

Please complete this quiz by recording your answers on the answer sheet provided.

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Questions for Module 2 part 1: Buncher Clinical Trials

1. How would you characterize “placebo effects” in clinical trials?
 - a. Placebo effects are not real and therefore not important in clinical trials.
 - b. Placebo effects might reduce disease but do not cause side effects.
 - c. Placebo effects might be both positive and negative.
 - d. Placebo effects can cause side effects but do not reduce disease.
2. Which of these groups can be characterized as NOT blinded even when the study is blinded and the group will stop the study early if efficacy has been demonstrated in the middle of the trial?
 - a. Institutional Review Board
 - b. Data Safety and Monitoring Committee
 - c. Informed Consent Committee
 - d. Protocol Committee
3. Which of the following “control groups” is optimal to test a new medication when there are already two effective medications available for that indication?
 - a. Placebo control
 - b. Positive control
 - c. Historical control
 - d. Patient serves as own control
4. In “double blind” or “double masked” clinical trials, which of the following groups, while preferably or OK to blind, is not necessary to be blinded?
 - a. Patients in the study
 - b. Parents of pediatric patients
 - c. Treating physician
 - d. Evaluating physician
 - e. Interviewers
5. Many principles of clinical trials are up to hundreds or more years old. One principle is newer (actually about 70 years old). Which is the newest principle?
 - a. Blindfold the participants
 - b. Use a controlled comparison
 - c. Randomly allocate the treatments
6. When do you usually un-blind the investigators in a double blind clinical trial?
 - a. As soon as the last patient has taken her/his last medication
 - b. As soon as the last patient completes the trial period
 - c. After all decisions on who to include in the trial based on the actual circumstances in the study (e.g., how much medication was taken) are made
 - d. After the data from the study have been analyzed by the statisticians but before writing the final report
7. The concept of an “intent-to-treat” analysis is
 - a. One decides on the inclusion and exclusion criteria before the study
 - b. One expresses in the informed consent the type of patients who are expected to participate in the study
 - c. An expression of the material in a study protocol that describes the patients in the study

- d. A concept that the study groups will be analyzed as the trial was randomized and that the principal result will not be based on groups created based on the outcome results in the study.
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Questions for Module 2 part 1: Daniels Study Design

1. Which of the following study designs is interventional rather than observational?
 - a. Case-control study
 - b. Cohort study
 - c. Cross-sectional study
 - d. Clinical trial
 - e. Ecological study
2. Which of the following study designs is usually retrospective?
 - a. Case-control study
 - b. Cohort study
 - c. Cross-sectional study
 - d. Clinical trial
3. The most likely selection bias in a cohort study is due to
 - a. Selection of individuals with the exposure of interest
 - b. Loss to follow-up
 - c. Selection of individuals at risk for common disease
 - d. Evaluation of time between exposure and disease
4. It is easiest to obtain measures of disease incidence in which of the following study designs?
 - a. Case-control study
 - b. Cross-sectional study
 - c. Cohort study
 - d. Case series
 - e. Ecological study
5. A claim that something causes harm is best evaluated by
 - a. Case series
 - b. Cohort study
 - c. Randomized trial cross-sectional study
 - d. Ecological study
6. The effectiveness of a treatment or intervention is best evaluated by which of the following study designs?
 - a. Case series
 - b. Cohort study
 - c. Randomized trial
 - d. Cross-sectional study
 - e. Case-control study