Name: _____**KEY**_____ **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 TWO types of pre-clinical trials mentioned.

   Animal - Researchers administer the vaccine to animals, and later try to infect them with the targeted pathogen. The appropriate animal model can be valuable in determining the potential immune response in humans.

   Cell and Tissue Culture - Candidate vaccine viruses are grown in mammalian tissue culture of cells with a finite lifespan. The virus is then extracted, purified, and tested or modified.

2. **Name** ONE way an IND application differs from a BLA form.

   Could include any of the following, or any variations of the following (can also include any responses not mentioned if supportive evidence is given)

   - IND precedes a BLA
   - IND is submitted after pre-clinical trials
   - BLA is submitted after clinical trials

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	Efficacy = (2000-157)/2000*100 Efficacy = 92.15%	Viable for use, continue with this formula
Study size: 1500 Number of sick: 405	Efficacy = (1500-405)/1500*100 Efficacy = 73%	Not viable for use as efficacy is too low

Study size: 2100 Number of sick: 483	Efficacy = (2100-483)/2100*100 Efficacy = 77%	Not viable for use as efficacy is too low
Study size: 1650 Number of sick: 511	Efficacy = (1650-511)/1650*100 Efficacy = 69.03%	Not viable for use as efficacy is too low
Study size: 1800 Number of sick: 216	Efficacy = (1800-216)/1800*100 Efficacy = 88%	Viable for use, continue with this formula

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	1419/4730 = 0.3 0.3 (100%) = 30%	30% of the batches congealed, which is a rather large percentage. This indicates a major mistake made during the production process.
After testing 30 vaccine batches, 6 batches have a slightly higher temperature	6/30 = 0.133... 0.133 (100%) = 20%	20% of the batches are different, while smaller than 30%, is still not small enough. This indicates a major mistake made during the production process.

After testing 3,120 vaccine batches, 140 batches have a different color	140/3120 = 0.045 0.045 (100%) = 4.5 %	4.5% of the batches have a different color, a relatively small percentage
After testing 400 batches, 48 batches have been corrupted by a miscommunication between two employees	48/400 = 0.12 0.12 (100%) = 12 %	12% of the batches are different, however, not due to the process, but by human error. Therefore, the employees should be reprimanded and our formula retested (just in case).

5. **Name** THREE items required to be on a vaccine label.

   Answers could include any of the following:

   - Highlights limitation statement
   - Drug names, dosage form, route of administration, and controlled substance symbol
   - Initial U.S. approval
   - Boxed warning
   - Recent major changes
   - Indications and usage
   - Dosage and administration
   - Dosage forms and strengths
   - Contraindications
   - Warnings and precautions
   - Adverse reactions