




FROM INNOVATION TO THE PATIENT:

The Pharmaceutical Research & Development Process

STEM²D Topic:
Science

Target Population:
Students, ages 11-14

From Innovation to the Patient: The Pharmaceutical Research & Development Process is part of the STEM²D Student Activities Series. Developed by FHI360 and JA Worldwide as part of Johnson & Johnson's WiSTEM²D initiative (**W**inning in **S**cience, **T**echnology, **E**ngineering, **M**ath, **M**anufacturing, and **D**esign), the series includes more than 10 interactive and fun, hands-on activities for youth, ages 11-18 globally.

FROM INNOVATION TO THE PATIENT:
The Pharmaceutical Research & Development Process

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ACTIVITY DESCRIPTION

This unique hands-on activity introduces students to pharmaceutical research & development — the process of developing new medicines that improve and save patients' lives.

ESTIMATED TIME

This session typically takes **60 minutes** to complete and should be conducted in one session.

STUDENT DISCOVERIES

Students Will

- Participate in a team-based learning experience.
- Learn how STEM²D — science, technology, engineering, math, manufacturing, and design — subjects are involved in the pharmaceutical research & development process.
- Build important STEM²D skills, such as collaboration, creative thinking, and problem solving.
- Recognize that STEM²D offers diverse and exciting career opportunities.
- Have fun experiencing STEM²D.

GETTING READY

Materials

- Computer with projector, speakers, and Internet access
- PowerPoint: The Pharmaceutical Research & Development Process
- Video: Molecule to Medicine, embedded in in the PowerPoint
- Activity Leader Checklist
- Tell My Story Form

STEM²D Skills

- Collaboration
- Communication
- Creative Thinking
- Critical Thinking
- Decision Making
- Drawing Conclusions
- Problem Solving
- Teamwork

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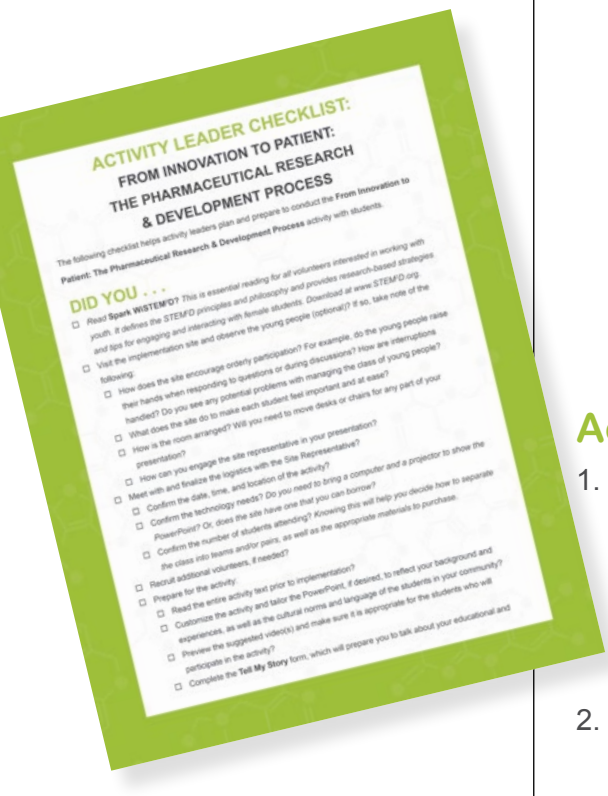
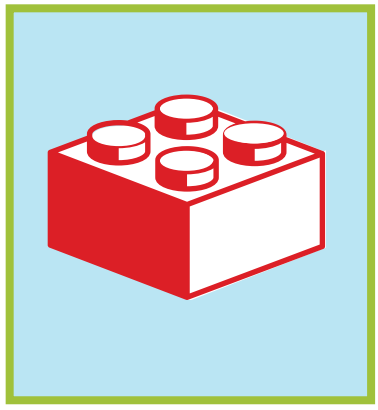
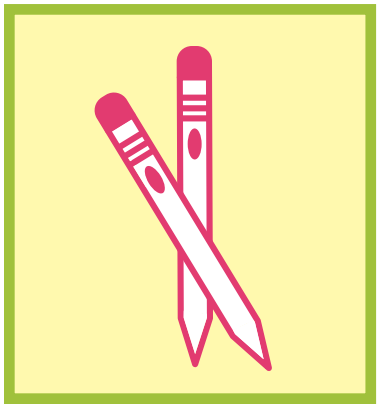

ACTIVITY LEADER CHECKLIST:
FROM INNOVATION TO PATIENT:
THE PHARMACEUTICAL RESEARCH
& DEVELOPMENT PROCESS

DID YOU . . .





- Student Handouts, *1 packet per student*
- Legos, *large box of Legos in various colors and sizes, minimum of 40-50 Legos per pair of students.*
- Pens / pencils, *1 per student*

Estimated Materials Cost

Activity leaders can expect to incur $40.00 - $50.00 in materials costs (if purchasing the Legos) when completing this activity with 20 students working in pairs. To eliminate this cost, consider asking colleagues to borrow Legos.

Activity Leader Preparation

1. Read **Spark WiSTEM²D**. This is essential reading for all volunteers interested in working with youth. It defines the STEM²D principles and philosophy and provides research-based strategies and tips for engaging and interacting with students. Download at www.STEM2D.org.
2. Review the Activity Leader Checklist (at the end of this document) for details and specific steps for planning, preparing, and implementing this activity.
3. See the **STEM²D Student Activities Overview** for additional information.

STEP-BY-STEP INSTRUCTIONS: FROM INNOVATION TO PATIENT: THE PHARMACEUTICAL RESEARCH & DEVELOPMENT PROCESS

1. **Welcome and Introductions (5 minutes)**
   - Start the PowerPoint.
   - Welcome the students.
   - Tell the students your name and your organization/company.
   - Ask students and volunteers to introduce themselves.
   - **(Today's Plan Slide)** Review the agenda. Explain that today the students will learn about the **pharmaceutical research & development process**—the process by which new medicines are discovered and made available to patients.
   - Indicate that they will also hear about the STEM²D careers involved in the process.

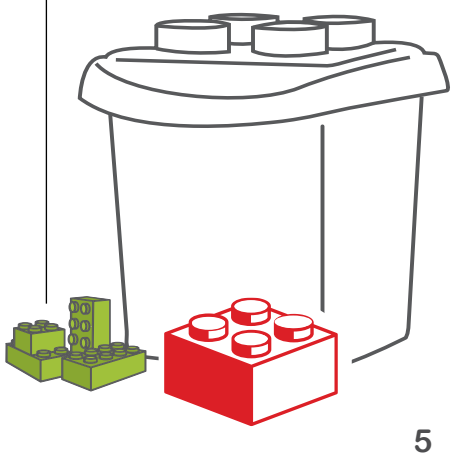
2. **Career Awareness: Science in the World of Work (10 minutes)**
   - Initiate a self-reflection and discussion activity. Have students complete the reflection questions on the Student Handouts. Encourage students to record what they currently know about STEM²D—science, technology, engineering, math, manufacturing, and — and careers in these fields. They can write or draw their responses.
   - **(My Story Slide)** Talk about your educational and career path. Use the Tell My Story form as the basis for your remarks. Be prepared to describe your job or a typical day. Provide information about your background, including:
     - When/Why you developed an interest in science.
     - The classes/courses you took in secondary school.
     - Your postsecondary path, including the institution you attended and your degree. *If you switched disciplines, make sure you explain why to the students.*
     - What your current position entails. *Be sure to include how you use science and what you do on a typical work day.*
     - How you are involved in pharmaceutical research & development.
   - Weave in facts about science and STEM²D careers:
     - Tell the students that your career is only one of the many careers available in the **STEM²D** disciplines.
     - Explain that STEM²D careers are **high-demand, high-growth careers** and are predicted to remain in demand over the next 10 years.

3. **Learning About the Pharmaceutical Research & Development Process (15 minutes)**
   - **(Molecule to Medicine Slide)** Set the Stage. Explain that "From Molecule to Medicine" is an award-winning movie created by Johnson & Johnson that offers an exciting behind-the-scenes journey through the pharmaceutical research and development process. Show the 5-minute video, which is embedded in the PowerPoint slide.
   - **(Pharmaceutical Research & Development Slide)** Review the video's basic concepts. Explain that pharmaceutical research and development (or R&D) is a complex endeavor.

CONVERSATION STARTERS:

Encourage discussion by asking open-ended questions:

- What do you know about STEM²D?
- What are some careers in the STEM²D sectors?
- When you consider your future what are you most excited about?
- Do you see yourself working in the STEM²D subjects? Why or why not?
- Do you see yourself working with others, for a large company, with your friends, for yourself? Why or why not?
- What does the perfect work day look like to you? Are you working alone or with others? Do you solve problems? Do you fix or build things?



KEY WORDS

- **Pharmaceutical Research & Development**

It may take up to 14 years to turn a molecule into a medicine that can change the way diseases are prevented, treated, and cured.

- The discovery and development of new medicines involve a range of scientific disciplines, including biology, chemistry, and pharmacology, among others.
- Highlight the following process:
  - **Basic research** is the first step. During this stage, researchers identify a **target**, such as a protein or nucleic acid, which regulates and controls a specific disease or condition. Typically, it involves industry researchers sifting through tens of thousands of compounds, looking for one that will hit the target.
  - **Preclinical trials** involve studying the most promising medicines using laboratory models and animal studies to answer basic questions about **safety** (risk to the patient) and **efficacy** (a desired result). If the medication is toxic, the scientists must go back to the drawing board and start all over again. Only one out of 50 medicinations pass this stage and make it to clinical trials in humans.
  - **Clinical Trials**, also known as clinical research, comprises a series of steps called phases, in which medications are tested on people or human tissues to make sure the medications are safe, tolerable, and have the desired result. Trials follow predefined plans or protocols, which are designed to answer a unique question, for which the subjects have to provide their consent for participation once all aspects of the protocol and known safety information have been explained. These trials are the most expensive phase, eating up 75% of development costs. For every five potential new medications entering clinical trials, one will make it to market.
  - **Approval and registration.** Government entities, such as the U.S. Food and Drug Administration (FDA), examine all submitted data related to the drug and make a decision whether to approve or not to approve registration of the drug.

- **(The R&D Journey Slide)** Remind students that it takes 14 years, on average, from innovation to making the medicine available to patients; approximately 1 in 100 research projects are brought from bench to market.
- Indicate that there are many different career opportunities in pharmaceutical research and development. Ask:
  - Based on the video, what types of careers do you think are available in the pharmaceutical research and development?
- After students provide several responses, highlight the following information:
  - Doctors, biotechnology scientists, chemists, biologists, pharmacologists, and biomedical engineers are just some of the many jobs available in this industry.
  - Stress the importance of building science skills during secondary school.
  - **(Science in the Workplace Slides)** If time permits OR you opted not to provide extensive details about your career, show one or more of the STEM²D Career Videos.

4. **Learning Activity: The Pharmaceutical R&D Challenge (20 minutes)**
   - **(Get Started Slide)** Instruct students to:
     - Choose a partner.
     - As a team, select at least 20 Legos.
     - Assemble the selected Legos in any manner to build a "target" – a protein or nucleic acid, which regulates and controls a specific disease or condition.
     - Complete the task in under 3 minutes.
   - **(Pharmaceutical R&D Challenge Slide)** After 3 minutes, call time and bring the large group back together. Introduce the challenge.
   - Indicate that students will work in pairs to navigate the R&D process and overcome potential challenges in order to develop a new "medicine" that can change the way diseases or conditions are treated, prevented, or cured.
   - Ask each team to give its newly assembled target to the

KEY WORDS

- STEM²D
- High-demand high-growth careers

KEY WORDS

- Basic research
- Target
- Preclinical trials
- Safety
- Efficacy
- Clinical trials
- Approval and registration

TIPS FOR WORKING WITH STUDENTS

Encourage discussion by asking open-ended questions:

- Tailor your remarks to meet student needs. Feel free to modify the language, examples, and analogies.
- Frequently check for understanding by asking questions, such as "What are the steps involved in making a new medicine available to patients?"
- Ask open-ended questions to stimulate discussion and student engagement. For example, ask: "How do you think the STEM²D subjects are involved in this process?"

student-pair on its right. All teams should now have a new target to address.

- **(Pharmaceutical R&D Challenge, Step 1: Basic Research Slide)** State:
  - You are now ready to begin basic research.
  - As a team, build a potential medicine that reversibly "fits" the target.
  - Choose Lego bricks of different colors and sizes to represent the active molecule that will interact with the selected target.
  - Assemble the Legos in any manner.
  - It is important that the medicine doesn't permanently bond to the target, you don't want the reaction to be irreversible in case there is a problem.
  - Therefore, you need to build the medicine so that the Lego pegs fit "male-to-male" with the target (or upside down from the way you would normally join Lego pieces).
  - In the real world, basic research takes about 4 years.
  - Today, you have 4 minutes to complete the task!
- Ask the teams if they have any questions and provide answers to those questions.
- Set your phone or other timer for 4 minutes and have students begin the task.
- **(The Pharmaceutical R&D Process, Major Steps Slide)** After 4 minutes call time. Indicate:
  - It's now time to see how your "medicine" fares in getting to market.
  - As you may recall, preclinical trials follow basic research.
- Ask students to recall the key information and goals of preclinical trials.
- **(Preclinical Trials (1 Year) Slide)** Be sure that the following key information and goals are identified:

- ✓ Preclinical trials test potential medicines with laboratory modeling and animal studies.
- ✓ There are three main goals of preclinical trials: 1) increase safety, 2) increase effectiveness, and 3) decrease side effects.

- **(The Pharmaceutical R&D Challenge, Step 2: Preclinical Trials Slide)** As part of the challenge, help teams review the findings from a recent preclinical trial of their medicine**.** Say:
  - Sometimes there are pitfalls in preclinical trials.
  - For example, the animal studies may reveal that the medicine is toxic. In our challenge, the red 2x2 Lego brick was found to be toxic in animals. If you used this ingredient, switch it out!
  - Or, the medicine could disintegrate. In our challenge, the yellow 1x1 Lego brick caused the pill to fall apart. If you used this Lego in your drug formulation, switch it out!
  - Did anyone make it through preclinical trials without needing to make revisions? *Most likely*, *very few teams will make it through preclinical trials without further modification. Stress this is why only a small number of potential medicines make it out of preclinical trials. Keep track of the number of potential medicines that advanced, untouched, into clinical trials.*
- **(The Pharmaceutical R&D Process, Major Steps Slide and Clinical Trials (4-8 Years) Slide)** Review the key concepts of a clinical trial:
  - Clinical trials follow preclinical trails.
  - Clinical trials are typically 4–8 years and involve three phases:
  - **Phase I:** Researchers test the new medication or treatment on a small number of healthy volunteers and patients to evaluate its **safety** (risk to the patient) and **tolerability** (degree to which adverse effects can be tolerated).
  - **Phase 2:** The medication is given to a larger group (20–300) of patients with the goal of safety and efficacy.

➤ Doctors, biotechnology scientists, chemists, biologists, pharmacologists, and biomedical engineers are just some of the many jobs available in this industry.

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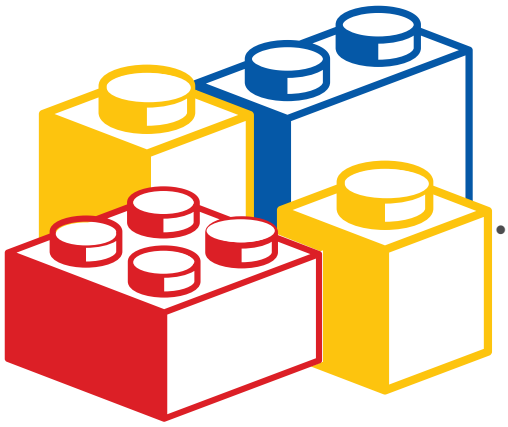
KEY WORDS

- Phase 1
- Tolerability
- Phase 2
- Phase 3
- Phase 4



- **Phase 3:** The new medication is tested on large groups of patients (300–3,000+) over many years and many locations to confirm its effectiveness, monitor side effects, and compare it to commonly used treatments.

- **(The Pharmaceutical R&D Process, Step 3: Clinical Trials Slide)** As part of the challenge, help teams review the findings of the clinical trial**.** Say:
  - Sometimes in clinical trials things do not go as expected.
  - For example, some patients may not be able to tolerate the medication or may get sick after consuming it. In our challenge, any green 2x3 Lego brick caused the patients to vomit. If your medication used this Lego, switch it out!
  - OR, the medication may not work as originally expected. In our challenge, the blue 1x2 Lego brick did not have the desired result. If you have this in the molecule, switch it out!
  - Did anyone make it through the clinical trials without needing to revise? *Keep track of the number of medications that advanced, untouched, to approval and registration.*
- **(Major Steps in the Process Slide and Step 4—Approval and Registration Slide)** Discuss the final steps of the pharmaceutical research and development process: Approval and Registration. Give the following information:
  - Even if the clinical trials are successful, the work is not done!
  - Challenges can still arise.
  - For example, another company could beat you to the market OR government agencies, such as the U.S. Food and Drug Administration (FDA), could have a new requirement.
  - Can you change your medication slightly, still have it fit the target, and meet all the earlier requirements? Remember: You cannot use the red 2x2, yellow 1x1, green 2x3, or blue 1x2 bricks!
- **(It Doesn't End Slide)** Say:
  - Once approved for patients, the company still has a lot to do to bring the new medicine to the marketplace.
  - Sales representatives must be trained in the use of the

new medication, the research, and the side effects, so that it can be introduced to doctors, patient advocates, hospitals, nurses, and other caregivers who are often hesitant to change their current practice.

- Even when the medicine is available to the public, clinical trials and research continue to ensure that it continues to be safe and has no unexpected or adverse side effects. New indications (uses) for the medication are also investigated and any new side effects are reported. This is known as **Phase 4.**
- Did any team make it to market unchanged?

- Congratulate these student-pairs on successfully discovering a new medication that has the potential to improve patient lives. Tell these teams that their new medication is 1 in 100 and only took 14 years in the making!

5. **Student Reflection (10 minutes)**
   - **(Reflection Slide)** Ask students to reflect on the activity. Have them spend a few minutes thinking about the following questions:
     - What did you learn about pharmaceutical research and development?
     - What did you learn about STEM²D careers and professionals?
     - Did your original thinking about STEM²D careers and professionals change? How?
     - Can you see yourself as a STEM²D professional? Why or why not?
   - Encourage students to record their thoughts on the Student Handouts.
   - After a few minutes, have students share their thoughts with their partner.
   - Call the large group back together after 5 minutes of sharing. Ask two or three student pairs to report what was discussed.
   - Thank students for actively participating. In closing, say:
     - There are many fascinating career opportunities in pharmaceutical research and development.

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Sales representatives must be trained in the use of the new medication, the research, and the side effects, so that it can be introduced to doctors, patient advocates, hospitals, nurses, and other caregivers who are often hesitant to change their current practice.

- I hope this activity broadened your knowledge of and interest in STEM²D and the diverse opportunities that are available.
- I encourage you to keep building your science knowledge and skills.
- You can do STEM²D!

Extended Learning

There are many ways to extend the learning of this activity:

- **Explore other industries.** Learn about the "value stream" or how other industries, such as the automobile, computer, or food industries, move from innovation to marketplace. As a team, research the industry and the phases of development. Compare and contrast with the drug discovery process. Note the STEM²D careers in this industry.
- **Go on a fieldtrip!** Visit a local company with research and development laboratories. Have students talk with employees about what they do and the STEM²D skills that are required.

Key Words

Here are some key words related to this activity:

Approval and registration is when the U.S. Food and Drug Administration (FDA) or other government entities examine all submitted data related to the drug and make a decision to approve or not to approve it.

Basic research is the first stage of pharmaceutical research & development; it involves extensive laboratory research.

Clinical trials, also known as clinical research, is the stage of development when potential medicines are tested on people to make sure they are safe, tolerable, effective, and have the desired outcome (efficacy). Clinical trials involve four phases:

- **Phase I:** Testing the potential medicine on a small number of healthy volunteers and patients with the goal of safety and tolerability.
- **Phase 2:** Testing the potential medicine on 20–300 patients with the goal of safety and efficacy.
- **Phase 3:** Testing the potential medicine on 300–3,000 or more

➤ **Only 1 in 100 new medications are brought to market each year; it takes 14 years, on average, from innovation to market. This process includes: basic research, preclinical trials, clinical trials, and approval/registration.**

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patients over many years and many locations with the goal of safety and comparison to standard of care.

- **Phase 4:** Post-marketing research gathers information from a larger and more diverse population, long-term effects of the potential medicine, and information on new uses for the medication.

Efficacy. The desired result.

High-demand, high-growth careers. Occupations predicted to have more positions available than qualified applicants over the next 10 years.

Pharmaceutical research & development. The process by which new medicines are discovered and made available to patients. This process involves basic research, preclinical trials, clinical trials, and approval and registration.

Preclinical trials are the second stage of drug development and involve potential drugs undergoing laboratory models and animal studies to answer basic questions about safety and effectiveness.

Safety: The risk to the patient.

STEM²D. The acronym used for the disciplines of science, technology, engineering, math, manufacturing, and design.

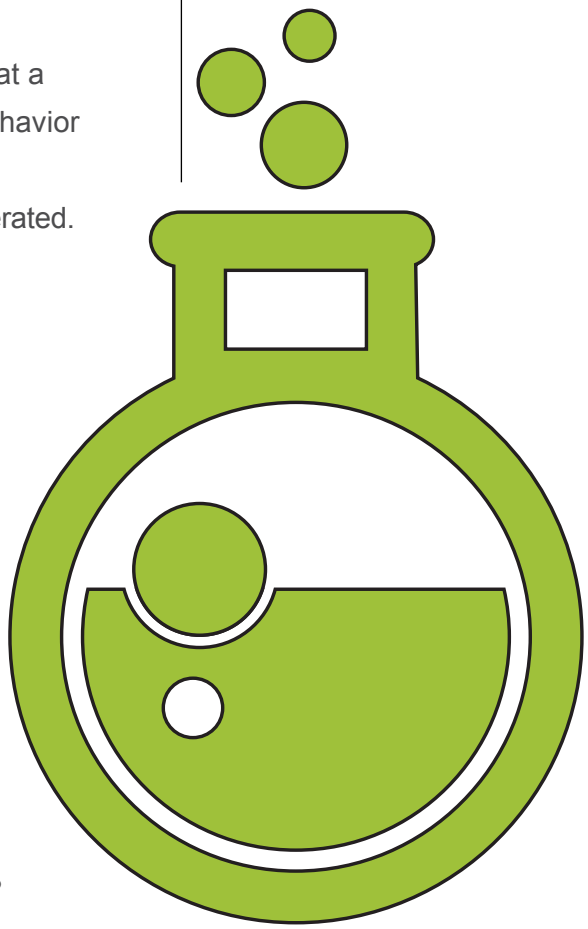
Target. A protein or nucleic acid within a living organism that a drug is directed to and/or binds to, resulting in a change behavior or function.

Tolerability. The degree to which adverse effects can be tolerated.

Activity Leader Reflections

After the activity, take a few moments to reflect on the following:

- What went well and what could be improved? What would you do differently next time?
- How comfortable did you feel talking about pharmaceutical research and development?
- Do you have a better understanding of STEM²D concepts?
- How useful was the information presented in the guide to implementing this lesson plan?
- Will you volunteer for this type of experience again?



Resources and References

Adapted from an activity developed by Holly Adams, Janssen Research & Development, Inc.

The following resources provide additional information or activities:

- US Library of Medicine. National Institutes of Health, Health & Human Services. Web August 15, 2016. https://www.nlm.nih.gov/services/ctphases.html

ACTIVITY LEADER CHECKLIST:

FROM INNOVATION TO PATIENT: THE PHARMACEUTICAL RESEARCH & DEVELOPMENT PROCESS

The following checklist helps activity leaders plan and prepare to conduct the **From Innovation to Patient: The Pharmaceutical Research & Development Process** activity with students.

DID YOU . . .

- ☐ Read **Spark WiSTEM²D?** *This is essential reading for all volunteers interested in working with youth. It defines the STEM²D principles and philosophy and provides research-based strategies and tips for engaging and interacting with students.*
- ☐ Visit the implementation site and observe the young people (optional)? If so, take note of the following:
  - ☐ How does the site encourage orderly participation? For example, do the young people raise their hands when responding to questions or during discussions? How are interruptions handled? Do you see any potential problems with managing the class of young people?
  - ☐ What does the site do to make each student feel important and at ease?
  - ☐ How is the room arranged? Will you need to move desks or chairs for any part of your presentation?
  - ☐ How can you engage the site representative in your presentation?
- ☐ Meet with and finalize the logistics with the Site Representative?
  - ☐ Confirm the date, time, and location of the activity?
  - ☐ Confirm the technology needs? *Do you need to bring a computer and a projector to show the PowerPoint? Or, does the site have one that you can borrow? Does the site have internet access? Can you use it during the activity to show the videos?*
  - ☐ Confirm the number of students attending? *Knowing this will help you decide how to separate the class into teams and/or pairs, as well as the appropriate materials to purchase.*
- ☐ Recruit additional volunteers, if needed?
- ☐ Prepare for the activity:
  - ☐ Read the entire activity text prior to implementation?
  - ☐ Customize the activity and tailor the PowerPoint, if desired, to reflect your background and experiences, as well as the cultural norms and language of the students in your community?
  - ☐ Preview the suggested video(s) and make sure it is appropriate for the students who will participate in the activity?

- ☐ Complete the **Tell My Story Form**, which will prepare you to talk about your educational and career path with the students? If desired, include key points about your story on the PowerPoint (see **Tell My Story Slide**).
- ☐ Determine how you will pair students? It is recommended that you randomly pair students; this will foster the skills needed to work with new people.

☐ Practice your presentation, including the hands-on, minds-on activity? Be sure to:

- ☐ Do the "Pharmaceutical Research & Development Challenge;" make sure you are able to easily explain the challenge and answer student questions, should the arise

☐ Obtain the required materials and photocopy the **Student Handouts**? *Be sure to secure 40-50 Legos of various colors and sizes per pair of students (see the* **Materials** *and* **Estimated Materials Costs** *sections). If cost is an issue, consider borrowing Legos from colleagues.*

☐ Set up the site appropriately for the activity? Specifically:

- ☐ Make sure tables and chairs are arranged to accommodate teams of students—four students per team. Each team will need an alarm kit.
- ☐ If additional volunteers are available, assign one adult to work with two or three teams.
- ☐ Set up the computer and projector for the PowerPoint presentation; be sure that speakers and an Internet connection are available.
- ☐ Have the alarm kits available for distribution to the teams during the "Time to Make Some Noise" portion of the activity.
- ☐ Bring a camera, if desired, to take photographs.

☐ Obtain and collect permission slips and photo release forms for conducting the activity if applicable?

☐ **Have fun!**

Tell My Story Form

This form will help volunteers serving as activity leaders prepare to talk about their **STEM²D** interests, education, and career path.

ABOUT YOU

Name: _____

Job Title: _____

Company: _____

When/Why did you become interested in STEM2D? _____

_____

_____

What do you hope young people will get out of this activity? _____

_____

FUN FACT

Share a little about your background. Ideas:

- Share a memory from childhood where you first had your spark or interest in STEM.
- Detail your journey; highlight what you have tried, what you learned, steps to success, etc.
- Failures or set backs are also great to talk about—difficulties, and/or challenges and how you overcame them.

EDUCATION AND CAREER PATH

What classes/courses did you take in secondary school and in college that helped or interested you most?

_____

_____

How did you know you wanted to pursue a STEM²D career?

_____

_____

What was your postsecondary path, including the institution you attended and your degree? *If you switched disciplines, make sure you explain why to the students.*

_____

What your current position entails. *Be sure to include how you use STEM²D on a typical work day.*

_____

_____

FROM INNOVATION TO THE PATIENT: THE PHARMACEUTICAL RESEARCH & DEVELOPMENT PROCESS

Student Handouts

Pre-Activity Brainstorming

Think about the questions listed below. Record your answers using phrases or pictures in the space provided.

What do you know about STEM²D—science, technology, engineering, math, manufacturing, and design?

What are some STEM²D careers?

What do you know about how medicine is created?

Reflection

Think about the activity and what you learned. Record your answers to the questions below using key phrases or drawing pictures.

What did you learn about pharmaceutical research & development?

What did you learn about STEM^{2}D careers and professionals?

Did your original thinking about STEM^{2}D careers and professionals change? How?

Can you see yourself as a STEM^{2}D professional? Why or why not?

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