ACRP
CCRA
ACRP Certified Clinical Research Associate

Latest Version: 6.0

Question: 1

A monitor is reviewing the design of a trial for a rare solid-tumor subtype in which very few patients are diagnosed each year. The protocol uses a single-arm design in which all participants receive the investigational therapy, with outcomes compared to a pre-specified historical benchmark rather than to a concurrent comparator group enrolled in the same trial. A site coordinator asks why a concurrent-comparator design was not used.
Which explanation best supports the sponsor's design choice?

A. Given the rarity of the tumor subtype, enrolling a large enough concurrent-comparator group within a reasonable timeframe would be difficult
B. A single-arm design was chosen because a historical benchmark controls for confounding as reliably as a concurrent comparator group would
C. A single-arm design was chosen because randomizing participants with a rare, serious tumor to a comparator arm would deny them the investigational therapy
D. A single-arm design was chosen because it measures the therapy's effect directly, whereas a randomized comparison only shows a difference between two groups

Answer: A

Question: 2

A participant withdraws permission for future trial visits but does not request removal of information already collected. The site proposes deleting all prior case report form data to honor the withdrawal. What should the monitor explain?

A. The participant must continue safety visits because prior data exist
B. The sponsor may collect new data without contact because the participant once consented
C. All prior data must be deleted whenever any form of withdrawal occurs
D. Stop future activity but retain prior data under the governing terms

Answer: D

Question: 3

A site replaces a mislabeled specimen tube but does not investigate why labels were repeatedly printed for the wrong visit. Which statement best describes the action?

A. It is preventive action because the error already happened

B. It is an effectiveness check because the tube was replaced
C. An immediate correction without root-cause action
D. It is a risk assessment because the site used a new tube

Answer: C

Question: 4

Across three visits, the monitor finds isolated missed assessments on different participants. Each was attributed to “staff oversight,” followed by reminder training, yet the pattern continues across different staff and shifts.
What is the strongest next step?

A. System-level root-cause analysis, CAPA, and effectiveness check
B. Close the findings individually because no single miss caused harm
C. Classify every miss as fraud because multiple staff are involved
D. Repeat the same reminder training after each new miss

Answer: A

Question: 5

During a monitoring visit at an epilepsy trial site, a CRA finds that a participant received a dose of investigational product that was double the protocol-specified amount due to a dispensing error, though the participant experienced no apparent adverse effects and the error was caught and corrected before the next dose. The monitor is determining how this finding should be characterized for reporting purposes.
Which characterization is most appropriate?

A. Not a deviation, because the error was identified and corrected by the site before the participant's next scheduled dose
B. A deviation attributable solely to the participant, since the investigational product dispensing error occurred outside the site's direct control
C. A deviation that should be evaluated as a potential violation, since a dosing error can affect safety and data integrity regardless of outcome
D. A minor protocol deviation that does not require classification as a violation, since no adverse effect occurred

Answer: C

Question: 6

What information should a trial-related contact report capture most clearly?

A. Only the monitor’s travel time
B. The participant’s full medical history
C. A prediction of the final study result
D. Who, what, when, decisions, and follow-up

Answer: D

Question: 7

While reconciling the investigator site file against the sponsor's trial master file for a NASH trial site, the monitor cannot find the protocol signature page documenting the PI's agreement to the current protocol version in either file. The coordinator recalls the sponsor collecting it at the initiation visit and believes the sponsor holds it; the sponsor's trial management team says the site was to retain the original and send a copy.
What should the monitor do?

A. Direct the site to file a copy of the protocol's title page in the investigator site file as a stand-in until the signed page is located.
B. Record it as missing from both files, and work with the site and sponsor to establish whether it exists, obtaining a signature if it does not.
C. Treat the document as non-essential, since the site's conduct of the trial already demonstrates that the PI agreed to the protocol.
D. Accept the site's account that the sponsor collected the page, and close the item as a trial-master-file matter for the sponsor's team to resolve.

Answer: B

Question: 8

Why must an IRB/IEC include members whose collective qualifications and perspectives support independent review?

A. Qualified, independent participant-protection review
B. To replace the investigator’s medical decisions
C. To manage the sponsor’s operational budget
D. To conduct source data verification for the investigator

Answer: A

Question: 9

A sponsor proposes excluding all participants older than the typical clinic population even though the investigational product has no identified age-related concern and the disease is common in older adults. Which issue should a monitor raise during protocol feasibility review?

A. Representativeness matters only after marketing and not during clinical development
B. It lacks a clear safety or scientific justification and limits representativeness
C. Older adults should be enrolled only in observational studies
D. A broader population removes the need for eligibility criteria

Answer: B

Question: 10

A device site reports an alarm that is not addressed in the protocol but is described in the current Instructions for Use. The investigator wants to improvise a reset sequence used for a similar commercial device.
What should the monitor advise?

A. Use the commercial-device sequence because the devices serve a similar purpose
B. Ask the monitor to perform the reset during the visit
C. Continue using the device while documenting the alarm as a minor issue
D. Use the current IFU and escalate through the authorized technical pathway

Answer: D

Thank You for Trying Our Product

For More Information – Visit link below:

https://www.examsboost.com/

15 USD Discount Coupon Code:

G74JA8UF

FEATURES

- ✓ 90 Days Free Updates
- ✓ Money Back Pass Guarantee
- ✓ Instant Download or Email Attachment
- ✓ 24/7 Live Chat Support
- ✓ PDF file could be used at any Platform
- ✓ 50,000 Happy Customer