

# 13

## Testing Medicines: A Clinical Trial

### INVESTIGATION

**IMAGINE THAT YOU** suffer from severe headaches several times a month. These headaches are so painful that you can't read, listen to music, or watch television. Regular headache medicines don't work very well for you. One day, you complain to your doctor about your headaches. She tells you that the local medical school is conducting clinical trials of a new headache medicine. She asks you and your parent if you would like to volunteer to be a part of this trial. You and your parent talk about it and decide that you would like to try being part of the trial.

Since medicine cannot be tested in the classroom, you will participate in a model of a clinical trial. In this model, differences in taste will equal differences in response to the medicine. Clinical trials usually involve several phases, and new medicines are tested on hundreds to thousands of people before they are approved for public use. In this model you are using only the students in your class as participants, similar to how many people a new medicine might be tested on in the first phase of clinical trials. The illustration on the next page, "Clinical Trial of a Headache Medicine," explains the model.

### GUIDING QUESTION

**How are medicines tested during a clinical trial?**

### MATERIALS

*For each group of four students*

- 1 sample cup of yellow lemon drink
- 1 sample cup of pink lemon drink

*For each student*

- 1 small tasting cup
- 1 Student Sheet 13.1, "Analysis of Clinical Trial"

**Clinical Trial of a Headache Medicine**



*The taste of the yellow lemon drink represents a headache.*



*The taste of the pink lemon drink represents the medicine taken to treat your headache.*



*If the pink lemon drink tastes the same as the yellow, there is no change in your headache.*

*If the pink lemon drink tastes better than the yellow, your headache is gone!*

*If the pink lemon drink tastes worse than the yellow, your headache is gone, but you experience side effects.*

**SAFETY**

Never taste materials or eat or drink in science class unless specifically told to do so by your teacher. Be sure that your work area is clean and free of any materials not needed for this activity. If you are allergic to lemons or other citrus fruits, juice drinks, or sugar, or if you have any other health issue that limits what you can eat, such as diabetes, tell your teacher and do not taste the drink samples in this activity.

**PROCEDURE**

1. Record your group number (found on the sample cups) in your science notebook; this represents the batch of medicine you received.
2. Fill your tasting cup halfway full of yellow lemon drink by carefully pouring from the sample cup into your tasting cup.
3. Taste the yellow lemon drink. Empty the cup.
4. Fill your tasting cup halfway full of pink lemon drink.
5. Taste the pink lemon drink.
6. Did the pink lemon drink taste the same, better, or worse than the yellow lemon drink? Record your response in a table like the one below.

**Results of Treatment**

	<i>Same as yellow lemon drink</i>	<i>Better than yellow lemon drink</i>	<i>Worse than yellow lemon drink</i>
<i>My response (Show with an X)</i>			
<i>My group's response (Show number of each)</i>			

7. Share your results with your group. Summarize your group's results in the "My group's response" row of your data table.
8. Have one person from your group report your group's results to your teacher.
9. After a class discussion of the results, record the class's results and create a bar graph of the class's data on Student Sheet 13.1, "Analysis of Clinical Trial."

10. Discuss the following with your group: Assume that the side effects of a headache medicine are mild, such as a slight stomach-ache. Do you think this medicine should or should not be sold to people suffering from a headache? Are there any trade-offs involved in your decision? If so, why did you make the decision you did?

## ANALYSIS

1. What body systems are a headache medicine likely to affect? Explain.
2. In this activity, what evidence do you have that the medicine does or does not have the desired effect of improving headaches?
3. Who was in the control group in this model of a clinical trial? Why is a control group included in clinical trials?
4. In this activity, if a person finds that the sweetened pink lemon drink (the medicine) tastes worse than the yellow lemon drink, the headache is gone, but there are side effects. If the side effects were serious, such as a risk of serious heart problems, would you recommend selling the medicine to people suffering from headaches? Explain your decision. What are the trade-offs involved in your decision?
5. In this activity, if a person finds that the medicine tastes better or worse than the yellow lemon drink, the headache is gone. Review the results of this model. Think about whether the medicine works and how often side effects occur. What would you conclude about the safety and effectiveness of this medicine for treating headaches? Support your conclusion with evidence.
6. How do the effects of the medicines described in this activity demonstrate interactions between body systems?

## EXTENSION

Ask your teacher to post your class data on the *SEPUP Third Edition Body Systems* page of the SEPUP website at [www.sepuplhs.org/middle/third-edition](http://www.sepuplhs.org/middle/third-edition). Your teacher will show you the data posted by other students. How do your results compare?