

Clinical Trial Summary

A clinical trial to test the effects and timing of the trial drug QVM149 for people with asthma

Thank you!

Novartis, the sponsor of this clinical trial, thanks the people who joined and helped make this clinical trial possible.

Overview of results

Trial number: **CQVM149B2209**



In this clinical trial, researchers studied if a trial drug named QVM149 helped people with asthma breathe easier when taken in the morning or in the evening.

What should I know about clinical trials?



A clinical trial is a type of research designed to learn more about how our bodies respond to trial drugs or other treatments. Do not use the results of only one clinical trial to make decisions about your health care.

Researchers wanted to study:



- The effects of QVM149 on how easily people could breathe after 14 days of treatment
- Any differences based on the time of day when people took QVM149
- If QVM149 had other effects on people's lungs
- The safety of QVM149 during the trial

Who was in this clinical trial?



37 male and female adults with asthma began this clinical trial.

What type of clinical trial was this?



This was a Phase 2 clinical trial, which tests a trial drug's safety and how well it works in a small number of people.

How was safety tested?



Trial doctors asked about and checked for any medical problems, called adverse events, that happened during this clinical trial. People reported adverse events but none were serious.

What did researchers learn in this clinical trial?



Researchers concluded that QVM149 helped people to breathe easier during this clinical trial. There was no difference in the effects when people took QVM149 in the morning or in the evening.

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Researchers need many clinical trials to learn if a drug or other treatment is safe and works well. This is a summary of the overall results of this clinical trial, not the results for each person in the clinical trial.

Do not use only the results of this clinical trial to make health decisions. Always talk to a doctor before making any changes to your treatments.

Why was this clinical trial needed?

Researchers are looking for a better way to treat asthma. Asthma is a disease that causes the airways of the lungs to swell, making it hard to breathe.

The symptoms of asthma include:

- Shortness of breath – feeling like you can't breathe fast enough or deeply enough to get enough air in your lungs
- Wheezing – a high-pitched whistling sound while breathing
- Coughing
- Chest tightness

There is currently no cure for asthma, but some medicines can help open the airways in the lungs to help people with asthma breathe easier. Medicines that can open the airways in the lungs are called bronchodilators. Some people manage their asthma with one bronchodilator, but other people may need more than one bronchodilator for their asthma.

QVM149 is a trial drug that researchers are testing. It is a mix of 3 medicines that are approved for doctors to prescribe separately to treat asthma or COPD (chronic obstructive pulmonary disease). At the time of this clinical trial, QVM149 was not an approved medicine.

Researchers designed this clinical trial to learn if QVM149 could help people with asthma to breathe more easily when taken in the morning or taken in the evening.

In this clinical trial, researchers wanted to learn:

- The effects of QVM149 on how easily people could breathe after 14 days of treatment
- Any differences based on the time of day when people took QVM149
- If QVM149 had other effects on people's lungs
- About any medical problems, called adverse events, that people reported

Who was in this clinical trial?

37 adults with asthma, 21 men and 16 women, began this clinical trial. They were 44-years-old on average.

Every person in this clinical trial had mild to moderate asthma. They also had:

- Taken a daily low or medium dose of an inhaled steroid to treat their asthma. An inhaled steroid is a medicine that a person breathes in to lower swelling of the airways.
- Asthma symptoms that were under control at least 4 weeks before the clinical trial began
- Asthma that responded to bronchodilators
- Good overall health

People couldn't be in this clinical trial if they had:

- Problems with bronchodilators similar to QVM149
- A severe asthma attack in the last year that needed emergency attention
- Problems doing repeated breathing tests
- Trouble breathing during the 14-day period before treatment started when they stopped taking their regular asthma medicines

Researchers conducted this clinical trial at 7 locations in 3 countries:

- 5 locations in Germany
- 1 location in the Netherlands
- 1 location in the United Kingdom

Each person started the clinical trial at different dates. This trial began in June 2017 and ended in February 2018. 3 people did not complete this clinical trial.

What type of clinical trial was this?

This was a Phase 2 clinical trial, which tests the safety of a trial drug and how well it works in a small number of people.

In this trial, researchers used a computer program to randomly assign people to 1 of 6 groups. Each group took QVM149 or a placebo in different orders and at different times of day.

A placebo looks like medicine but does not have any medicine in it. Using a placebo helps researchers better understand the actual effects of a trial drug. A placebo is used so that no one in the clinical trial knows when each person got the trial drug or the placebo. Some clinical trials are done this way because knowing what treatment people get can affect the results. Not knowing what treatment people get helps make sure the results are looked at fairly.

What happened during this clinical trial?

Before the testing of QVM149

During a 14-day period, trial doctors checked each person's health and asthma to make sure they could be in this clinical trial. Then, trial doctors asked people in the trial to stop taking certain medicines for 14 days before starting to take either QVM149 or the placebo.

During the testing of QVM149

Researchers assigned people to 1 of 6 groups. Then, they gave each person 2 inhalers, which are devices used to breathe medicine into the lungs. In this clinical trial, people took the placebo with an inhaler, just like QVM149. Every person used one inhaler one time in the morning and another inhaler one time in the evening to take the placebo or QVM149, whichever was assigned to their group.

By the end of 3 different 14-day periods, each person took:

- QVM149 in the morning and the placebo in the evening
- The placebo in the morning and QVM149 in the evening
- The placebo in the morning and the placebo in the evening

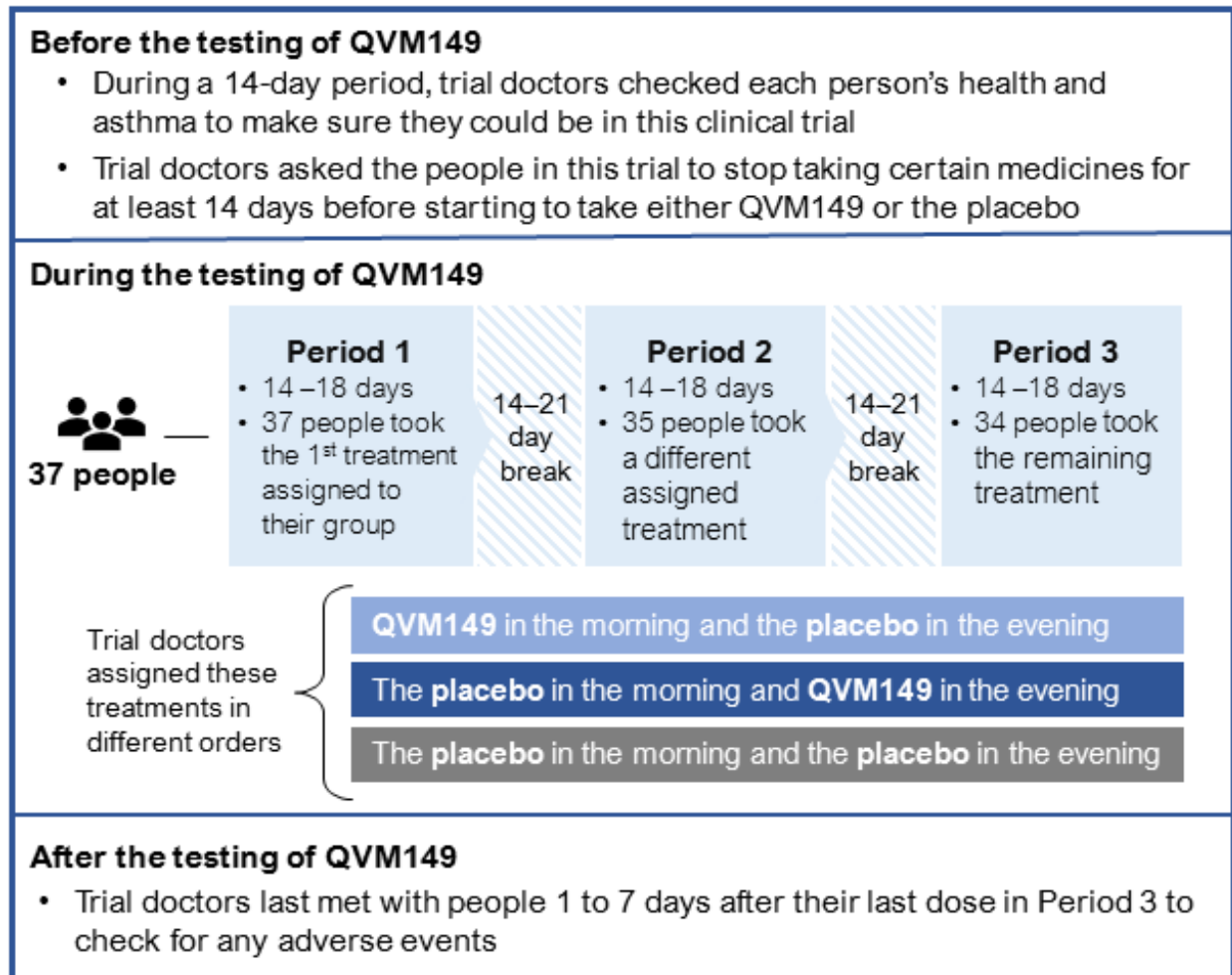
The people took the treatments above in different orders. After the last dose in each period, trial doctors checked how easily people could breathe over 24 hours.

Before starting Period 2 and Period 3, everyone took a break and stopped taking either QVM149 or the placebo. This break between periods lasted 14 to 21 days. This helped remove any effects from the previous treatment period.

After the testing of QVM149

Trial doctors last met with people in this clinical trial 1 to 7 days after the last dose in Period 3 to check their overall health and for any adverse events.

How researchers designed this trial:



What did researchers learn in this clinical trial?



This is a summary of the overall results of this clinical trial, not the individual results of each person. This is a summary of only one clinical trial. Do not use only the results of this clinical trial to make decisions about your health care.

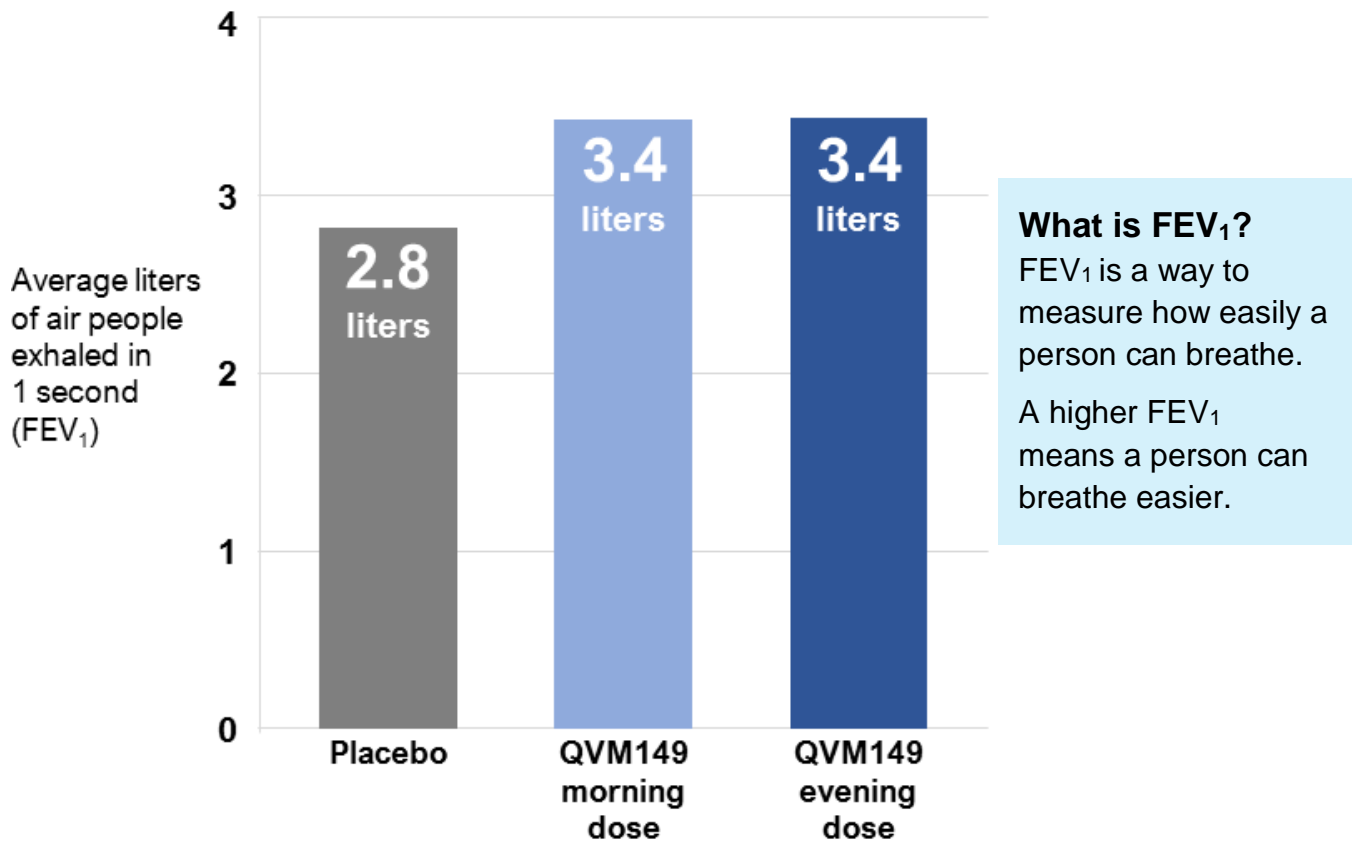
Always talk to a doctor before making any changes to your treatments.

Researchers concluded that QVM149 helped people breathe easier compared to the placebo. They also learned there was no difference in the effects when people took QVM149 in the morning or in the evening.

To check how easily people could breathe, researchers used a measure called Forced Expiratory Volume during 1 second or FEV₁. This is how many liters of air a person can exhale (blow out) with force in 1 second. Swelling narrows the airways in the lungs and lowers the amount of air a person can exhale. A higher FEV₁ means that a person can breathe easier.

At the end of each of the 3 periods in this clinical trial, trial doctors measured each person's FEV₁ many times over 24 hours. They compared the average of those measurements after each person took QVM149 in the morning, in the evening, or after they took only the placebo. When people in this trial took QVM149, their average FEV₁ was 0.6 liters higher compared to when they took the placebo, in the morning or evening.

Average FEV₁ from all periods of this clinical trial



What other key results did researchers learn?

In this clinical trial, researchers also learned that:

- **QVM149 helped people breathe easier for a full 24 hours**

To find out if QVM149 helped people breathe easier for a full 24 hours, trial doctors measured a person's FEV₁ 24 hours after the last dose of QVM149 in each period. Researchers found that the effects of QVM149 on FEV₁ lasted for 24 hours.

- **QVM149 helped people breathe easier between visits to the trial location**

To find out if QVM149 helped people breathe easier between visits, trial doctors had each person measure how well they could breathe at home using a peak flow meter 2 times a day. A peak flow meter is a handheld device that measures how fast a person can exhale air.

Researchers found that when measured at home:

- People could exhale more air when they took QVM149 than when they took the placebo
- The amount of air exhaled was similar when people took QVM149 in the morning or in the evening

What medical problems happened during the trial?



Medical problems that occur during a clinical trial are called adverse events. An adverse event is any unwanted sign or symptom that people report during a clinical trial. These problems may or may not be caused by the clinical trial or the trial drug. Researchers need many trials to know if a drug causes a medical problem. Researchers ask people to report all adverse events during a trial.

Trial doctors kept track of the adverse events that people reported. This summary only includes adverse events that were reported:

- By more than 5% (2 or more) of the people in this clinical trial
- From the start of the testing of QVM149 to the end of the clinical trial

One person left this clinical trial due to an adverse event before the start of Period 3.

Percent and number of people reporting adverse events during the testing of QVM149

	Placebo	QVM149 morning dose	QVM149 evening dose
Percent of people	50%	51%	66%
Number of people	18 of 36 people	18 of 35 people	23 of 35 people

How many serious adverse events did people report?



An adverse event is called serious when it is life-threatening, requires a hospital stay, can cause disability or permanent damage, or can cause a birth defect.

During this clinical trial, no one reported serious adverse events and no one died.

What types of adverse events did people report?

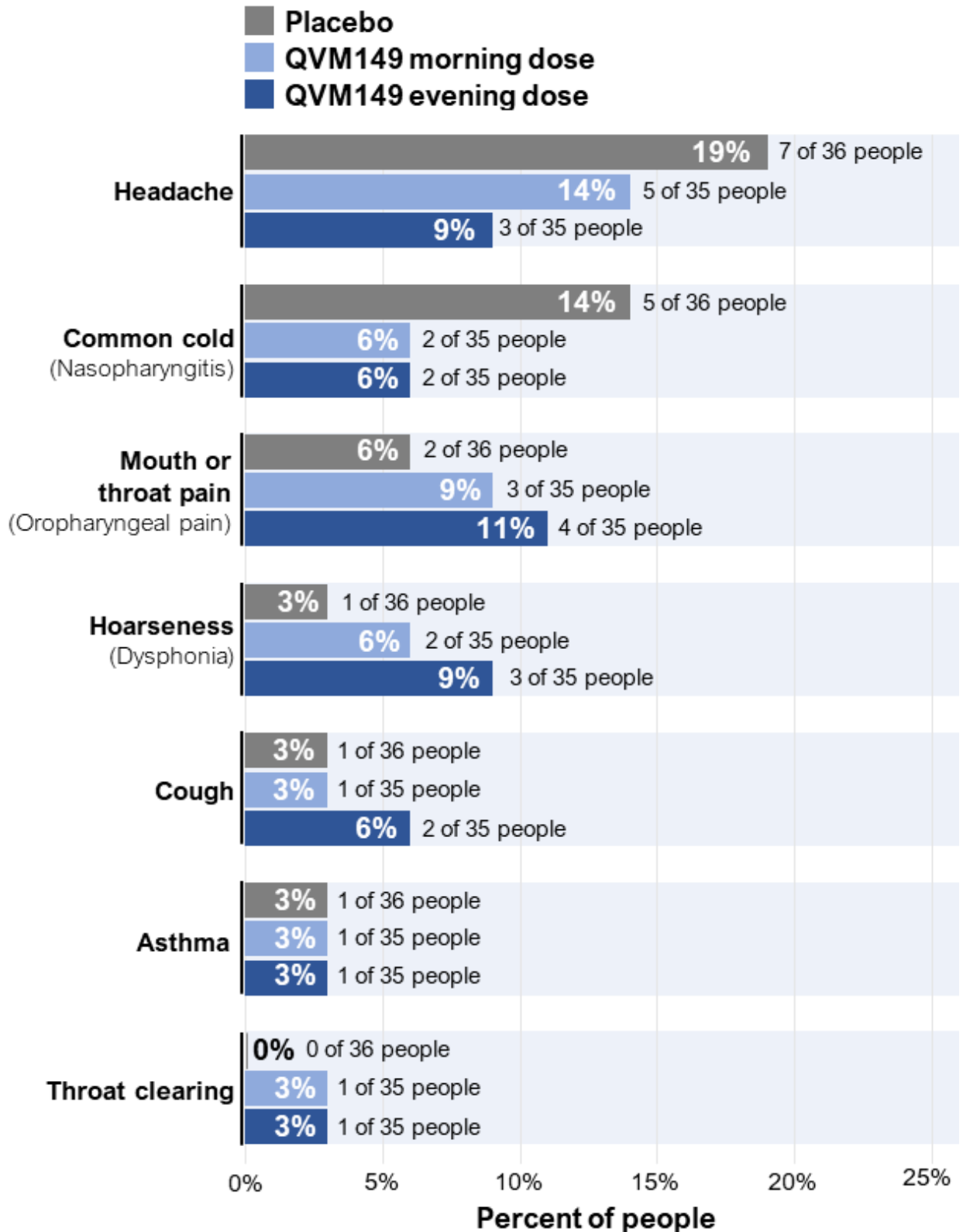


Some people reported medical problems or adverse events that were not serious. This section reports the most common adverse events that people said they had during this clinical trial.

From the start of the testing of QVM149 to the end of this clinical trial, people reported the following adverse events (from most to least commonly reported):

- Headache
- Common cold
- Mouth or throat pain
- Hoarseness
- Cough
- Asthma
- Throat clearing

Percent and number of people reporting adverse events by type during the testing of QVM149



Researchers concluded QVM149 and the placebo had similar safety results during this trial.



For more information about the adverse events reported by people in this clinical trial, visit novctrd.com. Use clinical trial number CQVM149B2209 to find the scientific summary.

How has this clinical trial helped?

The results of this clinical trial helped researchers learn more about the effects of QVM149. Researchers learned that QVM149 helped people in this clinical trial breathe easier compared to the placebo. They also learned QVM149 had similar effects when people took it in the morning or in the evening. Researchers also concluded QVM149 and the placebo had similar safety results during this trial.



The results presented here are for a single clinical trial. No single clinical trial can give a complete picture of the benefits and risks of a trial drug. The results of many trials are needed to find out which treatments can be used for people with asthma. This summary shows only the main results from this trial. Other clinical trials may provide new information or different results.

Where can I learn more about this and future clinical trials?

If you were in this clinical trial and have questions about the results, please speak with the doctor or staff where you took part in this clinical trial.



This is a summary of the results for one clinical trial.

You can find detailed results and more information about this clinical trial on the Novartis Clinical Trial Results website:

1. Visit novctrd.com
2. Click on “Clinical trial results” at the top right of the page
3. Read and scroll down, then click “I accept” to agree to use the information and the website
4. Type **CQVM149B2209** in the search box and click search

This clinical trial was registered on the following websites:

- ClinicalTrials.gov – <https://clinicaltrials.gov> – National Clinical Trial #NCT03108027
- European Union clinical register – <https://www.clinicaltrialsregister.eu/ctr-search> – EU Clinical Trial #2017-000644-17

If more clinical trials are planned, they will appear on the public websites listed above or at www.novartisclinicaltrials.com. When there, search for QVM149.

Full trial title: A randomized, double-blind, repeat dose cross-over study to assess the bronchodilator effects of once daily QVM149 following morning or evening dosing for 14 days compared to placebo in patients with asthma

Thank you!

Novartis would like to thank all of the people who participated in this clinical trial. The trial participants made this clinical trial possible and helped researchers answer important health questions and test a possible medical treatment. Many volunteers and many clinical trials are needed to advance medical science.

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