

# Why is this study being done?

Asthma inhalers use propellants that help push the medicine out of the inhaler and into the lungs. The propellants currently contained in all metered dose asthma inhalers, including those made by the pharmaceutical company GSK, contribute to greenhouse gas emissions. GSK is committed to making a positive impact on climate by creating a modified inhaler that uses the same asthma medicine (salbutamol/albuterol) but with an approximately 90% lower carbon footprint.

# What treatment will I get?

You'll be placed by chance, like flipping a coin, into 1 of 2 groups:

1. The commercial inhaler group, which will use a salbutamol/albuterol inhaler with the HFA-134a propellant. This propellant is currently used in commercially available asthma inhalers.
2. The modified inhaler group, which will use a salbutamol/albuterol inhaler with the HFA-152a propellant. This new propellant has an approximately 90% lower carbon footprint. The new propellant has been tested for safety in humans in a previous study.

Neither you nor the study doctor or staff will know which group you are assigned to.

# Welcome to the study!

Thank you for volunteering to help us in our quest to develop an inhaler with a low carbon footprint. While we have important research questions to answer, nothing is more important than your health and well-being.

Being in the study is voluntary and if you change your mind, you can leave the study at any time. We value your participation and are here to support you from the first visit to the final follow-up visit.

With much appreciation,  
The GSK Study 220735 Team

Your study doctor:

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Your study nurse:

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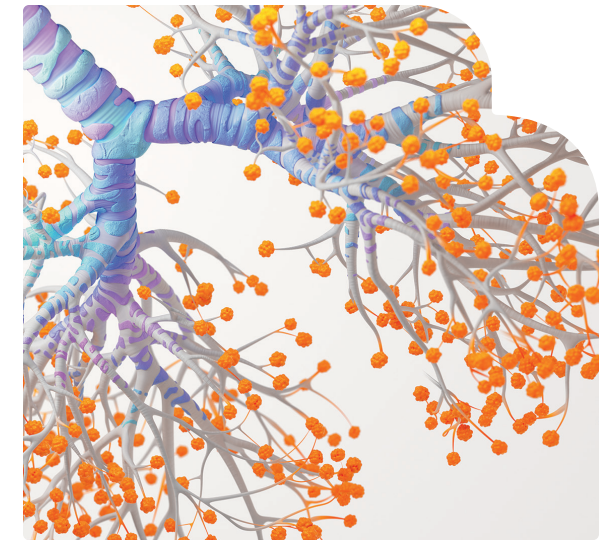
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Scan the code or visit  
[GSKLowCarbonInhalerStudy.com](https://GSKLowCarbonInhalerStudy.com).

PIN: 1234



# GSK Study 220735

Our commitment to healthy people and a healthy planet

A research study investigating a lower-carbon asthma inhaler

Welcome Guide



# What happens during the study?

During the study, you'll use the study inhaler for 12 weeks. Your study inhaler could be the commercially available inhaler or modified inhaler.

You'll visit the study clinic 8 times and have 1 phone call with the study staff. At clinic visits, the study doctor and staff will monitor your health and perform tests to answer research questions.

## Part A Screening

Up to 2 weeks  
1 or 2 visits\*

You'll have tests and health checks to see if you can be in the study.

## Part B Run-in

Up to 1 week  
1 visit

You'll replace your usual inhaler with the commercial inhaler to familiarize yourself with using the eDiary.

## Part C Study Treatment

12 weeks  
6 visits

You'll use the study inhaler and come to the study clinic for health checks and tests according to a schedule.

## Part D Follow-up

1 week  
1 visit

You'll have 1 final Follow-up Visit for health checks after you stop using the study inhaler.

\*If your asthma control tests need to be delayed or repeated, you may have 2 Screening Visits.

# What happens at study visits?

At study visits, you'll have tests and health checks so your study doctor and nurse can keep a close eye on your health and collect data for research purposes. Some tests will happen just a few times and others will happen every time you visit.



Physical exam



Vital signs



Lung function test



Blood test



Urine test



Pregnancy test (if applicable)



Heart activity test



Questionnaire



Asthma worsening assessment

Please see the inside of this brochure for a summary of the tests and health checks that will take place at each study visit. Each test is explained in further detail in the Glossary.

# What do I need to do between study visits?

Use your inhaler once daily and as required to relieve asthma symptoms. Bring back empty inhalers to your next visit.



Complete your eDiary twice daily, in the morning and evening, every day to document the number of puffs you have inhaled.



If you take 8 or more puffs for 2 days in a row, you and your study doctor will get an alert because it might mean your asthma is getting worse and requires medical attention.



Follow any special instructions the study staff gives you before specific visits.





# Study Visit Schedule



## Glossary

**Asthma worsening assessment:** At Visit 3, the study doctor will assess the severity or worsening of your asthma symptoms. Your health and safety are the number one priority. Depending on your asthma assessment, the study doctor may decide it is not in your best interest to continue the study.

**Blood test:** Blood samples will be taken from a vein, usually in the arm, 7 times during the study. The samples will be used for routine laboratory tests to check your general health.

**eDiary training and review:** You'll be trained how to use an electronic diary (eDiary) or app to track your use of the study inhaler. Complete the eDiary twice daily, in the morning and evening, every

day to document the number of puffs you took from your study inhaler. The study staff will review your eDiary throughout the study.

**Heart activity test:** The electrical activity of your heart will be measured using a relatively painless test called an electrocardiogram (ECG). For this test, you'll lie down and small sticky pads will be attached to your skin. The pads are connected by

wires to a computer that will pick up signals every time your heart beats.

**Lung function test:** Spirometry will be used to assess your lung function. For this test, you'll be asked to breathe deeply in and out, as far as you are able to, into a tube through a mouthpiece. The test measures the volume of your lungs, how well they fill with air when you breathe in and how fast they empty

when you breathe out.

**Physical exam:** The study doctor will check your overall health by examining your body, including your general appearance, head, eyes, ears, nose, throat, skin, abdomen, hands, and feet. The study doctor will listen to your heart and lungs. Your height and weight will be measured. At Visit 3, the study doctor will check for oral thrush, a fungal infection that can

occur with asthma inhaler use.

**Pregnancy test:** Participants who are able to have children will have their blood or urine tested for pregnancy throughout the study.

**Questionnaire:** You'll be asked to answer questions about various asthma symptoms, how often you use your inhaler, and how asthma affects your daily life. The questionnaire will take

approximately 10 minutes to complete.

**Study inhaler:** Your study inhaler may be the commercially available inhaler, which contains salbutamol/albuterol with the HFA-134a propellant or the modified inhaler, which contains the HFA-152a propellant.

**Urine test:** You'll be asked for a urine sample in a cup for laboratory testing. The

sample may be used for pregnancy testing.

**Vital signs:** These measurements include your body temperature, heart rate (how fast your heart beats), breathing rate (how many breaths you take in 1 minute), and blood pressure (how your heart is pumping and flowing through your blood vessels). They will be measured at each clinic visit.



Asthma worsening assessment



Blood test



eDiary training and review



Heart activity test



Informed consent



Lung function test



Physical exam



Pregnancy test



Questionnaire



Study inhaler



Urine test



Vital signs