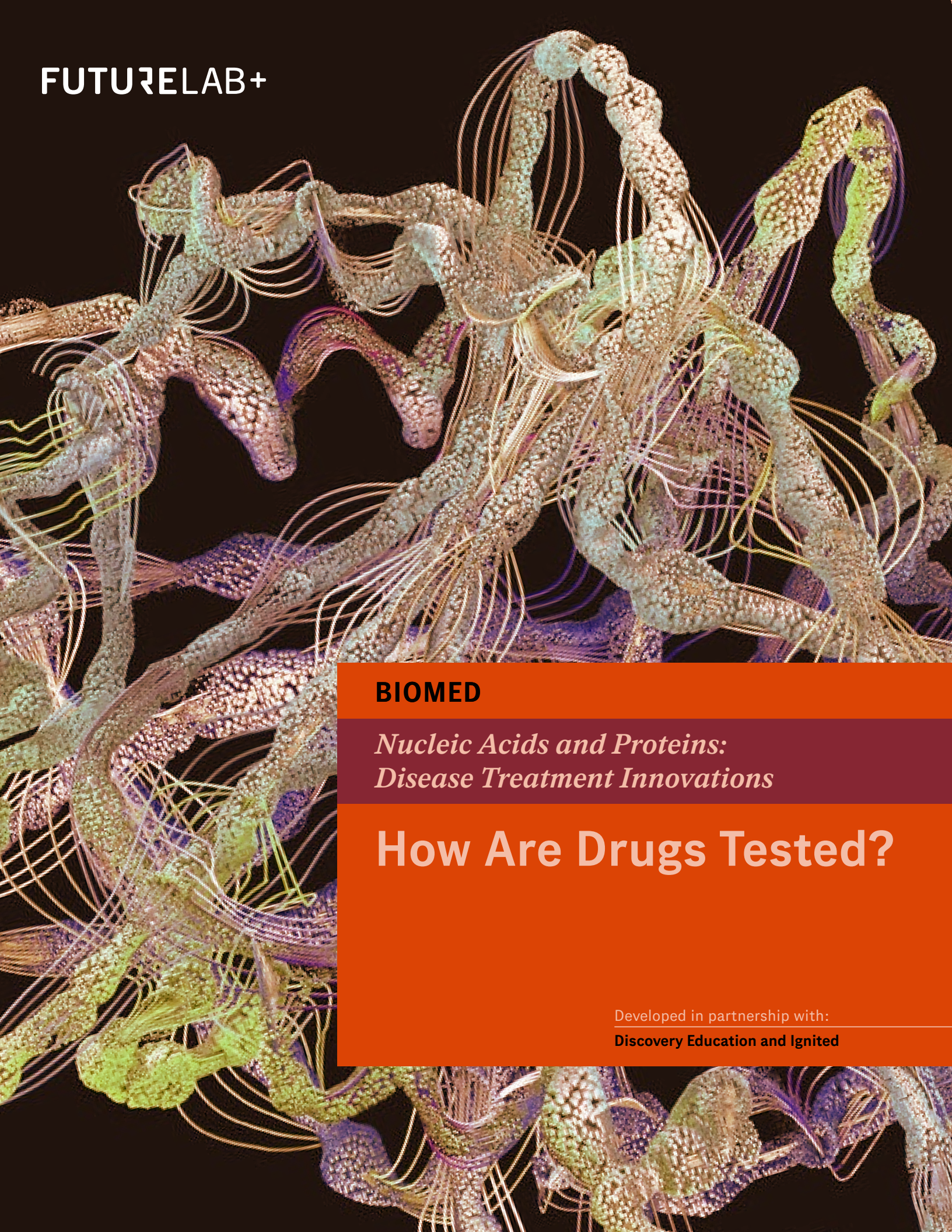
FUTURELAB+



BIOMED

Nucleic Acids and Proteins: Disease Treatment Innovations

How Are Drugs Tested?

Developed in partnership with:

Discovery Education and Ignited

In this Lesson Plan:

Print the **Teacher Section** →

Print the **Student Section** →

This document is separated into two sections, For Teachers [T] *and* Student Resources [S]*, which can be printed independently.*

Select the appropriate printer icon above to print either section in its entirety.

Follow the tips below in the Range field of your Print panel to print single pages or page ranges:

Single Pages (use a comma): T3, T6

Page Range (use a hyphen): T3–T6

Cover Image
This is an illustration of a protein.

BIOMED / NUCLEIC ACIDS AND PROTEINS: DISEASE TREATMENT INNOVATIONS

How Are Drugs Tested?

DRIVING QUESTION

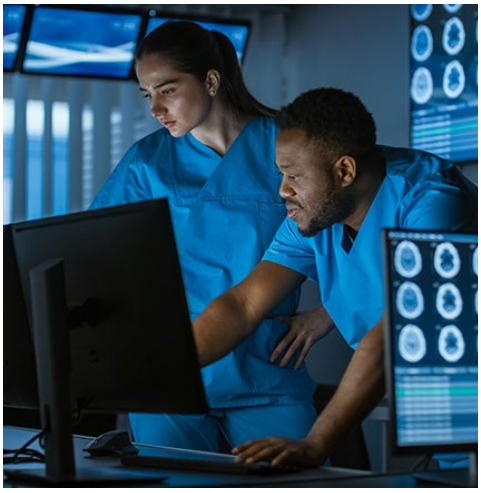
What is the complete process of developing a new medicine from bench to shelf?

OVERVIEW

Constant technological evolution has changed drug design in the past century. New techniques, including computer technology and artificial intelligence, have now combined with traditional methods to design more effective new drugs. However, through all of the changes and advancements, some of the steps involved with testing these drugs have remained relatively unchanged. Modern technology has just made these testing steps more efficient.

ACTIVITY DURATION

Five classroom sessions
(45 minutes each)



ESSENTIAL QUESTIONS

What part do pharmaceuticals play in modern life?

What are the many stages in the invention of new medicines?

How have new progressions in drug development affected the processes of drug testing?

OBJECTIVES

Students will be able to:

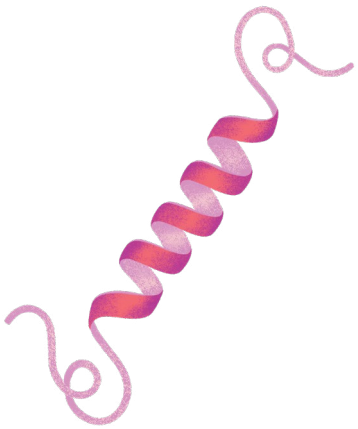
Identify and **analyze** the phases of drug testing.

Investigate current and past drug clinical trials using appropriate databases.

Critique the ethical dilemmas surrounding particular clinical trial case studies.

BACKGROUND INFORMATION

Drugs provide many benefits as treatments for chronic and infectious conditions. However, they are not a perfect solution as they do not work on everyone and can also be easily abused to our detriment.



Materials

- **Computers with Internet Access**
- **Writing Tools**
- **FDA Summary Timeline Rubric**
- **Ball-Toss Discussion Drug Discovery Assignment**
- **Ball-Toss Discussion Drug Discovery Rubric**
- **Phases of Drug Approval and Development Presentation Rubric**
- **ClinicalTrials.gov Assignment**
- **ClinicalTrials.gov Presentation Rubric**
- **Ethics Role-play Video Rubric**
- **Design Journal**

Pedagogical Framing

Instructional materials are designed to meet national education and industry standards to focus on in-demand skills needed across the full product development life cycle—from molecule to medicine—which will also expose students and educators to the breadth of education and career pathways across biotechnology.

Through this collection, educators are equipped with strategies to engage students from diverse racial, ethnic, and cultural groups, providing them with quality, equitable, and liberating educational experiences that validate and affirm student identity.

Units are designed to be problem-based and focus on workforce skill development to empower students with the knowledge and tools to be the change in reducing health disparities in communities.

SOCIAL-EMOTIONAL LEARNING

This lesson provides opportunities for students to accomplish critical academic goals while practicing the foundational social-emotional learning goals of self awareness and social awareness. Students will be required to recommend methods by which to increase racial and socioeconomic diversity in the drug development and testing process. This will require social awareness and social management skills. They will also be asked to analyze detrimental effects on populations and communities that might be underserved.

CULTURALLY AND LINGUISTICALLY RESPONSIVE INSTRUCTION

Students will be asked to bring their cultural and linguistic frameworks into the learning process in order to make suggestions for a redesign of an infographic that can more effectively deliver information to communities that may have little access to this information. This process will affirm the students' cultural heritage, while working to improve the final product. This leads to a more equitable classroom experience for all learners and empowers advocacy for self and community.

ADVANCING INCLUSIVE RESEARCH

Representation within clinical trials is crucial for success. When clinical trials do not include a wide diversity of participants (accounting for demographics, such as gender, race, age, and health history), it is impossible to get a complete picture of how a therapy performs for all people.

In order for the medical community to gather data from traditionally marginalized communities, it must work to demonstrate trustworthiness and develop relationships that lead to a willingness to share personal data.

COMPUTATIONAL THINKING PRACTICES

In this lesson, students utilize the computational thinking strategies of collecting data, analyzing data, and finding patterns to learn about how drugs are tested. Students examine clinical trials, which are experiments designed to test whether or not therapies are effective at treating diseases. Much as computer scientists design surveys and databases that gather user data, scientists construct clinical trials that must collect relevant data in a way that is easy to analyze. When collecting and analyzing data, students learn that they must control for bias and identify their own blind spots so that they do not confuse correlation, or patterns in data, with causation.

CONNECTIONS TO THE PRODUCT LIFE CYCLE

This lesson focuses on the **development** phase of the product life cycle, which focuses on clinical trial development and implementation. This phase includes a focus on personalized healthcare and requires collecting and analyzing data from as diverse a population as possible in order to know how well a therapy really works.

Have you ever wondered…

How long does it take for a drug to be approved for human use?

A drug discovery process can take as long as 10 to 20 years. Scientists and researchers work on synthesizing and mixing compounds that may lead to new drugs that treat illness and disease. The development process is the procedure to bring a potential drug from the initial compound form in the lab to FDA approval and finally to market as new drug therapy.

Why is it challenging to create a drug that targets a pathogen without harming healthy parts of the body?

The challenge resides in accurate targeting, destruction, and removal of the pathogens without damaging surrounding cells and tissues. Newer treatments surrounding more targeted responses, namely on the nucleic acid level, have made this easier to accomplish.

MAKE CONNECTIONS!

How does this connect to the larger unit storyline?

The process of drug design is an important aspect of the use of biotechnology to design products meant for the wellness of not only individuals but for populations and communities. Communities with high percentages of healthy inhabitants are generally more well off, with greater effectiveness of community services. Communities that are represented in drug development studies and clinical trials ensure proper representation concerning the efficacy of the drugs that are being tested.

How does this connect to careers?

Clinical trial coordinators are in charge of the set-up, conduct, and overall delivery of clinical trials. This involves activities at a site level, including assessing and following trial participants and other trial protocol-related activities.

Regulatory documentation scientists apply scientific writing, editing, document, and project management expertise and contribute to the functional excellence of regulatory documentation of clinical trials.

Quality engineers determine quality improvement parameters by identifying statistical methods relevant to manufacturing processes. They also establish statistical confidence and reliability by identifying sample size and acceptable error; determining levels of confidence.

How does this connect to our world?

With new and more prevalent infectious diseases worldwide, the race to produce effective therapeutics and pharmaceuticals to treat them has remained a vital component in the realms of biomedical research. Drug development and testing remain not only a large business generator but also a necessary and noble humanitarian quest.

Day 1

LEARNING OUTCOMES

Students will be able to:

Compile lists of effective medical discoveries.

Analyze the process of drug development.

Procedure

Teacher Note > *Teachers should share the FDA Summary Timeline Rubric for the Day 1 assignment with students prior to starting. Students may skew toward discoveries that have had a direct impact on them and/or their families and communities, i.e., if a student were to choose chemotherapy as one of their top medical discoveries, it may be because they or a relative had chemotherapy as a treatment for cancer. Practice sensitivity if this should occur and proactively establish guidelines with your class for both a safe and brave space for learning and discussion.*

Whole Group (15 minutes)

1 Provide students with blank sticky notes and have them answer the following questions anonymously:

- If you were creating a list of the top five medical drugs in human history, which single discovery has most significantly changed humans' lives for the better?
- Why would it earn a place on the list?

They will have one minute to write their responses and will be timed by the teacher.

Teacher Note > *Students may need to be presented with examples in order to jumpstart this activity.*

2 Students will add their sticky notes on a predetermined section of the board or classroom.

3 The teacher will select three to read out loud and engage the whole class in a *Round Robin* discussion about whether students support the three choices selected and why.

4 The teacher will then support or introduce the idea of drug development being a part of the larger landscape of medical discoveries. Identify any common themes among the student replies that align with drug development and testing.

5 Introduce the class to the drug development process by watching the NIAID video *How a Drug Becomes a Drug (3:48)* (either by one classroom widescreen/projector OR by individual student laptops) and have a quick discussion afterward.

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Day 1

Continued

Procedure

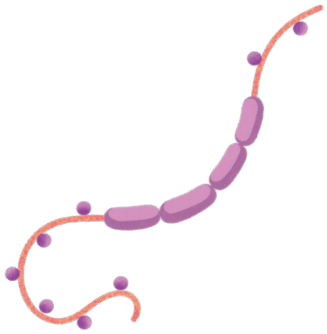
COMPUTATIONAL THINKING IN ACTION

Timelines are examples of how the computational thinking strategies of decomposition and developing algorithms can help us understand processes by breaking them down into sub-steps and then arranging them in order.

Individual (15 minutes)	
1	Individually, have students access the *United States FDA page Development and Approval Process* and also review *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*.
2	Students will read these pages and go to *Creately* to construct a summary of the process of drug development and approval. They should choose the "TIMELINE" template to use for their summaries.

Teacher Note > *Students will be asked to use Google credentials or create an account for Creately. If this is not an option, provide an alternative diagram creation tool, such as Draw.io or Visio.*

Small Group (10 minutes)	
1	Students work in pairs to compare each other's summaries as an Exit Ticket from the previous activity.
2	They will combine their ideas to create another summary .
3	All paired summaries will be turned in at the end of class.



Day 2

LEARNING OUTCOMES

Students will be able to:

Explore the various methods in which new drugs are discovered.

Describe the scientific process of producing a drug.

Analyze the time needed and associated costs with the development of a drug.

Procedure

Teacher Note > *In advance of this lesson, give the Ball-Toss Discussion Drug Discovery Assignment and the Ball-Toss Discussion Drug Discovery Rubric to the students along with the list of topics they will be researching to allow them optimal time to find their requisite information.*

Whole Group (10 minutes)	
1	The class will watch the American Chemical Society video *7 Steps to Drug Discovery* (3:06). Have students sketchnote in their **Design Journal** as they view the video. Ask them to note the seven steps detailed in the video.
2	Have a brief discussion with the class about the seven steps detailed in the video.

Teacher Note > *This video is laden with academic vocabulary that may require some additional scaffolding and support. Some frontloading of key vocabulary words, either as a homework assignment the day before or use a vocabulary game as an energizer prior to showing the video, is recommended.*

Small Group (35 minutes)	
1	Inform students that new drugs are often created in the laboratory, as they saw in the lesson on Day 1 and in the American Chemical Society video. However, sometimes new drugs are found in nature, such as Alexander Fleming's discovery of penicillin, an antibiotic that occurs naturally in some forms of mold. Tell students that they will participate in a class debate to uncover the pros and cons of each method.
2	Split the class into two groups (if it is a small class, i.e., 20 or less). If the class is substantially larger, you may split the two main groups into smaller sub-groups to ensure student participation. The two main groups will eventually come back together to defend their stances.
3	Group 1 will represent drug discovery in the laboratory. That group will watch the Genentech video *Finding Targets inside the Cell: Small Molecule Drug Discovery* (3:08).
4	Group 2 will represent drug discovery in nature. That group will watch the University of Michigan video *Drug Discovery in the Natural World* (5:11).

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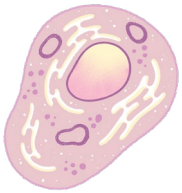
Day 2

Continued

Procedure



5 Each group will research the pros and cons of drug discovery in either a laboratory environment or in the natural world. Groups will participate in a "Ball-Toss Discussion" during which they will pose their method as the most effective. Provide students with links to the following resources from CancerQuest.org for additional information that will help them create their lists of pros and cons:

- **a.** *Sources of Drugs: Natural and Synthetic*
- **b.** *Pros and Cons of Natural and Synthetic Drugs*

6 Review the questions and statements that will be the topics discussed. Remember that each side will share why its method of drug discovery would be the most effective:

- **a.** Provide a brief history of your chosen method of drug discovery.
- **b.** Our method of drug discovery is more effective than the other because...
- **c.** Our method of drug discovery is more rewarding than the other because...
- **d.** Our method of drug discovery is more important than the other because...
- **e.** The videos representing both laboratory and environmental drug discovery demonstrate a startling lack of racial and ethnic diversity. What would your group do to ensure diversity in the near and distant future?
- **f.** How would an increase in diversity in the drug discovery process impact diverse populations and their respective communities?

7 For discussion: Student groups will move to opposite sides of the classroom. Move the desks so that each side is facing each other. Have students sit at their desks and take turns tossing a ball to discuss their positions on the discussion questions. Each side must alternate with the opposing side before speaking again. Only the student with the ball is allowed to speak and no student may speak twice in a row to ensure that many students have a chance to verbally participate in the discussion.

8 If the class does not have time to cover all of the discussion topics in the time permitted, they can be assigned as reflection for homework.

Day 3

Procedure

LEARNING OUTCOMES

Students will be able to:

Relate how the main phases of the drug approval process fit into the holistic view of drug development.

Whole Group (10 minutes)

1 The class will watch the NIH video *Discover NIMH: Drug Discovery and Development* (4:10).

2 Students will view the infographic *Drug Approval Process* on their computers. Give them time (five minutes) to digest the information they are viewing.

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Day 3

Continued

Procedure

Small Group (35 minutes)

1 Using the *Think-Pair-Share* method, have students pair up and discuss the information in the infographic above that was viewed earlier. In those pairs, they will answer the following questions.

a. What are the major events in the drug approval process?

b. What are the three most significant challenges that face scientists as they obtain approval for a particular drug?

c. If you were the designer of this infographic, what would you do to more effectively deliver this information to communities that may have less access to this information?

2 In the same groups, have students conduct a web search and collect information on Phases of Drug Approval and Development. With the collected information, ask them to produce a Presentation slideshow with four slides, with each slide detailing a different area of the development process. Provide copies of the *Phases of Drug Approval and Development Presentation Rubric* and give students the following headings to use for their slides:

a. Pre-Clinical Research, Clinical Trial Phase 0, and Clinical Trial Phase 1

b. Clinical Trial Phase 2

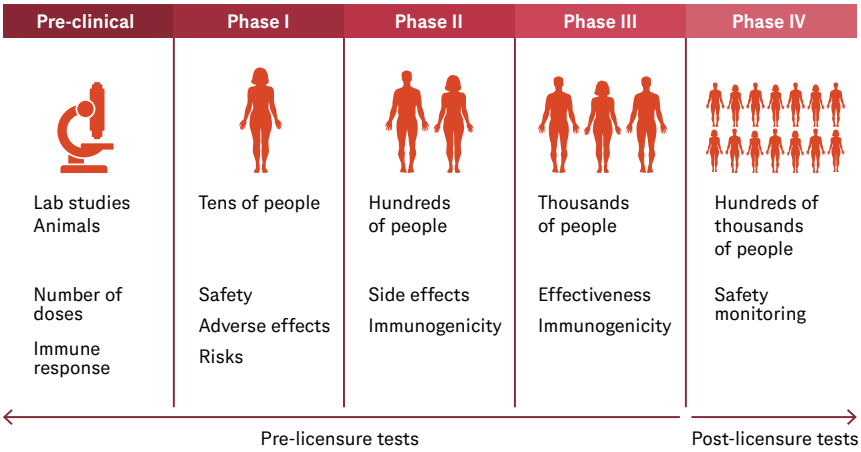
c. Clinical Trial Phase 3

d. Clinical Trial Phase 4

COMPUTATIONAL THINKING IN ACTION

Here, students use the computational thinking strategy of collecting data as they conduct web research on the clinical trial process.

The Phases of Vaccine Development



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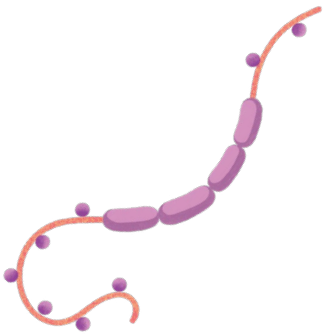
Day 3

Continued

Procedure



3 Requested Information Exemplar for the teacher is below:

Drug Approval Process Phases	Description
SLIDE ONE **Pre-Clinical Research**	In Vitro—Using laboratory methods, such as using test tubes and cell culture to perform research In Silico—Using computer modeling to research and predict drug interaction and efficacy Chemical—Performing toxicology studies on the proposed drug In Vivo—Using animal models to test out drug performance in living organisms
Clinical Trial Phase 0	Phase 0 trials are the first clinical trials done among people. They aim to learn how a drug is processed in the body and how it affects the body. In these trials, a very small dose of a drug is given to about 10 to 15 patients.
Clinical Trial Phase I	Phase I trials aim to find the best dose of a new drug with the fewest side effects. The drug will be tested in a small group of 15 to 30 patients. Doctors start by giving very low doses of the drug to a few patients. Higher doses are given to other patients until side effects become too severe or the desired effect is seen. The drug may help patients, but Phase I trials are to test a drug's safety. If a drug is found to be safe enough, it can be tested in Phase II clinical trials.
SLIDE TWO **Clinical Trial Phase II**	Phase II trials further assess safety as well as ascertains if a drug works. The drug is often tested among patients with a specific type of cancer. Phase II trials are performed in larger groups of patients compared to Phase I trials. Often, new combinations of drugs are tested. Patients are closely watched to see if the drug works. However, the new drug is rarely compared to the current (standard-of-care) drug that is used. If a drug is found to work, it can be tested in Phase III clinical trials.

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Day 3

Continued

Procedure

Drug Approval Process Phases	Description
SLIDE THREE **Clinical Trial Phase III**	Phase III trials compare a new drug to the standard-of-care drug. These trials assess the side effects of each drug to determine which drug works better. Phase III trials enroll 100 or more patients. Often, these trials are randomized. This means that patients are put into a treatment group, called trial arms, by chance. Randomization is needed to make sure that the people in all trial arms are alike. This lets scientists know that the results of the clinical trial are due to the treatment and not differences between the groups. A computer program is often used to randomly assign people to the trial arms. There can be more than two treatment groups in Phase III trials. The control group gets the standard-of-care treatment. The other groups get a new treatment. Neither the patient nor the doctor can choose the group. The patient will not know his or her group until the trial is complete. Every patient in a Phase III study is watched closely. The study will be stopped early if the side effects of the new drug are too severe or if one group has much better results. Phase III clinical trials are often needed before the FDA will approve the use of a new drug for the general public.
SLIDE FOUR **Clinical Trial Phase IV**	Phase IV trials test new drugs approved by the FDA. The drug is tested in several hundred or thousands of patients. This allows for better research on short-lived and long-lasting side effects and safety. For instance, some rare side effects may only be found in large groups of people. Doctors can also learn more about how well the drug works and if it is helpful when used with other treatments.

4 Groups will email their assignments to the teacher. Completed assignments in the teacher inbox will serve as Exit Tickets.

Day 4

Procedure

LEARNING OUTCOMES

Students will be able to:

Simulate the process, timeline, and associated costs of developing a drug.

Apply web and database sources to research various approved and ongoing governmental clinical trials.

Teacher Note > *This lesson will require students to do a significant amount of data mining to find the information being sought. Provide encouragement to those who may easily get frustrated trying to do an in-depth search (i.e., suggestions for countries/diseases, guided questions to assist with the Drug Development Overview, navigation tips for finding published results, etc.). The teacher will have the option to differentiate instruction by giving some students a smaller amount of information (one clinical study in the United States compared with one study conducted abroad).*

Small Group (15 minutes)

1 Students will log on to the *Drug Development Overview* virtual tutorial.

2 Students will proceed through the course and corresponding sections: Topic 1/Drug Development, Topic 2/Identify Phase Descriptions, Topic 3/ Time and Cost.

3 When finished, student groups will proceed to the next assignment.

COMPUTATIONAL THINKING IN ACTION

Students continue to utilize the computational thinking strategy of collecting data as they gather information from research studies and learn how to identify reputable sources.

Small Group (30 minutes)

Teacher Note > *ClinicalTrials.gov provides access to summary information on publicly and privately supported clinical studies on a wide range of diseases and conditions, and can be used to analyze research questions.*

1 Students will continue working in their same small groups to complete the *ClinicalTrials.gov Assignment*.

2 Using *Clinical Trials.gov*, groups will conduct an in-depth analysis of three clinical studies. Two studies must be from the United States, while the remaining one must be from a different countries outside the United States. For each study, the following information must be collected:

- Disease or Condition
- Intervention (for example, the medical product, behavior, or procedure being studied)
- Title, description, and design of the study
- Requirements for participation (eligibility criteria)
- Locations where the study is being conducted
- Contact information for the study locations
- Links to relevant information on other websites, such as National Library of Medicine's *MedlinePlus* for patient health information and *PubMed* for citations and abstracts of scholarly articles in the field of medicine

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Day 4

Continued

Procedure

3	If choosing a study that has published results, also include: • Description of study participants and the number of participants starting or completing the study, and their demographic data • Outcomes of the study • Summary of adverse events experienced by study participants
4	To assist students with their search, you can point them to certain tabs to find the information they are seeking, such as: • Using the "Find Studies" pulldown tab to utilize "Advanced Search", "See Studies by Topic", and "See Studies on Map". • Using the "Resources" pulldown tab to utilize "Trends, Charts, and Maps".
5	Collected Clinical Trial information should be added to the Presentation presentation from the previous class. Use the *ClinicalTrials.gov Presentation Rubric* to evaluate the additions to their presentation.
6	Choose the best ten entries based on the rubric and set up a digital *Gallery Walk* for the next class.

Individual (5 minutes)

Ask students to capture the role of pharmaceuticals in their **Design Journal**. They will explain the stages in the invention of new medicines and elaborate on new progressions in drug development affecting the processes of drug testing.

Day 5

LEARNING OUTCOMES

Students will be able to:

Evaluate student presentations from the previous class.

Create a role-play informative video based on ethics case studies on the use of human subjects in clinical trials and biomedical research.

Procedure

Teacher Note > *This section may contain sensitive topics for some students to navigate independently. Alternatively, the teacher can choose one topic in advance and have the class work on only that one topic with more teacher supervision, structure, and intervention to ensure a culturally sensitive and inclusive end product.*

Whole Group (5–8 minutes)

Students will choose one other group's presentation to view digitally and give feedback to that group. Reviewers can give feedback in the "notes" section at the bottom of each slide or add a final slide with all the feedback on it for the group.

Small Group (40 minutes)

1 In groups of four, students will read and research a case study involving ethical issues concerning pre-clinical and clinical biomedical research.

2 The case studies assigned to student groups will be:

- *RCR Casebook: First-in-Human Research: Selecting Appropriate Subjects*
- *Ethics in Animal Care and Use*
- *RCR Casebook: A Disturbing Lab Protocol*
- *Jesse Gelsinger—Death but one unintended consequence of gene-therapy trial*
- *The Tuskegee Timeline*
- *Ellen Roche—Healthy woman dies in research experiment*
- *Henrietta Lacks—The Immortal Life of Henrietta Lacks*

3 Students will assign themselves roles to play. For the sake of time, there should be no more than three roles assigned per group. The remaining group members will be recorders/directors, etc. Depending on the particular case study, these roles could be any of the following:

- Clinical Trials Coordinator
- Regulatory Documentation Scientist
- Quality Engineer
- Doctor
- Patient
- Principal Investigator
- Laboratory Technician
- Veterinarian

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Day 5

Continued

Procedure

4 Students will develop a short (2–3 min) script for their ethical issues video of the particular case their group has selected or that the teacher has assigned. Provide the *Ethics Role-play Video Rubric* as a guide for their presentation.

Teacher Note > *Make sure to review group scripts before students make the video, ensuring accuracy of information as well as checking for harmful stereotypes or racially biased interpretations.*

5 Students will use Animoto or similar software to create their videos and can choose a template that will fit with the way they want to present the case study (as an informative video, an investigation/news story, an awareness advertisement, etc.). They can record video clips on their cell phones and drop them into Animoto to create their video presentations.

National Standards

Next Generation Science Standards

Science and Engineering Practices

Obtaining, evaluating, and communicating information

Critically read scientific literature adapted for classroom use to determine the central ideas or conclusions and/or to obtain scientific and/or technical information to summarize complex evidence, concepts, processes, or information presented in a text by paraphrasing them in simpler but still accurate terms.

Crosscutting Concepts

Patterns

Different patterns may be observed at each of the scales at which a system is studied and can provide evidence for causality in explanations of phenomena.

Scale, Proportion, and Quantity

Algebraic thinking is used to examine scientific data and predict the effect of a change in one variable on another (e.g., linear growth vs. exponential growth).

Cause and Effect

Empirical evidence is required to differentiate between cause and correlation and make claims about specific causes and effects.

Career and Technical Education (CTE)

A5.1

Use the Internet and World Wide Web to collect and share scientific information.

A7.1

Identify agencies at the local, state, and federal levels.

A7.2

Be aware of the role of agencies in promoting patient safety, quality control, and entrepreneurship.

A9.1

Describe the major steps of a product's move through a company's product pipeline.

5.4

Interpret information and draw conclusions, based on the best analysis, to make informed decisions.

5.6

Read, interpret, and extract information from documents.

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FDA Summary Timeline Rubric

Group Members _____

Score	4	3	2	1
Clarity	Clear main idea concerning drug development and approval process.	Marginally clear main idea concerning drug development and approval process.	Main idea concerning drug development and approval process is unclear or not specifically stated in the writing.	The main idea is not present.
Content	All important details are included.	Important details are included, but some might be missing.	Some critical information is missing.	Contains only some details.
Organization	Details are in a logical order.	Ideas are mostly in a logical order.	Ideas are somewhat random.	Ideas are not in a logical order.
Understanding	Demonstrates a clear understanding of the process of drug development and approval in the text.	Demonstrates an adequate understanding of the process of drug development and approval.	Demonstrates a basic understanding of information in text.	Demonstrates little or no understanding.
Paraphrasing	Is characterized by paraphrasing of the main idea and significant details.	Is characterized by paraphrasing of the main idea and significant details, with some copying of key phrases.	Is characterized by substantial copying of key phrases and minimal paraphrasing.	Is characterized by the substantial copying of indiscriminately selected phrases or sentences.
Final Score				

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Ball-Toss Discussion Drug Discovery Assignment

Directions

Group 1 *will represent drug discovery in the laboratory. That group will watch the Genentech video Finding Targets inside the Cell: Small Molecule Drug Discovery.*

Group 2 *will represent drug discovery in nature. That group will watch the University of Michigan video Drug Discovery in the Natural World.*

Finding Targets inside the Cell: Small Molecule Drug Discovery

Drug Discovery in the Natural World

1. Each group will research the pros and cons of drug discovery in either a laboratory environment or in the natural world and defend their method as the most effective.
2. The following are the questions or statements that will be the topics discussed in the debate. Remember each side will debate why its method of drug discovery would be the most effective:
    a. Provide a brief history of your chosen method of drug discovery.
    b. Our method of drug discovery is more effective than the other because…
    c. Our method of drug discovery is more rewarding than the other because…
    d. Our method of drug discovery is more important than the other because…
    e. The videos representing both laboratory and environmental drug discovery demonstrate a shocking lack of racial and ethnic diversity. What would your group do to address this concern in the near and distant future?
    f. How would an increase in diversity in the drug discovery process impact the majority and minority populations and their respective communities?
3. For debate: Student groups will move to opposite sides of the classroom. Move the desks so that each side is facing each other. Students will sit at their desks and take turns tossing a ball to discuss their positions on the debate questions. Each side must alternate with the opposing side before speaking again.

    Only the student with the ball is allowed to speak.

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Ball-Toss Discussion Drug Discovery Rubric

Group Members _____

Score	4	3	2	1
Respect for Other Team	All statements, body language, and responses were respectful and used appropriate language.	Most statements, body language, and responses were respectful and used appropriate language.	Occasionally, statements and responses were disrespectful and used inappropriate language.	Statements, responses and/or body language were consistently disrespectful.
Information	All information presented in this discussion was clear, accurate, and thorough.	Most information presented in the discussion was clear and accurate but was not always thorough.	Some information was accurate, but there were some minor inaccuracies.	Information had some major inaccuracies or was unclear.
Rebuttal	All counter-statements concerning drug discovery are accurate, relevant, and strong.	Most counter-statements concerning drug discovery are accurate, relevant, and strong.	Some counter-statements concerning drug discovery are factually incorrect, weak, or irrelevant.	Counter-statements concerning drug discovery are inaccurate and/or irrelevant.
Use of Facts/ Statistics	Every major point is well supported with several relevant facts, statistics and/or examples.	Every major point is adequately supported with relevant facts, statistics or examples.	Some points are supported with facts, statistics or examples, but the relevance was questionable.	No relevant facts, statistics, or examples used.
Organization	All statements are clearly tied to an idea (premise) and organized logically.	Most statements are tied to an idea (premise) and organized logically.	Some statements are tied to an idea (premise) and not very organized.	Statements are not tied to an idea at all and not at all organized.
Understanding of Topic	The group clearly understood the topic of drug discovery in-depth and presented their information forcefully and convincingly.	The group seemed to understand the topic of drug discovery, and most of the main points were presented with ease.	The group seemed to have an adequate understanding of the topic of drug discovery, but didn't present with ease.	The group did not show an adequate understanding of the topic, or present with ease.
Final Score				

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Phases of Drug Approval and Development Presentation Rubric

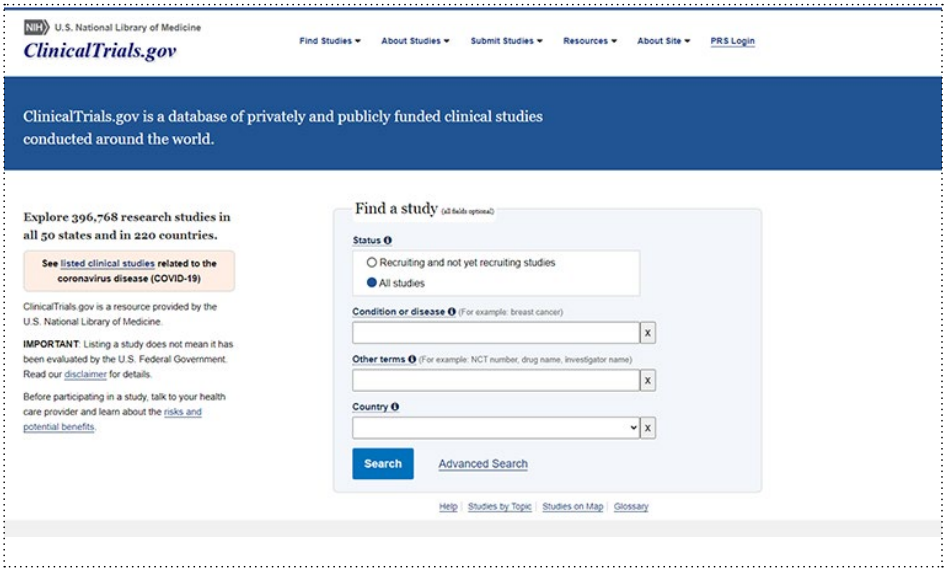
Group Members _____

Score	4	3	2	1
Content	Content is accurate; all required information concerning the process of drug development and approval is presented in a logical order.	Content is accurate; some required information concerning the process of drug development and approval is missing and/or not presented in the most logical order but it is still generally easy to follow.	Content is questionable; a significant amount of the required information concerning the process of drug development and approval is missing and/or not presented in a logical order, making it somewhat difficult to follow.	Content is inaccurate; a significant amount of the required information concerning the process of drug development and approval is missing and not presented in a logical order, making it difficult to follow.
Slide Creation	Presentation flows well and logically; the presentation reflects the extensive use of tools in a creative way.	Presentation flows well, tools are used correctly, and overall presentation is interesting.	Presentation is somewhat disorganized; some tools are used to show acceptable understanding.	Presentation is very disorganized; tools are not used appropriately.
Slide Transitions	Transitions are smooth and enhance the presentation.	Smooth transitions are used on most slides.	Very few transitions are used and/or they distract from the presentation.	No transitions are used.
Visuals	Images are appropriate and layout is pleasing to the eye.	Images are appropriate but layout is somewhat cluttered.	Images do not complement the content of the presentation.	No images.
Mechanics	No spelling or grammatical errors; text is in the authors' own words.	Few spelling and grammatical errors; text is in authors' own words.	Some spelling errors Some grammar errors; most of the text is in the authors' own words.	Many spelling and or grammar errors; text is copied.
Presentation Skills	Well-rehearsed; no pronunciation errors or other mistakes.	General level of rehearsal; few pronunciation errors or other mistakes.	Acceptable level of rehearsal; some pronunciation errors or other mistakes.	Low level of rehearsal; numerous pronunciation errors or other mistakes.
Final Score				

FUTURELAB+

ClinicalTrials.gov Assignment

Directions
Complete the steps below with your assigned group.

Step	Description	Details
1	Log onto *ClinicalTrials.gov* from the NIH National Library of Medicine.	
2	Groups will conduct an in-depth analysis of five clinical studies, three studies must be from the United States, while the remaining two must be from two different countries outside the United States. For each study, the following information must be collected:	☐ Disease or Condition ☐ Intervention (for example, the medical product, behavior, or procedure being studied) ☐ Title, description, and design of the study ☐ Requirements for participation (eligibility criteria) ☐ Locations where the study is being conducted ☐ Contact information for the study locations ☐ Links to relevant information on other websites, such as National Library of Medicine's *MedlinePlus* for patient health information and *PubMed* for citations and abstracts of scholarly articles in the field of medicine

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ClinicalTrials.gov Assignment

Continued

Step	Description	Details
3	If choosing a study that has published results, also include:	☐ Description of study participants (the number of participants starting and completing the study and their demographic data) ☐ Structure of study (i.e., placebo-controlled? double-blind?) ☐ Outcomes of the study ☐ Summary of adverse events experienced by study participants
4	To assist with your search, you can use certain tabs to find the information you are seeking, such as:	☐ Using the *Find Studies* pulldown tab to utilize *Advanced Search*, *See Studies by Topic*, and *See Studies on Map*  ☐ Using the *Resources* pulldown tab to utilize *Trends, Charts, and Maps* 
5	Finalized Presentation presentation.	☐ Collected Clinical Trial information should be added to the Presentation presentation from the previous class.

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ClinicalTrials.gov Presentation Rubric

Group Members _____

Score	4	3	2	1
Content	Content is accurate and all required information about clinical trials is presented in a logical order.	Content is accurate; some required information about clinical trials is missing and/or not presented in a logical order but is still generally easy to follow.	Content is questionable; information about clinical trials is not presented in a logical order, making it difficult to follow.	Content is inaccurate; information about clinical trials is not presented in a logical order, making it difficult to follow.
Slide Creation	Presentation flows well and logically; the presentation reflects the extensive use of tools in a creative way.	Presentation flows well, tools are used correctly, and overall presentation is interesting.	Presentation is somewhat disorganized; some tools are used to show acceptable understanding.	Presentation is very disorganized; tools are not used appropriately.
Slide Transitions	Transitions are smooth and enhance the presentation.	Smooth transitions are used on most slides.	Very few transitions are used and/or they distract from the presentation.	No transitions are used.
Visuals	Images are appropriate and layout is pleasing to the eye.	Images are appropriate but layout is somewhat cluttered.	Images do not complement the content of the presentation.	No images.
Mechanics	No spelling or grammatical errors; text is in the authors' own words.	Few spelling and grammatical errors; text is in authors' own words.	Some spelling errors Some grammar errors; most of the text is in the authors' own words.	Many spelling and or grammar errors; text is copied.
Presentation Skills	Well-rehearsed; no pronunciation errors or other mistakes.	General level of rehearsal; few pronunciation errors or other mistakes.	Acceptable level of rehearsal; Some pronunciation errors or other mistakes.	Low level of rehearsal Numerous pronunciation errors or other mistakes.
Final Score				

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Ethics Role-Play Video Rubric

Group Members _____

	Score	3	2	1
	Content	Students incorporate the professional roles with a high degree of accuracy, address ethical issues throughout their role-play scenario, and present information that is scientifically valid.	Students incorporate professional roles with a moderate degree of accuracy, address ethical issues two or three times in their role-play scenario, and present information that is mostly valid scientifically, but contains two or three mistakes.	There is little to no incorporation of professional roles by students, they barely mention or address any ethical issues in their role-play scenario, and the information presented has four or more scientific inaccuracies.
	Storyboard and Script	Six or more storyboards and terms are used well, and students accurately incorporate grammar and vocabulary learned in class.	Four or five storyboards and/or terms are used, and students use proper grammar and vocabulary but some mistakes are present.	Three or fewer storyboards and/or terms are used, and students use grammar and vocabulary incorrectly which affects understanding.
	Creativity and Delivery	Interesting situation allowing students to creatively showcase learned language and display a natural delivery with a high level of confidence.	Situation enables some use of creative language and students display a level of natural delivery, although some awkward moments or pauses present.	Uninspired situations with little creative use of language and student delivery appear to lack confidence or is unnatural with long pauses.
	Video Production	Video is well shot, steady, and easy to hear, and editing is clean with quality transitions and logical sequencing.	Video is mostly steady with decent audio quality, and transitions and sequencing are mostly logical.	Video is shaky and hard to hear, transitions are abrupt, and sequencing is hard to follow.
	Final Score			

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