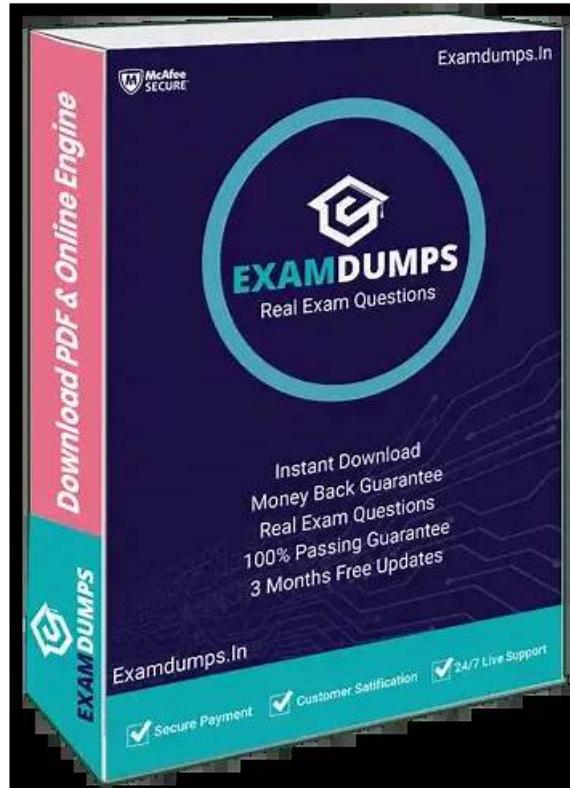


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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<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 2	<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 3	<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 4	<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.
Topic 5	<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.

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SCDM Certified Clinical Data Manager Sample Questions (Q33-Q38):

NEW QUESTION # 33

A study takes body-composition measurements at baseline using a DEXA scanner. Which information is needed to correctly associate the body-composition data to the rest of the study data?

- A. Study number and subject number
- **B. Subject number and visit number**
- C. Subject number
- D. Study number and visit number

Answer: B

Explanation:

To properly associate body-composition data (from a DEXA scanner) with other study data, both the subject number and the visit number are required.

According to the GCDMP (Chapter: Data Management Planning and Study Start-up), every clinical data record must be uniquely identifiable and linkable to a specific subject and study event. The subject number identifies the participant, while the visit number defines the temporal context in which the measurement was taken.

Without both identifiers, data integration becomes ambiguous-especially if multiple assessments occur over time (e.g., baseline, week 12, end of study). Including both ensures data traceability, integrity, and alignment with the protocol-defined schedule of events.

Study number (option A) alone does not distinguish between visits or subjects, and visit number alone (option C) lacks linkage to the individual participant.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Study Start-up, Section 4.4 - Data Linking and Identification Requirements ICH E6 (R2) GCP, Section 5.5.3 - Data Traceability Principles FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Identification Requirements

NEW QUESTION # 34

A study is using blood pressure as an efficacy measure. Which is the best way to collect the data?

- **A. Measurement using study-provisioned equipment**
- B. Measurement using existing equipment at sites

- C. Collecting the data from the medical record
- D. Asking the study subjects what their blood pressure usually runs

Answer: A

Explanation:

When a clinical study uses blood pressure (BP) as an efficacy endpoint, the most reliable and standardized method of data collection is through study-provisioned equipment.

According to the GCDMP (Chapter: CRF Design and Data Collection), data collected for primary efficacy endpoints must be consistent, accurate, and standardized across all investigative sites. Using study-provided calibrated equipment ensures that measurements are taken under uniform conditions, eliminating inter-site variability due to differences in devices, calibration, or measurement methods.

Collecting BP data from medical records (option A) risks inconsistent timing and techniques. Using each site's own equipment (option B) introduces variability, while patient self-reports (option D) lack reliability and objectivity.

Thus, the best practice is to provision and standardize all equipment used to collect endpoint-related physiological data, ensuring regulatory-quality results suitable for analysis.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 5.1 - Standardization of Clinical Measurements ICH E6 (R2) GCP, Section 5.5.3 - Data Accuracy and Equipment Standardization FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Data Capture and Standardization Requirements

NEW QUESTION # 35

Which method would best identify clinical chemistry lab data affected by a blood draw taken distal to a saline infusion?

- A. Abnormally low urine glucose values in a dataset
- B. Abnormally high sodium values in a dataset
- C. Lab values from a blood draw with a very low sodium and very high other values
- D. Lab values from a blood draw with a very high sodium and very low other values

Answer: D

Explanation:

If a blood sample is drawn distal (downstream) from a saline infusion site, it may become contaminated with saline, leading to abnormal laboratory results. Saline contains a high concentration of sodium chloride, which artificially elevates sodium while diluting other blood components.

Therefore, such samples would display:

Very high sodium levels, and

Abnormally low levels of other analytes (e.g., proteins, glucose, potassium).

This abnormal pattern (option B) is a classic indicator of saline contamination.

Per the GCDMP (Chapter: Data Validation and Cleaning), cross-variable consistency checks are critical for identifying biologically implausible patterns, such as this one, which indicate pre-analytical errors rather than true physiological changes.

Hence, option B accurately describes the data signature of a contaminated blood draw.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 6.2 - Logical and Consistency Checks for Laboratory Data ICH E6(R2) GCP, Section 5.1.1 - Data Quality and Biological Plausibility Checks FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - Detecting Laboratory Anomalies

NEW QUESTION # 36

Which protocol section best defines data needed for the primary study analysis?

- A. Protocol synopsis
- B. Study schedule of events
- C. Study endpoints section
- D. ICH essential documents

Answer: C

Explanation:

The study endpoints section of the protocol best defines the data required for the primary study analysis.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Management Planning and Study Start-up), the endpoint section specifies the critical efficacy and safety variables upon which the study's success criteria are based. These endpoints directly determine what data elements must be collected, validated, and analyzed. For example, if the primary endpoint is "change in systolic blood pressure from baseline to week 12," then data collection must include baseline and week 12 systolic blood pressure values and corresponding timepoints.

The schedule of events (option A) lists when data are collected but not their analytical relevance. The protocol synopsis (option C) provides a summary, while the ICH essential documents (option D) refer to trial documentation standards, not endpoint specifications.

Thus, the study endpoints section defines the core analytical data requirements for clinical data managers, biostatisticians, and programmers.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Study Start-up, Section 5.2 - Defining Data Needed for Endpoints ICH E6 (R2) Good Clinical Practice, Section 6.3 - Trial Objectives and Endpoints FDA Guidance for Industry: Clinical Trial Endpoints for Drug Development and Approval

NEW QUESTION # 37

There is a modification to the CRF and a sudden increase in the number of queries generated in the EDC system. Which action is most likely to reduce the number of queries?

- A. Introduce a source data verification process
- B. Make some of the existing edit checks manually
- C. **Review the edit checks for correctness**
- D. Have the monitor close the queries

Answer: C

Explanation:

When a CRF modification leads to a sudden increase in EDC queries, the most likely cause is an error or misconfiguration in the edit checks introduced during or after the change. Therefore, the first step should be to review the edit checks for correctness.

The GCDMP (Chapter: Database Design and Validation) emphasizes that any database or CRF modification should trigger retesting of affected validation rules. Incorrect logic, thresholds, or missing conditional statements in automated edit checks can cause false or redundant queries, leading to unnecessary data management burden and site frustration.

Manually handling edit checks (option A) or adding SDV (option B) does not address the root cause. Having monitors close queries (option D) would mask the problem rather than resolve it.

Thus, the correct corrective measure is Option C - review and validate the edit checks to ensure proper functionality.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Validation, Section 5.5 - Edit Check Testing and Review ICH E6 (R2) GCP, Section 5.5.3 - Validation and Change Control for Electronic Systems FDA 21 CFR Part 11 - System Validation and Change Documentation

NEW QUESTION # 38

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