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Certified Clinical Data Manager Exam

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There is no denying that no exam is easy because it means a lot of consumption of time and effort. Especially for the upcoming CCDM exam, although a large number of people to take the exam every year, only a part of them can pass. If you are also worried about the exam at this moment, please take a look at our CCDM Study Materials, whose content is carefully designed for the CCDM exam, rich question bank and answer to enable you to master all the test knowledge in a short period of time.

SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<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 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"> 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 4	<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 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.

SCDM Certified Clinical Data Manager Sample Questions (Q80-Q85):

NEW QUESTION # 80

An astute monitor discovers that a site is using nebulized albuterol rather than the inhaler provided in the study screening kit for the albuterol challenge. Which is the best response from the Data Manager?

- **A. Query the site to enter a Protocol Violation**
- B. No response is needed, the problem does not impact data
- C. Update the CRF Completion Guidelines and notify all sites of the update
- D. Contact the Ethics Committee

Answer: A

Explanation:

In this scenario, the site has deviated from the approved study protocol by using a different formulation (nebulized albuterol instead of inhaler). This is considered a protocol deviation or violation, depending on study definitions.

Per GCDMP (Chapter: Data Validation and Cleaning) and ICH E6(R2), Data Managers are responsible for ensuring that all protocol deviations affecting data integrity or subject safety are accurately captured and documented within the clinical database.

The appropriate action is to issue a data query prompting the site to record the deviation in the designated section (e.g., "Protocol Deviations" CRF).

Option A: Incorrect - it affects data comparability.

Option B: Escalation to the Ethics Committee is handled by the sponsor, not the Data Manager.

Option C: Updating the CRF guidelines is premature; first, the deviation must be logged and assessed.

Therefore, option D (Query the site to enter a Protocol Violation) is the correct and compliant action.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 6.2 - Query Management and Protocol Deviations ICH E6(R2)

GCP, Section 4.5 - Compliance with Protocol FDA Guidance for Industry: Oversight of Clinical Investigations - Compliance and Protocol Deviation Reporting

NEW QUESTION # 81

Which information is most useful in working with sites to catch up a backlog of unresolved queries at sites?

- **A. List of late queries by site and summary table**

- B. Graph and summary table of clean cases by site
- C. Graph of expected versus actual enrollment
- D. Table of outstanding queries counts by site

Answer: A

Explanation:

The most effective information for addressing a backlog of unresolved queries at investigative sites is a list of late queries by site combined with a summary table.

According to the GCDMP (Chapter: Communication and Issue Escalation), timely and structured feedback to sites is critical for efficient query resolution. A detailed list of late or overdue queries, accompanied by summary statistics (e.g., counts, durations, status), enables data managers and monitors to prioritize follow-up actions, target problem areas, and provide focused support or retraining to underperforming sites.

While query count summaries (option B) are helpful for overview metrics, they lack the specific information (query ID, date, field, status) required for targeted follow-up. Graphs of enrollment or clean cases (options A and C) are unrelated to discrepancy resolution performance.

Thus, the combination of detailed lists and summarized performance metrics offers both granularity and a high-level overview - the optimal tool for query management communication.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Communication and Issue Escalation, Section 5.1 - Site Query Management Reports ICH E6 (R2) GCP, Section 5.18.4 - Communication Between Monitors and Sites FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section on Query Metrics and Site Performance Review

NEW QUESTION # 82

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

- A. Abnormally high sodium values in a dataset
- B. Abnormally low urine glucose 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 # 83

What are the key deliverables for User Acceptance Testing?

- A. Training
- **B. Test Plan/Script/Results**
- C. eCRF Completion Guidelines
- D. Project Plan

Answer: B

Explanation:

The key deliverables for User Acceptance Testing (UAT) are the Test Plan, Test Scripts, and Test Results.

According to the GCDMP (Chapter: Database Design and Validation), UAT is the final validation step before a clinical database is released for production. It confirms that the system performs according to user requirements and protocol specifications.

The deliverables include:

UAT Test Plan: Defines testing objectives, scope, acceptance criteria, and responsibilities.

UAT Test Scripts: Provide step-by-step instructions for testing database functionality, edit checks, and workflows.

UAT Test Results: Document actual test outcomes versus expected outcomes, including any deviations and their resolutions.

These deliverables form part of the system validation documentation required under FDA 21 CFR Part 11 and ICH E6 (R2) to demonstrate that the database has been properly validated.

Project Plans (option A) and Training (option B) occur in earlier phases, while eCRF Completion Guidelines (option D) support site data entry, not system validation.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Validation, Section 5.3 - User Acceptance Testing Deliverables FDA 21 CFR Part 11 - Validation Documentation Requirements ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - System Validation Records

NEW QUESTION # 84

In a study conducted using paper CRFs, a discrepancy is discovered in a CRF to database QC audit. What is the reason why this discrepancy would be considered an audit finding?

- A. Discrepancy not explained by the CRF completion guidelines
- **B. Discrepancy not explained by the data handling conventions**
- C. Discrepancy not explained by the protocol
- D. Discrepancy not explained by the data quality control audit plan

Answer: B

Explanation:

In a CRF-to-database quality control (QC) audit, auditors compare data recorded on the paper Case Report Form (CRF) with data entered in the electronic database. If discrepancies exist that cannot be explained by documented data handling conventions, they are classified as audit findings.

Per GCDMP (Chapter: Data Quality Assurance and Control), data handling conventions define acceptable data entry practices, transcription rules, and allowable transformations. These conventions ensure that CRF data are consistently interpreted and entered. If a discrepancy deviates from these established rules, it indicates a process gap or error in data entry, validation, or training.

Discrepancies justified by protocol design or CRF guidelines would not constitute findings.

Therefore, option C (Discrepancy not explained by the data handling conventions) correctly identifies the criterion for a true QC audit finding.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 6.1 - Data Handling Conventions and QC Auditing ICH E6(R2) GCP, Section 5.1 - Quality Management and Documentation of Deviations FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Data Verification and Audit Findings

NEW QUESTION # 85

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