Human Clinical Trials

*Most often used in developing __________________ drugs.

Are the following statements, Phase 1, Phase 2 or Phase 3?

1. _____ Uses test to determine a drug’s effectiveness.
2. _____ Involves 1,000-3,000 volunteer patients.
3. _____ Takes approximately two years.
4. _____ Takes approximately three years.
5. _____ A drug’s interaction with the human system, including how it is absorbed, distributed, metabolized and excreted and duration of effect is determined.
6. _____ Conducted to confirm the results of earlier tests and further identify any adverse reactions.
7. _____ Involves a small number of healthy volunteers.
8. _____ Takes approximately one year
9. _____ Animal and human tests are conducted at this stage as researchers continue to assess the safety of the drug
10. _____ Involve 100-300 volunteer patients

After human clinical trials are completed, a firm files a ______ with the _____________. NDA stands for ____________ ____________ ____________.

Currently it takes approximately ______ years from initiation of animal and other lab studies through all phases of clinical _______________ and submission of ______ to the ________ for approval.

For each new medicine approved, the cost is ______________ of ____________ of dollars.