

Knowledge Checks

Directions: Review the statement, and then select true or false.

1. Patient-generated health data can be used in each stage of medical device development.
 - a. True
 - b. False

Answer: _____

Directions: Review the question below. Select which statement is not a potential benefit of using real-world data in clinical research.

2. Which of the following statements is not a potential benefit of using real-world data in clinical research?
 - a. Real-world data can give a broader view of how medical devices perform in real life.
 - b. Real-world data always capture relevant information based on patients' lived experience.
 - c. Real-world data can track how well a device works over time.

Answer: _____

Directions: Review the question below. Select all that apply.

3. Which of the following can be examples of how patient-generated health data are collected as part of a clinical study?
 - a. A person can check their heart rate several times a day using a smartwatch.
 - b. A person can report symptoms as they occur by answering survey questions on a mobile application.
 - c. Activity data such as the number of steps taken per day can be collected automatically by using a sensor or electronic counter.

Answer: _____

Directions: Review the question below. Select all that apply.

4. Which of the following are common sources of real-world data?
 - a. Electronic health records
 - b. Registry
 - c. A clinical study specific visit, not a part of routine care

Answer: _____

ANSWER KEY:

1. **The correct answer is A.** Patient-generated health data can help device companies design new devices or device features that better meet patients' needs. It can be a source of data for a clinical study. Also, in the Product Launch/Post-Market stage, it can help device companies and regulators spot safety problems that didn't show up in earlier testing.
2. **The correct answer is B.** Some potential benefits are that real-world data can provide information about how medical devices work in real life over time and across different groups of people. A consideration is that these data may, but do not always, include other relevant information, such as medical history.
3. **The correct answer is A, B, & C.** Patient-generated health data are information gathered by patients, not providers, such as information from a smartwatch, sensor, or mobile application.
4. **The correct answer is A & B.** Remember, real-world data come from sources like electronic health records or a registry. Real-world data do not come from a clinical study specific visit that is not a part of routine care.