



Parent Guide



innovation Research & Training

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FIRST EDITION



Dear Parents,

Welcome to *DigiKnowIt News*!

DigiKnowIt News is an online resource for children ages 8 to 14 years designed to educate children about clinical trials. Your child will take part in fun, interactive, and informative activities to learn about all aspects of research.

By using *DigiKnowIt News*, we believe that youth will gain new knowledge about clinical trials, feel more confident in their ability to communicate and ask questions about a study, and develop more positive attitudes toward being in a clinical trial.

There are two resources for parents:

1. Parent Guide

- This Parent Guide will provide you with:
 - An overview of clinical trials designed specifically for children;
 - Brief descriptions of the parts of the *DigiKnowIt News* website: Investigations, Spotlights, and Comics; and
 - Strategies to support and encourage your child to use *DigiKnowIt News*.

2. Parent Videos

- You will also be able to hear from parents with children of all ages who have already been in a clinical trial. As part of these videos, parents share their experiences deciding to be part of a clinical trial and what it was like for them and their children to be part of a clinical trial.

Your support of your child's involvement in *DigiKnowIt News* will play an important role in your child learning from this resource.

Please contact us with any questions you might have about *DigiKnowIt News*.

Sincerely,

Dr. Alison Parker and Dr. Tracy Scull

Background on pediatric clinical trials

What is a clinical trial?

A clinical trial is a type of research study that tries to learn if and how new treatments might work to improve health for a particular population of people. Treatments can be anything from a new medicine or medical device, to an exercise program, or even health education.

Clinical trials provide a safe and controlled way for doctors and researchers to study these new treatments.

- It is important to remember that researchers or doctors cannot promise that a treatment will work for a child as part of a clinical trial.
- This research can help us understand how it works with children as well as help researchers and doctors treat children better in the future. Learning that a treatment doesn't work is just as important as learning that it does work!

Why are clinical trials with children important?

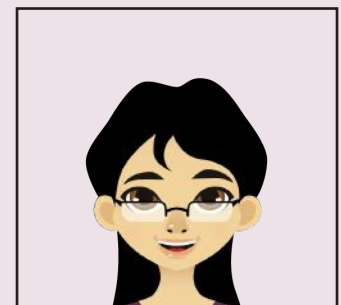
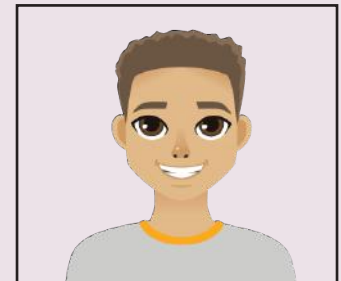
Currently, less than 20% of clinical trials are pediatric clinical trials, or clinical trials with children less than 18 years old. We need more children and teens to participate in clinical trials so that we can learn how children may respond to different types of treatments. This information helps health professionals provide the best possible care for children.

Sometimes, children are provided with treatments that have only been tested with adults because there have not yet been clinical trials with youth. This can be dangerous because children's bodies are not like adults' bodies, and children may react to treatments in different ways than adults.

Why don't more children participate in clinical trials?

- Some families might not be aware of the opportunities that are available or the benefits of participating in research.
- Some children might also be afraid of participating in research because of a fear of needles or a new treatment or interacting with new people.

We believe that *DigiKnowIt News* can provide children (and their families) with information about clinical trials that can help when they make a decision to be part of a clinical trial in the future.



Reasons for your child to participate in a clinical trial

Why should my child with a chronic illness participate in a clinical trial?

1. Your child can help others who have a similar illness or disease.
2. Your child can contribute to science, which may allow researchers and doctors to discover new treatments that can help other children in the future.
3. Your child may get better medical care with new treatments and access to new health-care specialists because they are monitored so closely as part of the clinical trial.
4. Your child may get access to a treatment that is not yet available to the public.
5. Your child can develop skills such as communicating their health questions and concerns to researchers and health professionals.



Why should my healthy child participate in a clinical trial?

1. Your child will be part of a comparison group in which doctors and researchers can compare the health of your child and that of children with a chronic illness or disease.
2. Your child can help other children who have a chronic illness or disease.
3. Your child can contribute to science, which may allow researchers and doctors to discover new treatments that can help other children in the future.
4. Your child may get better medical care with new treatments and access to new health-care specialists because they are monitored so closely as part of the clinical trial.
5. Your child can develop skills such as communicating their health questions and concerns to researchers and health professionals.



What is DigiKnowIt News?



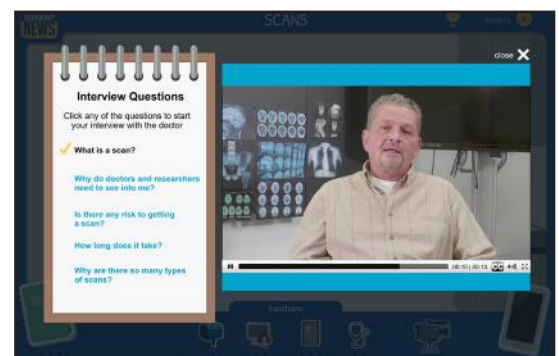
DigiKnowIt News is a fictional, youth-run news organization. It was created to teach children information about clinical trials in a fun way using animations, cartoon characters, interactive activities, games, and videos of real people. By providing them with information about clinical trials, children can confidently make decisions about their health and any future research opportunities. *DigiKnowIt News* was developed with the help of children, parents, researchers, and health professionals.

DigiKnowIt News has three main parts: Investigations, Comic Books, and Spotlight videos. We provide more information about all three below.

Investigations

✓ Children are tasked with being investigative journalists for *DigiKnowIt News*. In each investigation, children are given an assignment from the *DigiKnowIt News* Editor and asked to learn about different aspects of clinical trials and write a blog (Please note: the blog is only published within *DigiKnowIt News* and is not available to the public).

✓ Children can explore different sources throughout each investigation to collect information to help write their blog. There are many different types of activities within *DigiKnowIt News* to keep children engaged and interested in learning. For example, children might interview a doctor or a same-aged peer who has been in a clinical trial. Or, they might do an online DigiSearch or watch an animated video on DigiTube to learn about new terms or procedures.



Investigations

✓ Children will also watch reenactments of real world situations where a child their age is participating in some aspect of a clinical trial, and they will get to choose what happens next!

✓ When children are ready, they can write a short blog post that pulls together the information they learned during the investigation.

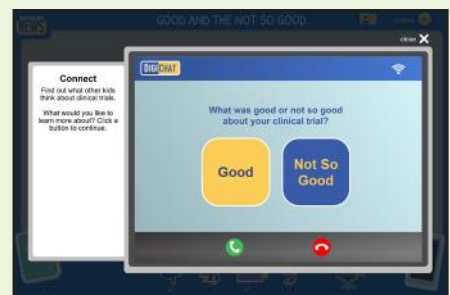
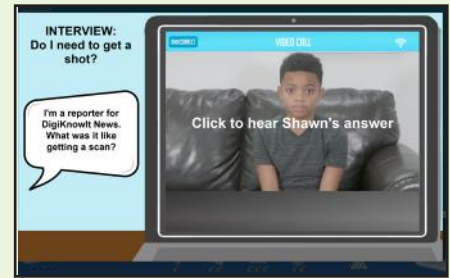
There are four main investigations that your child can complete:

✓ Mystery of Clinical Trials

Children learn about clinical trials, why they are important, and why it is important for children to participate in them. Children learn new vocabulary that is often used in clinical trials, and what their role might be if they decide to participate. They are also introduced to individuals that might be involved in clinical trials, such as doctors or researchers.

✓ Good and Not So Good

Children learn about the good things that might happen (like helping others) and not-so-good things (like missing time with friends) that might happen if they decide to participate in a clinical trial. Children also learn a variety of new tools (like making a pros and cons list) to help them to make an informed decision about participating in a trial.



Investigations

Know Your Rights

Children discover the rights they have as participants in a clinical trial. They learn about informed consent and the many safety measures in place to keep them safe if they decide to participate. Knowing their rights allows children to speak up for themselves before, during, and after a clinical trial.

Who to Talk to

Children learn who to talk to if they have questions or concerns about a clinical trial as well as the types of questions they should ask. Children also learn more about making the decision to leave or quit a study and how to be confident in telling others what they want.

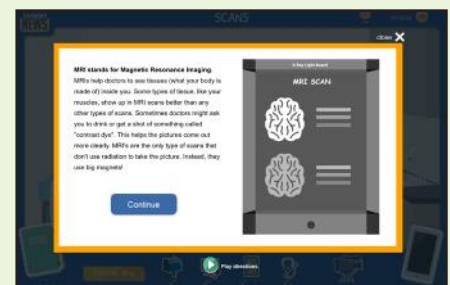
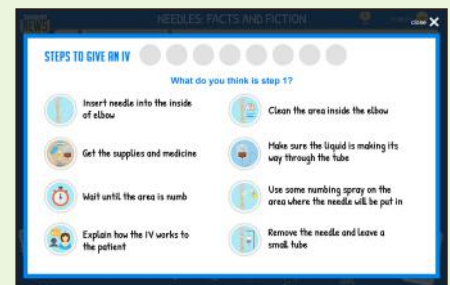
Other possible investigations may include:

Needles: Facts and Fiction

Children learn about the different ways that needles may be used in clinical trials including blood draws, IVs, and injections.

Scans

Children explore the various types of scans (like MRIs, X-rays, and CT scans) that might be used in clinical trials, including learning about their functions, appearances, and sounds.



Comic Books

- The comic books include stories about children who are thinking about participating in a clinical trial or are actually participating in a trial.
- In each comic book, your child will be able to choose a main character to follow. They will also be able to choose if they would like to have the comic read aloud to them.
- There are also many surprise clickable parts throughout the comic books to keep your child engaged and interested in the story. Click on them to make a bird sing, to bake a pizza, or to see a comic book character sign their study forms.
- *DigiKnowIt News* has one main comic with four issues, or chapters, and several shorter comics.

Chronicles of the Clinical Trial

This comic follows a character who is deciding whether or not to participate in a clinical trial. Each issue focuses on a particular aspect of the character's experience in the clinical trial.

Other possible comics might include:

MRI Mission

This comic follows a character who is getting a MRI for the first time.

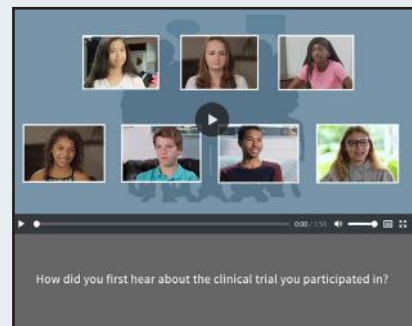
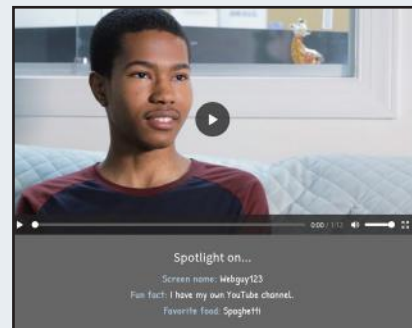
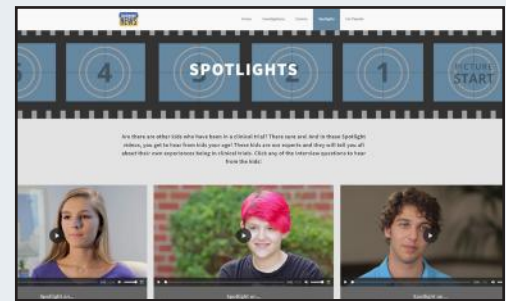
Power of Pizza

This comic follows a character who is getting blood drawn.



Spotlights

- The spotlights are short videos that give children a chance to hear from all kinds of other kids. These videos include interviews with youth who have already participated in pediatric clinical trials.
- The videos cover many topics, and your child can watch as many videos as s(he) would like. Some videos focus on just one youth, and others include many youths.
 - What is a clinical trial?
 - Why did you decide to be in a clinical trial?
 - Why do you think it is important to ask questions?
 - What are some benefits or good things about being in a trial?
 - What are some not so good things about being in a trial?
 - How did you know the trial would be safe?
 - What would you want other kids to know about participating?
 - What was it like to have your blood drawn?
 - What was it like to get a scan?



How will my child use *DigiKnowIt News*?

- Your child will follow the link to *DigiKnowIt News* that you will receive in your email.
- The first time they go to the *DigiKnowIt News* website, they should watch the Introduction video. This will give your child an overview of the entire website.
- Your child can then decide which part of *DigiKnowIt News* they would like to explore. There is no set order. They can decide the order in which they take part in the investigations, comics, and spotlights.
- *DigiKnowIt News* can be explored at times that work for you and your child. Also, your child can return to use any part of it, at any time.
- Your child should complete *DigiKnowIt News* within one week of getting access to the link.
- Closed captioning is available.



What can I do as parent to support my child using *DigiKnowIt News*?

1. Review *DigiKnowIt News* website yourself

You can review the investigations, comics, and spotlights that your children will learn from. You may learn something new, too!

For a list of useful terms related to clinical trials, see pages 16-17.



2. Watch the Parent Videos

We asked multiple parents to share their experiences being part of a clinical trial with their child. The parents discuss many topics such as the importance of youth participating in clinical trials, whether clinical trials are safe, the first meeting with the research team, and advice for other parents. Hearing from parents provides insight into what it might be like for your child to participate in a clinical trial in the future.



3. Discuss the content and ask questions

To support your child's learning from *DigiKnowIt News*, you can:

- **Discuss various topics with your child, for example:**
 - The importance of children participating in clinical trials.
 - The types of questions your child might ask a researcher or doctor if she or he was in a clinical trial.
 - The ways that researchers and doctors keep children safe in clinical trials.



- **Ask your child questions**

- For a list of example questions to ask your children, see page 15.



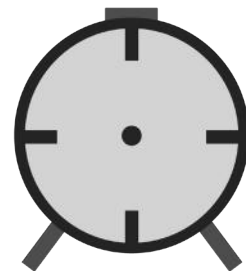
- **Do an activity together**

- Create a list of the pros and cons of participating in a clinical trial and what the decision might be and why.
- Write your own comic book.
- Create a poster to teach others about the importance of clinical trials.



4. **Provide encouragement and reminders**

1. You may wish to sit with or near your child as they go through *DigiKnowIt News* to learn with your child or support their participation.
2. To encourage them, you may discuss why it is important to complete *DigiKnowIt News*. They will learn a lot of new information and skills and be able to make informed decisions in the future about clinical trials or other areas related to their health.
3. Ask to read or print out your child's blogs as part of the Investigations.
4. Provide reminders throughout the week for your child to engage in the *DigiKnowIt News* website.



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Questions to ask your child as they go through *DigiKnowIt News*

1. What is a clinical trial?
2. Why do you think clinical trials are important?
3. Why is it important for kids to be in clinical trials?
4. Can you explain regular care to me?
5. How are treatment groups and control groups different?
6. Will you know what group you'll be in during the study? Why or why not?
7. What kind of form do you have to sign as a child?
8. What does assent mean to you?
9. What kind of form do I have to sign since I'm an adult?
10. What should we expect to see in these forms?
11. Can you tell me some rights you have as a participant?
12. Can you tell me about some of the steps that researchers and doctors take to keep participants safe?
13. Why is it important to ask questions when you are deciding to be in a clinical trial?
14. Who can you talk to if you have questions or concerns?
15. What are some examples of questions that you might ask a doctor or a researcher?
16. Do you have to stay in the study if you want to leave?
17. Can you tell me some benefits of (not) being a participant?
18. Can you tell me some down sides to (not) being a participant?

Useful Terms

- **Adherence** – Participants have responsibilities they must follow as part of agreeing to be in a study (e.g., taking pills at certain times of day, writing in a journal when asked, etc.)
- **Assent** – Individuals under the age of 18, and some adults, cannot give legal consent. Instead, children and adolescents are given the basic information on the study and are asked to participate.
- **Clinical trial** – A research study that is conducted to learn about new treatments or medicines.
- **Consent** – The legal agreement from an adult to participate, or allow another individual to participate, in a study. A consent form should include:
 - A. A description of the study
 - B. The purpose of the study
 - C. What the participant will be doing
 - D. Risks and benefits of participation
 - E. If compensation will be provided
 - F. Knowledge that participation is voluntary
 - G. A confidentiality statement
 - H. Contact information
- **Control group** – This group is identical to the treatment group except that participants do not receive the actual treatment. This group is used as a comparison to the actual treatment.
- **Data Safety Monitoring Board** - Consists of a group of people whose jobs are to keep careful track of the study as it progresses. They may suggest changes or stop the study all together if they think the participants' safety is at risk.
- **Double blind study** – Participants do not know what group they are in (treatment or control), and the researchers do not know what group participants are in either.
- **Healthy controls** – Healthy participants and their information is used and compared to the information of participants with an illness or disease.
- **Informed consent** – The process of giving an individual the perceived benefits and risks of the study before he or she decides to participate in the study.

Useful Terms

- **Institutional Review Board (IRB)** – Consists of a group of people who review proposal for research studies to ensure the safety of the participants. They need to know exactly how participants will be kept safe by the researchers.
- **Clinical trial** – A research study that is conducted to learn about new treatments or medicines.
- **Participant rights:** There are many rights for participants as part of participating in a clinical trial. Some of these include:
 - A. To be told how your information will be kept confidential
 - B. To choose to stay or leave study
 - C. To be given time to decide (without pressure) to be in the study or not
 - D. To be told why the research is being done
 - E. To be told what is going to happen
 - F. To be able to ask questions
 - G. To be told the risks of participation
 - H. To be told the benefits of being in the study
 - I. To be told if there are any costs that come with being in the study
 - J. To be given a copy of consent form
 - K. To be told of any other treatments that exist if you decide not to participate
 - L. To be told who to contact with any questions you may have
 - M. To choose to not participate at all
- **Placebo** – Participants are sometimes in a placebo control group. For example, if they are testing a new medicine, the placebo medicine would have the same appearance and dosage requirements but it will not contain the actual treatment medicine in it, rather it might contain saline.
- **Protocol** – A detailed set of activities for the study that the researcher has created and must follow.
- **Randomization** – Participants of a study are randomly placed into groups through chance rather than by choice to decrease any potential biases (e.g., age, sex, religion, ethnicity)
- **Regular care** – The healthcare that individuals typically receive from their primary care provider.
- **Treatment group** – Participants receive the treatment as part of the clinical trial.

