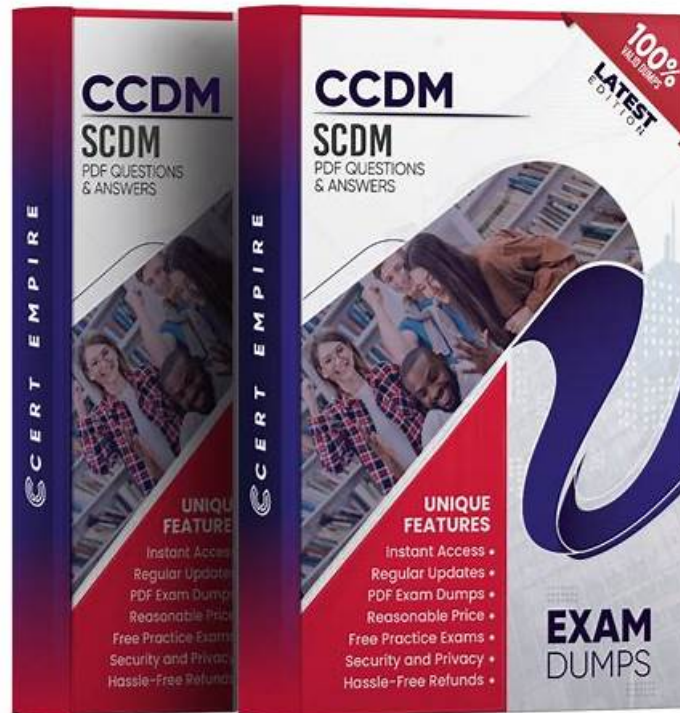


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Certified Clinical Data Manager exam practice questions play a crucial role in Certified Clinical Data Manager CCDM exam preparation and give you insights Certified Clinical Data Manager exam view. You are aware of the Certified Clinical Data Manager CCDM exam topics, structure, and a number of the questions that you will face in the upcoming Certified Clinical Data Manager CCDM Exam. You can evaluate your Salesforce Certified Clinical Data Manager exam preparation performance and work on the weak topic areas. But here is the problem where you will get Certified Clinical Data Manager exam questions.

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"> • 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 | <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 4 | <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 5 | <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. |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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SCDM Certified Clinical Data Manager Sample Questions (Q127-Q132):

NEW QUESTION # 127

Which protocol section most concisely conveys timing of data collection throughout a study?

- A. Study endpoints section
- B. Protocol synopsis
- C. ICH essential documents
- **D. Study schedule of events**

Answer: D

Explanation:

The Study Schedule of Events (SoE) section in the protocol is the most concise and comprehensive representation of the timing of data collection throughout a study.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Management Planning and Study Start-up) and ICH E6 (R2) GCP, the SoE outlines what assessments, procedures, and data collections occur at each study visit (e.g., screening, baseline, treatment visits, follow-up). This table is a foundational tool for CRF design, database structure, and edit-check development, ensuring alignment between the protocol and data management systems.

While the study endpoints section (A) defines what is measured, and the protocol synopsis (C) summarizes the design, only the schedule of events (B) specifies when data collection occurs for each parameter. The ICH essential documents (D) pertain to regulatory documentation, not study visit timing.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Planning and Study Start-up, Section 4.1 - Using the Schedule of Events for Database Design ICH E6 (R2) GCP, Section 6.3 - Trial Design and Schedule of Assessments FDA Guidance for Industry: Protocol Design and Data Collection Standards

NEW QUESTION # 128

Which attribute is NOT a characteristic of a standardized data collection element?

- A. A standard set of values used to respond to a data collection question
- B. An unambiguous definition for the data element
- **C. A strictly enforced requirement for the positioning of each data element on a case report form**
- D. A unique set of data storage metadata, including a variable name and data type

Answer: C

Explanation:

A standardized data collection element has well-defined metadata, consistent naming conventions, and controlled terminology to ensure uniform data collection and interoperability across studies.

Key attributes, as per GCDMP and CDISC standards, include:

A clear definition of meaning (A)

A controlled set of response values (C)

Metadata specifications like variable names, formats, and data types (D) However, the physical positioning of a data element on a case report form (B) is a matter of form layout design, not a characteristic of data standardization. While consistent form structure aids usability, it is not part of data standardization or metadata management principles.

Hence, option B is correct - form positioning is not a standardized data element attribute.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Standards and Data Integration, Section 4.1 - Data Element Standardization CDISC CDASH Implementation Guide, Section 3.2 - Standardized Data Collection Elements and Metadata ICH E6(R2) GCP, Section 5.5.3 - Data Handling and Standardization

NEW QUESTION # 129

A study uses commercially available activity monitors and collects data for each patient weekly by selecting and downloading the data from the manufacturer's website. There are 100 patients in the study and it takes the Data Manager 20 minutes per file to download, import, and process the data. Assuming that the distribution of work is uniform over the six-month trial, how many Data Managers are needed for the activity data alone?

- A. Ten percent of a Data Manager per month
- B. Two Data Managers per month
- C. Fifty percent of a Data Manager per month
- **D. One Data Manager per month**

Answer: D

Explanation:

This question tests workload estimation and resource planning, which are fundamental competencies outlined in the Good Clinical Data Management Practices (GCDMP, Chapter on Project Management in Data Management). The task is to determine the Data Manager effort required based on the frequency and duration of data collection and processing activities.

Let's calculate step by step:

Number of patients: 100

Frequency: Weekly (once per week)

Duration: 6 months \approx 26 weeks

Time per file: 20 minutes

Total time per week:

$100 \text{ patients} \times 20 \text{ minutes} = 2,000 \text{ minutes per week}$

$= 2,000 \div 60 = 33.3 \text{ hours per week}$

Total hours over 6 months:

$33.3 \text{ hours/week} \times 26 \text{ weeks} = 866 \text{ hours total}$

A full-time Data Manager typically works \sim 160 hours per month, so over six months:

$160 \times 6 = 960 \text{ hours total full-time capacity.}$

Therefore, the workload of 866 hours is approximately equivalent to one full-time Data Manager working across the six-month period:

$866 \div 960 \approx 0.9 \text{ FTE (Full-Time Equivalent).}$

This aligns most closely with Option D: One Data Manager per month (i.e., a full-time resource is required throughout the duration of the trial).

According to the GCDMP Project Management chapter, accurate resource estimation is critical in ensuring data management timelines are met without overloading staff or compromising data quality. The estimation process must consider not just the raw data download time but also associated data processing, verification, and upload into the clinical database.

Other options underestimate the effort significantly:

A (10%) and B (50%) do not account for cumulative weekly workload across multiple patients.

C (Two Data Managers) overestimates, as one Data Manager working full-time can manage the load efficiently.

Therefore, Option D is correct - approximately one full-time Data Manager (1.0 FTE) is required for the activity data alone during the six-month trial.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Project Management in Data Management, Section 5.3 - Workload Estimation and Resource Allocation SCDM GCDMP, Chapter: Data Handling and Processing - Effort Estimation for Repetitive Data Tasks ICH E6 (R2) Good Clinical Practice, Section 5.1 - Quality Management and Resource Planning FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Operational Considerations for Data Management Activities

NEW QUESTION # 130

A statistician analyzes data from a randomized, double-blind, placebo-controlled study and finds that the placebo outperformed the investigational product. Which of the following is a plausible explanation for this?

- A. The investigational product performed well in this study population.
- **B. The treatment codes were incorrectly entered into the database.**
- C. The placebo was intended to contain medicinal properties.
- D. Sites appropriately dispensed the investigational product to the subjects.

Answer: B

Explanation:

In a randomized, double-blind, placebo-controlled study, if statistical analysis shows that the placebo appears to outperform the investigational product, a likely cause is a data management or coding error, particularly in treatment code entry or mapping. According to the GCDMP (Chapter: Database Design and Build), treatment assignment data - typically stored in randomization or code-break files - must be accurately integrated into the clinical database. Any mismatch between randomization codes, subject identifiers, or treatment arms can lead to incorrect grouping during analysis, producing false conclusions such as placebo superiority. The Data Manager should initiate a root cause review of randomization data integration and treatment mapping. The placebo is never designed to have active medicinal effects (option A). Option D is incorrect because the described scenario implies a data inconsistency, not true efficacy differences. Proper verification of randomization coding and reconciliation between data management and statistical programming systems are essential.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Build, Section 6.1 - Randomization and Treatment Code Management ICH E6 (R2) GCP, Section 5.5.3 - Data Verification and Coding Accuracy FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Mapping and Validation Requirements

NEW QUESTION # 131

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

- A. SNOMED terms used in the therapeutic area
- B. Data elements used in clinical registries in the therapeutic area
- **C. A CDISC therapeutic-area implementation guide**
- D. Forms used by other sponsors in the same therapeutic area

Answer: C

Explanation:

When efficacy data are not covered by existing CDISC SDTM domains, the first resource the Data Manager should consult is the CDISC Therapeutic Area Implementation Guide (TAIG) for that therapeutic field.

According to the GCDMP (Chapter: Standards and Data Mapping), CDISC's Therapeutic Area User Guides (TAUGs) and Implementation Guides provide standardized data structures, variable definitions, controlled terminology, and implementation examples for specific diseases or therapeutic areas. These guides ensure consistency across studies, promote interoperability, and align data collection with regulatory submission expectations.

Consulting other sponsors' forms or external registries (options A and C) can be informative but do not provide authoritative CDISC-compliant standards. SNOMED terms (option B) address medical terminology, not structural data domain definitions. Therefore, Option D is correct-CDISC TA Implementation Guides are the recognized primary reference when extending or designing SDTM-compliant CRFs.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Standards and Data Mapping, Section 4.2 - Use of CDISC Standards CDISC Therapeutic Area User Guides (TAUGs) - Implementation Guidance for Domain Extension FDA Data Standards Catalog - CDISC Therapeutic Area Standards

NEW QUESTION # 132

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