Clinical Trial Study: Lowered Heart Attack Risk

Background: How a New Drug Gets Approved

An experimental drug is tested first in test tubes and petri dishes, then in live animals. These studies are called **preclinical trials.** Only after it appears that a drug is both safe and effective in animals is it allowed to proceed to clinical (or human) trials.

Clinical trials are conducted in **phases**. The studies in each phase address different questions:

In **phase I trials**, researchers test an experimental drug for the first time in a small group of people (20-80) in order to evaluate its safety, determine a safe dosage range, and identify side effects. Note that phase I trials make no determination about the drug's effectiveness in human subjects.

In **phase II trials**, the experimental drug is given to a larger group of people (100-300) to see whether it is effective and to further evaluate its safety. Note that these studies are designed to evaluate the effectiveness of the drug for only one particular use ("indication") in patients with the disease or condition under study and to determine the common short-term side effects and risks.

In **phase III trials**, the experimental drug is given to a large group of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare its effectiveness to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

Scenario

You and your group are executives in a major pharmaceutical company. Together you are responsible for the introduction to market of a new aspirin derivative. The company's scientists have developed a promising new drug called Spiron. It is closely related to aspirin, and **it is hoped** that it will have **fewer of the harmful effects** of aspirin (stomach upset) but **still have the same therapeutic effects** of aspirin, both acute (pain relief) and chronic (lower risk of second heart attack).

Spiron has showed great promise in animal testing as well as in human studies up through phase II clinical trials. You are now preparing to launch phase III human trials, the final experiments required to submit a new drug to the U.S. Food and Drug Administration (FDA) for final approval. If Spiron is successful in these studies, it can be prescribed to patients.

Your task is to design a study to evaluate the **chronic effects** of Spiron, in particular, **lowered heart attack risk, as well as any harmful side effects.**

Assignment

Your task is to design a study to evaluate the **chronic effects** of Spiron, in particular, **lowered heart attack risk**, as well as any harmful side effects.

Use the space provided below and the "Questions for Thought" to brainstorm ideas about how you will design this study. When you have an experimental design that you think is complete, **record it in your laboratory notebook.**

Questions for Thought

Focus on the following questions when considering your experimental design. These need not be done in any particular order, and in fact should be considered together.

1. What are you going to measure, and how are you going to measure it? In other words, what will be the assay in your study?

2. Who will you recruit as subjects for your study?

3. In detail, describe how you will collect data from your subjects. Will you need to follow up with your subjects? Why and how?