**Summary:**
 The curricula developed for use with the StepStone software provides a motivating and engaging learning environment. Specific details for using the software are provided in an accompanying “StepStone How-To” document.

This module uses the concept of clinical trials to teach the scientific method. Students will have the opportunity to guide their own learning through a variety of “learning objects” intended to provide critical thinking about and application of required science standards.

**Keywords:** blind trial, clinical trial, conclusion, controlled variable, data, dependent variable, experiment, hypothesis, independent variable, placebo, randomization, reliability, scientific method, scientific question, validity, variable

**Subject TEKS:**

* Scientific Processes All Sciences
	+ (2) Scientific investigation and reasoning. The student uses scientific practices during laboratory and field investigations.
* (B) design and implement experimental investigations by making observations, asking well defined questions, formulating testable hypotheses, and using appropriate equipment and technology;
* (C) collect and record data using the International System of Units (SI) and qualitative means such as labeled drawings, writing, and graphic organizers;
* (D) construct tables and graphs, using repeated trials and means, to organize data and identify patterns; and
* (E) analyze data to formulate reasonable explanations, communicate valid conclusions supported by the data, and predict trends.
	+ (3) Scientific investigation and reasoning. The student uses critical thinking, scientific reasoning, and problem solving to make informed decisions and knows the contributions of relevant scientists.
		- analyze, evaluate, and critique scientific explanations by using empirical evidence, logical reasoning, and experimental and observational testing, so as to encourage critical thinking by the student;
		- (D) relate the impact of research on scientific thought and society, including the history of science and contributions of scientists as related to the content.

**NGSS Science and Engineering Practices:**

* Ask questions that can be investigated within the scope of the classroom, outdoor environment, and museums and other public facilities with available resources and, when appropriate, frame a hypothesis based on observations and scientific principles.
* Plan an investigation individually and collaboratively, and in the design: identify independent and dependent variables and controls, what tools are needed to do the gathering, how measurements will be recorded, and how many data are needed to support a claim.
* Conduct an investigation and evaluate the experimental design to produce data to serve as the basis for evidence that can meet the goals of the investigation.
* Collect data to produce data to serve as the basis for evidence to answer scientific questions or test design solutions under a range of conditions.

**Grade Level:** 6th - 9th

**Learning Objectives:**

1. Describe the steps in the scientific method.
2. Ask a scientific question that defines a problem.
3. Develop a hypothesis that shows cause and effect, correlation, or comparison.
4. Identify independent, dependent, and controlled variables.
5. Design an experiment that correctly uses variables.
6. Describe a clinical trial.
7. Explain the phases of clinical trials.
8. Compare clinical trials to the scientific method.
9. Contrast reliability and validity.
10. Explain how the research concepts randomization, blind trials, and placebos help prevent bias.
11. Describe how the clinical trials process contribute to the overall cost of pharmaceutical drugs.

**Time Required:** will vary depending on lesson implementation and learning objectives chosen

**Materials:**

* Devices with internet access

**Background and Concepts for Teachers:**

The Scientific Method

The scientific method is a logical problem-solving approach used by scientists. The goal of this method is to discover cause and effect relationships by asking questions, carefully gathering and examining the evidence, and seeing if all the available information can be combined into a logical answer. Scientists generally include the following components in the scientific method:

* Define a question
* Gather information and resources (observe)
* Form a hypothesis
* Test the hypothesis by performing an experiment and collecting data in a reproducible manner
* Analyze the data
* Interpret the data and draw conclusions
* Publish results
* Retest (frequently done by other scientists)

While often described as a linear series of steps, the scientific method is an iterative process that may involve backing up and repeating steps based on new information.

A scientific question may be based on a specific observation, as in "Why is the sky blue?" or an open-ended inquiry, as in "How can I design a drug to cure this particular disease?" Good questions should involve finding and evaluating evidence from previous experiments, personal scientific observations or assertions, as well as the work of other scientists.

A hypothesis is a prediction based on prior knowledge that may explain a phenomenon. It should be a clear and simple statement that can be tested. A hypothesis can be written in three ways.

* Cause and effect or if…then statements: “**If** women with knee osteoarthritis take glucosamine and chondroitin supplements during a weight loss and fitness program **then** their symptoms of pain will lessen.”
* Correlation: “**Taking glucosamine and chondroitin supplements** during a weight loss and fitness program **will lessen symptoms of pain** in women with knee osteoarthritis.”
* Comparison: “**Women** with knee osteoarthritis **who take glucosamine and chondroitin supplements** during a weight loss and fitness program will have less symptoms of pain **than women who don’t**.”

Scientists test hypotheses by conducting experiments. The purpose of an experiment is to determine whether observations of the real world agree with or conflict with the predictions made in a hypothesis. A **controlled experiment** is a scientific test done under controlled conditions, meaning that just one (or a few) factors are changed at a time, while all others are kept constant. Variables are the factors that change in an experiment and include the independent variable (the component of the experiment changed by the scientist), the dependent variable(s) (which might change in response to the independent variable) and the controlled variables (all other factors which are kept constant and used for comparison).

 Results are obtained from data analysis and describe what the experiment produced. Results will also help determine the next actions scientists should take. If the experimental evidence rejects the hypothesis, a new hypothesis is required. Once a hypothesis is strongly supported by evidence, a new question can be asked to provide further insight on the same topic.

 A conclusion is a summary of the experiment. The conclusion should state the hypothesis and whether the results of the experiment supported the hypothesis. The conclusion may also discuss further experiments or tests that could be done to support findings from the current experiment.

Clinical Trials

 Clinical trials are research studies performed in people or animals that are aimed at evaluating a medical, surgical, or behavioral intervention. They are the primary way that researchers find out if a new treatment, like a new drug, diet or medical device is safe and effective.

 Clinical trials advance through four phases to test a treatment, find the appropriate dosage, and look for side effects. If, after the first three phases, researchers find a drug or other intervention to be safe and effective, the FDA approves it for clinical use and continues to monitor its effects.

* A **Phase I trial** tests an experimental treatment on a small group of often healthy participants (ex. 20 to 80) to judge its safety and side effects and to find the correct drug dosage.
* A **Phase II trial** uses more participants (ex.100 to 300). While the emphasis in Phase I is on safety, the emphasis in Phase II is on effectiveness. This phase aims to obtain preliminary data on whether the drug works in people who have a certain disease or condition. These trials also continue to study safety, including short-term side effects. This phase can last several years.
* A **Phase III trial** gathers more information about safety and effectiveness, studying different populations and different dosages, using the drug in combination with other drugs. The number of subjects usually ranges from several hundred to about 3,000 people. If the FDA agrees that the trial results are positive, it will approve the experimental drug or device.
* A **Phase IV trial** for drugs or devices takes place after the FDA approves their use. A device or drug's effectiveness and safety are monitored in large, diverse populations. Sometimes, the side effects of a drug may not become clear until more participants have taken it over a longer period of time.

Research Concepts

 Scientists implement several techniques to ensure experimental data is accurate and unbiased. Experimenter bias is the phenomenon by which the outcome of an experiment leans towards a result expected by the experimenter. To prevent such bias, researchers try to ensure that experiments are valid, (they measure what they purport to measure) and reliable (they provide consistent results when administered on different occasions). Further, scientists may employ techniques such as randomization (randomly assigning participants to trial groups), blind trials (researchers and/or participant are ignorant of whether they are receiving treatment), and placebos (a product that looks like the new drug, but it does not contain the active ingredient) in order to obtain accurate data.

**Vocabulary / Definitions:**

* **Blind trial** - a trial in which the patients do not know if they are receiving the treatment or a placebo
* **Clinical trial -** research studies performed in people (or animals if it is a veterinary study) that are aimed at evaluating a medical, surgical, or behavioral intervention
* **Conclusion** - a statement based solely on measurements and observations made during the experiment
* **Controlled variable -** factors that the scientist keep constant in an experiment
* **Data -** the measurements such as time, temperature, mass, etc. and/or observations obtained from an experiment
* **Dependent variable** - the factor that the scientist measures or observes to see how it responds to changes in the independent variable
* **Experiment** - a detailed procedure designed to test a hypothesis
* **Hypothesis -** a possible explanation about why something happens based on knowledge, observations, and background research
* **Independent variable -** the variable tested or changed by the scientist
* **Placebo -** a product that looks like the drug of interest, but it does not contain the active ingredient
* **Randomization -** amethod based on chance by which study participants are assigned to a treatment group
* **Reliability -** how consistently a method measures something
* **Scientific method -** a logical problem-solving approach used by scientists
* **Scientific question -** a question that may lead to a hypothesis and help us in answering (or figuring out) the reason for some observation
* **Validity -** how accurately a method measures what it is intended to measure
* **Variable -** the components of an experiment that change

**Lesson Introduction / Motivation:**
 Students begin by taking the “pre-test” in order to assess their current knowledge and understanding. This may also enable students to recognize concepts about which they would like to learn more or to which they need to pay particular attention.

 The student-centered design of this module allows for multiple introduction / motivation activities. Students may begin the unit on their own by reading the “Meet a Scientist” biography or “Backpack Adventure” stories or by watching one or more “Scientist Videos”. Each of these learning objects provide students with insights into the history or application of clinical trials and should motivate students to dig deeper into the required standards presented / studied later. These learning objects also contain processing questions that can be answered and shared in class or in an on-line portfolio such as Google Docs.

 Alternately, teachers could introduce the module by facilitating a group discussion (virtually in a chat room or in person) about the impact of COVID-19 on schools, businesses, communities, and families. Questions to help guide the discussion might include:

* Why did schools and business have to close during the COVID-19 pandemic?
* Why weren’t you allowed to congregate with friends or family outside of your immediate family?
* What had to happen in order for schools and businesses to reopen?
* Why didn’t doctors or scientists just try using various medications on people to prevent or cure Coronavirus?
* Why did it take so long to develop a vaccine for Coronavirus?

 Give students ample time to discuss and record their answers and then share their ideas with the entire class. Use these ideas to introduce the concept of clinical trials and how they utilize the steps of the scientific method. This activity incorporates the student-centered classroom philosophy, as students will be developing ideas and theories on their own as the teacher facilitates the activity.

**Exploration/Explanation:**
 Students should next examine the required concepts (standards) of clinical trials Setting up classroom stations can promote student collaboration, problem solving, and critical thinking. Stations also provide students with a common base of experiences. These stations may include any or all of the following learning objects:

* *Essential Knowledge* – students use various types of note outlines to record information about required content from an interactive video presentation. Students can then compare and discuss their notes to ensure the acquisition of key concepts.
* *Backpack Adventures* – students read (independently or as a read aloud) a fictional story with factual content about key concepts and individuals related to the scientific method. Students can then answer questions, create timelines, compare fact vs. fiction, or perform other related activities to reinforce required concepts.
* *Meet a Scientist* – students read (independently or as a read aloud) a short biography about a scientist instrumental to the development of the scientific method. They will then answer questions relating to the scientist and his/her work. Students could also role-play and describe how they would have solved the problem/answered the question facing the scientist. Additionally, students could ask additional questions they have about the scientific method after reading about the scientist’s work.
* *Scientist Videos* – students learn how real scientists use the scientific method in various short videos describing research, careers, or other aspects of their field of study. Students will then answer questions and/or discuss how the concepts they learn in class are applied in the real world.
* *Real Science Review* – students read an actual research article related to clinical trials (edited to middle school readability) and then review it using the scientific method as scaffolding. For instance, students will identify the hypothesis, data collection methods, relevance, etc.
* *Practice* – students can choose various on-line activities to gain or reinforce knowledge about the scientific method. Activities include videos, matching/labeling games, flashcards, mnemonics, quizzes, etc.

Another option for utilizing this module is to have students choose either “Backpack Adventures”, “Meet a Scientist”, “Scientist Videos”, or “Real Science Review” and complete (read/watch and answer questions) accompanying activities at home. They would journal on paper or through an on-line portfolio such as Google Docs about three main ideas, provide three vocabulary words and definitions, and/or construct three questions. As a class or in small groups students would share information and use it to complete note outlines, practice activities, or other class activities (see “Elaborate” section).

**Elaborate:**

* Clinical Trials Case Study – students will use case study templates found in the “Make a Note of That” learning object to analyze a theoretical clinical trial.
* Medopoly –students will go through the stages of Clinical Trials in a board game format. Everything needed for the game, except place markers for the board, are included via printable PowerPoint templates.
* Clinical Trial Recruitment Ad – students will design a recruitment ad for a clinical trial based upon an existing pharmaceutical advertisement. An accompanying teacher instruction page provides activity details.

**Assessment/Evaluation:**

The Clinical Trials module includes a post-test, which can be used for an overall learning assessment. Other opportunities for assessment include student output at any of the learning object stations, journaling requirements as detailed in the “Explore/Explain” section above and/or any of the “Elaborate” activities.

Please email us your comments on this lesson: cvmpeer@cvm.tamu.edu
In your email, please include the title of the lesson and the grade level to which the lesson was applied.