

Understanding

Clinical Trials

Ages 7-12

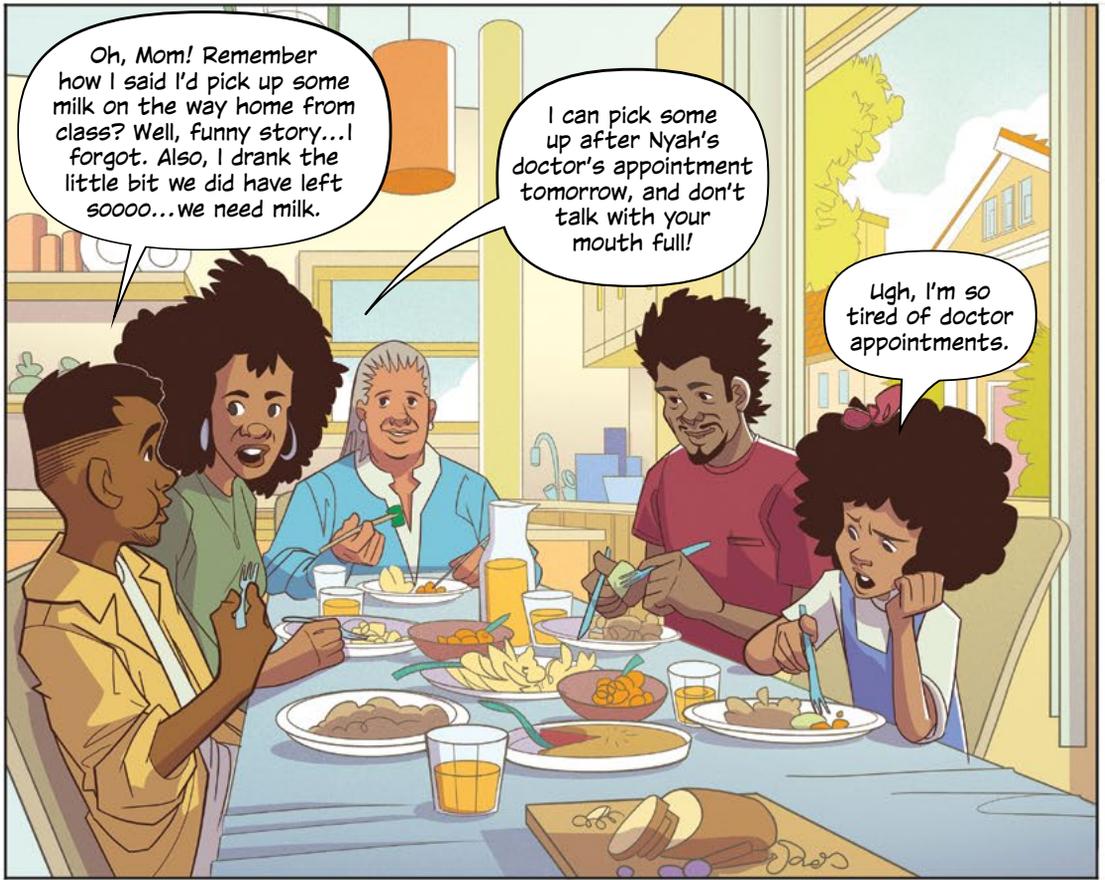


Featuring:

Nyah and her family

The stars of this book





Oh, Mom! Remember how I said I'd pick up some milk on the way home from class? Well, funny story...I forgot. Also, I drank the little bit we did have left soooo...we need milk.

I can pick some up after Nyah's doctor's appointment tomorrow, and don't talk with your mouth full!

Ugh, I'm so tired of doctor appointments.



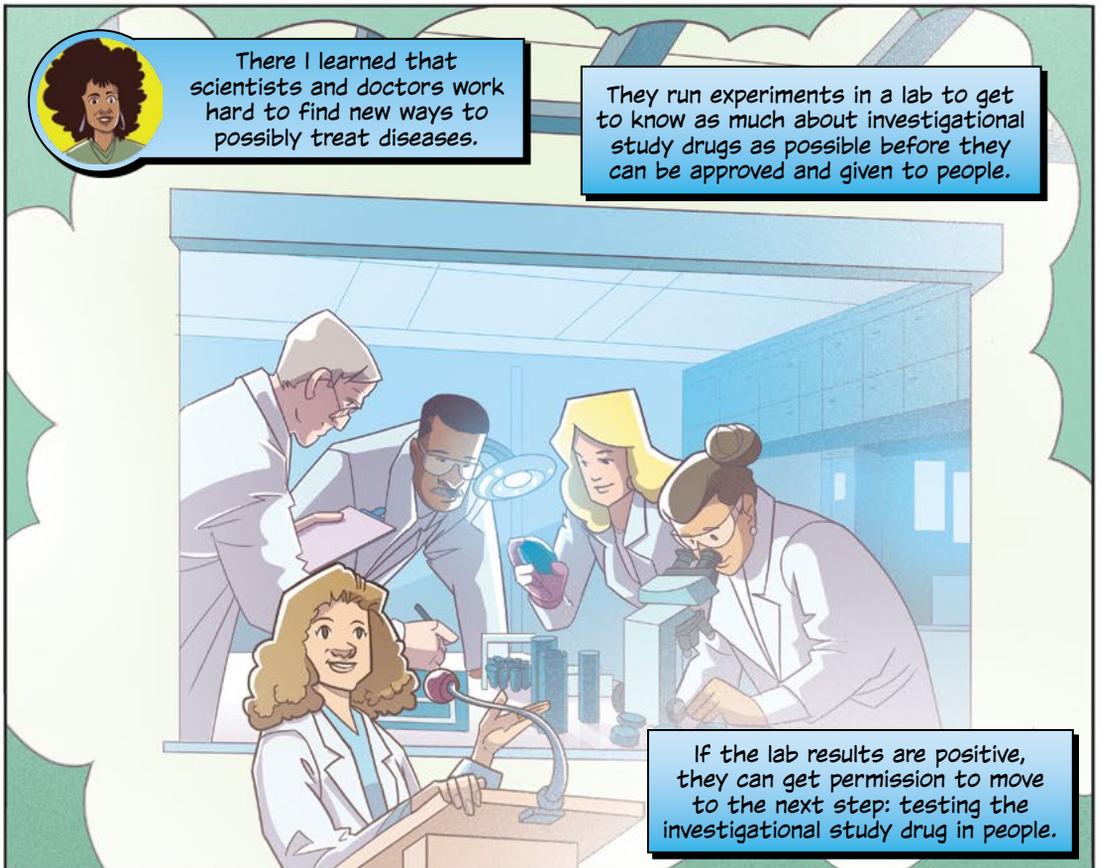
This isn't like the other appointments, Nyah. This is about you possibly joining a clinical trial.

Cool! I've been learning about those in some of my pre-med classes!

I...I'm of course excited about anything that could help Nyah. But...what are clinical trials?



Great question!
I had the exact same
one until I went to
that community
event hosted by
a local clinic.



There I learned that
scientists and doctors work
hard to find new ways to
possibly treat diseases.

They run experiments in a lab to get
to know as much about investigational
study drugs as possible before they
can be approved and given to people.

If the lab results are positive,
they can get permission to move
to the next step: testing the
investigational study drug in people.



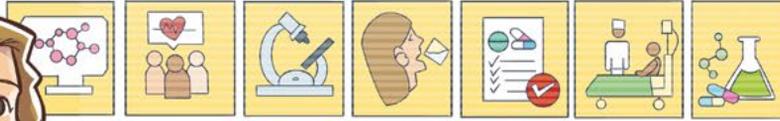
The tests with people are called clinical trials or clinical studies.



CLINICAL TRIALS



A lot of people are involved in deciding if an investigational study drug can be tested in people and how to do it safely.

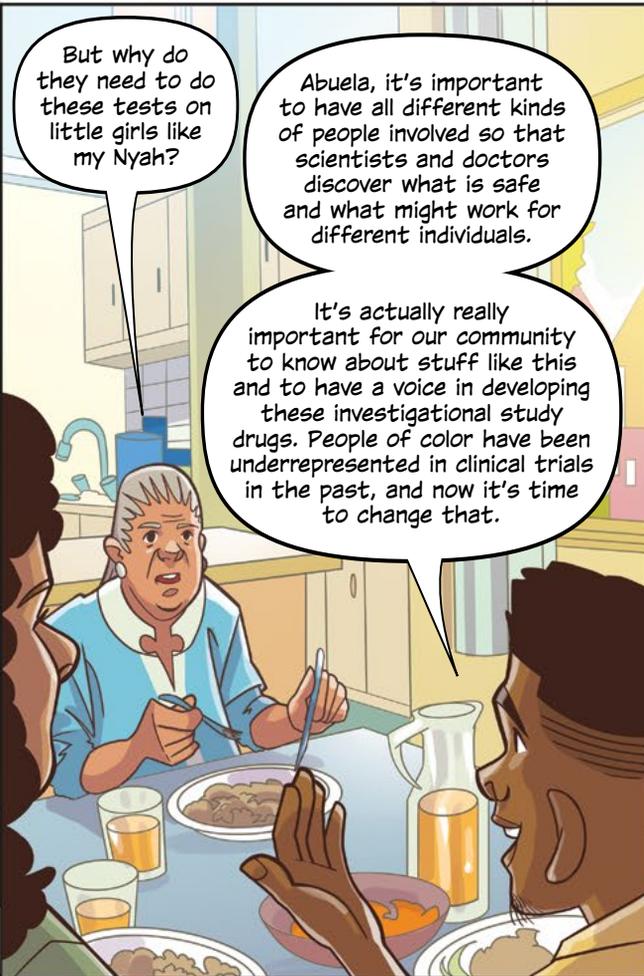


But why do they need to do these tests on little girls like my Nyah?

Abuela, it's important to have all different kinds of people involved so that scientists and doctors discover what is safe and what might work for different individuals.

It's actually really important for our community to know about stuff like this and to have a voice in developing these investigational study drugs. People of color have been underrepresented in clinical trials in the past, and now it's time to change that.

And putting my body where my mouth is, I think I'll tag along to your doctor's appointment tomorrow, Nyah. I'd love to learn more firsthand.



THE NEXT DAY AT NYAH'S DOCTOR'S APPOINTMENT

Thank you so much for coming in today. I'm Nurse Dominique and I'm going to get us started. Doctor Perry will be in momentarily.

To begin, do you have any questions?

I do! Ignoring the fact that I'm cute, fun, and a joy to be around, why exactly do you need me for this clinical trial?

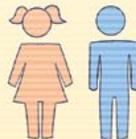
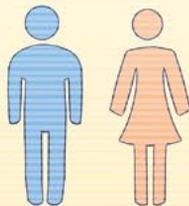
What a great question! Actually, we have a little video presentation that I think will help answer that question and so many more!

So, some studies are just for kids because the investigational study drug is just for kids.

Then there are investigational study drugs that are for adults and kids. The problem is that a kid's body and an adult's body work differently. This means an investigational study drug might be safe for an adult but not safe for kids, which is why we study both kids and adults in some instances.

Adults

Kids





But also not all kids are the same!



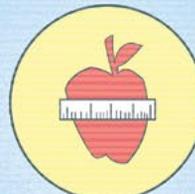
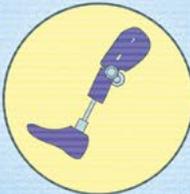
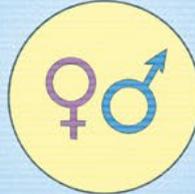
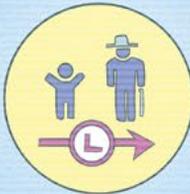
Think about all the ways kids can be different from each other.

Well, me and my best friend both have black hair, but mine is curly and hers is straight.

Yes! How we look is just one way we are different.



Age, sex/gender, ethnic background, and physical abilities make us different. So do our lifestyles—like the food we eat, how we exercise, and the environment we live in.

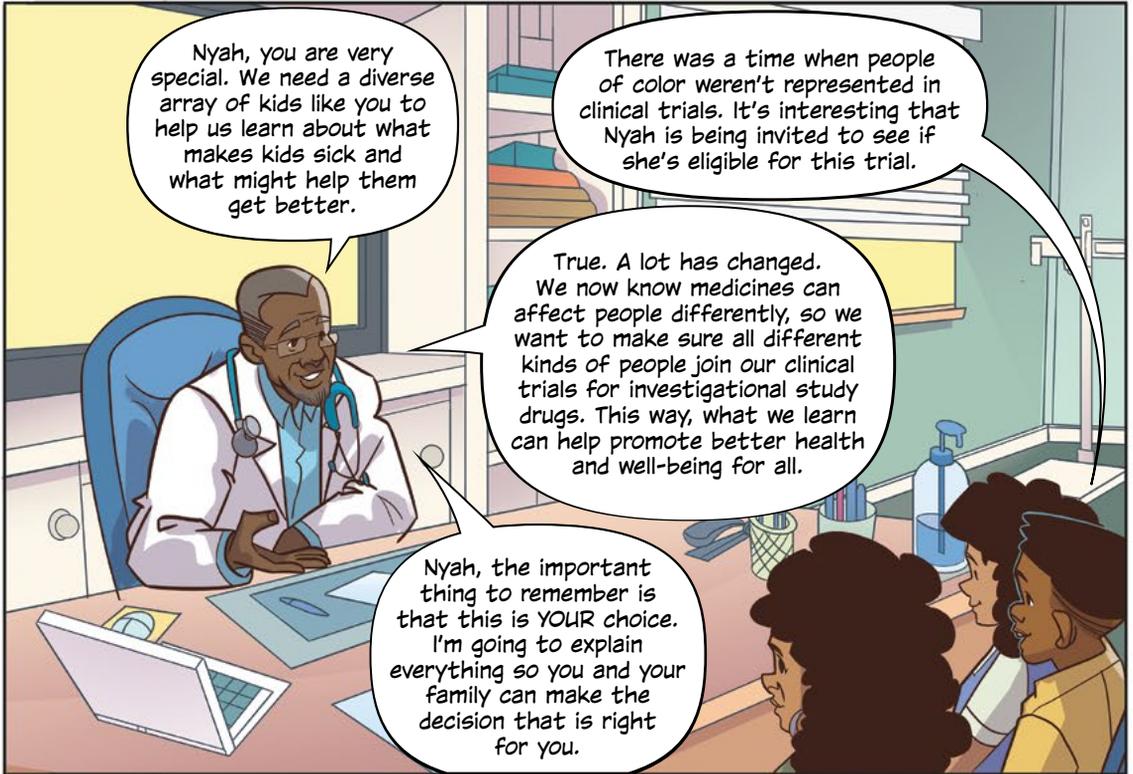


All of these things can make diseases, medicines, investigational study drugs, and vaccines affect kids differently. This is why studies need kids from all different backgrounds!



I know I'm special, but I didn't know I was that special!

Sounds like a perfect time for me to step in! Hi, everyone. I'm Doctor Perry.

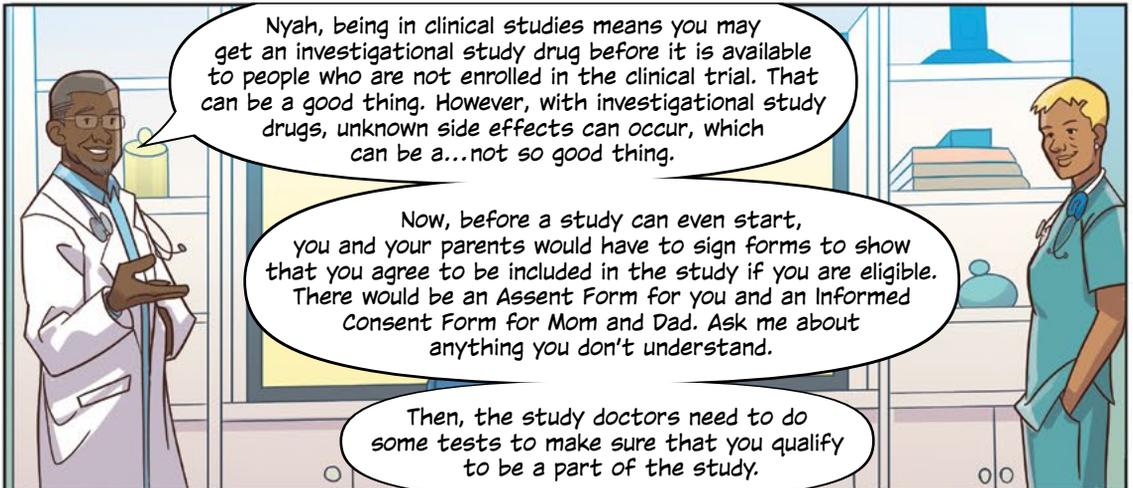


Nyah, you are very special. We need a diverse array of kids like you to help us learn about what makes kids sick and what might help them get better.

There was a time when people of color weren't represented in clinical trials. It's interesting that Nyah is being invited to see if she's eligible for this trial.

True. A lot has changed. We now know medicines can affect people differently, so we want to make sure all different kinds of people join our clinical trials for investigational study drugs. This way, what we learn can help promote better health and well-being for all.

Nyah, the important thing to remember is that this is YOUR choice. I'm going to explain everything so you and your family can make the decision that is right for you.



Nyah, being in clinical studies means you may get an investigational study drug before it is available to people who are not enrolled in the clinical trial. That can be a good thing. However, with investigational study drugs, unknown side effects can occur, which can be a...not so good thing.

Now, before a study can even start, you and your parents would have to sign forms to show that you agree to be included in the study if you are eligible. There would be an Assent Form for you and an Informed Consent Form for Mom and Dad. Ask me about anything you don't understand.

Then, the study doctors need to do some tests to make sure that you qualify to be a part of the study.

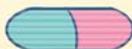


These usually include blood tests and other tests that help the doctors understand your disease.

The tests may show that you do not qualify for the study.



Now, if you are able to join the study, you'll receive the investigational study drug or a placebo, which looks like the investigational study drug but has no medicine in it.



STUDY
DRUG



PLACEBO

Umm, another question! Why would I be given something that didn't have any medicine in it?!

Excellent question with an interesting answer! You see, having some kids take a placebo lets doctors see if the investigational study drug has any benefits.



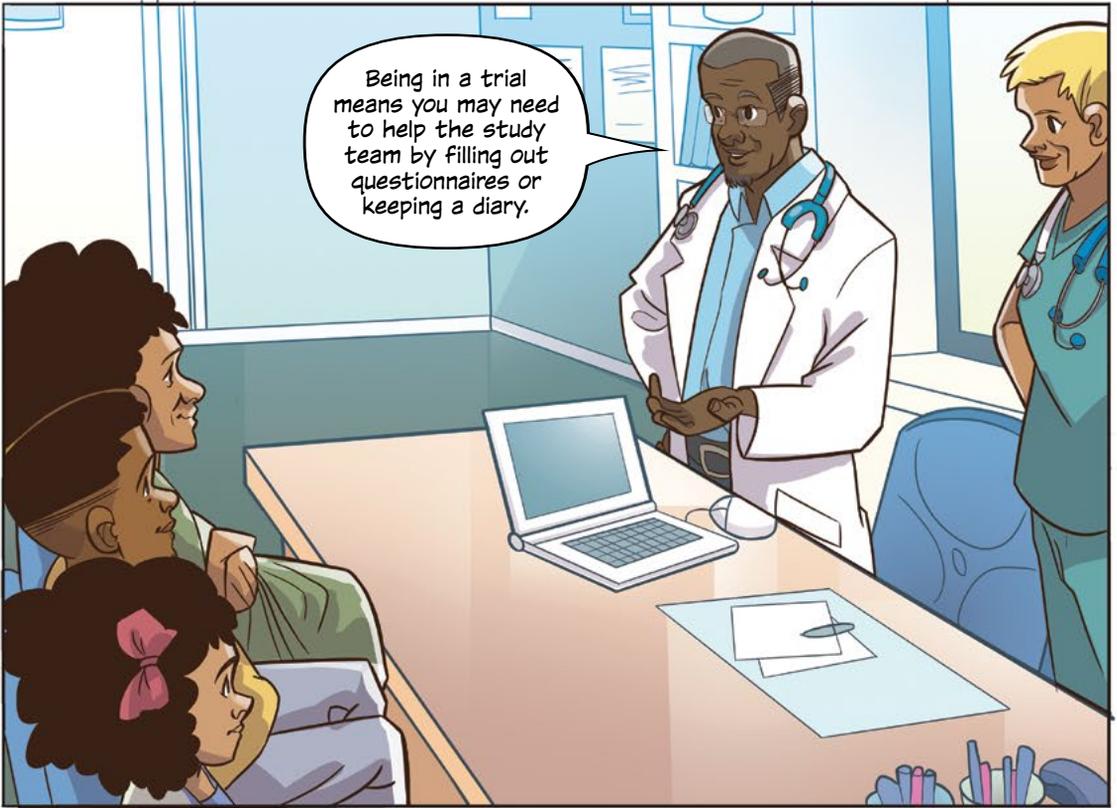
You'll have a schedule that lets you know when you need to visit the study clinic for health checks and tests. Some tests are repeated every time and some may happen only a few times.

Sun	Mon	Tue	Wed	Thu	Fri	Sat		
					1	2		
3	X	4	5	6	7	8	9	
10		11	12	13	14	15	16	
17		18	19	X	20	21	22	23
24		25	26	27	28	29	30	



Now, it's important to remember that the investigational study drug may or may not help you.

Also, since we don't know about all of the effects of an investigational study drug, it's important to tell your parents right away if you don't feel well!



Being in a trial means you may need to help the study team by filling out questionnaires or keeping a diary.

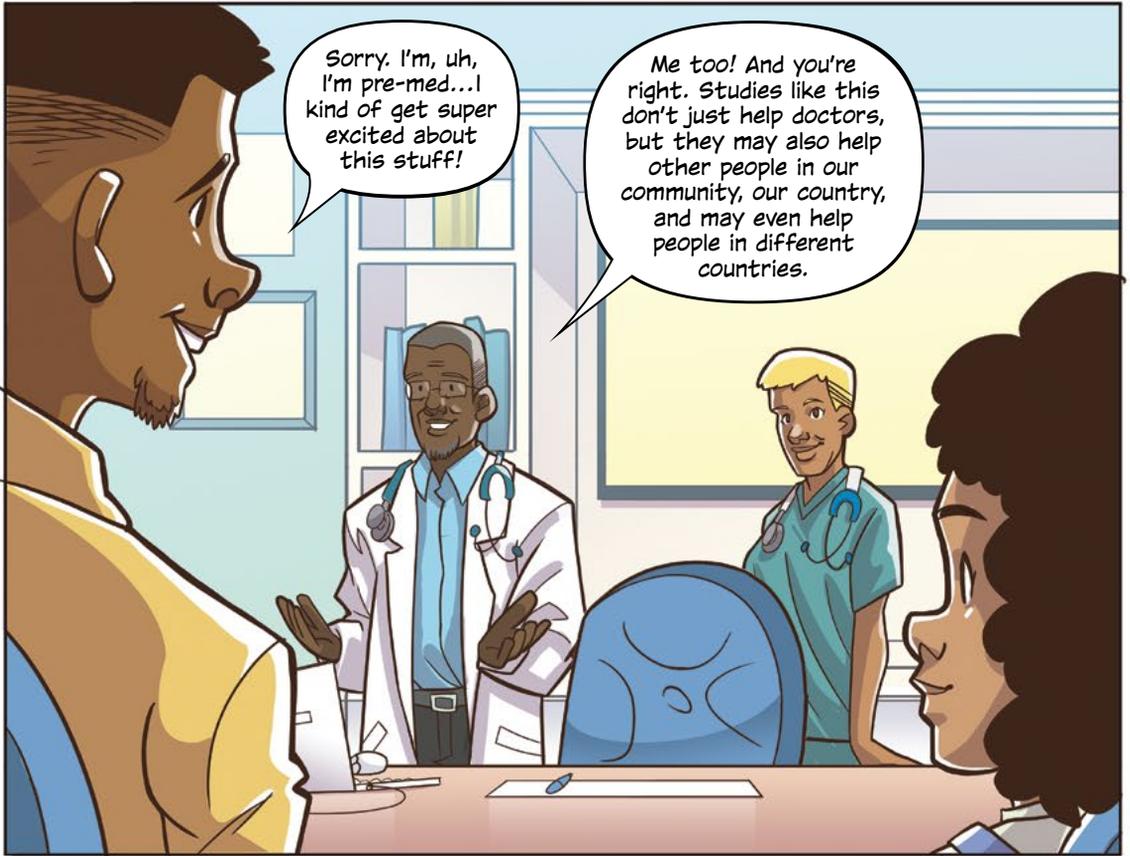


What's really cool is being a part of a clinical trial means you could be part of history!

You're helping to advance medical science that could change people's lives around the world! This is way bigger than the project we did for diversity month at your school.



HOW AWESOME IS THAT?!



Sorry. I'm, uh, I'm pre-med...I kind of get super excited about this stuff!

Me too! And you're right. Studies like this don't just help doctors, but they may also help other people in our community, our country, and may even help people in different countries.



My teacher asked us to think about how we can help our community outside of school. Maybe this is it! By being part of a study, I might be able to help doctors find out how an investigational study drug works in different kids.

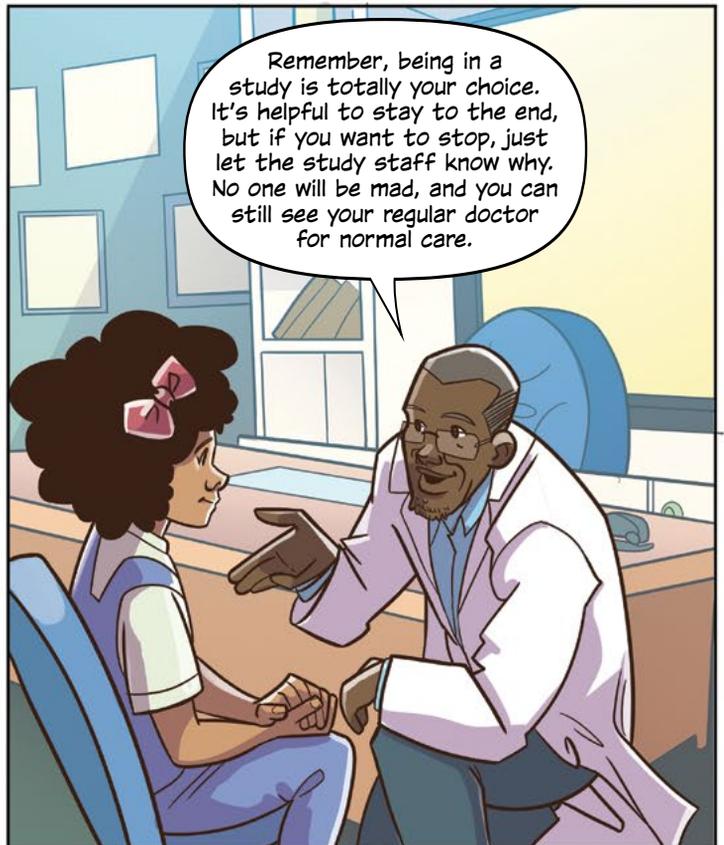


But, Nyah, even though we've talked about the importance of having a diverse group of kids in our trial, our first priority is making sure we're helping you! That's why doctors and nurses and study staff will be keeping a close eye on your health for side effects and will regularly check to see if the investigational study drug is safe and effective.

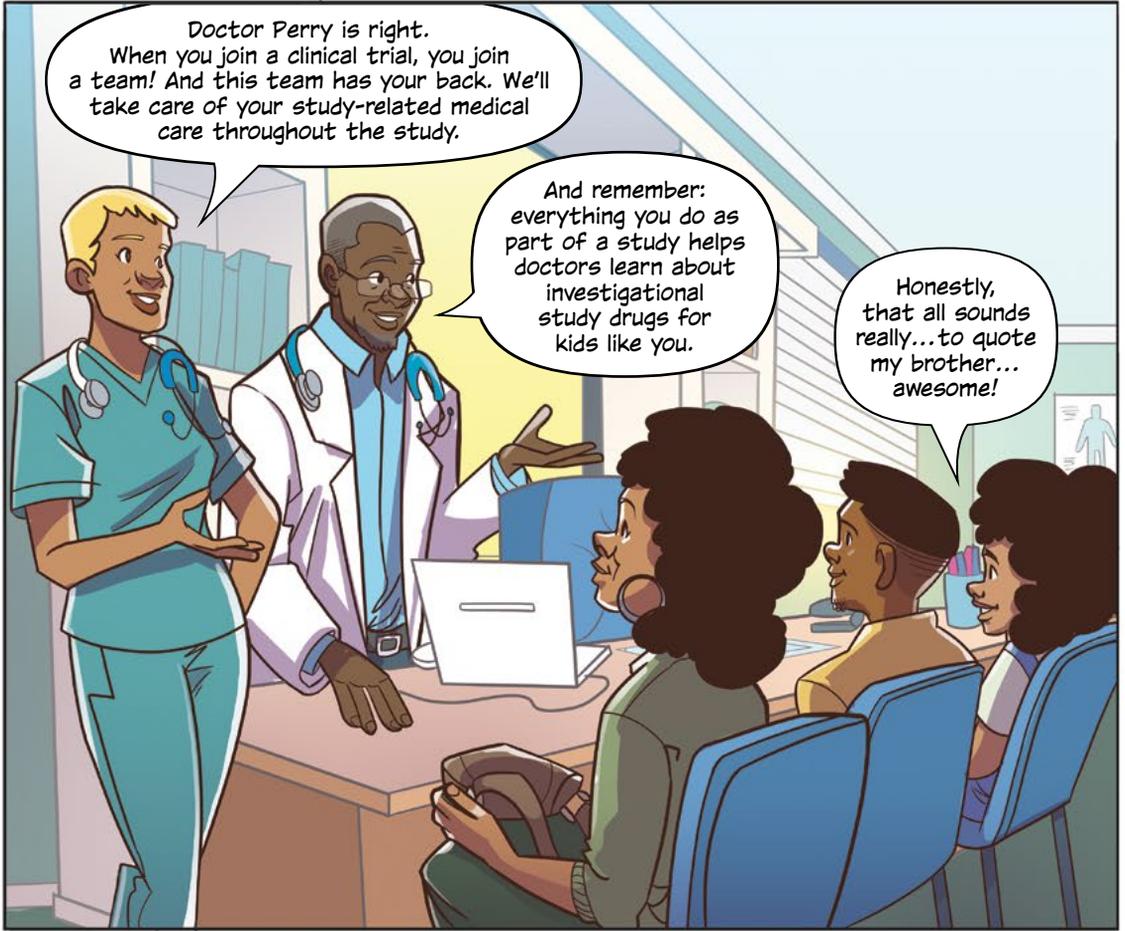
But...what if it doesn't work?



It's important for everyone to know that not all trials are successful. Some trials are canceled if the investigational study drug does not work well enough, or if there are too many side effects.



Remember, being in a study is totally your choice. It's helpful to stay to the end, but if you want to stop, just let the study staff know why. No one will be mad, and you can still see your regular doctor for normal care.



Glossary

Assent:

A kid gives their permission for doctors to include them in a clinical trial if eligible.



Clinical trial:

A type of research study performed to learn about an investigational study drug to see if it works and is safe for people to take.



Informed consent:

A parent/guardian gives their permission for doctors to include their child in a clinical trial if eligible.



Placebo:

A treatment that contains no active medicine. Having some kids take a placebo lets doctors see if the investigational study drug is effective.



Side effects:

Unwanted and often unpleasant effects of an investigational study drug or study test. Side effects may go away on their own or they may need to be treated. When you are in a clinical study, it's important to tell the study doctor about anything that bothers you.

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