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Question: 1

A device shows a safety concern before approval and, separately, a different concern after it is approved and marketed.

Which statement about reporting across these periods is correct?

- A. Reporting is required in neither period unless a participant files a complaint.
- B. Reporting obligations exist only before approval and end once the device is marketed.
- C. Safety reporting applies in both the pre-approval and post-approval periods.
- D. Reporting obligations begin only after approval, during post-market use.

Answer: C

Question: 2

A newly identified serious risk of the investigational device emerges during an ongoing trial.

What is required for participants already enrolled?

- A. Inform participants of the new risk only if they experience a related event.
- B. Update consent with the new risk and re-consent the enrolled participants.
- C. Note the risk in the study file and leave the enrolled participants uninformed.
- D. Apply the new information only to participants enrolled after the risk was identified.

Answer: B

Question: 3

A participant's compliance with a home-use device appears low based on device-usage data.

Which management response is appropriate?

- A. Discuss and re-instruct the participant, document it, and assess data impact.
- B. Take no action as long as the participant continues to attend visits.
- C. Record the participant as compliant to keep the site's compliance rate high.
- D. Remove the participant's data because low compliance makes it unusable.

Answer: A

Question: 4

A site is preparing for a possible inspection and reviews its essential documents and device accountability.

Which approach best reflects genuine inspection readiness?

- A. Create the missing records shortly before the inspection to present a complete file.
- B. Focus only on the documents most likely to be requested and set the rest aside.
- C. Rely on the sponsor to provide the site's records during the inspection.
- D. Maintain complete, current, accurate records throughout, not last-minute.

Answer: D

Question: 5

A sponsor is developing a risk-management strategy for a first-in-human implantable device study where prior human data are limited.

Which strategy best reflects sound risk management for this design?

- A. Treat the risks as minimal, taking the device's completed bench testing as sufficient.
- B. Use staged enrollment, close monitoring, and pre-defined stopping rules.
- C. Enroll the full planned study sample all at once.
- D. Rely on a post-hoc analysis to identify the study's risks after the enrollment has already been completed.

Answer: B

Question: 6

Before a device study begins, the site must confirm that specialized equipment is fit for use.

Which step best supports this?

- A. Assume the equipment is ready because it was used in a previous unrelated study.
- B. Qualify and calibrate the equipment and document its readiness before use.
- C. Rely on the manufacturer's delivery as sufficient confirmation of readiness.
- D. Calibrate the equipment only after the first participant procedure is performed.

Answer: B

Question: 7

Which best describes the ethical principle of fair (equitable) participant selection in a device trial?

- A. Selection is left to recruiter discretion without defined eligibility criteria.
- B. Selection favors the most easily available population to speed up study enrollment.
- C. Selection rests on scientific and safety criteria, not convenience or vulnerability.
- D. Selection targets vulnerable groups because they are more likely to agree to enroll.

Answer: C

Question: 8

In a device study enrolling adolescents, the protocol requires both a parent's or guardian's consent and the adolescent's participation.

Which combination correctly reflects the ethical requirement for these minors?

- A. Both consent and assent are set aside for these minors whenever the study is judged to be of minimal risk.
- B. The parent's consent alone is obtained, and the adolescent's own views are treated as an optional consideration.
- C. The adolescent provides consent for herself, and the parent is simply informed of the enrollment decision afterward.
- D. The representative consents, and the adolescent gives capacity-appropriate assent.

Answer: D

Question: 9

A site needs to manage the return of recalled investigational devices from participants who use them at home.

Which approach best maintains accountability and participant safety during the recall return?

- A. Identify affected participants, arrange safe return, and document disposition.
- B. Collect the returned units while leaving out any record of which participant returned each particular device.
- C. Ask the participants to discard the recalled units at home and then skip the return records for those units.
- D. Delay the recall return of the units until the participant's final scheduled study visit.

Answer: A

Question: 10

A coordinator must distinguish a protocol deviation from a protocol violation after a scheduling error in a device trial.

Which distinction is correct?

- A. Deviations and violations are identical terms with no meaningful difference.
- B. A deviation is more serious than a violation and always requires expedited reporting.
- C. A violation is a deviation affecting rights, safety, or data; not every one is.
- D. Every protocol deviation is automatically a protocol violation regardless of its impact.

Answer: C

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