

CCDM Reliable Test Topics - 100% Efficient Questions Pool

CCDM Test 2023-2024 Questions and Answers 100% Correct

A Certified Dietary Manager is dissatisfied with prices from current vendors. The Manager should first:

- a. ask vendors to lower their prices.
- b. ask the consultant to recommend other vendors.
- c. complete a comparison study of vendors.
- d. discontinue purchasing from the current vendors. - ANSWER-c. complete a comparison study of vendors.

The best way to prepare frozen peas is to: a. slowly cook the peas at 200°F (93.3°C) so they do not dry out.

- b. cook them rapidly until they reach an internal temperature of 140°F (60.0°C).
- c. cook them to 120°F (48.9°C) and hold them in the steam table to come up to temperature.
- d. cook them in batches throughout the service time. - ANSWER-d. cook them in batches throughout the service time.

Beans and legumes are essential protein substitutes for clients who are:

Choose one answer.

- a. lactose intolerant.
- b. vegan.
- c. ovo-lacto-vegetarian.
- d. lacto vegetarian. - ANSWER-b. vegan.

When preparing goals for the foodservice department, a Certified Dietary Manager must show that the goals are:

Choose one answer.

- a. narrow.
- b. broad.
- c. listed on the bulletin board.
- d. transferrable to other departments. - ANSWER-b. broad.

When purchasing food, a Certified Dietary Manager must develop specifications to ensure that:

Choose one answer.

- a. government commodities are used when available.
- b. eggs are delivered in a timely manner.
- c. milk arrives at a temperature below 41°F (5°C).
- d. canned fruits are packed in water or juice. - ANSWER-c. milk arrives at a temperature below 41°F (5°C).

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>> CCDM Reliable Test Topics <<

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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<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 2	<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 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">• 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">• 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.

SCDM Certified Clinical Data Manager Sample Questions (Q68-Q73):

NEW QUESTION # 68

Electronic submission standards require that an individual subject's complete CRF should be provided as what type of file:

- A. Rich Text Format (.rtf)
- B. Statistical Analysis System (.sas)
- C. Microsoft Word (.docx)
- D. Portable Document Format (.pdf)

Answer: D

Explanation:

Electronic submission standards, as established by FDA, CDISC, and ICH, require that an individual subject's complete Case Report Form (CRF) be submitted as a Portable Document Format (.pdf) file. The PDF format is universally recognized and accepted because it ensures that the structure, format, and visual fidelity of the CRF are preserved exactly as originally designed, regardless of software or hardware environment.

According to the FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format (2006) and CDISC SDTM standards, sponsors must include a subject-level CRF in PDF form for each participant in the submission dataset. This requirement ensures that reviewers can trace data points from analysis datasets back to their source entries in the CRF, fulfilling the principles of data traceability and transparency.

The Good Clinical Data Management Practices (GCDMP) also support this requirement, emphasizing that CRF archiving should maintain readability and regulatory accessibility. Formats like RTF, DOCX, or SAS datasets are not acceptable substitutes for regulatory CRF submission because they may alter formatting, structure, or introduce modifiable content, violating FDA data integrity principles.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Archiving and Submission FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format, April 2006 CDISC SDTM Implementation Guide, Section 5.3 - CRF Representation and Traceability

NEW QUESTION # 69

In a study, data are key entered by one person after which a second person enters the data without knowledge of or seeing the values entered by the first. The second person is notified during entry if an entered value differs from first entry and the second person's decision is retained as the correct value. Which type of entry is being used?

- A. Single entry
- B. Third-party compare
- C. Manual review
- **D. Blind verification**

Answer: D

Explanation:

The described process is Blind Verification, also known as double data entry with blind verification. In this method, two independent operators enter the same data. The second operator is blinded to the first entry to avoid bias. When discrepancies arise, the system flags them for review, and the second entry (or an adjudicated value) is retained as the correct one.

According to GCDMP (Chapter: Data Entry and Data Tracking), blind double data entry is used primarily in paper-based studies to minimize transcription errors and ensure data accuracy.

Single entry (D): Only one operator enters data.

Manual review (B): Involves post-entry checking, not during entry.

Third-party compare (C): Used for reconciling external data sources, not CRF data.

Hence, option A (Blind verification) is the correct and CCDM-defined process.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Entry and Data Tracking, Section 5.1 - Double Data Entry and Verification Methods ICH E6(R2)

GCP, Section 5.5.3 - Data Entry and Verification Controls FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.2 - Data Accuracy and Verification

NEW QUESTION # 70

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

Answer: A

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 # 71

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

Answer: D

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 # 72

According to ICH E6, developing a Monitoring Plan is the responsibility of whom?

- A. Monitor
- **B. Sponsor**
- C. Data Manager
- D. CRO

Answer: B

Explanation:

According to ICH E6(R2) Good Clinical Practice (GCP), Section 5.18.1, the Sponsor is ultimately responsible for developing and implementing the Monitoring Plan.

The Monitoring Plan defines:

The extent and nature of monitoring (e.g., on-site, remote, risk-based).

The responsibilities of monitors.

The communication and escalation procedures for data quality and protocol compliance.

While the CRO (B) or Monitor (D) may perform monitoring activities under delegation, the Sponsor retains legal accountability for ensuring a compliant and effective plan is developed and maintained. The Data Manager (C) may contribute by outlining data review workflows, but is not responsible for authoring or owning the plan.

Therefore, option A (Sponsor) is the correct answer.

Reference (CCDM-Verified Sources):

ICH E6(R2) GCP, Section 5.18.1 - Purpose and Responsibilities for Monitoring SCDM GCDMP, Chapter: Regulatory Compliance and Oversight, Section 5.3 - Sponsor Responsibilities in Monitoring and Quality Assurance FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor Responsibilities (2013)

NEW QUESTION # 73

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