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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<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 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">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	<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 5	<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.

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It is not hard to know that Certified Clinical Data Manager torrent prep is compiled by hundreds of industry experts based on the syllabus and development trends of industries that contain all the key points that may be involved in the examination. Therefore, with CCDM exam questions, you no longer need to purchase any other review materials, and you also don't need to spend a lot of money on tutoring classes. At the same time, CCDM Test Guide will provide you with very flexible learning time in order to help you pass the exam.

SCDM Certified Clinical Data Manager Sample Questions (Q131-Q136):

NEW QUESTION # 131

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

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

Answer: B

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 # 132

A study collects blood pressure. Which is the best way to collect the data?

- A. High/Low radio button
- B. Two continuous variables
- C. Coding a verbatim field with a MedDRA diagnosis
- D. Check boxes for twenty-point increments

Answer: B

Explanation:

Blood pressure is a quantitative physiological measurement, typically consisting of two continuous numeric values: systolic and diastolic pressure. Therefore, the most appropriate and scientifically valid method of data collection is to use two continuous variables (e.g., systolic = 120 mmHg, diastolic = 80 mmHg).

According to the GCDMP (Chapter: CRF Design and Data Collection), data fields must be designed to capture the most precise, accurate, and analyzable form of clinical data. Numeric data should be collected using numeric data types to allow for range checks, calculations (e.g., mean arterial pressure), and statistical analysis.

Options such as categorical representations (radio buttons or check boxes) introduce rounding, data loss, and analytic limitations. Coding a verbatim diagnosis (option A) is inappropriate for numeric vital sign data and violates the principle of capturing data at the most granular level.

Thus, the correct and validated method per CCDM standards is two continuous variables, ensuring accuracy, traceability, and analytical flexibility.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 4.2 - Best Practices for Quantitative Data Capture ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Accuracy and Collection Standards FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Data Format and Structure Requirements

NEW QUESTION # 133

A Data Manager is designing a CRF for a study for which the efficacy data are not covered by the current SDTM domains. Which search should the Data Manager do?

- A. Use controlled terminology covering the needed concepts
- B. Work with the study team to define new data elements
- C. Advise the study team not to collect the data

- D. Search for relevant data element standards

Answer: D

Explanation:

When existing SDTM (Study Data Tabulation Model) domains do not cover specific efficacy data, the best practice is to first search for relevant data element standards that may be available through CDISC CDASH (Clinical Data Acquisition Standards Harmonization) or other recognized industry standards.

Per GCDMP (Chapter: Standards and Data Integration), Data Managers must ensure that new CRF elements are consistent with standardized definitions, controlled terminology, and data models to support interoperability, future analysis, and regulatory submission.

If no existing standards exist, only then should the Data Manager collaborate with the study team to define new elements - but standard searches always come first.

Thus, option C is correct - search for relevant data element standards ensures alignment with CDISC best practices and regulatory expectations.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Standards and Data Integration, Section 5.1 - Use of CDISC Standards in CRF Design CDISC CDASH Implementation Guide, Section 4.1 - Standardization of Data Collection Fields FDA Study Data Technical Conformance Guide (SDTCG), Section 2.4 - Use of Standard and Custom Domains

NEW QUESTION # 134

In an EDC study, user training and access must be monitored and addressed when all the following situations occur EXCEPT:

- A. Study team members are reassigned to a different role within the study.
- B. Site staff is new to the study.
- C. Site staff moves off of the study.
- D. A software upgrade is made that does not impact site staff or study team members.

Answer: D

Explanation:

In Electronic Data Capture (EDC) studies, proper user training and access management are essential for maintaining data integrity, security, and regulatory compliance. According to the Good Clinical Data Management Practices (GCDMP) and FDA 21 CFR Part 11, EDC systems must ensure that only qualified and trained personnel can access study data, and that all access rights reflect current study responsibilities.

User training and access must therefore be reviewed and updated whenever:

Site staff leave the study (access revocation is required),

New site staff are added (training and credentialing are required), and Study team members change roles (access levels must be modified accordingly).

However, if a software upgrade occurs that does not impact the functional roles, user permissions, or data handling processes, retraining or reauthorization is not required. This is because such updates do not alter compliance-critical workflows or user interactions.

Therefore, the exception is C - when a software upgrade does not affect users.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture Systems, Section 7.1 - User Access and Training Controls FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures, Section 11.10(i) & (k) ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - System Security and User Training

NEW QUESTION # 135

A Data Manager is designing a report to facilitate discussions with sites regarding late data. Which is the most important information to display on the report to encourage sites to provide data?

- A. List of outstanding forms
- B. Expected versus actual forms entered
- C. Total number of forms entered to date
- D. Number of forms entered in the last week

Answer: A

Explanation:

In managing site data timeliness, the most actionable and effective tool is a report listing all outstanding (missing or incomplete) CRFs.

According to GCDMP (Chapter: Communication and Study Reporting), Data Managers must provide site-level performance reports highlighting:

Outstanding CRFs not yet entered,

Unresolved queries, and

Pending data corrections.

Such reports help sites prioritize and address data gaps efficiently.

Option A and D are historical metrics without actionable context.

Option B gives a general overview but lacks specific site-level actionability.

Hence, option C (List of outstanding forms) provides the clearest and most motivating feedback to sites for timely data entry and query resolution.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Communication and Study Reporting, Section 5.3 - Data Timeliness and Reporting Metrics ICH

E6(R2) GCP, Section 5.1.1 - Sponsor Oversight and Data Communication Requirements FDA Guidance for Industry:

Computerized Systems Used in Clinical Investigations, Section 6.5 - Site-Level Data Timeliness Reporting

NEW QUESTION # 136

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