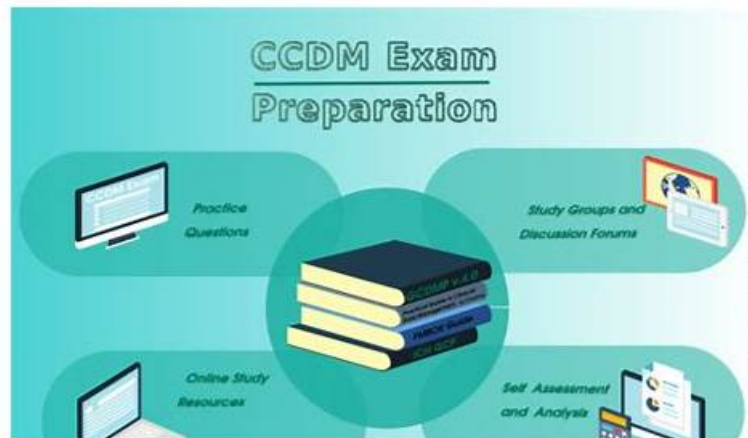


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SCDM Certified Clinical Data Manager Sample Questions (Q127-Q132):

NEW QUESTION # 127

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

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

Answer: D

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 # 128

In an EDC study, an example of an edit check that would be inefficient to run at data entry is a check:

- A. Against a valid list of values.
- **B. Across visits for consistency.**
- C. Against a valid numeric range.
- D. On the format of a date.

Answer: B

Explanation:

In Electronic Data Capture (EDC) systems, edit checks are categorized based on when and how they are executed - typically immediate (at data entry) or batch (post-entry). Checks that require data from multiple visits or forms are generally inefficient to run at data entry because they depend on information that may not yet exist in the system.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Validation and Cleaning), cross-visit consistency checks - such as comparing baseline and follow-up blood pressure or verifying date order between screening and dosing - should be executed as batch or scheduled validations, not at the point of data entry. Running these complex checks in real time can slow system performance, increase query load unnecessarily, and confuse site users if related data are not yet entered. Conversely, edit checks against valid ranges, formats, or predefined value lists (options A, C, and D) are simple, local validations ideally performed immediately at data entry to prevent basic errors.

Therefore, cross-visit consistency checks (Option B) are best executed later, making them inefficient for real-time data entry validation.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.4 - Real-Time vs. Batch Edit Checks FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Edit Checks and Data Validation Logic CDISC SDTM Implementation Guide - Section on Temporal Data Consistency Validation

NEW QUESTION # 129

Which information should be communicated by the Data Manager at regular intervals throughout a study?

- **A. Percent data entered and clean**
- B. Site staffing changes
- C. Serious and unexpected safety events
- D. Planned versus actual enrollment

Answer: A

Explanation:

The Data Manager (DM) plays a critical role in maintaining transparent communication with the clinical study team regarding data quality and study progress. One of the most essential metrics regularly reported by the DM is the percentage of data entered and cleaned.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Communication and Study Reporting), these metrics provide insight into study status, data readiness for interim analysis, and timeline predictability for database lock. Regular communication includes:

Percent of CRFs entered and verified

Percent of queries resolved

Outstanding data issues or missing pages

Other options fall outside the Data Manager's direct responsibility:

A (Enrollment) is typically reported by clinical operations.

B (Staffing changes) are handled by site management.

D (Safety events) are communicated by the safety/pharmacovigilance team.

Thus, option C correctly reflects the Data Manager's responsibility for ongoing study communication.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Communication and Study Reporting, Section 5.3 - Study Metrics and Status Updates ICH E6(R2)

GCP, Section 5.1.1 - Communication and Oversight in Quality Management FDA Guidance for Industry: Computerized Systems

Used in Clinical Investigations, Section 6.5 - Data Status Reporting

NEW QUESTION # 130

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

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

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 # 131

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

- A. LLT, HLGT, HLT, PT, SOC
- B. LLT, HLGT, PT, HLT, SOC
- C. LLT, PT, HLGT, 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 HLGs by body system or etiology (e.g., cardiac disorders, infections).

Thus, the correct order - from most specific to least specific - is:

LLT → PT → HLT → HLG → 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 # 132

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