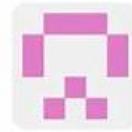


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SCDM CCDM Exam Syllabus Topics:

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">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 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">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 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 (Q144-Q149):

NEW QUESTION # 144

Which statement applies to the CRF Completion Guidelines (CCGs) for a multinational study?

- A. CCGs can instruct sites to write in their local language as long as the CRA is fluent in this language
- B. CCGs must contain the list of acceptable abbreviations to be used in the CRF
- C. CCGs must be translated and back-translated in each local language used in the study
- D. CCGs can instruct sites to use any abbreviations if they are documented in the subject source notes

Answer: B

Explanation:

The Case Report Form (CRF) Completion Guidelines (CCGs) are critical documents that guide site staff on how to accurately and consistently record data on CRFs across all participating sites, especially in multinational trials.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), one of the key components of the CCGs is a list of acceptable abbreviations and conventions to be used during CRF entry. This standardization ensures data consistency across languages and countries, reduces ambiguity during data review, and facilitates database design and coding accuracy.

While translation (A) may be useful for training materials, it is not required for CCGs unless specified by regulatory bodies. Options C and D are incorrect because data collection should adhere to standardized terms in English (or the study's official language) - allowing free use of local languages or arbitrary abbreviations introduces inconsistencies.

Hence, option B - "CCGs must contain the list of acceptable abbreviations to be used in the CRF" - is correct.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 5.3 - CRF Completion Guidelines and Standardization ICH E6(R2) GCP, Section 5.5.3 - Consistency and Data Recording Requirements FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.2 - Data Entry Conventions and Documentation

NEW QUESTION # 145

For a study, body mass index is calculated from weight and height. Which information is needed to document the transformation?

- A. Algorithm associated with the calculated value
- B. Algorithm and algorithm version associated with the calculated value
- C. User ID making the change and reason for change
- D. Algorithm documented in the Data Management Plan

Answer: B

Explanation:

When derived or calculated variables (like Body Mass Index) are created, it is essential to document the algorithm used and its version to ensure full data traceability and reproducibility.

According to GCDMP (Chapter: Database Design and Derived Data), every derived field must include metadata describing:
The derivation algorithm (e.g., $BMI = \text{weight} [\text{kg}] / \text{height}^2 [\text{m}^2]$)

The version of the algorithm (if updates or revisions occur)

Any associated data sources or transformation rules

This ensures consistent calculation across systems, prevents discrepancies during regulatory submissions, and aligns with FDA and CDISC documentation expectations.

Option B lacks version control, which is critical for traceability. Option C describes audit trail data (not derivation metadata), and option D refers to broader documentation, not specific algorithm traceability.

Hence, option A (Algorithm and algorithm version associated with the calculated value) is the correct and compliant answer.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Derived Data and Algorithms, Section 5.3 - Documentation and Metadata Requirements ICH E6(R2) GCP, Section 5.5.3 - Derived Data and Validation Traceability FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Data Definitions (Define.xml)

NEW QUESTION # 146

The Scope of Work would answer which of the following information needs?

- A. To determine the number of data transfers budgeted for a project
- B. To look up which visit PK samples are taken
- C. To find the name and contact information of a specific clinical data associate
- D. To look up the date of the next clinical monitoring visit for a specific site

Answer: A

Explanation:

The Scope of Work (SOW) is a project management document that defines what services are included in the work agreement between the sponsor and the CRO or vendor. It outlines deliverables, responsibilities, timelines, and budget allocations.

According to the GCDMP (Chapter: Project Management in Data Management), the SOW includes specifications such as:

The number and frequency of data transfers,

Database build and lock milestones,

Quality control deliverables, and

Resource allocation for data management tasks.

The SOW does not cover operational site-level details such as monitoring schedules (B), protocol sampling details (C), or personnel contact lists (D).

Therefore, option A (number of data transfers budgeted for a project) correctly identifies a use case directly addressed in the SOW.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Project Management, Section 4.1 - Scope of Work and Resource Planning ICH E6(R2) GCP, Section 5.5 - Sponsor Oversight and Data Management Responsibilities PMI Project Management Framework - Scope Definition and Deliverable Specifications

NEW QUESTION # 147

An organization conducts over fifty studies per year. Currently each study is specified and set-up from scratch. Which of the following organizational infrastructure options would streamline database set-up and study-to-study consistency?

- A. Implementing controlled terminology for adverse events
- B. Maintaining a library of form or screen modules
- C. Improving the form or screen design process
- D. Adopting an ODM compliant database system

Answer: B

Explanation:

To improve efficiency and ensure consistency across multiple studies, the most effective infrastructure solution is to maintain a centralized library of standardized forms or screen modules (e.g., CRF/eCRF templates).

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Database Design and Build), using a form library allows reuse of validated data collection modules for commonly collected domains such as demographics, adverse events, and vital signs. This reduces database setup time, enhances uniformity in data definitions, and ensures alignment with standards such as CDISC CDASH and SDTM.

While adopting ODM (A) provides standardized data exchange and interoperability, it does not inherently reduce setup workload. Improving design processes (C) enhances efficiency but doesn't guarantee consistency, and implementing controlled terminology (D) helps with coding standardization, not database structure.

Therefore, option B - maintaining a library of form or screen modules - provides the most direct and sustainable improvement for scalability and quality.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 5.3 - Use of Standard Libraries and Templates CDISC CDASH Implementation Guide, Section 3.2 - Reusable CRF Modules and Standardization ICH E6(R2) GCP, Section 5.5.3 - Standardization and Reuse in Data Collection Systems

NEW QUESTION # 148

At a cross-functional study team meeting, a statistician suggests collecting blood gases electronically through the existing continuous hemodynamic monitoring system at sites rather than having a person record the values every five minutes during the study procedure. Assuming that sending, receiving, and integrating these data are possible, what is the best response?

- A. Manual recording is preferred because healthcare devices are not validated to 21 CFR Part 11 standards
- B. Manual recording is preferred because the sites may forget to turn on the machine and lose data
- C. Electronic acquisition is preferable because more data points can be acquired

- D. Electronic acquisition is preferable because the chance for human error is removed

Answer: C

Explanation:

Assuming the data transfer, integration, and validation processes are properly controlled and compliant, electronic acquisition of clinical data from medical devices is preferred because it allows more frequent and accurate data collection, leading to higher data resolution and integrity.

Per the GCDMP (Chapter: Technology and Data Integration), automated data collection minimizes manual transcription and reduces latency in data capture, ensuring both efficiency and completeness. While manual processes introduce human transcription errors and limit frequency, continuous electronic data capture can record thousands of accurate, time-stamped measurements, improving the study's analytical power.

However, option D slightly overstates the case - human error is reduced, not entirely eliminated, since setup, calibration, and integration still involve human oversight. Therefore, option C is the best and most precise response, emphasizing the advantage of more robust and complete data capture.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Technology and Data Integration, Section 5.4 - Automated Data Acquisition and Validation ICH E6(R2) GCP, Section 5.5.3 - Validation of Computerized Systems and Electronic Data Sources FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - Direct Data Capture from Instruments and Devices

NEW QUESTION # 149

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