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CCDM certification exam - Part 1 Questions and answers Newest RATED A+ 2025/2026

Access Control - Policy and procedure that defines accessibility to a physical space or electronic source of information. The policy usually includes the concept of audit trails, either paper (ie.signature log) or electronic.

Adverse Drug Reaction (ADR) - In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions.

Adverse Event (AE) - In a subject or clinical-investigation subject administered a pharmaceutical product, any untoward medical occurrence which does not necessarily have a relationship with the treatment.

Analysis Dataset/ Analysis File - The final data set, including derived items and excluding redundant data points, which is used to perform the analyses required for safety assessment, efficacy assessment, submission to regulatory authorities, or other review. (Can be 1 or more files)

Annotated CRF - A document that maps the names of collected items to their corresponding database tables, variable item names, forms, visits and any other objects needed for someone to correctly analyze data collected in a trial. Required for someone to understand where variables for analysis originate.

Applicable Regulatory Requirements - Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products.

Application Service Provider (ASP) - A vendor who provides, manages and distributes software based services to customers over a network

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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 2	• 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 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	• 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 5	• 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.

SCDM Certified Clinical Data Manager Sample Questions (Q78-Q83):

NEW QUESTION # 78
The Scope of Work would answer which of the following information needs?

- A. To determine the number of database migrations budgeted for a project
- B. To find the name and contact information of a specific clinical data associate
- C. To look up the date of the next clinical monitoring visit for a specific site
- D. To look up which visit PK samples are taken

Answer: A

Explanation:
The Scope of Work (SOW) is a contractual document that outlines the specific deliverables, responsibilities, timelines, and budgetary details for a given project between the sponsor and the contract research organization (CRO).
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Communication), the SOW defines what work will be performed, how many resources are allocated, and the expected deliverables. This includes detailed information such as:
The number of database builds or migrations,
Timelines for deliverables (e.g., database lock),
Responsibility distribution between sponsor and CRO, and
Budget parameters for defined activities.
Therefore, if a Data Manager needs to determine how many database migrations are budgeted for a project, the SOW is the correct document to reference.
Information such as PK sample scheduling (option A), site monitoring dates (option B), or staff contact details (option D) would be found in operational plans or contact lists, not in the SOW.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 6.2 - Scope of Work Definition and Deliverables ICH E6 (R2) GCP, Section 5.5.3 - Documentation and Responsibilities for Data Management Tasks FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor and CRO Agreements

NEW QUESTION # 79
Which of the following tasks would be reasonable during a major upgrade of a clinical data management system?

- A. The data archive should be migrated to an offsite database server.
- B. The ability to access and read the clinical data archive should be tested.
- C. All of the data formats in the archive should be updated to new standards.
- D. All of the case report forms should be pulled and compared to the archive.

Answer: B

Explanation:
During a major system upgrade, it is critical to verify that archived data remain accessible, readable, and intact following the implementation.
According to the GCDMP (Chapter: Database Lock and Archiving), regulatory requirements such as 21 CFR Part 11 and ICH E6(R2) mandate that archived data must remain retrievable in a human-readable format for the duration of retention (often years after study completion).
Therefore, as part of validation and verification testing, organizations must confirm that existing archives can still be accessed using the upgraded system or compatible tools.
Option A: Updating archive formats could alter original data integrity (noncompliant).
Option C: Migration offsite is an IT infrastructure task, not directly tied to the upgrade process.
Option D: Comparing CRFs to archives is unnecessary unless data corruption is suspected.
Hence, option B (testing archive accessibility) is the correct and compliant approach.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Lock and Archiving, Section 5.4 - System Upgrades and Archive Validation ICH E6(R2) GCP, Section 5.5.3 - System Validation and Data Retention FDA 21 CFR Part 11 - Data Archiving, Retention, and Retrieval Requirements

NEW QUESTION # 80
It has been identified that ten adverse events were not reported in the trial prior to the database lock. What action should be taken to determine the next step?

- A. Notify upper management immediately so the monitor can contact the site.
- B. Evaluate the potential effect of the omission on the validity of the safety and efficacy analysis.
- C. Get the AE data entered immediately so the database can be locked again.
- D. Check the data from all sites again before relocking the database.

Answer: B

Explanation:
When adverse events (AEs) are discovered after a database lock, the appropriate first step is to evaluate the impact of the missing data on the integrity, safety analysis, and regulatory validity of the study results.
According to GCDMP (Chapter: Data Quality Assurance and Control), any post-lock data discovery requires a root cause assessment and impact analysis before deciding whether to unlock the database. The key question is whether the missing AEs:
Affect primary safety endpoints,
Introduce bias in safety reporting, or
Alter efficacy conclusions.
Based on the assessment, the Data Management and Biostatistics teams determine if unlocking and correction are justified. Simply entering data immediately (A) or repeating checks (D) without analysis may violate data control procedures.
Hence, option B is correct - the first step is to assess the impact on data validity and analysis.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 5.5 - Post-Lock Findings and Impact Assessment ICH E6(R2) GCP, Section 5.1.1 - Quality Management and Risk Assessment FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Post-Lock Data Management

NEW QUESTION # 81
A study team member states that data entry can be done by clerical personnel at sites. Which are important considerations?

- A. Data entry at sites requires study-specific training on how to use the EDC system to enter data and respond to data discrepancies identified by the system
- B. Historically in clinical research site study coordinator roles have been filled by people with clinical or clinical research experience
- C. The person at the sites who enters the data usually also understands which data in the medical record are needed for the study, where to find them and which value to choose
- D. It is possible that clerical personnel could be hired by sites because data entry requires little training and use of clerical personnel would reduce burden on sites

Answer: A

Explanation:
Although clerical staff can technically perform data entry, data entry in clinical research requires study-specific training, particularly in the use of the Electronic Data Capture (EDC) system and understanding data discrepancy resolution procedures.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection) and ICH E6 (R2), individuals responsible for data entry at clinical sites must be qualified by education, training, and experience. This includes understanding how to navigate the EDC system, enter data according to CRF Completion Guidelines, and appropriately respond to queries or system-generated edit checks.
Untrained clerical personnel may inadvertently introduce errors, violate Good Clinical Practice (GCP) standards, or fail to recognize protocol-relevant data. Therefore, the Data Manager must ensure that site users receive study-specific and system training before gaining access to the EDC environment.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 5.2 - Investigator Site Training and Data Entry Requirements ICH E6 (R2) Good Clinical Practice, Section 4.1.5 - Qualified Personnel and Training Requirements FDA 21 CFR Part 11 - User Access and Training Provisions for Electronic Records

NEW QUESTION # 82
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. 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.
- B. Additional sites will likely have increased query rates since site training is occurring closer to study close.
- C. The distribution of subjects selected for quality control will need to be stratified to allow for the twelve new sites.
- D. The database set-up will need to be changed to allow for additional sites as they are added to the study.

Answer: A

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 # 83
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