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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	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 2	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	• 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 4	• 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	• 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.

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SCDM Certified Clinical Data Manager Sample Questions (Q123-Q128):

NEW QUESTION # 123

If database auditing is used for data quality control during a study, which is the optimal timing of the audits?

- A. Periodically throughout the study
- B. After the first few cases have been entered
- C. Immediately following database lock
- D. A week or two before database lock

Answer: A

Explanation:

Database audits are conducted to ensure ongoing data accuracy, completeness, and compliance throughout the lifecycle of a clinical trial. According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control), quality audits are most effective when performed periodically during study conduct, rather than waiting until study completion.

Performing audits periodically allows early detection of data entry errors, protocol deviations, and system inconsistencies, thereby reducing the risk of large-scale data issues before database lock. This proactive approach aligns with risk-based quality management principles outlined in ICH E6(R2) and ensures corrective actions are implemented in real time.

Options A and B represent reactive quality control, which occurs too late to prevent data issues. Option C (after first few cases) provides initial validation but does not ensure continuous oversight.

Therefore, option D - "Periodically throughout the study" - represents the optimal and compliant timing for quality audits of the database.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 5.3 - Ongoing Quality Control and Auditing ICH E6(R2)

GCP, Section 5.1.1 - Quality Management System and Risk-Based Monitoring FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Data Review and Auditing Practices

NEW QUESTION # 124

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

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

Answer: D

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 # 125

What additional task does the site study coordinator role perform when utilizing an EDC application compared to paper CRF?

- A. Medical record abstraction
- B. Resolving queries
- **C. Data entry**
- D. Data curation

Answer: C

Explanation:

In paper-based trials, site staff (e.g., study coordinators) record data manually on paper Case Report Forms (CRFs), which are later transcribed by data entry personnel into an electronic database.

However, in EDC-based studies, the site coordinator is directly responsible for entering data into the EDC system. This eliminates the need for centralized double data entry and shortens data cleaning timelines.

The GCDMP (Chapter: Electronic Data Capture Systems) states that EDC systems shift certain tasks, including data entry, initial query response, and source verification preparation, to the site level. Yet, data entry remains the most significant additional responsibility compared to paper-based studies.

Option A (Query resolution) is performed in both EDC and paper-based systems.

Option C (Data curation) is typically a Data Management function.

Option D (Medical record abstraction) is part of source documentation, not specific to EDC.

Thus, option B (Data entry) is correct - it is the additional site coordinator duty unique to EDC environments.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Electronic Data Capture (EDC) Systems, Section 5.3 - Site Responsibilities and Workflow Changes ICH E6(R2) GCP, Section 5.5.3 - Data Entry and Role Delegation in Computerized Systems FDA Guidance for Industry:

Computerized Systems Used in Clinical Investigations, Section 6.2 - Site-Level Data Entry Controls

NEW QUESTION # 126

What does 21 CFR Part 11 dictate in regards to a minimum expectation of EDC training prior to access?

- A. Training must include an exam
- B. Training must be face to face
- **C. Training must be performed**
- D. Training must be in the user's native language

Answer: C

Explanation:

Under FDA 21 CFR Part 11, organizations using electronic systems must ensure that all system users are trained to perform their assigned functions before gaining access to the system. The regulation requires documented evidence of training but does not specify how it should be conducted (e.g., exam-based, in person, or language-specific).

The GCDMP (Chapter: Computerized Systems and Compliance) further clarifies that personnel training should include instruction on system functionality, audit trails, data entry procedures, and electronic signatures to maintain compliance and data integrity. Training must be performed and documented but does not require a specific format or delivery method. Therefore, option A-Training must be performed-is correct, as it reflects the minimum regulatory expectation per FDA and SCDM standards.

Reference (CCDM-Verified Sources):

FDA 21 CFR Part 11, Section 11.10(i) - Personnel Training Requirements

SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 5.4 - System Training and Documentation ICH E6(R2) GCP, Section 2.8 - Qualified Personnel and Training Requirements

NEW QUESTION # 127

A study team member wants to let sites enroll patients before the system is ready. Which are important considerations?

- A. If the study were audited, enrolling subjects prior to having the EDC system ready would become an audit finding
- B. Starting the study prior to the EDC system being ready will delay processing of milestone-based site payments
- C. There is no way to identify, report and track adverse events and serious adverse events without the EDC system in place
- **D. Without the ability to capture the data electronically, the data cannot be checked or used to monitor and manage the study**

Answer: D

Explanation:

Enrolling subjects before the Electronic Data Capture (EDC) system is ready poses major data integrity and compliance risks. The primary issue is that data cannot be accurately captured, validated, or monitored without the system in place.

Per the GCDMP (Chapter: Data Management Planning and Study Start-up), data collection systems must be fully validated, tested, and released before enrollment begins to ensure:

Real-time data entry and quality control

Proper tracking of adverse events (AEs/SAEs)

Audit trails and traceability for regulatory compliance

Option A highlights the most critical consequence - without an operational EDC, data collection and verification processes cannot occur, compromising data quality and study oversight.

While options B, C, and D may be partially true, they are secondary effects. The fundamental consideration is data capture capability and monitoring control, making option A correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Management Planning and Study Start-up, Section 4.2 - EDC Readiness and System Validation

ICH E6(R2) GCP, Section 5.5.3 - Computerized Systems Validation Before Use FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.1 - System Qualification Prior to Data Entry

NEW QUESTION # 128

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