Useful Background Information

All new drugs and medical/surgical devices have to be approved by the Food and Drug Administration (FDA). The products must be shown to be safe and effective. Approval is based on a staged process involving preclinical research (often done on animals) and a multiple-stage of clinical studies in humans (or in animals if the product is for veterinary medicine). This lesson explains how this process works. In the process, students will gain an appreciation for how difficult and expensive this process is.

The Veterinary Black Bag Program

Project Goals:

- Develop Veterinarian's Black Bags (VBBs) of instructional items and pamphlets for middle school teachers to support classroom visits by local veterinarians.
- Provide professional development for veterinarians and teachers on how to use items in the VBBs
- Promote inquiry-based thinking about health-related subjects while emphasizing the value of biomedical research and promoting careers in science.

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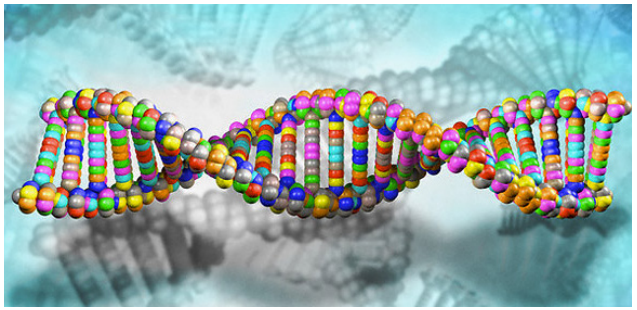
http://peer.tamu.edu/VBB/Summary.asp

Clinical Trial Process

Follow Up Lesson

The instruction in this module includes:
Presentation on *Clinical Trial Process*
Follow-up lessons on:
Clinical Trial Process
Data Analysis
Clinical Trial Business

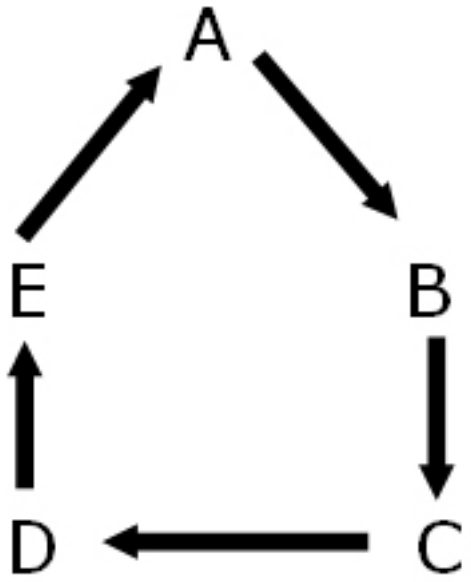


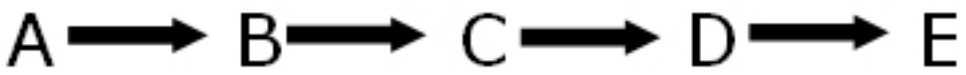
Summary of Lesson Content

This background material does NOT involve a visit from a veterinarian. It is a stand-alone instructional unit that explains how drugs and medical devices are developed. This unit could be considered pre-requisite to all the other units, because issues about research and development usually arise in the other units.

Objectives

1. Explain the difference between preclinical research and clinical trial testing.
2. Explain what a biochemical pathway is and why that helps in new-drug development.
3. Construct a concept map showing the relationships and processes in pre-clinical trials and Phase I-IV clinical trials.





Questions to Ask

Why do animals need to be used in pre-clinical trials?

Why do humans have to be used in the clinical trial process?

What effect do you think this process has on the time it takes to develop pharmaceuticals and medical appliances/procedures?

What effect do you think this process has on the cost of pharmaceuticals and medical appliances/procedures?

What, if any, changes in the process do you think could be made? Why?