

Choose the **BEST** answer. (4 points each)

Which of the following is **TRUE**:

(1) In a Phase I clinical trial of a drug,

- a) participants are healthy and we are testing safety
- b) participants are patients and we are testing safety
- c) participants are patients and we are testing efficacy (and safety)
- d) participants are healthy and we are testing efficacy (and safety)

(2) CRISPR-CAS9 is a gene editing tool with potential to treat HIV that works by

- a) binding to the p24 HIV antigen and cleaving it to make it harmless
- b) using a special RNA sequence to find the viral genes in cell DNA to delete by the CAS enzyme
- c) using the CAS DNA sequence to bind irreversibly to the viral genome
- d) inserting genes into cell DNA that provide immunity to HIV

(3) Drug approval by the FDA involves:

- a) approval of an IND at the end of clinical trials and of an NDA before clinical trials
- b) approval of both an IND and an NDA before clinical trials start
- c) approval of both an IND and an NDA at the conclusion of successful clinical trials
- d) approval of an NDA at the end of clinical trials and of an IND before clinical trials

(4) The FDA:

- a) can order removal of a drug from the market, even if previously approved
- b) evaluates clinical trial data submitted before approving a drug
- c) controls the dose, formulation and labeling of prescription drugs on the market
- d) all of the above are true

(5) With respect to funding drug research, the NIH

- a) typically funds all aspects of drug development
- b) provides funding to academic researchers on an as-needed basis
- c) may use a competitive grant funding mechanism (RO1) providing ~\$1.25m/5 years
- d) does not allow grants to small biotech start-ups

(6) The structure at the right is

- a) acyclovir
- b) tamiflu
- c) fentanyl
- d) amantadine

