The ARIA study for adolescents with asthma

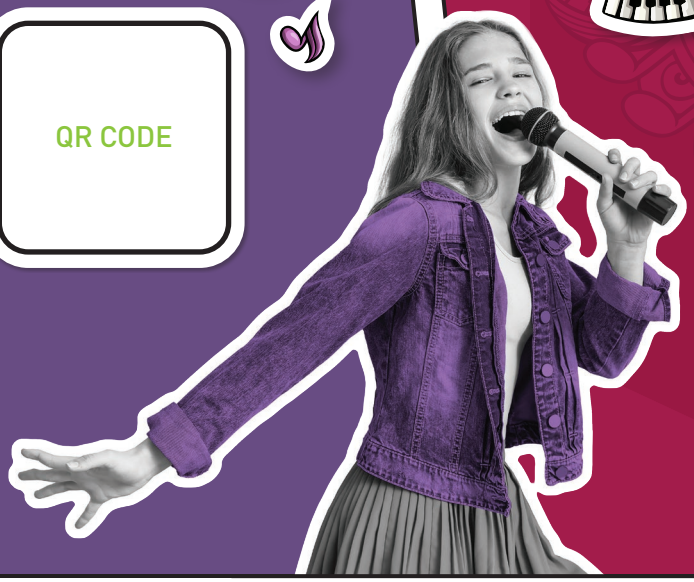
A quick reference guide to support discussions with caregivers of potential study participants

Thank you for your interest in learning about the ARIA study. This fact sheet provides more details about the study that you can share with caregivers of potential study participants. If caregivers have any questions or would like to know more, please direct them to scan the QR code or call the local study site at the number below.

What is this study?

The ARIA study is evaluating an inhaled study drug that consists of a combination of 3 medicines. This combination of medicines is currently approved in several countries as the first once-daily, single-inhaler, triple therapy for the maintenance treatment of asthma in adults 18 years of age and older. This study will compare the study drug to an approved asthma maintenance medication (in certain countries) in adolescents with asthma.

QR CODE



Who is this study enrolling?

This study is for adolescents 12 to 17 years of age who have been diagnosed with asthma for at least 1 year. The study sponsor, GSK, is committed to ensuring clinical study participants are representative of the population affected by asthma.

Why is the ARIA study important?

Despite the availability of several treatment options, some individuals may still have difficulty controlling their asthma symptoms. Researchers continue to explore study drugs for people with asthma through clinical studies.

How is the study drug being tested?

At the beginning of the ARIA study, all participants will be given a study-provided Ellipta inhaler to take once daily for 4 weeks.

After this period, participants will be randomly assigned (by chance) to receive a study-provided Ellipta inhaler being investigated to take once daily for 24 weeks. Participants, caregivers, and the study team will not know the inhaler assignment. Participants will also receive an inhaled "rescue" medicine (albuterol/salbutamol) to take as needed for asthma symptoms during the study.

How long will this study last?

Participants will be in this study for approximately 7 months and have at least 6 study visits over this period. Depending on the visit, study visits may occur at the study clinic, over the telephone, or remotely (e.g., at home).

How will participants' health be monitored in this study?

During the study, participants will visit the study site regularly for several types of tests and assessments. These may include:

- Physical examinations
- Vital signs measurements (blood pressure and heart rate)
- Breathing assessments
- Questionnaires
- Blood tests

Not all of these activities will occur at every visit.

What are the benefits and risks of being in this study?

Participating in a clinical study contributes to medical knowledge. The results of these studies can make a difference in the care of future individuals by providing information about the benefits and risks of study drugs. Any study has risks, which may include things that make a participant feel unwell. Approved drugs or study drugs may cause side effects. The study staff will review potential risks with caregivers before study enrollment.

Is participating in this study mandatory?

Taking part in a clinical study is voluntary. If a person is eligible to enroll, they may choose to join the study but leave at a later date without giving a reason.

How can caregivers learn more about the ARIA study?

To learn more, please direct caregivers to scan the QR code or call our local study site at the number below. The study team can also schedule a screening appointment to explain the study in detail.

Study site phone number:

GSK | ARIA Asthma Research in Adolescents