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Quiz CCDM Certified Clinical Data Manager Realistic Reliable Dump

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SCDM Certified Clinical Data Manager Sample Questions (Q52-Q57):

NEW QUESTION # 52

When a hospitalized subject in a cardiovascular trial experiences a repeated but mild episode of tachycardia, the physician decides to extend the subject's hospital stay for continued observation. How would this event be characterized?

- A. Serious adverse event
- B. Spontaneous adverse event
- C. Adverse event
- D. Severe adverse event

Answer: A

Explanation:

This event qualifies as a Serious Adverse Event (SAE) because it resulted in a prolonged hospitalization, even though the episode itself was mild.

According to ICH E2A and GCDMP (Chapter: Safety Data Handling and Reconciliation), an adverse event is considered "serious" if it results in any of the following outcomes:

Death,

Life-threatening situation,
Hospitalization or prolongation of existing hospitalization,
Persistent or significant disability/incapacity, or
Congenital anomaly/birth defect.

The severity (mild, moderate, severe) describes intensity, while seriousness describes regulatory significance and medical outcome. Thus, a mild tachycardia episode leading to extended hospital stay meets the regulatory definition of an SAE.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Safety Data Handling and Reconciliation, Section 5.2 - Definition and Classification of Serious Adverse Events ICH E2A - Clinical Safety Data Management: Definitions and Standards for Expedited Reporting, Section II - Seriousness Criteria FDA 21 CFR 312.32 - IND Safety Reporting: Serious Adverse Event Definitions

NEW QUESTION # 53

A study team member wants to let sites enroll patients before the system is ready. Which are important considerations?

- A. Starting the study prior to the EDC system being ready will delay processing of milestone-based site payments
- B. If the study were audited, enrolling subjects prior to having the EDC system ready would become an audit finding
- **C. Without the ability to capture the data electronically, the data cannot be checked or used to monitor and manage the study**
- D. There is no way to identify, report and track adverse events and serious adverse events without the EDC system in place

Answer: C

Explanation:

Enrolling subjects before the Electronic Data Capture (EDC) system is ready poses major data integrity and compliance risks. The primary issue is that data cannot be accurately captured, validated, or monitored without the system in place.

Per the GCDMP (Chapter: Data Management Planning and Study Start-up), data collection systems must be fully validated, tested, and released before enrollment begins to ensure:

Real-time data entry and quality control

Proper tracking of adverse events (AEs/SAEs)

Audit trails and traceability for regulatory compliance

Option A highlights the most critical consequence - without an operational EDC, data collection and verification processes cannot occur, compromising data quality and study oversight.

While options B, C, and D may be partially true, they are secondary effects. The fundamental consideration is data capture capability and monitoring control, making option A correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Management Planning and Study Start-up, Section 4.2 - EDC Readiness and System Validation ICH E6(R2) GCP, Section 5.5.3 - Computerized Systems Validation Before Use FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.1 - System Qualification Prior to Data Entry

NEW QUESTION # 54

For a study, body mass index is calculated from weight and height. Which information is needed to document the transformation?

- A. User ID making the change and reason for change
- **B. Algorithm and algorithm version associated with the calculated value**
- C. Algorithm associated with the calculated value
- D. Algorithm documented in the Data Management Plan

Answer: B

Explanation:

When derived or calculated variables (like Body Mass Index) are created, it is essential to document the algorithm used and its version to ensure full data traceability and reproducibility.

According to GCDMP (Chapter: Database Design and Derived Data), every derived field must include metadata describing:
The derivation algorithm (e.g., $BMI = \text{weight} [\text{kg}] / \text{height}^2 [\text{m}^2]$)

The version of the algorithm (if updates or revisions occur)

Any associated data sources or transformation rules

This ensures consistent calculation across systems, prevents discrepancies during regulatory submissions, and aligns with FDA and CDISC documentation expectations.

Option B lacks version control, which is critical for traceability. Option C describes audit trail data (not derivation metadata), and

option D refers to broader documentation, not specific algorithm traceability.

Hence, option A (Algorithm and algorithm version associated with the calculated value) is the correct and compliant answer.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Derived Data and Algorithms, Section 5.3 - Documentation and Metadata Requirements ICH E6(R2)
GCP, Section 5.5.3 - Derived Data and Validation Traceability FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Data Definitions (Define.xml)

NEW QUESTION # 55

A sponsor may transfer responsibility for any or all of their obligations to a contract research organization. Which of the following statements is true?

- A. A description of each of the obligations being assumed by the contract research organization is required.
- B. Any written description is not transferred to the contract research organization.
- C. A description of each of the obligations being transferred to the contract research organization is not required.
- D. A general statement that all obligations have been transferred is acceptable.

Answer: A

Explanation:

Under ICH E6 (R2) Good Clinical Practice and 21 CFR Part 312.52, when a sponsor delegates or transfers obligations for a clinical trial to a Contract Research Organization (CRO), there must be a written description of each specific obligation being assumed by the CRO.

According to the Good Clinical Data Management Practices (GCDMP), while sponsors may outsource responsibilities such as data management, monitoring, or biostatistics, ultimate accountability remains with the sponsor. The documentation of the transfer of responsibilities ensures regulatory transparency and compliance.

This written agreement, often referred to as a Transfer of Obligations (TOO) document, defines exactly which duties the CRO is responsible for (e.g., CRF design, data cleaning, database lock), as well as any retained sponsor oversight. A general statement that "all obligations are transferred" (option D) is insufficient per regulatory expectations, as sponsors must retain traceability of responsibility.

Therefore, Option B is correct - a detailed written description of transferred obligations is required.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Compliance and Oversight, Section 5.2 - Sponsor and CRO Responsibilities ICH E6 (R2) Good Clinical Practice, Section 5.2.1 - Transfer of Trial-Related Duties and Functions FDA 21 CFR 312.52 - Transfer of Obligations to a Contract Research Organization

NEW QUESTION # 56

Which information is most useful in working with sites to catch up a backlog of unresolved queries at sites?

- A. Table of outstanding queries counts by site
- B. Graph of expected versus actual enrollment
- C. List of late queries by site and summary table
- D. Graph and summary table of clean cases by site

Answer: C

Explanation:

The most effective information for addressing a backlog of unresolved queries at investigative sites is a list of late queries by site combined with a summary table.

According to the GCDMP (Chapter: Communication and Issue Escalation), timely and structured feedback to sites is critical for efficient query resolution. A detailed list of late or overdue queries, accompanied by summary statistics (e.g., counts, durations, status), enables data managers and monitors to prioritize follow-up actions, target problem areas, and provide focused support or retraining to underperforming sites.

While query count summaries (option B) are helpful for overview metrics, they lack the specific information (query ID, date, field, status) required for targeted follow-up. Graphs of enrollment or clean cases (options A and C) are unrelated to discrepancy resolution performance.

Thus, the combination of detailed lists and summarized performance metrics offers both granularity and a high-level overview - the optimal tool for query management communication.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Communication and Issue Escalation, Section 5.1 - Site

NEW QUESTION # 57

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