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Exam CCDM Cram Questions & CCDM Practice Questions

Taking Lead2Passed Certified Clinical Data Manager (CCDM) practice test questions are also important. These SCDM CCDM practice exams include questions that are based on a similar pattern as the finals. This makes it easy for the candidates to understand the Certified Clinical Data Manager (CCDM) exam question paper and manage the time. It is indeed a booster for the people who work hard and do not want to leave any chance of clearing the CCDM exam with brilliant scores.

SCDM Certified Clinical Data Manager Sample Questions (Q123-Q128):

NEW QUESTION # 123
A study team member wants to let sites enroll patients before the system is ready. Which are important considerations?

- A. Without the ability to capture the data electronically, the data cannot be checked or used to monitor and manage the study
- B. There is no way to identify, report and track adverse events and serious adverse events without the EDC system in place
- C. Starting the study prior to the EDC system being ready will delay processing of milestone-based site payments
- D. If the study were audited, enrolling subjects prior to having the EDC system ready would become an audit finding

Answer: A

Explanation:
Enrolling subjects before the Electronic Data Capture (EDC) system is ready poses major data integrity and compliance risks. The primary issue is that data cannot be accurately captured, validated, or monitored without the system in place.
Per the GCDMP (Chapter: Data Management Planning and Study Start-up), data collection systems must be fully validated, tested, and released before enrollment begins to ensure:
Real-time data entry and quality control
Proper tracking of adverse events (AEs/SAEs)
Audit trails and traceability for regulatory compliance
Option A highlights the most critical consequence - without an operational EDC, data collection and verification processes cannot occur, compromising data quality and study oversight.
While options B, C, and D may be partially true, they are secondary effects. The fundamental consideration is data capture capability and monitoring control, making option A correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Management Planning and Study Start-up, Section 4.2 - EDC Readiness and System Validation
ICH E6(R2) GCP, Section 5.5.3 - Computerized Systems Validation Before Use FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.1 - System Qualification Prior to Data Entry

NEW QUESTION # 124
The result set from the query below would be which of the following?
SELECT Pt_ID, MRN, SSN FROM patient

- A. Wider than the patient table
- B. Longer than the patient table
- C. Shorter than the patient table
- D. Narrower than the patient table

Answer: D

Explanation:
In a SQL (Structured Query Language) database, the SELECT statement specifies which columns to display from a table. In this query, only three columns - Pt_ID, MRN, and SSN - are being selected from the patient table.
This means the resulting dataset will contain:
The same number of rows (records) as the original table (assuming no WHERE filter), and Fewer columns than the full table.
In database terminology:
"Wider" refers to more columns (fields).
"Narrower" refers to fewer columns (fields).
Since this query retrieves only 3 columns (out of potentially many in the original table), the result set is narrower than the patient table, making option D correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 5.1 - Relational Databases and Query Logic ICH E6(R2) GCP, Section 5.5.3 - Data Retrieval and Integrity Principles FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.4 - Database Query Controls

NEW QUESTION # 125
In development of CRF Completion Guidelines (CCGs), which is a minimum requirement?

- A. CCGs must include a version control on the updated document
- B. CCGs are developed with representatives of Data Management, Biostatistics, and Marketing departments

- C. CCGs must be signed before database closure to include all possible protocol changes affecting CRF completion
- D. CCGs are designed from the perspective of the Study Biostatistician to ensure that the data collected can be analyzed

Answer: A

Explanation:

Case Report Form Completion Guidelines (CCGs) are essential study documents that instruct site staff on how to complete each field of the CRF correctly. A minimum requirement for CCGs, according to Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), is that they must include version control.

Option A describes an important design consideration but not a minimum compliance requirement. Option B is inaccurate, as CCGs must be approved and implemented before data collection begins, not after. Option D includes an irrelevant stakeholder (Marketing).

Therefore, option C-"CCGs must include a version control on the updated document"-is correct and compliant with CCDM and GCP standards.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 4.3 - Development and Maintenance of CRF Completion Guidelines ICH E6(R2) GCP, Section 8.2.1 - Essential Documents and Version Control Requirements

NEW QUESTION # 126
Which competency is necessary for EDC system use in a study using the medical record as the source?

- A. Screening study subjects
- B. Training on how to log into Medical Records system
- C. Using ePRO devices
- D. Resolving discrepant data

Answer: B

Explanation:

In studies where the medical record serves as the source document, the Electronic Data Capture (EDC) system users (typically study coordinators or site personnel) must have appropriate training on how to access and log into the medical record system. This competency ensures that data abstracted from the electronic medical record (EMR) are complete, accurate, and verifiable in compliance with Good Clinical Practice (GCP) and Good Clinical Data Management Practices (GCDMP).

According to the GCDMP (Chapter: EDC Systems and Data Capture) and ICH E6(R2), all personnel involved in data entry and verification must be trained in both the EDC and the primary source systems (e.g., EMR). This ensures that the integrity of data flow-from source to EDC-is maintained, and that personnel understand system access controls, audit trails, and proper documentation of source verification.

While resolving discrepant data (C) and screening subjects (A) are part of study operations, the competency directly related to EDC system use in EMR-based studies is the ability to properly log into and navigate the medical records system to extract source data.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Electronic Data Capture (EDC), Section 5.1 - Source Data and System Access Requirements ICH E6(R2) Good Clinical Practice, Section 4.9 - Source Documents and Data Handling FDA Guidance: Use of Electronic Health Record Data in Clinical Investigations, Section 3 - Investigator Responsibilities

NEW QUESTION # 127
A study has an expected enrollment period of one year but has subject recruitment issues. Twelve new sites are added toward the end of the expected enrollment period to help boost enrollment. What is the most likely impact on data flow?

- A. The database set-up will need to be changed to allow for additional sites as they are added to the study.
- B. The distribution of subjects selected for quality control will need to be stratified to allow for the twelve new sites.
- C. Additional sites will likely have increased query rates since site training is occurring closer to study close.
- D. A bolus of CRFs at the end of the study will result in the need to increase data entry and cleaning rates to meet existing timelines.

Answer: D

Explanation:

Adding multiple new sites late in the enrollment period creates a concentrated influx of new data near the end of the study. These sites typically start enrolling patients later, resulting in a "bolus" of Case Report Forms (CRFs) that must be entered, validated, and

cleaned within a shorter timeframe to meet database lock deadlines.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Data Flow), late site activation compresses the timeline for data management tasks, necessitating increased resources for data entry, query management, and cleaning. Data management teams must anticipate this surge and plan accordingly-either by increasing staffing or revising timelines to prevent bottlenecks and maintain quality.
While option D (increased query rates) can occur, it is a secondary effect. The most direct and consistent impact is the surge in data volume requiring expedited processing near study end.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Project Management, Section 5.3 - Managing Changes in Site Activation and Data Flow ICH E6(R2) GCP, Section 5.1 - Quality Management and Oversight

NEW QUESTION # 128

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