

## What is a clinical trial?

A clinical trial is a scientific study in which participants are assigned to one or more investigational drugs to answer questions about the treatment to see if it works, works better than other treatments, and has side effects.

## What is an investigational drug?

An investigational drug is a substance that is being tested in clinical trials. It has been approved by an ethics committee for testing in people, and may or may not be approved by the government health agency for treatment for this condition.

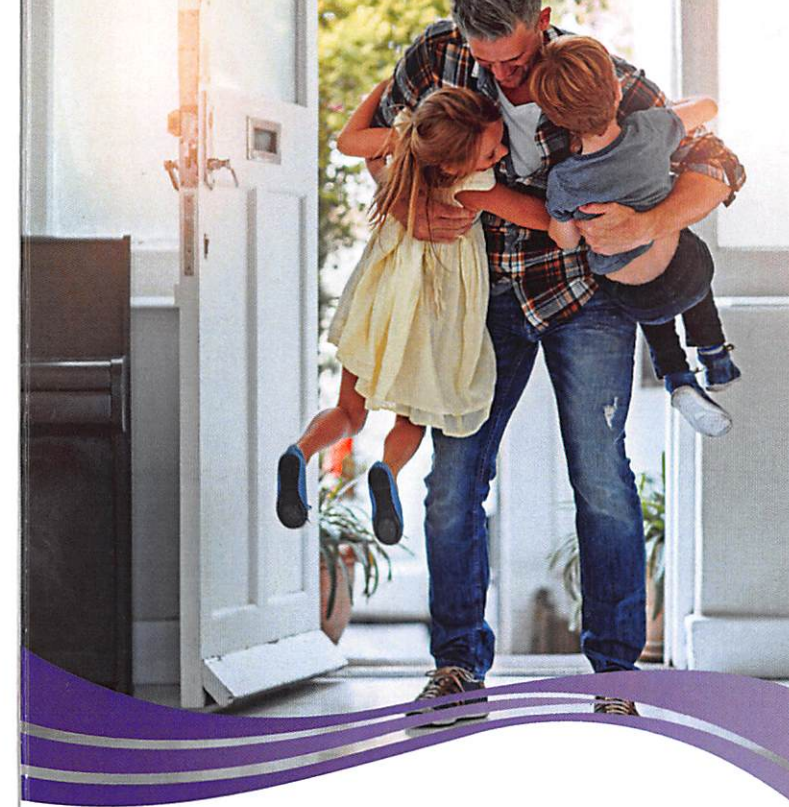
## Why should I take part in this study?

Clinical trials or studies are important for medical advances. Current treatments for diseases are only available because of research study volunteers.

# AVILLION

**Thank you for your interest  
in the MANDALA study.**

For more information,  
please contact:



**Let these be the moments  
that take your breath away,  
not asthma.**

Consider taking part in asthma research —  
so you can keep taking part in what matters most.

Information about the MANDALA study for asthma in adults  
and children 4 years of age or older

Protocol number: AV003

 The  
**MANDALA**  
Study



## Why is this study important?

Currently, there are several treatment options to help manage symptoms of moderate to severe asthma. These treatments may include inhaled corticosteroids, albuterol, and/or anti-inflammatory medication. These treatments can be used as needed to prevent or relieve symptoms.

Although these treatments are commonly used and can be effective, doctors continue to research treatment options for patients with asthma through clinical studies.

Pharmaceutical companies use clinical research studies like this one to learn more about investigational medications before they are made available to the public. Study volunteers can help us in this important research for the treatment of asthma. Thank you for considering participation in this trial.

## What is the purpose of this study?

MANDALA is a clinical study researching 2 doses of budesonide and albuterol inhalation suspension (BDA MDI). This study medication will be compared to an albuterol metered dose inhaler (albuterol MDI). Safety and efficacy of BDA MDI will be compared with albuterol MDI to relieve symptoms in adults and children 4 years of age or older with moderate to severe asthma.

## Who can participate in this study?

To be eligible for this study, you or your child must be:

- At least 4 years of age or older
- Diagnosed with asthma
- Willing to sign an Informed Consent form

Your doctor will review other study requirements with you to confirm if you or your child may qualify.

## How long will the trial last?

The study will consist of these time periods and clinic visits as follows:

### Screening period

About 2 to 4 weeks (14 to 28 days)

### Treatment period

At least 24 weeks and up to 36 weeks

## What can I expect if I decide to participate?

If enrolled in the study, you or your child will be randomly assigned to 1 of 3 treatment groups. Neither you nor your study doctor will know the treatment group to which you or your child is assigned.

**The treatment groups and the ages that may be assigned to each are as follows:**

BDA MDI 80/180 µg as needed	age ≥4 years
BDA MDI 160/180 µg as needed	age ≥12 years
Albuterol MDI 180 µg as needed	age ≥4 years

The study site staff will instruct you on how to administer the study medication. You or your child will visit the study site at least nine times over a minimum 6-month period, with possible additional visits every 3 months until the study is completed. Another visit will be required if you or your child complete the study early for any reason. Also, you will receive a follow-up phone call 2 weeks after the end of the study.

Lab tests, a physical exam, and other assessments and questionnaires will be conducted at the in-clinic visits. Not all activities will occur at every visit.

## What are my costs to take part in this trial?

You will receive all study-related procedures and the investigational product at no cost. You will also be reimbursed for your time participating in this study.

## What risks are involved if I decide to participate?

There are possible risks involved with any clinical study. Your study doctor will review the risks with you, and you or your child will be closely monitored throughout the study.