

# Your clinical study

An illustration of a family walking on a city sidewalk. On the left, a woman with curly brown hair, wearing a teal sweater and red pants, is walking. In the center, a young girl with brown hair in a ponytail, wearing a pink striped shirt and teal pants, is walking. On the right, a young man with dark hair, wearing a light blue hoodie and yellow pants, is walking. They are walking past a building with large windows and a city skyline in the background. Two large trees are on either side of the sidewalk.

Their  
mother

Sara

Alex

As Sara and her family walked from the train to the doctor's office, she asked her brother, "Alex, did you know that I'm a medical hero?"

"Wow!" said Alex. "You are?!"

"That's right, your sister is a **medical hero!**" said their mother.



Later, at the doctor's office, Alex asked, "Wait, What's a medical hero?"

Sara's doctor, Dr. Smith, said, "A medical hero is an important part of a research team! A research team also has scientists and study doctors."

Alex was curious and wanted to learn more. "What does a research team do?" asked Alex.

"A research team studies a new medicine in something called a **clinical study**," answered Dr. Smith. "In a clinical study, medical heroes use a new treatment to help the rest of the team learn about it. Then doctors and other experts decide if it can become a regular treatment that's safe for everyone to use."

"Cool! What did you use this new medicine for?" asked Alex.



Hard to breathe

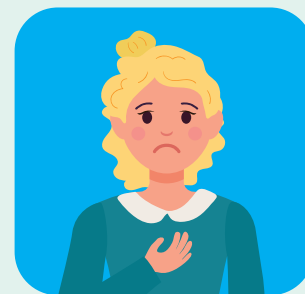


Chest tightness

People with asthma sometimes find it hard to breathe or feel chest tightness



Coughing



Wheezing

Asthma can make people cough or wheeze



Hard to sleep

Sometimes asthma can make it hard to sleep at night

## Why the research was needed

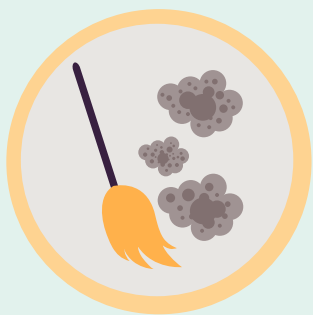
"I have asthma," explained Sara. "Asthma makes it hard for me to breathe sometimes, or makes me cough or wheeze. It also can stop me from doing things like playing soccer. Sometimes, asthma can even make it hard to sleep at night. I helped my research team study a new medicine for asthma."

"I thought you already take asthma medicine," said Alex.

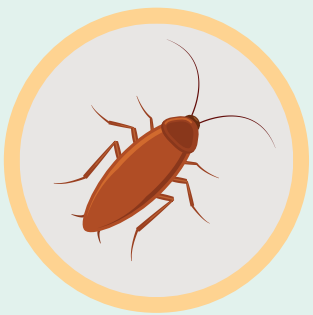
"Yeah, I do. But, that medicine doesn't always make me feel better. That's why we're trying to find out if a new medicine can help more."



## Clinical Study Results



Dust



Bugs



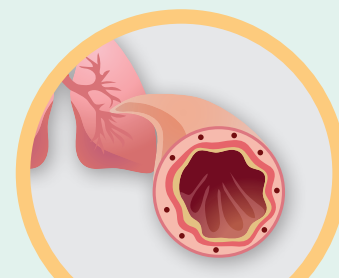
Pets

Common  
allergens

"Sara's asthma can be worse when she's around some things that are often found indoors, like dust, bugs, and pets," said their mother.

"Yes. These things are called allergens," said Dr. Smith.

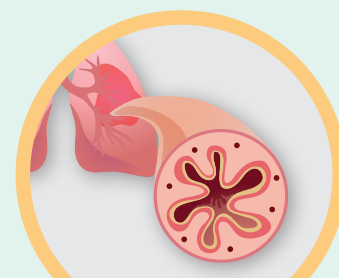
Dr. Smith explained further. "Allergens can make Sara's lungs **swell**. This means that they're **swollen**. When her lungs are swollen, it can be hard for Sara to breathe."



Lung tubes  
without asthma



Lung tubes  
with asthma

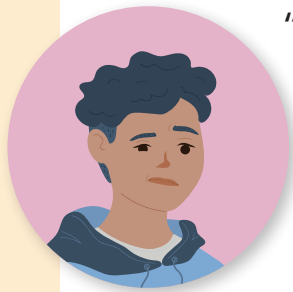


Lung tubes during  
an asthma attack

What swollen lung  
tubes look like up close



## What treatment was studied?



"The new medicine we studied is called omalizumab." said Dr. Smith.

Alex squinted at Dr. Smith and tried to repeat what he said. "Oma-what?"

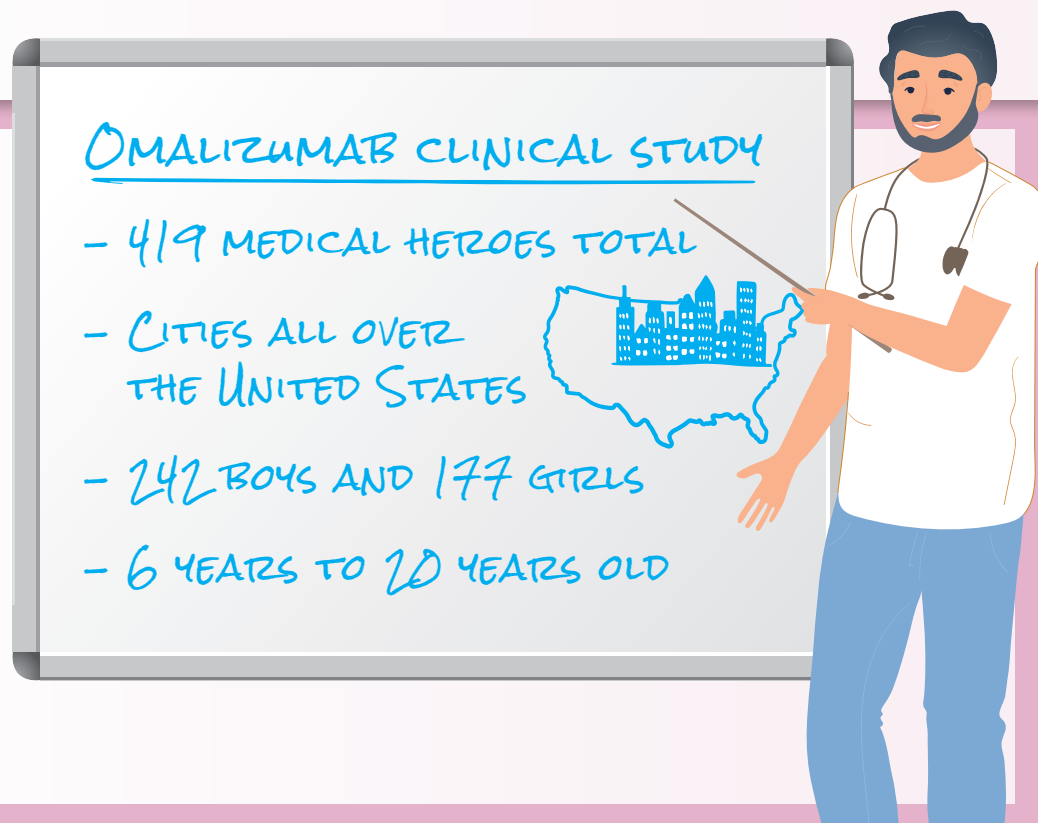
Dr. Smith smiled and spoke more slowly. "It's called ow-muh-li-zoo-mab. Omalizumab can stop allergens from making lungs swollen. So, scientists and doctors think it could help kids with asthma breathe better."

## Who was in the study

Dr. Smith pointed to a white board. "We tested omalizumab in a clinical study. 419 medical heroes took part in the clinical study."

"Wow, there were that many other medical heroes?" said Sara.

"Yes! You and all the other medical heroes are also called participants. All of the participants lived in cities in the United States, like New York. There were 242 boys and 177 girls. The youngest was 6 and the oldest was 20. All the participants helped us learn how well omalizumab works and how safe it is."



## What happened in the study



Sara thought back to her time during the clinical study. "I did a lot during the study!"

"You were a big help!" said Dr. Smith. He showed them these charts.



Each participant was in the clinical study for about 1 year.



All of the participants got shots of omalizumab in the study.

- Some participants got a shot 1 time every month.
- Other participants got a shot 2 times every month.



1 time  
each month

or



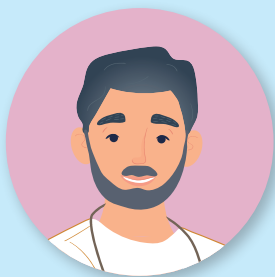
2 times  
each month

- 208 participants got shots of omalizumab.
- 211 participants got shots of only salt water. Shots of salt water in a clinical study are called a placebo shot.



A computer decided who got omalizumab and who got a placebo shot.

Some participants get a placebo because it helps us understand if the new medicine actually works.



All of the participants visited their doctor's office. The doctors made sure the participants were OK during the study. Sometimes the participants did medical tests when they visited their doctor's office. These tests helped doctors check how healthy the participants were.



"I remember letting doctors take my blood with a needle," said Sara.

Alex made a face. "Did that hurt!?"



"Only a little!" Sarah said proudly.

"It helped us learn how the medicine worked in your body!" said Dr. Smith.

All of the participants told doctors about their asthma during the clinical study. The problems caused by asthma are called **symptoms**.



"Ah, right," remembered their mother. "Sara told doctors that she had asthma symptoms 2 days during 1 week."

"What did we learn about omalizumab?" asked Sara. "Did it work?"

"**Yes,**" said Dr. Smith. He looked at his clipboard. "To learn this, the participants told us how many days they had asthma symptoms. The participants who got omalizumab had fewer days with asthma symptoms than the participants who got a placebo. This means that omalizumab did work in this study."



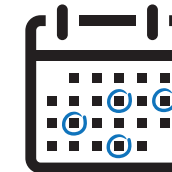
### Results of the study:

#### OMALIZUMAB GROUP:



FEWER DAYS WITH SYMPTOMS

#### PLACEBO GROUP



NORMAL NUMBER OF DAYS  
WITH SYMPTOMS



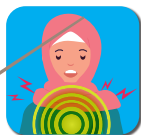


## Medical problems during the study:

### 3 MOST COMMON MEDICAL PROBLEMS



ASTHMA



AN INFECTION IN PARTS OF YOUR BODY THAT HELP YOU BREATHE, LIKE THE LUNGS



AN INFECTION IN THE PARTS OF YOUR BODY AROUND YOUR FACE THAT HELP YOU BREATHE, LIKE THE NOSE.

Their mother nodded. "Got it. But I know that sometimes medicine can cause medical problems. Did any participants have medical problems during the study?"

"Yes. We keep a list of all the medical problems that happen to participants, even if we don't think they were caused by the new medicine. The 3 most common medical problems in this study were:

- Asthma
- An infection in parts of your body that help you breathe, like the lungs
- An infection in the parts of your body around your face that help you breathe, like the nose"

"Wow, you learned a lot!" said Alex.

"So, me being in the study was helpful?" Sarah asked Dr Smith.

"Yes! You and all the other medical heroes made it possible for us to learn more about how omalizumab works in children. We couldn't have done it without you. Thank you!"



### Where to learn more about the study

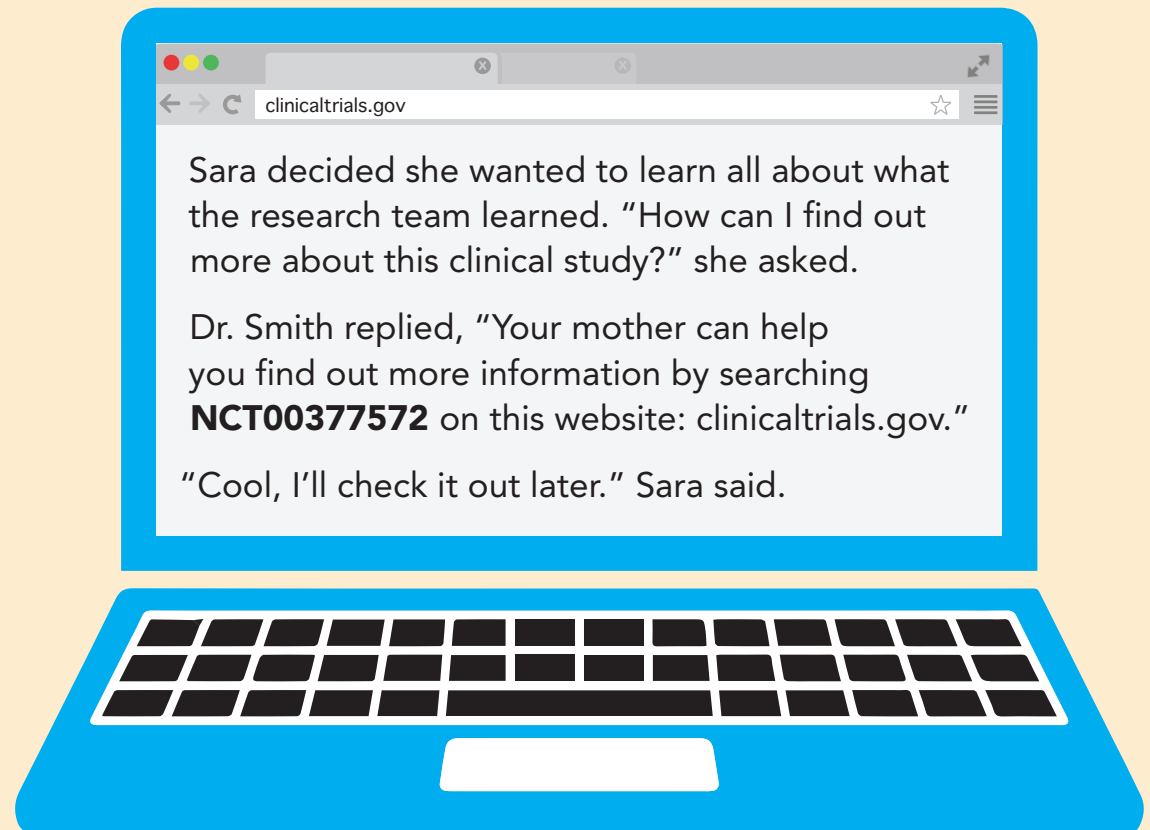


"What happens next?" asked Sara.

Alex's eyes lit up. "ICE CREAM???"

Their mother rolled her eyes and changed the subject. "Will research teams study omalizumab again in more clinical studies?" she asked.

"Yes. We learned a lot from this clinical study, but we can learn even more in other clinical studies. It takes a lot of research to really know about a new medicine."





"Now, let's get some ice cream!" Sara said as she headed for the door.

Alex jumped up from his chair and followed his sister. "YAY!"

Their mother raised her arms and ran to catch up with her children. "I didn't say—" She sighed. "OK, fine, since your sister did such a helpful job. Thank you to all the medical heroes and doctors who helped us learn more!" she said.

Psssttt. I have a feeling you're a medical hero too. Check the last page for your official medical hero certificate!





# CONGRATULATIONS!



## YOU ARE A REAL MEDICAL HERO

Medical heroes like you have chosen to give the extraordinary gift of your participation in research studies to find new treatments and cures for diseases. Your decision to be a clinical trial volunteer is a selfless act because it always carries risk, but it may not result in any direct personal benefit. Thank you.

