uBEATS Teacher's Guide:

FDA Approval Process

(Grades 11-12)

This teacher guide is a supplementary text to support the use of the uBEATS "FDA Approval Process" module for grades 11-12.

To help students develop the knowledge necessary for an incredible future in health care, we created UNMC Building Excellence in Academics Through STEM (uBEATS), an online health science resource for Nebraska students.

UNMC uBEATS modules are short (15 minutes or less), interactive online health science modules to supplement curriculum taught in grades 6 – 12. These do not replace curriculum but are a supplement for teachers and students incorporating evidence-based information and UNMC expert guided material. Each module is chunked into sections with formative and summative assessments with immediate feedback provided.

Tips on how to utilize uBEATS modules:

- Internet access is required to view uBEATS modules.
- For those who have access to one-to-one technology, modules can be used in or outside of the classroom as a topic introduction, extension, or review.
- For classrooms without individual student devices modules can be used in whole group instruction. Formative assessment questions can use the teacher's preferred call and response method and summative assessment questions can be displayed on the board and answered individually by students or printed and distributed to students after viewing the module.

Objectives

- Describe the mandatory preclinical process that is conducted prior to the FDA approval process.
- Explain the importance and purpose of each clinical trial phase.
- Describe the types of facts that must be established prior to official FDA approval for each drug.

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Introduction

The path from demonstrating that a drug has promising therapeutic potential to the production of an approved drug by the FDA is a daunting, rigorous, and expensive process that involves several phases. The cost from taking a new drug from concept to market is estimated to be above $1.3 billion dollars and this process can take anywhere between 10-15 years. Each phase of the drug approval process serves a vital role in developing and ensuring that drugs that reach the marketplace are both safe and effective. In this module, the important features of each of the different trial phases will be outlined and discussed.

Prior Knowledge

Before beginning this module, the student should understand the Next Generation Science Standards (NGSS) featuring Three-Dimensional Learning.

Core Idea PS1.B. Chemical Reactions

- Many substances react chemically with other substances to form new substances with different properties. This change in properties results from the ways in which atoms from the original substances are combined and rearranged in the new substances. A Framework for K-12 Science Education

Science and Engineering Practices **NGSS**

- Constructing explanations and designing solutions

Crosscutting Concepts **NGSS**

- Structure and function

Key Terms/Vocabulary

United States Food and Drug Administration (FDA), preclinical, clinical, pharmacy, pharmacology, chemistry, toxicity, Investigational New Drug Application (IND), efficacy, dose, placebo, therapeutic, cohort, randomized trial, controlled trial, blinded trial, New Drug Application (NDA), pharmacokinetics, surveillance, pediatric, geriatric, indications, complications.

Science Standards

This module is related to the content of UNMC High School Alliance: Introduction to Pharmacy Science and Practice.

The profession of pharmacy is quite diverse; from medicinal chemistry and the discovery of novel therapeutic agents to the monitoring of pharmacologic effects in humans. Thus, the purpose of this class is to demonstrate to the student the wide range of expertise needed within a profession. Students will walk through the history of pharmaceuticals, how products are discovered and manufactured, and how to implement pharmacology into patient care. Finally, the students will discuss the future of medicine as seen with Personalized Medicine.

Nebraska's College and Career Ready Standards for Science 2017 Nebraska Science Standards

SC.HSP.3 Structure and Properties of Matter

- SC.HSP.3.3.D Evaluate a solution to a complex, real-world problem based on prioritized criteria and tradeoffs that account for a range of constraints, including cost, safety, reliability, and aesthetics, as well as possible social, cultural, and environmental impacts.

Extensions of the lesson

- To help students become more familiar with the Key Terms of this module, the teacher can use the vocabulary list for a classroom Word Wall or integrate the vocabulary into classroom word games during review sessions.
- To help the students see personal relevance, suggest that they examine the data sheet provided by the pharmacy for a prescription medication used in the home.
- As student misconceptions become apparent, the teacher may need to reinforce these important concepts:
  - The U.S. Food and Drug Administration (FDA) has a rigorous process for ensuring the safety and effectiveness of new drugs created by research. This approval process takes at least 10 years.
  - Before clinical trials can be conducted with humans, preclinical trials must be done with live animals to detect potential safety hazards of the new drug.
  - Phase I clinical trials are done with fewer than 100 human volunteers in order to determine safe dosing ranges and to identify common side effects. This phase is completed with only healthy individuals. It does not test to see how effective the medicine might be for a particular condition.
  - Phase II clinical trials test 100-300 volunteers who have the targeted condition. Some of the test subjects are given the new medicine and other test subjects are given a placebo. This phase is designed to find out how effective the drug is at various doses and methods of delivery.
  - Phase III clinical trials take the longest time and include the greatest number of volunteers (more than 1,000) in order to confirm that the drug is safe and effective for large cohorts of test subjects having the targeted condition.

- After these three phases of clinical trials successfully demonstrate that the drug is safe and effective, the New Drug Application can be submitted to the FDA for independent review. The drug can be manufactured and sold only if the FDA approves this application.
- Even if approval is granted, the FDA may require additional study in Phase IV clinical trials to assess long-term risks and benefits, and to monitor the drug's effects within special populations.

Enrichment

- For information about Healthcare Career Opportunities, see UNMC's Careers in Healthcare.
- Students should be watchful in current events for recent stories about prescription drugs (e.g., opioids).
- An example of a classroom activity is FDA Case Study.
- To make connections in your community, contact local universities, medical centers, drug manufacturers, and pharmacists.