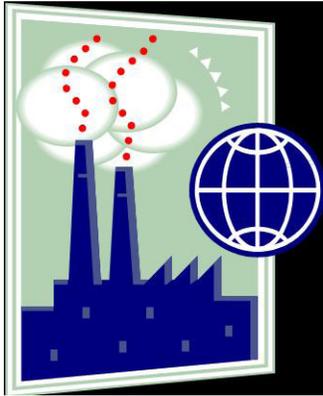


# THE PLAYERS



THE SPONSOR



CONTRACT RESEARCH ORGANIZATION (CRO)



STUDY SITE COORDINATOR

## 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.



PEER

PARTNERSHIP FOR ENVIRONMENTAL  
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<http://peer.tamu.edu/VBB/Summary.asp>

## Clinical Trial Business

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*

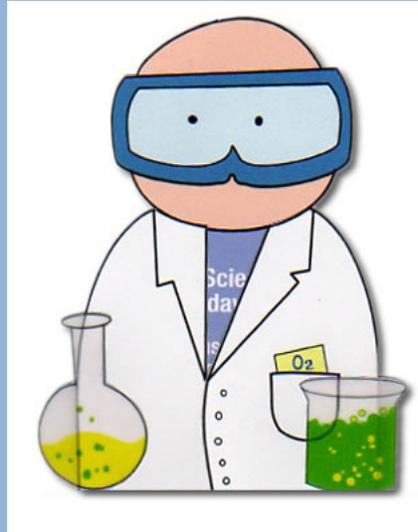
## Summary of Lesson Content

### Objectives

Students will explain the role of businesses in the pre-clinical trial process and the clinical trial process. They will also explain what a CRO or equivalent “in house” organization is and does.

Students will demonstrate an understanding of the problems encountered in testing of new drugs and medical procedures.

Students learn how companies identify their business needs to pursue clinical trial testing.



### Activity

Students will be assigned groups to develop a business plan for phase III clinical testing. They will be advised of key elements that make up a business plan:

1. What is it we (the company) want to do?
2. Do we have enough preliminary data and approval for this stage of development (Phase III)?
3. Who will do the testing and how will we have it done?
4. How can we know that the results support continued investment?
5. How long should it take?
6. What can we do to minimize costs without sacrificing the value of the results?
7. What are the bases for the cost estimates?

### Growing Need for Pharmaceutical Innovation

#### Growth in Health Care Spending as % of GDP

Country	1960	1970	1980	1990	2000
Austria	4.3	5.3	7.6	7.1	8.0
Canada	5.4	7.0	7.1	9.0	9.1
Germany	4.8	6.3	8.8	8.7	10.6
Britain	3.9	4.5	5.6	6.0	7.3
USA	5.1	6.9	8.7	11.9	13.0