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Certified Clinical Data Manager Exam

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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none">Review Tasks: This section measures the skills of Data Managers and involves reviewing protocols, CRFs, data tables, listings, figures, and clinical study reports (CSRs) for consistency, accuracy, and alignment with data handling definitions and regulatory requirements.
Topic 2	<ul style="list-style-type: none">Design Tasks: This section of the CCDM exam measures skills of Data Managers and covers how to design and document data collection instruments, develop workflows and data flows, specify data elements, CRF forms, edit checks, reports, database structure, and define standards and procedures for traceability and auditability.
Topic 3	<ul style="list-style-type: none">Coordination and Project Management Tasks: This domain evaluates the skills of a Clinical Systems Analyst in coordinating data management workload, vendor selection, scheduling, cross-team communication, project timeline management, risk handling, metric tracking, and preparing for audits.

Topic 4	<ul style="list-style-type: none"> • Testing Tasks: This section measures the skills of Data Managers and involves creating test plans, generating test data, executing validation and user acceptance testing, and documenting results to ensure systems and processes perform reliably and according to specifications.
Topic 5	<ul style="list-style-type: none"> • Data Processing Tasks: This section measures skills of Clinical Systems Analysts and focuses on handling, transforming, integrating, reconciling, coding, querying, updating, and archiving study data while maintaining quality, consistency, and proper privileges over the data lifecycle.

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SCDM Certified Clinical Data Manager Sample Questions (Q124-Q129):

NEW QUESTION # 124

Electronic submission standards require that an individual subject's complete CRF should be provided as what type of file:

- A. Portable Document Format (.pdf)
- B. Statistical Analysis System (.sas)
- C. Rich Text Format (.rtf)
- D. Microsoft Word (.docx)

Answer: A

Explanation:

Electronic submission standards, as established by FDA, CDISC, and ICH, require that an individual subject's complete Case Report Form (CRF) be submitted as a Portable Document Format (.pdf) file. The PDF format is universally recognized and accepted because it ensures that the structure, format, and visual fidelity of the CRF are preserved exactly as originally designed, regardless of software or hardware environment.

According to the FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format (2006) and CDISC SDTM standards, sponsors must include a subject-level CRF in PDF form for each participant in the submission dataset. This requirement ensures that reviewers can trace data points from analysis datasets back to their source entries in the CRF, fulfilling the principles of data traceability and transparency.

The Good Clinical Data Management Practices (GCDMP) also support this requirement, emphasizing that CRF archiving should maintain readability and regulatory accessibility. Formats like RTF, DOCX, or SAS datasets are not acceptable substitutes for regulatory CRF submission because they may alter formatting, structure, or introduce modifiable content, violating FDA data integrity principles.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Archiving and Submission FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format, April 2006 CDISC SDTM Implementation Guide, Section 5.3 - CRF Representation and Traceability

NEW QUESTION # 125

Which database table structure is most appropriate for vital signs data collected at every-other visit for each patient in a study?

- A. One record per patient
- B. One record per patient per visit
- C. One record per visit

- D. One record per patient per study

Answer: B

Explanation:

In a relational clinical database, the most efficient and normalized structure for data collected repeatedly over time-such as vital signs-is one record per patient per visit.

Each patient will have multiple records, one for each visit when vital signs are assessed. This structure supports:

Time-based analysis (e.g., trends across visits),

Accurate data linkage with visit-level metadata, and

Efficient querying for longitudinal data.

According to the GCDMP (Chapter: Database Design and Build), the relational design principle dictates that data should be stored at the lowest unique level of observation. Since vital signs vary by both patient and visit, the combination of patient ID + visit ID forms a unique key for each record.

Option A (per visit) lacks patient identification, while options B and D aggregate data too broadly, losing temporal detail.

Thus, option C (One record per patient per visit) correctly represents the normalized design structure.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 4.2 - Normalization and Table Structure CDISC SDTM

Implementation Guide, Section 5.3 - Visit-Level and Observation-Level Data Structures ICH E6(R2) GCP, Section 5.5.3 - Data Handling Principles

NEW QUESTION # 126

What should be done if the site continues to provide inconsistent data after several re-queries?

- A. Escalate the issue to the appropriate site contact personnel
- B. Continue to re-query until the site changes the data
- C. Gently lead the site to the correct response
- D. Do nothing, the data will remain inconsistent

Answer: A

Explanation:

If a clinical site continues to provide inconsistent or illogical data after multiple queries, the correct course of action is to escalate the issue to the appropriate site contact personnel, typically the Clinical Research Associate (CRA) or Site Monitor.

According to the Good Clinical Data Management Practices (GCDMP), persistent data discrepancies often indicate a misunderstanding of the protocol, CRF instructions, or data entry procedures at the site level. Repeatedly re-querying the same data without escalation wastes time and risks introducing bias or error. By escalating through formal communication channels, the issue can be clarified through re-training, documentation review, or site monitoring visits.

The GCDMP emphasizes that escalation ensures data accuracy, site accountability, and protocol adherence, maintaining both data quality and regulatory compliance. Data managers must document the escalation process in the Data Management Plan (DMP) and ensure proper follow-up resolution is achieved.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Communication and Issue Escalation, Section 4.2 -

Handling Persistent Data Discrepancies ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Communication

FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section on Issue Escalation

NEW QUESTION # 127

All of the following are preparation processes the data manager needs to take prior to database closure EXCEPT:

- A. Performing SAE reconciliation between the clinical and safety databases.
- B. Checking for uncoded terms in all panels that are coded.
- C. Ensuring study close out visits have been complete.
- D. Ensuring all data expected for the study has been received.

Answer: C

Explanation:

Before database lock, the Data Manager must confirm that all collected data are complete, validated, and reconciled across systems. This includes:

Ensuring data completeness (B) - confirming all expected forms and data files have been received.

Verifying coded data (A) - ensuring no pending terms remain in coding dictionaries like MedDRA or WHO Drug.

Performing SAE reconciliation (C) - cross-checking the clinical database against the safety system for accuracy.

However, ensuring study close-out visits (D) is not a data management function; it falls under clinical operations and monitoring responsibilities. While data management may review confirmation of site close-outs, the activity itself is not part of pre-database lock procedures.

Therefore, option D correctly identifies the exception-an activity outside the data manager's direct scope of responsibility before database closure.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.3 - Pre-Lock Validation and Reconciliation Activities ICH

E6(R2) GCP, Section 5.5.3 - Data Handling and Quality Control Prior to Lock FDA Guidance for Industry: Computerized Systems

Used in Clinical Investigations, Section 6.1 - Database Management and Lock Procedures

NEW QUESTION # 128

A Clinical Data Manager reads a protocol for a clinical trial to test the efficacy of an antiviral to counteract a new epidemic. The stated primary efficacy endpoint is 3-month survival. Which data element is needed for the primary efficacy endpoint?

- A. Cause of death
- B. Birth date
- C. Date of autopsy
- **D. Death date**

Answer: D

Explanation:

When the primary efficacy endpoint in a clinical trial is 3-month survival, the key data element required is the death date. This is because the survival endpoint is determined by calculating whether the subject lived or died within a defined time frame from study enrollment or randomization.

According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the Clinical Data Manager (CDM) must identify and ensure the capture of all critical data elements necessary to evaluate the study endpoints. For time-to-event analyses (e.g., survival studies), accurate event dates (death date) are essential for endpoint derivation and statistical analysis.

Other data elements such as cause of death or date of autopsy (options B and C) may support secondary analyses or safety reviews but are not necessary to determine the survival endpoint itself. Similarly, birth date (option D) contributes to demographic data but is unrelated to the primary efficacy outcome.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Study Start-up, Section

4.4 - Critical Data Identification for Endpoints ICH E9 - Statistical Principles for Clinical Trials, Section 2.2.3 - Time-to-Event Data Considerations FDA Guidance for Industry: Clinical Trial Endpoints for Drug Development

NEW QUESTION # 129

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