

UNDERSTANDING

CLINICAL TRIALS



Ages 7 - 12

 jumohealth®

ALSO FEATURING:

SAM

The star of this book



INTRODUCING
THE MEDIKIDZ

The Medikidz are superheroes who live on Mediland, a planet shaped like the human body. They are experts in health and illness, and their mission is to teach you all about your body and how illness affects it.



ABACUS Guardian of
the Medikidz



AXON Expert on: the
brain and nerves



CHI Expert on: the lungs
and respiratory system



GASTRO Expert on: the
digestive system



PUMP Expert on: the heart
and blood vessels

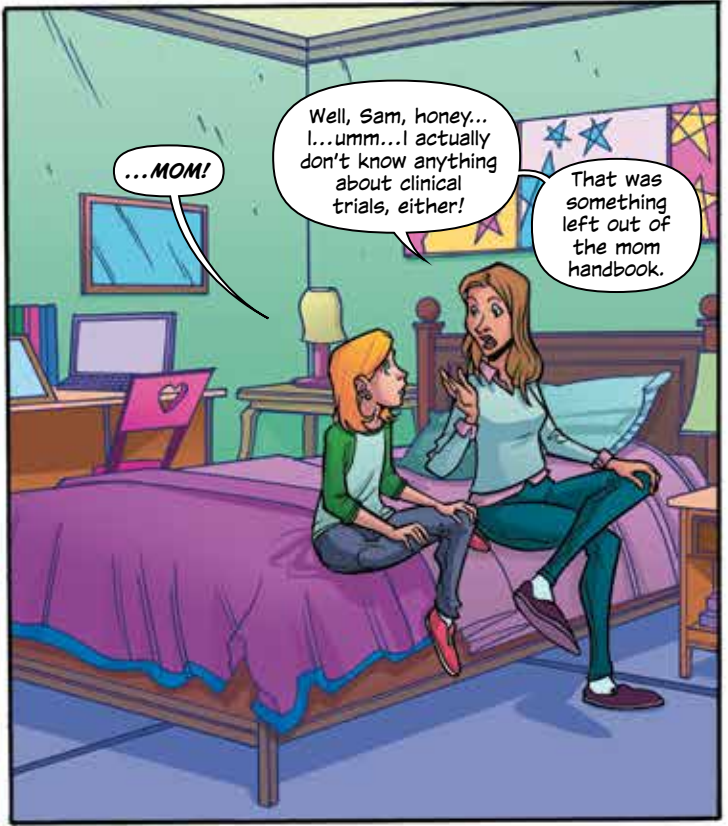


SKINDY Expert on: the
skin and bones



I have to make a decision about whether or not I'm going to do this clinical trial, but...I'm kind of scared!

I don't know anything about it. You always have all the answers, so that's why I'm asking you...



...MOM!

Well, Sam, honey... I...umm...I actually don't know anything about clinical trials, either!

That was something left out of the mom handbook.



But don't worry! We'll figure it out together. We can always look things up on the internet.

Why *look things up* when you can be *teleported up*?! We love medicine and educating!

The
MEDIKIDZ!

Sam, we heard you and your mom need some help understanding clinical trials.

And luckily for you, we're doing a clinical trial ourselves!

Right this way to my super top-secret hidden lab!

I don't think most secret labs have a **GIANT SIGN** pointing to them.

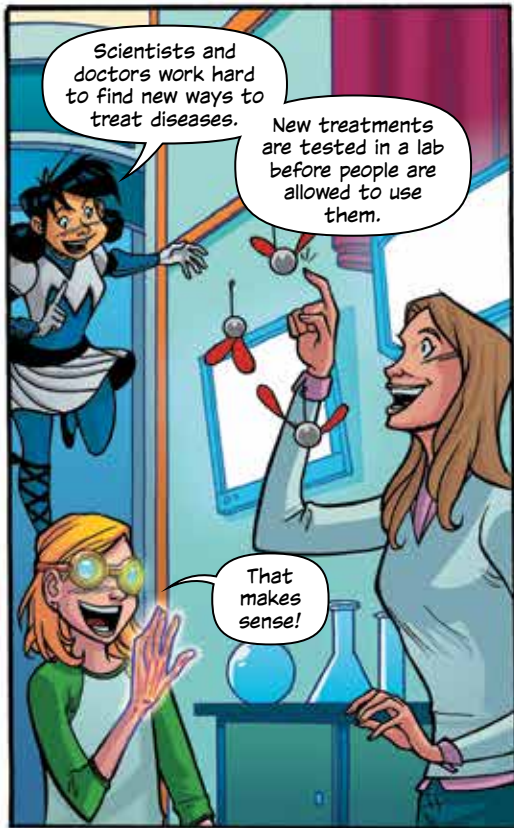
I admit that I sometimes forget where I hide supersecret things, so I make super big signs. It's still cool!



Behold! This is where I make all my greatest inventions... and sometimes take naps.

WHOA!

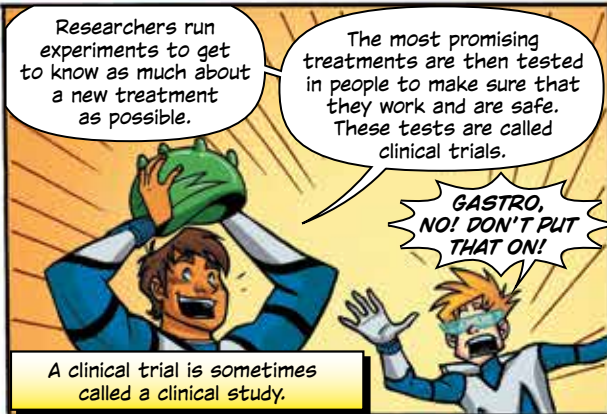
And your father thinks his workshop is cool!



Scientists and doctors work hard to find new ways to treat diseases.

New treatments are tested in a lab before people are allowed to use them.

That makes sense!

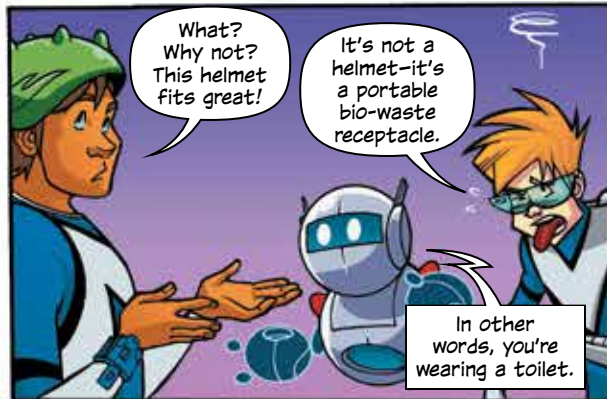


Researchers run experiments to get to know as much about a new treatment as possible.

The most promising treatments are then tested in people to make sure that they work and are safe. These tests are called clinical trials.

GASTRO, NO! DON'T PUT THAT ON!

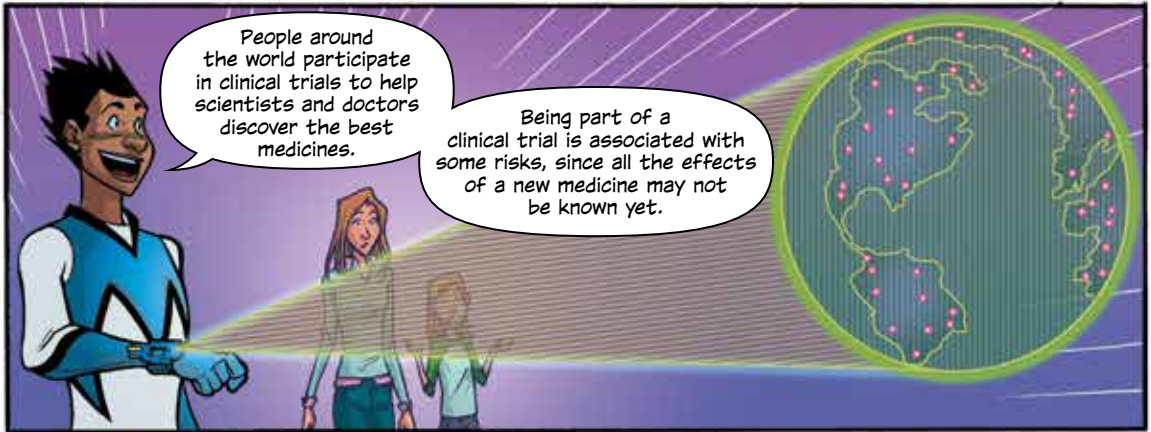
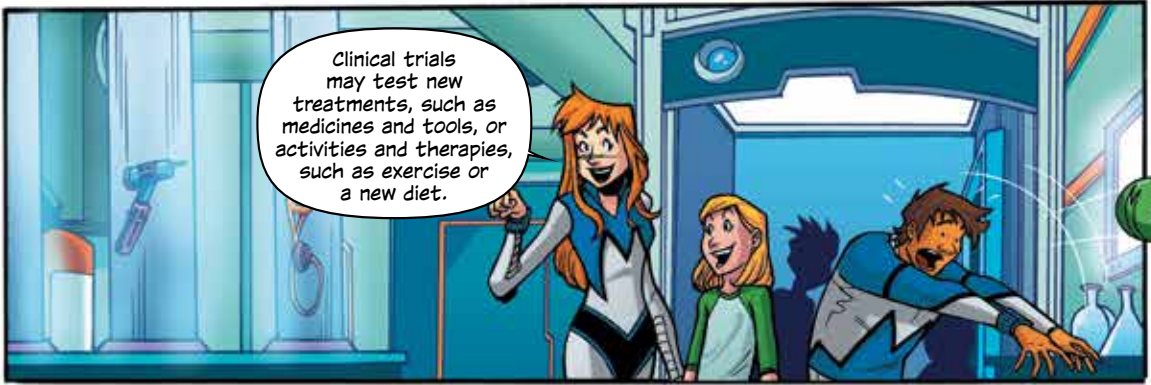
A clinical trial is sometimes called a clinical study.



What? Why not? This helmet fits great!

It's not a helmet—it's a portable bio-waste receptacle.

In other words, you're wearing a toilet.



Inside Mediland's bloodstream...



Whoa!

It's very red in here. And red happens to be my favorite color!

Let's move, team-lots to do.



So why would doctors need kids for clinical trials? Why not just use adults?

That's because kids' bodies and adults' bodies work differently. Doctors need to make sure the treatments also work safely on kids, and without too many side effects.



Okay, so who are we doing this clinical trial on? Kids? Teens? Adults?

In Mediland, we're able to do things a little differently.

Yeah, when we want to see how a new medicine works on cells in the body...



...we test it directly **on** the cells of the body!

And today we'll be testing a new treatment on the **immune system**, your body's natural defense against invaders like germs!

Whoa!



Immune cells, we've come to try a new treatment on you, one that is supposed to make you stronger.

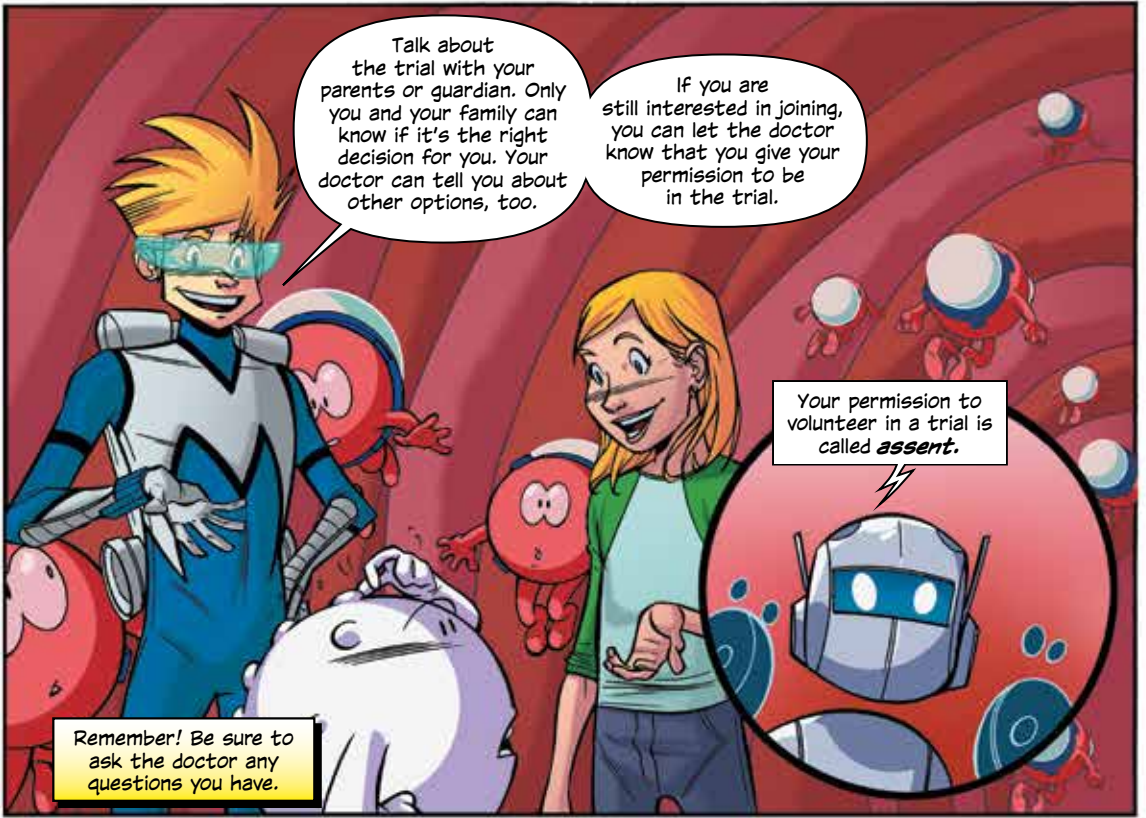
Who here wants to try a new treatment that might help you attack germs better?

The doctors will tell you what to expect if you join a trial. You can then take some time to decide whether or not you want to join.

YEAH!

WOOOT!

WE DO!



Talk about the trial with your parents or guardian. Only you and your family can know if it's the right decision for you. Your doctor can tell you about other options, too.

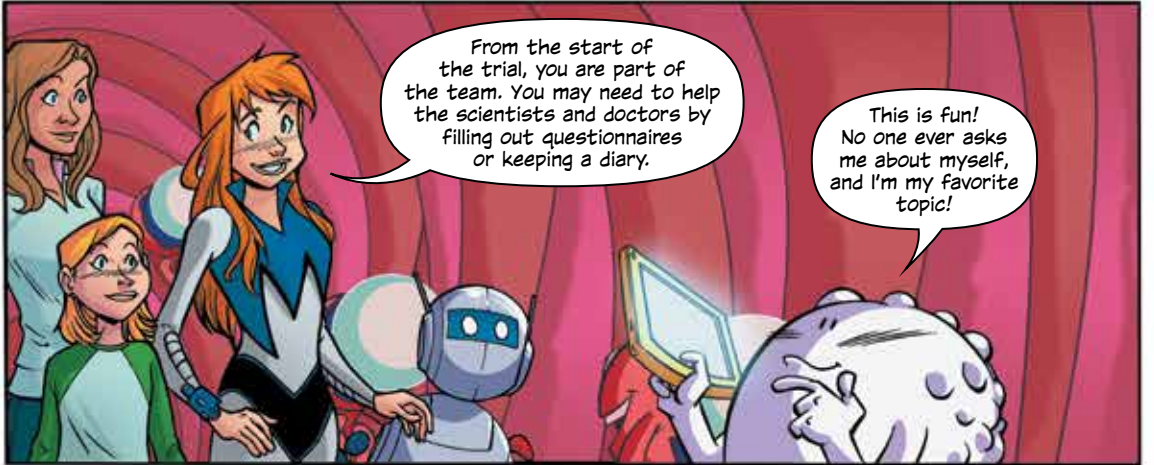
If you are still interested in joining, you can let the doctor know that you give your permission to be in the trial.

Your permission to volunteer in a trial is called **assent**.

Remember! Be sure to ask the doctor any questions you have.



Your parents also need to give their permission. Their permission is called **informed consent**.





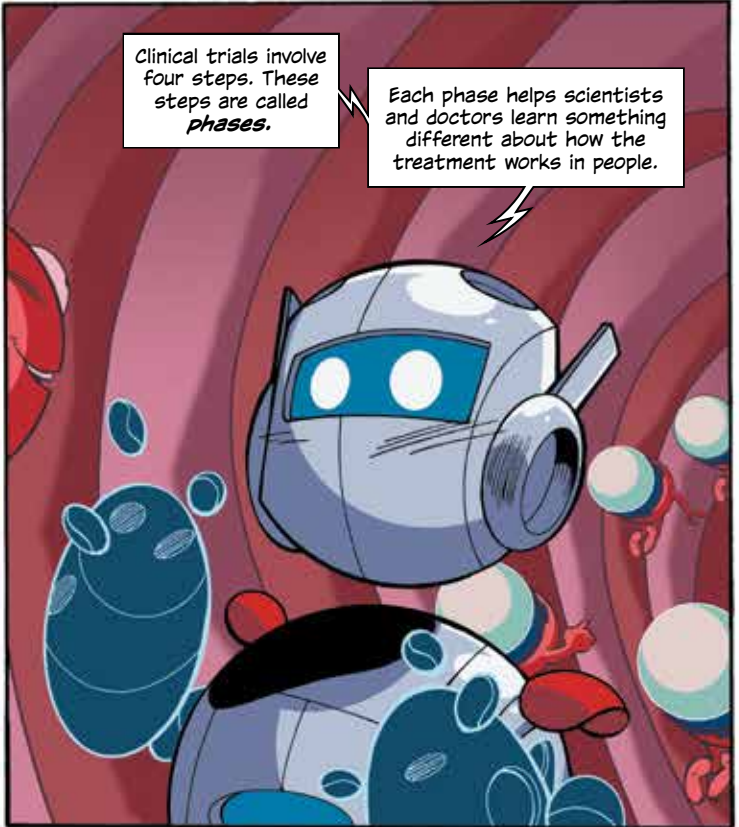
Okay, let's see how well you normally work. Blast away!

You got it!



Hmmm, good. But I think we can do better!

Let's get this clinical trial started!



Clinical trials involve four steps. These steps are called **phases**.

Each phase helps scientists and doctors learn something different about how the treatment works in people.



You guys ready?

Phase 1 trials are when a new treatment is tested in people for the first time to see if it's safe. Sometimes, even healthy volunteers are involved in Phase 1 trials.

In this phase, we don't know yet whether the treatment really works or what side effects it might have.

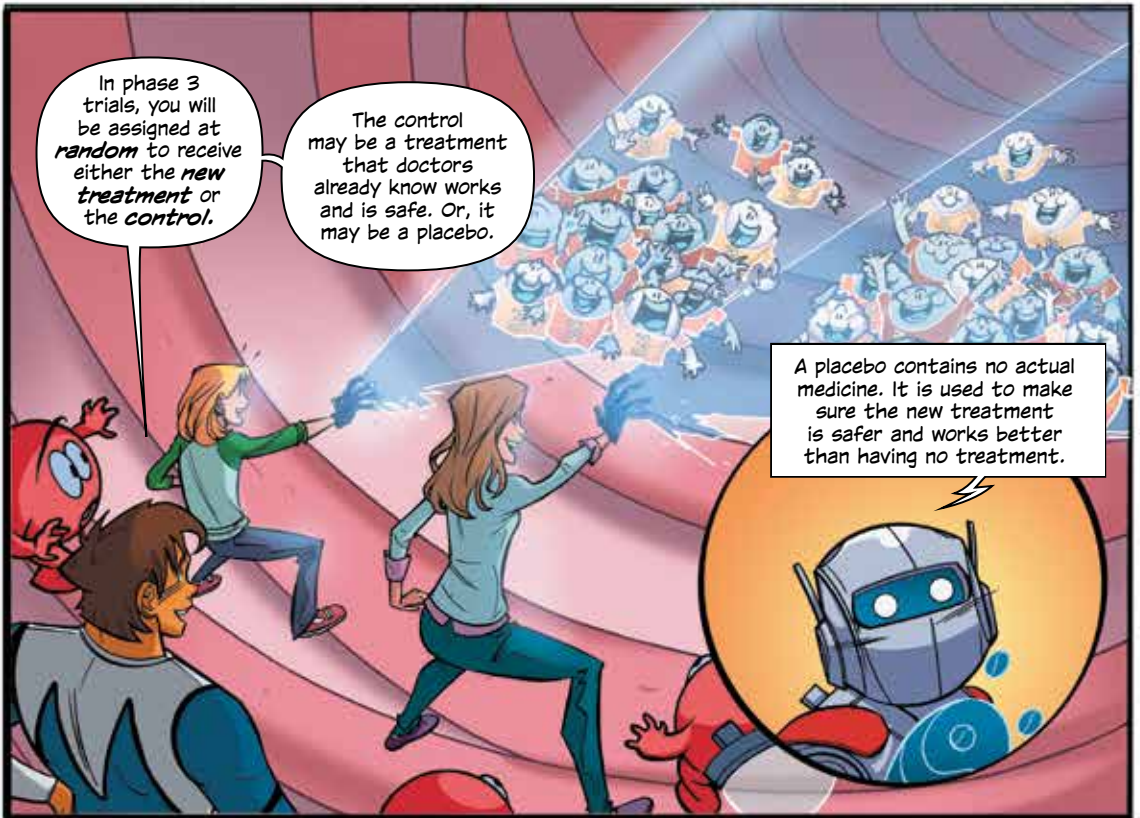


Phase 2 trials look at safety and how a new treatment works on a larger group of people who need it. People who have a disease, for example.



Phase 3 trials compare a new treatment against a **control** to see which one is best.

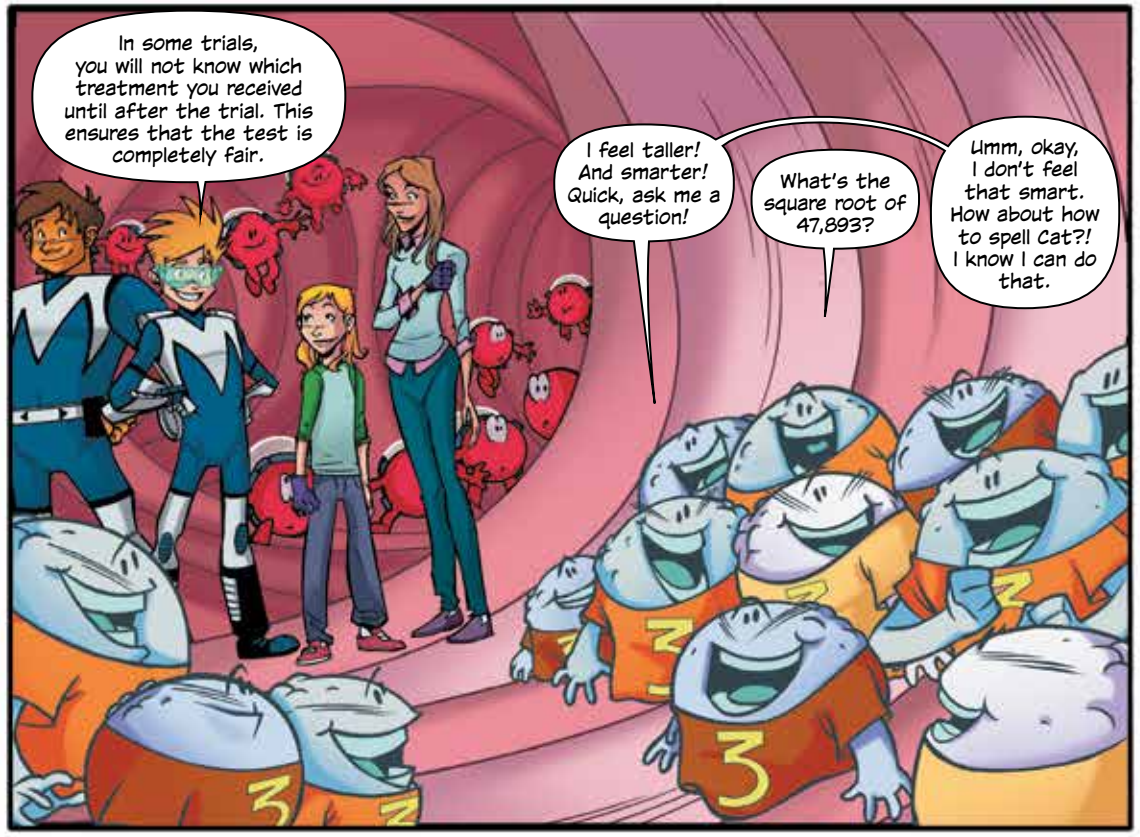
We're ready to do our part!



In phase 3 trials, you will be assigned at **random** to receive either the **new treatment** or the **control**.

The control may be a treatment that doctors already know works and is safe. Or, it may be a placebo.

A placebo contains no actual medicine. It is used to make sure the new treatment is safer and works better than having no treatment.

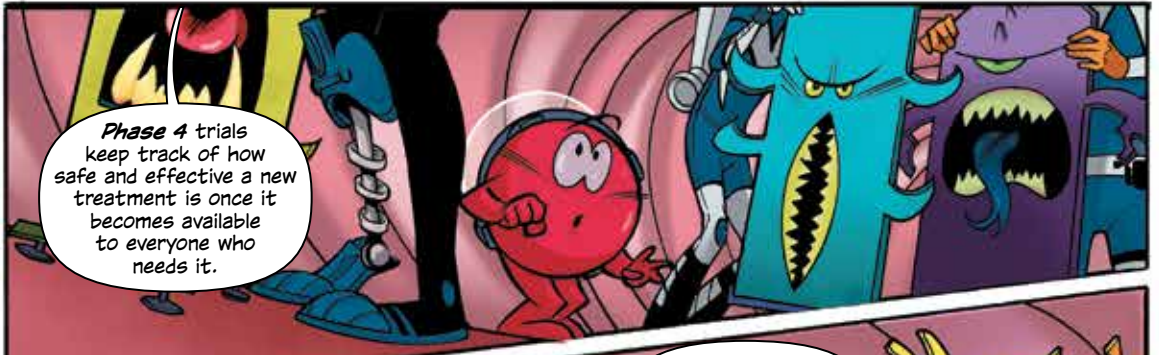


In some trials, you will not know which treatment you received until after the trial. This ensures that the test is completely fair.

I feel taller! And smarter! Quick, ask me a question!

What's the square root of 47,893?

Umm, okay, I don't feel that smart. How about how to spell Cat?! I know I can do that.



Phase 4 trials keep track of how safe and effective a new treatment is once it becomes available to everyone who needs it.



Time for us to see how effective this treatment was at making the immune cells stronger!

Ready. steady. **GO!!!**



Did I do that?

That looks pretty effective to me!

Me too!

Not all trials are successful. Some trials are canceled if the new treatment does not work well enough, or if there are too many side effects. Let's head back to HQ!

Back at Medi-HQ...

That was awesome!

Yes, but you should remember that trials can also be tough for the people taking part.

Indeed, having regular tests and seeing your doctors can take up a lot of time. You may also develop an unexpected health problem.

So what happens if Sam wants to stop taking the new treatment or wants to quit the trial?

No problem! You can stop being in a trial whenever you want.

It is helpful if you stay in the trial until the end. But if you do want to stop, let the doctors and researchers know why.

The good news is that while you're in a trial, you might get a new medicine before anyone else. However, you may also happen to have side effects with the new medicine.

Remember, you're contributing to medical research while in a trial, which means everything you do helps doctors learn about better treatments for people like you!



Wow, Mom, we learned a lot today!

Let's make sure we got it all.



A clinical trial is a test to see if a new treatment works and is safe to use.

Diseases and medicines can affect children and adults differently, so the research team needs to know that the new treatment works well for children, too.



Before we join a trial, we'll need to know what will happen during the trial, including the challenges and possible risks.

If I do decide to participate, my parents and I will then give permission so that I can join the trial.



My doctors will keep a close eye on me during the trial and do tests to make sure I'm okay.



You can stop being in the trial at any time.



Perfect! You two nailed it!



Thanks, Medikidz!

Yes, thank you all so much for helping Sam and me understand clinical trials!

It's what we do!

Teleporting you back home now!

Later...

I just want you to know how much we appreciate you taking time to consider being part of the trial, Sam.

I have thought about it...

...and yes, I would like to take part!

The end!

GLOSSARY



WHAT ARE CLINICAL TRIALS?

Clinical trials are a type of research that studies tests and treatments in people. Before new tests and treatments become widely available, a clinical trial is needed to check how well they work and how safe they are.

PERMISSION

Your permission to join a clinical trial is called **assent**.

Your parents or guardian also need to give their permission. This is called **informed consent**.

Even after agreeing to join, you can change your mind and leave the trial at any time.



CONTROL TREATMENT

In a clinical trial, a new treatment might be tested against a control. A control is either a treatment that is already proven to work or a placebo.

PLACEBO

A placebo looks exactly like the treatment being tested in the clinical trial but it doesn't actually contain any medicine.



PLACEBO NEW TREATMENT

SIDE EFFECTS

These are unwanted and usually unpleasant reactions to the treatment that may happen during the trial.

RISKS

The risks of a clinical trial include:

- Serious side effects that a new treatment may cause
- The new treatment may not work or may not be any better than current treatment
- You may not receive the new treatment—you may be in the control or placebo group

GLOSSARY



PHASES OF A CLINICAL TRIAL

Testing new treatments in clinical trials follows a series of steps called phases:

1

PHASE 1

Phase 1 trials test a new treatment in people for the first time. These trials aim to find the best dose of the new treatment with the fewest side effects.



2

PHASE 2

The new treatment is now given to a larger number of people to see how well it works and how safe it is.



3

PHASE 3

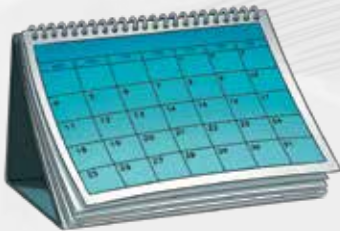
Phase 3 trials compare a new treatment with the current best treatment, comparing the side effects of each and seeing which one works best.



4

PHASE 4

Once a new treatment becomes available to the public, Phase 4 trials aim to assess how well the treatment works and how safe it is over a long period of time.



UNDERSTANDING CLINICAL TRIALS

ISBN 978-1-64954-035-5

Editor In Chief

Columba Quigley, MD

Authors

Kimberley Maxwell, PhD
Shawn deLoache

Peer Review

Patrick A. Zweidler-McKay, MD, PhD

Art

Bruno Büll and Gisela Pizzatto (Inks)
Áthila Fabbio (Pencils)
Marcelo Ferreira (Layouts and Editor)
Daniel Rodrigues, Israel Maia Jr. and Felipe Rostodella (Colors)
Felipe Rostodella (Letters)



Jumo Health and its logo, Medikidz, In My Words, and In My Shoes are registered trademarks of Jumo Health, Inc. All other trademarks are the property of their respective owners.

The health information contained herein is provided for educational purposes only and is not intended to replace discussions with your health care provider. All decisions regarding patient care must be made with a health care provider, considering the unique characteristics of the patient.

© 2020 Jumo Health, Inc. All Rights Reserved.



Jumo Health develops age appropriate, educational resources for patients and caregivers for use throughout their medical journey.

By working with providers, manufacturers, and advocacy groups, we ensure our resources are available at the moment of diagnosis, during a treatment regimen, or while participating in a clinical trial. With the belief that an informed patient is a compliant patient, Jumo Health designs practical solutions using popular mediums. With experience providing resources to more than 70 countries in 80 languages, and covering more than 200 topics, our mixed media solutions range from comic books to animated videos, are evidence based and peer reviewed, and pay careful attention to health literacy and reading comprehension barriers.



To learn more about our educational resources, please visit:

JumoHealth.com



Scan
here for
more
books!