Developing a New Flu Prevention Drug

Teacher Information

science take-out
just add students™

Summary

Students conduct simulated laboratory tests and analyze data to determine if a new flu prevention drug is safe and effective.

Core Concepts

- Clinical trials are scientific experiments used to determine if a drug is both safe and effective.
- Development and scientific testing of new drugs is a time consuming and expensive process.

Time Required

3-4 forty-minute class periods

Kit Contains

- Tubes of liquid representing Human Volunteers 1-3
- Cups for Human Volunteers 1-3
- Toothpicks for stirring
- Tube of "FLUSTOP"
- Plastic dropper for "FLUSTOP"
- Graduated measuring cup
- 2 plastic bags "For Influenza Tests"
- Experimental Group Test Sheet
- Control Group Test Sheet

Teacher Provides

- Tap water
- Safety goggles
- Paper towels for clean-up

Warning: Choking Hazard

This Science Take-Out kit contains small parts. Do not allow children under the age of seven to have access to any kit components.

Teacher Resources

Videos – The following videos can be used as an introduction to the drug development and testing processes. Consider showing one of these videos before starting Part 2:

- **How a Drug Becomes a Drug** is a 4 minute video from the National Institute of Allergy and Infectious Disease that begins with describing basic research and also describes clinical trials. https://www.youtube.com/watch?v=U96He401wj4

- **Introduction to How Drugs are developed** is an animated 2 minute video that describes the phases of clinical research. It is particularly engaging for below average learners as an introduction. https://www.youtube.com/watch?v=wvDvAEmq-cM&app=desktop

- **Medical Research** provides short videos about clinical trials. The link below opens to a video on the phases of clinical trials. Scroll down to see other brief videos about clinical trials. http://research.emedtv.com/clinical-trials-video/different-phases-of-research-studies-video.html

- **Clinical Drug Trial Phases Explained** is a 4 minute video describing clinical trial phases and what happens after clinical trials. https://www.youtube.com/watch?v=1FDB8vsOE0g&app=desktop

- **The Drug Discovery Process** a 3 minute video describing the drug discovery and clinical testing process. https://www.youtube.com/watch?v=DhxD6sVQEYc&app=desktop

Additional Resources:

- **The Drug Development Process** website from the FDA provides information about the drug development process. http://www.fda.gov/forpatients/approvals/drugs/default.htm

- **The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective** provides a variety of resources about the drug development and approval process. http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm

- **FDA Drug Approval Process** infographic. http:/www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf

- **NIH Clinical Research Trials and You** provides a wealth of information about clinical research. http://www.nih.gov/health/clinicaltrials/index.htm

Reusing the Kit

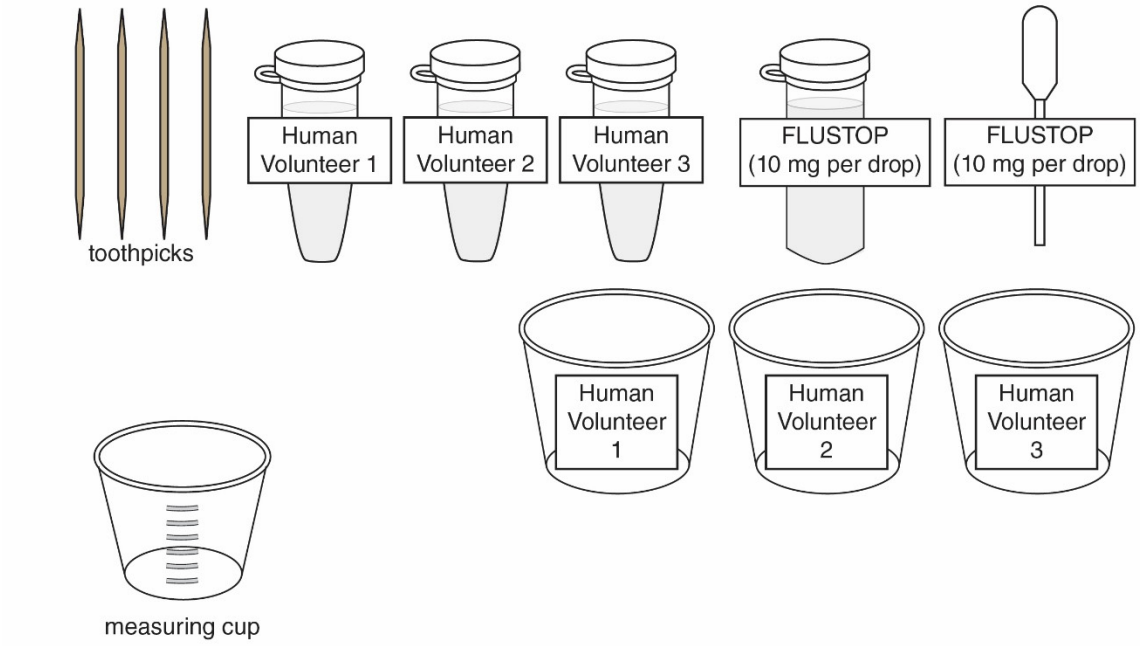
Teachers will need to instruct students on how to handle clean-up and return of the reusable kit materials. For example, teachers might provide the following information for students:

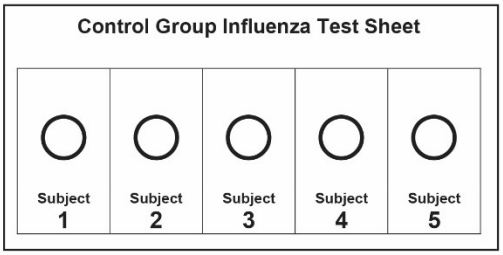
Discard	Return to kit bag
• "For Influenza Tests" plastic bags and their contents (liquid and paper) • Toothpicks • Human Volunteer 1-3 cups and liquid in these cups	• Human Volunteer 1-3 tubes • FLUSTOP tube • FLUSTOP dropper • Small measuring cup

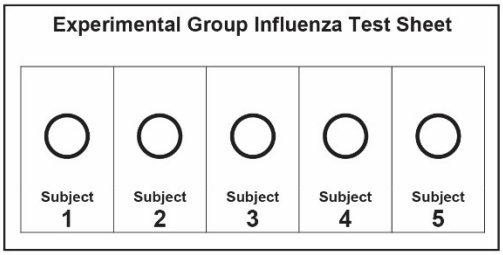
Refills for **Developing a New Flu Prevention Drug** kits are available at www.sciencetakeout.com. The **10 Kit Refill Pack** includes the following materials:

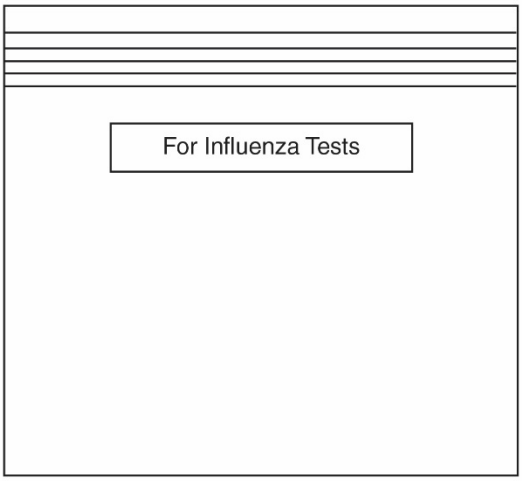
- Instructions and Quick Guide for refilling kit
- Graduated droppers for refilling tubes
- 10 mL of Human Volunteer 1 solution
- 10 mL of Human Volunteer 2 solution
- 10 mL of Human Volunteer 3 solution
- 20 mL of FLUSTOP
- 10 of each Human Volunteer 1-3 cups
- 10 Experimental Group Test Sheets
- 10 Control Group Test Sheets
- 40 toothpicks
- Small bag of "Influenza Test Powder"
- Small scoop

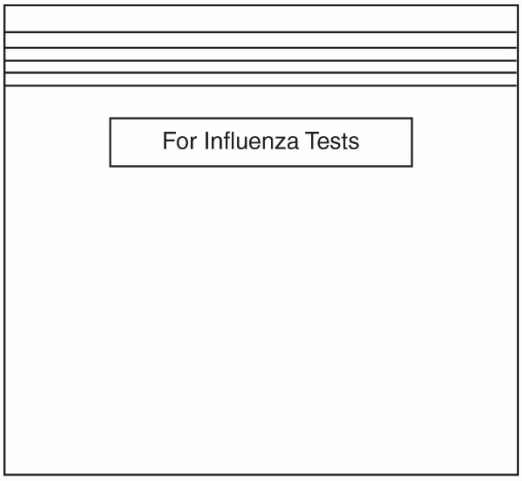
Kit Contents Quick Guide











Read these instructions before using Science Take-Out kits

Parental or Adult Supervision Required

This kit should be used only under the supervision of an adult who is committed to ensuring that the safety precautions below, and in the specific laboratory activity, are followed.

Safety Goggles and Gloves Strongly Recommended

We encourage students to adopt safe lab practices, and wear safety goggles and gloves when performing laboratory activities involving chemicals. Safety goggles and gloves are not provided in Science Take-Out kits. They may be purchased from a local hardware store or pharmacy.

Warning: Choking and Chemical Hazard

Science Take-Out kits contain small parts that could pose a choking hazard and chemicals that could be hazardous if ingested. Do not allow children under the age of seven to have access to any kit components. Safety Data Sheets (SDS) provide specific safety information regarding the chemical contents of the kits. SDS information for each kit is provided in the accompanying teacher instructions.

Chemicals Used in Science Take-Out Kits

Every effort has been made to reduce the use of hazardous chemicals in Science Take-Out kits. Most kits contain common household chemicals or chemicals that pose little or no risk.

General Safety Precautions

1. Work in a clean, uncluttered area. Cover the work area to protect the work surface.
2. Read and follow all instructions carefully.
3. Pay particular attention to following the specific safety precautions included in the kit activity instructions.
4. Goggles and gloves should be worn while performing experiments using chemicals.
5. Do not use the contents of this kit for any other purpose beyond those described in the kit instructions.
6. Do not leave experiment parts or kits where they could be used inappropriately by others.
7. Never taste or ingest any chemicals provided in the kit - they may be toxic.
8. Do not eat, drink, or apply make-up or contact lenses while performing experiments.
9. Wash your hands before and after performing experiments.
10. Chemicals used in Science Take-Out experiments may stain or damage skin, clothing or work surfaces. If spills occur, wash the area immediately and thoroughly.
11. At the end of the experiment, return ALL kit components to the kit plastic bag. Dispose of the plastic bag and contents in your regular household trash

No blood or body fluids from humans or animals are used in Science Take-Out kits. Chemical mixtures are substituted as simulations of these substances.

Developing a New Flu Prevention Drug

Teacher Answer Key

Part 1: FLUSTOP in the News

Base your answers to questions 1–5 on the news article below. *Note: FLUSTOP is a fictitious (pretend) drug, not a real drug.*

New Drug in the Fight Against the Flu

Scientists announced the discovery of FLUSTOP, an antiviral drug that prevents influenza (the flu). The antiviral drug prevents the reproduction of the influenza virus that causes the flu.

Scientists administered a FLUSTOP pill to an experimental group of 20 monkeys each day for five days. For a comparison, a control group of 20 other monkeys was given a placebo pill (a pill that did not contain FLUSTOP) for five days. Both groups of monkeys were then exposed to the influenza virus that causes the flu.

Mucus was collected from the monkeys' noses three days after the monkeys were exposed to the influenza virus. Scientists tested the mucus samples and found that 90% of the monkeys who received a placebo had influenza viruses in their nasal mucus after three days. Only 10% of the monkeys who were treated with FLUSTOP had influenza viruses in their nasal mucus after three days.

In the future, FLUSTOP may be used in people to stop the influenza virus before it causes flu symptoms. Scientists caution, however, that further testing is needed to provide evidence that FLUSTOP is both safe and effective for use by humans.

1. Describe the <u>experimental</u> group for the scientists' experiment.

2. Describe the <u>control</u> group for the scientists' experiment.

3. Explain why it is important to include a control group in a well-designed experiment?

4. A placebo is fake medication that looks like the real medication but does not contain any substance likely to have an effect.

   a) What is the placebo given to the control group of monkeys?

   b) Explain the purpose of the placebo that was given to the control group of monkeys.

5. Explain why scientists test FLUSTOP on animals before they test it on humans.

Part 2: Phase 1 Clinical Trials

Before FLUSTOP can be sold to humans, it must be scientifically tested to determine if it is safe and effective for use by humans. Human testing begins with **Phase 1 clinical trials** that are conducted to determine the dose of the FLUSTOP that is safe for humans. This testing is done with healthy volunteers who do not have flu symptoms.

Thirty healthy human volunteers signed informed consent forms indicating that they understood the risks involved in participating as research subjects. These volunteers were paid for participating in the research.

> ***Informed consent*** is a process for getting permission before enrolling a participant in a clinical trial. An informed consent form includes a description of:
>
> - What will happen to participants during a clinical trial.
> - The risks, benefits, and uncertainties related to participation in the clinical trial.

1. What is the purpose of the informed consent form that the human volunteers signed?

You will conduct tests on three of the volunteers to determine what dose of FLUSTOP is safe for humans.

2. Pour the entire contents of the Human Volunteer 1 tube into the Human Volunteer 1 cup.

3. Add 1 drop of "FLUSTOP—10 mg per drop" to the Human Volunteer 1 cup. Stir with a clean plastic toothpick for 10 seconds. Observe the color of the liquid in the cup.
   - A colorless liquid indicates that the volunteer is healthy.
   - A pink or red color indicates that an unsafe amount of FLUSTOP has been given to the volunteer.

4. Repeat step 3 and count the number of drops that need to be added to turn the color of the liquid in the cup to a pink or red color. Be sure to add 1 drop at a time and stir for 5 seconds between adding drops.

5. Use the data table on the following page to record the number of drops of FLUSTOP needed to change the color of the liquid in the Human Volunteer 1 cup from colorless (safe) to pink or red (unsafe).

Human Volunteer #	Drops of FLUSTOP needed to turn LIQUID to pink or red	Highest dose (drops) of FLUSTOP that is safe for this volunteer	Highest dose (milligrams) of FLUSTOP that is safe for this volunteer. (1 drop = 10 mg)
1			
2			
3			

6. Pour the entire contents of the Human Volunteer 2 tube into the Human Volunteer 2 cup.

7. Add 1 drop of "FLUSTOP—10 mg per drop" to the Human Volunteer 2 cup. Stir with a clean plastic toothpick for 10 seconds. Observe the color of the liquid in the cup.
   - A colorless liquid indicates that the volunteer is healthy.
   - A pink or red color indicates that an unsafe amount of FLUSTOP has been given to the volunteer.

8. Repeat step 7 and count the number of drops of FLUSTOP needed to turn the color of the liquid in the Human Volunteer 2 cup to a pink or red color. Be sure to add 1 drop at a time and stir for 5 seconds between adding drops.

9. Use the data table above to record the number of drops needed to change the color of the liquid in the Human Volunteer 2 cup from colorless (safe) to pink or red (unsafe).

10. Pour the entire contents of the Human Volunteer 3 tube into the Human Volunteer 3 cup.

11. Add 1 drop of "FLUSTOP—10 mg per drop" to the Human Volunteer 3 cup. Stir with a clean plastic toothpick for 10 seconds. Observe the color of the liquid in the cup.
    - A colorless liquid indicates that the volunteer is healthy.
    - A pink or red color indicates that an unsafe amount of FLUSTOP has been given to the volunteer.

12. Repeat step 11 and count the number of drops of FLUSTOP needed to turn the color of the liquid in the Human Volunteer 3 cup to a pink or red color. Be sure to add 1 drop at a time and stir for 5 seconds between adding drops.

13. Use the data table above to record the number of drops needed to change the color of the liquid in the Human Volunteer 3 cup from colorless (safe) to pink or red (unsafe).

14. Complete the data table by writing the highest dose (drops) of FLUSTOP that is safe for each human volunteer. *Hint: This would be 1 drop less than the number of drops of FLUSTOP needed to turn the liquid to pink or red.*

15. Complete the data table by writing the highest dose (milligrams) of FLUSTOP that is safe for each volunteer. *Hint: 1 drop contains 10 milligrams of FLUSTOP.*

16. Which human volunteer is most sensitive to the harmful effects of FLUSTOP? _____

17. Explain why it was not appropriate to use the average milligrams of FLUSTOP to determine the safe level of FLUSTOP that should be used for further human testing.

18. From the results of the Phase 1 clinical trials, what is the highest dose of FLUSTOP that could safely be used for further human testing? Remember that each drop contains 10 mg of FLUSTOP. Express your answer in milligrams (mg).

19. Explain why it was important to test the FLUSTOP on more than one volunteer.

20. **Summarize**: Explain the purpose for Phase 1 Clinical Trials.

Part 3: Phase 2 Clinical Trials

A **Phase 2 clinical trial** is a scientific experiment used to determine if a drug is safe and effective for use by humans. For the FLUSTOP Phase 2 clinical trial, 200 people who had not had the flu or a flu vaccination were recruited as research subjects.

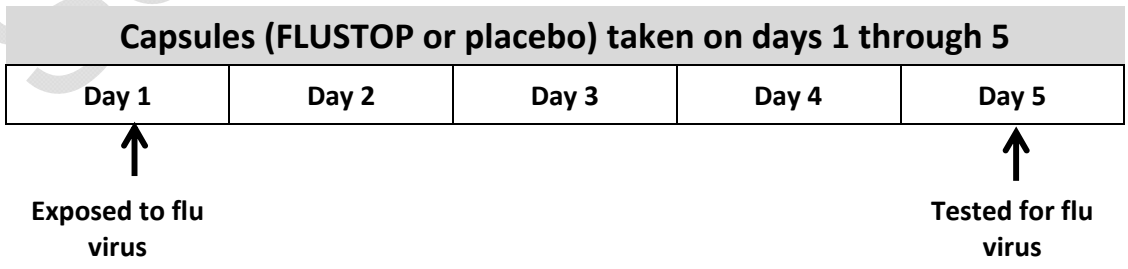
The research subjects were randomly assigned to either the experimental group (100 subjects) or the control group (100 subjects). **Random assignment** is used to create experimental and control groups that are approximately the same at the beginning of an experiment. The procedure involves flipping a coin to determine whether a subject is assigned to the experimental or control group.

1. What is the purpose for a Phase 2 clinical trial?

2. Why is it important that the researchers randomly assign research subjects to the experimental group or control group?

Members of both the experimental group and the control group were exposed to the influenza (flu) virus on day 1. Because the subjects might experience mild to serious flu symptoms or transmit the flu virus to their families or friends, the research subjects were confined to a hospital isolation setting for five days after exposure to the flu virus.

Members of the experimental group each took one 60 mg capsule of FLUSTOP on days 1 through 5. Members of the control group each took one placebo capsule on days 1 through 5. The placebo capsule looked like FLUSTOP, but only contained inactive ingredients.



3. An informed consent form was used to make sure that research subjects understand the potential risks of participating in the Phase 2 clinical trial. List at least two things that should be included on the informed consent form for the Phase 2 clinical trial. *Hint: Read the information in the box at the top of page 3.*

4. How were the experimental group and the control group different?

5. How were the experimental group and the control group the same?

On day 5, the researchers tested all of the research subjects to see if they had influenza viruses that had reproduced. The researchers used cotton swabs to collect mucus from the noses of all research subjects. Each cotton swab was then tested for influenza virus.

You will conduct tests to determine if the mucus samples collected from some of the research subjects contain influenza viruses. You will test the mucus samples from 5 research subjects in the experimental group and 5 research subjects in the control group.

6. Use the small measuring cup to add 20 mL of tap water to each of the bags labeled "For Influenza Tests." These bags contain a small amount of test powder.

7. Close the bags completely and gently swirl the contents of the bag for 1 minute

8. Open one of the bags and place the **Experimental Group Influenza Test Sheet** into it. Completely seal the bag so it does not leak. Lay the bag flat on your lab table or desk.

9. Open the other bag and place the **Control Group Influenza Test Sheet** into it. Completely seal the bag so it does not leak. Lay the bag flat on your lab table or desk.

10. Observe the circles on both the experimental group and control group test sheets.
    - Pink circles represent people who have the influenza virus in their nasal mucus.
    - White circles represent people who do not have the influenza virus in their nasal mucus.

11. Complete the data table below for the experimental group and the control group.
    - Record the number of white circles and pink circles on the test sheets.
    - Calculate the percentage of people who have influenza viruses in their nasal mucus.

Group	**White Circles (do not have influenza virus)**	**Pink Circles (have influenza virus)**	**Total Circles**	**Percentage of people who have influenza virus in their nasal mucus**
Experimental (FLUSTOP)			5	
Control (placebo)			5	

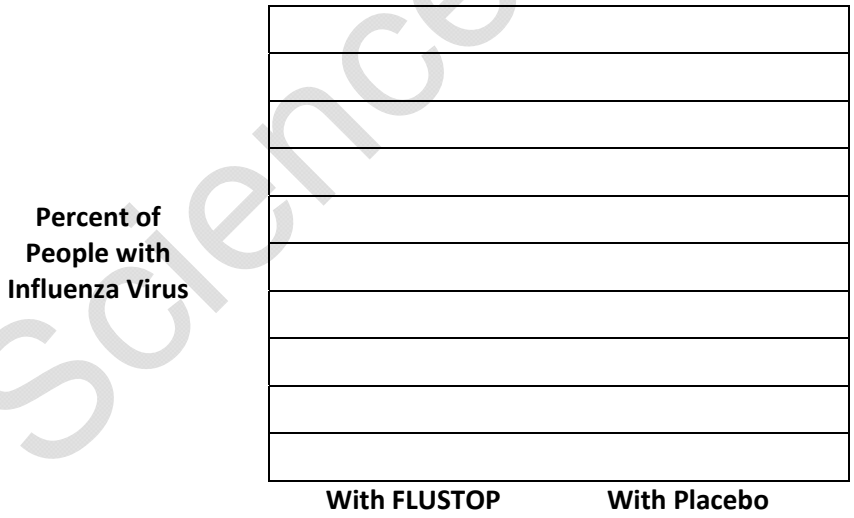
Additional tests were conducted to test for the influenza virus in the remainder of the research subjects. The total results of the tests that you conducted and the additional tests are shown in the table below.

12. Complete the data table below by calculating and recording the percentage of people who have influenza viruses in their nasal mucus. *Note: There are not 100 total subjects in each group because some of the original research subjects dropped out of the research study.*

Group	Total Subjects Tested	Subjects with influenza virus in nasal mucus	Percentage of people who have influenza virus in their nasal mucus
Experimental (FLUSTOP)	90	18	
Control (placebo)	96	80	

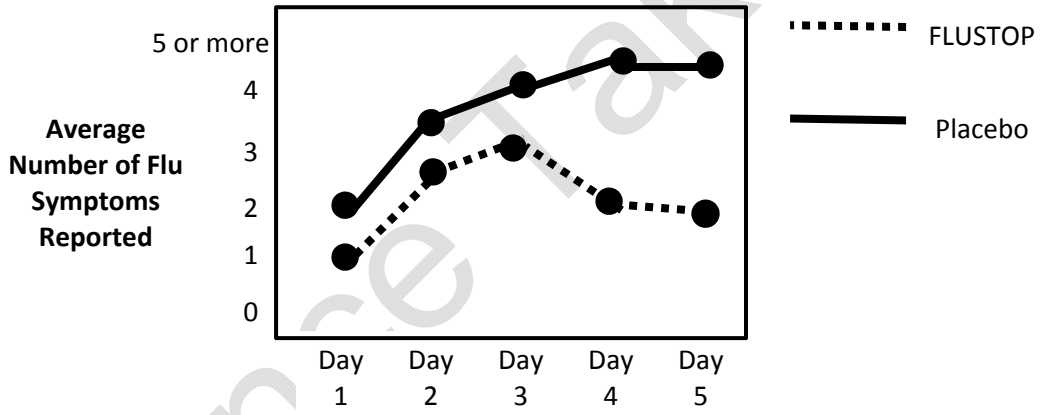
13. Use the graph grid below to make a bar graph to summarize the results of the Phase 2 Clinical Trials in the data table above. Be sure to write a scale on the vertical axis.

The Effect of FLUSTOP on the Percentage of People with Influenza Virus



14. Based on the information in your data table and bar graph, is FLUSTOP effective at preventing influenza virus infection? Explain your answer, and support your answer with information from your data table and graph.

Research subjects in the experimental group and the control group were asked to complete a survey about the flu **symptoms** that they experienced during each of the five days. The graph below summarizes the results of analyzing the surveys from the experimental group and control group.



15. Based on the information in the graph above, is FLUSTOP effective at reducing flu symptoms? Explain your answer, and support your answer with information from the graph.

The researchers also collected information on **side effects** that the research subjects experienced during the experiment. The table below provides information on the percent of research subjects that reported side effects.

Percent of research subjects that reported side effects	With FLUSTOP	With Placebo
Nausea (without vomiting)	6%	2%
Vomiting	3%	1%
Diarrhea	10%	7%
Bronchitis	2%	2%
Abdominal pain	2%	2%
Dizziness	3%	2%
Headache	2%	2%
Insomnia (difficulty sleeping)	1%	1%
Fatigue	1%	1%

16. Based on the information in the table above, what side effects are likely caused by FLUSTOP? Explain how you arrived at your answer.

17. Do you think these side effects are severe and frequent enough to stop further testing of FLUSTOP with larger numbers of people? Explain why or why not.

Part 4: Phase 3 Clinical Trials

Phase 3 clinical trials involve a large number of research subjects so that scientists can see how FLUSTOP works in a wide variety of people. The Phase 3 clinical trial involved 3,000 research subjects. Data was collected by 50 doctors from different locations across the United States.

Each doctor recruited 60 research subjects who:

- Had not been vaccinated with the influenza vaccine.
- Had recently been exposed to a family member who had the flu.

Children under the age of 12 and women who were pregnant or breast feeding were excluded (not accepted) as research subjects.

One half of the research subjects were randomly selected to be given a 5 day treatment of one FLUSTOP capsule per day. The other half of the research subjects were randomly selected to be given one placebo capsule per day for 5 days. Data was collected on day 6. The data table below summarizes the results of the Phase 3 clinical trial.

Data collected on day 6	With FLUSTOP	With Placebo
Influenza virus in nasal mucus	21%	85%
0 symptoms of flu	75%	10%
1-2 symptoms of flu	20%	30%
3 or more symptoms of flu	5%	60%
Nausea/vomiting	7%	3%
Dizziness	4%	2%
Diarrhea	10%	6%
Worsening of heart disease	4%	1%
Worsening of liver disease	7%	1%
Worsening of diabetes	6%	2%

1. Why is it important to include a large number of research subjects in a Phase 3 clinical trial?

In an experiment, the **independent variable** is the variable that is varied or manipulated by the researcher, and the **dependent variable** is the response that is measured. An independent variable is the presumed cause, whereas the dependent variable is the presumed effect.

A **controlled variable** is a variable that is held constant or kept the same in both the experimental and control group to prevent its effect on the outcome of the experiment.

Base your answers to questions 2 through 4 on the information in the box above.

2. What is the independent variable in this Phase 3 clinical trial?

3. List <u>two</u> dependent variables that were measured or observed in this Phase 3 clinical trial.

4. List at least <u>two</u> constants or controlled variables that should be kept the same in both the experimental group and the control group in this clinical trial.

5. Based on the side effects observed during the Phase 3 clinical trials, list at least <u>two</u> warnings that should be included in the prescription information provided for doctors or their patients.

Section 1 Chemical Product and Company Information

Science Take-Out
80 Office Park Way
Pittsford, NY 14534
(585)764-5400

CHEMTREC 24 Hour Emergency
Phone Number (800) 424-9300
For laboratory use only. Not for drug, food or household use

.

Product	Vinegar (1-3%), phenolphthalein (0.04%)
Synonyms	"Human Volunteer" solutions (simulated)

Section 2 Hazards Identification

This substance or mixture has not been classified at this time according to the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals.

Signal word: Not classified
Pictograms: None required
Target organs: None known

GHS Classification: Not classified

GHS Label information: **Hazard statement(s):** Not classified.

Precautionary statement(s):

P264: Wash hands thoroughly after handling.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P332+P313: If skin irritation occurs: Get medical attention.

P337+P313: If eye irritation persists: Get medical attention.

Ca Prop 65 - This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Section 3 Composition / Information on Ingredients

Chemical Name	CAS #	%	EINECS
Water	7732-18-5	99.84 - 99.92%	231-791-2
Acetic Acid	64-19-7	0.04 - 0.12%	200-580-7
Phenolphthalein	77-09-8	0.04%	201-004-7

Section 4 First Aid Measures

INGESTION: Call physician or Poison Control Center immediately. Induce vomiting only if advised by appropriate medical personnel. Never give anything by mouth to an unconscious person.

INHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

EYE CONTACT: Check for and remove contact lenses. Flush thoroughly with water for at least 15 minutes, lifting upper and lower eyelids occasionally. Get immediate medical attention.

SKIN ABSORPTION: Remove contaminated clothing. Flush thoroughly with mild soap and water. If irritation occurs, get medical attention.

Section 5 Fire Fighting Measures

Suitable Extinguishing Media: Use any media suitable for extinguishing supporting fire.

Protective Actions for Fire-fighters: In fire conditions, wear a NIOSH/MSHA-approved self-contained breathing apparatus and full protective gear. Use water spray to keep fire-exposed containers cool.

Specific Hazards: Data not available.

Section 6 Accidental Release Measures

Personal Precautions: Evacuate personnel to safe area. Use proper personal protective equipment as indicated in Section 8. Provide adequate ventilation.

Environmental Precautions: Avoid runoff into storm sewers and ditches which lead to waterways.

Containment and Cleanup: Absorb with inert dry material, sweep or vacuum up and place in a suitable container for proper disposal. Wash spill area with soap and water.

Section 7 Handling and Storage

Precautions for Safe Handling: Read label on container before using. Do not wear contact lenses when working with chemicals. Keep out of reach of children. Avoid contact with eyes, skin and clothing. Do not inhale vapors, spray or mist. Use with adequate ventilation. Avoid ingestion. Wash thoroughly after handling. Remove and wash clothing before reuse.

Conditions for Safe Storage: Store in a cool, well-ventilated area away from incompatible substances.

Section 8 Exposure controls / Personal Protection

Exposure Limits:

Chemical Name	ACGIH (TLV)	OSHA (PEL)	NIOSH (REL)
Acetic Acid	None established	None established	None established

Engineering controls: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower and fire extinguishing material. Personnel should wear safety glasses, goggles, or faceshield, lab coat or apron, appropriate protective gloves. Use adequate ventilation to keep airborne concentrations low.

Respiratory protection: None should be needed in normal laboratory handling at room temperatures. If misty conditions prevail, work in fume hood or wear a NIOSH/MSHA approved respirator.

Section 9 Physical and Chemical Properties

Appearance: Clear, colorless liquid.
Odor: None
Odor threshold: Data not available.
pH: Data not available.
Melting/Freezing point: Data not available
Boiling point: Data not available.
Flash point: Data not available

Evaporation rate (Water = 1): Data not available.
Flammability (solid/gas): Data not available.
Explosion limits: Lower/Upper: Data not available
Vapor pressure (mm Hg): Data not available.
Vapor density (Air = 1): 2.07
Relative density (Specific gravity): Data not available.
Solubility(ies): Complete in water.

Partition coefficient: Data not available
Auto-ignition temp.: Data not available
Decomposition temp.: Data not available
Viscosity: Data not available.
Molecular formula: Mixture
Molecular weight: Mixture

Section 10 Stability and Reactivity

Chemical stability: Stable

Hazardous polymerization: Data not available.

Conditions to avoid: Data not available
Incompatibilities with other materials: Data not available.
Hazardous decomposition products: Data not available.

Section 11 Toxicological Information

Acute toxicity: Data not available
Serious eye damage/irritation: Data not available
Germ cell mutagenicity: Data not available
Skin corrosion/irritation: Data not available
Respiratory or skin sensitization: Data not available
Carcinogenity: Data not available

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity: Data not available
Aspiration hazard: Data not available
STOT-single exposure: Data not available
STOT-repeated exposure: Data not available

Potential health effects:
Inhalation: May be harmful if inhaled.
Ingestion: May be harmful if swallowed.
Skin: May cause mild irritation.
Eyes: May cause mild irritation.

Signs and symptoms of exposure: To the best of our knowledge the chemical, physical and toxicological properties have not been thoroughly investigated. Specific data is not available. Exercise appropriate procedures to minimize potential hazards.
Additional information: RTECS #: Data not available

Section 12 Ecological Information

Toxicity to fish: No data available
Toxicity to daphnia and other aquatic invertebrates: No data available
Toxicity to algae: No data available
Persistence and degradability: No data available
Mobility in soil: No data available
Bioaccumulative potential: No data available
PBT and vPvB assessment: No data available
Other adverse effects: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Section 13 Disposal Considerations

These disposal guidelines are intended for the disposal of catalog-size quantities only. Federal regulations may apply to empty container. State and/or local regulations may be different. Dispose of in accordance with all local, state and federal regulations or contract with a licensed chemical disposal agency.

Section 14 Transport Information

UN/NA number: Not applicable
Hazard class: Not applicable
Exceptions: Not applicable
Shipping name: Not Regulated
Packing group: Not applicable
2012 ERG Guide # Not applicable
Reportable Quantity: No
Marine pollutant: No

Section 15 Regulatory Information

A chemical is considered to be listed if the CAS number for the anhydrous form is on the Inventory list.

Component	TSCA	CERLCA (RQ)	RCRA code	DSL	NDSL	WHMIS Classification
Acetic Acid	Listed	5,000 lbs (2270 kg)	Not listed	Listed	Not Listed	Uncontrolled Product

Section 16 Additional Information

The information contained herein is furnished without warranty of any kind. Employers should use this information only as a supplement to other information gathered by them and must make independent determinations of suitability and completeness of information from all sources to assure proper use of these materials and the safety and health of employees.
NTP: National Toxicology Program, IARC: International Agency for Research on Cancer, OSHA: Occupational Safety and Health Administration, STOT: Specific Target Organ Toxicity, SE: Single Exposure, RE: Repeated Exposure, ERG: Emergency Response Guidebook.

Revision Date: July 17, 2018 Supercedes:

SAFETY DATA SHEET

GENERAL STORAGE CODE GREEN

Section 1 Chemical Product and Company Information

Science Take-Out
80 Office Park Way
Pittsford, NY 14534
(585)764-5400

CHEMTREC 24 Hour Emergency
Phone Number (800) 424-9300
For laboratory use only. Not for drug, food or household use

Product	1% Sodium Carbonate
Synonyms	"FLUSTOP - 10 mg per drop" (simulated)

Section 2 Hazards Identification

Signal word: WARNING
Pictograms: GHS07
Target organs: None known.

GHS Classification:
Eye irrit. (Category 2A)

GHS Label information: **Hazard statement(s):**
H319: Causes serious eye irritation.

P**recautionary statement(s):**

P264: Wash hands thoroughly after handling.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313: If eye irritation persists: Get medical advice/attention.

Ca Prop 65 - This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Section 3 Composition / Information on Ingredients

Chemical Name	CAS #	%	EINECS
Water	7732-18-5	99%	231-791-2
Sodium carbonate	497-19-8	1%	207-838-8

Section 4 First Aid Measures

INGESTION: Call physician or Poison Control Center immediately. Induce vomiting only if advised by appropriate medical personnel. Never give anything by mouth to an unconscious person.

INHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

EYE CONTACT: Check for and remove contact lenses. Flush thoroughly with water for at least 15 minutes, lifting upper and lower eyelids occasionally. Get immediate medical attention.

SKIN ABSORPTION: Remove contaminated clothing. Flush thoroughly with mild soap and water. If irritation occurs, get medical attention.

Section 5 Fire Fighting Measures

Suitable Extinguishing Media: Use any media suitable for extinguishing supporting fire.

Protective Actions for Fire-fighters: In fire conditions, wear a NIOSH/MSHA-approved self-contained breathing apparatus and full protective gear. Use water spray to keep fire-exposed containers cool.

Specific Hazards: Data not available.

Section 6 Accidental Release Measures

Personal Precautions: Evacuate personnel to safe area. Use proper personal protective equipment as indicated in Section 8. Provide adequate ventilation.

Environmental Precautions: Avoid runoff into storm sewers and ditches which lead to waterways.

Containment and Cleanup: Sweep or vacuum up and place in a suitable container for proper disposal. Wash spill area with soap and water.

Section 7 Handling and Storage

Precautions for Safe Handling: Read label on container before using. Do not wear contact lenses when working with chemicals. Keep out of reach of children. Avoid contact with eyes, skin and clothing. Do not inhale dusts. Use with adequate ventilation. Avoid ingestion. Wash thoroughly after handling. Remove and wash clothing before reuse.

Conditions for Safe Storage: Store in a cool, well-ventilated area away from incompatible substances.

Section 8 Exposure controls / Personal Protection

Exposure Limits:

Chemical Name	ACGIH (TLV)	OSHA (PEL)	NIOSH (REL)
Sodium carbonate	None established.	None established.	None established.

Engineering controls: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower and fire extinguishing material. Personnel should wear safety glasses, goggles, or faceshield, lab coat or apron, appropriate protective gloves. Use adequate ventilation to keep airborne concentrations low.

Respiratory protection: None should be needed in normal laboratory handling at room temperatures. If misty conditions prevail, work in fume hood or wear a NIOSH/MSHA approved respirator.

Section 9 Physical and Chemical Properties

Appearance: clear, colorless liquid.
Odor: No odor.
Odor threshold: Data not available.
pH: Data not available.
Melting/Freezing point: Data not available.
Boiling point: Data not available.
Flash point: Not flammable.

Evaporation rate (Water = 1): Data not available
Flammability (solid/gas): Data not available.
Explosion limits: Lower/Upper: Not flammable.
Vapor pressure (mm Hg): Data not available
Vapor density (Air = 1): 0.7 (water)
Relative density (Specific gravity): Data not available.
Solubility(ies): Data not available.

Partition coefficient: Data not available.
Auto-ignition temp.: Data not available.
Decomposition temp.: Data not available
Viscosity: Data not available.
Molecular formula: Na_2CO_3
Molecular weight: 105.99

Section 10 Stability and Reactivity

Chemical stability: Stable

Hazardous polymerization: Will not occur.

Conditions to avoid: Excessive temperatures.

Incompatibilities with other materials: Data not available.

Hazardous decomposition products: Carbon dioxide.

Section 11 Toxicological Information

Acute toxicity: Oral-rat LD50: 4090 mg/kg ; Inhalation-rat LC50: 2.3 mg/l/2 hours ; Dermal-rat LD50: 2210 mg/kg

Skin corrosion/irritation: Data not available
Serious eye damage/irritation: Data not available
Respiratory or skin sensitization: Data not available.
Germ cell mutagenicity: Data not available

Carcinogenity: Data not available

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity: Data not available
Aspiration hazard: Data not available

STOT-single exposure: Data not available
STOT-repeated exposure: Data not available

Potential health effects:

Inhalation: May be harmful if inhaled. Causes respiratory tract irritation.
Ingestion: May cause irritation of the digestive tract. May be harmful if swallowed.
Skin: May be harmful if absorbed through skin. Causes skin irritation.
Eyes: Causes eye irritation.

Signs and symptoms of exposure: Burning sensation, cough, wheezing, laryngitis, shortness of breath, headache, nausea, vomiting.
Additional information: RTECS #: VZ4050000

Section 12 Ecological Information

Toxicity to fish: LC50 - Lepomis macrochirus (Bluegill) - 300 mg/l - 96 h.

Toxicity to daphnia and other aquatic invertebrates: EC50 - Daphnia magna (Water fl ea) - 265 mg/l - 48 h
Toxicity to algae: No data available
Persistence and degradability: No data available
Bioaccumulative potential: No data available
Mobility in soil: No data available
PBT and vPvB assessment: No data available
Other adverse effects: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Section 13 Disposal Considerations

These disposal guidelines are intended for the disposal of catalog-size quantities only. Federal regulations may apply to empty container. State and/or local regulations may be different. Dispose of in accordance with all local, state and federal regulations or contract with a licensed chemical disposal agency.

Section 14 Transport Information

UN/NA number: None assigned
Shipping name: Not Regulated
Hazard class: Not applicable
Packing group: Not applicable
Reportable Quantity: No
Marine pollutant: No
Exceptions: No
2012 ERG Guide # Not applicable

Section 15 Regulatory Information

A chemical is considered to be listed if the CAS number for the anhydrous form is on the Inventory list.

Component	TSCA	CERLCA (RQ)	RCRA code	DSL	NDSL	WHMIS Classification
Sodium carbonate	Listed	Not Listed	Not Listed	Not Listed	Not Listed	E;D2B

Section 16 Additional Information

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