DUMPSARENA

ACRP Certified Professional Exam

ACRP ACRP-CP

Version Demo

Total Demo Questions: 13

Total Premium Questions: 133

Buy Premium PDF

https://dumpsarena.co

sales@dumpsarena.co

sales@dumpsarena.co
dumpsarena.co

Topic Break Down

Topic	No. of Questions
Topic 1, Clinical Trial Operations	43
Topic 2, Study and Site Management	27
Topic 3, Ethical and Participant Safety Considerations	47
Topic 4, Data Management and Informatics	16
Total	133

QUESTION NO: 1

Who on the local site research study team is accountable for the unblinding documentation of IP?

A. Regulatory manager

B. CRC

C. Pharmacist

D. PI

ANSWER: D

Explanation:

PI is correct because the principal investigator has ultimate responsibility at the site for conduct of the clinical trial, including ensuring that investigational product (IP) is managed according to the protocol, applicable regulatory requirements, and sponsor instructions. Although the principal investigator may delegate operational activities—such as pharmacy handling, maintaining randomization materials, or preparing documentation associated with an emergency unblinding—the delegation does not transfer the investigator's overall accountability for appropriate site records and trial conduct.

Unblinding can affect trial integrity, subject safety, and the reliability of efficacy and safety data. The principal investigator must therefore ensure that any unblinding is authorized when required, performed according to the protocol's emergency code-breaking procedure, promptly documented in the applicable source and trial records, and communicated to the sponsor as specified. This oversight includes ensuring the documentation identifies the reason, timing, affected participant where applicable, personnel involved, and required notifications, while preserving blinding for staff who should remain blinded. ICH Good Clinical Practice assigns the investigator responsibility for investigational product accountability and for conducting the trial in compliance with the approved protocol. See ICH E6(R2) Good Clinical Practice Addendum and the FDA's Investigator Responsibilities guidance.

QUESTION NO: 2

During a multi-center, double-blind, placebo-controlled Phase III clinical trial evaluating a novel oncology drug, the following situation occurs:

An interim analysis performed by the DSMB reveals that the investigational product (IP) shows a statistically significant improvement in progression-free survival (PFS) compared to the placebo. However, a sub-group analysis indicates a higher incidence of Grade 4 hepatotoxicity in patients with pre-existing mild liver dysfunction.

The sponsor, upon reviewing the DSMB report, decides to unblind the affected sub-group to assess safety. The trial protocol specifies that unblinding should only occur if a life-threatening situation is identified.

What is the most appropriate next step the sponsor should take?

A. Immediately unblind the entire trial to ensure patient safety.

B. Submit the DSMB findings to the IRB/IEC and await their guidance before proceeding.

C. Conduct an urgent protocol amendment to include specific monitoring for hepatotoxicity and submit to the IRB/IE

D. Request the DSMB to conduct a full risk assessment and recommend whether the sub-group should be unblinded.

ANSWER: D

Explanation:

Request the DSMB to conduct a full risk assessment and recommend whether the sub-group should be unblinded. The DSMB is the independent body established to review accumulating trial data, including important safety signals and the benefit-risk balance, while preserving the integrity of a blinded trial. Grade 4 hepatotoxicity is a serious, clinically important signal that warrants urgent expert evaluation, particularly because it appears concentrated in participants with pre-existing liver dysfunction. However, the protocol limits unblinding to a life-threatening situation, so the sponsor should not independently depart from that prespecified safeguard merely to explore the signal further. The DSMB should assess the

severity, clinical outcomes, timing, plausibility, distribution by treatment assignment, and whether immediate protective measures are needed. Its recommendation can address whether targeted unblinding is justified, whether enrollment of the affected population should pause, and whether protocol or informed-consent changes are necessary. This approach protects participants while maintaining appropriate independence and minimizing operational bias from disclosure of treatment assignments. FDA guidance describes data monitoring committees as independent groups that monitor study data and make recommendations regarding trial continuation or modification; ICH Good Clinical Practice likewise emphasizes protection of trial participants and reliable trial conduct. See FDA Data Monitoring Committee Guidance and ICH Efficacy Guidelines.

QUESTION NO: 3

Which of the following should be considered when implementing a risk-based monitoring plan?

A. 100% source document review is mandatory.

B. Centralized monitoring must be incorporated in any trials.

C. Monitoring schedule must be pre-defined in the monitoring plan.

D. On-site monitoring frequency may change depending on the quality of the data.

ANSWER: D

Explanation:

On-site monitoring frequency may change depending on the quality of the data. Risk-based monitoring is a quality-management approach in which the sponsor identifies the trial processes and data that are critical to participant protection and the reliability of trial results, then tailors monitoring activities to the risks identified. Monitoring is therefore not static: findings from central review, prior monitoring, protocol deviations, data trends, site staffing changes, enrollment patterns, and the timeliness and accuracy of data can indicate that a site needs more intensive oversight or, where performance is consistently reliable, a less frequent on-site presence. The monitoring plan should describe the overall strategy and the processes for documenting and escalating findings, while allowing appropriate adjustments as risks emerge or change during the study. This adaptive approach helps focus resources on issues most likely to affect participant safety, rights, or data integrity, rather than applying the same visit frequency to every site regardless of performance. ICH Good Clinical Practice states that the extent and nature of monitoring should be based on considerations including the objective, purpose, design, complexity, blinding, size, and endpoints of the trial. See the ICH E6(R2) Good Clinical Practice Addendum and the ICH E6(R3) Guideline.

QUESTION NO: 4

A sponsor transfers database programming and data-cleaning activities to a CRO. A quality review later identifies that the CRO did not perform a required edit-check test before production release. Who retains ultimate responsibility for ensuring appropriate oversight of the transferred activity?

A. CRO

B. Principal Investigator

C. Sponsor

D. IRB/IEC

ANSWER: C

Explanation:

Sponsor is correct. A sponsor may transfer trial-related duties and functions to a CRO, but the sponsor retains ultimate responsibility for trial quality and data integrity. The sponsor must maintain appropriate oversight of the CRO, including qualification, documented responsibilities, performance monitoring, and escalation of significant deficiencies.

The CRO is responsible for performing the contracted work in accordance with agreed requirements, and its failure requires investigation and corrective action. However, delegation does not transfer the sponsor's overarching accountability. The investigator is not responsible for sponsor-level database controls, and the IRB/IEC does not oversee operational validation of a sponsor's data-management vendor.

QUESTION NO: 5

Prior to initiation of a clinical trial, review by an IRB/IEC is required for which of the following documents?

A. Protocol, informed consent, and clinical trial agreement

B. IB, site coordinator CVs, and information about payments and compensation available to subjects

C. Protocol, IB, and information about payments and compensation available to subjects

D. Protocol, site coordinator CVs, and clinical trial agreement

ANSWER: C

Explanation:

Protocol, IB, and information about payments and compensation available to subjects is correct because these materials give the IRB/IEC the core information needed to make its prospective ethical review before trial activities begin. The protocol describes the study's scientific rationale, objectives, design, procedures, eligibility criteria, and safety monitoring; this enables the committee to determine whether risks are reasonable in relation to anticipated benefits and the importance of the knowledge expected. The Investigator's Brochure provides the available nonclinical and clinical information about the investigational product, allowing an informed assessment of foreseeable risks and appropriate safeguards. Information on payments and compensation available to subjects must also be reviewed so the IRB/IEC can evaluate whether payment arrangements or reimbursement could unduly influence a person's decision to participate and whether injury-related compensation information is ethically and clearly presented. ICH Good Clinical Practice expressly identifies the protocol, Investigator's Brochure, and available subject-payment/compensation information among the documents an IRB/IEC should obtain for review. This review is part of the independent protections that must be in place before a sponsor initiates a trial at a site. See ICH E6(R2) Good Clinical Practice, section 3.1.2 and the FDA's Institutional Review Boards Frequently Asked Questions.

QUESTION NO: 6

A participant experiences an acute medical emergency during a blinded trial. The treating physician states that knowledge of the assigned treatment is necessary to make an immediate treatment decision. What is the MOST appropriate action?

A. Wait for sponsor authorization before unblinding under any circumstances.

B. Unblind all participants at the site to preserve consistency in study conduct.

C. Unblind the participant only through the protocol-defined emergency procedure.

D. Withhold treatment until the next scheduled safety assessment.

ANSWER: C

Explanation:

Unblind the participant only through the protocol-defined emergency procedure is correct. Blinding should be preserved whenever possible because it protects the integrity of the trial. However, participant safety takes precedence when treatment assignment is necessary for immediate clinical management. The investigator should use the approved emergency unblinding process, disclose only the information needed for care, and document the reason, timing, and personnel involved.

Delaying medically necessary care to preserve the blind is inappropriate. Routine unblinding of the participant, investigator, or site team without a clinical need can bias subsequent assessments. Contacting the sponsor may be appropriate when feasible, but it must not delay an emergency procedure required for participant safety.

QUESTION NO: 7

During device accountability reconciliation, the coordinator finds that one investigational device is recorded as received from the sponsor but cannot be located in the device storage area or linked to a participant. What should the site do FIRST?

A. Create a replacement accountability entry so that the received and available quantities agree.

B. Immediately secure available inventory, verify records and locations, and notify the PI and sponsor of the discrepancy.

C. Wait until the next monitoring visit to determine whether the monitor can locate the device.

D. Assign the device to the next eligible participant if it is later found.

ANSWER: B

Explanation:

The site should immediately secure the available inventory, verify the accountability records and storage locations, and notify the PI and sponsor of the discrepancy according to the study procedures. Investigational device accountability must permit reconstruction of device receipt, use, return, and disposition. A missing device may represent a documentation error, a storage error, an unauthorized use, or an actual loss, and it requires prompt investigation and escalation.

Creating a replacement accountability entry without determining what occurred would compromise the record. The site should not wait until routine closeout reconciliation, because timely investigation may identify a participant-safety issue, a security concern, or a need for sponsor-directed corrective action.

QUESTION NO: 8

A root cause analysis should be:

A. Specific to a clinical trial.

B. Written by the investigator.

C. Validated before use in a CAPA.

D. Focused on issues of non-compliance.

ANSWER: D

Explanation:

Focused on issues of non-compliance. Root cause analysis is a structured quality-management activity used after a deviation, error, recurring deficiency, or other instance of non-compliance is identified. Its purpose is not merely to describe what happened or assign responsibility; it is to determine the underlying process, system, training, communication, oversight, or control failures that allowed the issue to occur. Understanding those underlying causes enables the clinical-trial team to develop corrective actions that address the present problem and preventive actions that reduce the likelihood of recurrence.

This focus supports protection of participant rights, safety, and well-being, as well as the reliability of trial data. ICH Good Clinical Practice requires quality management to identify important risks and to implement actions that address issues affecting trial conduct and data reliability. A well-documented analysis of a non-compliance event provides the evidence-based foundation for a proportionate corrective and preventive action plan, including ownership, timelines, effectiveness checks, and escalation where appropriate. See the ICH E6(R2) Good Clinical Practice addendum and the FDA's Corrective and Preventive Actions information.

QUESTION NO: 9

A centralized review identifies that one site has a substantially higher rate of missing primary-endpoint assessments than other sites. The site's data are otherwise entered on time, and no similar pattern is observed elsewhere. What is the MOST appropriate next step?

A. Increase routine monitoring frequency at every participating site.

B. Conduct targeted follow-up to determine the cause of the missing assessments.

C. Exclude the site's participants from the primary analysis immediately.

D. Revise the primary endpoint to use only data that are already available.

ANSWER: B

Explanation:

Conduct targeted follow-up to determine the cause of the missing assessments is correct. The cross-site pattern is a risk signal that may reflect site workflow failures, inadequate training, scheduling problems, protocol misunderstanding, or other factors that could affect the reliability of the primary endpoint. Targeted follow-up allows the sponsor to assess the scope and cause of the issue and determine whether corrective action, additional training, or an on-site visit is needed.

Increasing monitoring uniformly at every site is not proportionate when the signal is concentrated at one site. Automatically excluding the site's data before understanding the issue could introduce bias and does not address participant-protection concerns. Changing the endpoint after data collection has begun would not resolve a site-specific conduct problem.

QUESTION NO: 10

During a routine inventory, site staff find that investigational product was stored outside the protocol-required temperature range overnight. The product appears unchanged and is needed for a participant visit later that day. What should the site do FIRST?

A. Dispense the product because there is no visible evidence of damage.

B. Quarantine the affected investigational product and notify the sponsor.

C. Return the product to active inventory after documenting the excursion.

D. Destroy the affected product and record the destruction in the accountability log.

ANSWER: B

Explanation:

Quarantine the affected investigational product and notify the sponsor is correct. A temperature excursion may affect product quality, stability, potency, or suitability for use even when no visible change is apparent. The affected product should be segregated from usable stock, the excursion should be documented, and the sponsor or authorized designee should provide disposition instructions.

Dispensing the product based on its appearance is not appropriate because site personnel cannot independently determine whether the product remains acceptable for use. Replacing the product in active inventory risks accidental dispensing, while discarding it before sponsor direction could compromise accountability and prevent an appropriate investigation.

QUESTION NO: 11

The PI did not record the relationship to IP in the medical chart when assessing an adverse event. The CRC noticed the omission and brought it to the PI's attention. How should this be addressed?

A. The CRC should write a note to file.

B. The PI should amend the medical chart.

C. The PI should notify the monitor.

D. The CRC should amend the medical chart.

ANSWER: B

Explanation:

The PI should amend the medical chart. The investigator is responsible for the medical care of trial participants and for ensuring that source records are accurate, complete, contemporaneous, and attributable. An adverse-event assessment includes the investigator's clinical judgment regarding its relationship to the investigational product (IP). Because that judgment was omitted from the participant's medical/source record, the PI should complete the missing assessment using an appropriate, traceable correction or late entry consistent with institutional policy and applicable recordkeeping requirements. The amendment should preserve the original record, identify what was added or corrected, and be dated and signed or otherwise authenticated by the PI. This creates a reliable source record that supports the adverse-event information reported in the case report form and allows monitors, auditors, and regulators to reconstruct what occurred. The CRC appropriately identified the omission and escalated it to the PI, but the relationship assessment itself is an investigator determination and must be documented by the qualified investigator. ICH Good Clinical Practice requires investigators to ensure the accuracy, completeness, legibility, and timeliness of reported trial data and to maintain essential documents that demonstrate proper trial conduct. See ICH E6(R2) Good Clinical Practice Addendum and FDA Guidance: Electronic Source Data in Clinical Investigations.

QUESTION NO: 12

When designing a clinical trial, why is it important to define the study population?

A. To support the study objectives

B. To determine the study objectives

C. To determine where to conduct the study

D. To support subject recruitment to the study

ANSWER: A

Explanation:

Defining the study population is important **to support the study objectives**. The population specification translates the scientific question into clear eligibility criteria, including the disease or condition being studied, relevant baseline characteristics, and factors that could affect safety or outcome assessment. This ensures that enrolled participants are appropriate for evaluating the investigational product in relation to the protocol's stated primary and secondary objectives. A clearly defined population also permits meaningful interpretation of efficacy and safety findings, because the results can be attributed to a known group rather than an अस्पष्ट or heterogeneous collection of participants. It further establishes the population to which trial conclusions may reasonably apply, while protecting participants through criteria that account for foreseeable risks and contraindications. Under ICH Good Clinical Practice, the protocol must state the trial objectives and describe the selection and withdrawal of subjects, including inclusion and exclusion criteria. These elements need to align so that the design can generate reliable evidence responsive to its objectives. The U.S. FDA likewise identifies definition of the study population as a central design consideration for obtaining interpretable clinical evidence. See ICH E6(R2) Good Clinical Practice and FDA ICH E8(R1): General Considerations for Clinical Studies.

QUESTION NO: 13

The sponsor calls the site and informs the research team that they have decided to temporarily suspend the study. What step should the research team take FIRST?

A. Schedule participant for early termination visit.

B. Inform participant and assure proper care is provided.

C. Inform the monitor of the termination of the study.

D. Inform the IRB/IEC of the study closure.

ANSWER: B

Explanation:

Inform participant and assure proper care is provided. is the first action because protecting research participants' rights, safety, and well-being remains the investigator and site team's overriding responsibility throughout a trial, including when enrollment or study conduct is temporarily suspended. The team should promptly identify affected participants, communicate the suspension in an understandable and appropriately documented manner, and determine what immediate clinical follow-up, safety assessments, treatment transition, or referral is needed. This is particularly important for participants receiving an investigational intervention or those whose continued monitoring is necessary to manage potential risks after treatment stops. Participant communication should clarify how to obtain study-related medical assistance and whom to contact with questions or symptoms. The investigator must ensure appropriate medical care for adverse events and clinically significant laboratory findings, even after investigational treatment is discontinued. ICH Good Clinical Practice states that the rights, safety, and well-being of trial subjects are the most important considerations and that the investigator is responsible for adequate medical care related to trial participation. See ICH E6(R2) Good Clinical Practice and the FDA's guidance on investigator responsibilities for protecting study subjects.