

### Knowledge Checks

**Directions:** Review the question below. Select which statement is **not** a role of a patient advisor for a medical device clinical study.

1. Which of the following statements is NOT a role of a patient advisor for a medical device clinical study?
  - a. Share insights on real-life experience with a medical condition that could be treated by a medical device.
  - b. Recommend strategies to enhance the recruitment of clinical study participants.
  - c. Receive treatment as part of a clinical study.

**Answer:** \_\_\_\_\_

**Directions:** Review the statement, select true or false.

2. Patient advisors can only provide input during the design stage of a medical device clinical study.
  - a. True
  - b. False

**Answer:** \_\_\_\_\_

**Directions:** Review the scenario below. Select which statement is an example of a suggestion a patient advisor might provide.

3. You are a patient advisor supporting a clinical study for a new medical device designed to monitor blood glucose levels. The study has been struggling to enroll enough participants. During a meeting, the research team asks for your feedback and suggestions to improve patient recruitment. Which of the following statements is an example of a suggestion a patient advisor might provide?
  - a. Connect with community organizations, local health care providers, and patient advocacy groups recommended by the patient advisor.
  - b. Don't provide benefits, such as transportation assistance.
  - c. Use a lot of medical language in the recruitment materials.

**Answer:** \_\_\_\_\_

**Directions:** Review the scenario below. Select which recommendation you might make to the clinical study team as a patient advisor.

4. During the same study, the clinical study team notices a high rate of drop out at a specific study step. As the patient advisor, which recommendations might you make to the clinical study team?
  - a. Tell participants not to follow the study protocol if it is causing discomfort or inconvenience.
  - b. Don't ask participants about their experience, like those who dropped out, and share information gathered to the research study team objectively.
  - c. Offer recommendations to reduce a particular burden of the study, such as adjusting the number of required clinic visits.

**Answer:** \_\_\_\_\_

**Directions:** Review the question below. Select which steps you would recommend to someone looking to learn more about patient advisors.

5. What steps do you recommend to someone looking to learn more about patient advisors?
  - a. Explore FDA's resources, including additional trainings and opportunities to engage with advisory committees.
  - b. Get connected with patient organizations to find out about upcoming
  - c. opportunities to be considered as a patient advisor.
  - d. Participate in patient panel discussions or surveys.
  - e. All of the above

**Answer:** \_\_\_\_\_

**ANSWER KEY:**

- 1. The correct answer is C.** Patient advisors may provide input at multiple stages of medical device development, including during clinical studies, but they are not study participants or caregivers of study participants.
- 2. The correct answer is B.** In addition to sharing valuable insights at all stages of a medical device clinical study (design, conduct, analysis, and dissemination of results and feedback), patient advisors can provide input into all stages of medical device development.
- 3. The correct answer is A.** Patient advisors can help to identify patient advocacy groups, community organizations, and local providers to help recruit patients.
- 4. The correct answer is C.** Reducing study burdens can help decrease dropout rates and improve results. Select the Continue button to continue.
- 5. The correct answer is D.** When looking to learn more about patient advisors, explore FDA's resources, get connected with patient organizations, and participate in patient panel discussions.