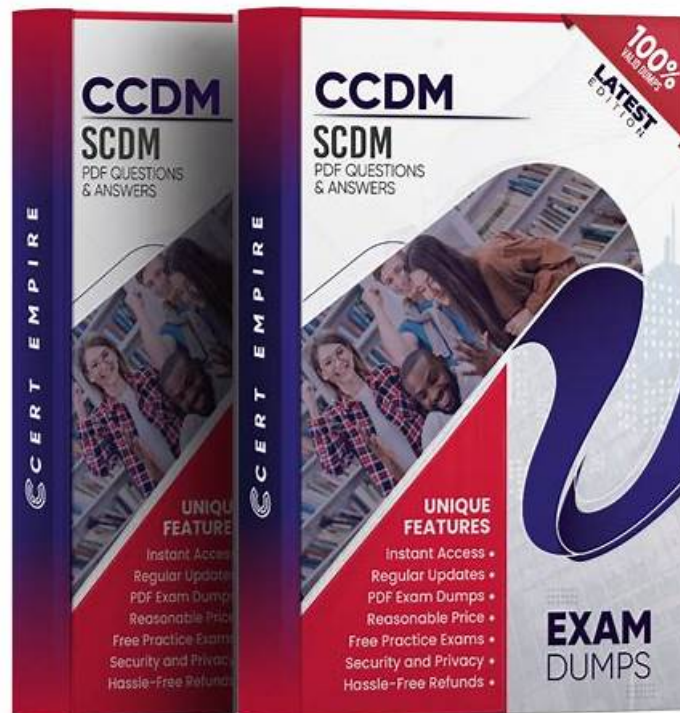


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SCDM Certified Clinical Data Manager Sample Questions (Q77-Q82):

NEW QUESTION # 77

Which of the following laboratory findings is a valid adverse event reported term that facilitates auto coding?

- A. Elevated HDL

- B. Abnormal SGOT
- C. ALT
- D. Increased alkaline phosphatase, increased SGPT, increased SGOT, and elevated LDH

Answer: A

Explanation:

When coding adverse events (AEs) using MedDRA (Medical Dictionary for Regulatory Activities), valid AE terms must correspond to specific, medically meaningful concepts that match directly to a Preferred Term (PT) or Lowest Level Term (LLT) in the dictionary.

Among the options, "Elevated HDL" (High-Density Lipoprotein) represents a single, medically interpretable, and standard term that can directly match to a MedDRA LLT or PT. This makes it suitable for auto-coding, where the system automatically maps verbatim terms to MedDRA entries without manual intervention.

In contrast:

ALT (B) and Abnormal SGOT (C) are incomplete or nonspecific; they describe test names or qualitative interpretations rather than events.

Option D lists multiple findings, making it too complex for automatic mapping. Such compound entries would require manual coding review.

According to GCDMP (Chapter: Medical Coding and Dictionaries), a valid AE term should be:

Clinically interpretable (not just a lab test name)

Unambiguous

Single-concept based, not a collection of results

Thus, option A (Elevated HDL) is correct, as it aligns with MedDRA's single-concept, standard terminology structure suitable for auto-coding.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Medical Coding and Dictionaries, Section 5.3 - Auto-coding and Verbatim Term Management ICH M1
MedDRA Term Selection: Points to Consider, Section 2.1 - Coding Principles ICH E2B(R3) - Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports

NEW QUESTION # 78

A protocol amendment adds three data elements to the vital signs screen and two additional data-collection time points. Which is best practice for handling changes to the form completion guidelines?

- A. Notify sites of the change without a guideline update
- **B. Update the guidelines and notify sites of changes prior to implementing the change**
- C. Rely on the revised CRF to enforce the changes without updating guidelines or notifying sites
- D. Update the guidelines and post the new version on the trial portal

Answer: B

Explanation:

The best practice when implementing a protocol amendment that affects CRF content or data collection timing is to update the eCRF completion guidelines and notify sites before implementing the change.

According to the GCDMP (Chapter: CRF Design and Data Collection), the eCRF Completion Guidelines (eCRF CG) are an essential study tool that instructs site personnel on accurate and consistent data entry. When new data elements or collection time points are added, the guidelines must be revised, version-controlled, and communicated to all users prior to implementation to ensure sites collect and enter data correctly.

Simply relying on the revised CRF (option C) or updating the document without notification (option B) violates communication and training standards. Likewise, notifying sites without updating the documentation (option D) leaves insufficient reference material for data entry compliance.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 5.5 - Managing CRF Revisions and Site Communication ICH E6 (R2) GCP, Section 5.18.4 - Communication of Protocol Amendments and Documentation Updates FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Site Communication and Documentation Management

NEW QUESTION # 79

The best example of a protocol compliance edit check is:

- A. An edit check that fires when a field is left blank
- B. An edit check that fires when a value is outside of the normal range for vital signs
- **C. An edit check that fires when a visit date is outside the specified window**
- D. An edit check that fires when an invalid date is entered

Answer: C

Explanation:

A protocol compliance edit check is designed to ensure that the data collected adheres to the specific requirements defined in the study protocol, such as visit timing, procedure windows, and eligibility criteria.

The example in option A - an edit check that triggers when a visit date falls outside the protocol-specified window - directly verifies compliance with the study design. This type of check supports real-time monitoring of protocol adherence, a critical quality and regulatory requirement under GCDMP and ICH E6(R2).

Other options are examples of general data validation checks, not protocol compliance:

B: Ensures clinical plausibility (data range check).

C: Ensures completeness (missing data check).

D: Ensures format correctness (system validation check).

Thus, option A best represents a protocol compliance edit check, confirming that collected data conform to the visit schedule defined in the protocol.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.4 - Protocol Compliance Edit Checks ICH E6(R2) GCP, Section 5.1.1 - Quality Management and Compliance Controls FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - Edit Check Design and Validation

NEW QUESTION # 80

Every database lock should follow documented approval of which stakeholders?

- A. Clinical/Scientific Representative, Data Manager
- **B. Clinical/Scientific Representative, Data Manager, Biostatistician**
- C. Clinical/Scientific Representative, Biostatistician, Programmer
- D. Clinical/Scientific Representative, Biostatistician

Answer: B

Explanation:

According to the Good Clinical Data Management Practices (GCDMP), the database lock (DBL) process signifies the formal closure of the clinical trial database, ensuring that no further changes can be made to the data before statistical analysis. This process must be documented, controlled, and approved by key study stakeholders to ensure data accuracy, completeness, and readiness for analysis.

The GCDMP specifies that database lock should occur only after all data cleaning, discrepancy resolution, and reconciliation activities are complete. The lock authorization typically requires the approval of the Clinical/Scientific Representative (to confirm clinical completeness), the Data Manager (to confirm data integrity and query closure), and the Biostatistician (to confirm readiness for statistical analysis).

This tri-party approval ensures that the database reflects final, verified data consistent with the clinical protocol, and that the statistical analysis dataset derived from the database is accurate and auditable. The approval process is documented via a Database Lock Authorization Form or Sign-off Log, which becomes part of the permanent trial master file (TMF).

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Lock and Archiving, Section 7.1 - Lock Procedures and Approvals ICH E6 (R2) GCP, Section 5.5.3 - Data Handling and Record Keeping FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Database Closure

NEW QUESTION # 81

In a cross-functional team meeting, a monitor mentions performing source data verification (SDV) on daily diary data entered by patients on mobile devices. Which of the following is the best response?

- A. Diary data to be source data verified should be randomly selected
- **B. Diary data to be source data verified should be selected using a risk-based approach**
- C. All diary data should be source data verified
- D. The diary data should not be source data verified

Answer: B

Explanation:

The best response is that diary data to be source data verified should be selected using a risk-based approach.

According to the GCDMP (Chapter: Data Quality Assurance and Control) and FDA Guidance on Risk-Based Monitoring (RBM), not all data require full SDV. Electronic patient-reported outcome (ePRO) or mobile diary data are typically direct electronic source data (eSource) captured at the time of entry, which already ensures authenticity and traceability.

A risk-based SDV approach focuses verification efforts on data critical to subject safety and primary efficacy endpoints, as defined in the study's Risk Assessment Plan or Monitoring Plan. Random or full verification of low-risk data (like diary compliance metrics) adds unnecessary effort and cost.

Thus, Option C aligns with current regulatory expectations and data management best practices.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.3 - Risk-Based Monitoring and SDV ICH E6 (R2) Good Clinical Practice, Section 5.18 - Risk-Based Quality Management FDA Guidance for Industry: Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring (2013)

NEW QUESTION # 82

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