How a Cancer Trial Ended in Betrayal

Part I—"Background"

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Birmingham, Alabama— After Bob Lange spent 8 weeks rubbing an experimental cream, BCX-34, from a prominent biotech company BioCryst, on the fiery patches on his body, researchers at the University of Alabama at Birmingham told him the drug was defeating the killer inside him. He felt grateful. "I believed it," he recalls. "I actually thought I might be cured."

But it was a lie. The drug had no effect on Lange's rare and potentially fatal skin cancer. And the two key people testing the drug knew it. Lange and 21 other patients were victims of fraud—a scheme made possible by the close tie between the university and the state's most prominent biotech company.

—*The Baltimore Sun*, June 24, 2001

In this case study, we will conduct a small-scale "clinical trial" in class to simulate the above real clinical trial that was conducted by the University of Alabama at Birmingham and the biotech company BioCryst to study the effects of an experimental drug, BCX-34, in treating skin cancer (malignant) cutaneous T-cell lymphoma. The objectives of this case study include the following:

- to learn the basics of scientific research in a clinical trial;
- to learn the principles of the scientific method; and
- to consider the ethical issues involved in clinical trials.

Please write concise answers to the following questions:

1. What was the disease being treated?
2. What was the drug being tested?
3. What was the *hypothesis* underlying the clinical trial?
4. What kind of *experiments* could be used to test the hypothesis?

Image Credit: Detail from "Job and His Wife" by Albrecht Dürer, c. 1504.
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Part II—"The Main Characters"

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The following are the main characters involved in the clinical trial that was conducted by the University of Alabama at Birmingham and the biotech company BioCryst. Please pay special attention to the job descriptions for the clinician and the scientist. You will be asked to play these roles in a simulated clinical trial.

- **Bob Lange and 21 other patients**, who had a rare and potentially fatal form of skin cancer, were participating in the clinical trial of BCX-34 directed by Dr. W. Mitchell Sams Jr., Chairman of the Department of Dermatology at the University of Birmingham at Alabama.

- **Harry W. Snyder Jr.—MD**
  Dr. Snyder was the scientist who ran the BCX-34 studies for BioCryst. Job description for the scientist:
  - Prepare the experimental drug for clinical use. Half of the tubes should contain the experimental drug and half should contain the placebo.
  - Generate random codes for the tubes. Keep a record (the KEY) on the code of the tube and whether it contains the experimental drug or a placebo. This KEY is confidential and should only be seen by the scientist during the clinical trial.
  - At the end of clinic trial, obtain the Clinical Record from the clinician and compare it with the KEY to correlate the treatment effect and the presence or absence of the experimental drug in the treatment.

- **Renee Peugeot—RN**
  Ms. Peugeot, a nurse, was given "total responsibility" by Dr. Sams to conduct the company-funded study of BCX-34 in clinics. Job description for the clinician:
  - Distribute coded tubes of cream to patients to rub on their skin lesions. Keep a record of the code on the tube and to which patient the tube is distributed. The codes on the tubes are randomized and do not contain information on whether a particular tube contains the experimental drug or a placebo.
  - Monitor the size of skin lesions by tracing the circumference. Record changes in the size and colors of the lesion during the treatment.
  - Keep a Clinical Record of the treatment effect on the patient. This Clinical Record is confidential and should only be seen by the clinician during the clinic trial.

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Part III—"Clinical Trial"

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The class will be separated into two groups. One group will play the role of the clinician (the Clinician Group), and the other group will play the role of scientist (the Scientist Group). One person from each group will be asked to play the role of Peugeot (a clinician) and Snyder (a scientist), respectively. This sub-group will be referred to as the "Peugeot-Snyder" group. The people in this sub-group will receive special instructions provided by the instructor.

Scientist Group Exercise

1. Assign codes (for example, using three-digit numbers: 867, 705, etc.) to 10 index cards that represent tubes of cream in the clinical trial.
2. Randomly pick 5 cards to contain the experimental drug and 5 cards to contain the placebo. Keep a record (the KEY for the clinical trial) of the code on each card and whether it contains the experimental drug or placebo. ***Keep the KEY confidential during the clinical trial.***
3. Give the coded cards to the Clinician Group.

Wait for the Clinician Group to hand over the Clinical Record. In the meantime, read about the Clinician Group exercise.

Clinician Group Exercise

Wait for the coded cards from the Scientist Group. In the meantime, read about the Scientist Group exercise.

1. After receiving the coded index cards from the Scientist Group, give one card to each "patient," who is represented by one sheet of paper that contains two photos of skin lesion (see Handout).
2. Monitor the size of skin lesions in the photo by tracing the circumference. Compare the lesion size *before* and *after* the treatment. Record the effect of treatment on each patient. ***Keep the Clinical Record confidential during the clinical trial.***

After the Scientist Group and the Clinician Group have completed the above tasks, the two groups convene to open the KEY and to correlate the treatment effects with the presence or absence of the experimental drug in the treatment.

Compare the results obtained by the large group (Scientist Group and the Clinician Group) with that obtained by the "Peugeot-Snyder" group. Discuss any discrepancies that might exist between the two.