Name: \_\_\_\_\_ Date: \_\_\_\_\_

**Directions:** Answer the following questions as you move through the game.

0. **Use the space below to take notes** on the company and vaccine you choose.

1. **Name and describe** the <u>TWO</u> types of pre-clinical trials mentioned.

2. **Name** <u>ONE</u> way an IND application differs from a BLA form.

3. **Phase III:** For each of the following phase III results fill out the table below.

Scenario	Show your work	Decision
Study size: 2000 Number of sick: 157		
Study size: 1500 Number of sick: 405		
Study size: 2100 Number of sick: 483		
Study size: 1650 Number of sick: 511		
Study size: 1800 Number of sick: 216		

4. **Quality Control**: For each of the given quality control scenarios fill out the table below.

Scenario	Show your work	Reason for/against
After testing 4,730 vaccine batches, 1,419 batches have congealed		

After testing 30 vaccine batches, 6 batches have a slightly higher temperature	
After testing 3,120 vaccine batches, 140 batches have a different color	
After testing 400 batches, 48 batches have been corrupted by a miscommunication between two employees	

5. **Name** <u>THREE</u> items required to be on a vaccine label.