

# Essential Element 2: Quiz

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### Results

#### Score for this question group: 40%

1. When evaluating the ethics for a clinical trial, active comparator, placebo, and standard of care should be considered.
  - True Your answer
  - False
2. There is general agreement that placebo-controlled trials pose less risk of harm to individual research participants than active control trials.
  - True Your answer
  - False
3. All of the arms of a study should be evaluated against the standard of care that research participants would or could receive if not enrolled in re...
  - True
  - False Your answer
4. In a clinical trial, the choice of control impacts: (Check all that apply)
  - Ethical acceptability
  - Endpoint that can be studied
  - How results can be interpreted
  - Degree to which bias can be minimized
  - Public and scientific credibility of results
  - Acceptability of results by regulatory authorities Your answer
5. The Council for International Organizations of Medical Sciences (CIOMS) and the World Medical Association (WMA) recommend that research participant...
  - True
  - False Your answer
6. What can influence the selection and use of active controls?
  - a) Ineffective comparator (type, dosage, regimen)
  - b) Selection of patient population
  - c) Availability and accessibility of effective intervention
  - e) All of the above Your answer
  - f) A and C only
7. Which of the following statements are true? (Check all that apply)
  - A trial with an active comparator is considered one of the least reliable ways to demonstrate safety and efficacy of an intervention because it provides a valid baseline to distinguish between effective treatment and ineffective treatment.
  - When the use of placebo control can reasonably be expected to result only in temporary or minor discomfort, it is generally considered ethical to use placebo. Your answer
  - A placebo-controlled trial can be justified if there are no established effective interventions for the treatment of the disease or condition under study.
  - When a placebo-controlled trial is preferred scientifically, but there is greater than temporary or minor discomfort, it is ethical to proceed without establishing risk management strategies.
8. What does "standard of care" refer to? (Check all that apply.)
  - The best available care for a specific condition anywhere in the world.
  - What a reasonable physician would do in prescribing care to a patient. Your answer
  - Consensus of the medical speciality or accepted treatment guidelines in a particular part of the world.
  - Regimen chosen by the physician if no single standard exists.

9. Which of the following questions should be considered for choosing a control?
- Is standard treatment considered to be effective?
  - Are there medically sound reasons to use placebo?
  - Could this trial benefit future patients to the point that a reasonable person with an average degree of altruism and risk-aversiveness would consent to being randomized in this trial?
  - All of the above Your answer
10. For multi-regional clinical trials, researchers need to consider whether the proposed active control is available to all study sites and accessible...
- True Your answer
  - False

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