

UNDERSTANDING CLINICAL TRIALS



Ages 13 - 17

EVER WONDERED WHAT A CLINICAL TRIAL IS?

Clinical trials are research studies that help doctors and scientists learn more about a disease and new ways to improve treatment.

They are essential to studying drugs with the goal of approving only the safest and most effective ones.

This book, *Understanding Clinical Trials*, explains why clinical trials are needed and what might be involved if you decide to join one.



UNDERSTANDING CLINICAL TRIALS



Game night,
David's basement.

Ah! Again?!
This level is so tricky!

Yeah, man!

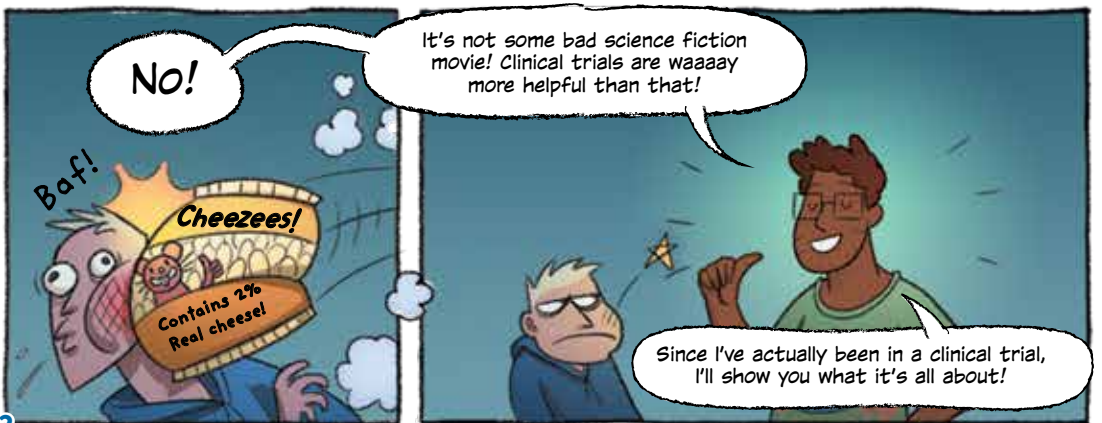
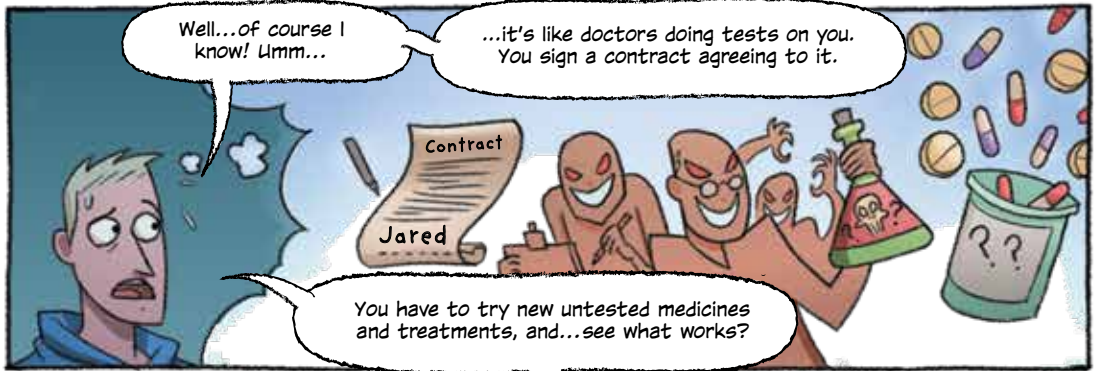
Almost as tricky
as clinical trials.

Yeah.

Wait... what?!

Clinical trials!
It sounds scary, but
you'd be surprised! Let's
take a look.

Dude,
who are you
talking to??



There better be more snacks on the next few pages.

Snacks and learning!



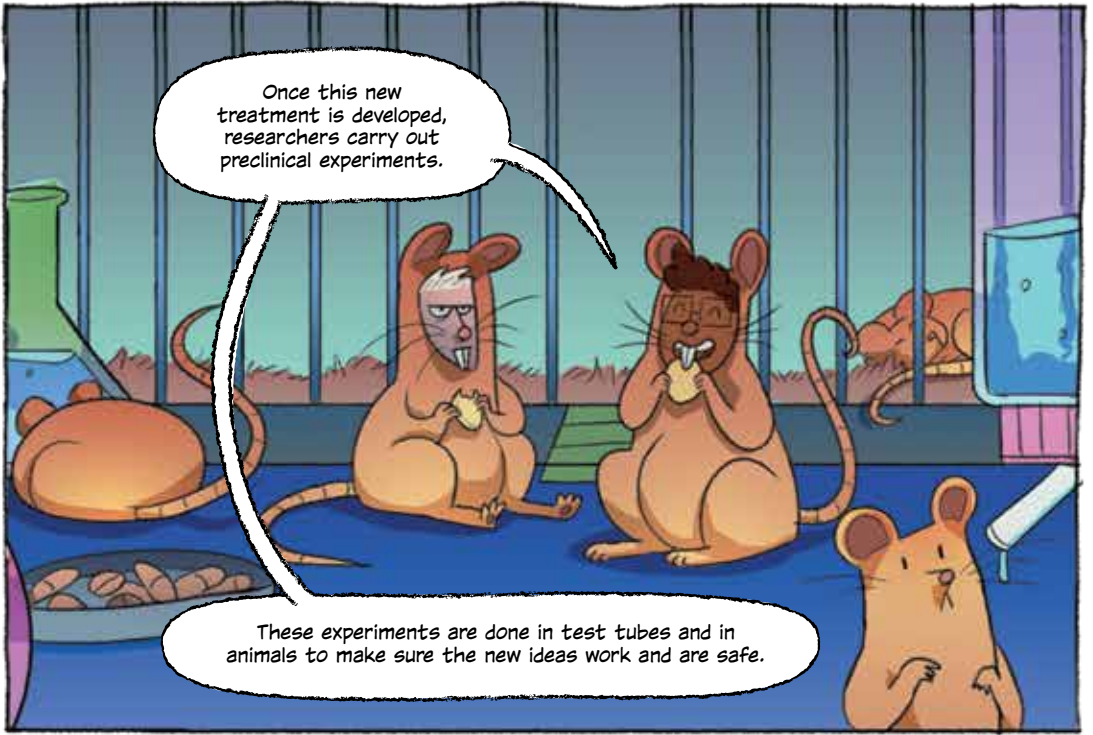
First, researchers come up with an idea for a new or better way to treat a disease.

This idea is something like a new medicine or a medical device that could be used to prevent people from getting sick...



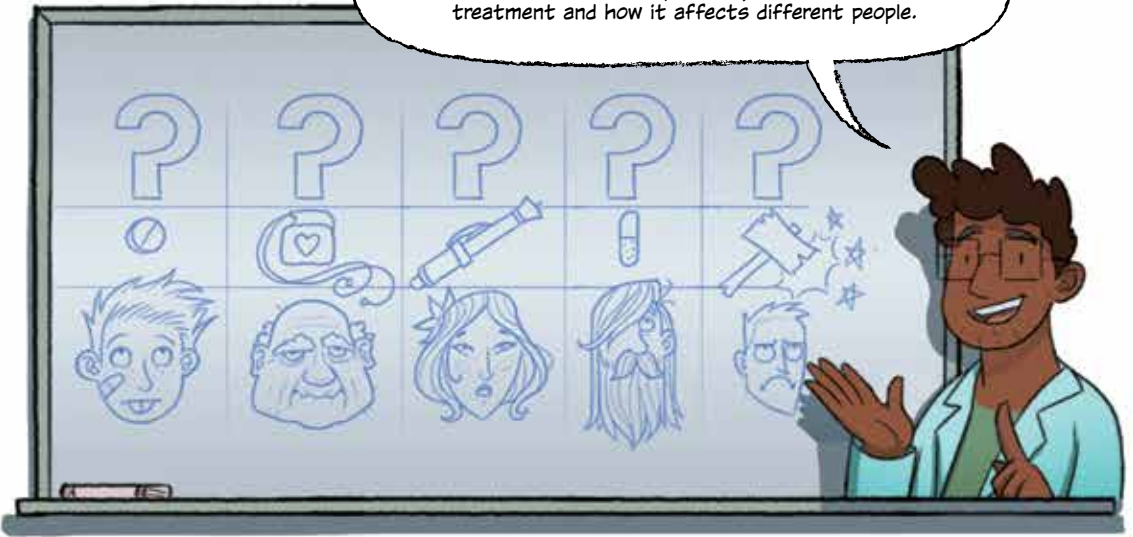
...or to help those who are sick feel better!





Let me explain.

Clinical trials, also known as clinical studies, help doctors and researchers answer specific questions about a new treatment and how it affects different people.



The main questions being:

1. What is the safest dose of the new treatment?

Um. No.

Bingo!



2. How well does it work for people?

Nope?

Yes!



Clinical trials are an important step for making medical breakthroughs available to the people all over the world who need them.



So if a new medicine gets through the preclinical stage, they just start giving it to people? I'm no doctor, but that doesn't sound like very good science to me!

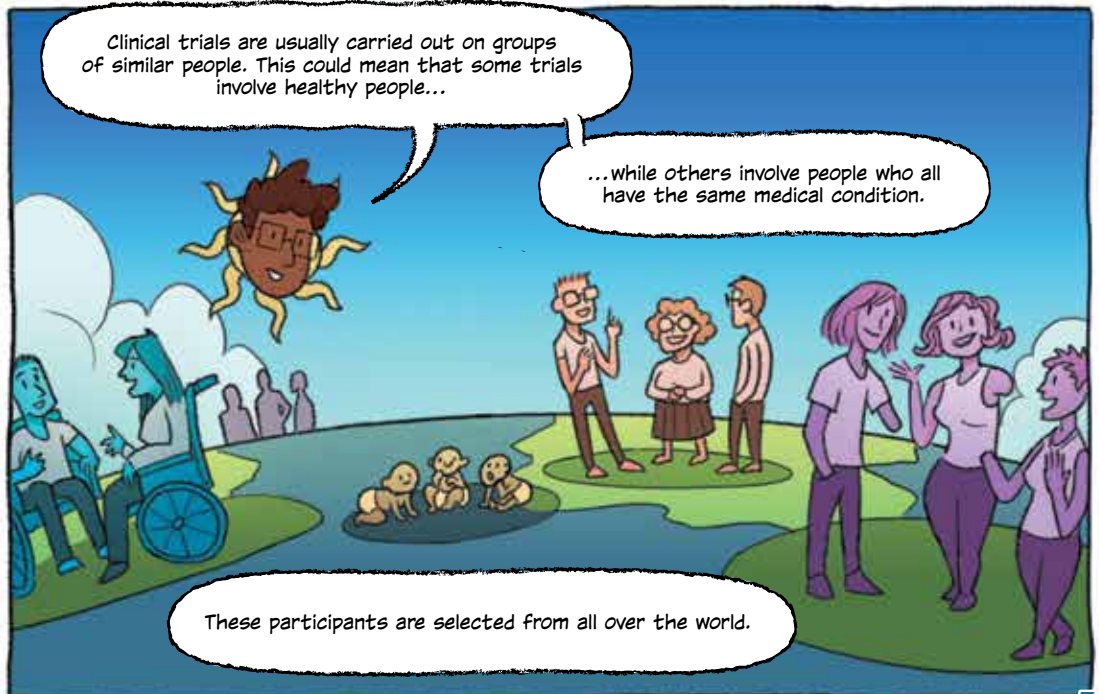
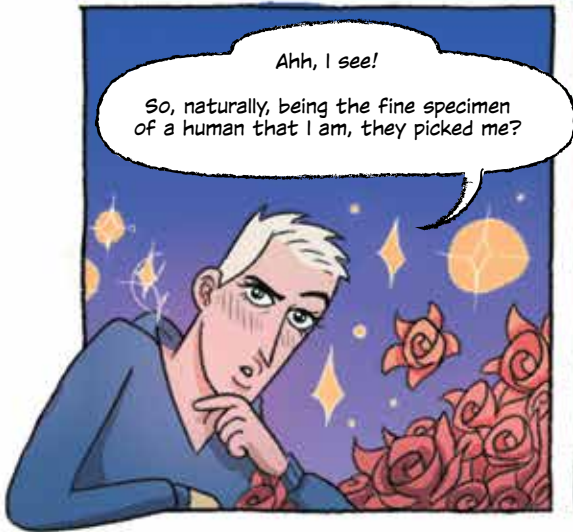


What treatments are being tested in the trial?

Who can join the trial?



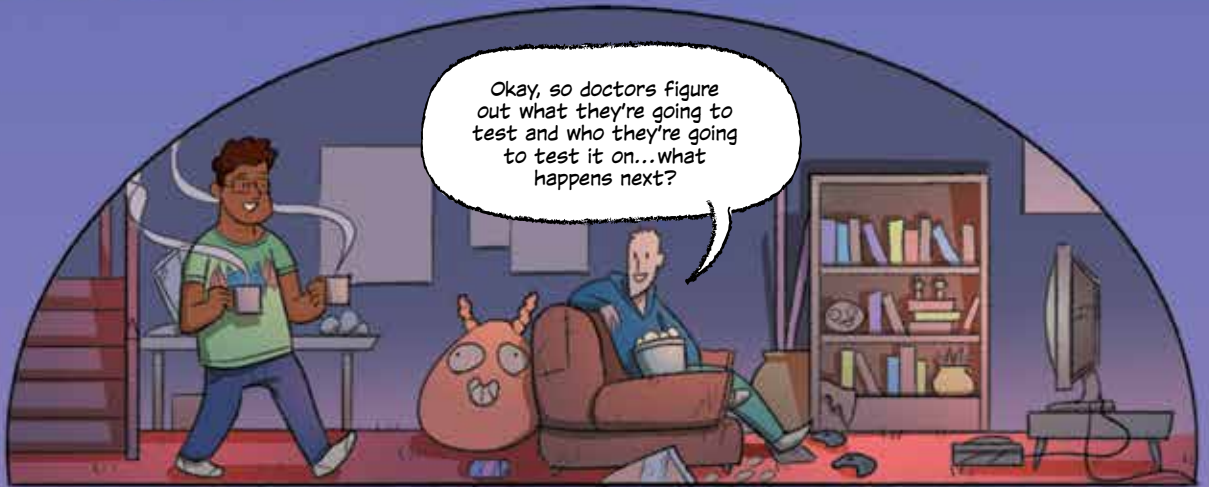
Researchers and doctors spend countless hours designing a clinical trial before it starts, sorting through tons of important questions and details while making a plan for running the study!





Probably not the beach.

Where the trial takes place is different for each study, so it could be at a local hospital, clinic, university, or at your doctor's office.

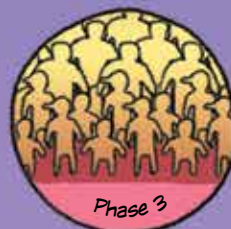


Okay, so doctors figure out what they're going to test and who they're going to test it on...what happens next?



There are four different types, or phases, of clinical trials.

Each phase helps researchers and doctors learn more about how a new treatment works in people.




A Phase 1 trial is the first test of a new treatment in a small group of people, to see if it's safe.




Phase 1




Next up are phase 2 trials, which happen in a larger group of people to see how well the new treatment works while monitoring for side effects.




Phase 2



Phase 3 trials involve even more people to see if the new treatment is more effective than previous treatments and is equally safe. After that, doctors can prescribe it to everyone who needs it!



Phase 3



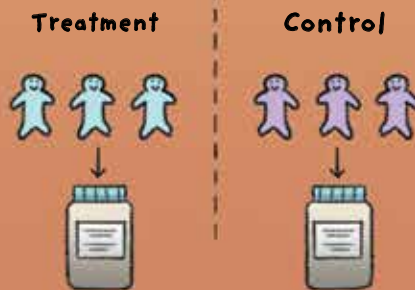
Phase 4 trials keep track of how safe and effective the treatment is.




Approved
Phase 4



Does everyone get the same new treatment?

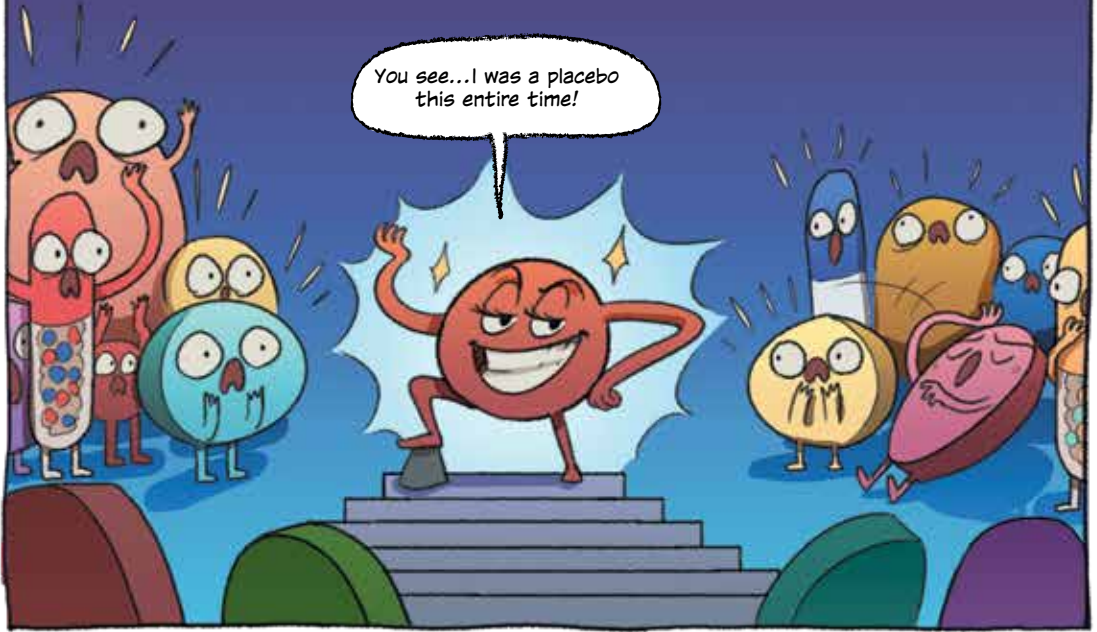
Well, not always. Some clinical trials compare a new treatment with a "control" treatment.



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

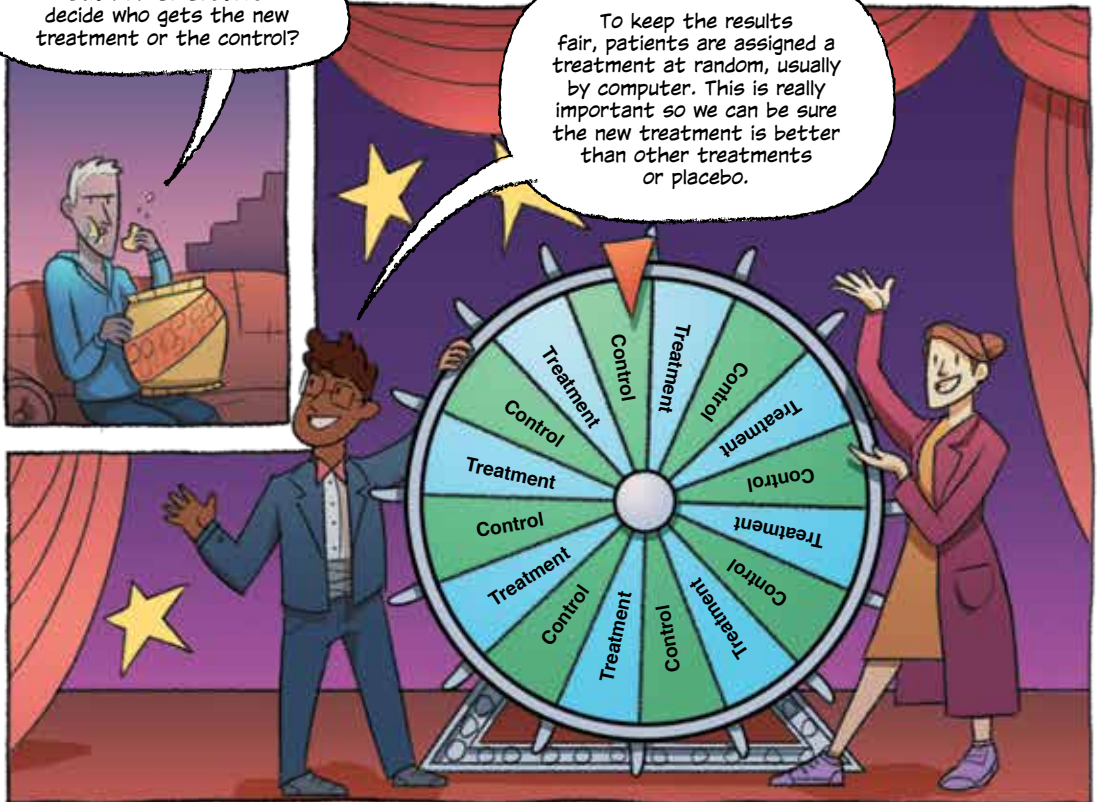
A placebo is a harmless substance that contains no medicine. This helps doctors to be sure that patients don't report feeling better just because they are getting a new treatment.

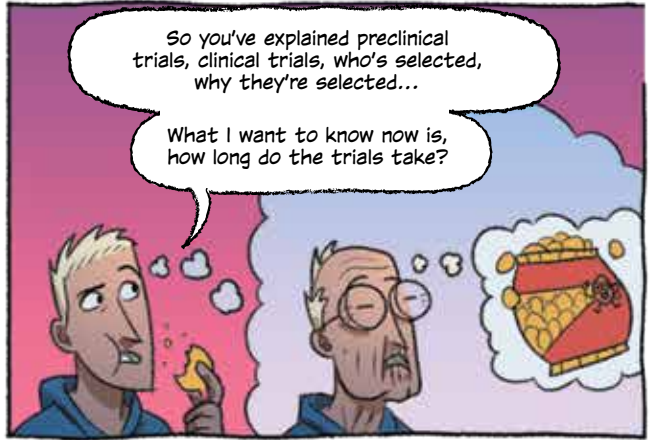
You see...I was a placebo this entire time!

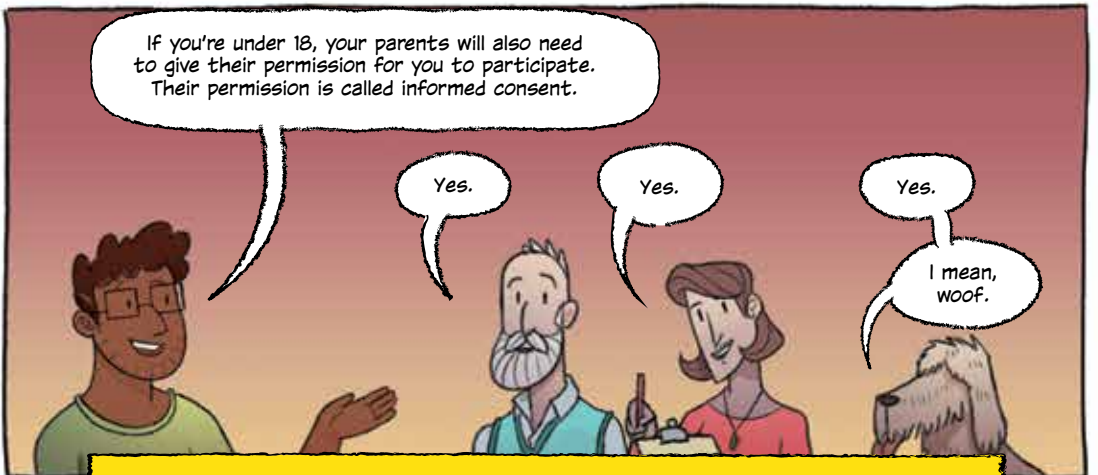
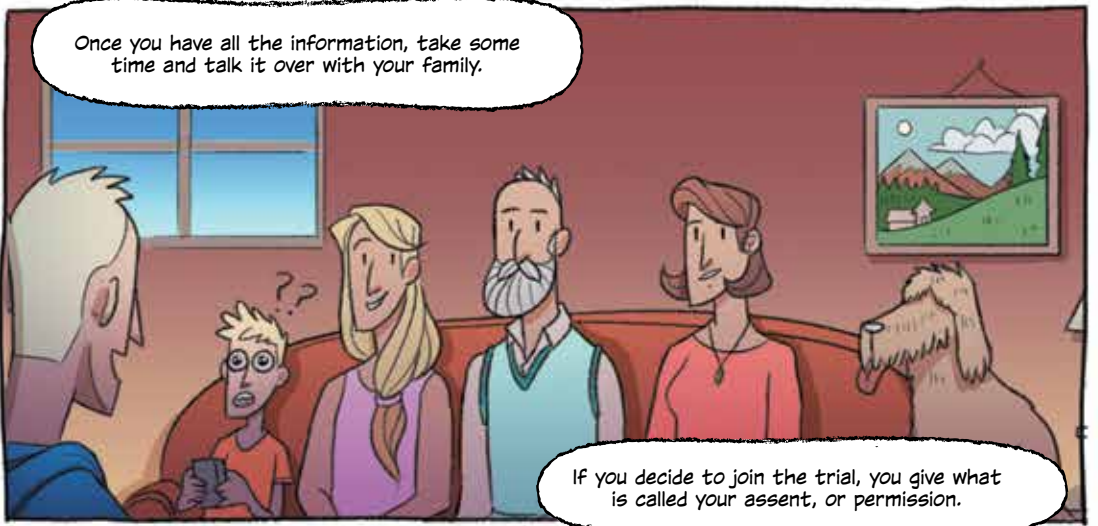
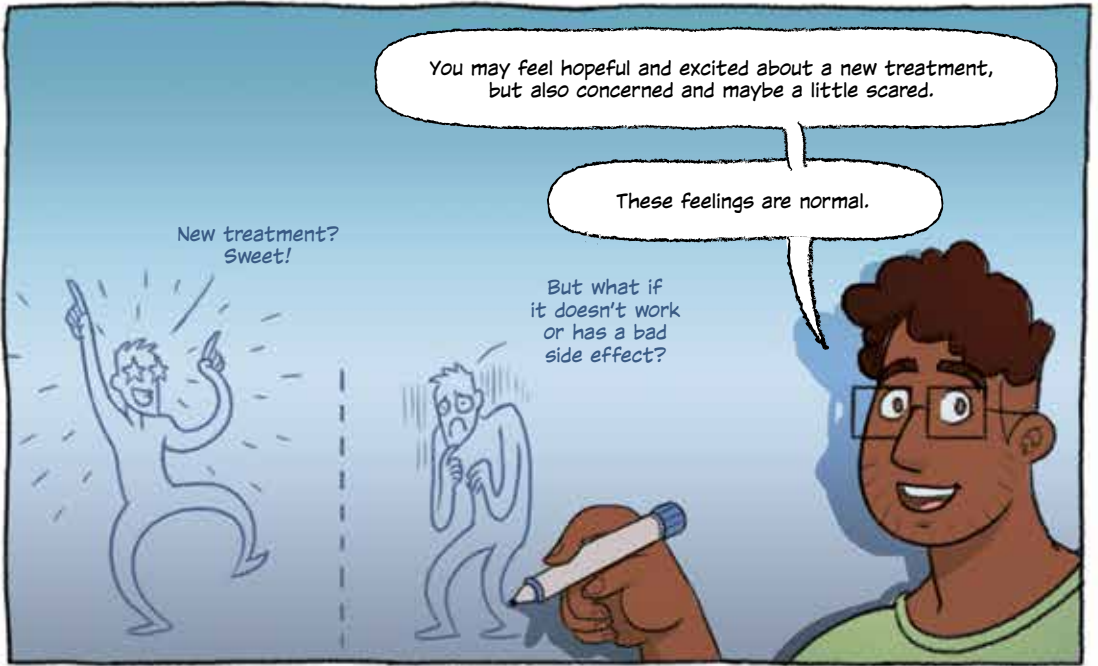


But how do doctors decide who gets the new treatment or the control?

To keep the results fair, patients are assigned a treatment at random, usually by computer. This is really important so we can be sure the new treatment is better than other treatments or placebo.







Assent and consent aren't a contract. They just show that you agree to join the trial.



Before you start a trial, you may have a physical exam and some tests, like blood tests or scans.



These tests are needed to make sure you are appropriate for the trial.

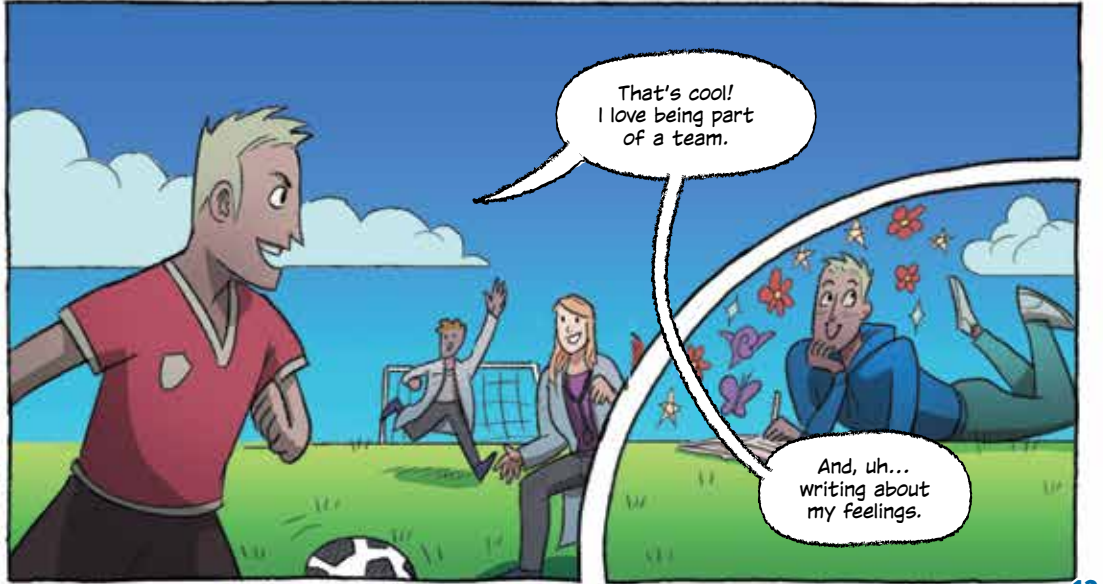


Aw yeah! I'm ready inside and out! Bring it on!!

RESEARCH TEAM

If you decide to join the trial, you'll be part of the research team.

You may be asked to help out with the research by filling out questionnaires about your health or by keeping a diary about how you feel.



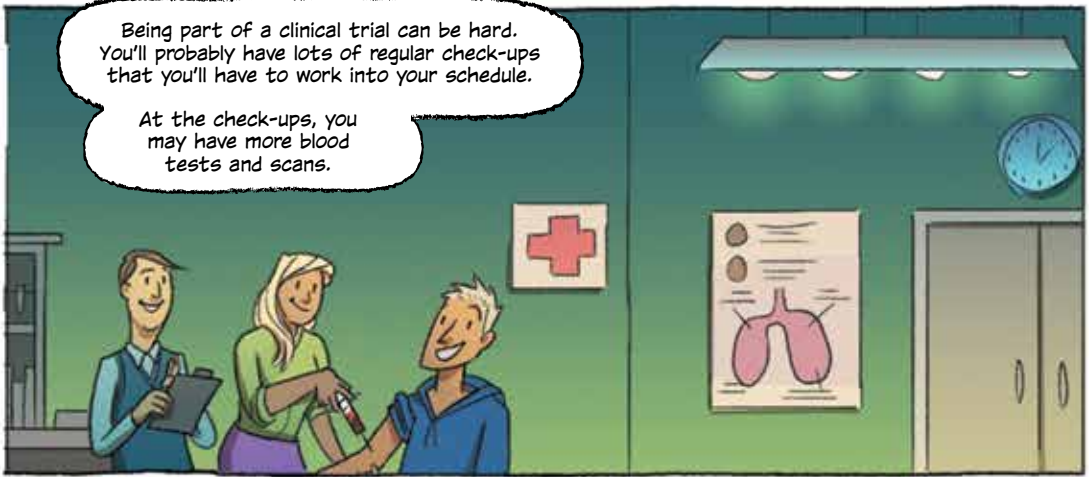
That's cool! I love being part of a team.

And, uh... writing about my feelings.



Doctors, nurses, and other health care professionals will keep a close eye on you during the trial to see how you're doing.

Okay, that's good to hear. If I'm taking some new medicine, I definitely want to know people have my back!



Being part of a clinical trial can be hard. You'll probably have lots of regular check-ups that you'll have to work into your schedule.

At the check-ups, you may have more blood tests and scans.



Is there anything else I should be on the lookout for?



Well, as with all medicines, there can sometimes be side effects.

So it's important to let the doctors and nurses know if you feel sick at any point.

Something else that you have to keep in mind is that not all trials are successful.

A trial may show that the treatment doesn't work or that there are too many side effects, and so they may stop the trial early.

Yeah, that makes sense. I mean, that's why they're doing the trial in the first place—to make sure it works and is safe!



Let's say I agree to do the clinical trial... but it turns out I don't like it, or it's taking up too much time, or something.

Then what happens?



Then you can stop, man!
No worries.

You can leave the trial whenever you want. Just let your doctors and researchers know and explain why.

But if you can, it helps to stay until the end of the trial.

Scientists and doctors work hard to develop better treatments and medical solutions.



Clinical trials help make sure all new treatments work and are safe.



Being part of a clinical trial isn't always easy, but you won't be in it alone.



And you are helping people all over the world get better treatment.



Thanks, David!

With your help explaining things, I now know more about clinical trials and don't feel so nervous.

Aw, no worries, man!



You're cleaning this mess up on your own, though.

What mess?!



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 the doctors already know is effective or a placebo.

GLOSSARY



PLACEBO



NEW TREATMENT

PLACEBO

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

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, usually in a small group. These trials aim to find the best dose of the new treatment with the fewest side effects.



2

PHASE 2

Next, the new treatment is 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 works better.



4

PHASE 4

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



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