Essential Element 3: Quiz

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1. At the population level, it is important to determine if the study can achieve the stated outcomes and has the potential to answer the questions being asked.

    - ○ True
    - ○ False

2. At the *individual* participant level, the study should be reasonable and ethical, and safeguards against unnecessary or unacceptable risk or undue burden should be discussed in the protocol.

    - ○ True
    - ○ False

3. A participant in a study is informed that there is a broad range of options early in the trial and that the options will change as the study progresses without those changes being made transparent. What is this an example of?
(Choose the best answer)

    - ○ Use of unequal randomization
    - ○ Washout period for participants who need therapy
    - ○ Adaptive trial designs
    - ○ Continuing treatment with a failed therapy

4. A single arm, open-label efficacy study of a novel drug with patient-reported outcomes of mental health issues:

    - ○ Cannot easily be replicated and is potentially biased
    - ○ Is a scientifically valid, ethical study

5. Which points should be considered in the choice of study design?
(Check all that apply.)

    - ☐ Will the individual study participant improve his/her health through this study?
    - ☐ Is the chosen study design adequate to answer the question defined by objectives and hypotheses?
    - ☐ Are all the assessments, and their total number, necessary and not overly burdensome?
    - ☐ Does the design in any way compromise the individual or expose the participant to harm?

6. It is critically important in a first-in-human (FIH) study to justify the choice of dose given for the first time and the safety of any increase in dose.

    - ○ True
    - ○ False

7. Using unequal randomization by exposing two times or three times as many participants to the experimental drug or therapy than to the placebo is not ethical, even if it is statistically demonstrable that the sample sizes are adequate.

    - ○ True
    - ○ False

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