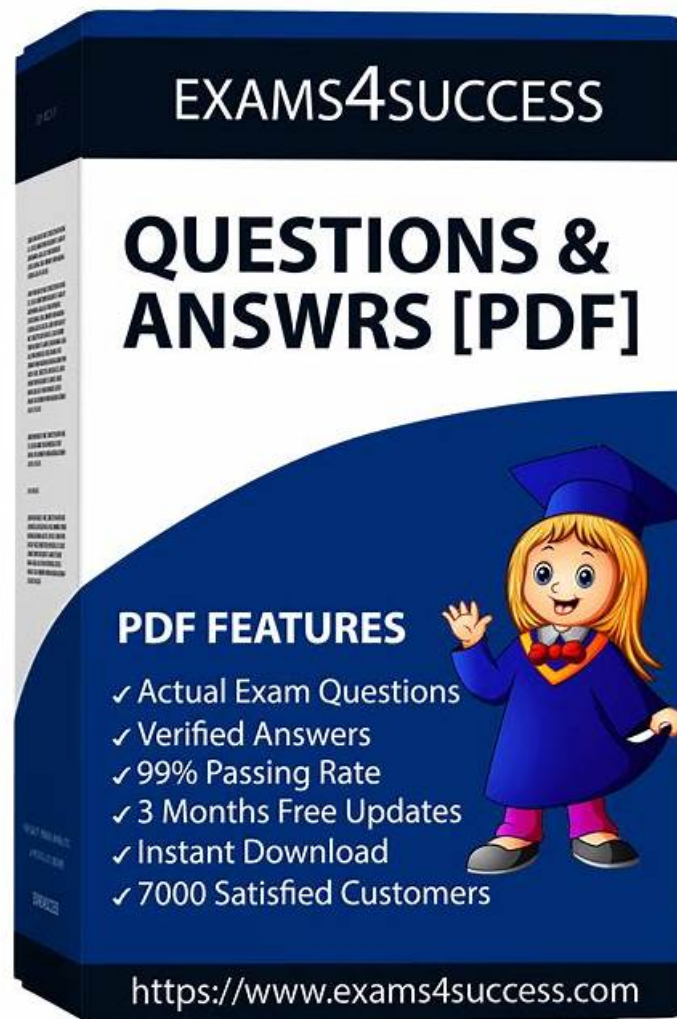# Real CCDM Exams - CCDM Related Exams

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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	• 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 3	• 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 4	• 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	• 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.

>> Real CCDM Exams <<

What is the importance of preparation-evaluation before the final certification SCDM CCDM exam?

It is known to us that the CCDM exam has been increasingly significant for modern people in this highly competitive word, because the CCDM test certification can certify whether you have the competitive advantage in the global labor market or have the ability to handle the job in a certain area, especial when we enter into a newly computer era. Therefore our CCDM practice torrent is tailor-designed for these learning groups, thus helping them pass the CCDM exam in a more productive and efficient way and achieve success in their workplace.

SCDM Certified Clinical Data Manager Sample Questions (Q100-Q105):

NEW QUESTION # 100
Which of the following laboratory findings is a valid adverse event reported term that facilitates auto coding?

- A. ALT
- B. Elevated HDL
- C. Increased alkaline phosphatase, increased SGPT, increased SGOT, and elevated LDH
- D. Abnormal SGOT

Answer: B

Explanation:
When coding adverse events (AEs) using MedDRA (Medical Dictionary for Regulatory Activities), valid AE terms must correspond to specific, medically meaningful concepts that match directly to a Preferred Term (PT) or Lowest Level Term (LLT) in the dictionary.
Among the options, "Elevated HDL" (High-Density Lipoprotein) represents a single, medically interpretable, and standard term that can directly match to a MedDRA LLT or PT. This makes it suitable for auto-coding, where the system automatically maps verbatim terms to MedDRA entries without manual intervention.
In contrast:
ALT (B) and Abnormal SGOT (C) are incomplete or nonspecific; they describe test names or qualitative interpretations rather than events.
Option D lists multiple findings, making it too complex for automatic mapping. Such compound entries would require manual coding review.
According to GCDMP (Chapter: Medical Coding and Dictionaries), a valid AE term should be:
Clinically interpretable (not just a lab test name)
Unambiguous
Single-concept based, not a collection of results
Thus, option A (Elevated HDL) is correct, as it aligns with MedDRA's single-concept, standard terminology structure suitable for auto-coding.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Medical Coding and Dictionaries, Section 5.3 - Auto-coding and Verbatim Term Management ICH M1
MedDRA Term Selection: Points to Consider, Section 2.1 - Coding Principles ICH E2B(R3) - Clinical Safety Data Management:
Data Elements for Transmission of Individual Case Safety Reports

NEW QUESTION # 101

The Medical Dictionary for Regulatory Activities (MedDRA) structure is in which of the following hierarchical orders, from most specific to least specific?

- **A. LLT, PT, HLT, HLGT, SOC**
- B. LLT, PT, HLGT, HLT, SOC
- C. LLT, HLGT, HLT, PT, SOC
- D. LLT, HLGT, PT, HLT, SOC

Answer: A

Explanation:
The MedDRA (Medical Dictionary for Regulatory Activities) is a standardized medical terminology used for coding and analyzing adverse event (AE) and medical history data in clinical trials. Its hierarchical structure supports aggregation, analysis, and reporting across varying levels of medical specificity.
From most specific to least specific, the hierarchy is as follows:
Lowest Level Term (LLT): The most granular term, often reflecting the verbatim text reported by the investigator.
Preferred Term (PT): The standardized medical concept representing one or more LLTs describing the same condition.
High Level Term (HLT): A grouping of related PTs describing similar medical conditions.
High Level Group Term (HLGT): A broader grouping of related HLTs.
System Organ Class (SOC): The highest level of classification, grouping HLGTs by body system or etiology (e.g., cardiac disorders, infections).
Thus, the correct order - from most specific to least specific - is:
LLT → PT → HLT → HLGT → SOC, which corresponds to option D.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Medical Coding and Dictionaries, Section 5.2 - MedDRA Hierarchical Structure ICH M1 MedDRA
Terminology Guide, Version 26.0 - Hierarchy Overview ICH E2B(R3) Guidelines - Clinical Safety Data Management

NEW QUESTION # 102

Which is a minimum prerequisite that should be in place before choosing an EDC system?

- A. Updated governance documentation
- B. Completed installation qualification
- **C. Knowledge of functional requirements**
- D. Draft validation plan

Answer: C

Explanation:
Before selecting an Electronic Data Capture (EDC) system for a clinical trial, it is essential to have a clear understanding of the functional requirements. This serves as the minimum prerequisite to guide system selection, ensuring that the EDC solution aligns with the protocol needs, data workflow, security requirements, and regulatory compliance.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Computerized Systems and Compliance), functional requirements describe what the system must do-such as data entry capabilities, edit checks, query management, user roles, audit trails, and integration with external systems (e.g., labs, ePRO). This understanding allows sponsors and CROs to evaluate vendor systems effectively during the selection and qualification phase.
Other options:
B . Installation qualification and D. Validation plan occur after system selection.
C . Governance documentation supports operations but is not required before choosing the system.
Hence, option A is correct - the first and most essential prerequisite before EDC selection is a solid understanding of the functional requirements.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 4.2 - Requirements Gathering and System Selection
FDA 21 CFR Part 11 - System Validation and Intended Use Requirements ICH E6(R2) GCP, Section 5.5.3 - Computerized
System Selection and Qualification

NEW QUESTION # 103

ePRO data are collected for a study using study devices given to subjects. Which is the most appropriate quality control method for the data?

- A. Programmed edit checks to detect out of range values after submission to the database
- B. Programmed edit checks to detect out of range values upon data entry
- C. Data visualizations to look for site-to-site variation
- D. Manual review of data by the site study coordinator at the next visit

Answer: B

Explanation:
When electronic patient-reported outcomes (ePRO) devices are used, data are captured directly by subjects through validated devices and transmitted electronically to the study database. To ensure real-time data quality control, programmed edit checks should be implemented at the point of data entry - that is, as subjects input data into the device.
According to Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), front-end programmed edit checks are the optimal method to prevent entry of invalid or out-of-range values in ePRO systems. This helps maintain data accuracy at the source, minimizing downstream queries and data cleaning workload.
Options A and B involve post-submission or manual review, which is less efficient and not compliant with the principle of first-pass data validation. Option C (visualization) is a valuable secondary QC method for trends, but not for immediate data validation.
Therefore, option D is correct - programmed edit checks upon data entry ensure immediate validation and higher data integrity.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.3 - Automated Edit Checks and Front-End Validation ICH E6(R2) GCP, Section 5.5.3 - Computerized System Controls and Validation FDA Guidance for Industry: Electronic Source Data in Clinical Investigations (2013), Section 6 - Real-Time Data Quality Control

NEW QUESTION # 104

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 # 105

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SCDM certification CCDM exam can give you a lot of change. Such as work, life would have greatly improve. Because, after all, CCDM is a very important certified exam of SCDM. But CCDM exam is not so simple.

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