

# Clinical Trial Results Summary

A Trial to Learn how much Mometasone Alone and in Combination with Indacaterol gets into the blood in 6- to 12-year-old Children with Asthma

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**Protocol number: CQMF149G2203**

## Thank You!

Novartis sponsored this trial and believed it is important to share what was learned from the results of this trial with the parents (or guardians), their children, and the public.

Thanks to the parents (or guardians) and their children for taking part in this trial for the drug mometasone combined with indacaterol, also known as QMF149. They helped researchers learn more about how mometasone combined with indacaterol works in children with asthma.



**If the parents, guardians, or their children have any questions about the trial results, please talk to the doctor or staff at the trial site. The summary shows the results of a single clinical trial. Other clinical trials may have different findings.**

# Why was the research needed?

Researchers were looking for a better way to treat asthma in children already taking asthma medications. Asthma is a condition that causes the airways of the lungs to swell, become narrower, and filled with mucus. This means that less oxygen can travel into the lungs, making it harder for a person to breathe.

The first step in research is to conduct a pharmacokinetic (PK) study, which measures the amount of trial medication that gets into the participant's blood.



PK studies aim to find out how a drug moves through the body, how long it takes to be absorbed, how it circulates within the body, and how it is metabolized (breaks down).

The trial medications studied were:

**Mometasone furoate** (referred to as mometasone in this document) is one of the medicines approved for patients with asthma.

**Indacaterol acetate** (referred to as indacaterol in this document) is an approved medication for asthma.

**QMF149** is a combination of mometasone and indacaterol and is an approved medicine for asthma in adults and young adults over 12 years of age.

## How long was this trial?

This trial started in June 2021 and ended in April 2022. The entire duration, from enrolling the first child to the last child completing the trial, was around 11 months.

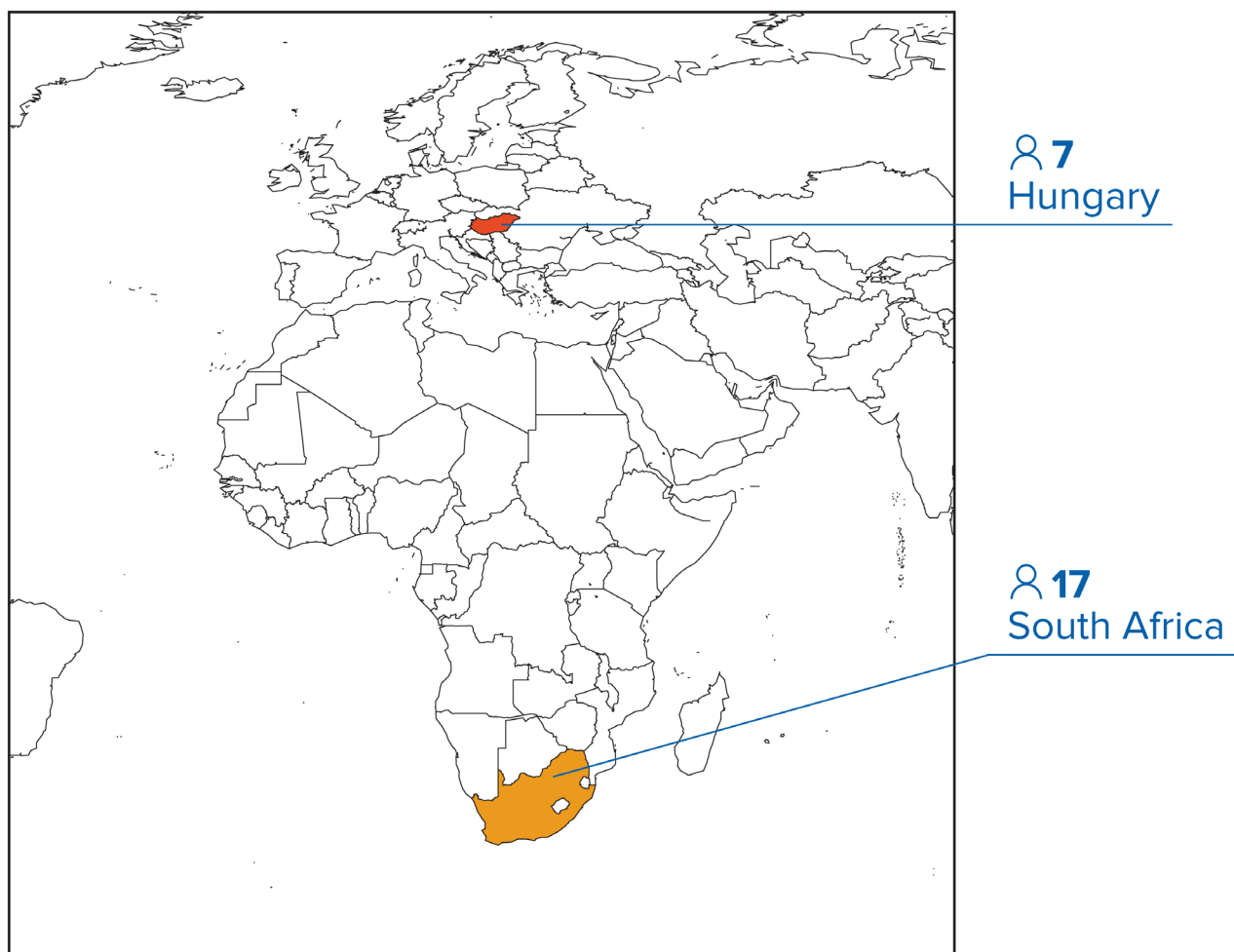
When the trial ended, researchers created a report of the trial results. This summary is based on that report.

# Who was in this trial?

Children could take part in this trial if they:

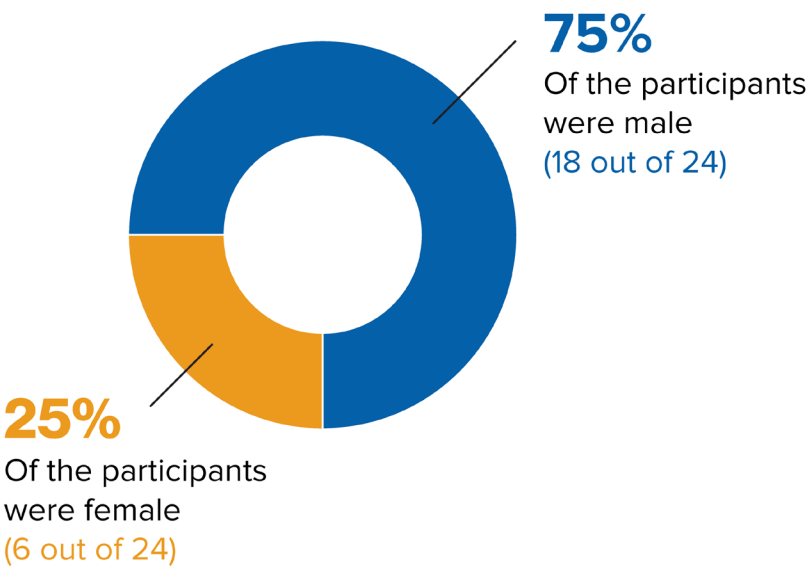
- were 6 years to 12 years of age and had asthma, confirmed by the doctor, for at least 6 months before they started the trial
- were using low-dose inhaled steroids as asthma-controlling therapy for at least 4 weeks
- were familiar with the use of an inhaler device
- did not have a history of any other long-term lung condition besides asthma or any other important medical condition that could affect the trial results

A total of **24 children from 2 countries participated** in this trial. 17 participants were from South Africa and 7 were from Hungary.

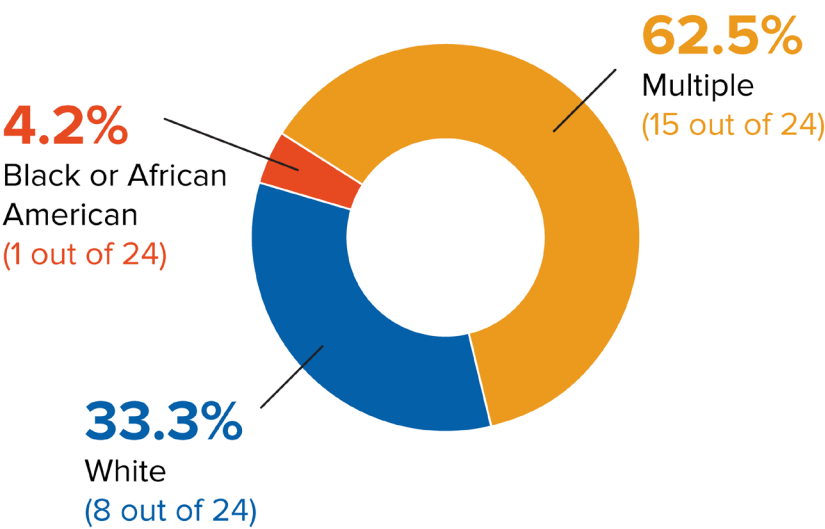


The average age of the children in this trial was 9 years old. The age of the children ranged from 6 to 11 years.

### Children’s Gender



### Children’s Race



# What treatments did the children take?

This was a trial where the children and their parents (or guardians), trial doctors, and trial staff knew what medication each child received. All children in this trial received the same medications.

## Trial Medications

There were two medications studied, mometasone alone and mometasone combined with indacaterol also known as QMF149. These were given using an inhaler, which is a device that enables the delivery of medicine directly to a person’s lungs through inhalation.

Drug	Pronounced as
Mometasone	moe-met-a-son
Indacaterol	inda-kate-rol

Single dose  
**Mometasone**  
via Twisthaler®



**Mometasone** is a standard inhaled steroid medication that is commonly used to help bring down the swelling in the airways of the lungs. Mometasone was given using a Twisthaler® device.

Single dose  
**QMF149**  
via Breezhaler®



**QMF149** is the inhaled drug that researchers were studying for the treatment of uncontrolled asthma. QMF149 is a combination of two medications: **indacaterol** 75 micrograms is an approved asthma medication that relaxes the tightened muscles of the lung airways; and **mometasone** 40 micrograms, is a steroid medication that helps bring down the swelling in the airways of the lungs. QMF149 was given using a Breezhaler® device.

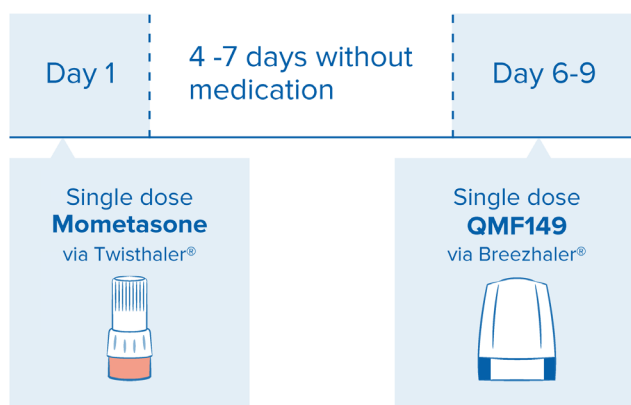
# What happened during this trial?

## BEFORE TREATMENT up to 14 days



The doctors checked the children to make sure they could be in this clinical trial.

## DURING TREATMENT



During these visits, blood samples were collected on day 1 and between days 6 and 9 (on the day QMF149 was given). The trial doctors measured how much study drug was in the children's blood after they inhaled either mometasone alone or the combination of mometasone and indacaterol, also known as QMF149. Rescue medications such as salbutamol were available in case of need.

## AFTER TREATMENT up to 30 days



The study doctor or clinic staff called the parents (or guardian) to review their child's health and how they were feeling.

# What were the main results of this trial?



**How fast does the body process mometasone and how much mometasone can be found in the blood, when given alone or as part of QMF149?**

The researchers found that the average highest level of mometasone and overall exposure during the first 6 hours, when given alone or combined with indacaterol (QMF149), was about the same.

This showed the researchers that both mometasone when given alone and combined with indacaterol (QMF149), reached similar levels in the children's blood.

## What medical problems did the children have during the trial?

Medical problems that happen in clinical trials are called "adverse events."

A lot of research is needed to know whether a drug causes an adverse event. During a trial, all adverse events are recorded, whether or not they are thought to be caused by the trial drug. When new drugs are being studied, researchers keep track of all adverse events children have.



An adverse event is any sign, symptom, or disease that participants have during a trial.

An adverse event is considered "serious" when it is life threatening, causes lasting problems, or the participant needs hospital care. These problems may or may not be caused by the trial drug.

This section is a summary of the adverse events that happened during this trial. The websites listed at the end of this summary may have more information about all the adverse events that happened in this trial.

### How many children had adverse events?

The adverse events that happened during the trial are listed in the table below. In this trial, three out of twenty-four children (12.5%) who received mometasone reported at least 1 adverse event. None of the children had to stop the drug due to adverse events. There were no serious adverse events.

## What adverse events did the children have?

Among the three adverse events that happened in children who received mometasone, the Twisthaler device failed on two occasions (8.3%) and was considered to be a mild adverse event and not related to the study treatment. The devices were not replaced. One child (4.2%) had the flu (influenza). There were no serious adverse events.

## How was this trial useful?

The trial helped researchers to learn that the single dose of mometasone and mometasone in combination with indacaterol (QMF149) behaved similarly in children with asthma between 6 and 12 years of age.

QMF149 was also well-tolerated by all the children.

This trial helped Novartis proceed to a large study, CQMF149G2301, to evaluate the effectiveness of QMF149 in treating symptoms of mild to moderate asthma in children between 6 and 12 years of age.

## Where can I learn more about this trial?

More information about the results and adverse events in this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website, [www.novctrd.com](http://www.novctrd.com).

Please follow the below steps:



You can find more information about this trial on the following websites:

1. [www.clinicaltrials.gov](http://www.clinicaltrials.gov) Use the NCT identifier NCT04589663 in the search field.
2. <https://www.clinicaltrialsregister.eu/ctr-search> Use the EudraCT identifier 2020-002036-78 in the search field.

**Full clinical trial title:** An open-label, two-period, single-sequence, crossover study to compare the systemic exposure of a single inhaled dose of mometasone furoate (MF) when administered alone via the MF Twisthaler® (TH) to a single inhaled dose of QMF149 indacaterol /MF fixed dose combination when administered via the Concept 1 (Breezhaler®) device in ≥6 to <12-year-old asthma patients.



## Thank You!

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Thank you for taking part in this trial. As a clinical trial participant, you belong to a large community of people around the world. You helped researchers answer important health questions and test new medical treatments.

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Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide.

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[www.novartisclinicaltrials.com](http://www.novartisclinicaltrials.com)

