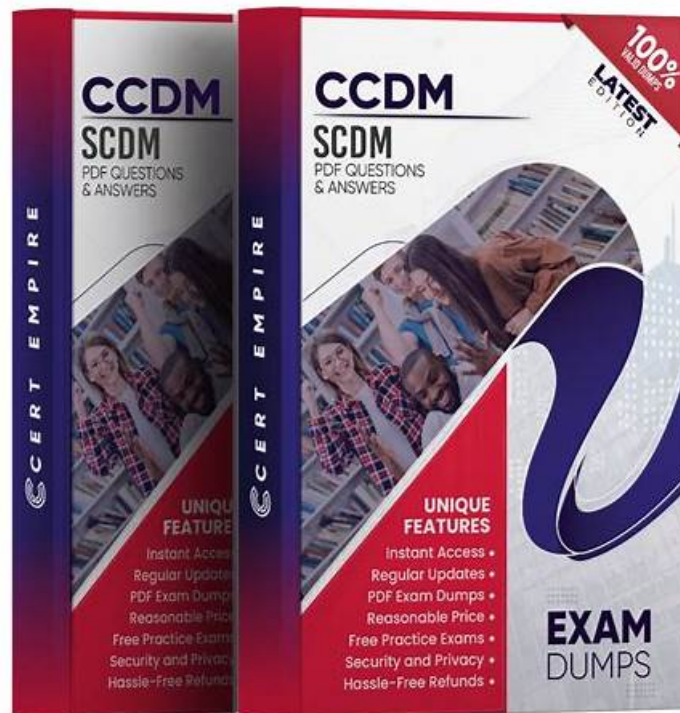


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SCDM Certified Clinical Data Manager Sample Questions (Q76-Q81):

NEW QUESTION # 76

For ease of data processing, the study team would like the database codes for a copyrighted rating scale preprinted on the CRF. What is the most critical task that the CRF designer must do to ensure the data collected on the CRF for the scale are reliable and will support the results of the final analysis?

- A. Consult the study statistician regarding the change and determine that database codes will not influence the analysis.
- B. Complete the requested changes to the instrument and ensure the correct database codes are associated with the appropriate responses.
- C. Consult the independent source and determine database codes will not influence subject responses.
- **D. Consult the independent source of the rating scale for approval and document that continued validity of the tool is not compromised.**

Answer: D

Explanation:

When using a copyrighted or validated rating scale (e.g., Hamilton Depression Scale, Visual Analog Pain Scale), any modification to the original instrument, including preprinting database codes on the CRF, must be approved by the instrument's owner or licensing authority to ensure the validity and reliability of the instrument are not compromised.

According to the GCDMP (Chapter: CRF Design and Data Collection), validated rating scales are psychometrically tested tools. Any visual or structural modification (such as adding codes, changing layout, or rewording questions) can invalidate prior validation results. Therefore, the CRF designer must consult the independent source (copyright holder) for approval and document that the validity of the tool remains intact.

Merely consulting statisticians (option B) or verifying database alignment (option D) does not ensure compliance. Thus, Option C ensures scientific and regulatory integrity.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 6.1 - Use of Validated Instruments and Rating Scales ICH E6 (R2) GCP, Section 5.5.3 - Validation of Instruments and Data Capture Tools
 FDA Guidance for Industry: Patient-Reported Outcome Measures - Use in Medical Product Development to Support Labeling Claims, Section 4 - Instrument Modification and Validation

NEW QUESTION # 77

Which metrics report listed below would best help identify trends in the clinical data?

- A. Last patient/last visit date to data lock date
- **B. Query frequency counts per data element**
- C. Number of subjects screened/enrolled
- D. Percent of data/visits cleaned

Answer: B

Explanation:

The Query frequency counts per data element (Option B) is the best metric for identifying data trends and potential systemic data issues in clinical trials.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control), trend analysis involves identifying recurring data issues across subjects, sites, or variables to detect training gaps, protocol misinterpretation, or CRF design flaws. A high number of queries generated for specific fields (e.g., visit date, lab values, or dosing information) may indicate systemic problems such as unclear CRF instructions or site-level misunderstandings.

While metrics such as percent of data cleaned (A) and time to database lock (B) reflect overall progress and efficiency, they do not identify specific data pattern issues. The number of subjects screened/enrolled (C) pertains to recruitment rather than data quality. Therefore, query frequency per data element provides actionable insights for quality improvement, process refinement, and early identification of potential risks.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 6.3 - Metrics and Trend Analysis ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Risk-Based Quality Review and Data Trends
 FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section 6 - Data Metrics and Trend Evaluation

NEW QUESTION # 78

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

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

Answer: C

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 # 79

A study is collecting pain levels three times a day. Which is the best way to collect the data?

- **A. Using ePRO with reminders for data collection at each time point**
- B. Sites calling patients daily and administering a pain questionnaire
- C. Study subjects calling into an IVRS three times a day to enter pain levels
- D. Using paper pain diary cards completed by study subjects

Answer: A

Explanation:

The optimal method for collecting frequent patient-reported pain data is through electronic Patient-Reported Outcomes (ePRO) with built-in reminder functionality.

According to the GCDMP (Chapter: Electronic Data Capture Systems), ePRO systems provide a validated, real-time, and user-friendly interface for subjects to record time-sensitive data accurately. The use of automated reminders ensures compliance with protocol-specified data collection times, improving data completeness and accuracy.

Paper diaries (option A) are prone to recall bias and backfilling, while daily site calls (option B) are resource-intensive and introduce human error. IVRS systems (option C) are acceptable but less efficient and user-friendly than modern ePRO applications, which can integrate timestamp validation, compliance monitoring, and real-time alerts.

ePRO systems also comply with FDA 21 CFR Part 11 and ICH E6 (R2) for audit trails, authentication, and validation, making them the preferred solution for repeated PRO data collection.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture (EDC) Systems, Section 6.1 - Use of ePRO for Repeated Measures FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 5 - ePRO Compliance and Validation ICH E6 (R2) GCP, Section 5.5.3 - Electronic Data Systems and Recordkeeping

NEW QUESTION # 80

If a data manager generated no additional manual queries on data in an EDC system and the data were deemed clean, why could the data appear to be not clean during the next review?

- A. The medical monitor can override safety information entered in the system.
- B. The CRA can change the data during a quality review of source to database.
- **C. The study coordinator can change the data due to re-review of the source.**
- D. The data manager may have accidentally changed the data.

Answer: C

Explanation:

In an Electronic Data Capture (EDC) system, even after a data manager completes all manual queries and marks data as "clean," the data may later appear unclear if the site (study coordinator) makes subsequent updates in the system after re-reviewing the source documents.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Electronic Data Capture Systems), site users maintain the authority to modify data entries as long as the system remains open for data entry. The EDC system audit trail captures such changes, which can automatically invalidate prior data reviews, triggering new discrepancies or changing system edit-check statuses.

This situation commonly occurs when the site identifies corrections in the source (e.g., wrong date or lab result) and updates the EDC form accordingly. These post-cleaning changes require additional review cycles to ensure the database reflects accurate and verified information before final lock.

Options B, C, and D are incorrect - CRAs and medical monitors cannot directly change EDC data; they can only raise queries or request updates.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture Systems, Section 6.3 - Post-Cleaning Data Changes and Audit Trails ICH E6 (R2) GCP, Section 5.5.3 - Data Integrity and Change Control FDA 21 CFR Part 11 - Electronic Records: Change Documentation Requirements

NEW QUESTION # 81

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