

CCDM Reliable Test Duration, CCDM New Question

CCDM Test 2023-2024 Questions and Answers 100% Correct

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

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

The best way to prepare frozen peas is to:

- slowly cook the peas at 200°F (93.3°C) so they do not dry out.
- cook them rapidly until they reach an internal temperature of 140°F (60.0°C).
- cook them to 120°F (48.9°C) and hold them in the steam table to come up to temperature.
- 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.

- lactose intolerant.
- vegan.
- ovo-lacto-vegetarian.
- 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.

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

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

Choose one answer.

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

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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	<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 2	<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 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"> • 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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SCDM Certified Clinical Data Manager Sample Questions (Q106-Q111):

NEW QUESTION # 106

Which information is required by most systems to specify data entry screens?

- A. Help text, review parameters, and answers
- B. User role, access level, and permissions
- C. Data type, prompt, and response format
- D. Page number and total number of pages

Answer: C

Explanation:

When designing or configuring data entry screens within an Electronic Data Capture (EDC) system, three critical components are required for each field:

Data Type - Defines the nature of the data (e.g., text, numeric, date).

Prompt - The label or question displayed to the user.

Response Format - Specifies how the user enters or selects data (e.g., free text, drop-down, checkbox).

According to the GCDMP (Chapter: EDC Systems and Database Design), these three attributes form the logical data structure required to build and validate data entry interfaces. They ensure consistency in how information is captured, displayed, and validated during data entry.

While user roles (A) and help text (D) are system-level configurations, not field-level specifications, page numbers (C) relate to printed CRFs rather than digital data screens.

Therefore, option B (Data type, prompt, and response format) correctly identifies the essential information needed to define data entry screens.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: EDC Systems and Database Design, Section 4.3 - Screen Design Specifications CDISC CDASH Implementation Guide, Section 3.2 - Data Field Attributes ICH E6(R2) GCP, Section 5.5.3 - Data Capture and Input Standards

NEW QUESTION # 107

On a dose escalation study, the Data Manager notices one site has a much higher number of queries than other sites and most are older than 30 days. The Data Safety Monitoring Board will meet in three weeks. What should the Data Manager providing CRO oversight do?

- A. Call the site directly and ask the study coordinator about the concerns
- B. Notify the CRO's Clinical Leader about the concerns
- C. Ignore it for now and check back next week
- **D. Consult the CRO's Lead Data Manager and the CRO's Project Leader**

Answer: D

Explanation:

The correct action is to consult the CRO's Lead Data Manager and CRO's Project Leader (Option C) to ensure the issue is addressed through the appropriate oversight and escalation process.

According to the GCDMP (Chapter: Project Management and Communication), when a sponsor Data Manager identifies significant data management issues under CRO oversight - such as aging queries or site performance disparities - communication must follow the established governance and escalation pathway defined in the Scope of Work (SOW) and Data Management Plan (DMP).

Directly contacting the site (Option B) bypasses the CRO's chain of command and violates communication protocols. Notifying only the Clinical Leader (Option A) is insufficient, and ignoring the issue (Option D) jeopardizes the Data Safety Monitoring Board (DSMB) review timeline.

Therefore, Option C ensures a documented, collaborative approach to problem resolution within the contractual oversight structure.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 7.1 - Oversight of CRO Data Management Activities ICH E6 (R2) GCP, Section 5.2 - Contract Research Organization Responsibilities
 FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor and CRO Roles and Communication Pathways

NEW QUESTION # 108

Which document contains the details of when, to whom, and in what manner the vendor data will be sent?

- **A. Data Transfer Agreement**
- B. Communication Plan
- C. Data Management Plan
- D. Project Plan

Answer: A

Explanation:

A Data Transfer Agreement (DTA) defines the operational and technical details for transferring data between a sponsor and an external vendor (e.g., central lab, ECG vendor). It is a formalized, controlled document specifying what data will be sent, when transfers will occur, the transfer method, file structure, encryption or security protocols, and the recipients of the data.

The DTA is developed jointly by the sponsor and vendor before production data transfers begin. According to the GCDMP, Chapter on External Data Transfers, this agreement ensures both parties share a clear understanding of timing, responsibility, and data content to minimize errors and ensure regulatory compliance.

The Data Management Plan (DMP) outlines general data handling processes but does not capture the technical specifics of vendor data transfer logistics. The Project Plan (A) and Communication Plan (B) are broader operational tools and not specific to data transfer protocols.

Hence, option C (Data Transfer Agreement) is the correct answer, as it precisely governs the procedural and technical framework of vendor data exchange.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: External Data Transfers, Section 4.1 - Data Transfer Agreements and Specifications ICH E6(R2) Good Clinical Practice, Section 5.5 - Trial Management, Data Handling, and Record Keeping

NEW QUESTION # 109

An asthma study is taking into account local air quality and receives that data from the national weather bureau. Which information is needed to link research subject data to the air-quality readings?

- **A. Location and time identifiers**
- B. Location, time, subject and site identifiers
- C. Location, time and subject identifiers
- D. Location identifier

Answer: A

Explanation:

When integrating external environmental data such as air quality readings with clinical study data, it is essential to use location and time identifiers to properly align the environmental data with subject-level data.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Management Planning and Study Start-up), external data sources (like national weather or pollution databases) must be merged using common linkage variables that allow synchronization without breaching subject confidentiality. In this case:

Location identifiers (e.g., city, postal code, or region) align the subject's study site or residential area with the environmental dataset. Time identifiers (e.g., date and time of data collection) ensure that the environmental readings correspond to the same period as the subject's clinical observations.

Including subject identifiers (option C or D) is unnecessary and would pose privacy and data protection risks. Instead, linkage is typically done at the aggregate (site or regional) level, maintaining compliance with HIPAA and GDPR.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Integration and External Data Handling, Section 4.3 - Linking External Data Sources ICH E6 (R2) GCP, Section 5.5.3 - Data Traceability and External Data Management FDA Guidance for Industry: Use of Electronic Health Record Data in Clinical Investigations, Section 5.2 - Linking and Integration Principles

NEW QUESTION # 110

What does 21 CFR Part 11 dictate in regards to a minimum expectation of EDC training prior to access?

- A. Training must be in the user's native language
- B. Training must be face to face
- **C. Training must be performed**
- D. Training must include an exam

Answer: C

Explanation:

Under FDA 21 CFR Part 11, organizations using electronic systems must ensure that all system users are trained to perform their assigned functions before gaining access to the system. The regulation requires documented evidence of training but does not specify how it should be conducted (e.g., exam-based, in person, or language-specific).

The GCDMP (Chapter: Computerized Systems and Compliance) further clarifies that personnel training should include instruction on system functionality, audit trails, data entry procedures, and electronic signatures to maintain compliance and data integrity. Training must be performed and documented but does not require a specific format or delivery method.

Therefore, option A-Training must be performed-is correct, as it reflects the minimum regulatory expectation per FDA and SCDM standards.

Reference (CCDM-Verified Sources):

FDA 21 CFR Part 11, Section 11.10(i) - Personnel Training Requirements

SCDM GCDMP, Chapter: Computerized Systems and Compliance, Section 5.4 - System Training and Documentation ICH E6(R2) GCP, Section 2.8 - Qualified Personnel and Training Requirements

NEW QUESTION # 111

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