, factors affecting their attitudes and decisions, physician care and how that affects their asthma management.

Laying the groundwork in terms of protocol development, obtaining regulatory approvals and patient recruitment is a significant and critical component of ASTRO-LAB. Following nearly a year of discussion, scientists submitted the final version of the study protocol to the project's ethics and advisory boards for approval. The protocol was validated and the related patient consent forms, patient information sheets, case report forms and questionnaires were developed. Most of the requisite regulatory approvals have already been obtained.

To date, 800 general practitioners have been recruited to participate. Patient recruitment is ongoing in France and the United Kingdom, with over 1 000 patients already enrolled, of whom 479 are children.

Significant progress was achieved with regard to drug exposure validation and adherence measurement. Researchers developed specific adherence markers for their study. Their first pilot linkage between prescription database and French claims database had a matching rate equal to 85%.

**ASTRO-LAB** scientists are working hard to increase the efficacy and safety of LABA use for the treatment of asthma in both adult and child populations. Study outcomes will help in developing better guidelines for asthma management and improve patient outcomes.

Moreover, these study protocols may prove valuable in assessing other drugs and discerning between prescribing habits and...
usage habits to draw appropriate conclusions.

**Related information**

**Report Summary**

Periodic Report Summary 2 - ASTRO-LAB (ASSESSMENT OF THE SAFETY OF LABAS IN ASTHMA IN ROUTINE CARE BY COMBINING HEALTH-CARE DATABASES AND DIRECT PATIENT FOLLOW-UP)

**Keywords**

Bronchodilator, asthma, drug safety, long-acting beta-2 adrenergic agonists, adherence measurement

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