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SCDM Certified Clinical Data Manager Sample Questions (Q123-Q128):

NEW QUESTION # 123

ACME Intervention Co. is testing a new carotid artery stent in patients with coronary artery disease, in hopes of proving superiority over the current standard of care. After a subject signs consent, the surgeon enrolls the patient and retrieves information on which stent to use, but the surgeon does not share this information with the subject. Yesterday, the surgeon was instructed to use the control stent. Today, the surgeon has completed two surgeries: the first one the surgeon was instructed to use the control stent; the second one the surgeon was instructed to use the test stent. In what type of trial is the surgeon participating?

- A. Open label
- B. Double-blind
- C. Cross-over
- **D. Single-blind**

Answer: D

Explanation:

This scenario describes a single-blind trial, in which only one party—typically the subject—is unaware of the treatment assignment, while the investigator or surgeon knows which intervention is being administered.

In this case, the surgeon receives instructions on which stent (test or control) to use, meaning they are aware of treatment allocation. However, the subject is blinded to which device is being implanted. This setup minimizes subject bias while maintaining procedural safety since the surgeon must know which product to use.

Double-blind (A): Neither subject nor investigator knows the treatment.

Open-label (B): Both subject and investigator know the treatment.

Cross-over (D): Each subject receives both treatments in different periods.

Thus, the correct answer is C. Single-blind, as only the participant remains blinded in this surgical device trial design.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Clinical Trial Phases and Protocols, Section 3.2 - Study Blinding and Randomization Concepts ICH E6(R2) GCP, Section 1.10 - Definition of Blinding/Masking FDA Guidance for Industry: Design Considerations for Pivotal Clinical Investigations for Medical Devices, Section 5.3 - Blinding in Device Studies

NEW QUESTION # 124

A Clinical Data Manager is drafting data element definitions for a new study. One of the definitions provided is:

"Baby's crown to heel length measured lying on back, measured physical quantity, precision of 0.1." Which of the following is missing from the definition?

- A. Enumeration
- B. Data type of the data element
- **C. Unit or dimensionality of measure**
- D. Discrete values for a drop-down list

Answer: C

Explanation:

A complete data element definition in clinical data management should include:

Name and clear description of the data element,

Data type (e.g., numeric, text, date),

Precision or scale (if numeric), and

Unit or dimensionality of measure (e.g., centimeters, inches).

In this example, while the data type ("measured physical quantity") and precision (0.1) are defined, the unit of measurement (e.g., centimeters or inches) is missing. This omission leads to ambiguity and could cause serious discrepancies when comparing or analyzing measurements.

The GCDMP (Chapter: Database Design and Build) emphasizes that units and dimensionality must be explicitly defined and consistently applied in all CRFs, metadata dictionaries, and data transformations.

Thus, option D (Unit or dimensionality of measure) is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 5.2 - Metadata and Data Element Definitions CDISC CDASH

NEW QUESTION # 125

For clinical investigational sites on an EDC trial, which of the following archival options allows traceability of changes made to data?

- A. PDF images of the final eCRF screens for each patient
- B. Storing the computer used at the clinical investigational site
- C. Paper copies of the source documents
- **D. ASCII files of the site's data and related audit trails**

Answer: D

Explanation:

Regulatory agencies such as the FDA and ICH require that electronic data be retained in a format that preserves audit trails and traceability.

While PDF images (option C) provide a static representation of data, they do not preserve the underlying audit trail (i.e., who changed what, when, and why). The ASCII data files with corresponding audit trails (option D) provide complete transparency and comply with 21 CFR Part 11 and GCDMP archival standards.

Option A (storing computers) is unnecessary and impractical, and Option B (paper source documents) are site records, not system archives.

Hence, option D is correct - ASCII data files with audit trails meet traceability and compliance standards.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.4 - Archival Formats and Audit Trail Retention ICH E6(R2) GCP, Section 5.5.3 - Data Integrity, Audit Trails, and Record Retention FDA 21 CFR Part 11 - Electronic Records; Audit Trail and Retention Requirements

NEW QUESTION # 126

Which of the following ensures that the trials are conducted and the data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s)?

- A. Data Management Plan (DMP)
- B. Statistical Analysis Plan (SAP)
- C. CRFs
- **D. Standard Operating Procedures (SOP)**

Answer: D

Explanation:

Standard Operating Procedures (SOPs) are formal, controlled documents that define standardized processes to ensure clinical trials are conducted in compliance with Good Clinical Practice (GCP), the study protocol, and regulatory requirements (such as ICH and FDA).

According to Good Clinical Data Management Practices (GCDMP) and ICH E6(R2) GCP, SOPs are fundamental to quality management systems. They describe how tasks are performed, ensuring consistency, accountability, and traceability across all studies and team members. Proper adherence to SOPs guarantees that data are accurately generated, documented, and reported in compliance with ethical and regulatory standards.

Other options serve different purposes:

SAP (B) defines statistical methodology, not compliance control.

DMP (C) focuses on study-specific data handling, not organizational compliance.

CRFs (D) are tools for data collection but do not enforce compliance by themselves.

Therefore, option A (SOP) is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Quality Management and Compliance, Section 5.1 - Role of SOPs in Regulatory Compliance ICH E6(R2) GCP, Section 2.13 and 5.1.1 - Quality Management Systems and SOP Requirements FDA 21 CFR Part 312.50 - Sponsor Responsibilities and Compliance Systems

NEW QUESTION # 127

What action should a data manager take if an investigator retires in the middle of an EDC trial and the replacement does not agree to use EDC for the remainder of the trial?

- A. Talk with the clinical research associate to identify alternative sites.
- **B. Explore other options for the site with the study team**
- C. Discuss the use of the site's data with the project statistician.
- D. Notify the project manager and request that the site be closed.

Answer: B

Explanation:

When an investigator retires mid-study and the replacement refuses to use the Electronic Data Capture (EDC) system, the data manager must not take unilateral action but rather collaborate with the study team to explore acceptable solutions.

Per the GCDMP (Chapter: Project Management in Data Management), any deviation from the established data capture method - particularly a change that affects regulatory compliance, data consistency, or site operations - requires a cross-functional assessment. The study team, which includes clinical operations, project management, regulatory affairs, and data management, should evaluate feasible alternatives such as:

Allowing paper CRF entry followed by centralized data transcription,

Retraining site staff on EDC use, or

Temporarily suspending data entry until compliance can be restored.

Immediate site closure (option A) or unilateral decisions by data management (options C and D) violate escalation and communication protocols. Collaborative decision-making ensures continuity, compliance, and data integrity, in line with ICH E6 (R2) GCP and FDA 21 CFR Part 11.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 5.2 - Handling Site and Investigator Changes ICH E6 (R2) Good Clinical Practice, Section 4.1 - Investigator Responsibilities FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on EDC Operations and Site Management

NEW QUESTION # 128

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Sjogren of the Air Force Office of Scientific Research, whose support CCDM has allowed the author to investigate the field of statistical signal processing, The Need for String Manipulation Classes.

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