UNDERSTANDING CLINICAL TRIALS
(YOUNGER KIDS)
Dear parents

This book is intended to help you and your family understand clinical trials and what your child might experience if he/she decides to join.

MEET THE CHARACTERS

Cody, Rose, and MEDBOT
The stars of this book
All I want to do is go home and play some video games... but can I?! NOOOOO!

I have a ton of homework to do!

Speaking of, do you know who's going to have, like, a TON of make-up homework? Jamie!

I haven't seen her in class for days!

Oh, yeah, that's because she has joined a clinical trial for her diabetes.

Trial? What is that?!

See, clinical trials are how doctors and scientists test new medicines.

But wait a second, Cody, how do you know so much about clinical trials?
Sure! Come on, Rose, let's head to the cafeteria!

Well, for one we're going to need some room! And also...the cafeteria lady sometimes gives me the left-over desserts!

Axon, my favorite Medikid, made me this awesome robot, Medbot!

You met the Medikidz and got a robot?!

Medbot is filled with tons of medical information that I can share with other kids!

Cool! Hey, Cody, do you think you could teach me about clinical trials?

Because I was actually in one last year! The Medikidz came and helped me understand what clinical trials are about.

And that's not all!
Okay, the cake was good, but I'm here for the knowledge!

So, the first thing you need to know is that scientists and doctors are always studying new ways to prevent, detect, and treat disease.

To start with, these new treatments are tested in a lab to see how they work!

Show her, Medbot!

Okay, so first the medicines get tested in the labs. What happens next?

Well, the most promising treatments, ones that look like they might work, are then tested in... you guessed it... clinical trials!

Cool... but what exactly is a clinical trial?
Not only do these new treatments need to be tested in adults, but they also need to be tested in kids!

See, us kids aren’t just little adults! Our bodies work differently than adult bodies, which means disease and medicines can affect us differently.

Okay, so that’s why there are clinical trials that include kids like Jamie!

Basically, a clinical trial is a test to see if a new treatment is safe, and also to check how well the treatment works in the body.

Each clinical trial is carried out on a group of similar people from around the world with the same illness.
You can choose to join the trial or not. Either way, it won’t change your relationship with your doctor.

So, how do you join a clinical trial in the first place?

Is there a sign-up sheet like for basketball, or do you, like, get an email alert or something?

My doctor told me and my parents about mine, and that’s how most people find out about them.

We talked it over and figured out that we wanted to do it.

If you and your parents decide to take part in the trial, you let the doctors know. You need to give your permission, also called assent, to join the trial.

Your parents also need to give their permission, which is called informed consent.

GOT IT!

You can choose to join the trial or not. Either way, it won’t change your relationship with your doctor.
During a trial, the doctors keep a close eye on you to make sure you are doing okay and to see how well the treatment is working. They might also give you a diary so you can answer some questions on how you feel.

Okay, so if I give permission and my parents give permission, what happens next?

Well, before a trial can start, your doctor will give you a check-up and run some tests...

...usually things like blood tests, x-rays, and scans.

If everything looks good, you can join the trial.
Clinical trials usually involve four steps called phases.

Each phase helps scientists and doctors learn something different about the treatment.

Phase 1 trials usually test a new treatment in a small group of adults - healthy volunteers or a group of people who have the same disease - to see how it works and whether it’s safe.
Phase 2 trials test how a new treatment works on a larger group of people who need it—for example, people who have a disease.

Phase 3 trials are different from Phase 1 and 2 because they compare a new treatment against a control to see which one is best.

Phase 3 is usually when clinical trials with kids start.
A control may be a treatment that doctors already know works and is safe.

Or, it may be a placebo*, which looks just like the treatment but doesn’t actually have any medicine in it!
Come on, I’ll tell you the rest on the way home! It’s tofu loaf night, so... it’s not like I’m in a rush.

So how do I know if I’m getting the medicine or the uh...what did you call it? Placebo!

That’s the thing, you won’t!

You’re assigned to a treatment or control group at random, and so you don’t know which treatment you are receiving.

This helps make sure that the test is completely fair.

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

You’re assigned to a treatment or control group at random, and so you don’t know which treatment you are receiving.

Come on, I’ll tell you the rest on the way home! It’s tofu loaf night, so... it’s not like I’m in a rush.
Okay, so what else do I need to know about being in a clinical trial?

Well, I guess the other big thing is that being in one can be tough, sometimes.

Having all those regular tests and doctors’ visits can take up a lot of time. I remember feeling a little overwhelmed.

Oh yeah, that makes sense! Can you stop if you want to?

Totally! You can stop being in a trial whenever you want. You just have to let the doctors and researchers know.

But I will say this, even though being in the clinical trial was tough at times, I was glad that I joined...

...especially because clinical trials help doctors find new and better medicines.
Okay, well this is my stop! And perfect timing too, because now you know everything I know about clinical trials!

Awesome, thanks for teaching me about them!

Speaking of teaching, now it's your job to help others understand clinical trials!

The Medikidz handle things in outerspace, but down here on earth, we can help other kids understand science and the body.

Awesome!

Thanks so much, Cody! I'll see you tomorrow! Enjoy your night of... umm... tofu loaf and homework!

You're welcome! And thank goodness Medbot has tofu-loaf eating capabilities.
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