

## Task 4: How do we know vaccines are safe?

You know that vaccines can keep your body safe by helping it prevent disease. But how do we know that vaccines are safe to put in our bodies? In this task you will **discover** how you feel about the safety of vaccines. You will use real-world data to **understand** how clinical trials help create safe vaccines. Then you will think about how you and your community feel about the safety of vaccines so that you can **act** to share this information with others.

### ***Discover: How do I decide if something is safe?***

Using something new can sometimes make you feel unsure or unsafe. In this activity, you will think about what helps you feel safe about using something new. You will also think about how your identity influences your decision to use something new. Finally, you will think about what steps you would take to make sure a new product is safe to use.

1. Imagine someone asked you to try a product that was brand new, like a kind of snack or a hand lotion. Now consider the list below. Which of these would make you feel safe using the new product?
  - a. Your best friend said it was safe.
  - b. The government in your country or town said it was safe.
  - c. Your doctor said it was safe.
  - d. Your religious leader said it was safe.
  - e. The people who make the product described how they tested it to make sure it was safe.
  - f. You watched a TikTok® video that said it was safe.
  - g. Ten people tried it and nothing bad happened to them.
  - h. Ten thousand people tried it and nothing bad happened to them.
2. List the statements from step 1 in order from what would make you feel least safe to most safe. Use the letter of each statement to record your list in your journal.

**Least Safe**

**Most Safe**

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*Figure 16: An example of how to record the order of statements from step 1*

3. Take out your identity map from Task 1.
  - a. Are there parts of your identity that helped you decide how to order these statements?
  - b. For example, if your friends are really important to you, you might have listed “Your best friend said it was safe” as the statement that made you feel the safest.
4. If you can, ask other people to do the activity in steps 1 and 2. You could ask the people in your household, your classmates, or your team.
5. Compare how you and other people put the statements in order.
  - a. Did anyone put their statements in a different order than you? What were their reasons?
  - b. How did their identity affect the way they ordered the statements?

*Emotional Safety Tip: There are no wrong or right answers. Different people can have different opinions. Considering different opinions helps people think better. It may feel difficult to disagree with someone or have them disagree with you. Remember, disagree with ideas, not with people.*

6. Now imagine you were asked to make a new product. You need it to be safe for everyone to use. Answer the following questions by yourself or with others.
  - a. What steps would you take to make sure the product was safe?
  - b. How would you convince other people that it was safe?

***Understand:*** How do we make sure vaccines are safe?

The vaccines that protect people from COVID-19 are new products. But the people who developed these vaccines followed very specific steps to make sure that each vaccine is safe for people to use. These steps are called clinical trials. A **clinical trial** is a process to make sure that a medical drug, procedure, vaccine, or new product is safe and that it does what it is supposed to do. A clinical trial has very specific steps. These steps are called phases. These phases always happen in the same order. In this activity, you will learn about the phases of a clinical trial.

1. Read the paragraph above. Then think quietly to yourself about the following question: Why might you feel safe using a new product if you knew it had been through a clinical trial?

There are many smart, ethical, honest doctors, scientists, and others that work to develop medications to help with various illnesses and health problems. In order to know that they are safe, they ask for volunteers to help with their research in clinical trials.

—Dr. Valerie Montgomery Rice, MD, FACOG

2. Record your answer in your journal. You will think about it again in the Act activity.
3. Read the information in the Phases of a Clinical Trial for a Vaccine box. It describes how researchers make sure a vaccine is safe to use and that the vaccine works. This section will help you understand some real-world data about COVID-19 vaccines that you will find in step 4.

### *Phases of a Clinical Trial for a Vaccine*

Each clinical trial for a vaccine has four phases. Different things happen in each phase, but every phase of a clinical trial has:

- **Participants:** These are the people who are part of a clinical trial. They are always volunteers, meaning that they choose to be a part of the clinical trial.
- **Researchers:** These are the people who plan and carry out the clinical trial.
- **Informed consent:** In each phase, the researchers explain the risks of being in a clinical trial to the participants. Then, the participants sign a form saying that they understand the risks. This is called informed consent. Participants can leave the trial at any time if they change their mind.

### **Vaccine Safety**

It's important to know that any phase of a clinical trial will stop if the vaccine causes a serious side effect, death, or does not help prevent the disease. Think of this like moving through four different gates in a row. You have to

get through the first gate before you can move through the next three.

Before Phase 1 even begins, a vaccine is tested on animals. If the vaccine is safe in animals, Phase 1 can begin.

In Phase 1, the vaccine is tested on 10 to 100 participants. Researchers check whether there are serious side effects or deaths. If the vaccine is safe to use, Phase 2 can begin.

In Phase 2, several hundred participants try the vaccine. The researchers may try to find the right amount of the vaccine (the dose) that prevents disease. They may observe whether the vaccine works to prevent disease. If the vaccine is still safe to use, Phase 3 can begin.

In Phase 3, thousands or tens of thousands of participants try the vaccine. These participants must be similar to the people who will eventually use the finished vaccine. For example, the COVID-19 vaccine is meant to be used around the world. So Phase 3 participants for this vaccine are all different ages, races, genders, and have different medical conditions. Researchers make sure the vaccine is safe, that they are using the right dose, and that the vaccine prevents disease.

### **Government Approval**

If Phases 1, 2, and 3 are successful, then the vaccine might be given to people outside of the trial. But the researchers or companies that run the clinical trials for vaccines do not make this decision. This decision is made by governments agencies and scientists. They review the clinical trials and decide whether to approve the vaccine.

It is important to know that a vaccine may never be safe for certain people. For example, people who have a weakened immune system cannot get a vaccine. The vaccine will not work the way it should and the risk is too high.

After a vaccine is approved, the researchers continue to keep track of any problems caused by the vaccine. If the researchers notice serious problems, the government might stop using the vaccine until the problems are solved. This is sometimes called Phase 4 of a clinical trial.

4. Examine Figure 17. It describes the participants in Phase 3 of three actual COVID-19 vaccine clinical trials. Remember, the vaccines tested in these trials are meant to be used by people around the world. Answer the following questions in your journal or discuss them with your team.
  - a. Write the word Notice and list everything you notice about the data in Figure 17.
  - b. Write the word Think and describe whether you think Figure 17 includes the participants you would want for a COVID-19 vaccine trial. Why or why not?
  - c. Write the word Wonder and list everything you still wonder about these clinical trials.

Clinical trial	Number of participants	Race of participants	Age range of participants
A	More than 40,000	American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or other Pacific Islander, White, Multiracial	18 to 100 years old
B	More than 40,000	American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or other Pacific Islander, White, Multiracial	16 to 91 years old
C	More than 30,000	American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or other Pacific Islander, White, Multiracial	18 to 95 years old

Figure 17: Data from Phase 3 of three actual COVID-19 vaccine clinical trials<sup>10, 11, 12</sup>

5. You just learned about how important it is to have many different kinds of people as participants. It is also important to include many different kinds of people as researchers. Read what one expert says below.

The development of one of the COVID-19 vaccines was led by a Black woman scientist, Dr. Kizzmekia Corbett. A diverse group of scientists and researchers had seats at the table as the vaccine was developed.

—Dr. Valerie Montgomery Rice, MD, FACOG

6. Now imagine you are in charge of a clinical trial for a new vaccine. Your job is to make sure the vaccine is safe and that it works. Figure 18 lists information about several imaginary clinical trials. The column on the left has information that could affect each clinical trial. Examine each piece of information and decide if you would stop that clinical trial. Then record why you made that decision in your journal or discuss it with your group.

Information about the clinical trial	Would you stop this clinical trial? Why or why not?
The participants signed an informed consent form.	
In Phase 1 of the clinical trial almost all the participants get very sick and have to go to the hospital.	
A clinical trial is testing a vaccine that will be used by people around the world; 95 percent of the participants are White.	
Before Phase 1 the vaccine is tested on animals. None of the animals got sick or died.	
Phase 3 of the clinical trial has 10 participants.	

In Phase 2 the researchers try several different doses of the vaccine with the participants.	
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Figure 18: Information about several imaginary clinical trials

7. If you are working in a team, compare your answers with other people. What helped you make your decisions? Did anyone decide something different?
8. How do clinical trials make sure that vaccines are safe to put in your body? Record the answer to this question in your journal.

**Act:** *How can I help my community understand the safety of vaccines?*

One of the main goals of clinical trials is to find out whether vaccines are safe. In this activity, you will think about how you and your community feel about the safety of new vaccines. Then you will act to share this information with others.

1. Think about what you learned about clinical trials for vaccines. Record your ideas in your journal or discuss with your team.
  - a. How do clinical trials help keep people safe?
  - b. What do you think are the most important parts of a clinical trial?
2. In the Understand activity you answered the following question: Would you feel safe getting a vaccine if you knew it had been through a clinical trial?
  - a. Has your answer changed? If so, how?
3. Take out your Community Concerns list. Is there any information you found out during this task that would be useful to share with your community?

Write down the information next to those concerns. For example:

- a. One common concern about vaccine clinical trials might be that clinical trials do not include participants who share the health concerns, age, gender, or race of people in your community. Answer the following questions based on what you know.
  - Did the three COVID-19 vaccine clinical trials in the Understand activity have many different types of participants?
  - Why is that important?
- b. Maybe people in your community are worried that vaccines may not be safe to put in their bodies. Based on what you know:

- How do clinical trials help make sure vaccines are safe to use?
- 4. Pick one question or concern from your Community Concerns list that you could share information about.
- 5. Decide how you will share that information.
  - a. Who in your community will you share this information with?
  - b. What method or methods do you think would be most helpful?
    - For example, if several people answered that they would feel safest after watching a TikTok® video about a new product, you could make a TikTok® video for your community that explains how clinical trials work.
- 6. Now put your ideas into action.

I believe, particularly for the COVID-19 vaccine, that hearing from trusted members of a community is so important. This might be church members, neighborhood leaders, or even celebrities who need to come forward and say why they got the vaccine and how they feel now. Individuals want to hear that people who look or think like them got the vaccine and are safe.

—Dr. Stephanie Marton, MD, MPH

### *Additional Resources*

Find out more information at the Vaccines Story Map at [bit.ly/3n9QHxv](https://bit.ly/3n9QHxv).