

**AVILLION**

 **The DENALI**  
Study



**CHILD:**  
Information for  
children ages 4 to 11

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

**The DENALI Clinical Trial**

A study for people with asthma

This guided script is meant to assist during  
the informed consent process.

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## Introduction

- This consent guide explains the study. Read the Informed Consent form (ICF) for additional explanations
- If patients cannot read this form, then the parent or guardian will read it
- Explain that the study staff is doing a research study and this means asking people questions and doing tests to learn new things
- These pages may use words that patients do not understand. Tell them to ask parent(s) or the study doctor or the nurse to explain any words they do not understand
- Patients should ask any questions that they may have and as many times as they would like
- Patients can ask questions at any time
- Patients can say "No" or "Yes" to being in the study, and no one will be upset if they say "No"
- Patients can say "No" at any time during the study
- The staff will still take care of patients who do not want to be in the study
- Patients are being asked to be in this study because they are 4 years old or older, and the doctor has said they have asthma (trouble breathing)

## Why is this study being done?

- This study will find out if a medicine called PT027 can help people with asthma better than other medicines
- In this study, patients will be given an inhaler containing the assigned study drug to use daily and a "reliever" Ventolin® inhaler containing albuterol to use for asthma symptoms
- No other asthma medications are allowed in the study
- The patient's inhaler will contain one of three medications: budesonide/albuterol, albuterol sulfate, or placebo
- Patients and their study doctor will not know which medicine is in their inhaler
- The study staff will also find out if patients feel bad after taking the medicine
- The study staff wants patients to help find out if this medicine works

## What will happen to enrolled patients?

- Patients may not be allowed to continue in this study after the first visit
  - If this happens, the study doctor will explain why
- Patients will come to the clinic at least 6 times
- Patients can ask to stop the study any time

- At clinic visits, we will:
  - Ask questions about how the patient is feeling
  - Ask patients to answer some questions with the help of their mother or father or the person who takes care of them
  - Take some blood and urine samples
  - Do some tests to check the heart and lungs
  - Do some tests to check the patient's health
- At home, the patient's mother or father (or the person who takes care of them) will give them the study medicine to inhale (breathe in) for asthma symptoms
- Patients can ask the study doctor questions about this study at any time
- Patients may or may not feel better from the study medicine, but patients will be helping others by adding to what we learn about the study medicine
- Some people may feel sick when they take the study medicine, like their throat or mouth might hurt, they may cough a lot, they may get a rash where the skin gets red, bumpy and may hurt, or other side effects not yet known
- If patients feel sick or hurt when they are in the study, they should tell their parents or the person who takes care of them so that they can tell the study doctor

## What if a patient does not want to get the study medicine?

- If patients start the study but at a later time decide they no longer want to be in the study, they can quit the study at any time
- Patients can say "No" even if their parent says "Yes," and no one will be upset
- Nobody will be mad if a patient doesn't sign the Informed Consent form (ICF) or if patients change their mind later
- Patients do not have to take part in this study
- If a patient does not want to take part, they should tell their mother or father or the person who takes care of them, and/or the study doctor
- If there are new things that the study doctor finds out about the study medicine, patients will be told right away, and they can decide to stay in this study or stop being in the study

## Patients may have questions

- Ask if the patient has any questions, or if there is anything they do not understand