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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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	• 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 3	• 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	• 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	• 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 (Q118-Q123):

NEW QUESTION # 118
For clinical investigational sites on an EDC trial, which of the following archival options allows traceability of changes made to data?

- A. Storing the computer used at the clinical investigational site
- B. Paper copies of the source documents
- C. PDF images of the final eCRF screens for each patient
- D. ASCII files of the site's data and related audit trails

Answer: D

Explanation:
Regulatory agencies such as the FDA and ICH require that electronic data be retained in a format that preserves audit trails and traceability.
While PDF images (option C) provide a static representation of data, they do not preserve the underlying audit trail (i.e., who changed what, when, and why). The ASCII data files with corresponding audit trails (option D) provide complete transparency and comply with 21 CFR Part 11 and GCDMP archival standards.
Option A (storing computers) is unnecessary and impractical, and Option B (paper source documents) are site records, not system archives.
Hence, option D is correct - ASCII data files with audit trails meet traceability and compliance standards.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.4 - Archival Formats and Audit Trail Retention ICH E6(R2) GCP, Section 5.5.3 - Data Integrity, Audit Trails, and Record Retention FDA 21 CFR Part 11 - Electronic Records; Audit Trail and Retention Requirements

NEW QUESTION # 119
Which statement is true regarding User Acceptance Testing (UAT) in an EDC application?

- A. Data should not be collected in a production environment until UAT is completed
- B. Every rule should be tested with at least one "pass" and one "fail" scenario
- C. The extent of UAT (i.e., the number of test cases and rules) cannot be risk-based
- D. System tools in EDC do not remove the need for UAT

Answer: A

Explanation:
In Electronic Data Capture (EDC) system validation, User Acceptance Testing (UAT) is a mandatory phase that must be completed before data collection begins in the production environment.
According to the GCDMP (Chapter: Database Design, Validation, and Testing) and FDA 21 CFR Part 11, UAT ensures that the EDC system meets all protocol-specific, functional, and regulatory requirements before it is deployed for live use. The goal is to verify that the system performs exactly as intended by simulating real-world user interactions with test data in a validated test environment.
Data collection prior to UAT completion would violate validation requirements and risk noncompliance with ICH E6 (R2) GCP Section 5.5.3, which mandates that all computerized systems be validated and tested before use.
While options A and C describe correct components of testing strategy, the key regulatory requirement is that UAT must be completed and approved before live data entry begins. Option D is incorrect - risk-based UAT is an accepted modern validation approach under both FDA and GAMP5 principles.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Validation, Section 5.3 - User Acceptance Testing FDA 21 CFR Part 11 - Validation of Electronic Systems (Section 11.10(a)) ICH E6 (R2) GCP, Section 5.5.3 - Validation Before Use in Production Environment

NEW QUESTION # 120
A protocol is updated mid-study to add an additional procedure about which data needs to be collected. Which of these statements applies?

- A. The DMP should be updated to reflect the changes to the protocol and stakeholders notified
- B. The DMP does not need to be updated until the end of the trial and all updates are included in the DMP to indicate what happened in the trial
- C. The DMP does not need to be updated as it represents the data at the beginning of the trial only
- D. The DMP should be updated to reflect the changes to the protocol, but this update does not need to be communicated

Answer: A

Explanation:
When a protocol is amended mid-study, resulting in additional data collection requirements, the Data Management Plan (DMP) must be updated accordingly and all relevant stakeholders must be notified.
According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the DMP is a living document that defines all data management processes for a clinical study. It must accurately reflect the current data flow, CRF design, validation procedures, and reporting structure. Any protocol amendments affecting data capture, structure, or analysis require immediate DMP revision and distribution to ensure alignment across data management, clinical, and biostatistics teams.
Failure to update and communicate DMP changes can lead to misalignment in data handling and introduce compliance risks during audits or inspections. Therefore, Option B is correct: the DMP must be updated and the change communicated to all stakeholders (e.g., sponsor, CRO, clinical operations, biostatistics).
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Plan (DMP), Section 5.3 - Maintaining and Updating the DMP ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Documentation of Protocol Changes and Data Handling Procedures FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Data Management Documentation

NEW QUESTION # 121
Data characterizing the safety profile of a drug are collected to provide information for which of the following?

- A. Product labeling
- B. Efficacy meta-analyses
- C. Survival curves
- D. Quality of life calculations

Answer: A

Explanation:
Safety data collected during a clinical trial are used primarily to support product labeling, ensuring accurate communication of a drug's risks, contraindications, and adverse reactions to healthcare providers and patients.
According to the GCDMP (Chapter: Safety Data Handling and Reconciliation) and ICH E2A/E2F guidelines, all adverse events (AEs), serious adverse events (SAEs), and laboratory abnormalities are analyzed and summarized to define the safety profile of an investigational product. These data form the basis for regulatory submissions such as the Clinical Study Report (CSR) and product labeling (e.g., prescribing information), as required by the FDA and other regulatory authorities.
While safety data may contribute indirectly to analyses such as survival curves (option A) or quality of life metrics (option D), their primary regulatory function is to inform product labeling and post-marketing surveillance documentation.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Safety Data Handling and Reconciliation, Section 4.3 - Use of Safety Data in Regulatory Submissions ICH E2A - Clinical Safety Data Management: Definitions and Standards for Expedited Reporting FDA Guidance for Industry: Adverse Event Reporting and Labeling Requirements

NEW QUESTION # 122
What additional task does the site study coordinator role perform when utilizing an EDC application compared to paper CRF?

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

Answer: D

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 # 123
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