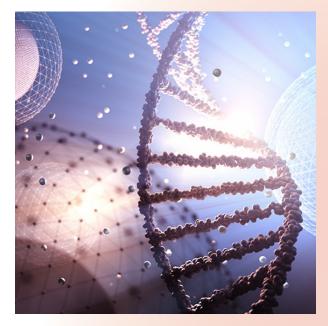


#### **Mystery Disease Conference Project**



#### BACKGROUND

As advances continue to be made in the field of biotechnology, diseases that have evaded a cure, such as heart disease, HIV, and Alzheimers, may finally be meeting their match. Innovative techniques that involve nucleic acid and protein sequencing, isolation, assays, and editing have unlocked new possibilities for treatments of disease and potential cures. In this unit you have learned that an understanding of the central dogma of Biology—the transmission of information from DNA to RNA and the building of proteins—has allowed scientists to create ways to better understand the role that these molecules play in disease. It has also inspired ways to help monitor, treat, and perhaps even stop diseases by preventing them altogether, using biochemical tools such as CRISPR-Cas9.

As new biotechnological techniques and treatments are discovered and created, there are strict approval processes and guidelines to ensure that they are effective and safe for humans before they are ever available to the public. Extensive clinical trials are an important part of the drug approval process, and allow these drugs to be tested and important data to be gathered. However, there are ethical dilemmas that come with this, and ensuring that all populations and groups of people are included in these trials provides important data that can impact how the drug is used and who is treated with it.

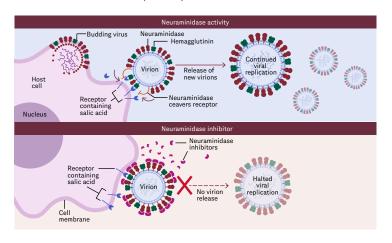
# Examples of Drug Mechanism of Action Models and Animation, Clinical Trial Flowchart, and Pecha Kucha

#### PROJECT SUMMARY

You are part of a drug research and development team that has been given the opportunity to present at a mock Mystery Disease Conference. You will be introduced to a specific disease that has conventional treatments, but does not yet have a cure by reading the profile of a patient who suffers from the disease. Your presentation will be given in the style of a Pecha Kucha, where you will prepare 20 slides and discuss each slide for 20 seconds. Your presentation should introduce the audience to the patient and disease, and introduce an innovative drug delivery system or technology that could help to cure or prevent the disease. In your role as a project manager, biomedical technician, clinical researcher, or health information specialist, you will choose a patient profile and

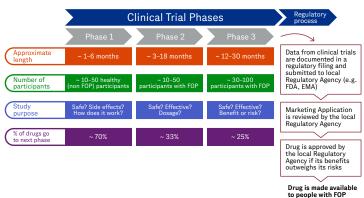
work with your group to research information about the disease with which your patient is diagnosed, including the mechanism of the disease and the benefits and drawbacks of conventional treatments. Next, your group will design a potential innovative drug delivery system for the disease, using information about nucleic-acid and protein-based treatments from the lessons in this unit. This will include a sketch or animation of how the drug delivery system will work to be included in the Pecha Kucha. To end the presentation, your group will outline a detailed clinical trial plan that will give important data about the drug's effectiveness, while ensuring equity to all people to begin the pathway to the drug's approval by the FDA.

#### Neuraminidase (Influenza viral disruptor) Mechanism of Action (model)



#### Clinical Trial Flowchart

How a Drug Moves Through Clinical Trials and Gets to People with FOP



Proton Pump Inhibitor Mechanism of Action (animation) *Link to example*  Huntington's Disease Pecha Kucha *Link to example* 

#### **Proposal Requirements**

#### Research for the project must include:

- Information about the disease, including the disease mechanism, symptoms, causes, and demographics using data.
- 2 A cost and benefits comparison with traditional treatments to manage symptoms.
- 3 An explanation of the potential drug's target that is related to the disease mechanism.
- 4 Brainstorming about how the drug innovation will work and if it will use nucleic acid or protein modification, isolation, or purification.
- An explanation about how the innovative drug delivery system could work to cure the disease.

# The Drug Mechanism of Action 2-D Model or Animation must include:

- 1 Images that clearly represent the disease mechanism and drug mechanism.
- 2 Arrows, steps, or captions to help the viewer understand how the drug will work.
- 3 The incorporation of color to help distinguish among objects in the model or animation more easily.

#### The Flowchart or Timeline must include:

- Details on how a clinical trial would be held for the drug innovation, including specific steps or phases and the data that would be collected.
- 2 An explanation of how various groups would be included in the trial to ensure equity.

#### The Petcha Kucha Slideshow must include:

- 1 20 images that relate directly to the presentation and add imagery to help convey the message.
- 2 One or more slides should include the 2-D model or animation of the drug innovation mechanism.
- 3 Slides should be set to appear for 20 seconds each for the presentation

<b>Engineering Design Pro</b>	cess Journal
Name	Group Members
Start Date	
Due Date	

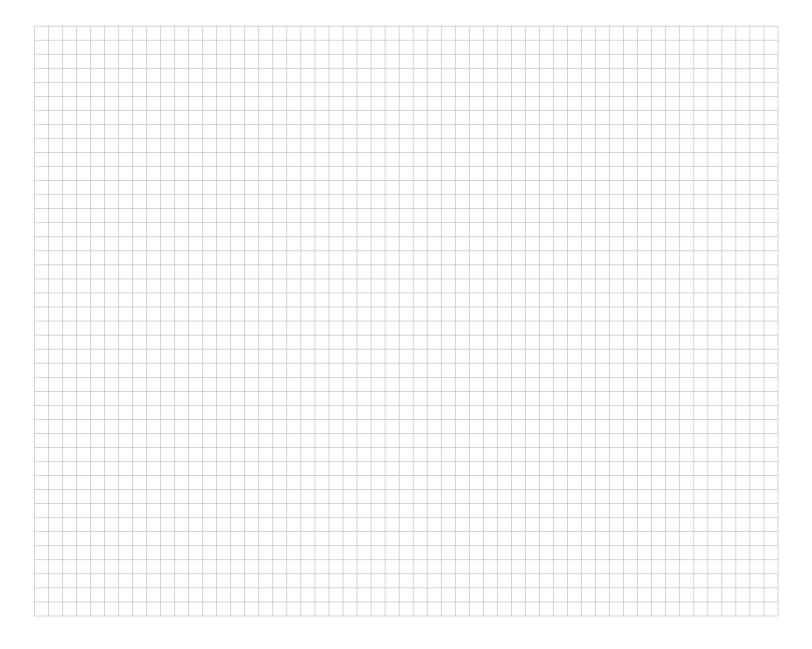
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Engineering Design Process Journal

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#### **Step 2: Brainstorm**

Discuss initial ideas for your drug innovation with your group. In the space provided, create a concept map, flow chart, or other type of graphic organizer showing how you might connect information about the use of nucleic acids and proteins in biotechnology to potential cures for the disease incorporating these techniques. What will be the goal of each piece of the presentation to inform and inspire?



answering your questions?

of your ideas. What resources are available to assist you in

Engineerin	g Design Pro	cess Journal									
Step 1: Define the Problem	Step 2: Brainstorm	Step 3: Research and Generate Ideas	Step 4: Identify Criteria and Specify Constraints	Step 5: Explore Possibilities	Step 6: Select an Approach	Step 7: Develop the Design Proposal	Step 8: Make a Model or Prototype	Step 9: Test and Evaluate Design Using Specifications	Step 10: Refine the Design	Step 11: Modify and Present for Market	Step 12: Communicate Processes and Results
Step 3: R	esearch an	ıd Generate	eldeas			Resource	e List				
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Possible Questions Generate a list of specific questions that need to be answered.	Research Results	Any Additional Design Ideas Generated During Research Notes or sketches

#### **Question Prompts**

- What are some additional demographics or background that might be helpful to know about your patient's disease?
- What are some of the available drugs or treatments for this disease? What are the benefits and limitations for these drugs or treatments?
- What will the target be for your drug delivery system?
- What data and resources might be helpful in the creation of a clinical trial for your drug delivery system?

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Engineering Design Process Journal Step 1: Define the Step 12: Step 2: Step 6: Step 8: Step 9: Step 11: Step 4: Step 5: Step 7: Step 10: Brainstorm Research Identify Make a Model Test and Modify Explore Select an Develop Refine the Communicate or Prototype Problem and Generate Criteria Possibilities the Design Evaluate and Present Processes Approach Design Ideas and Specify Proposal Design Using for Market and Results Constraints Specifications **Lesson Connections LESSON 2: DNA Modification** Use the capture sheets and information learned from this lesson to answer the following questions: How do scientists use Cas9 to modify DNA? What are the controversies surrounding genetic modification? How can genetic modification be applied to medical science?

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Engineering Design Process Journal Step 1: Define the Step 12: Step 2: Step 4: Step 5: Step 6: Step 8: Step 9: Step 11: Step 7: Step 10: Brainstorm Research Identify Make a Model Test and Modify Explore Select an Develop Refine the Communicate Problem and Generate Criteria Possibilities the Design or Prototype Evaluate and Present Processes Approach Design Ideas and Specify Proposal Design Using for Market and Results Constraints Specifications **Lesson Connections LESSON 3: DNA Isolation and Purification** Use the capture sheets and information learned from this lesson to answer the following questions: How is DNA extracted from the nucleus of a cell? How can gel electrophoresis use the properties of DNA to create a DNA fingerprint? How can DNA be used to prescribe specific medicine to patients?

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Engineering Design Process Journal Step 1: Define the Step 12: Step 2: Step 6: Step 8: Step 9: Step 11: Step 4: Step 5: Step 7: Step 10: Brainstorm Research Identify Make a Model Test and Modify Explore Select an Develop Refine the Communicate Problem and Generate Criteria Possibilities the Design or Prototype Evaluate and Present Processes Approach Design Ideas and Specify Proposal Design Using for Market and Results Constraints Specifications **Lesson Connections LESSON 7: Protein Assays** Use the capture sheets and information learned from this lesson to answer the following questions: Why do medical professionals need to determine the quantity and identity of proteins in a sample? How do some protein assays detect specific proteins while other assays do not? How do Biuret protein assays and ELISAs differ?

Step 1: Define the Problem	Step 2: Brainstorm	Step 3: Research and Generate Ideas	Step 4: Identify Criteria and Specify Constraints	Step 5: Explore Possibilities	Step 6: Select an Approach	Step 7: Develop the Design Proposal	Step 8: Make a Model or Prototype	Step 9: Test and Evaluate Design Using Specifications	Step 10: Refine the Design	Step 11: Modify and Present for Market	Step 12: Communica Processes and Results
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Step 1: Define the Problem	Step 2: Brainstorm	Step 3: Research and Generate Ideas	Step 4: Identify Criteria and Specify Constraints	Step 5: Explore Possibilities	Step 6: Select an Approach	Step 7: Develop the Design Proposal	Step 8: Make a Model or Prototype	Step 9: Test and Evaluate Design Using Specifications	Step 10: Refine the Design	Step 11: Modify and Present for Market	Step 12: Communica Processes and Result
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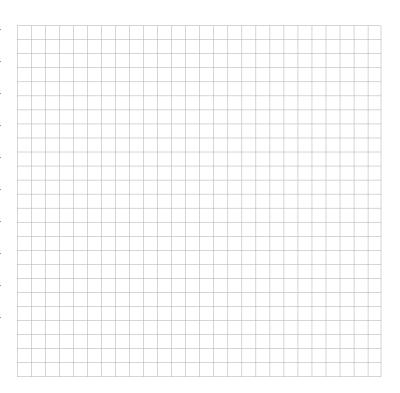
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efine the roblem	Brainstorm	Research and Generate Ideas	Identify	Explore Possibilities	Select an Approach	Develop the Design Proposal	Make a Model or Prototype		Refine the Design	Modify and Present for Market	Communica Processes and Results
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Engineering Design Process Journal Step 1: Define the Step 2: Step 3: Step 5: Step 6: Step 7: Step 8: Step 9: Step 10: Step 11: Step 12: Brainstorm Research Identify Explore Select an Develop Make a Model Test and Refine the Modify Communicate or Prototype Problem and Generate Criteria Possibilities Approach the Design Evaluate Design and Present Processes for Market and Results Ideas and Specify Proposal Design Using Constraints Specifications **Step 4: Identify Criteria and Specify Constraints** What are specific criteria and constraints for your chosen innovation challenge? Criteria **Constraints** Potential Materials Needed

Engineering Design Process Journal

Step 1: Step 2: Step 3: Step 4: Step 5: Step 6: Step 7: Step 8: Step 9: Step 10:	Step 11:	Step 12:	
Define the Brainstorm Research Identify Explore Select an Develop Make a Model Test and Refine the	Modify	Communicate	
Problem and Generate Criteria Possibilities Approach the Design or Prototype Evaluate Design	and Present	Processes	
Ideas and Specify Proposal Design Using	for Market	and Results	
Constraints Specifications			

Step 5: Explore Possibilities
Review your ideas from Steps 2 and 3 of the design process. Explore some of your ideas in more detail. Record your results in the space provided. Possible results can reflect testing, experiments, simulations, peer review, etc. Be sure to include any data collected or group discussion and feedback.



Engineering Design Process Journal

Step 1:	Step 2:	Step 3:	Step 4:	Step 5:	Step 6:	Step 7:	Step 8:	Step 9:	Step 10:	Step 11:	Step 12:
Define the	Brainstorm	Research	Identify	Explore	Select an	Develop	Make a Model	Test and	Refine the	Modify	Communicate
Problem		and Generate	Criteria	Possibilities	Approach	the Design	or Prototype	Evaluate	Design	and Present	Processes
		Ideas	and Specify			Proposal		Design Using		for Market	and Results
			Constraints					Specifications			

#### Step 6: Select an Approach

Use the following decision matrix to assist in selecting one of your ideas for further development. To use the tool, complete the following steps:

- 1 Enter the criteria and constraints of the project in the first column.
- 2 Use a numeric value to rate each solution against the criteria or constraint. (2 = totally meets the requirement, 1 = somewhat meets the requirement, 0 = does not meet the requirement)
- 3 Total the columns and circle the highest score.

Criteria or Constraint	Sketch/Idea 1	Sketch/Idea 2	Sketch/Idea 3
<b>Other criteria:</b> A single rating for your own "nice-to-have" desirable criteria and universal design criteria (such as <i>Robustness, Aesthetics, Skill Required, Safety):</i>			
Total			

Engineering	g Design Pro	cess Journal									
Step 1: Define the Problem	Step 2: Brainstorm	Step 3: Research and Generate Ideas	Step 4: Identify Criteria and Specify Constraints	Step 5: Explore Possibilities	Step 6: Select an Approach	Step 7: Develop the Design Proposal	Step 8: Make a Model or Prototype	Step 9: Test and Evaluate Design Using Specifications	Step 10: Refine the Design	Step 11: Modify and Present for Market	Step 12: Communicate Processes and Results
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Engineering Design Process Journal

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Problem		and Generate	Criteria	Possibilities	Approach	the Design	or Prototype	Evaluate	Design	and Present	Processes	
		Ideas	and Specify			Proposal		Design Using		for Market	and Results	
			Constraints					Specifications				

#### Step 8: Make a Model or Prototype

In the space below, insert or sketch pictures showing your drug innovation's proposed mechanism of action (how it will work in the body or cell and what it will target to disrupt and stop the disease).

Step 1:	Step 2:	Step 3:	Step 4:	Step 5:	Step 6:	Step 7:	Step 8:	Step 9:	Step 10:	Step 11:	Step 12:			
Define the Problem	Brainstorm	Research and Generate Ideas	Identify Criteria and Specify Constraints	Explore Possibilities	Select an Approach	Develop the Design Proposal	Make a Model or Prototype	Test and Evaluate Design Using Specifications	Refine the Design	Modify and Present for Market	Communicat Processes and Results			
Step 9: T	est and Ev	aluate Desig	gn Using S	pecificatio	ons									
	you test or resentation	obtain feed n?	back abou <sup>.</sup>	t your myst	ery	What data will you collect during testing?								
In the spa and the r		document tl	ne type of	test you co	nducted									
Descripti	ion of Test	Performed				Test Results								

Step 1:	Step 2:	Step 3:	Step 4:	Step 5:	Step 6:	Step 7:	Step 8:	Step 9:	Step 10:	Step 11:	Step 12:
Define the Problem	Brainstorm	Research and Generate Ideas	Identify	Explore Possibilities	Select an Approach	Develop the Design Proposal	Make a Model or Prototype		Refine the Design	Modify and Present for Market	Communicat Processes and Results
Step 10:	Refine the	Design									
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tep 1: Define the Problem	Step 2: Brainstorm	Step 3: Research and Generate Ideas	Step 4: Identify Criteria and Specify Constraints	Step 5: Explore Possibilities	Step 6: Select an Approach	Step 7: Develop the Design Proposal	Step 8: Make a Model or Prototype	Step 9: Test and Evaluate Design Using Specifications	Step 10: Refine the Design	Step 11: Modify and Present for Market	Step 12: Communicat Processes and Results		
Step 11: Modify and Present for Market  What changes (if any) did you make to your presentation after considering data and feedback in the Test and Evaluate Design Using Specifications and Refine the Design steps of this project?  If this were for an actual new drug proposal (rather than a fict							Presentation of the Product  The Pecha Kucha Mystery Disease Presentation must include:  1 A slideshow (Google Slides, PowerPoint, Keynote) containing exactly 20 slides with each containing an image that is timed to be displayed for 20 seconds before automatically moving to the next slide.  2 One or more of the images in the slideshow must be a 2-D model or animation that shows your drug innovation's proposed mechanism of action.  3 A flowchart or timeline showing a proposed clinical trial for the drug innovation.  4 Features that are targeted to your specific audience. (For example, if your target audience is non-English speaking, it may be helpful to add pages that are translated in that language or record a second PSA video with a voiceover in the native language of that group.)						
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Engineering	g Design Pro	cess Journal									
Step 1: Define the Problem	Step 2: Brainstorm	Step 3: Research and Generate Ideas	Step 4: Identify Criteria and Specify Constraints	Step 5: Explore Possibilities	Step 6: Select an Approach	Step 7: Develop the Design Proposal	Step 8: Make a Model or Prototype	Step 9: Test and Evaluate Design Using Specifications	Step 10: Refine the Design	Step 11: Modify and Present for Market	Step 12: Communicate Processes and Results
Summariz	e your resu	ate Process Its by answ est element	constraints ses and Re ering the f ts about yo	ollowing que pur present	ation?	3 How share know such at-ris Exploimpro	would your e it with a cooledge or voor as a group ik of your dimin the reast overwents you	presentations  presentations  presentations  presentations  presentations  ommunity to cabulary as of newly-disease?	on change that may n s a group c iagnosed p	if you were ot have the of drug rese patients or	e to e medical archers,